



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Science Preparedness and Response: Creating a Coordinated Science Preparedness Framework for Emergency Public Health Research

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ASPR brings together policy, science and response





Science Preparedness



Vision Statement – *A nation prepared with the scientific research and infrastructure necessary to make evidence-based decisions in the face of public health and medical threats. Communities, responders, and the nation can leverage science, to inform short- and long-term preparedness, response, and recovery efforts.*

Mission Statement – *ASPR improves the health and resilience of the nation through leadership and coordination of collaborative emergency science preparedness, response and recovery efforts that leverage a whole-of-community all-hazards approach before, during, and after large scale public health and medical emergencies and disasters.*



<http://www.phe.gov/Preparedness/planning/science/Pages/action.aspx>



What is Science Preparedness?



- Science preparedness is a **collaborative effort** to establish and sustain a **scientific research framework** that can enable emergency planners, responders and the whole-of-community to better **prepare for, respond to, and recover from** major public health emergencies and disasters.
- Science preparedness is not a practice in and of itself. It is the result of the **coordination and integration** of sound **scientific research**, a **comprehensive research infrastructure**, leading **public health practices**, and all-hazard **emergency management efforts**



www.PHE.gov/SciencePreparedness



Why Science during Response?



- The advancement of applied outcome measures through scientific research **before**, **during** and **after** a disaster or public health emergency provides a finite window of opportunity to identify, collect and analyze critical and time-sensitive data and information needed to protect the health and safety of responders, communities and our Nation, both immediately and long term.
- NBSB: *“Each disaster constitutes a critical opportunity in what may be a brief window of time to conduct scientific research that could lead to improved assistance to those affected by the event, and improve capabilities for responding to future disasters.”*





Five core elements



- I. Coordination and Integration
- II. Scientific Research
- III. Research Infrastructure
- IV. Public Health Practice
- V. Emergency Management



Coordination and Integration



- ASPR leverages a ‘whole-of-community’ and ‘all-hazards’ approach to bring together the **scientific research, public health, and emergency management** communities.
- In order to derive applied outcome measures, science preparedness leverages collaboration between government agencies, private sector, academic institutions and community organizations, and provides a forum for communicating, coordinating and integrating disaster scientific research with public health and medical preparedness, response and recovery efforts.



Coordinated Approach



April 2011: Call to Action: Include Scientific Investigations as an Integral Component of Disaster Planning and Response. NBSB

- <http://www.phe.gov/Preparedness/legal/boards/nprsb/Documents/nbsbrec14.pdf>

September 25, 2012: ASPR Scientific Preparedness and Response for Public Health Emergencies Workshop

- <http://www.phe.gov/Preparedness/legal/Documents/scientific-prep-report.pdf>

April 7, 2014: NIEHS Disaster Research Response Exercise, Port of Los Angeles

- <http://tools.niehs.nih.gov/wetp/events.cfm?id=2537>

June 13-14, 2014: Institute of Medicine, Disaster Research Response Workshop

- <http://iom.edu/Activities/PublicHealth/MedPrep/2014-JUN-13.aspx>

November 17, 2014: APHA Special session on disaster science and preparedness

- <https://apha.confex.com/apha/142am/webprogram/Session42366.html>

Other on-going meetings, working groups and collaborative efforts...



Scientific Research



- When facing a disaster, **access to accurate, timely and reliable information is critical** to improving health outcomes and saving lives.
- The advancement of scientific research **before, during and after** a disaster or public health emergency enables scientists to **operate within a finite window of opportunity** to identify, collect, analyze, and share critical and **time-sensitive data** that may be available only during the immediacy of the event or incident.
- This information forms an **evidence base** for making **immediate, short-term and long-term decisions** that protect the health and safety of responders, communities and our Nation.

