

**Proceedings of the  
NIH Workshop on the Enrollment and Retention of  
Participants in NIH-funded Clinical Trials**

**July 25, 2014**

## **Introduction**

The mission of NIH is to advance fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. Clinical trials are essential for discovery and improvement in the treatment of human diseases and conditions. NIH is composed of 27 Institutes and Centers (ICs), 24 of which conduct and/or provide funding to support a wide range of clinical trial research aimed at improving the diagnosis, treatment, and prevention of human diseases and conditions. In addition to funding clinical trials, NIH plays an important role in providing critical infrastructure and resources necessary for the conduct of clinical trials.

The NIH Workshop for the Enrollment and Retention of Participants in NIH-funded Clinical Trials, held on July 25, 2014, provided a forum for clinical trial stakeholders to explore new strategies and innovative approaches that have been identified and developed to address challenges to clinical enrollment and retention and to improve clinical trial participation. To help plan the workshop, NIH consulted via a teleconference with more than 100 stakeholders to gather their perspectives on ideas to explore in the workshop. The workshop focused on some of the challenges to clinical trial enrollment and retention; the social, cultural, and demographic factors that affect clinical trial participation; the role of stakeholder collaborations and partnerships; and innovative strategies to increase clinical trial enrollment; and it involved presentations, panel discussions, and a poster session.<sup>1</sup> Presenters and discussants represented the full range of stakeholders associated with the clinical trial enterprise, including public foundations, patients and patient advocacy groups, public and private research sponsors, researchers, and clinicians.<sup>2</sup> Attendees represented a variety of groups, including clinical investigators, public and private research sponsors, clinicians, public foundations, patient advocacy groups, and industry.<sup>3</sup>

## **Opening Remarks**

Pamela McInnes, D.D.S, Deputy Director, National Center for Advancing Translational Sciences (NCATS), NIH, opened the meeting with remarks about the clinical research enterprise. She noted that clinical trials are an essential tool for translating research findings into effective treatments and for supporting improvements in the day-to-day lives of patients. This translation process is complex, requiring the collective efforts of all stakeholders, including investigators, institutions, funders, and, most importantly, the individuals who place their trust in us by enrolling in clinical trials. Clinical trial research can only succeed if researchers are able to recruit and retain sufficient numbers of research participants.

Dr. McInnes reflected on the current challenges in enrolling and retaining research participants. These challenges are evident at the level of organizations/institutions (e.g., organizational boundaries between health care delivery and research that limit research opportunities,<sup>4</sup> inaccessibility of research sites to many communities)<sup>5</sup>, researchers (e.g., tracking and monitoring participants throughout trials,<sup>6,7</sup> conducting clinical trials with increasingly limited financial resources), health care providers (e.g., growing pressure on health care providers to see more patients in less time, lack of awareness of clinical

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<sup>1</sup> The workshop agenda is posted at: <https://auth.osp.od.nih.gov/sites/default/files/FAgndaNIH%20CTWkshpmhQC.pdf>

<sup>2</sup> An archived webcast of workshop is available at: <http://videocast.nih.gov/summary.asp?live=14355&bhcp=1>

<sup>3</sup> The workshop was attended by 173 in-person and approximately 210 live webcast participants.

<sup>4</sup> The Clinical Trials Enterprise in the United States: A Call for Disruptive Innovation. Califf, RM et al. Discussion Paper. IOM Forum on Drug Discovery, Development, and Translation. April 13, 2012

<sup>5</sup> Barriers to Clinical Trial Participation: A Comparison of Rural and Urban Communities in South Carolina. Kim SH et al. J Community Health. 39:562–571. 2014

<sup>6</sup> Managing Clinical Trials. Farrell et al; Trials. 11:78. 2010

<sup>7</sup> Maximizing Retention in Community-based Clinical Trials. Davis LL et al. J of Nursing Scholarship. 34:1, 47-53. 2002

trial opportunities<sup>8,9,10</sup>) and participants (e.g., inclusion and exclusion criteria that may exclude certain populations such as those with multiple chronic conditions,<sup>11,12</sup> reimbursement for ancillary costs associated with clinical trial participation).<sup>13</sup> Ensuring that the percentage of trial participants mirrors the population affected by the disease or condition under study has been and remains a significant challenge.<sup>14,15</sup>

Dr. McInnes described NIH efforts to help address these challenges. NIH is developing new methods for improving education and outreach strategies for prospective participants through such projects as “Clinical Trials and You,” an NIH website designed to help people learn more about clinical trials and how to participate.<sup>16</sup> Information for researchers, health care providers, and patients is available on ClinicalTrials.gov, a repository of active, recruiting, and completed clinical trials, which was established in 2000.<sup>17</sup>

ICs are undertaking activities to raise awareness about the need to increase the enrollment and retention of participants in clinical trials. For example, the National Cancer Institute (NCI) is actively working with outside organizations to identify strategies to improve clinical trial enrollment and retention: NCI and the American Society of Clinical Oncology recently co-sponsored a symposium that brought together researchers, health care providers, patient advocates and educators in order to examine different factors influencing clinical trial enrollment, as well as new strategies to facilitate clinical trial participation. Attendees of the symposium advanced a number of recommendations to improve enrollment at the patient/community, physician/provider, and site/organization levels.<sup>18</sup> Another example is ResearchMatch, a free, secure, clinical research registry recently launched by the National Center for Advancing Translational Sciences. The goal of this tool is to reduce recruitment costs and increase enrollment by bringing together people who are trying to find research studies and researchers who are looking for people to participate in their studies, thus enabling public involvement in clinical trial research. In mid-August 2014, ResearchMatch listed about 63,000 volunteers and more than 2,000 researchers representing nearly 100 different institutions.<sup>19</sup>

ICs are also addressing issues in clinical trial diversity. The National Institute on Minority Health and Health Disparities sponsors a Research Centers in Minority Institutions Translational Research Network.

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<sup>8</sup> The Project IMPACT Experience to Date: Increasing Minority Participation and Awareness of Clinical Trials. Powell JH et al. J of the National Medical Association. Vol. 100, NO. 2. 2008

<sup>9</sup> Time Use in Clinical Encounters: Are African-American Patients Treated Differently? Oliver MN et al. J of the National Medical Association. 93(10): 380-85. 2001

<sup>10</sup> Disparities In Patient Experiences, Health Care Processes, And Outcomes: The Role Of Patient-Provider Racial, Ethnic, And Language Concordance. Cooper LA and Powe NR. The Commonwealth Fund. 2004. Available online at: [http://www.commonwealthfund.org/programs/minority/cooper\\_raceconcordance\\_753.pdf](http://www.commonwealthfund.org/programs/minority/cooper_raceconcordance_753.pdf).

