Compiled Public Comments on Request for Information for Strategies for Maximizing Public Engagement in NIH Supported Clinical Research

June 12, 2024 – August 14, 2024

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Submit date: 6/13/2024

I am responding to this RFI: On behalf of myself

Name: Lee Saddleback

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: Student wanting to become a Doctor/Medical Researcher

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
Developing more connections and engagements with other large and innovative research organizations such as St. Jude Children's Research Hospital, Mayo Clinic, Cleveland Clinic, John Hopkins Hospital, and Harvard Medical School, as well as with institutions that specialize in other fields like technology and development, for example, NASA, MIT, and Oak Ridge National Laboratory.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Large events, social media events, surveys, and school events.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
Surveys, community events and gatherings, social media events(such as livestreams), sharing of information and events with news outlets more frequently, and more frequent engagement and event hosting with large and important communities and areas, such as New York City, Los Angeles, Chicago, Cambridge, Oak Ridge, Fort Liberty, Virginia Beach, Tampa, and Yellowstone National Park. You can also do the same with overseas cities such as Tokyo, London, Paris, Beijing, Moscow, Capetown, Lagos, Mexico City, Canberra, Abu Dhubai, New Delhi, Seoul, Berlin, Vancouver, Tehran, Dubai, Hong Kong, and Shanghai.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   Reaching out to St. Jude Children's Research Hospital and developing connections and cooperations such as research on Acute Lymphoblastic Leukemia and ways to increase efficiency of medical care. Additionally, you could do the same with institutions like Mayo Clinic and Cleveland Clinic.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Lack of awareness of opportunities, importance, events, and benefits.

Email: STEVEMOBSLAYER@gmail.com

Submit date: 6/16/2024

I am responding to this RFI: On behalf of myself

Name: Julie McCarthy, PhD

Name of Organization: McLean Hospital / Harvard Medical School

Type of Organization: Healthcare Provider or Hospital System

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Clinician/Healthcare Provider, Investigator/Researcher, Research Participant

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Provide funds to give honorariums to community advisory board members. Actively disseminate trainings on community engagement (e.g., Harvard Catalyst). Create NOFOs that help people create these partnerships. Require more plans to enhance diverse perspectives across NOFOs.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Allow government employees through the Indian Health Service to receive research payments to participate as community advisory board members or receive compensation for participation in research that may be beyond their existing roles. When trying to partner with this organization, we were told that such employees would not be allowed to receive compensation for involvement in research, so cost-sharing as we had hoped was not possible in a way that feels fair, and it made it logistically challenging and we are not currently pursuing a proposal given this and other limited bandwidth and leadership support barriers to such partnerships. Create a brief toolkit or communication campaigns to market the benefit of working with researchers to groups/institutions in underserved communities. Many may not realize this is an option or now how to make these connections happen.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Create a budget line for such partnerships, and explicitly build in time to develop such partnerships in the NOFO. It takes a lot of time to build trust and work out logistics with people

operating outside of an existing research infrastructure.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Money. Give trainings to researchers with role plays on how to engage with community partners - specific language, example email templates, example marketing materials, etc. An accessible toolkit for step by step how to do community engagement and offering ongoing NIH-supported consultations to help people engage in this work. Offer a predoctoral T32 in this area, as many learn about this approach later in their careers.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Time limitations, no compensation, work during typical work hours, lack of awareness, lack of childcare, lack of clear expectations.

Email: jmccarthy@mclean.harvard.edu

Submit date: 6/18/2024

I am responding to this RFI: On behalf of myself

Name: Krista Forbes, M.Div, MPH

Name of Organization: St. John Baptist Church

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Cultural Practitioner

Role – Other:

Other roles identified with when engaging/working with researchers:
Cultural Practitioner , Organizational Official, Community-Based Clinic Investigator

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Strategies for researchers to partner with members of the community should include:
   1 - Researchers have a responsibility to the community to engage and conduct open conversations about: what research they are doing, how it will improve health of the community and to share what has already been done and the results.
   2 - Identify organizations that represent those who are often underrepresented in biomedical research. These groups would include: women, people of color, older americans, SGM groups and those from rural populations.
   3 - Collaborate with organizations that already host webinars, informational workshops, conferences, material distribution, etc. Community members are already familiar with the trusted voices from the community.
   4 - Offer funding to encourage community groups to conduct activities that include engagement and awareness of research program to aid in participation

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Ways for institutions conducting research to support community driven relationships is through funding opportunities that are fair and equitable.
   1. Funding: Community organizations who are the gate-keepers are often resource-thin yet request-heavy. Many external groups ask community to contribute to the design, plan and implementation of a qualitative component of a research project. There is no offer of financial support for the hours of work that is being asked to be done.

2.Reporting: When research questions or projects are complete, PIs and other leadership do not report any of the findings to the community members where the data was initially collected. This lack of communication from researchers further widens the trust gap that community has, making incentives offered suspicious at best.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

Approaches that research funders may consider to incorporate relationships among people, communities and researchers must make community engagement a priority. For instance, funders should consider policy changes that addresses the role of community advisory boards and their role along the research project.
2. Policy practices should also be reviewed and incorporated regarding ensuring diverse representation on Institutional Review Boards.
3. As FDA now has a requirement for companies to incorporate a diversity action plan, funders should review processes where there are opportunities to ensure researchers incorporate partnerships and scopes of work that includes community engagement.
4. Funders must inquire PIs to seek community engagement specialists to be part of the research project team, and perhaps offer incentives to researchers who build on a community engagement platform as part of their work.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

Things that may make people and communities more likely to engage with researchers:
1 - Researchers that look like them
2 - Research results back to the community
3 - partnerships with local institutions with similar interests of researcher: like local minority serving institutions and offer exposure to new technologies to assist in research work.
4 - Diverse Researchers as PIs: more women, more people of color, etc
5 - Assets and other research materials that are reflective of the communities being considered for partnership
6 - Pay equity for researchers

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Examples of things that detract from community participation with researchers:
1 - Negative comments being made about community engagement from researchers like: "there is no money for engagement", "it will take years to develop a community engagement plan", "does the work we are doing really need community engagement"
2 - Not asking about community partnership until the end of a project
3 - Returning to a community organization over and over again with no financial support
4 - Does not share information about available funding opportunities, research participation in other projects, community advisory board participation opportunities

5 - No cultural or emotional intelligence when in conversation with communities
6 - No diverse representation on research project team
7 - Research project activity is not held in convenient times or places
8 - Not hearing success stories of past research work
9- No sincere request made to participate by research team - no established relationship with community.

Email: krista.forbes14@gmail.com

Submit date: 6/21/2024

I am responding to this RFI: On behalf of myself

Name: Laurie Hassell

Name of Organization: University of Washington

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Member of the Public, Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Effective community/patient engagement doesn't operate effectively on a grant cycle. Investigators need time and resources to develop and maintain partnerships to effectively explore needs and priorities long before applications are submitted. Investigators who practice community engagement in their work are often disincentivized if tenure and promotion expectations do not accommodate the realities of building effective partnerships, extended timelines for project/study development and grant submission, and team based nature of publication and dissemination. Implementation of study findings within the communities/populations who benefit from study findings may not be expected of investigators and continuation of their partnerships after the study is complete to aid in implementation must be supported. Institutions can establish a culture of community engagement that enables investigators the time and resources to carry research innovations from development through conduct and implementation.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
NIH has the opportunity to model community engagement at all levels of the organization. Expecting funded investigators to engage in true community engagement is only part of the picture. Investigators respond to funding opportunities but the funding opportunities should also be informed during development long before FOAs are released. Enabling investigators to

meet communities where they means the FOAs not only address research topics informed by communities and patients but also are structured in such a way that enables community engagement. NIH can include community and patient collaborators in development of research agendas, development of FOAs and review of submitted applications. Who better to determine whether a grant application is feasible and relevant to communities than the communities themselves. It is not sufficient for communities to be advisors, though that's better than nothing. They should be collaborators, voting members and decision makers.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Email:

Submit date: 6/26/2024

I am responding to this RFI: On behalf of myself

Name: Sam Riffle

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Patient/Patient Advocate, Member of the Public, Investigator/Researcher

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
Have a minimum, representative 0.1% of all citizens, with individual sub-sampled ethnicities, composing their respective % of the overall 0.1% sample size. The Federal agencies should bias their research towards more OVER SAMPLING, than the current cherry picking, which has bias against the general public wellbeing.
0.1% of say 365,000,000 = 365,000, that would allow some age, sex, curr health, placebo, ... categories, so that at least 36,500 persons minimum representation would occur.
Phase I is most risky, so that population should never be less than 0.05% of the study, so above, 36,500/2 = 18,250 individuals
This is more fair, and gives a more statistically sound basis for Federal decision making.
For Rx developers, it makes a more serious commitment; There should be immediate TRANSPARENT research results, published in OPEN/Free to public disclosure, not later than 6Months after closing date of study, or the earlier close date of study.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Have institutions publish/educate communities, with online learning, to reach largest possible people/communities, wo respect to their condition, since family members may not have condition, but should be informed to help primary target iin making decisions.
All such outreach, proposals, status-updates, should be recorded and distributed by federal govt.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

At a minimum, have input from public/private Foundations dedicated to conditions addressed by funders. This can be the b-directional dialog, distribution referred to in 2).

There should be at least 1/3 funds directed to basic causality research, vrs Rx formulation research.

In the case of lp(a), researchers admit that they do not know mechanisms, or impacts of lowering lp(a) levels, since they do know know [positive or negative or unconsidered]consequences of doing so

... Is not that like driving down a road without konwing destination... only the Gas Station.value chain benefits.... and the risk of the unknowing passengers is ignored.

I know that is counter to the current $ oriented approach/ infrastructure, but YOU DID ASK for PERSONAL ENGAGEMENT.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

If results of trials are found to be more than 50% effective, then granted federal approval, the participants at any phase, should be given the right to receive the beneficial Rx, for the rest of the duration of their condition...

They put their lives at risk/ in either live or blind trial, ... not all may be able to afford Rx, at least make it covered by their insurances, for tier 1(Medicare)

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Barriers to reading medical/science literature;

No apparent Federal research into lp(a), all seems to be comming from companies pushing 'products' to lower a particular agent, rather than govt rsch into more causal, mechanistic studies.

The following info is voluntary disclosure, can be made public:

Although I am a symptomatic, I have >serious levels of lp(a) >338nm/L, and CAC>1,200, yet I am able to exercise, and be very active at 77. All the clinical trials I have requested to be in, have rejected me... for variuos reasons: most typically, you have never had mi, stroke... hey... isn't that a little late.. & would it not be better to have someone in studies, which might counter the ASSuMTIONS of the funding/agency/company sponsoring rsch ?

This is a followup to my prior results, & as mentioned I have high Lp(a), & high CAC, FH and renal issues in immed family's risk factors, yet not events, yet.

You must do something about wasting people's time... in what is qualification, what is not, wrt your oversite of Rx Company sponsored Rsch Study criteria:

I applied for study: ACCLAIM-Lp(a); which is:

https://trials.lilly.com/en-US/trial/465595?utm_source=family_heart_foundation&utm_medium=digital&utm_campaign=

Cardiovascular&utm_term=EZEF&externalRequestID=ad3a2010-33f0-11ef-bf21-395ac04d69cd&entityType=trial#referral
which states:
/--------------
Participants Must:
Have high lipoprotein(a) level, at least 175 nmol/L, and either:
" Be at least 18 years old and have had a cardiac event (like a heart attack or cardiac bypass surgery), a stroke, or peripheral arterial event (like a stent in an artery in the leg or an amputation)
Or
Be at least 55 years old and have risk factors for a cardiac event, like narrowing of the coronary or carotid arteries; a condition called familial hypercholesterolemia; or a group of other risk factors for cardiovascular disease"
/--------------------------
Clearly I am the latter category, since I have FH, and othr CVD factors.
Today I called the Lilley front end screening nurses, which said I qualified. They referred me to a 'local' rsch center, which then told me, that BECAUSE i had NOT actual adverse events, that I DIDNOT qualify.
The particular study was about kidney & Lp(a)... EZES study; There are apparently multiple substudies under the overall study.
ReCalling the Lilley Corp screening nurses hotline, they were either not aware of the actual criteria listed above, OR their internal databases are screwed up.
This is NOT the 1st time this has happened..
To me this reflect the need for more strict Federal oversight into what can be posted as a Clinical Trial qualification.. -or- the study sponsors should be required to update the criteria...
This constitutes a BARRIER to people.

Email: email.seRiffle@gmail.com

Submit date: 6/27/2024

I am responding to this RFI: On behalf of myself

Name: Jane McElroy

Name of Organization: University of Missouri

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Research Participant, Community-Based Clinic Investigator

In what setting do you primarily engage with researchers?:
Primary Care

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Engaging in community members is tough since 1) funding is short term and without guaranteed after the awarded period and 2) drafting proposals and getting feedback from the community is also tough since it requires ALOT of volunteer time by community members and little is clearly given back to these folks or the community. Further, the mission of the community organizations is rarely about research and implementing findings from research has very long trajectory of actionable items. Therefore, research engagement often relies on long standing relationships.
   With that being said, the material for community engagement has to 1) be relevant to them and their community; 2) communicated in a way that is understandable. Community member input is very important. For example, colorectal cancer screening is not an ideal way to talk about this topic to community members. Rather speaking about a 'colon cancer test' is what community members prefer---people were shy about the term 'rectal' and preferred test vs screening since community members said they go to the doctor and get tests run. Not screens. This kind of feedback took several meetings of an active community group; One can imagine the value of running groups to come up with tailored communication and this is rarely part of the project deliverables---it seems one is supposed to already know this.
   Both of these pieces need to be part of the partnership and that takes time which isn't as helpful given the structure of funding.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

The medical centers seem to use a business model and it is to make money to be in the black. Research may not align with most medical institutes' mission. Further, EHR used in clinical work has not be designed for research. It is a health record not designed for research protocol. Until the health system is motivated to join the research endeavor only a few places will be part of this. Although big data is the talked about approach and extracting clinical data to address questions, there are numerous limitations and one of the most troubling is the poor data quality and poor representation across the spectrum of patient demographics.

Either the institution needs to be financially motivated to include research as part of their mission (meet them where they are) or policy changes are imposed on health systems that require them to be involved in research for accredited.

Even if communities identify areas they find most relevant, most NIH funding does not support implementation science but rather basic science. Basic science is not an area of interest to people/communities. Increased value in pragmatic trials and implementation science research would provide some traction on having community members be invested in research.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

One of the best strategies is to have a policy that requires research projects or enrollment in clinical trials of federally qualified health centers (FQHCs) of patients and public health departments (PD) of community members. These entities receive substantial federal funding and are very good at addressing deliverables. At this time, without any incentive or requirement, the mission is patient care (FQHCs) and program implementation (HD). Engaging in research is really out of scope for these entities but they are the places which reflect people who are under-represented in research and could be excellent partners in the research enterprise.

Research funders' current strategy to provide substantial funding to well-established high powered city based institutions, generally. It would be helpful if the portfolio who who is funded was expanded to those who are less richly resourced (or maybe a few awards are intentionally funded to those who service rural communities)--These institutions therefore often work with community organizations; this is particularly clear for much funding related to rural health---given to metropolitan based institutions who spend the resources learning about issues outside of the urban environment--not really moving the needle forward. Further, less resources institutions have learned how to get things done on a showstring. Maybe set aside 2 or 3 awards specific to these less resourced institutions since the review panels rarely ignore the name of the institution when evaluating an application. From personal experiences, reviewers have scored prestigious institution application very high, though the actual application was poorly written--when asked about the score, the review said 'I'm confident they will do good work.' This confidence is not given to less well known places.

Provide a 'hard ship' adjustment to the budget for those who engage in community, rural, hard to reach populations since it is much more expensive to achieve sufficient sample size among these populations. Going to a very large healthcare system to recruit for a more common health outcome just costs much less than engaging in multiple smaller healthcare systems to achieve the same result. Just saying

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

   Reduce burden on clinicians to identify participants; allow patients to be approached about studies (reduce the gatekeepers); Policy change that anyone receiving federal support for health care has to allow researchers access to patients contact (the details would need to be sorted but this is one of the bottlenecks to human research--access to eligible patient panel).
   Provide opportunities for participation that describes the study in easy to understand language and ways to contact the researcher, if interested.
   Engage community health worker who can 'pitch' studies relevant to the community (not sure who pays for this)--that is the huge barrier. The need for community-based folks being involved in the research enterprise but finding money to support this person(s). For CHW, if the deliverables of health centers and FQHCs, who use CHWs, was research products, it is possible that CHWs could be the face of research projects with patients.
   Land grant extension faculty could be a potential source of a trusted member of the community; however, they are not in the business of research or really healthcare and this would entail a vision shift.
   Consider alternative 'payment' to the community. Instead of individual compensation, providing something for the community, such as new playground equipment or sponsoring a sports team uniforms (not sure this is an allowable expense or not) but if not, it should be since that would impact the community much more than given individuals $$.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

   1) not relevant to the community's concerns 2) lack of awareness by the research team of the burden on the participants (travel time, competing needs (who takes care of the kids), can't take off work to do it, 3) helicopter approach (researcher comes in and does their thing and then abandons the community--leave them without any idea of what is next, 4)expectation that community people will be altruist and provides limited benefits to the community--not hiring people in their community, not visiting the community for anything besides their project needs, 5) expectation of people volunteering their time to help an outsider, 6) virtually no groundwork to engage the community without attaching an ask to the engagement (concept of the research being self serving for the researcher, not for the community).

Email:

Submit date: 6/28/2024

I am responding to this RFI: On behalf of myself

Name: Cynthia Gerhardt, PhD

Name of Organization: The Research Institute at Nationwide Children's Hospital

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Clinician/Healthcare Provider, Community-Based Clinic Investigator, Investigator Researcher, Patient/Patient Advocate, Research Participant, Community Advocate, Member of the Public

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Providing education and resources for researchers to understand the importance of community engaged approaches from inception; building diverse teams; being trustworthy and building trust; culturally responsive practices; reducing barriers/exclusions to participation; etc.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   infrastructure to connect community partners and researchers; embedded community ambassadors; education and training for community partners and researchers; involvement of community partners in study generation, grant reviews, IRBs, etc.; reducing barriers to engaging partners (e.g., payment, contracting, etc.); communication and marketing about the importance of community partnerships to improve public health

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   train and engage partners in grant reviews, developing funding calls, etc.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

all of the above...needs to be a true partnership with ongoing communication and building of trust

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
lack of respect, trust, communication; lack of appreciation of barriers like payment, travel, burden of paperwork; lack of cultural responsiveness

Email:

Submit date: 6/28/2024

I am responding to this RFI: On behalf of myself

Name: Dr Annapuranam K

Name of Organization: Rajagiri College of Social Sciences

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Organizational Official

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Indian context

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Sociological perspective of health and health practices

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Government Agencies

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   culturally competence

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   no compensation

Email: kannapuranamrb@gmail.com

Submit date: 6/28/2024

I am responding to this RFI: On behalf of myself

Name: Vincent Vendtto

Name of Organization: University of Kentucky

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Investigator Researcher, Patient/Patient Advocate, Research Participant

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
Community pharmacies provide a geographically distributed network of recruitment sites for outpatient based clinical studies of diverse populations. Partnership with an research center provides a unique opportunity for impactful research. Approximately 90% of the US population lives within 5 miles of a community pharmacy, and community pharmacists are among the most trusted public health providers in both rural and urban communities. Participant recruitment at community pharmacies in the communities in which participants live and work provides a unique strategy for engagement of diverse communities at the county level and below.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
By leveraging the public trust for community pharmacists, participants are able to engage in research at the community level. Critically, research results must be reported back to participants in some capacity through direct communication with individual participants or "back-porch" chats where science communicators describe the data and its impact both locally and globally. This strategy of community pharmacy and "back-porch" data dissemination is focused on meeting people where they are.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
Launching activities community-pharmacy based research opportunities requires funding to build the infrastructure that builds upon the trust of community pharmacists. Through this

paradigm, there are also opportunities to build educational and promotional opportunities for pharmacy technicians and clinical trials managers to ensure such studies are facilitated similar to hospital-based studies. Therefore, agencies and non-profits who not only support research studies but incentivize pharmacies to shift their care paradigm toward research based care and reimbursement will have a significant impact on community health.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   In our experience, participants across Kentucky have been eager to be affiliated with the University of Kentucky. Our program called PROTECTS (Venditto et al. JAPhA 2024) was built in the context of the COVID pandemic and also offered fair compensation and SARS-CoV-2 testing through a CLIA certified lab to guide clinical care. Importantly, recruitment was also conducted through passive recruitment and participants were enthusiastic about engaging, and because advertisements and recruitment occurs through the community pharmacy, participants are generally initiating their interest in the study from a place of trust. This was also true among participants who did not receive the COVID vaccines.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Entering the community to take samples and leaving without reporting results is generally less impactful then ensuring continued engagement with participants. In general, community pharmacies remain pillars of their communities and the success of enrollment and engagement is based on the lasting infrastructure built within the community pharmacy. Conducting these recruitment activities in other locations of trust (churches, extension offices, etc) can also work, but when conducted in a hospital or acadmeic setting or a place that does not promote community fails to achieve the intended goal.

Email: vincent.venditto@uky.edu

Submit date: 6/30/2024

I am responding to this RFI: On behalf of myself

Name: Raza Ali

Name of Organization: Las Positas College

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Investigator Researcher, Cultural Practitioner, Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
As their keyboards click-clack late into the night, typing up a preprint paper for immediate release, our dad is manning the gas station store, the tip-tap of cash register buttons punctuating the buzz of fluorescent lights. In the prep room, you'll find them diluting aqueous solutions until the molarity's just right, while in the back of the family restaurant you'll find us doing the same with cilantro chutney (cost-cutting, rent went up again). While their data analysis software boots up with a whirr, ready to parse through convoluted results, we scour grocery store discounts, ballpoint pens prepared to circle the best deals. And while they blaze through the literature, reading tens of studies a day, we squint at legal forms printed in rigid black ink, devoid of the twists and turns of our calligraphic Urdu script. While you won't find us in the labs, you'll find us driving weathered yellow cabs, their cloth seats imbued with the lingering scent of cigarette smoke. But it doesn't have to be this way.
Pakistani-Americans are one of the most underrepresented groups in research roles, and I have a hypothesis to explain why. When my parents' generation came to this country, they aimed to create opportunity for their posterity. To them, emigration was an escape from the decades-long (and ongoing) government corruption and class structures that plagued the subcontinent by inhibiting social mobility. So when they arrived as immigrants to the United States, their first focus was putting halal food on the table, paying utility bills, and ensuring a roof over our heads. Thus came the corner stores, taxi services, and other mom-and-pop (more accurately ammi-and-abbu) businesses, which were seen as the epitome of the American dream. While this drive pushed our community toward success in many industries, participating in academia was—and continues to be—considered a luxury. Our people's apathy to research isn't fueled by a lack of ambition or capability but rather by the weight of more immediate priorities. From sending remittances to loved ones back home to supporting multi-generational households where family

members come and go, every dime is stretched to meet the needs of a whole ecosystem.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   With a strategic vision and collaboration with institutions, the Pakistani-American community should be incentivized to recognize that research is also an essential societal pillar—and one that we must actively participate in. When findings originate from within our community rather than from the outside, they will not just be more culturally informed but also foster relationships of trust and engagement. This idea is called homegrown research. As explained by Jennifer Bay, who coined the term at Purdue, homegrown research is a manifestation of research justice. It's a reclamation of intellectual self-determination that transforms academic inquiry from an ivory-tower institution into a public service. But this transformation requires reform from both communities. Homegrown research necessitates pragmatic experimental design rather than purely theoretical academic inquiry.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   A change is needed in the advertisement and awareness mechanisms, such that they originate from within community hubs and centers rather than from outside of them

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Email:

Submit date: 7/2/2024

I am responding to this RFI: On behalf of myself

Name: Fred Harris

Name of Organization: The LAM Foundation

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Member of the Public, Organizational Official

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Meet with influencers to share the need for the research by sharing the disparities that affect the community where research is needed.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   Make sure that you have a trusted Ali, and someone who can communicate the need for the research and the positive outcomes that it could bring. While also using the said incentives for participating.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Email: pastorharris@laminc.net

Submit date: 7/3/2024

I am responding to this RFI: On behalf of myself

Name: Dayna Wolter

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Caregiver Family Member

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Patient/Patient Advocate, Member of the Public

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   I am a brain health advocate since losing a family member to suicide/bipolar and being a patient advocate for another family member struggling with schizoaffective disorder. My recommendation is for the brain health research community to partner with groups such as NAMI and the Schizophrenia & Psychosis Action Alliance to get participation and real-life stories from family/loved ones in this area of research. It is very important for family members and caregivers to have a seat at the research table, since our loved ones are often not able to communicate or advocate for themselves. For example, doing focus groups or 1x1 interviews with caregivers/family members.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Something to explore with the National Alliance on Mental Illness (NAMI) for brain health, possible the American Foundation for Suicide Prevention (AFSP).

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   It is important that caregivers/family members feel heard, and do not have to be re-traumatized in discussing difficult events. From my perspective, having an empathetic approach and being transparent about what the research will be used for, how results will be disseminated or

impact a particular population, etc., would be all good things to share. I don't think technology is really the answer here, I think it is connecting to the local NAMI peer support groups, and other similar organizations like the one mentioned above. I've been in this space a long time, and it's very difficult to put all the puzzle pieces together. Virtual interviews are easiest, though I do understand they aren't always the best. Also, taking referrals of others who may know of folks to talk to may yield some new participants or populations.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Using any stigmatic language such as "committed suicide" instead of "died by suicide" or not using person-centered language (e.g., "psycotic person" or "schizophrenic" vs. "person struggling with xx disorder." It would probably not work to get someone to travel in person and spend the time, unless there is some compensation for travel modes and time involved (e.g., flights, taking PTO). Having a research-first approach versus a person-centered approach also can come across in a callous way. People going through SMI issues with loved ones already have a lot of trauma in their life, to add a bad "customer experience" during research in any way will not be helpful.

