Welcome to AAHRPP's July 2021 Webinar:

Protecting Research Participants During Emergencies

2021 AAHRPP Educational Webinar

Upcoming 2021-2022 Webinars:

October/November 2021: *Health Literacy in Research*

February 2022: *Successful Tools for Evaluating IRB Members*

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Save the Date for this IN-PERSON Event!!!

2022 AAHRPP Annual Conference

Grand Hyatt Denver, Colorado

May 24-26, 2022

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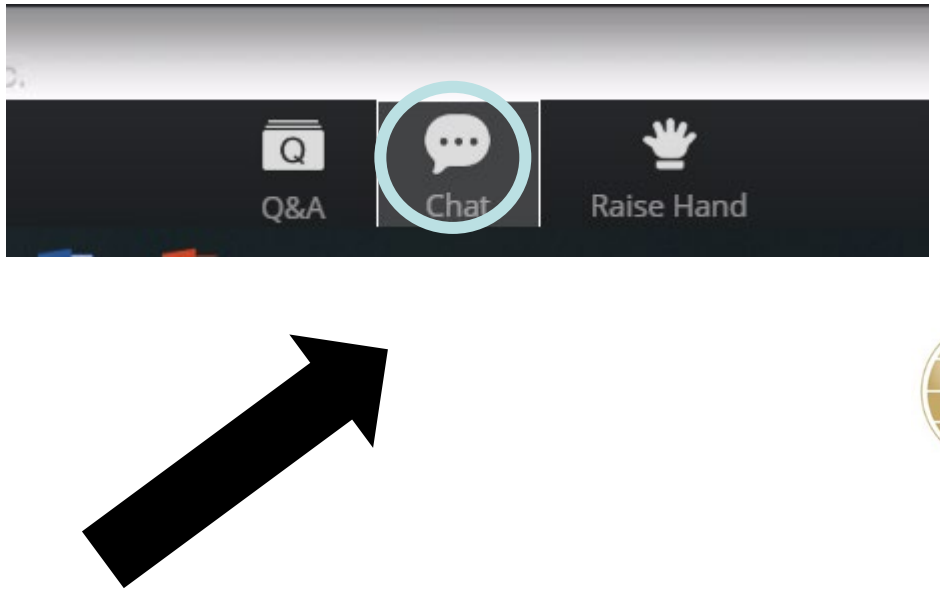
Technical Issues During the Webinar?

To ask Zoom-related technical questions, use the “Chat” icon



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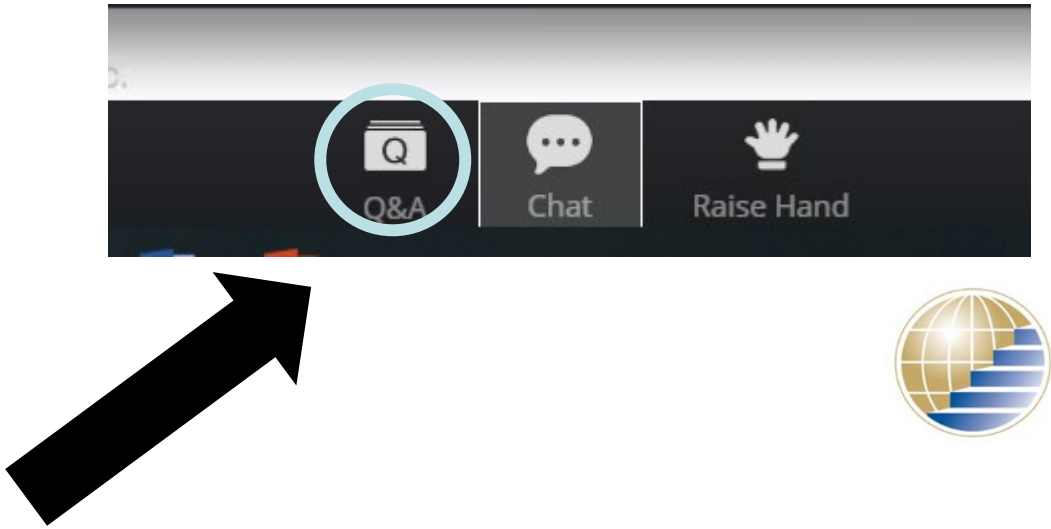
Questions for the Presenters?

To ask questions about the topic for the presenters, please use the "Q&A" icon:



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Presenter Introductions

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Nichelle Cobb, PhD

Senior Advisor for Strategic Initiatives

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Stephanie Henderson, CIP

HRPP Manager and IRB Administrator

Ochsner Clinic Foundation

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Association for the Accreditation of Human Research Protection Programs, Inc.®

Robert Hood, PhD

Director of Accreditation and Global Outreach

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Megan Kasimatis Singleton, JD, MBE, CIP

Assistant Dean, Human Research Protections and
Director of the HRPP
Johns Hopkins University School of Medicine

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Goals

Describe how emergencies may affect research programs

Identify collaborative strategies to implement and maintain emergency preparedness plans for HRPPs

Introduce new AAHRPP Element I.1.H. on emergency preparedness

Time for a poll

Does your organization have an emergency preparedness plan that includes provisions for research?