<sup>11</sup> Recruitment for a clinical trial of chronic disease self-management for older adults with multimorbidity: a successful approach within general practice. Reed RL et al. BMC Family Practice. 14:125. 2013

<sup>12</sup> Excluding Older, Sicker Patients from Clinical Trials: Issues, Concerns, and Solutions. Lind KD. “Insight on the - Issues 57”. AARP Public Policy Institute. 2011. Available at: [http://www.aarp.org/content/dam/aarp/research/public\\_policy\\_institute/health/2011/i57.pdf](http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2011/i57.pdf).

<sup>13</sup> Clinical Trial Enrollment of Rural Patients with Cancer. Paskett, ED et al. Cancer Practice, 10: 28-35. 2002

<sup>14</sup> The external validity of published randomized controlled trials in primary care. Jones R et al. BMC Family Practice. 10:5. 2009

<sup>15</sup> External Validity and Model Validity: A Conceptual Approach for Systematic Review Methodology. Khorsan R and Crawford C. J of Evidence-Based Complementary and Alternative Medicine. Vol 2014. 2014

<sup>16</sup> Information available at: <http://www.nih.gov/health/clinicaltrials/>.

<sup>17</sup> Information available at: <http://clinicaltrials.gov/>.

<sup>18</sup> The National Cancer Institute-American Society of Clinical Oncology Cancer Trial Accrual Symposium: summary and recommendations. Denicoff AM, McCaskill-Stevens W, Grubbs SS, et al. J Oncol Pract. 2013 Nov;9(6):267-76. Available at: <http://jop.ascopubs.org/content/9/6/267.long>.

<sup>19</sup> ResearchMatch. Accessed August, 2014. Available at: <https://www.researchmatch.org/about/>

This network is a national consortium composed of researchers at academic health centers, community health providers, and community organizations. The overarching goal of the network is to provide opportunities for multi-site and translational research among minority-serving and collaborating institutions to focus their collective efforts on addressing health disparities, and, through these opportunities, facilitate research participation in underrepresented populations.<sup>20</sup>

Fourteen ICs are promoting the involvement of community members in the design and implementation of clinical studies through partnership development, community needs assessment, and pilot intervention research studies. This research paradigm, called Community Based Participatory Research (CBPR), is aimed at engaging communities in designing studies and generating research results that will improve the health status of underserved populations. NIH support of CBPR has been increasing in terms of the number of participating ICs and projects supported. More than two dozen Funding Opportunity Announcements on CBPR have been released over the past decade.

More broadly, NIH continues to work to improve efficiencies for NIH-funded clinical trials and to strengthen NIH's stewardship of clinical trials. These efforts will optimize the quality, relevance, and feasibility of what is funded, increase efficiencies in how funded trials are conducted, and ensure access to all clinical trial results. For example, NIH will be issuing a policy to promote the use of a single institutional review board for research studies carried out at multiple sites and a policy to increase transparency of clinical trials by making the registration and submission of clinical trial results to ClinicalTrials.gov a condition of NIH funding. In the fall, NIH will launch a new electronic inclusion management system that will modernize the submission, reporting, and monitoring of data on the sex/gender, race, and ethnicity of participants enrolled in NIH-funded clinical research. These enhancements will improve the ability of investigators and NIH staff to monitor the progress of clinical trials.

Dr. McInnes pointed out that NIH can benefit immeasurably by tapping into the creativity, experience, and knowledge of the larger community of individuals and organizations that share our commitment to advancing public health through research, and that the workshop will highlight new strategies and innovative approaches to address clinical enrollment and retention challenges and to improve clinical trial participation.

Before concluding her remarks and turning the podium to the workshop moderator, Jacqueline Corrigan-Curay, M.D., J.D., Office of Science Policy, NIH, Dr. McInnes thanked speakers and panelists who have agreed to share their expertise and knowledge and attendees and webcast viewers for their interest in the issues and for the ideas they will share over the course of today's meeting. She also thanked the planning committee for helping to organize the meeting.

### **Current Challenges in Clinical Trial Participant Enrollment**

*Mary Woolley, M.A., Hon. D. Sc., President of Research!America*

Ms. Woolley discussed multiple challenges for enrolling participants, including the fact that trial designs are not standardized, that data collection is expensive and often redundant, that the incentives do not line up with the needs of patients, and that patients are not given enough opportunities to provide input on important aspects of clinical trials, such as the informed consent process.

Ms. Woolley discussed the results of recent studies that suggest that few people have participated in clinical trials, despite the fact that most people are aware of clinical trial research and believe it to be

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<sup>20</sup> Information on the RCMI Translational Research Network available at: <http://www2.rtrn.net/>.

valuable. Ms. Woolley made a number of recommendations to increase clinical trial participation, including: standardizing informed consent procedures across institutions and clinical trial regulations across countries, promoting data sharing through national initiatives (such as PCORnet, the National Patient-Centered Clinical Research Network), and using social media and new technologies to reach participants.

*Veronica Todaro, M.P.H., Vice President, National Programs, Parkinson's Disease Foundation*

Ms. Todaro discussed actions taken by her organization to try to bring about a culture change that involves evolving from “providing information for patients to developing solutions with patients.” She focused on the benefits of collaboration between researchers and people with Parkinson’s disease. She noted that achieving success in clinical trial enrollment depends on fostering more collaborations between the research community and the patient community, and designing a clinical trial with the patient populations’ needs in mind (i.e., inclusion/exclusion criteria that take into account the characteristics of the target patient population, informed consent documents that makes sense to the communities being recruited, dissemination plan for all participating individuals, etc.).

Ms. Todaro provided several examples of contributions that patients have made to clinical trial research, such as talking to their peers at conferences and serving on support groups for clinical trials; serving on national advisory boards and local IRBs; working with researchers to point out and resolve issues, such as problems with travel; and speaking at patient advocacy events. Patient advocacy events often take the form of a luncheon that honors clinical trial participants and includes thank-you gifts. Ms. Todaro advises researchers to participate in these events, because people are much more likely to express interest in taking part in a trial if the researcher shows interest by attending an event in person. Finally, Ms. Todaro discussed how her organization is using new strategies to incorporate patient perspectives into research by arranging for research advocates to work with researchers at research sites. Her organization plans to measure the impact of these efforts and to learn how to optimize interactions with patients in future studies. If successful, these types of strategies may significantly increase the number of potential participants who volunteer for clinical trial research.