Email:

Submit date: 7/11/2024

I am responding to this RFI: On behalf of myself

Name: Greg Merritt

Name of Organization: Patient is partner, LLC and PCORnet

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   What if we were able to shift incentives so that impact on patients was a metric for clinician/researchers and was as important as any journal publication or conference presentation
   What if there were more partnerships with patients to innovate in disseminating results (using AI to personalize results to patients or co- created podcasts, etc

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Co- creating with patients trials that are authentically "careful and kind" trials where care is paramount and participants are not subjects but partners in research. (Send flowers and card to families if participant dies during trial)
   Name trials after patients not current acronyms that make less sense simply because has always been this way

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Innovate in finding ways to fund patient co-creating questions that matter - why do researchers in other jobs get paid to write grant applications but patient partners do with the hope of funding. Think of new paradigms

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Work with behavioral economists to create "frictionless" participation based on science
Find ways to end beauracracies at academic institutions to pay patient partner contributions
Make trials more joyful
Expand bright spots and replicate!

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Social class and trust is paramount - how to innovate in this space
Find ways to lift patients out of poverty by explaining how they can learn ways to be trained and employed as clinical research assistants, etc

Email: greg@patientispartner.com

Submit date: 7/11/2024

I am responding to this RFI: On behalf of myself

Name: Tom Norris (Joseph T. Norris, Jr.)

Name of Organization: American Chronic Pain Association (ACPA)

Type of Organization: Patient/Community Advocacy Organization

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Member of the Public

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   a. Establish a mentor program requiring researchers to partner with a Person with Lived Experience
   b. Establish a list of best practices for patient engagement
   c. Establish a list of qualified people with lived experience

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   a. Establish a mentor program requiring researchers to partner with a Person with Lived Experience
   b. Establish a list of best practices for patient engagement
   c. Establish a list of qualified people with lived experience
   d. Establish a recognition program for those researchers working with people with lived experience
   e. Establish a community recognition program for those people with lived experience who participate as patient advisors in clinical trials
   f. Coordinate with other agencies to establish a list of experienced people with lived experience

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   1. Require these partnerships be part of the funding request

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

1. Widespread use of remote sensing devices (Apple watch, Fitbit, etc.)
2. Creation of a YouTube showing why participation of clinical trials is important to the population
3. Use video screens in waiting rooms to educate patients on the "what and why" of clinical trials
4. Publication of information on clinical trial participant availability on social media

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

1. Lack of knowledge of what a clinical trial is
2. Fear of personal damage from participating in clinical trial
3. Low compensation rates
4. Lack of clear (common) language in documentation
5. English only
6. Fear of jeopardizing current medical situation
7. Being too involved in just surviving one's medical situation to take the time to participate
8. Reputation of research institute
9. Lack of opportunity awareness
10. Technology divide

Email: tomn482171@aol.com

Submit date: 7/15/2024

I am responding to this RFI: On behalf of myself

Name: Erin Driver

Name of Organization: The Ehlers-Danlos Society

Type of Organization: Patient/Community Advocacy Organization

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Member of the Public

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   1. Openly talk with the patients about ALL aspects of the research including any and all possible negative effects to them due to the research trial
   2. Include close family members and caregivers who may live with and care for the patient in all aspects of the research trial, especially if the patient has any chronic illnesses and/or disabilities

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   1. Do more to make communities and patients aware of clinical research that is happening such as advertising on online forums, reaching out to community leaders and advocates, and hosting town hall meetings
   2. Have rewards for those patients participating in the research beyond free health care related to the research during the trial; rewards could include such things as care related to the research after the trial has ended and health insurance at no cost for the patient

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   1. Work with patients and their families and/or caregivers to ensure cooperation and understanding between the patient and the researcher as well as appropriate medical care during the research trial and, possibly afterwards especially if there are any long-term side effects that impact the patient/participant

2. Get community leaders and advocates involved to help ensure patients know about the research being done as well as how to participate and the benefits of participation

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

1. Have rewards for those patients participating in the research beyond free health care related to the research during the trial; rewards could include such things as care related to the research after the trial has ended and health insurance at no cost for the patient
2. Include patients needs into the rewards of participating in the research (I.e. if a wheelchair is needed, provide it even after the research is completed; provide transportation so patients can get to the research trials' locations; provide health insurance or continued admittance to the research department after the trial ends if necessary (i.e. admittance to a team of specialists for a rare disease such as MCAS or EDS which cause a lot of gastrointestinal and digestive issues)

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

1. No information received regarding the particulars of the research
2. No transportation to and from research facilities
3. No regard for the patients' feedback, concerns, or feelings
4. No rewards for participation in the research
5. No inclusion of family members and/or caregivers who need to know what the patient is doing

Email: erindriver003@gmail.com

Submit date: 7/15/2024

I am responding to this RFI: On behalf of myself

Name: Daphne Wright

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Investigator/Researcher, Patient/Patient Advocate, Research Participant, Community Advocate

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   wright4me4ever@gmail.com

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Email: wright4me4ever@gmail.com

Submit date: 7/15/2024

I am responding to this RFI: On behalf of myself

Name: Dora Shawley

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Community-Based Clinic Investigator, Investigator/Researcher, Organizational Official, Research Participant

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Never

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Have language interpreters available and point out any portions of the research that may infringe upon religious beliefs

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   More publication of research projects and types of participants needed.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Try to get grants from government and non profits. Some large corporations might. Find out if potential participants are connected with any companies/etc that might support fund raisers. Especially for rare disorders. Cancer easily receives a lot of funding but lesser known disorders do not.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   Convenience - if it's away from home for a rare disorder, is there somewhere cheap I can stay if I am a participant?

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Lack of awareness. Personally, I'm not concerned with compensation as much as where I rest my head at night, how I travel to get there, where do I get my meals.

Email:

Submit date: 7/17/2024

I am responding to this RFI: On behalf of an organization

Name: Jeanna M Benny

Name of Organization: BobbyJones Chiari Malformation Foundation

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Patient/Patient Advocate, Caregiver/Family Member, Community Advocate, Investigator/Researcher, Member of the Public, Other

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Never

1) **Strategies for researchers to best partner and work with people and communities.**
   Engagement and Transparency with a commitment to research and respectful relationships are essential and critical.
   Our Focus; 5mm rule from 1985 and 1986
   1. Position of Cerebellar Tonsils in the normal population
   2. Accuracy of Tonsil Position in determination of Chiari 1 Malformation

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   3. Cut Point is the highest position considered and a positive result, if zero is the cut point, then ANY patient with brain tonsils at zero or below is considered to have Chiari 1. This is according and acceptable by the neurological research team of Doctors at Washington University in St. Louis as of July 15, 2024
   Chiari Sensitivity is at 92? The Specificity is 99.5?

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   4. Cut Point of -5 is Sensitivity of 92.00? Specificity is 100?
   5. The Position of -4 is Sensitivity at 96.00? The Specificity is 99.5?
   This is a real problem and issue that no Doctor explains to the patient and or caregivers. Need to do better!

6. Aboulezz et al, 1985 and Barkovich et al 1986, is an Outdated Rule, while we need to have it brought forward for consideration, it needs to change to a boundary of CHOICE!
We are a Nation that is far more advanced in Medical Research in the year of 2024.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Thousands of potential patients and current patients are not getting their voices heard by many medical communities and this has been happening for decades.
Trust those to make change when we don't know how to advocate for what we don't know!
Again, responsibility and responses to those voices need to be transparent and communicated with respect.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
I have been fighting for human rights and better healthcare for over two decades, no one wants to hear the truth to be told.
Others in this day and age are ready to give up on the fight for truth and humanity.
Looking forward for a better future.
Thank you, Jeanna M Benny, parent advocate, Forensic Accountant CPA in Forensic Accounting in Missouri and BobbyJones Chiari Malformation Foundation Missouri Chairman

Email: bennybunch137@charter.net

Submit date: 7/17/2024

I am responding to this RFI: On behalf of myself

Name: Shazeen Suleman

Name of Organization:

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Community-Based Clinic Investigator, Cultural Practitioner , Research Participant, Caregiver/Family Member

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   My name is Shazeen Suleman, I use she/her pronouns and I am joining you from the traditional territory of the Ohlone people, now known as the bay area.
   My positionality informs the perspectives I will share with you today: my parents arrived in Canada as refugees and I am a Muslim woman of colour with a chronic illness, and an immigrant here in the US. I work as a pediatrician who primarily cares for newcomer children, including immigrants, refugees and undocumented children who have neurodevelopmental needs, building on decades of community development. My work can be viewed at www.thecompasslab.org

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   I want to share with you two perspectives that I've learned as a researcher who works along side immigrant communities AND also as a participant in trials, as someone with a chronic illness.
   In my experience, historically, this kind of work has not been valued the same way as other research has been, by funders, by research ethics boards and by academic institutions.
   Community engagement takes time, and it takes trust, which extend timelines and budgets.
   Being flexible around budgets and timelines, supporting community members to be co-investigators on research application (ie. do they really have to complete CITI modules or submit a biosketch? How would a community member be able to do this?)

We know that communities of color and especially immigrant communities have been excluded from studies and often report mistrust with institutions, But trust can be be rebuilt and brokered between individuals and institutions: from clinician to researcher and beyond: with schools, with settlement agencies, with community champions. True, equitable representation matters, which is one strategy funding agencies can use to require research teams to establish these links. Funding agencies can also specifically fund projects that demonstrate longstanding relationships, not just opportunistic ones for the purpose of a study, through letters of support and length of relationship.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

Our research is nothing without our participants, and yet often they are treated as a study ID or a number. Sometimes, we might give someone a gift card, but this may not be the way all communities want to be valued: I have certainly heard this from my participatory work with immigrant families. In addition to compensation for their labour, I have heard from newcomer families how important it is to be told how their role contributed to the study findings. They want to know: even in a flyer or small video in multiple languages or shared at a community event with food and activities.

As a participant, I echo these feelings. I have been motivated to join studies to contribute to science, and if I didn't have insight into what went on on the other side, I would likely have left. I've had no communication with the study team, the consent form was just shared in a giant 14 page document, and given questionnaires to fill out. Money can be offered, but it is not the only way to show value. I would call on funders to facilitate guidelines to ensure researchers do this kind of dissemination to show value; not just in the grant, but strategies that funds are withheld until dissemination is done.

Compensation is still essential, and there are many research ethics boards that make it very difficult for compensation to be given to community members, especially those who are more marginalized and whose voices need to be centred (ie. undocumented, unhoused, youth) who may not have the literacy level or SSN numbers. Funders can also play a huge role in ensuring research institutions have procedures in place within their research ethics/institutional review boards to permit this.

I would also encourage the NIH to look beyond cultural compentence, and more into cultural humility models.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

I have heard from newcomer families first hand that while trust is essential, a poor experience with the instuttion - even in an unrelated setting, like an Emergency Room - erodes that trust. A parent once told me "Why would I help you when the hospital treated me so badly?"

Researchers and clinicians are not used to seeing themselves as extensions of the system.
Helping providers see the interconnectedness is an essential strategy.
Participation that is not flexible, that requires travel without compensation and support or childcare, was also a barrier, in addition to not having translation.

Email: sulemans@stanford.edu

Submit date: 7/19/2024

I am responding to this RFI: On behalf of myself

Name: Fanta Waterman

Name of Organization: University of Illinois Chicago

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Cultural Practitioner

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Communities understand the value of clinical research which can lead to health opportunities for members of their community. However, the dynamics and power structures, as well as approaches to engaging participants, is often not considered when approaching the community for participation. Value holders in the community should be INCLUDED, not just engaged, from the inception of any intervention, to align the needs of the research with those of the community. Specifically, an alignment on the endpoints of the research should be prioritized to ensure not only are endpoints relevant to the community collected, but that these data are collected through a mechanism which increases the chance for effective participation by the community. Frameworks rooted in equity can support these efforts as they support identification of the correct persons to include/partner with.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   As a newer academic researcher, I've personally been discouraged from applying to grants because of the compensation guidelines for my partners. Especially with community based

health NGOs (I personally work with ones in the Caribbean), where passion - not dollars - are keeping these organizations running, NGO founders and program directors are expected to essentially volunteer to work with grant recipients because they can only be compensated according to their salary. Many of my partners don't EARN a salary unless they can contribute to a specific research effort at a certain percentage while running a nonprofit, and 5% here and there won't keep the lights on in their own home and is unsustainable. Said another way, founders of these organizations are often forced to keep NGOs as a second job while they earn a full-time salary doing unrelated work, disallowing these organizations the opportunity to consistently serve their communities independently and eventually make them self-sufficient, equal contributors to global health efforts. Unfortunately for many, this oversight by funders and philanthropic organizations lands as insulting for potential partners, and instead of sending a message of partnership and power-sharing, it insinuates a desire by those in power to maintain a perpetual cycle of poverty and charity.

Email: fwater2@uic.edu

Submit date: 7/19/2024

I am responding to this RFI: On behalf of myself

Name: Tonya Harris

Name of Organization: WeKonnect, LLC

Type of Organization: Professional/Scientific Organization/Association

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Member of the Public

Role – Other:

Other roles identified with when engaging/working with researchers:
Investigator/Researcher, Patient/Patient Advocate, Community Advocate, Caregiver/Family Member

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Never

1) **Strategies for researchers to best partner and work with people and communities.**
Before any engagement (or) strategy development process, one would need to identify a few basic quantities of any community before you go, such as the community's history, its layout, neighborhood relations/(ships), who identify as trusted voices in these communities, etc. Identifying and spending some time (6 months or less) creating listening sessions, etc., small community events, and activities will connect to what's often been very non-trusting individuals to get a sense of what's happening there. Then, explain in detail what is needed, who's going to be doing it, how long it will take, any compensation, etc., and whether they will be able to learn anything to help them with the study. Organizations like Town Watch, etc., could be very instrumental in providing contacts and giving you a sense of the area of interest. Once, my colleagues and I created an entire agenda/project without even asking participants what would work for them or if the things we presented were what they wanted and/or needed. The first year of a (3-year project) failed as we did not ask exactly what was needed; thus, no one showed up to see any of the project goals/objectives because we offered it in the evening, and they never came out at night(woman). They needed care for their children and had been interested in things their husbands could do, so they rescheduled these earlier and on Saturday morning. etc. This level of community mapping and assessment should influence whether the communities meet the merits of the study or not. Then, as you know, communities have misconceptions and fears about research and clinical trials and may not understand the differences, so that also needs to be flushed out as well. Then, communities have champions (or) folks they look up to even if they are a part of a less desirable group, they also need to be identified so all presence in these areas is known and given space to complete the tasks, like where here during these hours on these days, to spoke to those you're trying to help, etc. Walk the community during different times of day/night or drive-throughs. Identifying the cultural

nuances is so important prior to any work being done. This is to ensure you can begin to understand things, like where the children play or sell water near highways, what time the ice cream truck comes in the community, and the busiest barbershops/hair solan, libraries, social service offices, and laundry mats, food stores/markets. You'll even see the disparities and shortage of equity and quality in everything, everywhere. Those $5-$10 gift cards are also helpful while information is being gathered, etc. Usually, those in the local community are involved, especially those doing mapping research for addiction and its mitigation. Participants may want a sandwich and drink from the corner store, which could be arranged prior to the mapping activities with the merchant, etc.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Often, the language used by my researchers is cumbersome. Building relationships that will lead to partnerships with researchers and people within these communities, at the very least, requires a high level of scanning and investment and a sustainability plan once the project /research has been completed. The above examples are too uneven for many community members in underserved settings to understand? Thus, researchers are only hearing from a few instead of many. Door-to-door canvassing is an option as it gets more granular data. The traditional locations have become obsolete; thus, our paradigm needs to shift to more viable locations in communities to start to become truly successful in our data collection process. Extensive knowledge is necessary to provide researchers with significant information on today's challenges. Once that's been determined, tools around incentivizing persons should be based on what researchers need, from whom, and the research content, frequency, and length should be decided upon ways to implement incentives. These communities are in need, and outlining basic things and building on that would surely be a great ROI. Those who would benefit from this data collection process are the hardest to reach, and researchers need more viable places to identify and collect data. Such places could be social service offices which are an overlooked source of data. In front of supermarkets during certain times of the month, a short questionnaire/survey hosted by those workers who are representatives of these communities would get data as well as community parks, recreation centers, etc.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
A boarder more diverse group needs to determine this (approach) and a structure should be in place before selecting and assigning; where funding goes, to which set of communities, and to who in these communities gets resources? What are the rules and/or eligibility protocols/procedures, etc. Its been observed that the community based (grassroots CBO, Faith Based Organization FBO) are being left out of this work? Faith-based can be a trusted sources for some of this work but not of the NIDA priorities? Those in communities that have been identify need to have their voices heard to share these approaches first, not what's listed above, as they are the trusted sources. Not going to those in state/local leadership to identify

NIDA's priority locations should not be part of the selection process due to potential bias's.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   There has to be a more straightforward way to access this data without a lengthy training process. How can this be shortened or simplified to support those whose proficiency could be below average and who struggle to understand? Some of these examples are more relevant than others for this question, such as cultural competence training and culturally competent research models.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Elders in communities and trusted sources have experiences of generational trauma of those who participated in any research or clinical trial. Unless clearly understood, they may still say no because of these biases based on stories like Henrietta Lacks, etc. These examples are not as relevant as historical/generational traumas, the wounds of those underserved communities, etc. This is also true for Native Americans, as well as AAPI and the various Latin communities, etc. These stories live on in the lives of those who have suffered.

Email: 1wekonnect21@gmail.com

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Jeanna Marie Benny

Name of Organization: Bobby Jones Chiari Malformation Foundation

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Member of the Public, Other

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Focus: Post Traumatic Stress Disorder (PTSD): Symptoms, Causes, Women, and Children
   Information and Data retrieved from the Mayo Clinic(www.mayoclinic.org) and the Centers for Disease Control (www.cdc.gov)
   1. Post-Traumatic Stress Disorder in Children
      a. Reliving the event over and over in thought
      b. Nightmares and sleep problems
      c. Becoming very upset when something causes memories of the event
      d. Lack of positive emotions
      e. Intense ongoing fear or sadness
      f. Irritability and angry outbursts
   2.Changes in Physical and Emotional Reactions
      a. Being easily startled or frightened.
      b. Being mostly on guard for danger
      c. Self-destructive behavior, such as drinking too much or driving too fast
      d. Trouble concentrating
      e. Irritability, angry outbursts or aggressive behavior
      f. Overwhelming guilt or shame
   3. How PTSD affects those who care and are close in friendship and in families
      a. Withdrawn and Lonely
      b. Who will listen and take the concerns seriously
      c. Do individuals and caregivers really know how to REPORT the concerns about mental illness
      d. Memory loss is evident in most cases

e. Most patients need to be accompanied by a caregiver or legal guardian attending appointments at a Doctor's office

f. Listen with empathy, many individuals today do not take the time to listen

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

1. Try listening to our Veterans who suffer mainly from PTSD
2. Try listening to children who live with Adults who suffer from PTSD
3. Try listening and understanding others to implement proactive coping skills and solutions for both the children and the suffering Adults

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

1. The Obama Care Government Plan of 2008 was based for a tax incentive program after the success of the Bush administration, and not for the American people who suffer from PTSD and or Neurological disease.
2. The Obama Care Government Plan of 2008 was FINE based against the American People needing to be insured to keep down their pharmaceutical and health care cost.
3. The Obama Care Government Plan of 2008 is umbrellaed under Medicare and will drain our Social Security system by the year 2050, IF we don't correct it by the year 2035. The GDP math supports these financial findings for the future of our Nation.
4. Under the Obama Care Government Plan of 2008, no one can see PTSD or Neurological disease or Genetic mutations on the brain. Cost cutting legislation and negligence have been practiced for years.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

The Research Models mostly start in Europe. The European FDA is completely different from our FDA in the United States of America. Drug patents and other billions of dollars in projects for research, development, and technology take years of difficult and scientific studies.
PTSD requires many key and logical components that are ignored in our year of 2024.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Examples all over our United States of America DO INCLUDE no/unfair compensation, participation, lack of opportunities, and lack of awareness of opportunities.
We can all do better moving forward together.

Email: bennybunch137@charter.net

Submit date: 7/24/2024

I am responding to this RFI: On behalf of myself

Name: Heather Jones

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Research Participant, Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Making access to trials/research more readily available to the public.
   Brochure/flyer in PCP offices.
   I had to go seeking them out.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Making sure to follow-up with patients, staying in contact when supposed to. Being on time for the appointments themselves. Sometimes there are too many "hands" involved and one ends up dropping the ball.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   If they do not have funds, possibly partner with local businesses for gift cards. Write off for business, normally the person will spend more than the gift card amount, and the medical facility isn't out $. It also builds customer relationships of actually getting out and talking to people in the community about what they are doing/trying to do. It's also an opportunity to leave information about the upcoming trial/research to get the word out.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

People, relationships, being down to earth, just being real and taking time. Everyone knowing their time is just as valuable as the next persons no matter who they are.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Opposite of above.

Email: heatherhucksjones@gmail.com

Submit date: 7/29/2024

I am responding to this RFI: On behalf of myself

Name: Gwen Mayes

Name of Organization: GwenCo Health/HCMA

Type of Organization: Member of the Public

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Clinician/Healthcare Provider, Patient/Patient Advocate, Member of the Public, Community Advocate

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Develop protocols and informed consent procedures in multiple languages. Work with cultural, religious, and ethnic organizations to ensure proper language and phrases, incentives, etc.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Partnerships with patient advocacy organizations is essential with programs to 'alert' members or engage through webinars, townhall meetings, etc.
   Wide utilization of social media platforms emphasizing the advantages and importance of participating in research/clinical trials. Make efforts to grow the use of clinicaltrials.gov as a household go-to place for information rather than "google".

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Include in requirements for funding a plan for community engagement and public input on the design and implementation of research protocol.
   Require utilization for example for a Patient Advisory Council, for specific disease states, especially rare diseases.
   Require pharmaceutical companies to fund PSAs for TV or social media encouraging participation in research.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   Positioning the research protocol or study as furthering the knowledge of a disease or health condition that impacts the subject directly. Be specific in the explanation on how the findings will impact real world experience, practical day-to-day living, decrease costs or time in the hospital, etc. Be specific in layman terms and that the findings are more than theoretical.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Fears of being disadvantaged or exploited in research are rampant, especially among minorities and disengaged populations. There may be uncertainties for women who wish to have children and fear the impact on getting pregnant, fetus, birth, etc.
   Financial struggles diminish the altruistic tendencies to engage in research. When people cannot afford treatments and medications, they may be less likely to feel that participating in research has any value to them personally.

Email:

Submit date: 7/30/2024

I am responding to this RFI: On behalf of an organization

Name: Jeanna Marie Benny

Name of Organization: Bobby Jones Chiari Malformation Foundation

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Member of the Public, Patient/Patient Advocate, Other

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   1. Be Inclusive and have Diversification
      a. The Rare Disease Congressional Caucus (RDCC) is a bipartisan congressional caucus open to all members in both houses.
      b. This caucus works to advance legislation and education regarding specialized and uncommon health issues and diseases.
      c. This caucus promotes patient advocacy, regularly interfacing with nonprofit advocacy organizations.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   1. Be Inclusive and have Diversification and Respect for decades of Research
      a. Support legislation to improve health for families.
      b. There is existing legislation introduced to the US House and Senate that will have immediate, short term and long-term benefits.
      c. Patients living with Chiari, syringomyelia, EDS and their many related disorders are part of who an individual is, and this is living a long-term life.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

1. One such piece of legislation is the bipartisan HELP Copays Act
    a. Copay assistance programs help patients afford out of pocket expenses to cover specialty medications for chronic illnesses.
    b. Copay Accumulator Adjustment Programs (CAAPs) prevent those programs from counting toward a patient's deductible or maximum out-of-pocket expense.
    c. CAAPs are discriminatory toward people living with rare and chronic illnesses because they cancel out the cost savings for families receiving this copay assistance.
    d. Federal Health Savings Account Programs, (Health Tabletop Savings Plans), are before Federal Income Tax employee deductions.
    e. Most Federally charged health savings plans need to be re-seasoned and monitored for cost and price lists that are not supported and to include insurance companies who profit off of rebates and controlling the Doctors involved in the true system of excellent Patient Care.!!

4) Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.

1. The Community does want to engage with many researchers, resources and research institutions, yet many are turned away and made fun of when they are heard.
    a. Most Doctors do not take the time to listen to the patient.
    b. Needs need to be met for every individual patient.
    c. Brainstorming and communicating, with teamwork will help make for a better tomorrow.

5) Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.

