4th Annual
NIEHS Disaster Research Response
Federal Interagency Meeting

Natcher Conference Center, Rm. D
NIH Campus

March 10, 2017
Welcome & Introductions

“The knowledge that is generated through well-designed, effectively executed research in anticipation of, in the midst of, and after an emergency is critical to our future capacity to better achieve the overarching goals of preparedness and response: preventing injury, illness, disability, and death and supporting recovery.”

Lurie, Manolio, Patterson, Collins, & Frieden. New England Journal of Medicine. 368; Mar 2013
Today’s Meeting Goals

• Share 2016 disaster research activities that advanced infrastructure & processes

• Continue to refine a collective vision for a “National Disaster Research” capability

• Discuss opportunities for:
  – Integration
  – Empowerment
  – Engagement
  – Training
  – Funding
Agenda

• 12:45-1:00  HHS/ASPR Science Preparedness
• 1:00-2:30  Advancing Disaster Research
• 2:30-2:45  Break
• 2:45-4:15  Vision for Federal Research
• 4:15-4:30  Moving Forward
HHS ASPR Science Preparedness
HOW SCIENCE CAN SAVE LIVES: PREPAREDNESS AND RESPONSE IN DISASTERS

Federal Interagency Meeting on Disaster Research
March 10, 2017

Leremy Colf
HHS/ASPR Director of Disaster Science
Major Disaster Declarations

Top 10 Major Disaster Declarations by Type of Incident 1953-2014

- Severe Storm(s): 37.1%
- Flood: 32.8%
- Hurricane: 9.3%
- Tornado: 6.5%
- Snow: 2.6%
- Typhoon: 2.5%
- Fire: 2.3%
- Severe Ice Storm: 2.0%
- Earthquake: 1.3%
- Freezing: 0.8%

Source: CRS analysis based on data provided by FEMA.

Resilient People. Healthy Communities. A Nation Prepared.
Timeline: Major Public Health Emergencies

2001
- H5N1
- 9/11 and Anthrax attacks

2002
- Hurricanes Ike/Gustav
- Haiti Earthquake

2003
- H1N1
- 2008
- Japan Earthquake/Fukushima
- Isaac and Sandy

2004
- Hurricanes Katrina, Rita, Wilma
- Deepwater Horizon Oil Spill

2005
- H7N9
- 2011 Tornados

2006
- WV Chemical Spill
- Sandy Hook Shooting

2007
- Ebola
- OR Comm. College Shooting

2008
- MERS
- LA Floods

2009
- MERS
- Hurricanes Ike/Gustav

2010
- Zika
- Sandy Hook Shooting

2011
- H5N1
- 2011 Tornados

2012
- Ebola
- OR Comm. College Shooting

2013
- Zika
- OR Comm. College Shooting

2014
- Zika
- OR Comm. College Shooting

2015
- Zika
- OR Comm. College Shooting

2016
- Zika
- OR Comm. College Shooting

Resilient People. Healthy Communities. A Nation Prepared.
Why Does Research Matter for Disaster Preparedness and Response?

• Recent disasters have revealed gaps in information needed to respond effectively-- and missed opportunities to fill those gaps

• Science response aims to rapidly and effectively execute (or begin) research to resolve critical questions about the event

• Infrastructure for science response is needed

• Barriers to effective execution of research need to be addressed in advance of an event

• Using science to address gaps will not only improve the current response, but make us better prepared for future disasters
Examples from Recent Disasters: Zika Virus

- What were some of the science successes?
  - Identifying vector issues
  - Determining link between infection and microcephaly
  - Identifying priority groups for vaccination and treatment

- Where could we have done better?
  - Developing diagnostics
  - Understanding alternate routes of infection
  - Long-term care for affected infants
  - Addressing the treatment needs of pregnant women
What Can We Do?