### **Cultural and Social Considerations in Clinical Trial Enrollment and Outreach**

*Moon Chen, Ph.D., M.P.H., Associate Director for Population Research and Cancer Disparities, University of California at Davis*

Dr. Chen noted that because the majority of participants in clinical trials are white, trial populations do not reflect the population of the United States. With a growing focus on recruiting more minority populations,<sup>21</sup> cross-cultural communication presents one barrier to successful recruitment of minority populations. For example, the term “clinical trial” may be off-putting to potential participants because they interpret this to mean that they are being asked to be a “guinea pig” in an experiment, or they equate the term with being put on trial because of legal problems. Non-verbal cultural communication can also be an issue: for example, a downward gaze signifies respect in Asian populations but is construed as avoidance in Caucasian populations.

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<sup>21</sup> Chen MS Jr, Lara PN, Dang JH, Paterniti DA, Kelly K. Twenty years post-NIH Revitalization Act: enhancing minority participation in clinical trials (EMPaCT): laying the groundwork for improving minority clinical trial accrual: renewing the case for enhancing minority participation in cancer clinical trials. *Cancer*. 2014 Apr 1;120 Suppl 7:1091-6. doi: 10.1002/cncr.28575. Review. PubMed PMID: 24643646; PubMed Central PMCID: PMC3980490.

Studies have shown that minority populations are more willing to participate in research as they become more informed about clinical trial research.<sup>22</sup> Dr. Chen suggested that changing the jargon currently used in clinical trial research (for example, inviting people to be “research participants” rather than “clinical trial patients”) may encourage further willingness to participate. Providing additional information about the purpose and benefits of research,<sup>23</sup> as well as highlighting the altruistic nature of research participation,<sup>24</sup> may also increase the enthusiasm of minorities to participate in research. Dr. Chen concluded by saying it is wrong to discuss these populations as hard-to-reach, suggesting that they are “*hardly* reached, not *hard* to reach.” He described a model for increasing minority participation in clinical trials with five essential features (five “Ts”): 1) increase Trust between patient and provider; 2) allow Time for clinical trial discussions between clinicians and potential participants; 3) describe Tangible benefits for the patients to make participation worth their time and inconvenience; 4) be Trustworthy by having a consistent reputation with participants over time; and 5) have Tools to transcend cultural barriers.

*Joseph Ravenell, M.D., M.S., Assistant Professor, Center for Healthful Behavioral Change, New York University Medical Center*

Dr. Ravenell shared his experience recruiting African American men into clinical trials. He noted that one of the greatest challenges in enrolling these men is their lack of engagement with primary care,<sup>25</sup> which significantly limits recruitment opportunities through primary care providers. Dr. Ravenell explained that impediments to seeking health care for this population include fear of improper diagnosis, mistreatment, and experimentation; mistrust of the medical community; and feeling as if they do not need a doctor.<sup>26</sup> One successful strategy to reach this population is through the involvement of important and trusted cultural institutions, such as the church and the barbershop. These “micro-level” institutions provide a comfortable and trustworthy environment for clinical trial recruitment.

Dr. Ravenell discussed ten general strategies that researchers can use to encourage African-American men to participate in clinical research: providing incentives, both for participants and organizations; having dynamic, outgoing, personable team members; identifying the right neighborhoods to recruit; recruiting seven days a week, and not just during work hours; being flexible with time and location for enrollment; arranging staff composition to mirror the population being recruited; being culturally relatable and sensitive to communities and subcultures, such as those found at barbershops; holding team meetings to talk about cultural and social issues that are encountered during the recruitment process; being fearless about going into the community; and approaching every individual who appears to be part of the target population. Dr. Ravenell underscored the importance of partnering with respected and relevant organizations in communities, hiring a research team with diverse life experiences whose members can understand the culture of the study population, and being willing to engage the community.

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<sup>22</sup> Brown M, Moyer A. Predictors of awareness of clinical trials and feelings about the use of medical information for research in a nationally representative US sample. *Ethn Health*. 2010 Jun;15(3):223-36. doi: 10.1080/13557851003624281. PubMed PMID: 20336563.

<sup>23</sup> Tong EK, Fung LC, Stewart SL, Paterniti DA, Dang JH, Chen MS Jr. Impact of a biospecimen collection seminar on willingness to donate biospecimens among Chinese Americans: results from a randomized, controlled community-based trial. *Cancer Epidemiol Biomarkers Prev*. 2014 Mar;23(3):392-401. doi: 10.1158/1055-9965.EPI-13-0744. PubMed PMID: 24609848; PubMed Central PMCID: PMC4049566.

<sup>24</sup> Dang JH, Rodriguez EM, Luque JS, Erwin DO, Meade CD, Chen MS Jr. Engaging diverse populations about biospecimen donation for cancer research. *J Community Genet*. 2014 Mar 25. [Epub ahead of print] PubMed PMID: 24664489.

<sup>25</sup> Victor RG, Leonard D, Hess P, Bhat DG, Jones J, Vaeth PA, Ravenell J, Freeman A, Wilson RP, Haley RW. Factors associated with hypertension awareness, treatment, and control in Dallas County, Texas. *Arch Intern Med*. 2008 Jun 23;168(12):1285-93. doi: 10.1001/archinte.168.12.1285. PubMed PMID: 18574085.

<sup>26</sup> Ravenell JE, Whitaker EE, Johnson WE Jr. According to him: barriers to healthcare among African-American men. *J Natl Med Assoc*. 2008 Oct;100(10):1153-60. PubMed PMID: 18942276.

## **Recruitment and Outreach Considerations for Underrepresented and Vulnerable Populations**

*Jonathan Ellen, M.D., President, All Children's Hospital, Johns Hopkins Health System*

Dr. Ellen began his remarks by stressing that community engagement is crucial in order to recruit and retain participants from vulnerable populations. His research involves adolescents who live in socially disadvantaged communities. Dr. Ellen stressed that engaging with the community allows researchers to learn how to bring their work in line with community standards, and to successfully disseminate research findings. Ultimately, clinical research will only serve its intended purpose if the community is engaged in the work. Dr. Ellen argued that successful enrollment of vulnerable populations into clinical research requires only two things – trust and taking the time to build trust.

To provide context for his arguments, Dr. Ellen discussed the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN), a research network that has developed a three-pronged strategy for involving the community. The first prong is the Connect to Protect (C2P) program: a community-based participatory research program that mobilizes the patient community to collaborate with researchers in order to create their own agenda for building programs and social practices that serve as HIV prevention infrastructure in their particular community.<sup>27</sup> The second prong is the education program that introduces the concepts of clinical research to the community. For example, members of a research team might go into the community with slides explaining features of clinical research (i.e., an explanation of clinical research, various types of clinical trials, the concept of and reasons for randomization) in order to give community members an opportunity to ask questions and better understand clinical research concepts. The third prong is the design of community impact monitoring plans (CIMPs), which are written into trial protocols to address negative community outcomes that might arise as a result of study participation. During the process of study design, researchers must determine whether a CIMP is needed and, if so, think about potential consequences of research participation for the community, both predictable and unintended. They then create a plan for collecting the information needed to track community impacts, and finally, make an annual report to the CIMP oversight committee and ethics advisory committee and give those committees an opportunity to point out other potential impacts. Dr. Ellen stated that use of this three-prong approach has proven successful in recruiting and retaining participants from vulnerable populations in clinical research.