1. The 5. statement above says it all about LESS Likely. Thank you for allowing my voice to be heard. JMB

Email: bennybunch137@charter.net

Submit date: 8/1/2024

I am responding to this RFI: On behalf of an organization

Name: Jeanna Marie Benny

Name of Organization: Bobby Jones Chiari Malformation Foundation

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Member of the Public, Organizational Official, Patient/Patient Advocate, Other

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   1. Bill Descriptions for Votes that Affect YOU
      a. Bill H.R. 497, the "Freedom for Health Care Workers Act," would eliminate the Health and Human Services (HHS) Covid-19 vaccine mandate on healthcare providers furnishing items and services in Medicare-and Medicaid-certified facilities.
      b. This would prohibit HHS from publishing any substantially similar rule.
      c. The FDA Only approved of the Covid-19 vaccine for Emergency use ONLY!
      d. Stop pushing illegal sales of the Covid-19 vaccine in the United States of America

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   2. Bill Descriptions for Votes that Affect You
      a. SAFE ACT SB49 provides that not health care provider shall perform gender transition surgeries on any minor.
      b. The Missouri State House of Representatives passed SB49 on May 10, 2023, by a vote of 108 to 50.
      c. Marxist ideas have been evident and proven for years.
      d. It is immoral that people can choose their pronouns and identify as a different gender.
      e. Minors are not yet capable of giving informed consent and should not have the ability to a gender that contradicts their scientific classification

f. Irreversible damage is caused. The human brain isn't fully developed until the age of 25 and in adulthood.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
Approaches for research funders is that the Federal government create partnerships and fund different Nationally accredited research supported by 501 (c) (3) organizations like the Bobby Jones Chiari Foundation based in the State of New York.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
The economy hurts middle class and poor families from financial stability to continue to give to any 501(c)(3) organization.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
The economy of the year of 2024 hurts many people and communities to less likely want to engage with researchers and research institutions.
Thank you for this opportunity to help and serve. JMB

Email: bennybunch137@charter.net

Submit date: 8/2/2024

I am responding to this RFI: On behalf of myself

Name: Amy Lemke

Name of Organization: University of Louisville

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Investigator/Researcher, Community Advocate

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**

- Learn about the history, values and priorities of the particular community.
- Find out how a community prefers to be referred to. Individuals can be members of more than one community.
- Find a common language, and respectful terms, to use when discussing research and research participation in the particular community.
- Become knowledgeable in principles and methods of community engaged research (as a scientific discipline).
- Include community members on the research team (as part of the multi-disciplinary team).
- Include experts trained in rigorous community engaged research methods on the research team (as part of the multi-disciplinary team).
- Develop a community working group, such as a community expert board (CEB) to interface with before, during and after the research project is completed. Items for discussion could include the research priority/topic, research study design, recruitment methods, data collection methods, analysis, reporting/dissemination and data governance/sharing. Also how to maintain the partnership post-research project. Collect, maintain and share CEB discussion outputs with the community, researchers and research institutions.
- Find out what types of benefits community members are interested in for their participation in research (beyond participant compensation). Outline and provide benefit sharing or any other ways to give back to the community.
- Provide opportunities for bi-directional learning about the research of interest (both - researchers from community and community from researchers).

- Discuss researcher and community expectations of the partnership; possibly develop a memorandum of understanding.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   - Include the importance of developing and sustaining community partnerships as part of the institutional research mission statement.
   - Fund researcher/community partnership infrastructure building pilot awards.
   - Develop and support active and long-term Community Expert Boards to meet and inform current research priorities.
   - Add more than one community member to the IRB.
   - Offer complementary research training (such as community CITI training) to community members and historically underrepresented populations.
   - Broaden research teams to reflect characteristics of the communities they are working with.
   - Develop a network to match researchers and community studies that can be accessed by community members (both researchers and communities can use this to advance research topics of mutual interest). Some organizations have used websites to provide access to this type of partnership and collaboration.
   - Provide educational/training pipeline opportunities to increase diversity in the research workforce.
   - Provide education and expert support to IRB review of the potential risks and benefits of community-based and/or community engaged research, and provide guidance on the necessary components in a proposal (including human subjects) for successful community engaged research.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   - Require demonstration of partnership building and sustaining activities throughout the grant lifecycle (and beyond).
   - Allow budget items for the items needed above (regular meetings at convenient times in the community, etc.).
   - Require inclusion of community expertise and community engaged researcher expertise as part of the multi-disciplinary research team.
   - Recognize community member expertise and include these experts in development of programs and priorities.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

- Provide complementary research training for community members.
- Ask community members how they prefer to be compensated. Develop fair practices for compensation for study participation - such as same dollar amount for all types of participants (community, physicians, caretakers, etc.).
- Ask community members what would make study participation easier for them. Then provide that opportunity. For example, a research team may think that in-person interviews are the preferred method. However, when community members are asked what would work best for them, they may indicate telephone interviews (instead of in-person or Zoom interviews, for various reasons). Methods should be tailored, and time spent before the proposal is submitted exploring what research approaches would work best from the community perspective.
- Conduct community listening sessions – topics generated by community members and researchers.
- Acknowledge past concerns that have caused distrust in research and provide venues for open discussion about the issues and potential ways to move forward - if there is community interest.
- Provide community opportunity to learn about the potential value and benefits of research.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

- No acknowledgement of past/historical instances causing distrust.
- Research priorities do not match those of the community.
- Lack of research related information in multiple languages.
- Not finding out about preferred recruitment strategies and using recruitment methods that may not reach community members. For example, we learned that a particular community preferred getting trusted information from their primary care physician and a local newspaper (in their language) - and they suggested we use those methods for research recruitment.
- Lack of convenience and lack of flexibility in research methods.

Email: lemkeaa@gmail.com

Submit date: 8/2/2024

I am responding to this RFI: On behalf of an organization

Name: Dorothy C. Browne

Name of Organization: Shaw University

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?:

1) **Strategies for researchers to best partner and work with people and communities.**
2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Email:

Submit date: 8/6/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Making personal and professional connections ahead of research activities, involving community in decision-making, including well-respected elders in culturally appropriate ways

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Prioritizing needs of the community when thinking about incentives for participants

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Health literacy barriers, cultural history and historical trauma, reduced access to participation (e.g. transportation)

Email:

Submit date: 8/6/2024

I am responding to this RFI: On behalf of an organization

Name: Vaatausili Tofaeono

Name of Organization: American Samoa Community Cancer Coalition

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Organizational Official, Member of the Public

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Include a person from the community in the leadership of the study. Specifically as a Co-Investigator or higher (PI/MPI). The argument of a person not holding a doctoral degree in order to be in that position is not an effective one. This person has extensive knowledge of the community that is being researched and should be involved.
   Develop a community advisory board that is comprised of community leaders and senior leaders of the study. They do not have to be involved in day to day operations but meet quarterly to brief about the study and discuss overall direction.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Establishing a community advisory board
   Include incentives for participants to share knowledge
   Ensure study design follows cultural ways of knowing and sharing
   Design approaches that use frameworks that model community best practices.
   A dissemination plan that markets the results for multiple perspectives within the community.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Require funders to partner with community organization in their research design. Partner meaning at least a subaward that identifies a member of the organization be at least a co

investigator.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Conduct research in the community by the community. Especially in Indigenous populations.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Research that is conducted by people outside of the community.
Results that are not shared or disseminated to the community that were studied.
Manuscripts that do not acknowledge the community being studied.
Research that the community is not aware of.

Email: vtofaeoko@ascancer.org

Submit date: 8/6/2024

I am responding to this RFI: On behalf of an organization

Name: Ilima Ho-Lastimosa

Name of Organization: Waimanalo Learning Center

Type of Organization: Research Participant Organization

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Community-Based Clinic Investigator, Cultural Practitioner , Member of the Public, Organizational Official

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
Learn from the audience.
Know your audience.
Establish longterm relationships.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Be present.
Learn from the experts.
Know the cultural perspective.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
Be equitable.
Community is done giving away their mana!

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
All of this.
You need us. We no need you!

Trust and believe!

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
All of the above!
Helicopter research.
Stealers.
Biters!

Email: Ilima888@gmail.com

Submit date: 8/6/2024

I am responding to this RFI: On behalf of myself

Name: Alexxus Ho

Name of Organization: Ke Kula Nui O Waimanalo

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: Waimanalo Pono Research Hui Coordinator

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Clinician/Healthcare Provider, Community Advocate, Community-Based Clinic Investigator, Investigator/Researcher, Member of the Public, Research Participant

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
Building pilina with a community before entering in and asking. Giving access and rights to community for that research process. This is what we expect when other organizations come into Waimanalo and request acceptance into Waimanalo Pono Research Hui.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Hire people from within the community. Allow the working community to be apart of the whole research process.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
Build pilina first. Learn about the people, the community

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Recognize them and give back to them. Ask the communitied what they want

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Unfair compensation, helicopter research

Email: ho.alexxus@gmail.com

Submit date: 8/6/2024

I am responding to this RFI: On behalf of an organization

Name: Josie

Name of Organization: We Are Oceania (WAO)

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Organizational Official

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Cultural Practitioner , Organizational Official, Caregiver/Family Member, Member of the Public, Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Meet the people! And researchers owe an explanation to the people of they do research, why they research the topic, and why they want to research them. Build an approach that will allow the subjects to contribute feedbacks and ideas. As an exchange for the research to be conducted and data and knowledge collected from the community, build a resource kit for the community, in which it will allow to protect themselves from becoming exploited by researchers.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Give or teach communities tips and ways to know their human rights and to protect their communities from becoming victims to over exploitation. How to protect their indigenous knowledges.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   When working with the community, it is important to utilize their approaches. For example, honoring the traditional leadership system to understand the right channel of communication and implementation and execution of projects. To understand the dos and don’ts.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Give internet connection!
Help them with computers or technology to connect to the world and resources!

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Reciprocity! If we want to take, we must give!
Respect! How is the research going to help the people! Tangible outcome, maybe sponsor a student from that community in college!
Maybe donate books or educational tools.

Email: josie@weareoceania.org

Submit date: 8/8/2024

I am responding to this RFI: On behalf of myself

Name: Jane Chung-Do

Name of Organization: University of Hawai’i

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Member of the Public

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Centering everything on the relationship and not letting a grant be the starting point. Too many researchers come to the community with a grant already awarded or a grant idea without taking the time to get to know the community and their preferences and priorities as well as build trust and relationship. We must be given time and support to build meaningful relationships and trust to facilitate open and authentic dialogue.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Investing communities. Provide funding to the community (and provide funds to help them build capacity to manage these funds) and have them reach out to researchers who can provide the technical and scientific expertise. If we truly want equitable partnerships, we need to dismantle the existing power structures within academic. Also, provide capacity building training and funds directly to communities to increase their knowledge and skills in research so they can build their own protocols and expectations for how research should be done in their community.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Incentivize and support academic and research institutions to tailor and transform their policies and procedures to be more flexible and conducive to community based research. For example, yes we can partner with communities by subcontracting with them but the fiscal and admin demands of subcontracts on the community are great. Their payments are also often severely

delayed but the university and funders often still expect communities to still do the work according to the original deadline and front all the money and get paid much later. Ensure community partners can be MPI with the researchers even if they do not have the same degrees. Allow for honorariums of elders who provide their wisdom even if they don't have the conventional academic credentials. Allow for FOOD at all gatherings.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   Require all researchers to demonstrate STRONG evidence of existing relationships with the community they want to study and that they have meaningfully consulted with them and have community approval (not just a LOS). Require all researchers to give back the data to the community and to co-disseminate the findings together so that inaccurate and harmful narratives are not perpetuated. Require all researchers to have structures in place to ensure continuous and meaningful input are gathered throughout the entire research timeline. Require all researches to demonstrate how the study is building community capacity through employment, training, etc and to make sure their budget reflect equitable benefits.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   When researchers already have a grant and come to the community expecting them to participate when the grant is not aligned with community's vision. Even if the grant is a great idea, if researchers have no built relationship or trust with the community, the community is not going to participate. Too many researchers have done helicopter research!! We also need better and much more robust training for researchers on CBPR and community research ethics. Please create a community ethics/CBPR/cultural humility training that is separate from the conventional CITI or NIH training and require all researchers to complete it.

Email: chungjae@hawaii.edu

Submit date: 8/9/2024

I am responding to this RFI: On behalf of myself

Name: Monica Esquivel

Name of Organization: University of Hawaii at Manoa

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Community-Based Clinic Investigator

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Involving community early in the research process and providing equal voice. This includes community informed metrics for testing, dissemination to community, involving community members in interpreting results.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Establishing a position for community representation on IRBs, provide community with compensation for time in tyr planning process, reducing administrative burden for providing community sub awards.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Require co-PD to be from community, provide ample timelines for CBPR, create funding that prioritizes community led projects with academia as co-leads. Require demonstration of CBPR process in proposal

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   Having research activities take place in communities- data collection, dissemination, etc.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Having to travel to university settings for research.

Email: mesquivelrd@gmail.com

Submit date: 8/9/2024

I am responding to this RFI: On behalf of an organization

Name: Barbara E Bierer MD

Name of Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Clinician/Healthcare Provider

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Clinician/Healthcare Provider, Investigator/Researcher, Member of the Public, Organizational Official, Patient/Patient Advocate, Research Participant

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
Thank you for the opportunity to respond.
The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise.
It should be noted that we invited members of our community with lived experience (e.g., research participants, patient advocates, and research professionals) to take part in the creation of these responses. Where applicable, we also point to free, publicly available resources that the MRCT Center has created specifically with the engagement of patient advocates to support the engagement of participants.
One strategy to best partner with people and communities is for researchers to demonstrate their value by establishing a known presence in communities where they conduct their research and sharing information and resources that both support the priorities of the community and explicate how the proposed research furthers those priorities. Ideally, such a research presence would be established prior to the commencement of recruitment activities for any research activities. To accomplish this presence in earnest will require direct engagement with community leaders and community members to learn about lived experiences within the

community, to understand the community's health needs, and to show how participation in clinical research can help the community meet its health needs.

Further, the engagement approaches we recommend should recognize a community's history of prior experiences with government agencies, clinical researchers, and the institutions they represent. To that extent, the geographic location where the research is planned, the intended participant population, whether potential participants stand to benefit from the intended research, and the potential risks of participation are all crucial factors to consider.

Moreover, as clinical research increasingly becomes a global endeavor, situating individual engagement efforts and research efforts within the context of the global landscape of clinical research can help illustrate how community stakeholders who participate in clinical research can generate tangible returns with and for the people they care about.

Recommended strategies for researchers to establish and sustain effective and meaningful partnerships with people and the communities they represent include:

- The use of clear, understandable plain language throughout the engagement, including languages other than English. One such resource that is not only developed for patients and the public but also engages a team of patient advocates to develop plain-language clinical research definitions is the MRCT Center's Clinical Research Glossary www.mrctcenter.org/glossary.
- Early invitations to clarify need(s), identify key influencers, and integrate multiple perspectives of patients, caregivers, families, patient advocates, and extended community members/organizations into the development of projects/initiatives to generate and build on shared objectives or jointly held priorities.
- Time for relationship-building before and during engagement activities, including onboarding, regular meetings, and personal check-ins, all to ensure patients feel that they have value.
- Time for relationship-building prior to study recruitment, for example, having researchers and study staff be introduced, inquisitive, and caring before ever approaching a potential participant to recruit them to a study.
- Plans/budgets to compensate for time and effort.
- Defined process(es) for partnership with community sites, community groups, and their trusted members, processes that must be developed in collaboration with community partners.
- Ample opportunities to provide feedback across multiple modalities, including:
    - Terminology/imagery and communication that respect the preferences of intended audiences
    - Communication platforms and materials that are physically accessible and usable for intended populations, including imagery, audio, and videos that support written text.
    - Communication platforms and materials that are culturally and linguistically accessible and comprehensible to intended populations
- Active efforts to gain input from people with lived experience on aspects such as the science, portfolio, research question, trial design, endpoints, data collection, approach, risk/benefit ratio, and engagement plan to identify which aspects are important to or of interest to them, any limitations or considerations from a cultural or religious perspective, and any other components that are problematic or concerning.
- Regular updates on project status, interim outcomes, and reporting of results, both individual, when relevant, and aggregate. As a reference, recently updated guidance developed

with patient advocates is available for returning individual results at https://mrctcenter.org/return-of-individual-results/

- Periodic assessments of roles (institution and community) and whether partners and communities feel that they have had an active voice and been able to fulfill their roles.
- Ongoing expressions of gratitude for contributions and partnership.

Overall, successful partnerships require nurturing relationships with individual partners that support community relationships and, reciprocally, nurturing relationships with communities to support individual relationships.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

We recommend the following approaches for institutions to support bi-directional partnerships between researchers and people/communities:

- Invest in identifying and nurturing a collaborative network of people/community stakeholders that are available and interested in providing feedback on various health research-related issues directly to institutional representatives e.g. creating an advisory board on a determined basis.
- Develop budgets with earmarked departmental/institutional funding to support engagement activities that prioritize patient/community input on research objectives, study plan, including aspects of its design, conduct, endpoints, and outcome assessments,

- Train researchers to develop skills that support engagement including:
  - empathy and emotional intelligence
  - accessibility (and see https://mrctcenter.org/diversity-in-clinical-research/tools/abd_toolkit/)
  - cultural congruence
  - cultural humility
  - linguistic abilities
  - experience working with different populations
- Strongly encourage researchers to develop engagement plans that enumerate the ways in which people and communities have been, and will be, engaged. (and see https://mrctcenter.org/diversity-in-clinical-research/)
- Create participant-facing research-related templates that are easy to understand and not overly technical or legalistic.
-
- Establish a team of research navigators to help guide the research participant and support individualized research education– drawn from people who have participated in research before.
- Offer training programs, such as workshops and seminars, for people/community members to build their research literacy and capacity to meaningfully engage in research processes effectively.

- Acknowledge and celebrate the contributions of people/community members to research projects.
- Establish a post-study forum where researchers can communicate study outcomes to participants and community stakeholders, and where community members can debrief their experiences with researchers.

3) Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.

Approaches for research funders to incorporate partnerships between people, communities, and researchers into their programs and priorities:

- Identify research funding priorities based on the funders' own work and experiences with specific communities or issues of interest.
- Explicitly expect, proactively promote, and disburse funds earmarked to create/sustain engagement-by-design.
    - Strongly encourage Patient/Community Engagement Plans that specifically highlight how researchers integrated patient/community feedback into their proposals and the planned research.
- Prioritize research that involves people and communities in contributing to and reviewing the research study plan, including input on meaningful patient-centric endpoints, outcomes, and procedures, as well as plans to continue to involve key subject matter experts in ensuring the study is conducted in ways that work best for participants and support achieving the study's goals.

4) Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.

Examples of actions and behaviors that may make people and communities more likely to engage with researchers and research institutions include:

- Evidence of past successful engagement with people and communities that are not transactional – long-term presence and investment beyond the research itself.
- Evidence of patient-centered practices – doing, endorsing, and promoting patient-centric activities
- Remuneration to participants, accompanied by resources to help participants explore whether such payment(s) would affect whether participants (or their families) qualify for other means-tested social assistance or public benefits they may be receiving.
- Open communication, transparency, and ownership that acknowledges where research has harmed people and communities in the past and how the research enterprise has evolved to mitigate harms and protect participants.
- Clear demonstration that the research workforce includes representatives from the people/communities to be engaged.

- Participant-led dissemination of plain language research findings by encouraging participants to take an active role in sharing research findings through community presentations, storytelling, or co-authored publications.
- A return of tangible value to communities through capacity building – e.g., establishing community communication pathways and resource centers where participants can access information about the research and other available resources that could be of benefit to them.
- Remembering that participants are people first, not "subjects" and connecting on a personal level beyond the study – e.g., ask about work/school, family members, a favorite hobby, etc

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Examples of actions and behaviors that may make people and communities less likely to engage (or cause disengagement) with researchers and research institutions include:

- Perceptions that the researcher/institution has been transactional and only taken from, but not given back to, the people and communities being engaged.
- Affiliation with health centers that have caused harm in the past, for example, healthcare-related bankruptcy in specific groups of patients.
- Not offering any kind of appreciation to participants for their contributions.
- Failing to provide participants with updates on research progress and results. The MRCT Center has specifically developed resources to support the return of individual and aggregate results with practical steps (aggregate results: https://mrctcenter.org/resource/return-of-aggregate-results-to-participants-toolkit-version-3-1/ individual results: https://mrctcenter.org/return-of-individual-results/)
- Using jargon-heavy or highly technical language instead of plain language, images, or videos at the correct age/educational levels
- Complicated and time-consuming consent procedures
- Failure to speak directly with the participant, including children
- Scheduling appointments during work, school, or after-school activities
- Including activities or study items like wearables that make the person stand out as different at school, during after-school activities, or at a friend's house.
- Insensitivity to cultural differences and community norms.
- Failure to demonstrate a return on public investment following study completion. How has this study made a difference? What happens next?

Email:

Submit date: 8/10/2024

I am responding to this RFI: On behalf of an organization

Name: Jeanna Benny

Name of Organization: Bobby Jones Chiari Malformation Foundation

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Member of the Public, Patient/Patient Advocate, Other

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   1. The Family and Medical Leave Act of 1993 (Public Law 103-3 Enacted February 5, 1993)
      A. This act is to grant family and temporary medical leave under certain circumstances
      B. It is enacted by the Senate and House of Representatives of the United States of America in Congress assembled.
      C. Title I --General Requirements for Leave. Sec 101 to Sec 109 Supports Employment and benefits protection.
      D. Title II --Leave for CIVIL SERVICE EMPLOYEES. Sec. 201. Supports Employment and benefits protection.
      E. Title III --Commission on Leave. Sec. 301 to 306. Supports Employment and benefits protection.
      F. Title IV -- Miscellaneous Provisions. Sec. 401 to 405. Supports Employment and benefits protection.
      G. Title V -- Coverage of Congressional Employees. Sec. 501 to 502. Supports Employment and benefits protection.
      H. Title VI --Sense of Congress. Sec. 601. Supports Employment and benefits protection.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   2. Findings and Purposes. Most ARE NOT supported by the EEOC and OSHA. EEOC examines cases after you are dead and or near death!!
      A. The number of single-parent households are increasingly and significantly growing.

B. It is important for the development of children and the family unit that fathers and mothers be able to participate early childrearing
and the care of family members who have serious health conditions.
C. Notices of health issues are needed for employers, schools, colleges, and Universities for accommodations for those who are
medically and mentally challenged.
D. Employment standards that apply to one gender and or age ONLY have serious potential for encouraging employers to
DISCRIMINATE against employees and applicants for employment who are of that gender.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

3. It is the Purpose of the Act of 1993:
   A. To balance the demands of the workplace.
   B. To entitle employees to take reasonable leave for medical reasons.
   C. To accomplish the purposes described above under question number one.
   D. To promote the goal of equal employment opportunity for women and men, young and elder, pursuant to such clause.
   E. Retaliation, and threats of firing are NOT Tolerated by the Purpose and Freedom of this Law!!
   F. United we should stand in support of each other and different perspectives.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

1. Listen, listen, listen. Concerns have a voice.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

2. Less likely to want to engage in listening, creates confusion for excellent patient care and goals.
   a. Opioid pain management and or managers are not fitting for anyone.
   b. Pain management needs to fit each individual person suffering from either a day, months, of pain and or years of pain.

Thank you for allowing my advocating voice. JMB

Email: bennybunch137@charter.net

Submit date: 8/12/2024

I am responding to this RFI: On behalf of myself

Name: Tariro Kutadza

Name of Organization: Zimbabwe National Network of PLHIV

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Organizational Official, Patient/Patient Advocate, Research Participant

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
Citizen Science
Collaborative Citizen Science (CS) Approach
Definition: Collaborative citizen science projects involve the public in more comprehensive ways beyond just data collection. While scientists still define the research framework, the public can participate in data analysis, interpretation, and dissemination of findings.Citizen science is a collaborative approach that involves the public in scientific research, allowing non-professionals to contribute to data collection and analysis. Citizen science represents a significant shift in how scientific research is conducted, emphasizing collaboration between professional scientists and the public. By leveraging the skills and enthusiasm of volunteers, citizen science not only enriches scientific knowledge but also empowers communities to engage actively in addressing environmental and societal issues. CS can be effectively utilized in health research, providing a platform for public engagement and data collection that enhances the understanding of health issues and promotes community involvement in health initiatives.
Citizen science (CS) can be effectively utilized in health research, providing a platform for public engagement and data collection that enhances the understanding of health issues and promotes community involvement in health initiatives . There is need to promote awareness CS for its successful integration into the health research landscape.
https://www.healthai.agency/blog/citizen-science-for-pandemic-response

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Email: tarirokutadza63@gmail.com

Submit date: 8/12/2024

I am responding to this RFI: On behalf of myself

Name: Lorinda Riley

Name of Organization: University of Hawaii

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Member of the Public, Other

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
Ensure that there is a long-standing relationship.
Ensure that community participants are adequately compensated for their time.
Understand that everyone has family engagements so either include family or provide multiple time and modality options

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Ensure that community is included and engaged at the very beginning of projects where output our discussed
Ensure that dissemination material includes community dissemination. This can look like webinars, multiple community workshops, infographics, and other innovative products.
Encourage institutions Including NIH And the universities to a knowledge and count community dissemination on equal footing as peer-reviewed publication

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
Incorporate advisory groups On community rather than agencies and other academics
Require payment for a time. The same community members are constantly called on to help. Doing so without compensation puts a huge amount of stress on the individual, their families and the community.

Build an actual payment for stakeholders and advisors. Here I mean, not just those serving on community advisory reports but individuals who you constantly consult. This could be a cultural practitioner who provides advice on or how to reach out to people. These are informal consultations that are required in order to appropriately engage community on a day-to-day basis.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   Cultural humility is a requirement in any stage of research. Requiring training that is ongoing to explored individuals positional and biases is important
   Adequate compensation for time is critical
   Ensuring that the relationship is built up overtime is also important. This means that researchers need to engage community before there is even a project. It could be that they just recognized that they themselves are part of the community and that they care and so they show up to build trust Having cultural brokers or staff is one way to be able to build that community trust

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   Not understanding why are researchers interested in a project.
   Lack of trust in the researcher or institution. This could be from prior experiences with this researcher or other researchers. It could also just be a generalized mistrust of academics.
   Minimal compensation for time and lack of culturally appropriate engagement. One key example in Hawaii is not providing for participants, not providing food at meetings or during engagement, and not starting with culturally appropriate greetings, which may include prayer or position.