1. Address known gaps ahead of time

2. Facilitate research in a crisis

3. Develop and maintain strategic partnerships
Questions

Contact Information:

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Director of Disaster Science

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Advancing Disaster Research
Exploring Disaster Research Challenges & Needs
NIH Disaster Research Response Workshop: June, 2014
“Enabling Public Health Research During Disasters”

• Co-Sponsored by NIH, ASPR, CDC, IOM
  • Frame a national research agenda & action items
  • Integrate research into existing response structures
  • Identify critical research needs & priorities
  • Identify obstacles & barriers to research
  • Discuss structures & strategies needed for deployment
  • Share ideas, innovations, technology to support research
  • Explore data collection tools & sharing mechanisms

Provided a springboard for development of NIH DR2 Program efforts

*http://www.nap.edu/catalog.php?record_id=18967
Overview of the NIH Disaster Research Response (DR2) Program

Improving Disaster Responses, Reducing Health Impacts, and Preventing future harm through:

1. Improved access to data collection tools for researchers
2. Improved NIEHS & partner capability to quickly collect data
3. Trained researchers versed in disaster tools and issues
4. Integration into planning and emergency response systems
5. Research process including public health, academia, and impacted workers and communities
Disaster Research Model: 4 Focus Areas & Objectives

Efforts to overcome challenges and to facilitate timely research

- NAS Forums and Committees
- EHS Subject Matter Experts
- Community Concerns
- NIH, HHS, OSTP Groups

- IRB Review
- Funding
- Site Access
- OMB Review

Research Issues Identification & Prioritization

- Integration in Response
- EHS Research Network
- Community partners and other stakeholders

- Data Collection & Mgmt
- Medical Tests & Samples
- Logistics
- Training

Research Process Issues

Relationships, Integration & Coordination

Infrastructure & Implementation Challenges
Issue Identification and Prioritization

• What efforts exists to improve our capacity to identify important research issues and data gaps in response to a disaster?

• How do you currently acquire or collect this information?

• What progress have you made in developing a research agenda or gap analysis?

• How does your agency determine what research needs to be pursued?
Research Process Issues

Efforts to work through research “process” needs for developing or implementing a research response?

• Process for human subject ethical considerations?
  
• Process for OMB / Paperwork Reduction Act issues?

• How has your agency funded disaster research?
  • Intramural?
  • Extramural?

• How does your agency implement research?
  • Who participates?
  • Are they trained?
  • How do you gain access to sites/populations to implement research?
PUBLIC HEALTH EMERGENCY RESEARCH REVIEW BOARD (PHERRB) UPDATE

Julia Slutsman, PhD
NIH, Office of Human Subjects Research Protections (OHSRP)
What Is the PHERRB?

- Department of Health and Human Service (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)

- Mechanism to allow researchers conducting public health emergency research to request review by one of the NIH intramural IRBs

- Leverages IRBs’ subject matter and regulatory expertise
  - Any NIH intramural IRB can serve as the PHERRB
What does the PHERRB do?

• PHERRB will serve as IRB of record conducting human subject protections review for public health emergency research (PHER) studies; can serve as a single IRB
  - provides human subject protections/regulatory review only

• Criteria for PHERB Review:
  • PHER protocols conducted, supported, or regulated by HHS, and on a case by case basis - other agencies and sponsors;
  • protocols are generally multisite; single site studies may be reviewed on a case by case basis
  • protocols subject to 45 CFR 46 and/or 21 CFR 50 and 56
Planned PHERRB Objectives

• Conduct strategic planning with stakeholders internal and external to NIH to align with overall science preparedness priorities and develop 3-5 year strategic plan

• Integrate PHERRB into HHS-wide science preparedness planning efforts

• Integrate PHERRB operations into NIH intramural implementation of the sIRB policy and conduct evaluation of the PHERRB

• Position PHERRB as first stop for investigators grappling with human subjects protections issues in public health emergency research
Current Activities

• Engagement with NIEHS DR2 and other initiatives

• Piloting of PHERRB in the context of HHS Public Health Medical Counter Measures Enterprise (PHEMCE)