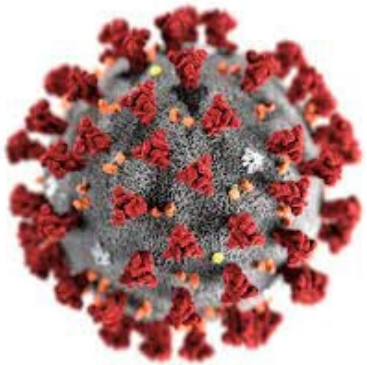
- Yes
- No
- I don’t know

ELEMENT I.1.H.

ELEMENT I.1.H.	The organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency.

AAHRPP Element on Aiding Preparedness (ASAP)

- Need to ensure sustainability of the HRPP during emergencies



General Principles

- Ensuring the safety and wellbeing of research participants is paramount
- Emergency preparedness is an integral part of the entire HRPP
- Organizations ensure sustainability of the HRPP
- As with all Standards and Elements, organizations have flexibility in how to meet this new Element

ELEMENT I.1.H.

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) The HRPP has an emergency preparedness and response plan, appropriate to the size and complexity of the HRPP, that addresses how continuity of operations will be maintained to ensure human participant protections during an emergency. (Element I.1.A.)

(b) The emergency preparedness and response plan is periodically evaluated and, when necessary, adjusted to ensure continuity of operations.

(c) Organizations provide education about the organization's emergency response and preparedness plan for IRB members and staff, researchers and research staff, and other persons in the HRPP. (Element I.1.E.)

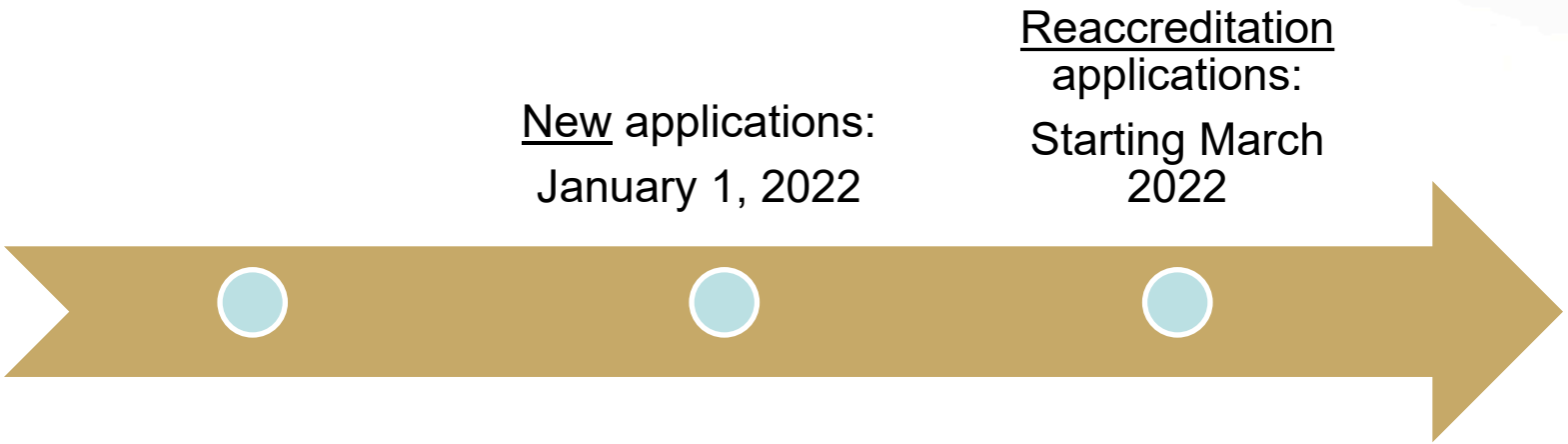
(d) Persons in the HRPP are knowledgeable about the organization's expectations during emergencies.

Tip Sheet 29: Emergency Preparedness and Response

Related Accreditation Element I.1.H.: The organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency.