Email: lorindar@hawaii.edu

Submit date: 8/12/2024

I am responding to this RFI: On behalf of an organization

Name: Elizabeth Lovinger

Name of Organization: Treatment Action Group

Type of Organization: Patient/Community Advocacy Organization

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Member of the Public, Other, Patient/Patient Advocate, Community Advocate

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
An NIH strategy for incorporating public voices in all phases and types of clinical research should start from the recognition that public participation in science is an ethical precept, a necessary ingredient for good science itself, and a fundamental human right. In developing a vision and framework for public voice in clinical research, TAG encourages the NIH Office of Science Policy and the NExTRAC Engage Working Group to consider the human right to enjoy the benefits of scientific progress and its applications (i.e., the right to science), a human right found in the Universal Declaration of Human Rights (Article 27), the International Covenant on Economic, Social, and Cultural Rights (Article 15), and many other human rights treaties and conventions. Key resources the NIH should examine include "CESCR General Comment No. 25," which provides an authoritative normative interpretation of what the right to science means by the United Nations human rights body charged with monitoring state compliance, and a recent report by the UN Special Rapporteur in the field of cultural rights on participation in science and science policymaking (see links at end).
Key concepts from these resources relevant for the NIH's present work on this topic include the following. First, general Comment No. 25 establishes that "[The right to science] cannot be interpreted as establishing a rigid distinction between the scientist who produces science and the general population, entitled only to enjoy the benefits derived from research conducted by scientists." In other words, people have a right to participate in research as more than clinical study participants or passive beneficiaries of science's assumed trickle-down benefits.
Second, the report of the Special Rapporteur argues that "access and participation in science are interdependent dimensions. There can be no meaningful participation in science if individuals do not have access to knowledge, data, technology, and applications." In other words, fostering participation in science depends on decreasing barriers and extending equitable access to the

benefits of science. This includes tangible benefits (e.g., new medicines, vaccines) as well as intangible benefits (e.g., knowledge, information, science-based policies).

Third, while there is sometimes an apparent tension between public voice and scientific expertise, this tension can be mediated with the right policy frameworks. The Special Rapporteur's report notes: "Science is a field in which expertise should prevail and experts must be guaranteed participation and space to make their opinions heard. The circle of experts who have enhanced participation, however, is not as exclusive as it used to be and experts are not the only ones with the right to participate in science." From TAG's experience advocating for the science needed to end the epidemics of HIV, tuberculosis, and hepatitis C virus, we know that the individuals and communities most affected by a disease or health condition hold a special expertise and should be acknowledged as equal participants in shaping the direction, conduct, dissemination, and translation of science to address these conditions. Lived experience should be valued and considered crucial as part of feedback and review, equal to academic and professional experience, and should be compensated as such.

Our experience teaches us that operationalizing participation requires rendering broad terms such as "communities" or "the general public" with greater specificity — moving from "breadth" (everyone) to "depth" (specific communities, constituencies, categories of participants). Community representatives should include those within the community who face the highest barriers to access due to such factors as poverty, criminalization, and stigmatization. Models of effective participation in clinical research may look different by setting, health condition, or stage of research, even if the underlying ethical and human rights concepts on which participation in science rests are shared.

Researchers should actively engage communities in every step of the research process, from protocol development and review to product uptake and awareness-raising. Engaging communities should be viewed as a continuous and iterative process, with different engagement approaches and outputs expected at different stages of the research cycle.

Links: General Comment No. 25: https://www.ohchr.org/en/documents/general-comments-and-recommendations/general-comment-no-25-2020-article-15-science-and; and Special Rapporteur report on right to participate in science: https://undocs.org/en/A/HRC/55/44

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

Community members may be more willing to engage with researchers and research institutions who have established trust and beneficial relationships with community leaders and institutions. Other facilitating factors may include fair compensation for research participation and a demonstrated commitment to inclusion. This inclusion could be defined as physically and developmentally accessible research facilities and materials, processes and language inclusive of all gender identities and sexual orientations, transportation and nutrition assistance, interpretation/translation services, and other considerations. Diverse racial and ethnic representation within study leadership, clinical and frontline staff, and promotional materials may also be important factors. Strategies should be developed to maintain communication with research sites and participants to ensure results are shared and communities don't feel abandoned after specific trials and research projects end.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

   Research funders should require researchers to have demonstrated relationships, including references and/or letters of support, with communities who will be eligible for research participation. Researchers should also be required to include historically underrepresented populations such as children, pregnant and lactating persons, persons living with HIV, and others in eligibility and recruitment unless a clinically relevant exception must be made. These requirements should be conditions for receiving funding awards and should be periodically reviewed for compliance.

   AAAS runs a Scientist-on-Call program where community and nonprofit organizations can request support from and partnerships with scientists on specific projects. Financial support to such programs and encouragement to set up similar programs by research institutions might aid in overcoming the (perceived) divide between researchers, their institutions, and community organizations. Not only will community organizations benefit from gaining easier access to specific expertise. These type of projects will also allow research institutions to develop trust within communities as a first step to building lasting collaborative approaches that are in based in human rights.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

   International clinical trial networks should ensure there are local community representatives on protocol teams to avoid situations where, for example, only American community representatives are providing feedback on protocols being implemented in African countries.

   Research institutions should invest time and resources into building partnerships with the communities in which they are located. This can include technical and financial support to local organizations, schools, etc. People and communities will be more likely to engage with researchers and research institutions when there is a continued investment in those communities after research activities have concluded (i.e., when they are not subjected to "helicopter research"), and when they are engaged by people who are native to their communities.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

   Community members may be less willing to engage with researchers and research institutions who are unknown to them and their communities and those who do not offer any compensation, accommodations, or services to facilitate their participation. Presence of police or security staff, requirements to provide government-issued ID upon entry, and/or study site co-location with government entities may be significant barriers to engagement.

   Researchers and research institutions need to provide detailed expectations on time commitment and timeline for any collaborative effort with communities and their organizations. Different understanding of timelines and what constitutes a quick turnaround or an appropriate time to respond to an inquiry can alienate communities who are unfamiliar with research timelines and who may require more immediate support.

It is essential that NIH reverse its policy that community members should not be compensated for their participation on Community Advisory Boards and other research advisory groups. In order to ensure that a diversity of community member voices are adequately reflected in the planning and implementation of research protocols, and in order to resolve the fact that their participation may be precluded by financial and other structural barriers (e.g., work, family obligations, etc), research projects need resources to provide community members with cash and non-monetary cash-equivalent incentives/honoraria.

Email: elizabeth.lovinger@treatmentactiongroup.org

Submit date: 8/12/2024

I am responding to this RFI: On behalf of an organization

Name: Jane Q. Yap

Name of Organization: Mayo Clinic PASAGE Study

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community-Based Clinical Investigator

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Community-Based Clinic Investigator, Investigator/Researcher, Member of the Public, Patient/Patient Advocate, Research Participant

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   There are many strategies that are useful and effective in engaging and partnering with community members of various backgrounds. However, our team has found two main strategies have worked well in maximizing public engagement in the research our group is conducting.
   The first strategy is to reserve funds and resources to create engaging and understandable material with the goal of bringing them to focus groups and community advisory boards (CABs) for review. Materials could include: graphics to summarize results, recruitment materials, and community presentations.
   The second strategy is to disseminate results of previous and ongoing studies to community advisory group leaders and their communities. Two ways to do this would be: (1) download PDF copies of study publications (2) create summaries/visual guides/graphics that summarize the results in layman terms. These can be sent to community advisory group leaders for distribution.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   The strategy our team has used with success has been to express genuine excitement in meaningfully engaging in events held by patient advocacy groups (PAGs). Many PAGs will hold annual conferences, annual walks, town halls, monthly meetings etc. Organizing attendance at these events demonstrates a commitment to learning from the community and forming long-lasting relationships. It is also important to have funds set aside to make financial donations to

PAGs and events they hold. Finally, have community advisory board (CAB) members review recruitment and study materials including social media recruitment posts, recruitment flyers, interview guides and other study related materials. Ensuring that any study team makes these suggested changes contributes to building trusting relationships with PAGs and ensures materials are respectful of community views and understandable to laypeople.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

To increase engagement with researchers and research institutions, compensation should be given to participants for the time they contributed to the study. This compensation would preferably take the form of a monetary gift card, but could also be meal or childcare vouchers. Additionally, CAB members should also be compensated for their contributions to the study. This could include monetary compensation, opportunities for authorship on manuscripts, and engagement in future research opportunities.

Additionally, to encourage involvement in research, having virtual participation (Zoom, phone call, etc.) options as an alternative to in-person surveying or interviewing is preferable. Study teams should also proactively cater to community accommodation needs; be prepared with interpreters and enabling captions when interviewing individuals with Deafness/hearing loss and be familiar with the specific needs of a community. Additionally, prioritize the language needs of participants; to the extent possible, provide study materials and conduct study activities in the preferred language of the participant.

Finally, rebuild community trust by listening to community members and providing an unbiased space for feedback and sharing thoughts. This includes creating spaces that openly facilitate conversation and assuring participants that there is no “right” answer to questions and all their thoughts are valuable.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

We have found that many of our research participants are turned away from a study without compensation or without fair compensation. Participants have expressed a need for more flexibility in participating outside of business hours and virtual methods of engagement where possible (e.g., surveys, appointments, interviews, etc.). For events that cannot be virtual, not having reliable interpreters/interpretation services was a deterrent for international individuals and those from the Deaf/hearing loss community. Physical barriers such as lack of accessible walkways and non handicap friendly spaces were also cited as deterrents from participating in on-site research studies. Previous negative research experiences led to distrust and disillusionment.

Email: pasagestudy@mayo.edu

Submit date: 8/12/2024

I am responding to this RFI: On behalf of myself

Name: Elizabette uribe

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate, Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Never

How often do people you know engage with researchers?: Never

1) **Strategies for researchers to best partner and work with people and communities.**
Work with PR agencies that are currently working with pharma companies

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Partnerships with pharmaceutical companies through PAGs

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
pharma companies

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Testimonials, Understand the burden of the disease but also the impact of every action and step forwards in terms of reasearch

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
long surveys

Email: eli_uribe@hotmail.com

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Chatsuda Auchieng

Name of Organization: HIV-NAT, Thai Red Cross AIDS Research Centre

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Following up of study participants any adverse events (connecting relationship and trust from study participants), giving people knowledge for the new or epidemic studies to the communities through community's members.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Health systems and Academic medical centers give the knowledge to the community and study participants i.e Mpox study and ask for their interests and voluntaries to participate in the study. It would be good to send the study to Community Advisory Board committee to review the studies (it is as the first opinion which we will get from community member who will transfer our studies to the communities).

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Approaching for research funders i.e. government agencies, other non-profit organizations, and pharmaceutical companies via website announcement, searching from the previous research announcement and ask for current year as well as keeping the good relationship with the formal sponsor and then writing a proposal or ask for their interested areas to approach fundings.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

Giving knowledge and good relationship to all stake holders, giving opportunities by approaching the potential participants who has been enrolled in the site, negotiating the fair compensation to study participants and importantly following up the formal or current study participants.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Long study period, most severe events, rumors or misunderstanding about the study information, fair selection of potential participants.

Email: chatsuda.a@hivnat.org

Submit date: 8/13/2024

I am responding to this RFI: On behalf of an organization

Name: Kate M. Nicholson

Name of Organization: National Pain Advocacy Center

Type of Organization: Patient/Community Advocacy Organization

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Organizational Official

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Clinician/Healthcare Provider, Community Advocate, Investigator/Researcher, Member of the Public, Patient/Patient Advocate, Research Participant

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
In general, researchers should establish advisory committees of people with lived or life experience for the duration of each project and include broad representation of historically marginalized populations. Ideally, researchers will engage advisors and other community partners meaningfully at every step, including priority setting and research design, analysis, implementation, evaluation, and translation. Finally, researchers should consider co-publishing with community advisors in journals, co-presenting at conferences, and making efforts to translate research beyond academic contexts back to impacted communities.
Researchers should
- Seek out established, member-led organizations to work with and/or identify individuals (e.g., if working on a project related to disability, seek out organizations led by disabled people).
- Consult with the community/people with lived or life experience about research priorities to ensure you are addressing issues that are important/valuable to them; this will help ensure you will get buy-in through the duration of the project and that your research is relevant and meaningful.
- Communicate transparently about the research's purpose and provide opportunities for people/communities to see how their input is being utilized.
- Develop culturally relevant and appropriate resources and materials using a combination of internal and external expertise (e.g., contractors, partner organizations, people with lived or life experience). Work to ensure that all materials from inception through translation are accessible, culturally and linguistically competent, and equally understandable to all participants.

- Recruit broadly among historically marginalized populations. Gather demographic statistics identifying race, gender, disability, gender identity, etc. Any demonstration of past successful engagement with community groups can build trust.
- Develop an understanding of the historical context of the community you seek to engage (e.g., What is this community's experience with researchers? What inequities does this community face?) and whether/how this must be addressed.
- Emphasize cultural humility, which encourages consistent reflection and self-critique (and de-emphasizes expertise and "competence" in other cultures). Also, encourage all team members to engage in bidirectional learning.
- Ensure the accessibility of all sites, transportation, communications, and other resources to people with disabilities. Meet people where they are, which may include recognizing issues with broadband access and conducting phone interviews, or setting up meetings at times convenient for those you wish to engage.
- Ensure that appropriate training is available to all research team members and all recruited partners with lived or life experience.
- Provide fair compensation for the individuals whose time and energy you are requesting.
- Whenever possible, build lasting relationships so that engagement may extend beyond the duration of individual studies.

2) Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.

Institutions are struggling to adapt to a paradigm shift that once perceived people with lived experience of diseases solely as subjects but now seeks to incorporate them as partners in the conduct of research. Many institutions lack the capacity to support this shift, which requires identifying community partners, offering training for researchers and people with lived experience, providing fair compensation, and generally navigating the integration of views from vastly different professional and community backgrounds.

Institutions should

- Fully acknowledge the expertise held by people/communities, including the expertise that comes from lived experience.
- Engage people/communities throughout the entire research process. This includes high-level engagement in priority setting to inform the research agenda, advisory council engagement, and wide recruitment of participants for input in the development, design, conduct, analysis, translation, and dissemination of work. Advisory bodies should reflect the representation of historically overlooked communities. Demographic data on the identities of all participants should be gathered.
- Budget for inclusion at every level. Designate sufficient time and funding to adequately plan for, recruit, train, and fully include people/communities. Institutions should consider building training protocols for both people with lived experience and researchers. They might run campaigns to educate communities about the importance of research and how they can

contribute. They should invest in building networks with community groups and even design novel ways of maintaining networks for matching researchers with trusted patient partners.

- Work to build trust and create an environment of bi-directional learning. This comes over time, and for some people/communities it may take more work than others because of previous experiences (see above re: understanding historical context). That said, doing this successfully will pay off both in the short term and in setting the stage for longer-term collaborations.
- Develop frameworks for shared decision-making and prioritization of health models that consider individual preferences in treatment options. This will enable research to meet needed treatment goals.
- Establish adequate funding structures to fairly compensate people with lived experience as a matter of equity, respect, and value.
- With regard to both large institutions and government funders, public engagement should be conceived of more widely than just including people with lived experience and the community groups supporting them. Achieving ends such as better clinical uptake, transparency, and accountability may require broader public engagement. Institutions and major funders should consider models from other fields, such as Ed Freeman's stakeholder engagement work in the corporate sector, which expanded the definition of corporate interests well beyond shareholders to include a variety of interest holders from consumers through suppliers. In the health context, such interest holders might include healthcare providers, payers, policymakers, and others.

3) Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.

Research funders share many of the same needs as institutions when it comes to capacity building for facilitating a paradigm shift in research toward public engagement.

Funders should

- Incorporate requirements into funding solicitations to facilitate broader engagement (e.g., community engagement, partnering with CBOs, community advisory boards).
- Require diverse project leadership and fund research that incorporates historically marginalized groups and that gathers demographics broken down by race, ethnicity, gender, gender identity, disability, SES, location (rural vs. urban), etc.
- Prioritize diverse hiring among internal leadership at the funder, especially with respect to those determining priorities or setting agendas.
- Provide broader funding to facilitate capacity building for public inclusion at every level, from outreach to recruiting, training, matchmaking, material development, communication, and compensation.
- Require applicants for funding to clearly demonstrate methods to ensure cultural competency. Fund or create training opportunities in bi-directional learning and cultural competency and ensure training of everyone engaged in research (researchers, community partners, people with lived or life experience).

- Require that materials are accessible to people with disabilities and equally understandable to everyone involved.
- Create funding opportunities for building novel types of community engagement and matchmaking services, such as the creation of networks or databases.
- Run campaigns to educate communities about the importance of research and how they can contribute. Fund communication across the continuum, from explaining why patient engagement is critical to translating research into action and disseminating results through community groups.
- Provide grants and resources to community organizations to build their capacity to engage in research activities.
- With regard to both large institutions and government funders, public engagement should be conceived of more widely than just including people with lived experience and the community groups supporting them. Achieving ends such as better clinical uptake, transparency, and accountability may require broader public engagement. Institutions and major funders should consider models from other fields, such as Ed Freeman's stakeholder engagement work in the corporate sector, which expanded the definition of corporate interests well beyond shareholders to include a variety of interest holders from consumers through suppliers. In the health context, such interest holders might include healthcare providers, payers, policymakers, and others.

4) Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.

Things that might make people and communities more likely to engage with researchers and institutions include:

- Equitable and flexible financial compensation for time, labor, and expertise (including lived experience expertise), as well as reimbursement for meals, transportation, child care, etc. (Urban Institute released a good compensation guide: https://www.urban.org/sites/default/files/2023-08/Equitable%20Compensation%20for%20Community%20Engagement%20Guidebook.pdf.) Be individualized and consider individual preferences and needs – for example, you may have participants on SSI or SSDI who have limits on income they can receive.
- Other forms of compensation or experience (e.g., for individuals, training opportunities, opportunities for career development; for organizations, sharing of findings in a format the community organization can use for advocacy/funding purposes).
- Flexible opportunities to engage so that there are no barriers to participation (i.e., do not require in-person or a computer; phone-only options should be provided, especially when recruiting from historically underrepresented groups). Flexible hours to participate outside of work and opportunities on-site in the community when possible.
- Disability accommodations, language access, and other requested or required community needs.
- Demonstrated past successes in engaging with people with lived and life experience, implicated communities, historically marginalized groups, and diverse participants or stakeholders.

- Clear and transparent information about research and roles, including an understanding of what will result from the participation of people/communities and, if they are not directly involved in the dissemination of results, how they will receive follow-up about the findings.
- Research and evaluation models that equitably involve community members in the research process (e.g., community-based participatory research, community-engaged research, culturally responsive and equitable evaluation).

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Things that might make people and communities less likely to engage with researchers and institutions include:

- Lack of front-end engagement of trusted community members or advocacy groups.
- Unclear understanding of the purpose/impact of the research or its benefit to the community. Lack of transparency regarding the focus and details of the research.
- Limited flexibility for scheduling or participation (e.g., being expected to miss work, arrange for transportation/ meals/ childcare), inaccessible options for participation, lack of or inequitable compensation.
- Erratic engagement.
- Inconsistent communication.
- Culturally inappropriate or insensitive materials. Lack of inclusiveness, less than respectful engagement, choppy or box-checking engagement (i.e. lack of meaningful engagement).
- A lack of demonstrated past work with people with lived or life experience and/or disrespectful engagement during initial inquiries.
- Any interaction that causes people to feel unwelcome or exposes them to team members who resent and don’t believe in the importance of public engagement.

Email: kate@nationalpain.org

Submit date: 8/13/2024

I am responding to this RFI: On behalf of myself

Name: Mercy Kukundakwe

Name of Organization: UC TRAC

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Patient/Patient Advocate, Member of the Public

In what setting do you primarily engage with researchers?:
Primary Care

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Create public or community engagement-based programs such as Community Advisory Boards comprised of key stakeholders to best guide these researches
   Collaborate with study patients, caregivers and family in these dialogues
   Design patient-led peer support groups
   Collaborate with community/cultural leaders
   Design and disseminate information using simple language
   Shorten and translate the science in the protocol for local people to understand
   Collect feedback via client satisfaction survey
   Hold research camps in communities especially the hard to reach etc

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   Hold debates, conferences, community camps,empowerment schemes etc

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   measure impact of their funding via surveys

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

Facilitation for their transport, meals and time
Shorter enrollment processes

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
unfair compensations sometimes its taxed

Email: mkukundakwe@idi.co.ug

Submit date: 8/13/2024

I am responding to this RFI: On behalf of an organization

Name: David Bergman

Name of Organization: American Association of Colleges of Osteopathic Medicine

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Organizational Official

Role – Other:

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

The American Association of Colleges of Osteopathic Medicine (AACOM) appreciates the opportunity to respond to the National Institutes of Health's request for information (RFI) to enhance public engagement in NIH-supported clinical research. NIH-funded clinical research is vital to transforming academic discoveries into clinical tools that address unmet patient needs, especially in underserved, rural, and hard-to-reach communities. To advance the goals of the ENGAGE Working Group and NIH's commitment to health equity, AACOM believes it is crucial to expand clinical research collaborations with colleges of osteopathic medicine (COMs) by increasing funding and representation opportunities for osteopathic medicine.

AACOM leads and advocates for osteopathic medical education (OME) to improve the health of the public. Founded in 1898 by the nation's osteopathic medical schools, AACOM represents all 41 colleges of osteopathic medicine (COMs) — educating more than 36,500 future physicians, 25% of all U.S. medical students — at 66 medical school campuses, as well as osteopathic graduate medical education professionals and trainees at U.S. medical centers, hospitals, clinics and health systems.

AACOM believes COMs can make important enterprise-wide contributions to NIH-supported clinical research studies. As one of the fastest growing medical fields, COMs are a vital part of the nation's healthcare system. In fact, in rural and underserved areas across America, these academic institutions serve as a vital lifeline to care. More than half of COMs are located in health professional shortage areas (HPSAs); sixty-four percent of COMs require their students to go on clinical rotations in rural and underserved areas; and eighty-eight percent state a public commitment to rural health. More than 86% of doctors of osteopathic medicine (DOs) who attend a COM and residency in a state, stay to practice in that state. Further, 41% of graduating 2021-22 osteopathic medical school graduates reported that they planned to practice in a medically underserved or health shortage area.

The DO workforce has also been critical to meeting surging primary care demands amid national physician shortages, with more than half of DOs practicing in family medicine, internal medicine, and pediatrics. The vast majority of COMs also provide clinical training in community-based settings that expose medical students to the unique healthcare needs of rural and underserved populations. Finally, these community-based medical education approaches have been indispensable to bridging primary care gaps and tackling health disparities in medically underserved areas, including rural communities.

Despite OME's contributions and national leadership in primary and rural care, COMs are significantly underfunded and underrepresented within NIH. This historic funding disparity and underrepresentation weakens research in areas where osteopathic medicine specializes and disadvantages osteopathic medical students in the residency selection process due to the lack of access to research opportunities. COMs receive just 0.1% of NIH funding ($55.4M) compared to 42% for MD institutions ($22.4B). The NIH has repeatedly suggested that osteopathic medicine is most closely linked to the National Center for Complementary and Integrative Health (NCCIH), including as recently as the fiscal year (FY) 2024 Congressional Justification (CJ), despite multiple clarifications that osteopathic research runs the full spectrum of NIH Institutes and Centers. The NCCIH is one of the smallest NIH funders to COMs, providing less than 2% of total funding, with the most currently coming from the National Institute on Aging, the National Institute of General Medical Sciences, and the National Heart, Lung, and Blood Institute.

In addition to underfunding, osteopathic researchers are underrepresented on NIH National Advisory Councils and study sections compared to allopathic researchers, with only 19 DOs across the 3,233 study section reviewers (compared to 493 MDs) and only two DOs among the 462 National Advisory Council members (compared to 213 MDs). Since 2020, AACOM has proposed nine nominees to six NIH councils which, regrettably, have not been accepted. To bolster public engagement, AACOM believes it would be valuable for the Working Group to help facilitate greater insight, through its recommendations to the Director, into the NIH's selection process for its National Advisory Councils to help ensure stakeholders, like AACOM, can develop and submit nomination packages that will have a greater rate of success. Further, we urge the Working Group to address these disparities in funding and representation to ensure that DOs and the communities they serve – particularly rural and underserved areas – benefit from NIH-supported research.

We would also like to highlight that a bipartisan group of U.S. Senators and Representatives has called on NIH to specifically address and remedy these longstanding issues. In a letter to former Acting NIH Director Dr. Lawrence Tabak, lawmakers recommended that NIH:

- Establish structured partnerships with the osteopathic medical education community, including AACOM;
- Establish a program to incentivize principal investigators from COMs;

- Consider opportunities to fund research projects that incorporate the osteopathic philosophy and OMT;
- Increase representation of osteopathic professionals on NIH advisory councils and study sections.

(See July 15, 2022 Letter: https://www.aacom.org/docs/default-source/advocacy/nih-coms-research-letter-7.18.22.pdf?sfvrsn=e1fa226a_3).

In the past several fiscal years, Congress has echoed these concerns in report language accompanying the FY22, FY23, FY24, and FY25 appropriations measures. For FY24 in particular, lawmakers recognized how increased access to research funding for osteopathic medical graduates can “significantly bolster NIH’s capacity to support robust recovery from the COVID–19 pandemic, address health disparities in rural and medically-underserved populations, and advance research in primary care, prevention, and treatment.” (See 118–84, page 129: https://www.congress.gov/118/crpt/srpt84/CRPT-118srpt84.pdf). Further, the report language directed NIH consider how to better integrate COMs into research activities and bolster representation on National Advisory Councils and study sections. As a starting point, AACOM encourages the Working Group to strongly consider the proposed recommendations from Congress to help address funding and representation gaps in the osteopathic medicine field. Furthermore, COMs bring important expertise and a rural health care focus that should be reflected in the NIH’s research portfolio and advisory bodies. As the Working Group explores how to meaningfully include all voices in NIH clinical research – including those from rural and underserved areas – it must recognize the vital role COMs play in delivering high-quality, person-centered care to these communities and improving health equity. Furthermore, it is critical that recommendations from the Working Group address obstacles that have impeded DOs from enriching the clinical research base for caring for rural America, and other disadvantaged communities, and propose meaningful policy solutions that take advantage of osteopathic medicine.

Lastly, while clinical trial participation is not the exclusive focus of this RFI, AACOM wishes to emphasize that COMs are an underutilized resource for expanding primary care and rural clinical research. As NIH Director Dr. Bertagnolli works to broaden access to clinical trials in rural and primary care settings, AACOM is eager to contribute to this effort. To that end, we requested a meeting with the Director in March 2024 to discuss the value of COMs in this work. Unfortunately, we have not yet received a response. We continue to remain highly interested in collaborating in this area and would appreciate any assistance in elevating this meeting request for the Director and her team.