• Exploring emerging reliance agreement templates
Planned Activities - 2017

• Develop and/or refine PHERRB business processes
• Review first protocol, publish manuscript describing initial PHERRB experience
• Create listing of key science preparedness stakeholders across ICs and Federal partners
  • Engage with stakeholders to elicit expectations and priorities
• Identify and engage IRBs routinely reviewing public health emergency research (PHER)
  • Explore funding resources for workshop of IRB Chairs to discuss best practices and challenges
  • Mobilize network of IRBs with capacity to review PHER for sharing of best practices, research into IRB review processes, etc.
Contact the PHERRB

PHERRB Mailbox: PHERRB@mail.nih.gov

NIH Office of Human Subject Protections Research (OHSRP),
Dr. Lynnette Nieman, Director
Website: http://ohsr.od.nih.gov/OHSR/index.php
Phone: (301)402-3444
Brief Update on the NIEHS Working Group

Joan Packenham, Ph.D.
Director, Office of Human Research Compliance (OHRC)
NIEHS IRB Vice-Chair
National Institute of Environmental Health Sciences
NIEHS Role in Disaster Response

NIEHS IRB Experienced in Disaster Research Review

- Reviewed: “HEAL Study” (Katrina) and “Gulf Long-Term Follow-Up Study” (Gulf Oil Spill)
- Disaster Related IRB Training Workshops
- Consultation with local IRBs
- IRB review and provisional approval of RAPIDD

2014 Development of the ”Rapid Acquisition of Pre and Post – Incident Disaster Data Study” (RAPIDD)

- Allows for early data collection during the response phase of a future disaster
- “Plug and Play” protocol  *(Umbrella Protocol)*
- Pre-approved generic protocol
IRB Review Challenges in Disaster Research

- Not business as usual
- Lack of best practices/guidance
- Concerns regarding expertise and qualifications of researchers
- Concerns regarding research interference
- Situational context on the disaster and the community impact
- Concerns regarding participant & community vulnerability and burden

“What makes disaster research unique is the circumstances in which otherwise conventional methods are employed. Put differently, it is the context of research not the methods that makes disaster research unique.” (R Stallings, 2002)
Special Considerations & Best Practices for IRB Review of Disaster Research Working Group

Purpose:

• To have an open & transparent discussion of human research protection issues in the context of disaster research

• To identify recommendations that would be instrumental in preparing and guiding IRBs to efficiently review protocols related to public health emergencies and disasters

Mission / Outcome:

• The development of special considerations for the NIH Human Research Protection Program and for IRBs who review public health emergency/disaster protocols
Inaugural Working Group Meeting
July 2016

Specific Aims

• Preparing IRBs for the review of disaster related protocols

• Outline duties of the IRB in the rapid review of research involving disaster-affected communities

• Identify participant burden for vulnerable populations after disasters

• Explore vulnerability as it relates to potential research participants and disaster communities

Breakout Groups Responded to 5 Disaster Scenarios
Working Group Recommendations

1. Preparing IRBs for Reviewing Disaster Research

2. IRB Responsibilities & Review Processes

3. Identify and Minimize Participant Burden

4. Address Research Participant Vulnerability and Informed Consent
Model: Vulnerability Review Considerations Continuum

Critical Review Factors

- Disaster type, magnitude, and aftermath
- Type of research/proposed study
- Time point in Disaster Management Cycle
- Potential Subject
- Community and social environment
- Subject health status, relationships, and stability
- Physical environment

Feedback loop throughout study
- Return of research results

Risk
Benefit
Participant Burden

IRB Preparedness
DISASTER EVENT
Response
Recovery
Mitigation
Years
Days
Future Directions

• Publication of Recommendations 2016 Working Group Meeting *(coming)*
• Development of disaster-related IRB training modules for IRBs and PIs
• Creating a toolkit of resources for IRBs and PIs to facilitate review of disaster protocols
• Reconvening of the working group to provide continued guidance on ethical dilemmas associated with disaster research
• Providing expert consultation to IRBs regarding review of disaster research
• Creating a central registry of studies
Infrastructure to Support Implementation

What efforts exist to build infrastructure to help support implementation of a disaster research response?

