



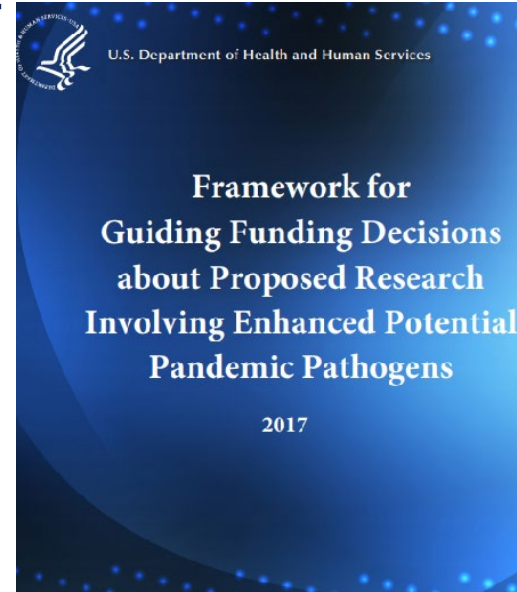
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Department of Health & Human Services Oversight & Management of Research with Potential Pandemic Pathogens

**D. Christian Hassell, PhD
Senior Science Advisor
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
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HHS Pre-funding Reviews of PPP

- The HHS P3CO Review is a two-step deliberative review process to guide funding decisions on proposed research that is reasonably anticipated to create, transfer, or use enhanced PPP:
 1. Funding agency review of research for scientific merit & criteria for enhanced PPP
 2. Department-level multi-disciplinary review of research risks & benefits, ethical considerations & risk mitigation plans



USG Oversight of Studies Involving Enhanced Potential Pandemic Pathogens

Scope

Federally funded projects anticipated to create, transfer, or use enhanced PPP

- **A PPP is one that satisfies both of the following:**
 1. It is likely highly transmissible & likely capable of wide & uncontrollable spread in human populations, &
 2. It is likely highly virulent & likely to cause significant morbidity &/or mortality in humans.
- **An enhanced PPP is a PPP resulting from the enhancement of a pathogen's transmissibility &/or virulence.**

HHS P3CO Review Committee

- The **HHS Potential Pandemic Pathogen Care & Oversight (P3CO) Review Committee** provides a department-level review of research, determined by the funding agency to be reasonably anticipated to create, transfer or use enhanced PPP;
- Purpose is to evaluate risks & benefits of the research, ethical issues & risk mitigation plans.
 - Disciplines required for the review include:
 - ✓ Scientific research, biosafety, biosecurity, MCM development & availability, national security, law, ethics, public health preparedness & response, biodefense, select agent regulations, & public health policy, as well as the funding agency perspectives & other relevant areas.

HHS P3CO Review Evaluation Criteria

1. Research is scientifically sound;
2. The pathogen is considered to be a credible source of a potential future human pandemic;
3. The potential risks as compared to the potential benefits to society are justified;
4. There is no feasible alternative method to address the same question in a manner that poses less risk;
5. The investigators have demonstrated the capacity & commitment to conduct the research safely & securely;
6. Research results are expected to be responsibly communicated;
7. The research will be subject to ongoing federal oversight; &
8. The research is ethically justifiable.

HHS P3CO Review Group Recommendations

- The HHS P3CO Review Group will guide Funding Agency decisions. Possible recommendations by the HHS P3CO Review Group include:
 - Research is acceptable for HHS funding;
 - Research is not acceptable for HHS funding;
 - Research is acceptable for HHS funding on the condition that certain experiments are modified;
 - Research is acceptable for HHS funding on the condition that certain risk mitigation measures are employed at the federal &/or institutional level.
- HHS P3CO Review Group will communicate the results of the HHS P3CO review to the funding agency.

Funding Decision

- The Funding Agency will:
 - Consider the recommendations resulting from the departmental-level review;
 - Make a funding decision, stipulating terms & conditions of award including additional risk mitigation measures if appropriate; &
 - Report relevant information on funding decisions to HHS & OSTP.

Feedback

ASM meeting, discussions with many interested parties

- Need better definition, specificity for *transparency*.
- Do benefits justify/outweigh the potential risks?
- Does the process engender trust? How can we better document the deliberative process that leads to the posted decision? (While maintaining the integrity of the peer-review process?)
- More information re the composition of the Committee, incl. expertise, background. Possible even identification of persons.
- More timely posting of decisions, related actions, timelines.
- The scope of the Framework is too narrow: only influenza, and even that does not include H7, etc. (ref. 2016 NSABB report, Figure 3).
- Possibility of a user-facility for testing?

Next Steps

- HHS will periodically ask the National Science Advisory Board for Biosecurity (NSABB) to review the HHS P3CO Review Process.
- HHS is committed to enhancing transparency about the review process & the funded projects to ensure public trust.

Science, Safety & Security (S3) Website

<https://www.phe.gov/s3/Pages/default.aspx>



Science Safety Security

Finding the Balance Together



S3 HOME

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Two Research Projects Reviewed Under Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens

Under the HHS P3CO Framework, the HHS P3CO Review Group determined that, in the case of both research proposals, the research is acceptable for HHS funding with recommended changes to increase the potential benefits while decreasing risks; suggested changes were included as terms and conditions of the awards.

[Learn more about the approval](#)



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Thank you