We believe the nation’s biomedical research enterprise will be well-served with more inclusive participation and commend the Working Group for putting forth this important RFI to drive progress in this area. Again, thank you for considering our perspectives and please know that we are happy to provide our full expertise and support to the Working Group. If you have any questions, please do not hesitate to contact me (dbergman@aacom.org; 703-801-5518).

David Bergman, JD
Senior Vice President, Government Relations and Health Affairs

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Email: aacomgr@aacom.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Marlene Wilson

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Other

In what setting do you primarily engage with researchers?:
Primary Care

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
Develop resources respectful of different cultures, facilitating open dialogues for decision-making, sharing results in a way that is valuable.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Encourage people/community members to establish shared decision-making on project milestones, prioritizing local community review and research questions and research proposals, specific research design factors, leveraging existing patient-clinician relationship.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
All participants must receive a benefit for their participation. Their participation can not come back at them.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
No/unfair compensation, participation opportunities only happening during typical work hours, lack of awareness of opportunities.

Email:

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Jeanna Benny

Name of Organization: Bobby Jones Chiari Malformation Foundation

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Member of the Public, Patient/Patient Advocate, Other

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
   1. H.R. 3832- 118th Congress
      A. This bill expands the priorities of the Biomedical Advanced Research and Development Authority (BARDA) to specifically include viral threats that have the potential to cause a pandemic.
      B. This bill expands the scope of innovation grants and contracts that may be awarded by BARDA to specifically include those that support research and development of certain manufacturing technology for medical countermeasures against viruses, including respiratory viruses, with pandemic potential.
   2. H.R. 485- Protecting Health Care for All Patients Act of 2023
      A. This bill prohibits all federal health care programs, including the Federal Employees Health Benefits Program, and federally funded state health care programs (Medicaid) from using prices that are based on quality-adjusted LIFE years that measure that discount the value of a LIFE based on disability, age, or terminal illness to determine relevant thresholds for coverage, reimbursements, or incentive programs.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

3. The Government Accountability Office must annually report on how the use of QUALITY adjusted life years negatively affects individuals with Intellectual and developmental disabilities.
4. This bill (H.R. 485) also reduces funding for the Prevention and Public Health Fund for FY 2024-FY2029.

3) Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.

What is Chiari Malformation?
What is Ehlers-Danlos Syndrome?
What is Syringomyelia?
What is Dysautonomia?
What is Hydrocephalus?
What is Idiopathic Intracranial Hypertension?
What is Postural Orthostatic Tachycardia Syndrome (POTS)?
What is Tethered Spinal Cord Syndrome?

4) Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.

5. RESEARCH
   A. Chiari Surgical Scale
   B. Craniocervical Instability Delphi
   C. Genetic Alliance Research Symposium
   D. American Public Health Association Meetings (at least quarterly)
   E. Think Tank Meetings (at least monthly)
   F. Research Colloquium Meeting (at least monthly)
   G. Symptom Burden Surveys (at least with every patient seen at every appointment)
   H. Telehealth Study (at least twice a year)

5) Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.

6. Earning the TRUST of the Patient and the Public in need of excellent patient care.
7. Communities will be more likely to want to engage with researchers and research institutions with a plan in place to meet certain
   criteria of invested and mutual goals.

*Please remember, Research, Education, Support, Advocacy.
Thank you for the Opportunity and again in sharing my advocating voice. JMB

Email: bennybunch137@charter.net

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Stephanie Kaplan

Name of Organization: American Society of Hematology

Type of Organization: Professional/Scientific Organization/Association

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: Medical and Research Society representing researchers and clinical researchers.

Other roles identified with when engaging/working with researchers:
Clinician/Healthcare Provider, Investigator/Researcher

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
The American Society of Hematology (ASH) has long been committed to combating inequities in hematology, supporting physicians and researchers from backgrounds underrepresented in medicine, and embracing diverse voices in the community. As part of this mission, ASH has created several key resources and initiatives to foster the design of hematology clinical trials that reflect the epidemiology of the disease and are inclusive of the population that will benefit from the therapeutic under investigation. The importance of designing clinical trials that reflect individuals in the real-world cannot be overstated, since trial results need to be generalizable. However, several groups (e.g., women, Blacks, Hispanics, the elderly, etc.) have been historically underrepresented in clinical trials, meaning the outcomes generated from those studies can't be applied to all patients. (1 & 2)
ASH, and its members have employed many strategies to effectively partner with people and communities. Including:
\- Establishing strong connections with patient-facing groups and local healthcare providers as these collaborations help the hematology researchers understand the unique needs and concerns of the patient population. For example, as part of ASH's multifaceted sickle cell disease (SCD) initiative, the Society founded the Sickle Cell Disease Coalition (SCDC), a group of over 100 national and global organizations to help amplify the voice of the SCD stakeholder community, promote awareness, and improve outcomes for individuals with SCD through cross organizational collaboration. ASH's ongoing engagement with the SCD community and provider groups through the Coalition has enhanced ASH and our members' understanding of the unique needs of patients with SCD. ASH members have indicated that outreach to community leaders specifically to highlight the value of clinical trial participation, helps with the dissemination of

trial information and ultimately improves participation in research initiatives from that community.

- Meeting patients where they are, an approach that involves going beyond the traditional clinical settings to engage with patients in their own communities. ASH members have found success giving talks and presentations to communities, in language they can easily understand and in areas they are familiar with and can easily access.
- Training the next generation of investigators on the importance of community engagement and strategies for connecting with diverse populations is essential. This is a core component of ASH's curriculum for its Clinical Research Training Institute (https://www.hematology.org/awards/career-enhancement-and-training/clinical-research-training-institute) – a year-long education and mentoring program that is geared towards training the next generation of clinical trialists. This will help equip future investigators to conduct meaningful research.

For additional resources, ASH refers the NIH to its DEI Toolkit for Clinical Trial Sponsors: https://www.hematology.org/-/media/hematology/files/dei/ash-dei-toolkit-for-clinical-trial-sponsors.pdf. Designed to help sponsors incorporate DEI principles throughout the trial life cycle, the toolkit includes actionable recommendations, reference articles, and additional resources from both national and international regulatory bodies and research organizations.

1. Sex, racial, and ethnic diversity in clinical trials: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10264921/#cts13513-bib-0001
2. FDA's Draft Guidance for Industry: Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies

2) Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.

Institutions performing research can support and incentivize active, bi-directional partnerships between researchers and people/communities through several key strategies:

- Ensuring that sponsors establish a local presence at trial sites can improve trust and engagement with patients. It is important to create a relationship with the research team and the community.
- Creating effective ways for patients and practitioners to identify clinical trials that they can participate in, through accessible platforms and clear, culturally and linguistically appropriate resources. Moreover, streamlining trial consent forms and ensuring that they are written in clear language that patients can understand is vital to ensure that patients are fully informed. Additionally, translating consent forms and resources into other languages is crucial to accommodate non-English speaking participants and enhance inclusivity.
- Providing funding support for all stakeholders participating in a clinical trial, especially lived experience experts (LEEs). It is critical for investigators to include as part of their research budget appropriate funding to compensate individuals who are participating in trials not only for their time, but also for some of the financial challenges that could impede them from

participating e.g., travel and housing costs, childcare assistance, etc.). In addition, researchers should consider adding LEEs as key personnel in their research grants and compensate them for their time

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

Research funders should forge partnerships between people, communities, and researchers in the following ways:

- Developing a framework for adequate funding support for LEEs participating in clinical trials. This might take the form of clear allowances for LEE support in the terms and conditions of the grant. One step further would be to require LEE engagement as a part of the funding mechanism.
- Engaging communities and incorporating their input in all clinical research supported by the NIH, particularly hematology focused research. This will foster trust within the community and help achieve research outcomes that would be relevant to the communities. An example of this critical engagement has been implemented by the ASH Research Collaborative SCD Research Network, which is fostering collaborative partnerships to accelerate progress in clinical research and improve outcomes for individuals living with SCD by expediting the development of therapeutics and generating high-quality evidence to support clinical decision-making. The Network provides support for SCD Community Advisory Boards have been established at each consortium to promote Network efforts that are informed by the needs and desires of those living with and caring for those with SCD; a national advisory board, elected from the local boards advises at the national level.
- Encouraging investigators to integrate health systems in their study designs since such systems highlight real world data that could inform hypothesis generation and protocol design.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

Specific examples of factors that may increase the likelihood of people and communities engaging with researchers and research institutions include:

- Leveraging telemedicine and other decentralized approaches for data collection to meet patients where they are.
- Taking advantage of patient-facing groups that offer trial navigation resources.
- Seeking the expertise of and providing funding support for LEEs participating in trials.
- Improving the navigation of ClinicalTrials.gov to ensure easier end user searches.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

In hematology, the following factors may make hematology patients and their caregivers less likely to want to engage with researchers and research institutions:

- Lack of awareness of existing trial participation resources for patients

- Mistrust in clinical research
- Insurance barriers
- Restrictive inclusion and exclusion criteria (e.g., requiring that all trial participants speak English)
- Limited funding provided to defray the cost of a patient's participation in a trial
- Lack of diverse personnel and opinions in clinical trial teams
- Limited time available to participate in trials – It is important to consider ways to reduce the amount of time needed to participate. For example, using telemedicine and constructing trials that keep the number and duration of visits that require time away from work or home to a minimum.

Email: skaplan@hematology.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: John Meade

Name of Organization: AVAC

Type of Organization: Patient/Community Advocacy Organization

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Community Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Organizational Official, Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
o Prioritize the translation of research and development materials into multiple languages that reflect the populations that will most benefit from products. Avoid jargon or technical language. An integral part of promoting diversity and equity is using language accessible to all.
o Proactively integrate the civil society/community's role and responsibilities within the research protocol.
o Ensure that the diverse perspectives of women, youth, persons with disabilities, and other marginalized groups from the communities served are not only heard but are leading and shaping research priorities.
o Promote diverse usage of publications, citations, and references by reevaluating the term "expertise". Actively seek out expert comments from the communities most affected and new and fresh voices instead of the same voices opining on views.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
o Utilize Good Participatory Practice mechanisms for community stakeholders to provide inclusive input at all stages of the research process – i.e. protocol development, during trial conduct and results dissemination.oo
o Ensure intersectional identities (gender, nationality, age, race/ ethnicity, etc.) most impacted by specific health conditions are actively involved throughout the research process.
o Improved direct involvement by the individuals impacted by product development to understand the usability and sustainability of continuation of product.o

- Current and future research projects should include the lived experiences of community stakeholders. When possible, community stakeholders should be an active part of the protocol leadership team. Develop and maintain a database of community organizations that can be integrated into research and development processes from the beginning.o Part of clinical trial funding should be devoted to expanding this database by actively engaging new community partners in addition to those more seasoned.
- Promote decentralized decision-making structures, giving those from low resource-settings more autonomy. This includes the ability to ask new questions
- Value and prioritize traditional knowledge and knowledge gained through lived experiences by engaging local communities in co-designing and co-leading programs to ensure their needs, expertise and insights drive the initiative.
- Ensure community experts are compensated fairly and in a timely manner for their contributions.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

- Create budgets/funds that are not in a silo and provide broad foundational support to community and civil society organizations to better support the engagement in research.
- Compensate community expertise. Publish or promote success stories to encourage additional support.
- Publish or promote success stories to encourage additional funding opportunities to engage community-based civil society organizations.o
- Investing in community infrastructure (e.g. staffing, tools) in the same way we invest in clinical infrastructure.
- Concrete planning/discussions/budgeting at the outset to include formative research with communities, translation of materials, and dissemination planning and to ensure sustainable, long-term funding and anticipated outcomes.
- Changes in the RFA process to encourage greater partnership between US and Global South institutions. This should include updating the review process to allow more Global South institutions to take prime grant roles.
- Incentives to attract investment, development, production in Global South geographies beyond profits.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

- Involvement of research through a lens that is trauma-informed and utilizing language that is not medical jargon so that research is accessible for all.
- Understand the social and political sensitivities around the specific area of work.
- Consider the other social determinants to accessing health and health products and integrate into research process.

o Explain how the communities will benefit from participation, in any form, and gather ideas from local leaders on the needs/demand from the community.o

o Involve past clinical trial volunteers/participants, when possible, in conversations with communities allowing for broader support and demystifying clinical trials.

o Implement training on cultural sensitivity to all site staff and protocol leadership.

o Ensure work planning considers the seasonal and geographic differences, such as for meeting times/approaches.

o Co-create equitable partnership standards between research entities and community partners to ensure mutual respect and equitable partnership practices including but not limited to:o clear, transparent criteria for partner selection and review processes to ensure fairness;

o Create feedback mechanisms for site engagement staff and CAB members to engage directly with trial leadership, including NIH program officers.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

o Medical distrust for populations impacted by historical events.

o Civil society representing marginalized communities are often asked to recruit on behalf of researchers and research institutions. This has been a popular practice within the research enterprise. This causes the community to feel taken advantage of by researchers who engage because they need access to the specific community.

o Geographic proximity to the trial site. Larger Metropolitan cities can often recruit very close to the center and do not need to engage semiurban, or rural populations. It is important community representation is inclusive of geographically diverse locations.

Email: john@avac.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Adam Fagen

Name of Organization: Association of Science and Technology Centers (ASTC)

Type of Organization: Professional/Scientific Organization/Association

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: Association representing public engagement practitioners

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   The Association of Science and Technology Centers (ASTC), a network of nearly 600 science centers and museums—and other allied organizations committed to engaging the public with science and technology—encourages NIH to broaden its definition of "public engagement" beyond the patient advocacy community. While patients and the patient advocacy community are obviously critical components of public engagement around clinical research, there is a much wider universe of people who should be engaged.
   NIH's clinical research portfolio includes not only clinical trials but a wide range of topics that will be relevant to or of interest to a broad cross-section of people, including many who are not yet aware of a future diagnosis. This commitment to broad public engagement means ensuring a voice for individuals of all backgrounds in discussions about research priorities, practices, and findings.
   In addition to being the right thing to do, research from ASTC and others has shown that U.S. adults have an appetite for engaging with science, including a specific interest in medical research. For example, a nationally representative survey conducted by ASTC and ScienceCounts revealed that 29% of adults in the United States report that a medicine-related topic (including biology, the human body, genetics, psychology, neuroscience, and general medicine) was their top science-related interest.
   We hope NIH will tap into the decades of work on "public engagement" in science education, including but not limited to education and outreach, diversity and inclusion, public participation in scientific research (such as "citizen science"), among other facets. By broadening the definition of "public engagement," NIH will better be able to tap into the rich body of knowledge that has proven effective for reaching diverse audiences. (For example, we suggest this resource for additional context on public engagement: https://informalscience.org/public-engagement/).

In particular, we urge NIH to proactively learn from practitioners and researchers with expertise and a long history of public engagement around scientific, medical, and socio-scientific topics. This includes—but is not limited to—our network of science centers and museums in nearly every community around the country, who are expert at meeting their audiences where they are and have deep expertise in engaging their communities around complex scientific topics, including those that may around public concern. For example, our member museums worked with a broad array of partners to cut through the polarizing vitriol around vaccines to provide fact-based understanding and enhance confidence around COVID-19 vaccination.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
Successful engagement of the public will require developing an environment that supports shared ownership and responsibility. The individuals and communities that researchers hope to engage must feel that their input and participation is desired, integral, and ongoing. While this could mean that researchers and researchers institutions cede sole responsibility for research projects and programs, it can help foster needed transparency that goes beyond one-way communication.
A true trusting relationship between researchers and the public will likely require the involvement of an array of community partners as research institutions themselves will likely not be seen as neutral in engagement around sensitive issues. As such, research institutions would benefit from involving other organizations that can help the community have trust and confidence in the process. Science centers and museums are among the many organizations that may be helpful in convening communities, fostering engagement, combatting misinformation, building coalitions, measuring impact, and more.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
Funders like NIH can underscore the importance of public engagement by making it an expectation of research projects, clinical trials, centers, and other efforts supported by the agency. This may mean requiring investigators to discuss their plans for robust public engagement as part of future funding applications—and developing review criteria that take these needs into account. It also means ensuring that study sections and other review groups include individuals with relevant expertise in public engagement, outreach, and communications.
NIH and other funders could further promote high-quality public engagement by supporting the development of resources, training materials, examples, and suggestions of how this work should be conducted, drawing upon the expertise of those with a history of successful public engagement around health-related and other similar topics.
Encouraging these kinds of initiatives and interactions would be consistent with how other U.S. federal agencies—namely, the National Science Foundation (NSF)—think about public engagement. NSF requires all proposals to meet two merit review criteria: “intellectual merit”—the potential for the proposed project to advance knowledge and understanding within its own

field or across different fields—and "broader impacts"—the potential for the proposed project to benefit society and contribute to the achievement of specific, desired societal outcomes. (See https://new.nsf.gov/funding/merit-review and https://new.nsf.gov/funding/learn/broader-impacts for additional information about NSF's merit review process.) Although broader impacts can incorporate many elements in addition to public engagement—including inclusion, STEM education, workforce development, national security, and economic competitiveness—this policy has been instrumental in creating a rich environment for scientific dialogue and public understanding of science.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

We stress the importance of fostering a trusting relationship between the public and researchers. This means developing a sense of shared ownership and responsibility, open dialogue, transparency in decision making, and co-creation of any products, activities, or initiatives. If public engagement is merely perceived as a check-the-box activity or one-way communication from researchers to the public, engagement efforts are not likely to be successful.

It is important to meet communities where they are, being proactive in reaching out to a broad array of audiences. This can mean physically meeting communities where they are—such as by holding events or advertising opportunities within communities, rather than at the research institution. It also means providing information and data in a format and at a level that will be accessible to those without substantial training and knowledge of complex scientific and medical topics. Further, investigators will need to find ways to position the research questions it hopes to discuss in a way that will be relevant to the audience. Again, NIH and its investigators can tap into the expertise of individuals and organizations who work at the intersection of science and society to help in translating this work into a form that will be accessible to the public.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

One of the biggest barriers to public engagement is a skeptical public who feels that researchers are not truly interested in their feedback or only pay lip-service to public engagement. As such, it is critical for researchers and research institutions to do more listening than talking and to meet their communities on the communities' terms.

More practically, this means avoiding situations where individuals are unable to speak up or feel uncomfortable doing so. It also means ensuring robust time for public input and discussion, times and locations that are accessible to public audiences and lowering the barrier to engage in the public form and one-on-one with researchers.

Email: afagen@astc.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Megan Lewis

Name of Organization: RTI International

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Other

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Our response to this question draws on RTI International's significant expertise across engagement-focused projects of differing sizes and scopes, including those funded by NIH, examples include our All of Us Research Program Engagement and Retention Innovator Award, the Healing Communities Study, the HEAL Harm Reduction Research Network, and CONNECTS, as well as many investigator-led R grants. RTI also leads engagement-focused projects funded by PCORI, EPA, FDA, DOEnergy, and CDC, among others. This experience spans working in partnership with a variety of communities experiencing marginalization and oppression, such as communities of color, people impacted by the criminalization of substance use and by the over-reliance on incarceration, and people experiencing inequitable health outcomes due to systemic racism, historical abuse, and neglect. These research partnerships utilize numerous engagement methods and approaches, depending on the research focus.
   Based on this experience we know that equitable and meaningful partnerships with communities during the clinical research process requires enhancing and building researchers' community engagement skills and mindsets. Engaging communities authentically in the research process in ways that do not tokenize their contributions requires researchers to genuinely value community perspectives and experiential knowledge. Valuing this perspective means acknowledging that their lived expertise is as important as academic knowledge across all phases of research, from developing research questions and areas of study through data collection and analysis to dissemination and the generation of next steps. This acknowledgement is critical to the success of research aiming to improve equitable outcomes for all. Gaps in methodological knowledge and skills on how to partner meaningfully, such as how to build relationships or involve communities in data analysis, are critical to fill. But we cannot ignore the importance of researchers' mindsets (Venkateswaran et al., 2023). RTI's

Equity-Centered Transformative Research Framework outlines how embedding principles of inclusion and equity in the research process requires a transformation of both the researcher and research process. Without an attention to equitable mindsets and processes, researchers who aim to engage communities might unintentionally cause more harm and widen existing rifts (Venkateswaran et al., 2023).

The community engagement affirmations shown below, guide RTI International's approach to community engagement, and are aligned with the principles of equity and inclusion. Because each approach to partnering with community members or organizations should be tailored to the specific community context and the research project, it is impossible to list all potential engagement strategies. Instead, we recommend the use of these values-based principles as a guide:

1) Prioritize human connection and embody a heartfelt approach to build trusting relationships.
2) Commit to deepening our understanding of equity, diversity, inclusion and belonging (EDIB) to advance social justice, including acknowledging our biases.
3)Acknowledge diversity between and within communities and utilize tailored and flexible approaches.
4) Commit to understanding historical inequities between institutions and communities and redistributing power equitably.
5) Use an asset-based approach that prioritizes building on community's strengths, resources, and interests to the benefit of all parties.
6) Hold ourselves accountable to ensure a collaborative and ethical engagement at every stage.

To achieve these values in community-engaged research, RTI's Transformative Research Unit for Equity provides training to academic researchers of all disciplines on how to embed principles of equity, diversity, and inclusion in the research process. The training focuses on how researchers can center the perspectives of those closest to or greatly impacted by the condition being researched in the study and how to partner with communities at any, or all parts, of the research process. Our training activities ask researchers to reflect on their worldviews which are shaped by their previous experiences, consider how their worldviews inform their own research process, and identify ways their worldviews might shift to align more fully with equitable inclusion. Workshops also build researchers' skills and knowledge related to developing trusting relationships with communities, using participatory action research processes, engaging inclusively with communities by using empowering and strengths-based language and becoming trauma-informed and culturally affirming.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

Our response to this question draws on RTI International's significant expertise across engagement-focused projects of differing sizes and scopes, including those funded by NIH, examples include our All of Us Research Program Engagement and Retention Innovator Award, the Healing Communities Study, the HEAL Harm Reduction Research Network, and CONNECTS, as well as many investigator-led R grants. RTI also leads engagement-focused projects funded by PCORI, EPA, FDA, and CDC. This experience spans working in partnership with a variety of communities experiencing marginalization and oppression, such as communities of color, people impacted by the criminalization of substance use and by the over-reliance on incarceration, and people experiencing inequitable health outcomes due to systemic racism, historical abuse, and neglect. These research partnerships utilize numerous engagement methods and approaches, depending on the research focus.

Based on this experience we know that research institutions, like academic medical centers, universities and health systems need to fundamentally rethink institutional transformations needed to embed community engagement as a research priority. Efforts need to be backed by institutional policies and resources so that these changes become the new standard for research quality and rigor. To do so, changes need to be embedded into existing formal and informal incentive structures, and in some cases, new structures and functions are needed to sustain the desired institutional transformation.

Institutions need to create a research climate and culture in which community-engaged research is expected, supported, and rewarded. Specifically, we suggest that organizations look to align their internal incentives for performance, promotion, and other rewards with institutional priorities to grow and support community-engaged research activities. Incentives should align to roles and responsibilities across teams and departments within the organization. Institutions play an important role in creating the organizational structures, supports, policies and procedures that reinforce expectations and accountability for conducting community-engaged research. These institutions can also reinforce NIH funding priorities, since many academic medical centers and universities require NIH funding for promotion and tenure decisions (Nokes, et al., CTS, 2013). Beyond internal institutional processes, institutions can work externally to build strong campus and community partnerships. We organized specific institutional strategies around the values-based framework RTI applies across many community-engaged research projects.

1) Prioritize human connection within and outside of institutions
    a. Develop campus-wide recognition programs that highlight engaged research successes and include community partners as part of the recognition.
    b. Use inclusive and plain language principles when engaging with community members and organizations.
    c. Build campus systems that catalogue community organization involvement so that researchers or administrators come to meetings aware of what the community has contributed in the past to the institution.
2) Deepen EDIB knowledge to support community-engaged research
    a. Provide implicit bias and other trainings for researchers to support expansion of EDIB knowledge.
3) Foster diverse communities and tailored approaches
    a. Develop campus-based mechanisms that engage and compensate community members in research functions via NIH CTSAs or other large scale research grants or campus initiatives.
    b. Partner with community groups to conduct outreach and hold townhalls in community spaces that educate community members about the important role they can play in research and advise them what to expect from an equitable partnership with researchers.
4) Develop an understanding of historical inequities

    a. Establish authentic partnerships with institutions that are building research capacity by developing cross-institutional programs with administrators and faculty from Minority-Serving Institutions (i.e., HBCUs, HSIs, TCUs, etc.).
    b. Develop programs to grow community partnerships in which R1 and robustly funded universities and research organizations take on more of the administrative responsibilities that smaller community-based organizations are not able to accomplish, and they do not get overstretched.

5) Develop programs to support asset-based approaches and capacity building for community-engaged research
    a. Provide training to researchers on partnership development approaches to enhance success at building meaningful and productive partnerships with community members and organizations.
    b. Create internal funding, sabbatical leaves or other financial supports that focus specifically on capacity building for researchers related to community-engaged research.

6) Implement accountable, collaborative, and ethical guidelines for community-engaged research.
    a. Expand tenure and promotion guidelines to recognize the importance of community-engaged research, which may take longer to get funded, complete and may involve larger research teams.
    b. Establish campus-level or school-level community advisory boards and compensate them for advice provided to chancellors and research administrators, Deans or Department chairs.
    c. Create a campus culture that recognizes and amplifies the importance of community involvement in campus research activities.
    d. Develop programs to support completion of regulatory requirements like community-friendly IRB trainings.

3) Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.