*Sybil Hosek, Ph.D., Clinical Psychologist, Department of Psychiatry, John H. Stroger, Jr. Hospital of Cook County*

Like Dr. Ellen, Dr. Hosek discussed challenges related to recruiting vulnerable populations, and shared her experience recruiting adolescents and young adults, mainly African American gay and bisexual men, into HIV prevention trials. Dr. Hosek noted that researchers are often wary of working with young people because of complicated ethical considerations surrounding research with these populations, and the fact that IRBs may be concerned about legal issues.<sup>28</sup> Dr. Hosek described four strategies that her team has used to increase recruitment into clinical trials: 1) engage community advisory boards as true collaborators; 2) recruit using methods that reach into the community; 3) use technology (such as Facebook, Grindr and Jack'd) to engage participants; and 4) make a sustained commitment to the community.

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<sup>27</sup> <http://www.adolescentaids.org/c2p.html>

<sup>28</sup> Andrasik MP, Chandler C, Powell B, Humes D, Wakefield S, Kripke K, Eckstein D. Bridging the divide: HIV prevention research and Black men who have sex with men. *Am J Public Health*. 2014 Apr;104(4):708-14. doi: 10.2105/AJPH.2013.301653. Epub 2014 Feb 13. PubMed PMID: 24524520.

Dr. Hosek highlighted examples of successful recruitment techniques that her group has used to overcome obstacles (e.g., low income, frequent relocations, unreliable cell phone service, transportation issues, HIV stigma within community) associated with recruiting these populations. One example is POWER, a CDC-funded clinical trial of an online HIV prevention program for African American youth that used a strong community advisory board and a chain referral technique (i.e., participants referred peers for recruitment) to reach enrollment goals. A second example was Project PrEPare, a trial of pre-exposure prophylaxis among young men who have sex with men, who were recruited at venues such as clubs and bars. PrEPare research staff developed city-specific marketing materials, a website to screen potential participants online so that they could reach people with transportation problems, and connected to potential participants through dating applications and social networking sites. Dr. Hosek focused on the importance of using technology, stating that young people change their address and phone number often, but rarely change their Facebook profile.

### **Panel Discussion on Enrollment Issues for Clinical Trial Participants**

The presentations were followed by a moderated panel discussion led by Marva Moxey-Mims, M.D., Deputy Director of the Division of Kidney, Urologic and Hematologic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases. Panelists included a clinician, Samuel Simha, M.D., President of the Academy of Physicians in Clinical Research; a clinical researcher, Edith Mitchell, M.D., Director of Center to Eliminate Cancer Disparities at Thomas Jefferson University Hospital; a patient advocate, John Walsh, Co-Founder and President of the COPD Foundation; a bioethicist, Nancy King, J.D., Co-Director for the Center for Bioethics, Health, and Society and Graduate Program in Bioethics at Wake Forest University; an expert in enrollment of minorities in research, Gary Puckrein, Ph.D., President and CEO of the National Minority Quality Forum; and an expert in industry recruitment approaches, Jill Abell, Ph.D., Senior Director of Clinical Effectiveness and Safety at GlaxoSmithKline.

Panelists spoke to the importance of engaging minorities and underserved populations, and designing trials that can successfully enroll the same types of patients who will eventually use the treatment being studied. Panelists endorsed Dr. Ravenell's approach for increasing minority participation in clinical research: to select appropriate recruitment sites within communities to reach populations and to select staff who reflect the demographics of the target group population.

Panelists discussed the importance of empowering patients to become clinical trial participants through awareness, knowledge and trust. Panelists also spoke to the importance of involving primary care physicians, principal investigators, participants, caregivers, patient advocacy organizations, peer health coaches, and others—each with clear roles and understanding tangible benefits from the beginning. One panelist emphasized the need to create a culture where conversations about participating in clinical trials are fully integrated into the health care environment, as opposed to being a one-time conversation. Several panelists argued for researchers to use a patient-centered model, meaning that they consider and address potential challenges for participants, as well as meaningful engagement activities, when designing the trial. In addition to empowering patients in the recruitment process, several panelists raised the need for clear, comprehensive, and truthful communication during the consent process, which may be enhanced through the use of video consent and other tools. Patients should understand the treatment options that are open to them already, and the differences between research and treatment. Limitations on the amount of time that physicians can spend with patients can be a barrier to successful recruitment.

Following the panel discussion, Jamie Roberts, M.A., Office of Clinical Research, National Institute of Neurological Disorders and Stroke, moderated a discussion among panelists, presenters, and members of the audience. Commenters from the audience included representatives from research hospitals, academia, professional societies, nonprofit organizations, and federal agencies.



A topic of discussion between panelists, presenters and audience members involved how to best reach diverse populations for clinical trial participation. One commenter suggested the use of clinical trial registries. Patients in the registries can give permission to be contacted for clinical trials and researchers can search the registries for potential participants. Patients and physicians can also search the ClinicalTrials.gov database for clinical trials that are open to recruitment. However, some institutions have resisted this option, concerned that patients will leave their current care provider to participate in a trial at another medical center.

Another commenter raised the issue of participant recruitment and retention for research on rare diseases for which the target population is, by definition, a minority. Panelists suggested successful recruitment strategies for these target populations would involve using “big data” to identify patients, working with primary care physicians to screen patients for diseases for which they are at risk, and coordinating with the institutions and associations that have a long history of reaching out to minority populations. Several panelists acknowledged that the current per-patient reimbursement standards don’t cover the high costs often needed to recruit hard-to-reach populations.

Panelists, presenters, and audience members also discussed how to best reach potential participants who may be at risk for developing a disease, specifically those at risk for diabetes. One panelist pointed out that about 80 percent of Americans with diabetes live in about 8,000 ZIP codes<sup>29</sup>, and researchers could use that geographical information to target health care providers and reach individuals at risk for developing the condition. A second suggestion was for researchers to consider involving behavioral scientists with expertise in theories of behavior change and perceptions of disease risk and susceptibility in order to craft recruitment messages appropriate to the target population. Several speakers discussed combining the opportunity for trial recruitment with free screenings and information on the condition, to provide a service to the community, possibly in partnership with insurance providers.