• What is the spectrum of infrastructure currently developed?
  – Guidance & Support Information
  – Surveys, Questionnaires, Protocols, Forms
  – Training
  – Personnel
  – Equipment (e.g., medical testing, environmental sampling, PPE)
  – User Availability (Intramural only? Extramural? Public access?)
NIH Disaster Research Response (DR2)

Data Science @ NIH

Disaster Research @ NIH
Backbone/Functional Platform

NIH Resources
DIMRC
DR2

Data
• Tools/Surveys/Instruments
• DataSets
• Common Data Element Repository (for standardization)

Literature
• PubMed
• PubSci
• Disaster Lit
Disaster Health Information Types

Peer-reviewed scholarly literature
- Journal articles
- Books
- Data

“Grey” Literature
- Reports
- Guidance documents
- Summaries
- Surveillance data
- Training materials
- Conference proceedings
- Databases
- Datasets
Open Access Repositories for Scholarly Literature

- **PubMedCentral**
  - All HHS agencies
  - NASA
  - NIST
  - EPA
  - DHS

- **Other Repositories**
  - Agriculture: PubAg
  - Defense: DTIC
  - Energy: PAGES
  - Transportation: NTL
  - NOAA: NOAA Repository
  - NSF: NSF Repository
  - USGS: USGS Publications Warehouse

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Research Methods in Child Disaster Studies: A Review of Studies Generated by the September 11, 2001, Terrorist Attacks; the 2004 Indian Ocean Tsunami; and Hurricane Katrina

Betty Pfefferbaum, Carl F. Weems, [...], and Amarsha Chakrabortty
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<td>Guideline/Assessment Tool</td>
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Data Science @ NIH

• NLM to be *epicenter* for data science @ NIH

• NLM Director is Acting NIH Director for Data Science

• Purpose of data science is to *accelerate discovery*
  • What data to collect? All pictures of your kids or a select set in an album?
  • Just as NLM determines what literature to select; will need to determine what data to collect and preserve
Data Science @ NIH

Follow the **FAIR** Principles

Findable, Accessible, Interoperable, Reusable

- PubMed Central to accept datasets in Fall 2017
- ClinicalTrials.gov already contains research results
- Promote Standards
Common Data Element Repository

A repository for electronic data capture instruments and forms recommended or required by NIH institutes and centers

- Search and find tools
- Export existing tools
- Build your own tool
- Standards
  - SNOMED CT, LOINC, RxNORM
Common Data Element Repository

RAPIDD
New Section
1. First Name
2. Last Name
3. Address
4. Current city
5. Current state
6. Current zip code
7. Age
8. Marital status
   - Are you married, have you ever been married or lived with the same partner for at least six months?
   - Single, has never married or lived as married

Passive Smoke Exposure Protocol
9. Time and location of passive smoke exposure [PhenX]
   - During childhood at home
   - During adulthood at home
   - During adulthood at work
   - During in social settings such as bars, restaurants, bowling alleys, bingo halls, and friends’ home
10. Were you exposed to smoke from other people’s cigarettes or tobacco products during childhood at home?
    - Yes
    - No
11. For how many hours per day?
Building Infrastructure for Research Response: Repository
*Surveys, Questionnaires, Protocols, Guidance, Forms*

- New tools identified from new literature review (2013-2016) and are in process of being added to the online repository

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<td>Social Support/Resiliency</td>
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<td>Specific Disasters</td>
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<tr>
<td>Lifestyle/Quality of Life</td>
<td>74</td>
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<tr>
<td>Mental Health/Cognitive Function</td>
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NIH DR2 Tools - Compiling Metadata for Repository

- Short Description and # of Items
- Purpose and Uses
- Mode of Administration
- Time to Administer
- Population of Interest
- Existence of Validity Studies
- Languages/Reading Level
- Special Interviewer Training
- History of Use in the Disaster Setting
- Professional Admin Requirements
- Ease of Use in Disaster
- Availability

Improvements under way:
- Tools: downloadable files (MS Word & EpiInfo) for paper or electronic entry
- Improved searching and sorting into categories
- Creation of Survey Builder functionality using EpiInfo
Rapid Acquisition of Pre/Post Incident Disaster Data (RAPIDDD) Protocol