Our response to this question draws on RTI International's significant expertise across engagement-focused projects of differing sizes and scopes, including those funded by NIH, examples include our All of Us Research Program Engagement and Retention Innovator Award, the Healing Communities Study, the HEAL Harm Reduction Research Network, and CONNECTS, as well as many investigator-led R grants. RTI also leads engagement-focused projects funded by PCORI, EPA, FDA, and CDC. This experience spans working in partnership with a variety of communities experiencing marginalization and oppression, such as communities of color, people impacted by the criminalization of substance use and by the over-reliance on incarceration, and people experiencing inequitable health outcomes due to systemic racism, historical abuse, and neglect. These research partnerships utilize numerous engagement methods and approaches, depending on the research focus.

Based on this experience we are aware of many ways that other research organizations and funders have established robust programs that center engaged research in their funding structures. The leader in this field is the Patient-Centered Outcomes Research Institute (PCORI). PCORI's mission is to center the patient voice in the entire research process and incorporate other interest-holders' perspectives to ensure that research evidence is disseminated and implemented in health care practice. [NOTE: PCORI currently uses "stakeholders." At RTI International we are moving toward more inclusive, less harmful language usage, hence the substitution of interest-holders.] PCORI supports their mission via a very large infrastructure that educates patients, community members and researchers about how to form partnerships to design and conduct engaged research, specific to comparative effectiveness research. They also fund awards that provide the building blocks for developing partnerships through their Eugene Washington Engagement Awards Program. PCORI acknowledges multiple interest-holder groups are important to accomplishing their mission, including patients, clinicians, researchers, purchasers, payers, industry, hospital and health systems, policy makers, and training institutions. Members of each of these groups can participate in PCORI advisory groups, which provide input on priority funding areas or other activities. PCORI makes it easy for community partners to be funded on awards and involves a variety of interest-holders on their merit review groups that review research proposals. Merit review group Interest-holders are not trained researchers and focus on review criteria that matches their expertise, including scoring the required engagement plan. Other governmental agencies also have centered the patient voice in their mission, and funding decisions, including the CDC, EPA, FDA, and CMS. Based on these examples, there are very concrete actions NIH can take to incorporate equitable partnerships between people, communities, and researchers into their programs and priorities to support clinical research. Some of these relate to reducing barriers to these partnerships, others relate to building capacity among community members, patients, researchers, and NIH staff.

Other governmental agencies also have centered the patient voice in their mission, and funding decisions, including the CDC, EPA, FDA, and CMS. Based on these examples, there are very concrete actions NIH can take to incorporate equitable partnerships between people, communities, and researchers into their programs and priorities to support clinical research. Some of these relate to reducing barriers to these partnerships, others relate to building capacity among community members, patients, researchers, and NIH staff.

1) Prioritize human connection within community members.
    a. Make engaged research one of the stated goals NIH uses to support its revised mission statement.
    b. Provide resources that make human connection possible, for example allowing costs for food or refreshments at meeting and community events.
2) Deepen EDIB Knowledge to support community-engaged research.
    a. Develop internal programs that educate program officers on the importance and benefits of engaged research.
    b. Develop internal programs that educate program officers on implicit bias and other EDIB knowledge.
3) Foster diverse communities and tailored approaches.
    a. Establish or embed community and patient advisory boards for each institute that help determine funding priorities.

b. Ensure community members on advisory boards have decision making authority that helps determine funding decisions.

c. Include trained community members on NIH grant review panels

4) Develop an understanding of historical inequities.

a. Develop a rubric to ensure community-based organizations receive equitable indirect funding rates, ensuring fair compensation for research participation.

b. Require that larger portions of research infrastructure grants awarded by NIH, like CTSAs, be devoted to community engagement and inclusive science cores.

c. Incentivize program officers to approve more research that involves community partnerships and engagement.

d. Extend CTSA funding mechanisms to R2 institutions to build research capacity.

e. Provide a waiver or expedited process for eRA Commons registration for staff from community-based organizations so that they can be included as key personnel in proposals.

f. Make proposal submission portals, such as eRA Commons and SAM.gov usable by community members and organizations.

5) Develop programs to support asset-based approaches and capacity building for community-engaged research.

a. Design and fund awards that help build partnerships between community members and researchers that can support the development of research collaborations.

b. Provide inclusive and accessible training programs that support community members' knowledge about the NIH research process.

c. Develop and provide guidance to help community members and organizations make informed choices about research partnerships that outline potential benefits and costs, as well as what to expect from equitable partnerships with researchers.

6) Implement accountable, collaborative, and ethical guidelines for community-engaged research.

a. Develop programs to support completion of regulatory requirements, like community-friendly IRB trainings.

d. Develop training and guidance on how to build a research budget from a community-based perspective.

4) Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.

Many scientists at RTI International have worked with community members and community-based organizations as partners in intervention, clinical, and observational research. From the professional experiences of staff at RTI, and particularly with minoritized, stigmatized, and historically underserved populations, we have been responsive to community partner requests and expectations to engage in research with us, aligned with the components of RTI's Equity-Centered Transformative Research Framework. For community organization partnership, examples that increase the likelihood of better more fair partnerships include:

1) Incorporating equitable compensation for their time, community expertise, professional/technical expertise, ideation, and material contributions, both for the proposal development/preparation activities and in the research project implementation budgets.

2) Streamlining, lower burden, and easier to use (than eRA Commons) NIH/federal system resources to allow flexibility and reflect variability in how community partners to demonstrate their commitment/planned roles on NIH proposals without draining their operational resources to complete the required forms.
3) Partnering prior to research proposals to secure equitable indirect rates with the funding agency to support the organization to maintain operational functions.
4) Providing effective, yet tailored, human subjects/scientific research training (similar to CITI training) without costs to the community members, to prepare them to engage with highly technical scientific teams.
5) Allowing time, post-award, for updates to planned study activities based on shifts in community needs and context.
6) Using asset/strengths-based framing to describe community/population settings and promote strengths/assets-based approaches to addressing planned health outcomes by funding agencies.
7) Prioritizing advanced planning of solicitation releases/due dates (6 months or more) to allow community organizations to build relationships and develop strong proposals with institutional partners.
8) Integrating requirements for research projects to deliver results of their studies in community settings through multiple modes, including briefings, social media materials, or community sharing sessions.
9) Creating opportunities for in-person partnering activities to facilitate trust, shared understanding, and sustained engagement.
For individuals, examples include:
1) Compensation for their participation that is aligned with real-life costs and expenses (e.g., childcare, transportation, time away from work, etc.) and cash, where possible, considering store specific gift cards do not account for personal needs/preferences and store accessibility across communities.
2) Co-location of research activities in community settings they already frequent.
3) Using technologies that allow research teams to transfer/confirm demographic/stable metrics between timepoints, rather than repeating full collection of such information.

4) Adjustment of study expectations and activities that account for community conditions and burden.
5) Helping community members understand the 'why' of research so they link their activities and participation with the larger goals for community and population health.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Across RTI International, research staff have observed several tension points with potential community partners interested in collaborating with institutions to conduct research. Specific actions that may lower interests of people and communities to engage with researchers and research institutions span multiple concepts, including alignment about expectations for meetings (time and participation), behaviors that deter engagement, and institutional compensation structures and institutional norms. In alignment with RTI's Equity-Centered Transformative Research Framework, RTI teams have collaborated closely with community partners to navigate many of the concerns as listed below, and especially those within RTI's institutional control.

In terms of research activities conflicting with day-to-day work norms, the concerns include:

1) Expecting community partner organizations to host meetings during traditional work hours and expecting community members to leave their employment to participate in research activities, particularly in resource-strained communities.

2) Hosting meetings in the eastern time zone without offering live sessions for persons in other time zones, for national projects

3) Repeating daily, high-frequency behaviors that de-value community partners (e.g., choosing appropriate terminology to reference communities or populations, regularly dismissing a partner's professional and personal expertise; using language that "others" non-researchers).

In terms of inclusion in key research discussions, concerns include:

1) Being excluded from meetings with NIH scientific leadership determining the directions of potential research activities.

2) Being excluded from decision-making meetings, or considered as less critical personnel in study leadership/direction meetings.

Regarding how community partners are engaged with their research partners, there example concerns include:

1) Having their recommendations categorized as optional, instead of essential, to the success of the study.

2) Being told that their recommendations for study improvement, recruitment, retention, and updating are not evidence-based, when it is more likely that there has not been an interest or resources to study their recommendations within their specific social, political, or geographical context.

3) Technical and scientific teammates being unwilling to share project-related information in plain language, and burdening community partners with the additional, perhaps uncompensated, labor of deciphering the technical language.

4) Technical teams and scientific investigators structuring meetings and study activities to alienate community partners, or make community partners uncomfortable when contributing comments and feedback about study activities and decisions.

5) Expecting that community partners acclimate to the norms of research institutions, rather than technical/institutional staff/institutional partners acclimating their approaches to the norms of a community organization/setting.

Regarding compensation and allowable costs, concerns include:

1) Being offered lower compensation compared to their institutionally- employed colleagues and co-investigators, particularly as the expectations associated with operational costs/decision planning vary, and might be absorbed in an institution, but cause distress for the organization in managing/completing regular day-to-day business/services, and lead community organizations to pull out of project commitments at late stages.

2) Having delayed compensation processes through institutions with extended compensation timelines, thus jeopardizing their economic stability, while expectations

remain unadjusted for the planned work.

3) Having the option to provide food in relevant research activity meetings, particularly as they need to happen after work hours.

4) Lack of clarity about community organizations leads as key scientific contributors through grant supplements (e.g., administrative supplements to existing NIH-funded projects).

Email: jnelson@rti.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Beth Mathews-Bradshaw

Name of Organization: Alliance for Aging Research, Talk NERDY Program

Type of Organization: Patient/Community Advocacy Organization

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Patient/Patient Advocate

Role – Other:

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member, Community Advocate, Investigator/Researcher, Patient/Patient Advocate, Research Participant

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
ASK! Many communities are never approached or asked. Get individual PIs, and institutions, involved within the community – not just one person, but multiple voices within the community. Involve engaged patient advocates in the research process early – at the protocol development stage. Publish research in open access journals so that the public has access to the materials…or make it available to consumers through the publisher, perhaps through patient organizations if you cannot get agreements with publishers for open access.
The #1 strategy Talk NERDY recommends is meaningful patient engagement and participation from the beginning to end of a study; not checking a box by including one person at one point in the process. Patients with lived experience and research advocacy experience can add invaluable insight to the creation and successful execution of clinical trials. Many advocate organizations provide training to their membership; investigators should reach out to those organizations and ask if they and any patients they have trained would be appropriate for this. Increase work with advocacy groups in the disease space to liaise with members, representatives, etc. Talk NERDY recommends including patient advocates with lived experience on all research teams.
Ensure that ALL populations are considered and preferably included in the clinical trial – particularly the special needs and disabled populations. Prioritize community engagement from the beginning of the process by involving the target community, while actively seeking input and feedback to co-create the research objectives together.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

Create and advertise workshops on research methods or work with advocacy organizations that are already doing this, such as the Alliance's Talk NERDY program. Give access to relevant data for decision-making. Provide clinical education for patient research advocates so they understand the conversation in the room. Have them involved in the research at the early planning, pre-first protocol draft phase. Consider including patient advocates who are on the research planning to be included as authors in any published research.

Make better use of community health care institutional level, i.e. hospitals, patient and family advisory committees as a starting point, to get your foot in the door so to speak, with a group that is invested in the outcome. Consider patient education such as screens in waiting rooms addressing clinical trials – what they are, how they work, why they are important, in language "regular people" can understand.

Have doctors and nursing staff be better educated on what research is available, have a list, here is research you might be interested in, at the GP and specialized physician level. Consider education of the GPs staff, and appropriate resources for the GP staff to access and be able to share.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

Funders could offer grants or prizes for research projects that demonstrate meaningful engagement with communities.

Provide appropriate levels of funding and make it contingent on meaningful patient engagement in the research – not pizza parties, not one focus group, but an engaged group of patients with lived experience that consult on the research throughout its development and execution.

Institutional buy-in is huge – institutions need to provide funding to researchers to include patients in the research process prior to receiving NIH grants. Patients need to be included at the initial discussions phase, at the first protocol draft phase, while milestones and logistical considerations are being discussed, but to do so, the institutions need to provide general funding for community engagement. Time is money, particularly in populations that may be environmentally disadvantaged and cannot afford to lose paid hours to participate in a trial either as an advisor or a research participant.

Have an actual concrete engagement plan with specific steps and goals. Make that a requirement of receiving funding.

Consider the creation of a Best Practices Tool for Clinical Trials, to address inclusion of diverse populations (tying into the inclusion plans now being required by FDA) including a list of compensation, and the use of a compensation tool such as the National Health Council's Fair Market Value Calculator – something that has universal acceptance, and how to include patient research advocates in the research process in a meaningful way throughout the duration of the study, and a section on Patient Advisory Boards – concrete guidance and expectations for training and inclusion in the research studies.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
Consider basic public service announcements (PSAs) on the radio and through social media.
Information in relatable terms on the research, including who to contact to ask about it.
Fair and appropriate compensation, including coverage of costs (child care, gas, parking, tolls), assistance with travel to the facility conducting the research (vouchers are NOT enough, many services will not help someone on a walker get out the door of their home due to insurance issues – figure those challenges out ahead of time to help those with economic challenges, those that live alone without a caregiver, etc). Pay by the hour – if someone sits there all day to interact with staff for 15 minutes, compensate by the hour – we suspect efficiency will improve when this is the case.
Also see training referenced in the questions above; help those that want to engage understand the language in the room, have more accessibility (after regular work hours), in-home visits, translators, make language understandable – run it by a non-researcher for clarity, for all publicly related information including informed consents, posters in waiting rooms, trial literature, etc., make them translatable.
Provide information on safety within earlier, related trials (Phase 1 for Phase 2 trials, Phase 2 for Phase 3 trials) and why you think this trial you are recruiting for is worthwhile.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Lack of trust, suspicion of participant safety, insufficient follow-up for clinical trial participants.
Unrealistic logistics (something that requires a 10-day hospital stay with family/caregivers attending). Respect a person's participation – time is money – do not expect someone to sit there for 6 hours waiting, be honest about expectations and time commitments up front, try to schedule for efficiency for participants, no compensation, NOT BEING ASKED, patriarchal or condescending staff, staff they are not comfortable revealing embarrassing health challenges to (gender, race-based).
Not being transparent in each step in the process/not giving information in laymen's terms, talking in 'technical language' that is not easy to understand. Lack of diversity.
Be aware of the tech divide for older, socially disadvantaged, special needs populations, and those living in geographic areas without adequate broadband. Alternative methods may need to be utilized in those cases.

Email: bmbradshaw@agingresearch.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Mary McGowan

Name of Organization: Foundation for Sarcoidosis Research (FSR)

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: CEO of FSR

Other roles identified with when engaging/working with researchers:
Community Advocate, Member of the Public, Patient/Patient Advocate

In what setting do you primarily engage with researchers?:
Community Based

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
'-Please support meaningful funding increases for the National Library of Medicine and dedicated public awareness and professional education efforts related to clinical trials participation and clinicaltrials.gov.
-Please provide resources for the National Institute on Minority Health and Health Disparities at NIH and the Office of Minority Health at HHS to assist with awareness and education activities and to ensure underserved, including rural populations, are being engaged.
-Please support funding and authorizations for the CDC to initiate a program for culturally competent navigators, an alumni guidance network, or similar support system to mentor and assist interested individuals through the clinical trials process.
-Please support outreach and collaboration with HRSA and the Community Health Centers Program to assist with clinical trials promotion and education, particularly in rural and underserved communities.
-Please leverage the Clinical and Translational Science Awards (CTSA) program and IDeA CTRs to bolster established community outreach efforts and direct them to critical areas (while supporting additional resources for new tasks).

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
'-Please continue to the support the efforts of the NIH CEAL Program, whose mission is to promote health equity, improve health outcomes, and strengthen community partnerships through community-engaged research to address racial, ethnic and socioeconomic health disparities.

-Please encourage academic and intramural partners to work closely to identify potential clinical trial recruitment by a) providing community education about clinical trials b) providing financial support that can be provided to FQHC, primary care, and safety net hospitals for their administrative work in supporting education and awareness of clinical trials amongst their populations.
-Please encourage academic centers to work closely with patient advocacy organizations and community based organizations during early stages of trial development.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
NIH should continue to harmonize certain efforts with FDA and HHS in general should be working to advance the outcomes and implement recommendations of the recent public Work Group report titled, "Enhancing Clinical Trial Study Diversity".

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
FSR has taken a deep dive into these issues and welcome you to review our white paper (see separate email). The following recommendations are drawn from our efforts to learn directly from the patient community:
-Please increase access include the utilization of telehealth technology, encouraging investigators to expand the hours of the clinic to accommodate appointments outside of 'work hours,' and to engage community physicians to partner with research institutions as a local touchpoint that can assume some of the monitoring and testing required by clinical trial participants.
-Please consider researchers to provide financial support for participants who are underemployed, travel cost reimbursement for the patient and companion (if needed), family care and pet care coverage, access to compensation for food and lodging
-Please encourage researchers to provide patients with a live liaisons who could be readily available to answer questions and provide information in a more patient-centric safe space.
-Please consider encourage researchers to education not only patients, by also loved ones and their communities about clinical trials.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
Our research has shown that the one of the most significant barriers to clinical trial participation beyond lack of awareness is concern over compensation and punitive externalities related to participation. A notable impact on clinical trial participation could be achieved through effective and timely reforms to compensation for clinical trials so that participants do not fear any financial consequences for participating (such as jeopardizing other assistance and eligibility). We view participation in a clinical trials as a public service and we join with other stakeholders, including clinical researchers in calling for a broad range of timely reforms, such as:
-Clarifying in statute with the US Department of Labor that the Family & Medical Leave Act (FMLA) already covers participation in a clinical trial and extends necessary protections.

-We further propose that for patients enrolling in clinical trials a federal tax credit for up to $5,000 for travel expenses associated with clinical trial participation should also be considered as part of this public policy response.
-Ensuring that any resources that help facilitate clinical trial participation are not taxed nor viewed as compensation in the traditional sense (with appropriate limits and guardrails).
-Provide flexibility to use HSAs to cover costs and items related to clinical trials participation.

Email: flaherty@hmcw.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Heather Cathrall

Name of Organization: Children's Hospital of Philadelphia

Type of Organization: Healthcare Provider or Hospital System

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: Research Administration that helps oversee a Research Family Partner Engagement Group at CHOP

Other roles identified with when engaging/working with researchers:
Caregiver/Family Member

In what setting do you primarily engage with researchers?:
Hospital/Health System

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   - Ensure the research team/institutional representatives making the community connections are members of the community or possess similar traits to those in the community (e.g. from similar backgrounds, ethnicities, demographics, languages spoken, etc.).
   - Making viable efforts over a prolonged period of time (can happen at an institutional level). Building connections takes time, energy, and commitment. The community wants to know researchers are committed to helping them before asking them to help the researcher.
   - Ensuring consistent and uniform representation from the Institution to the community (i.e. establishing a main institutional and community contact and uniform responsiveness so the community knows what to expect from the institution as a whole, as opposed to individual research teams which may vary in their level of training and responsiveness)
   - Active Listening – Before asking for support, the researchers need to understand what the community wants, what is important to them, what are unfulfilled needs they have, and what concerns they have related to research. Relationships are built on mutual trust, understanding, and commitment over time.
   - Give back to the Community – this can be in the form of educational information, resources, support, etc.
   - Understand how the community wants to hear about results of the research. Research teams should not simply conduct research and leave. There needs to be follow-up and ensuring that the community understands how their participation was helpful and what was learned from the project.

- Provide community realistic timelines on when they might hear back about results up front (e.g. data analysis may take longer than realized by those outside of research, so providing transparency and setting realistic expectations that the study team can meet is important)
- Understand barriers to research and proactively address them – meeting people in the community, providing transportation, childcare, translated materials, etc.
- Understanding logistic challenges to research and planning research to reduce burden/time for people participating.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   - Engage community advocates as part of research teams (we have a research family partners group at our hospital which does this type of work) and advisors (shared decision making and leadership)
   - Establish community boards to represent community interests/review research proposals (can be community lead or institutionally lead)
   - Find advocates already in the community to be community leads and engage the community
   - Provide funding to support community programs that address community health/wellness needs
   - Show consistency over time and give before asking to receive

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   - Encourage/require community engagement plans or letters of support in applications
   - Request detailed action plans for equity in enrollment, accessibility, recognition of barriers to research (including language barriers), dissemination of results to the community
   - Provide funding for teams to support the community, offset barriers such as transportation costs, and fairly compensate participants for their time
   - Provide funding to support researcher time to engage in prolonged community building and dissemination of results
   - During project updates for awarded grants, asking investigators to describe what community feedback they received and how they put community feedback into action.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**
   - Training investigators on community engaged research (this can also be in the form of requiring individual training or having an institutional group that supports this and can guide investigators in this space)

- Asking the community what information would be helpful for them before designing a study. The questions the community is interested in should help inform the research before it begins.
- Give to the community to fill their needs before asking them to participate.
- Define and know the community. Each community is different.
- Understand stressors outside of the research (e.g. socio-economic, cultural, historical concerns of the community) and approach in a culturally sensitive way
- Address barriers to participation (e.g. translate materials, offer interpreter services, be flexible in scheduling visits/meetings like weeknight or weekend availability)
- Get buy-in from the community at all stages; why are projects important and what can the community gain by participating (e.g. increased knowledge, health results, etc.)
- Ask for and incorporate community feedback and provide transparency when ideas from the community cannot be incorporated.
- Maintain contact and communication with the community between projects
- Fair compensation (understanding W9s cannot be filled out by everyone in all groups; sometimes items like diapers, food and supplies are more useful forms of compensation)
- Provide training, education, and employment opportunities to the community
- Provide resource and career fairs for community youth to increase the pipeline of diversity in research and provide career, mentorship, and training opportunities.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**
   - Asking for help without providing help back
   - Cultural ignorance
   - No compensation
   - No transportation/childcare coverage
   - Limited hours
   - Language that is not understandable
   - Condescending approach

Email: cathrallh@chop.edu

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Grace Wickerson

Name of Organization: Federation of American Scientists

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Organizational Official

Role – Other:

Other roles identified with when engaging/working with researchers:
Organizational Official

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   No response to this question

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   No response to this question

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**
   Public engagement researchers have documented the importance of partnerships and relationships with key local stakeholders, such as community based organizations (CBOs), in realizing the full breadth of participation with a given community and thus insight into key needs. The lived experience of community members can be an invaluable asset to the research process, informing and shaping research questions, process, and program evaluation. The current reality is that many CBOs do not have the opportunities, incentives, or capacity to engage in research processes. Promising methods for investments in relational infrastructure building (with examples from both within and outside of government) are below, and derived from FAS' work on documenting how to open up the scientific enterprise to participation (see here). Approaches described below also learn from and build upon the work of field leaders like the Association of Science and Technology Centers (ASTC), and their Community Science Framework and Approaches.

To enable the following methods, it will be necessary to build agency staffing capacity for investing in and managing partnerships and relationships between researchers and communities. Operationalizing this could look like creating “relationship directors” on programs that include or should include public participation and community engagement (PPCE) activities.
Methods for interfacing with communities, like citizen’s juries, online platforms, deliberative forums, and future-thinking workshops.
The Participatory Technology Assessment (pTA). Participatory technology assessments (pTA) are a class of methods for public deliberation on science and technology policy topics, including those deliberative dialogue methods developed by the Experts and Citizen Assessment of Science and Technology network, citizens’ assemblies, citizens’ juries, and consensus conferences, among other approaches. pTA usually occurs in three steps, all shaped by public input: 1) problem framing, 2) deliberation and 3) results and integration. When systematically integrated into research and development (R&D) processes, pTA can be used for anticipatory governance, that is, to direct decisions, policies, and investments toward desired outcomes and away from undesired outcomes. Most notably, a pTA for the National Aeronautics and Space Administration (NASA) helped lead to the creation of NASA’s Office of Planetary Defense.
Physical and digital tools for research, design experimentation, and open innovation led by community members.
Federal examples include:
Citizenscience.gov, authorized by the “Crowdsourcing and Citizen Science Act'' of 2016. Citizenscience.gov is the the hub for crowdsourcing and citizen science across the U.S. government, cataloging efforts of federally-supported citizen science, providing toolkits to actualize citizen science projects, and operating a community of practice to share knowledge. Citizenscience.gov has helped support +500 projects since its inception.
Challenge.gov, launched in 2010 as a part of Open Government Initiatives and formally authorized by the American Innovation and Competitiveness Act of 2017. Challenge.gov is the hub of federally-supported open innovation and price challenges. Since creation, Challenge.gov has supported +1,300 prize challenges from +100 federal agencies.
Non-federal examples include:
MakerNurse. Launched out of MIT, this initiative has worked to identify nurse-led innovation in care settings and bolster capacity for nurse-led R&D. They have built a community of innovative nurses and developed tools and resources for nurses to innovate at bedside more easily, including the first medical makerspace in the country at UT Galveston.
Count Me In (CMI). A patient-partnered cancer research initiative that empowers patients to share cancer samples, clinical information, and experiences to accelerate the pace at which new discoveries are made. By working to reduce the barriers to participation in research through digital technologies, CMI makes it much easier to study rare diseases and find cures.
Funding resources to build CBO capacity to meaningfully engage in R&D and support ongoing sustained partnership with affected communities.
Federal examples include the RADx-UP program from the NIH and Civic Innovation Challenge from NSF, both of which provided capacity-building funding to CBOs to meaningfully engage in science and engineering research, as well as to propose their own studies to advance public priorities (i.e. RADx-UP supporting the distribution of COVID-19 diagnostics and vaccines by CBOs).

Non-federal examples include:

Partners Advancing Climate Equity, a California government-led initiative which supported a cohort of climate justice leaders across the state by investing in their organizations, training them in community-asset mapping skills to identify transformative work opportunities, and aiding them in navigating the funding environment to accelerate organizational growth.

Rare as One, a Chan-Zuckerberg led initiative, that provides capacity to patient-led initiatives to unite rare disease communities and aid them in securing partners to lead research and discover cures and treatments for the diseases that impact their lives.