Hurricane Sandy Recovery Research: ASPR/NIEHS/CDC

<http://www.phe.gov/Preparedness/planning/science/Pages/research.aspx>



Research Infrastructure



- A sound research infrastructure is the foundation of science preparedness and is critical to employing disaster-related scientific research efforts in advance of, during and after disasters.
- Some of the major components comprising a disaster scientific research infrastructure include:
 - Rapid Institutional Review Board (e.g. **PHERRB**)
 - Pre-identified Scientific Research Responders and Research Networks
 - Pre-scripted Clinical and Scientific Research Protocols
 - Reliable and Accessible Data Sources
 - Static and Dynamic Funding Streams

<http://www.phe.gov/Preparedness/planning/science/Pages/infrastructure.aspx>



PHERRB



- DHHS established the **Public Health Emergency Research Review Board (PHERRB)** in 2012 to provide centralized, rigorous and expeditious human subject protections review of research studies addressing **public health emergencies (PHEs)**
 - <http://www.phe.gov/Preparedness/planning/authority/nhss/ip/Documents/nhss-ip.pdf>
 - PHEs include: natural disasters, biohazards including anthrax; chemical and radiological emergencies; oil spills; pandemic influenza or other infectious diseases; and other mass casualty events
- **National Institutes of Health (NIH)** designated to maintain **PHERRB** infrastructure and functions
 - Leverage expertise of NIH IRB members
 - Provide staff
 - Develop operating procedures
 - Maintain operations
 - OHSRP is the point of contact for PHERRB operations



The PHERRB does...