An additional topic raised in the discussion with the audience focused on the use of mobile health technologies for recruitment and follow up in clinical trials, as researchers have begun using these technologies at different time-points during clinical trials (e.g., for recruitment, informed consent, information sharing). One panelist urged caution with respect to this approach, stating that, while targeted online advertising for trial recruitment can be used, researchers should be aware that all materials about a clinical trial must be approved by the IRB. Another commenter discussed a community-based trial that partnered with a phone provider to study cardiovascular disease, diabetes, or lung disorders in women, particularly in underserved populations. The researchers in the community-based trial were able to give participants devices such as glucometers and smartphones, and found that allowing participants to keep the devices motivated participants to remain in the trial. One commenter asked for the panelists’ perspectives about using telemedicine for follow-up visits. The moderator stated that the use of remote technologies depends on the complexity of the protocol and follow-up visits.

Several panelists agreed that people who volunteer to participate in clinical trials should be compensated as a matter of respect, but they also cautioned that care should be taken to prevent such payments from becoming an inducement to participation. Panelists also discussed terminology, suggesting that “reimbursement,” “incentive,” and “stipend” are more precise terms for monetary incentives.

Finally, commenters and panelists discussed how best to enhance cross-cultural communication. One commenter offered the opinion that the word “subject” is dehumanizing and that it would be better to refer to the people who enroll in clinical trials as “patients” or “participants.” One panelist suggested that

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<sup>29</sup> Blue Cross and Blue Shield of Kansas City Takes a Stand Against Diabetes, April 2010, <https://www.bluekc.com/about/archive?articleid=31>

“patients” blurs the line between research and treatment, and many studies enroll healthy individuals. Another panelist suggested that it may be preferable to say “people with” or “individuals with” a disease.

### **Roles for Public Foundations in Clinical Trial Enrollment and Retention**

*Maria Freire, Ph.D., President, Foundation for the National Institutes of Health*

Dr. Freire discussed the role of the Foundation for the National Institutes of Health (FNIH) in advancing collaborations between biomedical researchers from universities, industry, and not-for-profit organizations. Dr. Freire explained that FNIH does not recruit participants directly for clinical trials; rather, it supports the management of key technical components to ease the burden of recruitment for complex trials. For example, in 2010, FNIH with NCI, the American Society of Clinical Oncology (ASCO), and five industry partners, convened a symposium on “Overcoming Barriers to Early-Phase Clinical Trials,” to investigate barriers that prevent patients, especially those in minority and elderly populations, from participating in early-phase clinical trials of innovative cancer therapies.<sup>30</sup> Dr. Freire also described FNIH’s involvement in the Lung Cancer Master Protocol (Lung-MAP) study—a multidrug, multi-sponsor, biomarker-driven clinical trial for patients with advanced squamous cell lung cancer. Enrollment in Lung-MAP includes over 200 study sites, several screening processes, and a range of treatment assignment and data collection procedures. For Lung-MAP, FNIH contributes to clinical trial progress by coordinating an oversight committee, managing the intellectual property issues, setting up agreements for data sharing and contracts with the pharmaceutical companies, and conducting project management.

### **Public Private Partnerships to Improve Patient and Public Awareness and Engagement**

*Vanessa Arnedo, M.P.H., Associate Director, Research Partnerships, Michael J. Fox Foundation*

Ms. Arnedo discussed recruitment strategies used by the Michael J. Fox Foundation (MJFF) for their clinical research and education projects, including the Fox Trial Finder,<sup>31</sup> which is an online matching tool for clinical trial recruitment and retention, and the Parkinson’s Progression Markers Initiative (PPMI). Ms. Arnedo focused her presentation on the strategies developed for PPMI, for which participants are requested to make a 3-5 year commitment. Participation requires several multi-day visits, extensive assessments, and invasive procedures. The number of research procedures was considered to be a disincentive for participants to enroll and remain in the study. To address participant concerns over the high level of commitment needed, study procedures were revised to include three tiers of recruitment planning, with process evaluations for each: 1) study launch and site activation; 2) providing ongoing support to study sites and recruitment through social media, pitching stories to the media, and holding in-person events to build physician referral networks around the study sites; and 3) an adaptive, tailored approach based on trend analysis, with strategy updates at key milestones.

For successful recruitment and retention of clinical trial participants, Ms. Arnedo recommended piloting ideas on a small scale before implementing them more broadly, and exploring multiple recruitment and retention approaches simultaneously. PPMI’s original cohort met enrollment goals through using adaptive techniques, such as shifting its focus from the general population to military veterans in order to address

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<sup>30</sup> Denicoff AM, McCaskill-Stevens W, Grubbs SS, Bruinooge SS, Comis RL, Devine P, Dilts DM, Duff ME, Ford JG, Joffe S, Schapira L, Weinfurt KP, Michaels M, Raghavan D, Richmond ES, Zon R, Albrecht TL, Bookman MA, Dowlati A, Enos RA, Fouad MN, Good M, Hicks WJ, Loehrer PJ Sr, Lyss AP, Wolff SN, Wujcik DM, Meropol NJ. NCI-ASCO Cancer Trial Accrual Symposium: summary and recommendations. *J Oncol Pract.* 2013 Nov;9(6):267-76. doi: 10.1200/JOP.2013.001119. Epub 2013 Oct 15. PubMed PMID: 24130252; PubMed Central PMCID: PMC3825288.

<sup>31</sup> <https://foxtrialfinder.michaeljfox.org/>

issues in recruiting male controls, and using novel online informed consent process to recruit specific mutation carriers in later PPMI cohorts.

Finally, Ms. Todaro emphasized that the patient community is a critical research partner in meeting retention goals. In order to ensure that the patient community remains involved in the research study, Ms. Todaro recommended creating study-specific ambassadors to reach out to the participant community, and showing continued participant support by hosting annual participant appreciation dinners. Additionally, retention activities can include keeping participants updated on study progress through biannual participant newsletters or quarterly study update calls.

*Jeff Vigne, President, Board of Directors, Friends of Patients at the NIH*

Mr. Vigne described the work of Friends of Patients at the NIH (formerly known as Friends of the Clinical Center) which, in collaboration with the NIH Clinical Center social work department, provides practical support to participants enrolled in NIH clinical trials at the NIH in order to increase participant enrollment and retention at the Clinical Center. Mr. Vigne highlighted the many focused services that this nonprofit organization makes available to NIH clinical trial participants, including: emergency financial needs (e.g., rent, mortgage, car payments, utilities), long-term housing, travel assistance, medical expenses, meals and activities on the NIH campus, and other services and amenities (e.g., refurbishment of Clinical Center waiting rooms). Mr. Vigne described the role that nonprofit organizations can play in successful clinical trial enrollment and retention by providing practical and logistical aide to clinical trial participants.