Public Interest Technology Innovation Fellowship, an ASTC-led, Arizona State University, ECAST, Museum of Science, Boston, and New America supported effort to train science engagement professionals in public engagement practice in pursuit of community-driven priorities.

Thriving Earth Exchange's Community Science Fellowships, a partnership between ASTC and the American Geophysical Union that connects technical experts with communities facing local challenges related to climate change, natural hazards, and natural resources. Over 12-months, the fellow and their community partner develop the principles, skills, and leadership capabilities to launch and manage community science projects.

Organized stakeholder networks for co-creation and community-driven innovation. Where possible, processes for co-production with communities should be formalized and standardized, such as through creating an office for co-production.

Non-federal examples include:

Healthy Flint Research Coordinating Center (HFRCC). HFRCC is an ongoing partnership between community organizations and academic institutions in Michigan. HFRCC evaluates and must approve all academic research conducted in Flint. HFRCC helps design proposed studies that align with community concerns and are historically contextualized. HFRCC also ensures that benefits flow directly back to the community, such as funding for implementation. Finally, all work done in Flint is made open access through this organization.

Patient-Led Research Collaborative (PLRC): PLRC is a patient-led research initiative studying the impacts of long COVID on patients, searching for treatments, and designing patient-centered policies needed for recovery. They have organized patient support groups to source patient-driven hypotheses; conducted online surveys to study LC populations and understand the impacts of disease on life, work, and return to health; and supported scientific research into phenotypes and treatments.

Coalitions that utilize research as an input for collective action and making policy and governance decisions to advance communities' goals.

Federal examples include: Environmental Protection Agency's (EPA) Participatory Science Initiative. The EPA supports community goals for environmental quality through funding, technical support, and tools. EPA's dispersed monitoring by the public demonstrates the power of being able to test new technologies at scale and learn how the findings of large-scale public technology use then informs vital policies for public health.

Non-federal examples include: Community Partners in Care (CPIC). CPIC was a collaborative research project funded by the NIH, which sought to improve depression care in primary care settings through community-engagement. It compared two ways of improving service delivery: 1) technical assistance coupled with culturally competent community outreach and 2) 4-6 month planning process between agencies and community members. They discovered that community-engaged processes like the 4-6 month planning period were more effective in decreasing houselessness, improving quality of life, increasing physical activity, and decreasing out-patient visits and hospitalizations.

Additional resources for consideration:

Sheehy, J., & Wickerson, G. (2024, February 7). Create an office of co-production at the National Institutes of Health. Federation of American Scientists. https://fas.org/publication/office-of-coproduction/

This policy memo proposes the creation of an Office of Co-Production within the National Institutes of Health (NIH) to increase public participation in medical research, aiming to rebuild trust and enhance health equity through collaborative, patient-involved research processes.

Ottinger, G. (2024, February 6). Establish data collaboratives to foster meaningful public involvement. Federation of American Scientists. https://fas.org/publication/data-collaboratives-public-involvement/

This policy memo proposes that federal agencies form Data Collaboratives in which staff and members of the public engage in mutual learning about available datasets and their affordances for clarifying policy problems in order to deepen community involvement in developing evidence-based policy.

Weller, N, Govani, M.S., Farooque, M. (2020, December 1). Supporting Federal Decision Making through Participatory Technology Assessment. Federation of American Scientists. https://fas.org/publication/supporting-federal-decision-making-through-participatory-technology-assessment/

This policy memo advocates to establish a special unit within the Science and Technology Policy Institute (STPI)—an existing federally funded research and development center (FFRDC)—to provide capacity for Participatory Technology Assessment (pTA) to the White House Office of Science and Technology Policy and across executive branch agencies. By doing this, the federal government can integrate public voice alongside expert assessments to ensure science and technology policy decisions deliver greatest benefit.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

“Powerful”, bidirectional, co-produced, and sustained modes of engagement are necessary to build trust with underserved communities (EO 13985 and 14022) who have both seen a legacy of and/or currently experience harm from government decision-making and research. Further, our understanding of which problems need “solving” by researchers (including through PPCE processes) are shaped often by those with the most power, capacity, and influence, rather than those facing the greatest injustices and marginalization. Finally, follow-through after PPCE can vary significantly, and frequently without ongoing communication with the stakeholders engaged. Without a sense of how research is influenced by engagement, and further what accountability there is to public voice in research, it is difficult to measure the value of engaging, especially for underserved communities.

“Powerful” methods of PPCE will rely on building relational capacity - researcher’s capacity to establish relations of trust and mutual accountability between citizens and researchers. Focusing on relationships as an objective of the framework is critical because:

Relationship building is culturally contextual. First and foremost, relationships provide social and scientific value in ways that remain distinct from traditional forms of knowledge, particularly westernized notions of scientific knowledge as objective and replicable. Strong relationships require acknowledgement of cultural, historical, ethical, and political contexts surrounding relationship building practices. This applies to awareness of the nature of relationships themselves (what relationships are and look like); as well as the practices surrounding relationship development, building, and maintenance; and, of course, awareness of the context surrounding the positionality of the individuals involved in the particular relationship in question.

Current practices lead to an unclear determination who ought to be in relationship with researchers, and what kind(s) of relationship. The task of identifying which stakeholders to engage and for what reason—plus developing and engaging in relationships with those stakeholders—does not come with a straightforward and replicable recipe. Building relationships with a variety of stakeholders in the context of a government PPCE initiative requires intentionality towards considerations of what kind(s) of relationships are appropriate and meaningful for which stakeholder(s).

Relationships are difficult to measure. Unlike many empirical measures of progress, relationships cannot be evaluated from one side alone. By virtue of being in relation with another, individual actors within the relationship need to reciprocate—or mutually invest in and value partnerships—to cultivate the relationship over time. Thus, the nature and evaluation of the relationship is always in flux and requires a constant state of negotiation and commitment from all actors involved in the relationship. Moreover, because relationships are reciprocal, emergent, and not time-bound, nearly all measures of the quality of a given relationship will be limited in what they say about the relationship.

Relationships are not time-bound. Moreover, relationships—and what makes them good—are not bound by time. There is no standard timeline for how long a relationship will take to build and thus no easy way of aligning the work of relationship building with typical project and academic timelines. Project goals may evolve over time, particularly as new stakeholders are involved or relationships develop and change, such that researchers should develop the capacity to adjust expectations and be flexible towards these changes.

Relational infrastructure, employees dedicated to building relationships with communities and maintaining infrastructure for relationship building practices, can combat past extractive patterns of engaging with community partners and build the field of expertise within research institutions on relationship-building. Fostering and bolstering ongoing capacities for authentic and reciprocal relationships requires deep and intentional investment in training and resource development programs, both for researchers and their partners as well as the engaged community. Relational infrastructure should be a focal point of the ENGAGE framework, with the development process of the framework being a test-case for examining relational capacity. For example, future engagements on framework-development could focus on what communities need to feel sustained and supported by researchers.

For a PPCE activity to powerfully engage communities and build community capacity to meaningfully inform, develop, and even shape research and program outcomes, researchers should consider the following four questions along the design process of the PPCE activity:

Problem Identification and Teaming: Is the researcher or research institution “ready” for powerful participation, i.e. is the relational infrastructure capacity in place to sustain engagement throughout the process of seeking engagement in research?

To be meaningful, it is critical to assess researcher and research institution “readiness” to perform these functions in a way that is empowering to the public. Building authentic and reciprocal relationships between research institutions, researchers and/or community partners is an ongoing capacity. Researchers, and research institutions will need to build both (1) community capacities to work with agencies through financial stipends, training and educational resources and (2) staff capacities to create authentic and reciprocal relationships with communities through training and investment in staff dedicated to managing partnerships

Before PPCE begins, the researcher and/or research institution need to account for the time and financial costs of community participation, including the use and distribution of financial stipends for participation in any aspect of the PPCE process. Researchers and research institutions should also invest educational resources in building community capacity for engagement, such as improving awareness of the research process and how public voice influences decision-making and strengthening community ties and relationships to ensure broad engagement. Building relational infrastructure (described above) can be a way of lessening the burden of engagement to communities.

Research staff should be trained to reflect upon awareness of their positionality and power dynamics periodically and throughout a community collaboration. In addition to the deep injuries of extractive research traditions, community relationships can be damaged by technocratic assumptions underlying the research process, including those that take lived experience for granted or minimize community sites of expertise in favor of institutional ones. Further, to navigate and manage expectations between researchers and community members requires dedicated staffing, such as “partnership or relationship liaisons”. Such a liaison could be responsible for procuring and managing partnerships, leading workshops and coaching sessions for researchers, and providing regular feedback to members of their research team on the nature and quality of interactions with community members.

Process Development: Is the research team open to sharing decision-making power, both on the research and program questions and on implementation of the PPCE process itself, with the public?

When seeking out PPCE, researchers will have questions they are looking to inform or answer through the engagement. Yet, how should researchers respond when communities have questions they need answered? Or needs that have not been identified as important to the PPCE process? Priorities misalignment combined with the power dynamics of the PPCE process can cultivate and exacerbate mistrust between research institutions and communities. Thus, in designing a powerful PPCE process, equity considerations from research question inception to process implementation are key to ensuring researcher responsiveness to community needs. A few ways to integrate equity into PPCE process include:

Design equity: When examining the need for PPCE on a research program or project, researchers could engage communities on question and process design to ensure it is aligned with both community and researcher priorities.

Procedural equity: While engaging in PPCE, researchers can listen to community needs and questions in addition to collecting responses and input on the set research questions. While additional engagement on these needs might require new or more nimble processes, it is critical to bidirectional engagement that ensures the researcher is responsive to public needs.

Distributional equity: When engaging communities on questions regarding research or programs, researchers should be intentional in reaching all members of the community, not only the loudest voices. This will require seeking out existing spaces where people already gather, and building relationships with those trusted leaders.

Evaluation: Is the researcher open to receiving feedback on the PPCE process from the engaged community and adapting its approach along the way (within statutory bounds)?

Ongoing assessments of the PPCE process, especially for “powerful” engagements, provides important touchpoints for researchers to assess not only the research process, but also the public benefit from the ongoing process. While statutory and resource bounds can put limitations on a researcher's ability to remain nimble and adaptive, such as changing the mode and method of engagement while in motion, evaluative frameworks can still provide helpful checkpoints to assess quality of the relational infrastructure being built. Questions for consideration could include:

In developing the PPCE process, how were the concerns of the underserved communities sourced, engaged with, and acted upon?

Does the design of the PPCE process explicitly consider the perspectives and concerns of marginalized communities? How are they involved in shaping the direction of the partnership?

How is the researcher building sustained relationships with communities as a part of the PPCE process? What can we use to assess relational quality (i.e., letters of endorsement)?

Sustainability: Can the relational infrastructure last beyond the scope of the PPCE activity? Is the research institution capable of maintaining built trust and sustained engagement beyond the research questions it sought to answer?

PPCE activities led by researchers are often time-bound and specific to project needs or clinical research requirements, making it challenging to sustain ongoing relationships with communities. Research institutions could consider creating funding and performance incentives for sustaining well-established and successful relationships for activities like research input, uptake, and implementation and aiding communities to build their sustained organizational capacity to engage meaningfully in future research processes. Important questions for assessing sustainability of partnerships include:

Do the community member(s) involved feel they can keep maintaining the benefits / program after researchers leave?

How do community members perceive the relationship with researchers?

Do community members feel there was benefit from engaging in PPCE, and how?

Are there demonstrable benefits researchers can point to in the community as a result of their partnership?

It is also important for research institutions to conduct ongoing assessments of the quality of relational infrastructure. More intentional monitoring of partnership effectiveness will aid researchers as they build programs for broad engagement with the public.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

No response to this question

Email: gwickerson@fas.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Alex Long

Name of Organization: GHTC

Type of Organization: Nonprofit Organization Other

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other:

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Infrequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   a. Prioritize the translation of research and development materials into multiple languages that reflect the populations that will most benefit from products. Avoid jargon or technical language. An integral part of promoting diversity and equity is using language accessible to all.
   b. Proactively integrate the civil society/community's role and responsibilities within the research protocol.
   c. Ensure that the diverse perspectives of women, youth, persons with disabilities, and other marginalized groups from the communities served are not only heard but are leading and shaping research priorities.
   d. Promote diverse usage of publications, citations, and references by reevaluating the term "expertise". Actively seek out expert comments from the communities most affected and new and fresh voices instead of the same voices opining on views.
   e. Maintain a regular system of continuously keeping the communities updated with the progress of the studies or trials.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**
   a. Utilize Good Participatory Practice mechanisms for community stakeholders to provide inclusive input at all stages of the research process – i.e. protocol development, during trial conduct and during results dissemination.oo
   b. Ensure intersectional identities (gender, nationality, age, race/ ethnicity, etc.) most impacted by specific health conditions are actively involved throughout the research process.

c. Improved direct involvement by the individuals impacted by product development to understand the usability and sustainability of continuation of product.o

d. Current and future research projects should include the lived experiences of community stakeholders. When possible, community stakeholders should be an active part of the protocol leadership team.

e. Ensure community experts are compensated fairly and in a timely manner for their contributions.

3) Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.

a. Concrete planning/discussions/budgeting at the outset to include formative research with communities, translation of materials, and dissemination planning and to ensure sustainable, long-term funding and anticipated outcomes.

4) Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.

a. Involvement of research utilizing language that is not medical jargon so that research is accessible for all.

b. Consider the other social determinants to accessing health and health products and integrate into research process.

c. Explain how the communities will benefit from participation, in any form, and gather ideas from local leaders on the needs/demand from the community.o

d. Ensure work planning considers the seasonal and geographic differences, such as for meeting times/approaches.

5) Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.

a. Medical distrust for populations impacted by historical events.

b. Geographic proximity to the trial site. Larger Metropolitan cities can often recruit very close to the center and do not need to engage semiurban, or rural populations. It is important community representation is inclusive of geographically diverse locations.

c. The lack of leading roles for local scientists or researchers in the study may create the impression that study is not representative of the local community.

Email: along@ghtcoalition.org

Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Priya Shete, MD, priya.shete@ucsf.edu on behalf of UC TB Research Advancement Center (UC TRAC), UCSF and UC Berkeley; Jonathan Golub PhD, MPH, jgolub@jhmi.edu on behalf of John Hopkins University (JHU) TB Research Advancement Center, JHU; Sylvia LaCour

Name of Organization: UC TB Research Advancement Center (UC TRAC), UCSF and UC Berkeley; UC TB Research Advancement Center TB Community Advisory Board (UC TRAC TB-CAB); John Hopkins University (JHU) TB Research Advancement Center, JHU; Seattle TB Research Advancement Cente

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:
Community Advocate

In what setting do you primarily engage with researchers?:

How often do you engage with researchers?:

How often do people you know engage with researchers?:

1) **Strategies for researchers to best partner and work with people and communities.**
The scientific community must take significant strides to align with communities closest to tuberculosis (TB). Both from a social justice framework to ensure their preferences and voices are acknowledged, and pragmatic reality that they are the true experts of their lived experiences, researchers could adopt the following strategies to become better partners:
Facilitate open dialogue through town halls, communities of practice, and focus groups to connect with advocates and communities closest to TB to set research priorities, identify critical gaps, and amplify voices of those disproportionately impacted and at greatest risk for adverse health outcomes. Often, the scientific community is consulted to classify these priorities and inequities, without taking time to learn about the community, ask them what they need to achieve their concept of health, and actively listen to their accounts of system failures. Researchers should partner with community-based organizations, especially those that reflect other characteristics of the communities who are affected (but may not necessarily be TB-specific). Scientists should work to connect activists, advocates, policy-makers, frontline workers, and local leaders in shared spaces to convert scientific advances to meaningful policy change.
Develop resources that are culturally relevant, sensitive, and co-created by the community that they serve. Community partners (particularly Survivors and peer supports) could vet and identify appropriate methods, content, dissemination practices, and weigh in on toolkits and models outlining how findings could apply to other settings. Community insights can reshape resources

into language that is more accessible to the public, and identify meaningful access points for reaching members. Furthermore, the use of non-stigmatizing language (see the Stop TB Partnership Language Guide) is imperative, not only in communication with the people affected by TB who are being engaged in the research, but in all research outputs. In addition, resources and documents shared with people affected by TB should be made available in lay language or with explanations of technical terminology, as well as in languages other than English, where relevant to the local context (with attention to local languages).

Build platforms and systems (eg. Community Advisory Boards) that enable investigators to engage with community throughout their study. Too often, investigators consult community perspectives during later stages of their studies, if at all. Particularly in the context of early-stage investigators (who serve as the next generation of leaders in TB science), exposure and access to community advisory boards, patient advocacy networks, and domestic and global members of civil society is critical. Building these relationships early-on in their careers will familiarize them with a greater breadth of lived experiences and inspire more impactful, community-aligned, equitable science. These platforms should prioritize the voices of those historically excluded from research and engage special populations (eg. people living with TB/HIV co-infection, people with diabetes, pregnant people, and drug users in the context of TB) from the initial concept and design stages, and provide adequate compensation and resources for those participating. Community advisory boards are meant for longitudinal support of studies that require a community engagement strategy embedded within the research program, and clearly outline roles, responsibilities, and expectations for those involved to maintain trust. The research community must consider additional recognition for the effort and participation of community members including Co-I status, authorship, and resources that allow for longitudinal engagement.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

Historically, the output-oriented, rather than process-oriented, nature of academia has limited the value attributed to long-term investments in community-building for effective community-centered research. A further challenge is the tendency for academia to operate in silos. This means that researchers may not see community engagement as within their purview, or, even if they do appreciate its value, that the types of partnerships with community-led organizations that underpin successful community engagement in research are often not in place, making routine and meaningful engagement challenging. Similarly, the lack of prioritization and incentivization of community engagement, particularly in quantitative research disciplines, means that opportunities for training researchers in how to meaningfully seek and incorporate community perspectives into research are lacking.

Overall it's important to note that partnerships should be initiated long before a study project commences, and extend long after it concludes. Community engagement strategies should be embedded within research programs and include specific compensation for community partners to allow for longitudinal support to extend beyond the life of the study. This is important both for developing trusted relationships, and engaging in an infrastructure that encourages long-term bidirectional partnerships. Approaches for institutions to perform research that are community-aligned are referenced below, and more than one should be pursued by each institution/researcher.

Developing community advisory boards (CABs). CABs are composed of activists, survivors, advocates, and members of civil society that can act in an advisory capacity, weighing in on a study design's feasibility, impact and relevance to improve TB prevention, diagnosis, treatment and care, and serving as a bridge between investigators and the communities in which research will be conducted. CABs may bring special attention to key populations (TB/HIV co-infection, people with diabetes, women, children, pregnant people, people who use drugs, those suffering from poverty or food insecurity, incarcerated populations, migrants etc), ensure study materials are clear and digestible for study participants, and facilitate feedback from these communities to increase study relevance and equitable design. CABs can also evaluate preferences and values of TB-affected individuals, community-led prioritization, person-centered outcomes, assessment tools, and service delivery models. CABs should be engaged throughout all points of research, from concept to dissemination phase, but should not replace the engagement of local partners.

Bilateral support and training: To facilitate meaningful engagement, resources and training should be offered to people affected by TB who serve on CABs and are interested in further developing their research literacy and associated skills. This will allow fuller participation than simply bringing a CAB onboard without supporting and empowering its members to voice their perspectives, knowledge, and concerns. However, this capacity-building / skills-development should go both ways - apart from community members being supported in increasing their scientific literacy, researchers themselves should also be supported to improve their ability to engage and communicate with community members effectively and respectfully. This includes improving their cultural competence and humility, especially if researchers are not from the region or culture in which they are conducting research. Examples of this include research on TB among and with Indigenous communities. Best practices for community engagement in research should therefore be part of research-based graduate program curricula, so that trainees can incorporate them into their work from the outset. Incentivization needs (including resources, cost-sharing, effort) cold be provided for those who undertake meaningful community engagement.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

An additional challenge to achieving effective and respectful community engagement is inherent in the nature of research conduct and funding, where budgets, milestones, grant cycles, and the rush to publish, may mean that researchers engage people affected by TB only at later stages of research, when research questions and priorities have already been set.

Two approaches are outlined below that funders could take to inspire partnership-building that include:

Require applicants to identify robust community engagement plans in their applications.

Funders should require applicants to outline how communities have been engaged from the concept phase (ideally even before), and how engagement will continue through the dissemination phase, with a particular emphasis on those at greatest risk for adverse health outcomes. Letters of support from community partners should be highly encouraged (to ensure that they are in agreement with the proposed study), and a plan should be required in which applicants identify how their research will empower participating communities and demonstrate equitable engagement with community partners and civil society, (addressing authorship, fair compensation, and longitudinal engagement).

Engage affected communities in developing RFAs, reviewing applications, and designing national and institutional strategic plans, research priorities and portfolio decisions. Funders could partner with community advisory boards (CABs) to ensure applicants have a sound plan to engage the community in their proposal, identify the focus of future funding requests and ensure that they are in alignment with presenting needs, gaps, and advances that would have the most transformative impact on population health.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

There are several examples of factors that can make communities more likely to engage with researchers and research institutions, including: ongoing engagement opportunities that offer fair compensation that includes both short and long-term benefits, longitudinal capacity-building and relationship-building, terms of reference (ie: outlining roles, responsibilities, and expectations), and being recognized as a valued expert engaged in decision-making and initial engagement through a transparent and inclusive model. Researchers should consider methods and actions to make participation more accessible (ie: language and transportation), along with a concerted effort to meet community in their own spaces through attending local meetings, events, and supporting their advocacy efforts.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

In diverse settings where a multitude of cultures and languages may be represented among communities affected by TB, these should be considered in equitable and comprehensive engagement efforts. The unique experiences of people in each of these groups are critical, and important nuances across and within communities must be acknowledged and incorporated meaningfully in TB research.

Examples of factors that discourage communities from engaging with researchers and research institutions include: unfair/no compensation, language issues, conflicts with work hours, lack of clarity and communication surrounding engagement (ie: expectations and responsibilities), and being brought in on a short-term basis, or at a later stage of the project, through a uni-directional model that only benefits the researcher/institution.

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Submit date: 8/14/2024

I am responding to this RFI: On behalf of an organization

Name: Rebecka Rosenquist

Name of Organization: CHOP PolicyLab

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Investigator/Researcher

Role – Other:

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
As we continue to learn from and strive to improve our work in community-engaged research, including through the Children's Hospital of Philadelphia (CHOP) PolicyLab's Community Partnerships in Research Program pilot grant program and more recently the CHOP Research Institute's Health Equity Research Methodology (HERMes) Gap Assessment, we offer the following recommendations of best-practice. In addition to these recommendations, we want to emphasize the importance of researchers receiving training on best practices when partnering and collaborating with communities.
Community involvement and decision-making:
- Partner with communities to prioritize needs, define project scope, and share decision-making [resource: Review of Community Based Research: Assessing Partnership Approaches to Improve Public Health https://www.annualreviews.org/content/journals/10.1146/annurev.publhealth.19.1.173].
- Create a community advisory board to consult with throughout the research process [resource: Developing a Community Advisory Board for Research Toolkit https://sc-ctsi.org/resources/developing-a-community-advisory-board-for-research-toolkit].
Building trust and sustaining relationships:
- Develop communication plans, conflict resolution protocols, and decision-making processes at the initiation of a project.
- Invest time and resources in building trustful relationships, approaching communities with humility and respect, and ensuring they feel safe and heard. Trainings on implicit bias, community-engaged research methods, and health equity will support relationship building.
- Researchers looking to work with communities should identify ways to engage in community-based activities that support community partners, e.g. workgroup participation, serving on

community-based organization boards, and volunteer service events [resource: Community Voice and Power Sharing Guidebook https://www.urban.org/sites/default/files/2024-03/Community-Engaged%20Surveys%2C%20From%20Research%20Design%20to%20Analysis%20and%20Dissemination.pdf].
Aligning research with community needs:
- Conduct assessments to align research with community interests, adjusting the study as needed [resource: Processes and Outcomes of a Community-Based Participatory Research-Driven Health Needs Assessment: A Tool for Moving Health Disparity Reporting to Evidence-Based Action https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5977395/].
- Engage individuals with lived experience in all phases of research, from question formulation to study design and analysis
- Where appropriate, include frameworks that are strengths-based and trauma-informed so as to not focus solely in a deficit-framework when working with communities.

Learning, adapting, and sharing results:
- Involve communities in data interpretation
- Reflect on and improve research strategies based on community feedback and past projects
- Share findings broadly using accessible formats and trusted outlets to benefit the community [resource: Application of community – engaged dissemination and implementation science to improve health equity https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8684008/]

Ensuring sustainability and inclusivity:
- Focus on sustainability by engaging stakeholders early, securing long-term funding, and aligning with broader initiatives [resource: Community Capacity Building and Sustainability: Outcomes of Community-Based Participatory Research https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3557849/].
- Diverse and inclusive research teams are crucial when engaging with communities, teams should be reflective of the community being served.

We would also highlight two resources that speak to strategies across these topics: A Researcher's Guide to Community Engaged Research: What is CEnR? https://guides.mclibrary.duke.edu/CENR_researchers/home; A guide to incorporating a racial and ethnic equity perspective throughout the research process https://www.childtrends.org/publications/a-guide-to-incorporating-a-racial-and-ethnic-equity-perspective-throughout-the-research-process

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

In addition to CHOP PolicyLab's Community Partnerships in Research Program which provides pilot grant funding and seeks to deepen community-academic partnerships, CHOP PolicyLab faculty recently led the Health Equity Research Methodology (HERMes) Gap Assessment (https://www.research.chop.edu/hermes/about). HERMes is an initiative of the CHOP Research Institute to evaluate infrastructure and resources for health equity-oriented research and bolster support for investigators, including research teams employing community-engaged research practices. As part of lessons learned from this assessment, we offer the following recommendations of best practice.