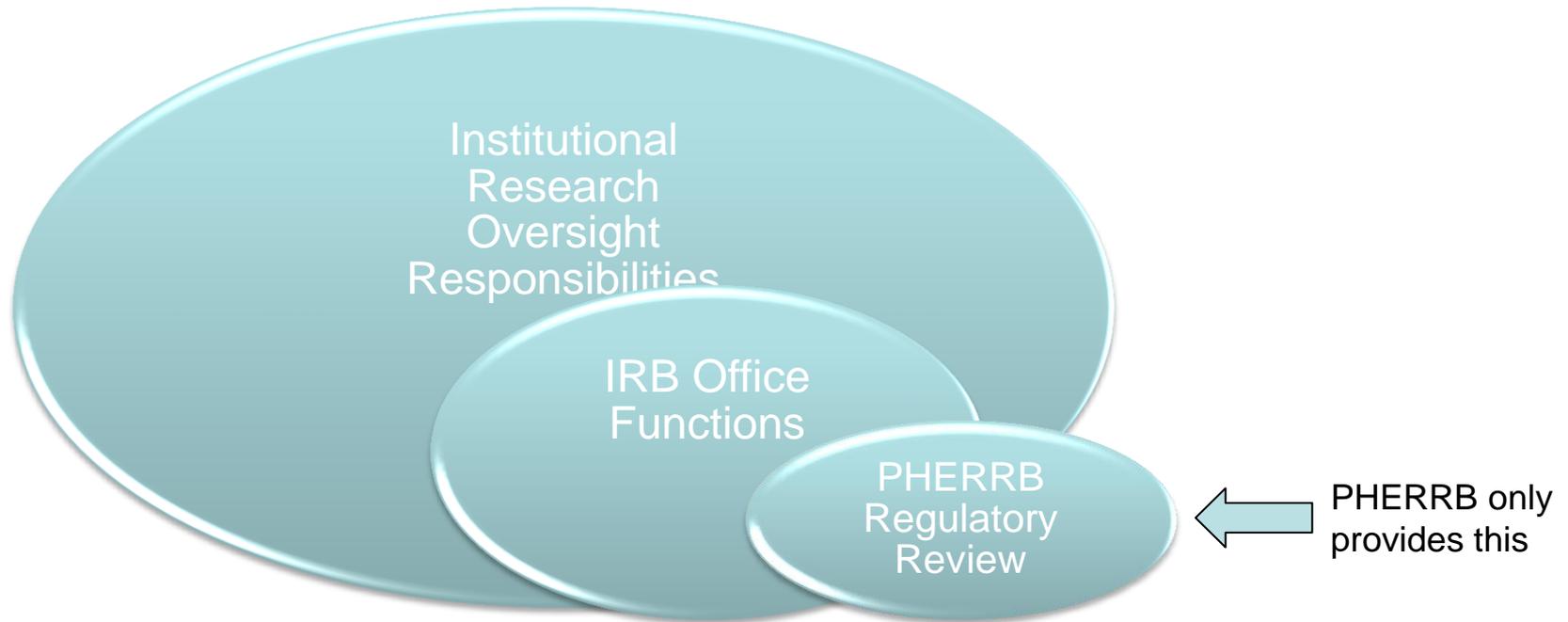


- PHERRB will serve as IRB of record conducting human subject protections review for public health emergency research (PHER) studies; will serve as a central IRB
 - provides human subject protections/regulatory review only;
 - conducts: initial review, continuing reviews, review of all amendments, the review of unanticipated problems and provides local context review;
 - PHERRB will operate under applicable federal regulations
- Criteria for PHERB Review:
 - protocols conducted, supported, or regulated by HHS;
 - protocols are multisite in nature or otherwise require multiple IRB review
 - protocols subject to 45 CFR 46 and/or 21 CFR 50 and 56



The PHERRB does not...

- Review by the PHERRB does not replace other institutional responsibilities (i.e. Principal Investigator (PI) training, adequacy of local resources, ancillary reviews)



Adapted from Emily Chi Folger, JD, Elizabeth Hohmann, MD, and P. Pearl O'Rourke, MD, Central IRBs: Models, Logistics, and Implications, PRIM&R Webinar, April 15, 2014.



Clinical Networks



“Recent disasters, such as Hurricane Sandy, the Deepwater Horizon oil spill, the 2009-H1N1 pandemic, underscored the importance of developing a capability to perform rigorous scientific studies in real time, potentially to shape the response to an unfolding crisis and to support recovery” -Robin Robinson, Ph.D., Dir. of the Biomedical Advanced Research and Development Authority (BARDA)

- BARDA has established a network of five clinical research organizations... to supplement NIH capabilities by **conducting clinical studies during public health emergencies** such as a pandemic.
- This capability will **enhance the nation’s science preparedness** by ensuring that clinical studies that address critical research questions for emergency response and recovery can be performed in a timely manner.
- In an emergency, the BARDA clinical studies network may use local institutional review boards or the national **PHERRB**... to review multi-site research studies on health problems arising in the context of a public health emergency.

<http://www.hhs.gov/news/press/2014pres/03/20140311b.html>



Public Health Practice



- ASPR and partners recognize Science Preparedness as critical link between public health practice and scientific research.
- Science Preparedness enables information and data collected for public health practice (e.g. public health surveillance) to be used for applied outcome measures and research purposes (e.g., health services research). **The benefits from investigations or research accrue to persons beyond the population under investigation.**
- In advance of, during and after disasters or public health emergencies, public health practice should address clearly articulated, important questions or hypotheses, and be appropriately designed to maximize the likelihood of producing a meaningful research study.

<http://www.phe.gov/Preparedness/planning/science/Pages/practice.aspx>

ASPR: Resilient People. Healthy Communities. A Nation Prepared.



Emergency Management



- The emergency management core element of science preparedness leverages applied outcome measures to ensure research efforts related to disasters and major public health and medical emergencies align with the greater preparedness planning, response and recovery efforts as required in the National Planning Frameworks, such as the:
 - National Response Framework (NRF)
 - National Disaster Recovery Framework (NDRF)
- ASPR's goal is to **ensure research related efforts enhance life-saving activities**.
- When integrated into emergency management, applied outcome measures and scientific research can **inform evidence-based decision making** for responders, incident commanders, communities and individuals.



Learn more about ASPR's efforts



 What is it?  Why does it matter?  What are we doing?  What you can do!

www.PHE.gov/SciencePreparedness

SciencePreparedness@HHS.gov



ASPR on the Web



PHE.gov:
www.phe.gov



PHE.gov Newsroom:
www.phe.gov/newsroom



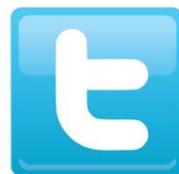
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