- Reduce the time it takes to initiate data collection
  - Pre-reviewed by IRB (*NIEHS IRB provisional approval granted May 2015*)
  - Standardized methods using established instruments
  - Pre-positioned study documents, questionnaires, supplies, and staff

- Initial Goal: Timely research of cohorts involved in disasters
  - Contact information for cohort development
  - Gather early survey information
IRB Approval Before Initiating Study

- **Specifications of the disaster submitted to IRB for approval before starting study**
  - Research setting
  - Sample size
  - Accrual duration
  - Procedures
  - Questionnaires
  - Outcomes of interest

Grantee Protocols:
- UTMB
- University of Iowa
DISASTER RESEARCH CAFÉ

BIOSPECIMEN COLLECTION

PROTOCOL SURVEYS

IRB ETHICS

SENDORS

CLINICAL TESTS

ENVIRONMENTAL SAMPLING

RESEARCH EMPOWERMENT
EXPOSURE SUPPORT
COMMUNITY ENGAGEMENT SUPPORT
COMMUNICATIONS SUPPORT
DATA MANAGEMENT SUPPORT
IRB GUIDANCE
TRAINING MATERIALS
Developing Training Materials, Field Guides, Go Kits

RAPIDD
Rapid Acquisition of Post-Incident Disaster Data Study

Procedural Reference Guide

Version 0.1
March 05, 2014

Biospecimen Collection
BREAK

Watch the DR2 Video from 2016

https://tools.niehs.nih.gov/wetp/index.cfm?id=2574#DR2
Creating the Vision for Federal Disaster Research
Vision: Science-based Disaster Preparedness, Response, and Recovery

INTEGRATION

Guidelines
Protocols

National Frameworks
Laws
Policies

Empowerment

Engagement

Collaboration
Coordination
Communication

Training
Funding

Pathways
Platform
Pillars
Vision: National Disaster Research Framework

- Guide coordination of cross-agency resources
- Develop polices & procedures for research responses
- Facilitate time-critical disaster research through strategic funding & infrastructure development
- Allow for integration into National Response & Recovery Frameworks
- Allow for the development of trans-disciplinary research enterprise focused on supporting disaster preparedness, response, & recovery
- Create cross-disciplinary training & sustainable career paths
Facilitated Discussion: Moving Forward
Short & Longer Term Opportunities

Integration
Coordination
Collaboration
Communication

Empowerment
Engagement
Training
Funding
Empowerment

- Processes to collectively understand research needs & gaps?
  - Website and platforms for all to use to support research?
  - Shared publications /articles on Disaster Research?

- Besides grants and posting of tools, how do we empower others to conduct disaster research?
  - Which groups are we targeting?
  - How do we measure our efforts? How do we go from theory to practice?
  - How do we incorporate technology to empower and engage?
  - Should we develop a “best practices” document for use by others?
Engagement of Stakeholders

• Who are the NGO stakeholders most likely to engage?
  • What is in it for them?
  • Is our engagement one of support, or something else?

• Do we have best practices for engagement?

• What progress have we made with citizen science?

• How do we promote local and private industry engagement?

• How to engage healthcare facilities & how to share patient data?

• How do we measure the impact of our engagement efforts?

• What are the goals and objectives for engagement?
Variety of Collaborations- Citizens & Researchers

- Environmental Measurements
- Community & Personal Exposures
- Research
- Education
- Technology
- Individual Health
Training

• How do we train and assist researchers (intramural & extramural)?
  – Understanding emergency response management?
  – Effective integration into response organization(s)?
  – Health and safety?
  – Effective use of tools, protocols, data management, risk communications?

• Who needs training?

• What is the curriculum?

• How is training best delivered?
Extramural Funding

- Can disaster research be written into grants, incl. SBIR?
- How can funding be coordinated across departments?
- Funding examples:
  - NSF Smart and Connected Health FOA
  - NSF RAPID funding mechanism
  - NIH mechanisms, supplementals, contracts
  - CDC fast track funding mechanism
Next Steps

• On-going communications with this group
• Common Disaster Research Briefing Slides
• Disaster Research Best Practice Guidance Document
• Other
Thank You!

http://dr2.nlm.nih.gov/