

# The Path Forward: NSABB's Deliverable 2

*Susan M. Wolf, J.D.*

*Joseph E. McDade, Ph.D.*

May 5, 2015

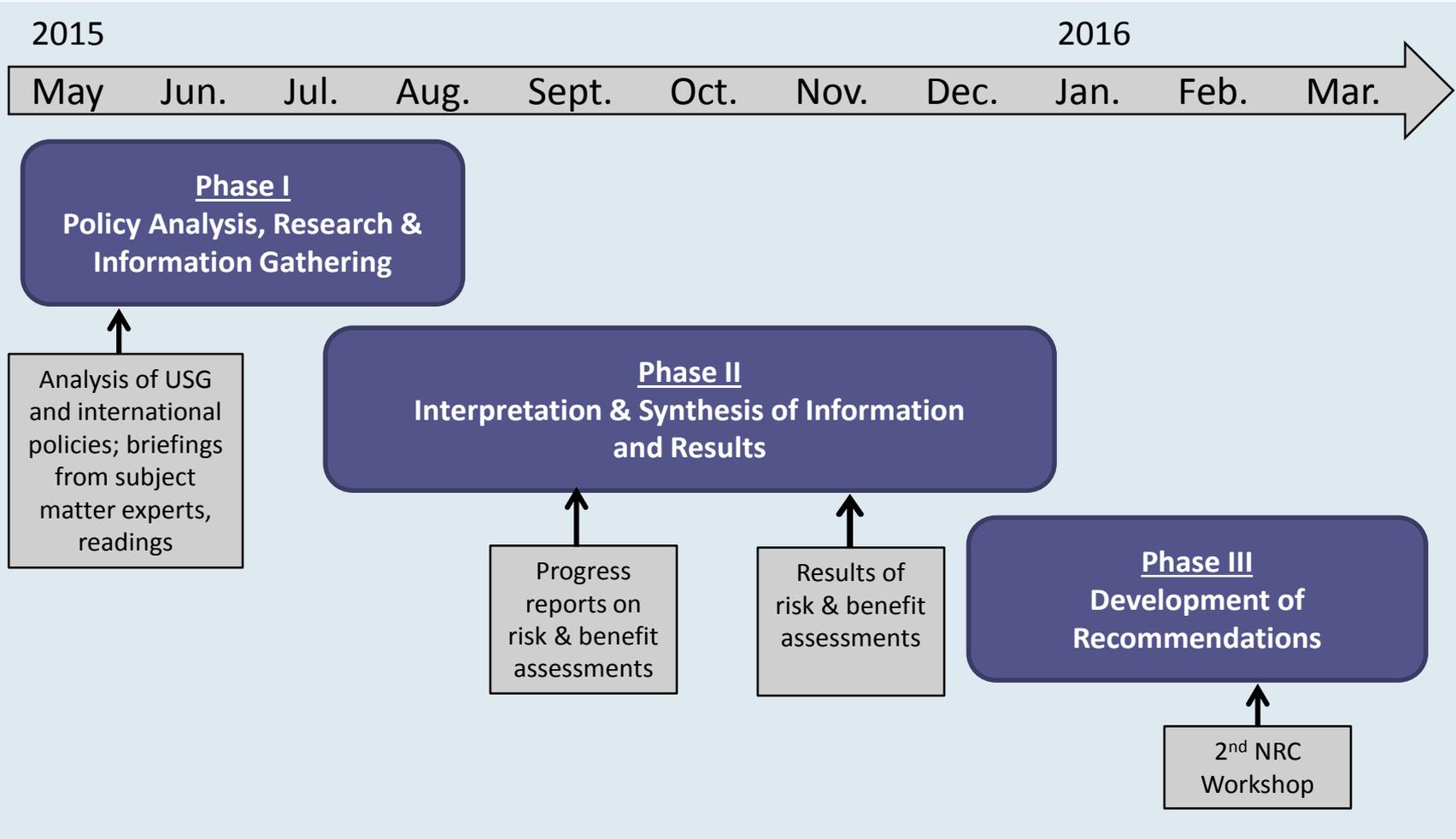
# NSABB Deliverable 2: Approach

**Deliverable 2:** Formal recommendations on a conceptual approach to the evaluation of proposed GOF studies

## **Key questions to consider:**

- What does the risk/benefit analysis tell us about the relative risks and benefits associated with the GOF studies involving pathogens with pandemic potential?
- Are there particular GOF studies that raise significant concerns?
- What are the ethical and policy considerations that should guide decisions about GOF studies?
- Do current policies, regulations, and guidelines adequately address & mitigate the potential risks of GOF studies involving pathogens with pandemic potential? Is additional oversight needed?
- How does GOF research fit into the overall scientific research and public health endeavor?

# NSABB Deliverable 2: Proposed Process for NSABB Deliberations



----->\*

Conduct of risk & benefit assessments

# Informing NSABB Deliberations

- What additional key inputs, sources of information, and areas of consideration will be important for NSABB’s ongoing deliberations?

| Topic  | Input   |
|--|---|
| <b>Policy (US)</b>   | Review of USG policies relevant to DURC, GOF, and oversight of research involving pathogens (e.g. HHS Framework, USG DURC policies, biosafety guidelines, select agent regulations)   |
| <b>Policy (International)</b>  | International (WHO, EU etc.) regulations and policies on biomedical research related to DURC and GOF; relevant US commitments under international law; summaries from relevant international meetings; materials issued by international scientific and public health societies, advocacy organizations, etc. |
| <b>Funding Agency Perspectives</b>   | Presentations from USG agencies and non-governmental funding bodies to include description of project review process and viewpoints of how GOF studies fit within a broader research portfolio  |
| <b>Broad Scientific Perspectives</b>   | Perspectives on GOF from highly respected scientists from diverse fields (Non-GOF/Flu/Coronavirus researchers); might include broader microbiology, synthetic biology, neuroscience, or other fields.   |
| <b>Ethics &amp; policy choices in moving from risk/benefit analysis to recommendations</b> | A commissioned review of ethical writings and frameworks for generating policy recommendations informed by risk/benefit analysis; briefings from those with expertise in creating DURC policy.  |
| <b>National Security</b>   | National security briefing to the NSABB; biosecurity analysis as part of commissioned risk assessment   |
| <b>Science communications--publishing and reporting</b>                                    | Perspectives from journal editors/publishers and science reporters about how GOF studies fit within a broader scientific context, how they are reviewed by journals, why they are published and what they contribute to the knowledge base; how they are received by the scientific community and public      |
| <b>Examples of placing limits on research--Smallpox as case study</b>                      | A review of the literature describing the history of the smallpox eradication and the decision-making process for restricting smallpox research   |