*Joe V. Selby, M.D., M.P.H, Executive Director, Patient-Centered Outcomes Research Institute (PCORI)*

Dr. Selby presented information on PCORnet,<sup>32</sup> a large, highly representative, national network for conducting research on data gathered from clinical practice. Objectives of PCORnet include: building a network with interoperable electronic health records (EHR), claims data, and patient-reported data on millions of individuals; supporting multicenter observational and interventional comparative effectiveness research (CER) studies; and using PCORI-funded resources to support a range of research activities involving a variety of partners.

Dr. Selby spoke to the importance of engaging patients, providers, and health system leaders in clinical trials. He discussed extending engagement to include participation in governing the uses of PCORnet, i.e., deciding which trials to conduct. He also discussed the inclusion of Patient-Powered Research Networks as an integral part of PCORnet. These networks are made up of a variety of stakeholder organizations, and include many perspectives, diseases and conditions, and populations. PCORnet is preparing to host multiple CER clinical trials; the first of which will be a randomized, controlled trial to identify the optimal maintenance dose of aspirin for secondary prevention in patients with coronary artery disease. The trial will require extensive use of EHRs to both identify patients and report outcomes.

### **Models to Identify and Support Clinical Trial Participants**

*Joseph Unger, Ph.D., Staff Scientist, Fred Hutchinson Cancer Research Center*

Dr. Unger presented his work on the influence of income disparities on clinical trial enrollment in the oncology setting. Dr. Unger asserted that income representativeness in clinical trials will improve feasibility, interpretability, and generalizability of trial results by enrolling a study cohort that is

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<sup>32</sup> <http://www.pcornet.org/>

representative of the patient population that will eventually use the new therapy.<sup>33,34</sup> Additionally, from a participant's perspective, income representativeness is a matter of fairness: because some trials offer the newest investigational treatments, everyone should have equal access to clinical trials, regardless of their ability to pay.

After developing a model to assess factors that influence participation in clinical trials in a study environment,<sup>35,36</sup> Dr. Unger has found income to be the only socioeconomic or demographic factor that is significantly associated with participation in oncology clinical trials. Given that lower-income patients may be more sensitive to the direct and indirect costs of trial participation (e.g., co-pays and coinsurance), Dr. Unger highlighted the importance of finding ways to help lower-income participants with the costs of participation. One option would be to compensate individuals for participating in federally-funded clinical trials. However, payment would have to be carefully calibrated to avoid undue influence,<sup>37</sup> as well as to allay concerns that participant payment would shift a disproportionate burden of research to lower-income patients.<sup>38</sup> Dr. Unger discussed a set of potential payment models<sup>39</sup> that could be used to support participants in clinical trials. Examples include the market model, which determines how much to pay in order to recruit the number and type of subjects needed in a given time frame; the reimbursement model, where payment is offered to reimburse participants for actual expenses; and the wage-payment model, where payment is offered to compensate for time, contribution to study, and effort/discomfort. Dr. Unger favors the wage-payment model, as it reduces concerns about undue influence. He concluded by stating that achieving income representativeness is important for strengthening the feasibility of the conduct of trials, interpreting results to all income levels, and ensuring fairness.

*Cynthia Bower, R.N., M.S., Associate Managing Director, Michigan Clinical Research Unit, University of Michigan*

Ms. Bower discussed her work to set up a mobile clinical research team in order to retain participants. The mobile clinical research team at the Michigan Institute for Clinical & Health Research (MCRU2U),<sup>40</sup> which provides clinical research services (such as blood draws) at off-campus sites, has transformed the overall business model of clinical research services in a way that positively affects stakeholders, principal investigators, and participants, especially underrepresented populations. The MCRU2U is a way to transfer the research skills and expertise of the clinical research staff to the chair, bedside, or home of research participants in a cost-effective way.

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<sup>33</sup> Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA*. 2004 Jun 9;291(22):2720-6. PubMed PMID: 15187053.

<sup>34</sup> Tejada HA, Green SB, Trimble EL, Ford L, High JL, Ungerleider RS, Friedman MA, Brawley OW. Representation of African-Americans, Hispanics, and whites in National Cancer Institute cancer treatment trials. *J Natl Cancer Inst*. 1996 Jun 19;88(12):812-6. PubMed PMID: 8637047.

<sup>35</sup> Javid SH, Unger JM, Gralow JR, Moinpour CM, Wozniak AJ, Goodwin JW, Lara PN Jr, Williams PA, Hutchins LF, Gotay CC, Albain KS. A prospective analysis of the influence of older age on physician and patient decision-making when considering enrollment in breast cancer clinical trials (SWOG S0316). *Oncologist*. 2012; 17(9):1180-90. PubMed PMID: 22723506; PubMed CentralPMCID: PMC3448411.

<sup>36</sup> Unger JM, Hershman DL, Albain KS, Moinpour CM, Petersen JA, Burg K, Crowley JJ. Patient income level and cancer clinical trial participation. *J Clin Oncol*. 2013 Feb 10;31(5):536-42. doi: 10.1200/JCO.2012.45.4553. PubMed PMID: 23295802; PubMed Central PMCID: PMC3565180.

<sup>37</sup> The Common Rule, including §46.11, can be found at: <http://www.hhs.gov/ohrp/policy/ohrpreulations.pdf>

<sup>38</sup> Grady C. Payment of clinical research subjects. *J Clin Invest*. 2005 Jul;115(7):1681-7. PubMed PMID: 16007244; PubMed Central PMCID: PMC1159153.

<sup>39</sup> Dickert N, Grady C. What's the price of a research subject? Approaches to payment for research participation. *N Engl J Med*. 1999 Jul 15;341(3):198-203. PubMed PMID: 10403861.

<sup>40</sup> McCammon MG, Conrad CM, Klug ZT, Myers CD, Watkins ML, Wiley JW, Bower CL. From an infrastructure to a service-based business model: 5 years of mobile clinical research at the University of Michigan. *Clin Transl Sci*. 2013 Feb; 6(1): 3-6. doi: [10.1111/cts.12023](https://doi.org/10.1111/cts.12023). PubMed Central PMCID: 3576720.

