Perspectives on Transparency and Security Regarding Enhanced PPP Research

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January 23, 2020

USG Potential Pandemic Pathogens Policy

- Potential pandemic pathogen (PPP) is a pathogen that satisfies both of the following:
  - Likely highly transmissible and likely capable of wide and uncontrollable spread in human populations
  - Likely highly virulent and likely to cause significant morbidity and/or mortality in humans

- Enhanced PPP results from enhancement of the transmissibility and/or virulence of a pathogen.
  - Enhanced PPPs do not include naturally occurring pathogens that are circulating in or have been recovered from nature, regardless of their pandemic potential.

In other words, this is USG funding/approval for research intended to increase the virulence or transmissibility of a pathogen that could initiate a pandemic

Transparency of Review Committee

- OSTP P3CO guidance: “To maximum extent possible, agencies’ enhanced PPP review mechanisms should provide transparency to the public regarding funded projects involving the creation, transfer or use of enhanced PPPs”

- But no public description of who has been part of the reviews since announcement of 2019 enhanced PPP work – unlike transparent public NIH study section rosters

- P3CO policy commits to “scientific research, biosafety, biosecurity, MCM development and availability, law, ethics, public health preparedness and response, biodefense, select agent regulations, and public health policy” -- unclear if that has happened?

Transparency of Review Process

- Public safety outweighs concern over trade secrets
- Ideally would include independent scientists outside government, who have no stake in the research
- Approval should require assent of state public health authorities, as was the case of the approval of the BI4 lab in Boston

Transparency of Decision-making Criteria

- No public information released regarding the content of the HHS decision process for the 2019 enhanced PPP research
- No qualitative or quantitative risk assessment released
- No basis to understand HHS decisions which public and scientific community have abiding interest in understanding
    - What does USG judge benefits of proposed research project to be?
    - What does USG judge specific risks of the proposed research to be?
- This information should be published in advance of the provision of funding for the work, with chance for public comment

Require High Level Approval for this Work

- *NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules*: "deliberate transfer of drug resistance trait to a microorganism when such resistance could compromise the ability to control the disease agent in humans, veterinary medicine, or agriculture" requires **"Major Action"**

- **Major Action** includes the requirement for signature of the NIH Director

- Given the potential harmful consequences of enhanced PPP research are initiation of epidemic or pandemic that may not be able to be stopped with a vaccine or antiviral, this approval should similarly require the signature approval of the NIH Director, or HHS Secretary.

- Currently not clear at what level of government this approval is made.

Establish Common International Approach to enhanced PPP Research

- OSTP P3CO guidance: "US government should engage with other countries about policies concerning creation, transfer and use of enhanced PPP, encouraging the development of harmonized policy guidance"

- Doesn't appear to be international consensus building happening w/ other countries, or w/ WHO, or w/ other countries' national academies

- This process should be transparent

- Do we want other countries to start approving and funding enhanced PPP research? If USG is funding it, what is our argument that other governments shouldn't be funding it?

- Since USG is funding this work (unclear if other countries are or are planning to fund it) USG has responsibility to try to set strong standards

Transparent, Strong International Standards

- Since USG is funding this work (unclear if other countries are or are planning to fund it) USG has responsibility to try to set strong standards
- If this work is going to be funded by the U.S. government and other governments, it's in interest of all countries if the work is restricted to the smallest number of laboratories, with criteria to include:

    - Globally exceptional records of biosafety
    - Experience with dangerous pathogens of the type under study
    - Exceptional staff training,
    - Biosecurity awareness and plans,
    - State-of-the-art-facilities and that operate under appropriate national policy framework that ensures the safety of the work.

Summary of Recommendations

- Transparency of review committee composition & skillset
- Transparency and independence of review process
- Transparency of decision-making criteria – publish specific risks, benefits, and risk assessment, in advance of provision of funding
- Require NIH Director or HHS Sec approval for the work
- Establish common international approach to approving and funding enhanced PPP research
- Set very strong international standards if this work is to be approved anywhere