[additional resource: Aligning the Goals of Community-Engaged Research: Why and How Academic Health Centers Can Successfully Engage with Communities to Improve Health https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3292771/]

Strategies for enhancing community engagement in research:

- Require or encourage community engagement in research recruitment, supported by technical assistance and resources.
- Address barriers to participation by promoting citizen science and engaging, results-driven activities for diverse groups to build trust and rapport.
- Support training for contractual teams, research business administrative teams, and Institutional Review Boards on the common processes and best practices for community engaged research.
- Streamline accessibility to translation and other language access services for investigators.

Providing funding and resources for community partnerships:

- Provide pilot grants and pre-federal funding to support the development of community partnerships, ensuring fair compensation and preventing burdens on community members.
- Offer enhancement funds for community engagement, including creating advisory boards, utilizing translation services, and other public engagement strategies.

Streamlining processes and reducing barriers:

- Reduce logistical barriers by streamlining payment processes, offering mentorship and training to trainees and junior investigators on community-academic engagement best practices, and providing resources like job aids, grant writers with community-engaged experience, and experienced research business managers.
- Conduct gap assessments and internal audits to identify resource needs, improve connections with the public, and strategize resource allocation.

[resource: Recognizing Cross-Institutional Fiscal and Administrative Barriers and Facilitators to Conducting Community-Engaged Clinical and Translational Research https://journals.lww.com/academicmedicine/pages/articleviewer.aspx?year=2021&issue=04000&article=00029&type=Fulltext]

Fostering shared governance and institutional support:

- Facilitate shared governance by involving community leaders in decision-making at the executive level.
- Build coalitions within institutions to emphasize the value of community-academic partnerships, instill a shared understanding, and reduce duplicative efforts.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

Integrating community voices in funding decisions:

- Include public representatives on executive leadership teams to co-design funding priorities and proposals.
- Incorporate community expectations into reporting requirements for funded research projects.

Supporting fair compensation and sustainable partnerships:

- Require research teams to include a compensation plan for community members in their proposals.
- Emphasize sustainable partnerships by requesting relationship-building and sustainability plans from applicants.
- Allocate equity enhancement funds to support relationship-building, advisory boards, and multilingual materials.

Encouraging flexibility and incorporation of lived experience:
- Encourage the use of qualitative and mixed-methods research to integrate participant voices, especially in pilot studies.
- Offer flexible timelines (e.g., no-cost extensions) to support meaningful, sustainable community-academic partnerships.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

People and communities are more likely to partner with researchers and research institutions who have demonstrated continuous partnerships and sustainable investment in the communities their work impacts. In support of this goal, we offer the following learnings from our community-engaged research projects and our programs that facilitate community-academic partnerships.

Strategies to support engagement:
- Researchers should identify and address barriers to participation - e.g., child care, transportation. They should ensure flexibility with scheduling and offer different modalities to engage in research - e.g., the ability to participate during evenings or weekends if needed due to work schedules; in-person or virtually, based on preference; access to a research and user-friendly video conferencing system.
- Community partners may benefit from formal training and professional development opportunities to expand their research capacity and support the development of equitable partnerships [resource: Connecting Community to Research: A Training Program to Increase Community Engagement in Research https://pubmed.ncbi.nlm.nih.gov/31178456/].

Strategies to support communication and transparency:
- Investigators should be transparent in making eligible participants aware of all research activities, and openly and honestly communicate with community partners and potential research participants.
- Researchers should commit to and invest in making their results public. They should also translate and disseminate their results via blog posts, websites, and social media to make them more accessible to the public.

Strategies to support compensation:
- Researchers and their institutions should ensure fair compensation of research participants that keeps up with inflation. This may be supported by an institution standardizing payments or providing brief annual recommendations on what to pay participants based on type of study, time, risk etc. Compensation should be timely and provided in appropriate formats [resources: Equitable Compensation for Community Engagement Guidebook https://www.urban.org/sites/default/files/2023-08/Equitable%20Compensation%20for%20Community%20Engagement%20Guidebook.pdf;

Beyond Incentives for Involvement to Compensation for Consultants
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4783164/].
Research team, project development, and recruitment strategies:
- Develop and maintain diverse and inclusive research teams and appropriate research staff training, including related to cultural competency, trauma-informed approaches, motivational interviewing, and crisis management.
- Recruitment and research activities should be physically, linguistically, and geographically accessible to participants.
- Investigators should provide a variety of language and reading-level options and pursue numerous recruitment methods - e.g. phone calls, emails, text messages, social media ads.

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

We offer the following as practices that must be avoided to not further entrench mistrust in research and research institutions, and support equity in research participation.
Related to research team and study design:
- When research staff do not share one or more identities with the population of interest, it is more likely that "insider-outsider" tensions arise [resource: Ethical challenges for the "outside" researcher in community-based participatory research https://pubmed.ncbi.nlm.nih.gov/15539542/].
- Community partners may be less likely to engage in research if they are not involved in discussions about study priorities and partnership expectations at the initial stages of a project.
- Extractive research that lacks clear benefits to the community and/or benefits researchers more than participants can discourage participation and engender mistrust. Researchers must recognize their positionality and the history of unethical and exploitative research and work to address these power dynamics [resource: Addressing power dynamics in community-engaged research partnerships https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7131972/].

Related to research project activities:
- A lack of fair and timely compensation may cause participants to feel that their time, effort, and insights are not valued, and uncompensated research activities may be perceived as exploitative.
- Rigidity in scheduling or not offering different modalities for participation in activities, such as phone or video appointments when in-person meetings are not feasible, can create unnecessary barriers. These demands can be especially challenging for individuals with limited resources or those with inflexible work schedules or caregiving responsibilities.
- Study materials that are not culturally competent and linguistically accessible may alienate individuals. Materials that do not reflect the target population or are not accessible may lead potential participants to feel that the research is not intended for them or that their perspectives are not valued.

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Submit date: 8/14/2024

I am responding to this RFI: On behalf of myself

Name: Yvette Delph

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: Over the past 35+ years, I have worked as a community advocate/activist, clinician, researcher, protocol team member, community educator, and clinical research network lead for developing materials and tools for research participants and potential partici

Other roles identified with when engaging/working with researchers:

In what setting do you primarily engage with researchers?:
Other

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Frequently

1) **Strategies for researchers to best partner and work with people and communities.**
   Suggested strategies for researchers to best partner and work with people and communities include:
   Identify and Prioritize Relevant Communities and Their Leaders
   The community engagement process should be initiated early in the research process and continue throughout the life cycle of a research program or clinical trial—from concept generation through results dissemination. Engaging the community begins with identifying respected community members who will help champion the interests of their communities. The key questions are: what are the relevant communities (consider also underserved, minority, and marginalized populations), and who represents them? Individual outreach efforts to relevant communities and organizations as well as open-invitation public forums may be useful for identifying interested communities and initiating dialog. It may also be helpful for researchers to identify, categorize, and prioritize communities based on their stake in the planned research, and possible community representatives based on their degree of influence within those communities. This will help researchers determine the type and level of engagement necessary for various stakeholders and utilize scarce time and resources most effectively and efficiently.

   Reach Out To Communities and Their Representatives
   Early, in-depth interviews and participatory engagement with community representatives can help researchers understand what is important to their communities. The perspectives and understanding of researchers and community residents alike should be explored to elucidate

expectations, gaps, preferred communication methods, misunderstandings, and other relevant information.

Develop a Roadmap for Community Engagement

In collaboration with community representatives and applying the information gathered, a plan for community engagement throughout the research life cycle should be developed. This plan would be geared towards:

- Facilitating community input into the research, building community capacity to understand the research and raise concerns, and developing sustainable partnerships.
- Helping researchers understand and respect community perspectives and cultural sensitivities.
- Understanding and addressing community perceptions of science and healthcare providers, and concerns about issues such as stigma, discrimination, confidentiality, as well as the risks and benefits of research participation.
- Quickly identifying and addressing community concerns and misunderstandings as they arise.
- Anticipating problems and agreeing on solutions.
- Supporting community awareness and understanding of clinical research.
- Strengthening community ownership of the research project and enlisting community support for research participation.
- Ensuring that research procedures and materials are understandable, accessible, and culturally appropriate.
- Facilitating dissemination of research results, as well as access to and uptake of beneficial interventions.

The development of resources and activities for potential research participants and communities is important. This includes flyers, posters, yard signs, videos, webpages, social media messages, advertisements, and activities such as presentations, displays, and booths at health fairs and other events. These resources and activities may be used to inform communities about research in general and about specific research projects; to facilitate study recruitment, conduct, participation, retention, and closing; and to disseminate results. In developing these resources and activities, researchers should:

- Solicit input from a wide range of stakeholders (e.g., community advisory board (CAB) members, community members, research nurses, and study coordinators). These stakeholders would assist with:
    - Suggesting and prioritizing resources and activities for development, as well as reviewing and providing input on drafts and practical options.
    - Developing glossaries and language guides to help ensure that language used in resources and activities is culturally sensitive, not stigmatizing, and understandable to the lay public in plain language without using scientific jargon
    - Developing meaningful metaphors to explain unfamiliar concepts and complex scientific information.
- Ensure the resources and activities are tailored to:
    - Specific needs (e.g., inpatient vs outpatient studies, technology requirements and capabilities) as the audiences and their specific requirements may vary.

o The range of different audiences, taking into consideration issues including cultural norms, language and dialect differences, accessibility (e.g., visual or hearing impairment), availability of technology, literacy levels, and trusted sources of information including media and social media preferences.

ï,§ Useful free color blindness and accessibility software to create accessible digital products:

- Accessible color palette generator Venngage (https://venngage.com/tools/accessible-color-palette-generator; Accessible Palette (https://accessiblepalette.com)
- https://www.section508.gov/create/

ï,§ Text should be at a reading level of US Grade 8 (approximately 13-14 years of age) or lower. The Flesch Kincaid Calculator can be used to show how readable text is by providing a Flesch Readability Ease score and the Flesch-Kincaid Grade Level score (https://goodcalculators.com/flesch-kincaid-calculator)

2) Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.

To support and incentivize meaningful partnerships, research institutions should require training for researchers on cultural sensitivity and on the value of good participatory practice (GPP). Providing glossaries and language dictionaries that give appropriate preferred terms, examples of culturally appropriate metaphors to explain research, and a collection of best practices are likely to be valuable tools. Research institutions should also support approaches to community engagement that include:

Listening, Service, and Advocacy as First Steps in Community Engagement

An important element of community engagement is helping communities identify health problems and social issues that affect their well-being and coming up with practical solutions. In engaging with local communities and organizations, research institutions should first demonstrate interest in and caring for the local community and that GPP is not an afterthought—that it is central to the planning and conduct of research. Principal investigators (PIs) and research teams should learn first-hand about community perspectives, cultural diversity, social norms, and decision-making dynamics within their local communities and help to debunk myths about research and discuss ethical and other concerns. They should listen to and work with communities to prioritize issues and generate solutions; they should also advocate for and arrange for needed help for them (e.g., health information, provision of or linkage to health and social services). Research institutions should educate the community on key issues about clinical research—such as randomization, placebos, standards of care, consent, safety, protection of research participants, use of data and samples, compensation for participation and for study-related injuries, and post-trial benefits—so that they can participate actively as informed partners in decision-making about the research. They should proactively discourage “helicopter” research in which communities are not research partners and research is conducted only for data and specimen collection.

The most effective community engagement teams become advocates for the local population. When data and specimen collection are completed, this should not be the end of partnerships with communities. Engagement activities should continue in advocating and planning for research that addresses community concerns and for ensuring community access to interventions proven beneficial by previous research. This will help community members to see research institutions as trusted partners—an especially important factor in research participation by since many people of color in the US don't believe that the health care system will act in their interest.

Research institutions should initiate relationships with local community organizations such as faith-based, BIPOC, ethnic, LGBTQIA+, sports, youth groups and organizations; tribal councils; groups that serve and advocated for marginalized populations; unions and workers in the agricultural, retail, hospitality, and manufacturing industries; and institutions such as nursing homes and assisted living facilities. This can be done through interviews, focus group discussions, and meetings with community and organizational members and leaders. Health fairs are also valuable ways to initiate relationships with community organizations and workers in local businesses.

Leveraging Institutional Media Departments to Facilitate Communication with Communities

Many research institutions have dedicated media and advertising departments. Research institutions should learn the preferred ways that community members and other stakeholders get and share information. Working together, research teams and their institutional media and advertising departments should carefully consider issues about media engagement, such as:

- Who and what are the key sources of information and influence on the communities?
- Which media are trusted by the various communities?
- Which members of the research team are best suited to address issues, be available for interviews, educate and provide information to journalists on specific topics?
- Build/strengthen relationships with local media journalists, editors, on-air personalities
- Strengthen knowledge of science and clinical research literacy among media institutions, journalists, and commentators
- Identify researchers to be available for interviews and to fact-check stories. It is important to strengthen their media communication skills, especially their ability to convey complex scientific information in plain, simple, succinct language and using metaphors understood by local communities to explain unfamiliar concepts.
- Provide information about diseases affecting the community
- Dispel rumors, myths, and stigma through trusted, responsible media and journalists
- Deliver accurate and timely messages through media platforms (print, broadcast, and electronic)

In addition to media communications, research institutions should develop and sustain forums for identifying and discussing mutual interests and areas of concern with the communities. Working with local organizations and community leaders to co-coordinate and co-host educational sessions and other activities for their communities, provides an opportunity for communities to see trusted voices unified in sharing science and addressing community concerns.

Establishment of Community Advisory Structures and Processes

Approaches that a research institution can implement to ensure meaningful community involvement where the community is a full partner in the research process include:

- Expert Panels are convened to review protocols and offer guidance and direction on considerations for their respective populations. These panels can include 10-12 scientists and community leaders who identify with the specific study population. Panel members represent diverse areas of biomedical, social, and behavioral science expertise, and dedicate their professional lives to working with and within their communities. Ongoing communication with panel members can highlight the need to address specific community needs and can inform early initiation of efforts to reduce participation burdens, costs for participants, as well as strategies that both improve the access communities have to the research, and the access research teams have to populations of interest. Panel members generally receive an honorarium for their effort.
- Inclusion of Community Members on Every Protocol Team. As specific clinical trial concepts are identified, community representatives should be added to the teams. Their input can help to ensure that burdens on the individual participant are reasonable (or that appropriate mitigation tactics can be utilized), that the resources and technologies used would be appropriate and accessible to all participants, and that informed consent materials use appropriate language and are understandable for potential participants.
- Community Working Groups (CWGs) help to ensure that the principles of community involvement are the foundation of all community engagement activities for any research endeavor. Organized and led by staff members tasked with overseeing community engagement efforts, CWGs facilitate community participation throughout the research process. They are generally composed of experienced community education staff members and community advisory board representatives and can be protocol-specific or can be used across a set of research studies or research program. CWGs provide guidance to study protocol teams and sponsors. This includes providing input into protocol development; adapting sample consent forms for local use; development of other study-related materials; informing strategies for study recruitment and retention; and assisting in monitoring any emerging issues in the community. Additional objectives of the CWGs include sharing information on successes and challenges related to community engagement; recruitment and retention successes and challenges; and identifying best practices and strategies to mitigate challenges. It is advisable that protocol team leadership only participate in CWG conference calls and meetings as invited guests related to specific topics. This ensures that the members can freely express any concerns related to study conduct without fear of repercussions.
- Community Advisory Boards. CABs are an active group of individuals that reflect and represent the local population(s) involved or impacted by the research and have insight regarding what works best in their local cultural and geographic context. CABs should promote and facilitate community engagement, and provide local community perspective(s) on the implementation of clinical research plan(s). CABs should meet regularly with the PI and other members of the research team to build trusting relationships where bidirectional communication can occur. CAB member responsibilities include reviewing protocols and informed consent materials; serving as a “focus group” for development of educational materials and messages; and advising on education and recruitment strategies, materials, events, and locations. CAB members also participate in community forums, including research updates and results announcements. They can be involved in street and community outreach activities, but should not serve as recruiters, which is a staff function with specific training and

regulatory requirements. CABs are independent and autonomous, and members are not site employees or beholden to the sites.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

Some initiatives that research funders should implement to foster community engagement include:

HHS Outreach Campaign for Education About Research

As the premier research institution, NIH should partner with other USG agencies (e.g., FDA, OHRP), patient advocacy groups, other community organizations, and media specialists to develop an outreach campaign to educate the general public about research – what it involves; protection of research participants; the need for and benefits of research; importance of enrolling diverse populations in clinical research; explanation of concepts like randomization, placebo, informed consent; acknowledgement of past research abuses and measures implemented to safeguard research participants. There is a much ignorance and misinformation about research, and it is critical that HHS/NIH partner with community groups to begin to address this. The information on the OHRP's website (https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/index.html) is valuable, but is probably not widely viewed by the lay public. The outreach campaign should actively disseminate such information much more broadly (e.g., through broadcast and social media and podcasts).

Community Engagement as a Component of Research Proposals

Good participatory practice (GPP)/community engagement (CE) throughout the research life cycle and an associated budget should be required in research proposals and funding requests to research funders. Incentives should be offered for plans to engage marginalized and underserved populations and people and communities that are distrustful about science or research.

Furthermore, successful applicants should be required to report on GPP/CE activities and there should be limitations on grantees'/contractors' ability to rebudget funding specified for this purpose. Resources and activities should not be limited to the usual recruitment, retention, CAB engagement, and dissemination of study results. They should include activities for broader community engagement, such as social media campaigns, focus groups, townhalls, and other outreach and education activities.

Community Engagement Plan for Research Ethics Reviews

The International Ethical Guidelines For Health-Related Research Involving Humans prepared by the Council for International Organisations of Medical Sciences states in Guideline 7: Community Engagement:

The research protocol or other documents submitted to the research ethics committee should include a description of the plan for community engagement, and identify resources allocated for the proposed activities. This documentation must specify what has been and will be done, when and by whom, to ensure that the community is clearly defined and can be proactively engaged throughout the research to ensure that it is relevant to the community and is accepted.

The community should participate, when feasible, in the actual discussion and preparation of the research protocol and documents.
(https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf. https://doi.org/10.56759/rgxl7405).
Research funders should provide encouragement and funding for implementing this guidance.
Fund Training and Research Into Community Engagement
Funders should solicit research proposals on research into community engagement approaches, including communication strategies and technologies, and the identification of successful strategies and their impacts and costs. Proposals that examine approaches to engaging marginalized populations and people and communities that are distrustful about science or research should be encouraged. Training in GPP and best practices for engaging and communicating with people and communities should also be funded.

4) **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.**

Things that may make people and communities more likely to want to engage with researchers and research institutions include:

- Participant-friendly research options (e.g., contracting with vendors who provide mobile phlebotomy and specimen collection services, remote/televisits, in-home visits)
- Shorter informed consent forms and ability to do remote consent processes with legally authorized representatives, including electronic signatures. This was particularly useful during the COVID-19 pandemic when relatives were not allowed into hospitals and ICUs, and may also be useful during research in emergency situations.
- Confidence that researchers are acting in the best interests of people and communities
- Research models that empower people and communities and reduce power imbalances between people/communities and researchers
- Learning from others who participated in research about their experiences

5) **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.**

Things that may make people and communities less likely to want to engage with researchers and research institutions include:

- Lack of trust in science and researchers as was seen during the COVID-19 pandemic
- Absence of mutual respect and bi-directional communication could result in a loss of trust, non-compliance, and even resistance from people and communities. Power imbalances between research teams and communities. Marginalized groups (e.g., sex workers, and certain ethnic, cultural, social, or religious groups) are often disempowered.
- Communities may feel used and coerced when researchers are insensitive to the issues that affect their lives.
- No results of previous research communicated, and no benefit realized from participating in research. Insufficient knowledge of the contributions that research has made.

- Rumors and misinformation about research and measures in place to protect research participants
- Possibility of receiving placebo
- Lack of ancillary care (medical care for conditions unrelated to the study)
- Lack of childcare, inconvenient study visit times, burden of in-person visits and procedures, intensity of research requirements
- Resistance of family and friends
- Concerns about privacy and confidentiality – especially in studies involving human genetic testing.

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Submit date: 8/15/2024

I am responding to this RFI: On behalf of an organization

Name: Taylor Nguyen

Name of Organization: Duke University

Type of Organization: Academic Institution

Type of Organization-Other:

Role most closely identified with when engaging/working with researchers: Other

Role – Other: Proposal Development

Other roles identified with when engaging/working with researchers:
Community Advocate, Member of the Public, Caregiver/Family Member

In what setting do you primarily engage with researchers?:
Academia

How often do you engage with researchers?: Frequently

How often do people you know engage with researchers?: Infrequently

1) **Strategies for researchers to best partner and work with people and communities.**
Effective community engagement in research involves several strategies, including synthesizing community input, using culturally responsive research-based messaging, investing in user-friendly design, and compensating participants.
• Community Involvement: Invite community members to share their opinions before and after studies are completed, and engage often-overlooked groups like parent groups, faith groups, and Indigenous groups. Compensate community participants for their participation in focus and advisory groups. Develop training programs for community leaders and academic partners to help underserved communities participate in research.
Research-Based Messaging: Use frameworks like those from the Frameworks Institute and National Standards for Culturally and Linguistically Appropriate Services (CLAS) to enhance the effectiveness of dissemination efforts.
• User Experience (UX) Design: Invest in good UX design for participant interfaces to eliminate barriers to participation and ensure tools are mobile-friendly.
• Compensation and Engagement: Ensure research staff are culturally and linguistically diverse to better engage with demographically diverse communities.
• Plain Language, Culturally Relevant, and Accessible Materials: Co-develop materials with patient and community partners using plain language guidelines, a culturally relevant framework, and translations into local languages.
• Stakeholder and Technology Partnerships: Engage with key stakeholders and technology innovators to streamline workflows and improve research outcomes.
• Communication and Dissemination: Create targeted communication plans including partnering with trusted messengers from the community to raise awareness and develop dissemination plans before, during, and post-enrollment.

2) **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities.**

- Integration into Community Activities: Build research activities into everyday community settings like churches and workplaces through consistent communications to normalize research participation and set expectations for roles and benefits.
- Established Relationships: Institutions should have established relationships with communities through advisory boards, panel participants, and co-investigators, involving them in funding opportunities, study design, and dissemination of results.
- Incentivizing Partnerships: Institutions can support and incentivize bi-directional partnerships with communities by encouraging early engagement, shared decision-making, inclusive research practices, and community-initiated research engagement.
- Additional Strategies: Additional strategies include education for health systems research on the importance of lived experience knowledge, conflict of interest training, collaboration roadmaps, and equitable data sharing and protection to foster impactful and reflective research.
- Recognizing Community Contributions: Maintaining communication with participants and their communities' post-trial, recognizing their contributions, and ensuring fair compensation and authorship opportunities can incentivize participation.

3) **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

- National Awareness Campaign: A standardized national awareness campaign could help legitimize and normalize research for the public quickly, acting as a national seal of approval.
- Incorporating PAG Feedback: Sponsors should incorporate feedback from Patient Advisory Groups (PAGs) into study designs and avoid performative actions so that PAG members' time and knowledge is respected.
- Community Engagement in Funding Applications: Funding applications should require sections on community engagement and allocate funds to adequately cover these costs.
- Practical Approaches for Funders: Funders can adopt several approaches to foster community-researcher partnerships, such as budget approval and mentorship, provide funding to support capacity building and project leadership, patient and family engagement, and integrating patient perspectives in clinical trial design.
- Dedicated Funding Streams and Training: Establishing dedicated funding streams for community-engaged research and providing training resources for effective collaboration.
- Transparency and Inclusion: Transparency in processes, involving partners early in the study, and creating patient, caregiver, and/or community advisory boards are essential for respectful and effective community engagement.

- Questions for Patients: Funders should ask patients or patient advocacy groups about areas needing more research or better solutions to ensure research aligns with patient needs.
- Long-term Funding and Community Outreach: Multi-year funding is crucial for sustained impact, and community outreach through marketing, social media, and career fairs can enhance engagement.

4) Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions.

- Gamification and Community Involvement: Gamifying research studies through badges, leadership boards, performance graphs, including meaningful stories, connecting with teammates, and avatars. Inviting the community into research sites can demystify academic institutions and increase participation.
- Bi-Directional Relationships and Trust: Building bi-directional relationships, offering fair compensation, and sharing previous study results can reduce participation burden and foster trust.
- Inclusive and Culturally Competent Research Models: Embed cultural responsiveness and bias training in all research projects. Implementing inclusive, accessible, and culturally competent research models, along with offering non-financial benefits and support services, can enhance community engagement and ensure integrity in research.
- Representation in Research: Representation in research matters. To effectively engage communities, researchers and study teams should be diverse and inclusive and represent the community they serve. Through community knowledge co-develop distinct strategies to foster trust and access for communities underserved through research.

5) Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions.

- Equitable access to sponsor tools: Specifically for NIH applications, Community Partners face barriers to inclusion as part of the Principal Investigator team. Gaining access to eCommons, a requirement to serve in a PI role, is administratively burdensome for many community organizations and prevents equitable leadership structures.
- Contracting and compensation structures: community organizations and academic research centers often face issues over contracting requirements and pay structures. Smaller organizations do not have large legal teams available to review and consider lengthy legal agreements with federal contracting terms. In addition, many of these organizations cannot afford to accept cost reimbursable agreements. Federal sponsors should engage the Federal Demonstration Partnership (FDP) to consider alternative contracting and payment structures for community organizations.
- Lack of Trust and Positive Relationships: Persistent challenges in recruiting individuals from marginalized communities needs to be studied more and may benefit from understanding value for research participation, building trust, and forming positive relationships between researchers and participants or community.

- Concerns Over Data Sharing and Ethical Practices: Issues like concerns over data sharing, predatory recruitment services, and declining public interest in sharing health data are significant barriers to participation.
- Practical Barriers to Participation: Inconvenient participation opportunities, tech and interface frustrations, and the need for frequent on-site visits or extensive processes deter many from engaging in research.
- Importance of Cultural Sensitivity and Representation: Lack of diversity and cultural empathy among researchers and study teams discourage participation from various communities. In addition, inherent biases in study teams may result in participants not being approached or asked to take part in research studies.

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