She described participant motivation as key to successful recruitment and retention, and presented three concepts: 1) people enroll in a study because of information that resonates with their motivation; 2) people are retained across the life cycle of a trial because of the experience they have (satisfaction vs. regret); and, 3) people find that adaptive business models, such as mobile clinical research services, can enhance their experience. Ms. Bower discussed that researchers need to consider participants' satisfactions and regrets, because trials with high dropout rates are costly and provide little benefit either to participants or society. Ms. Bower's research found that patients are most likely to enroll in a clinical trial when they have been diagnosed with the condition being studied. Other motivations cited were: having a loved one diagnosed with the condition under study, gaining access to a healthcare or medication, and receiving financial incentives. Ms. Bower concluded by noting that the MCRU2U has involved a participant special interest group consisting of ethicists, regulatory and compliance specialists, and specimen processing and laboratory experts, to ensure that the mobile approach is effective and engaging for research participants.

### **Strategies for Tracking and Monitoring Clinical Trial Participation and Post-trial Communication**

*Alan S. Go, M.D., Director, Comprehensive Clinical Research Unit, Kaiser Permanente Medical Group*

Dr. Go shared Kaiser Permanente North California's experience with enhancing recruitment and retention in clinical trials conducted in its integrated health care delivery system. Dr. Go described the Comprehensive Clinical Research Unit (CCRU),<sup>41</sup> which was created to leverage electronic health records to support physician and nurse teams across all Kaiser Permanente medical centers in Northern California. Dr. Go highlighted the challenges associated with accessing a variety of databases in order to identify individuals for inclusion in clinical trials. To address this challenge, Kaiser has set up a virtual data warehouse for all EHRs. The data warehouse has a query tool that can identify patients who meet inclusion and exclusion criteria. For example, the STABILITY Study<sup>42</sup> involved transformation of EMR data to quickly identify patients who appeared to meet the eligibility criteria, which reduced the screening failure rate.

Dr. Go presented several principles of successful recruitment and retention approaches used by CCRU, including: building relationships and trust from the start and recognizing that the patient participant is really doing researchers a favor; emphasizing transparency about what is being asked of participants; and customizing the trial experience, when possible. Dr. Go also detailed conversations with Kaiser patients, many of whom view the incorporation of clinical trial participation opportunities as an enhancement to clinical care through: more frequent follow-up and better access to experts, the provision of regular, tangible benefits (e.g., laboratory results) with personalized interpretation, regular study updates about progress and preliminary results, and coordination with patients' other treating physicians. To help patients, caregivers, and investigators obtain information about research studies, Kaiser has launched a searchable study site<sup>43</sup> where patients can locate studies and elect to receive email notifications about clinical trials for which they may be eligible. Dr. Go concluded by discussing the importance of developing and utilizing metrics to track enrollment, and continuously improving the process and experience of participants.

*Ann Partridge, M.D., M.P.H., Associate Professor of Medicine, Harvard Medical School*

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<sup>41</sup> <http://www.dor.kaiser.org/external/dorexternal/ccru/index.aspx>

<sup>42</sup> STABILITY Investigators. Darapladib for preventing ischemic events in stable coronary heart disease. *N Engl J Med.* 2014 May 1;370(18):1702-11. doi: 10.1056/NEJMoa1315878. Epub 2014 Mar 30. PubMed PMID:24678955.

<sup>43</sup> <http://kpstudysearch.kaiser.org>

Dr. Partridge discussed best practices for incorporating post-trial communication with study participants into the research plan. She stated that most research studies do not include plans for communication with former study participants or sharing study results after the conclusion of a clinical trial. Dr. Partridge stated that in the fields of epidemiology, occupational and environmental research, and community-based participatory research (CBPR), as well as in a growing body of literature on the ethics of dissemination, there are recommendations for disseminating findings to research participants. Dr. Partridge stated that one of the biggest barriers to sharing clinical research results is the manner in which the information is communicated: patients receiving information about clinical research often rely on health care providers, media, and family and friends to interpret the information, which can make it difficult to ensure that trial results are communicated carefully and accurately. Additionally, although most clinicians are willing to share clinical trial results, they have concerns about the logistical and resource burdens of communicating those results, as well as concerns about the emotional effects the information may have on patients.<sup>44</sup>

Dr. Partridge recommended specific strategies for successful communication with research participants, including: assessing resources needed for communications, building results-sharing into protocols from the beginning, being prepared to provide psychosocial support, genetic counseling, etc. She also highlighted some practices used by cancer researchers, such as: considering the difference between “offering results” and “sharing results;” considering whether an obligation exists to share information with next of kin; including information in informed consent documents about return of results; providing information in person, in writing, or on the study website, depending on the potential impact of these results; and, arranging for help lines, patient advocates, and support groups to handle questions and concerns. Dr. Partridge concluded that the current paradigm is shifting in response to partnerships between researchers, ethicists, industry, government, advocates, and patients.

### **Panel Discussion on Clinical Trial Partnerships and Participant Support**

Following the presentations, Carl V. Hill, Ph.D., M.P.H., Director of the Office of Special Populations at the National Institute on Aging, led a moderated panel discussion. Panel members included a clinician, Jonathan Davis, M.D., Vice-Chair of Pediatrics for Academic Affairs and Chief of Newborn Medicine at The Floating Hospital for Children at Tufts Medical Center; a clinical investigator, Virginia Howard, Ph.D. Professor of Epidemiology at University of Alabama; two patient advocates, Emil Chiauzzi, Ph.D., Research Director of Client Services at PatientsLikeMe, and Dana Dornsife, President of the Lazarex Cancer Foundation; a bioethicist, Mildred Cho, Ph.D., Associate Director for the Stanford Center for Biomedical Ethics at Stanford University; and, an industry representative, Jocelyn Ulrich, M.P.H., Director of Scientific and Regulatory Affairs at PhRMA.

Several panelists discussed the importance of engaging research participants and their communities across the spectrum of clinical trial research, from design to dissemination and implementation of research findings. Many panelists stated that teamwork and effective communication are essential to achieving this goal of engagement. More specifically, panelists agreed that researchers and physicians must build trust early, use a team approach, and ensure that recruiters know the protocol well. Several panelists noted the importance of the human touch, the effectiveness of community and patient navigators in recruitment and retention, and the significance of having a senior researcher or the principal investigator speak with participants and their families. Panelists also noted the need to avoid medical jargon when communicating with potential research participants, and the importance of using patients’ preferred communication styles.

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<sup>44</sup> Shalowitz DI, Miller FG. Communicating the results of clinical research to participants: attitudes, practices, and future directions. *PLoS Med.* 2008 May 13;5(5):e91. doi: 10.1371/journal.pmed.0050091. PubMed PMID: 18479180; PubMed Central PMCID: PMC2375946.

Panelists addressed the need to educate the public about general features of clinical trial research prior to recruitment for specific trials. One panelist suggested a national campaign to encourage participation in trials. Panelists suggested grade and middle school education programs, or clinical trial education in medical schools. One panelist noted that communities around Clinical and Translational Science Award (CTSA) sites are quite aware of trials, but this knowledge diminishes rapidly as distance from the CTSA site increases. Another panelist suggested establishing a system to allow participants to opt into clinical trial research generally, similar to the way organ donation is handled. Panelists stated that educational programs must stress the need to ensure that prospective participants understand the nature of and procedures in the protocol, and what will be expected of them if they consent to participate in research.

Panelists addressed how to engage and retain participants. One panelist noted that it is essential that patients understand to what they are giving consent, as experience has shown that some participants may drop out if they believe that they are randomized to the placebo arm. Another panelist suggested that hiring tracking coordinators can help monitor participants throughout long-term trials. Several panelists discussed the potential of social media and mobile health technologies to assist tracking tools and support retention. One panelist remarked on the importance of removing barriers to participation and the importance of viewing potential barriers from the patient's perspective. Financial constraints such as direct costs (co-pays and coinsurance) and ancillary costs (travel, time away from work) can be considerable barriers to participation.

Panelists discussed the evolving landscape of clinical trials. Several panelists addressed the need for clinical trial infrastructure, which may include establishing national registries, strengthening data quality and promoting interoperability for research using electronic health records, and developing general waivers that allow patients to agree to be approached by researchers. One panelist noted new ethical issues arising in clinical trial research: as patient advocacy groups fund more research, participants have more input on decisions about who decides what research gets done and how. When different stakeholders are involved in planning, conducting, and disseminating research, they may not all be bound by the same rules and ethical principles, and should be aware of potential conflicts of interest.

Betty Tai, Ph.D., Director, Center for Clinical Trials Network, National Institute on Drug Abuse, NIH, led the panelists and speakers in a moderated discussion with the audience. Comments from the audience included the perspectives of research hospitals, nonprofit organizations, professional societies, industry, and federal agencies.

A commenter again raised the issue about current financial barriers for participants and investigators, stating that many participants state that they aren't reimbursed for clinical trial travel expenses, and many investigators state that generally, they don't factor these types of costs into their budgets. Another commenter stated that some IRBs will not approve compensating participants on the grounds that it may be an undue influence, especially for research with disadvantaged communities or vulnerable populations (i.e., children). Several panelists suggested that NIH develop guidance to help researchers budget for reimbursing or compensating participants, or how organizations could partner with nonprofits to address payment issues. One panelist suggested that this guidance come in the form of a budget toolkit or template for researchers to consider when developing the budget for their clinical trial.

Another topic of discussion focused on collaborations with industry. One commenter discussed the need for systematic attempts to partner industry sponsors with government or academic centers to undertake clinical trials. A panelist noted that, while the National Center for Advancing Translational Science (NCATS) at NIH is well-suited to foster such collaborations, there are many more opportunities for partnerships that should be explored. Several panelists agreed that more interactions between industry, the government and academia are occurring now that occurred in the past, and that all parties are working to eliminate silos. One panelist pointed out that many of these partnerships are highly focused, and won't

necessarily lead to broad-based strategies to develop public-private collaborations for clinical trials research. However, the industry panelist noted that many industry sponsors are currently exploring ways to engage the academic sector and to improve the efficiency of the regulatory process for clinical research.

Commenters and panelists discussed the need for patient privacy in clinical trials. Commenters stated that privacy and confidentiality guidelines are difficult to navigate in the era of social media, and asked how others have overcome challenges when using social media as a recruitment and retention tool. One panelist discussed keeping recruitment information entirely separate from retention information online, while another discussed building social media concerns into the consent process by having people sign a HIPAA release so that researchers can re-contact participants. Both panelists noted the importance of protecting data, regardless of the strategies used to navigate privacy regulations when using social media as a tool for recruitment and retention.

The discussion also highlighted issues relating to IRBs. One participant noted that, too often, informed consent documents fail to convey sufficient information to allow individuals to make an informed decision about participating in research, and that a federated informed consent process might provide a solution. Another reminded participants that the Common Rule is being revised, and that the ANPRM proposed the use of a single IRB for multisite studies. One panelist noted that with the assistance of NIH, 40 hospitals in New England signed a reliance agreement through the Harvard Catalyst. Another participant reported that the CTSA program is also trying to adopt a single IRB model. Commenters and panelists also discussed informed consent documents. One suggestion was that informed consent documents should be separated into two parts – a section outlining the legal, contractual relationship between the institution and the participant and another with plain language, graphical elements, and visual aids to help individuals make informed choices about whether or not to participate in a clinical trial.

### **Closing Comments**

Following the final discussion and before adjourning, Dr. Corrigan-Curay thanked the speakers, panelists, and audience for their participation in the workshop and recapped of key themes addressed throughout the day.

- Building and sustaining trust, based on mutual respect between research and participant communities, is essential to successful enrollment and retention in clinical trials. Trust is especially important for reaching underrepresented groups, some of which may not interact with, or have limited access to, medical systems.
- Effective communication is essential throughout the clinical trial process, including post-trial communication. Clinical trial participants must be able to understand the protocol, and simplifying informed consent documents will help inform prospective research participants about risks and potential benefits of a trial. Outreach and recruitment strategies should be appropriate to the population and community, and use tailored communication that is sensitive to cultural values and heritage. Communications should be sensitive to the burdens of research participation from the participant's perspective, and utilize novel approaches to address burdens.
- Outreach and community involvement warrants consideration, as does the importance of using the patient perspective to develop innovative and customized methods to engage the specific participant community of interest. Education and communication strategies can ensure that participants have a good experience throughout the clinical trial so that they may become “ambassadors” who can dispel mistrust and increase research participation in their communities.



Clinical trial enrollment may also be enhanced through the use of more general strategies, such as increasing the diversity of the research team; educating physicians about the importance of clinical research, improving informed consent procedures; and using peers, symbols, and easy-to-understand terms in written materials relating to the clinical trial.

- Public foundations and stakeholder organizations play a significant role in improving clinical trial participation through a variety of activities. For example, these organizations can directly engage patient communities to increase clinical trial enrollment and provide ancillary financial care in order to ensure that research participants can continue to participate in a clinical trial. They can provide technical support and help sites to stay on track with their recruitment and retention goals.

The Workshop provided a variety of stakeholders the opportunity to discuss new strategies and innovative approaches that have been identified and developed to address challenges to clinical enrollment and retention and to improve clinical trial participation. It can serve as a catalyst to foster collaborations among stakeholders, allowing them to share ideas and strategies to advance the goals of clinical trial research, and ultimately, to promote public health.