- Practical examples
- Emerging best practices
- Flexibility

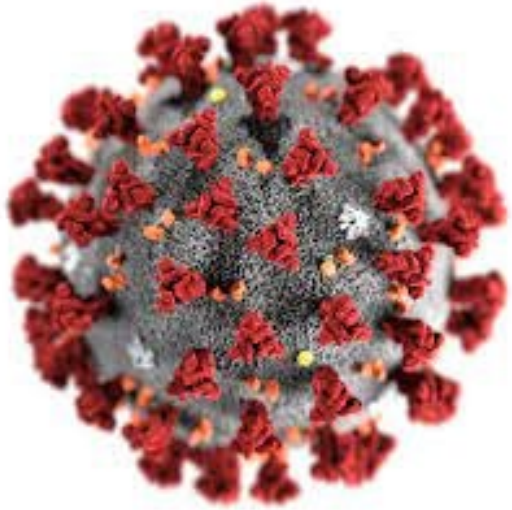
Timeline for review of policies



Getting Started

- Preparedness involves developing flexible plans that define a process for responding to emergencies (all-hazards approach)
  - Identify key questions
  - Describe a process to respond
- AAHRPP will focus on your plans and processes for responding
  - Emergencies involve uncertainty, may require immediate decisions, and guidance may be inconsistent and change rapidly, and there are limits to how much organizations can prepare in advance

What are emergency situations you can envision that could affect research in addition to hurricanes, cyberattacks, and pandemics?




SWELTERING HEAT
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PALM SPRINGS
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PHOENIX
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ALBUQUERQUE
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DALLAS
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TEXAS


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Emergency Planning for Research

- Both natural and man-made disasters can lead to urgent and severe humanitarian situations, including disruptions in (Jacobsen 2014,347-60):
  - Water supply, sanitation, and hygiene
  - Food security and nutrition
  - Shelter and essential non-food items
  - Essential health services for treatment of injuries and diseases, including psychological disorders

Emergency Planning for Research

- Examples of natural disasters:
  - Weather-related disasters: floods, landslides/mudslides, hurricanes/typhoons, tornadoes, winter storms
  - Geophysical disasters: earthquakes, tsunamis, volcanic eruptions
  - Climate-related disasters: droughts, extreme heat, extreme cold, wildfires/forest fires
  - Biological disasters: pandemic disease

Emergency Planning for Research

- Examples of man-made disasters:
  - Intentional: war, genocide, terrorism, refugee crisis (generally in international settings with unstable political environments)
  - Non-intentional: transportation accidents, hazardous materials incidents, utility failure, industrial accidents, explosions/fires, structural collapses (for example, a levee breach)

Emergency Planning for Research

- In terms of research administration, disasters may cause the following disruptions that should be anticipated, planned for, and mitigated:
  - Disruption to energy grids leading to large scale and sustained power failures
  - Disruptions to routine telecommunications systems
  - Destruction of back up telecom and energy systems
  - Destruction of physical facilities

What are the key tools you need for plan development?

- Leadership/Governance
- Communication
- Resources
  - Consider all Domains
    - Organization
    - IRB
    - Researchers

Consider a Proactive Risk Assessment

- What are the likely threats to the organization? To research specifically? To the community from which research participants might be drawn?
- How might these threats be mitigated?
- Can you leverage existing emergency response planning efforts to develop your HRPP plan?

Leadership & Governance

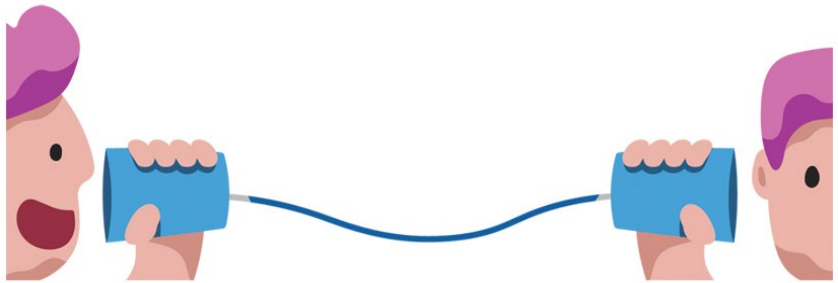
- Leadership and Governance
  - Mitigation: Committees, Task Forces to identify risks and prevention strategies
  - Preparedness: Planning committees
  - Response: Incident command, implementation
  - Recovery: Debriefing, rollback to “normal”, financial recovery, roll back into Mitigation

Leadership & Governance

- How does your IRB/HRPP fit into your organizational leadership/governance structure?
  - Seat at the table
  - Separate HRPP leadership/governance structure that implements organizational requirements?
- Who makes critical research decisions?
- Have an awareness of the various governing entities that may impact your HRPP decisions
- Create clear decision trees so staff/IRB members know who will be communicating decisions

Communication

- What are the most effective tools for different emergency situations
  - Email
  - Phone/text
  - Meetings [including virtual]
  - Centralized web resources



- What back-ups are in place when traditional communication channels are challenged?
- How do HRPP/IRB communication channels feed into organizational emergency communication channels?

Resources

- Access to Electronic Systems
- Access to Records
- Mechanisms to conduct business virtually including IT support
- Ability to hire temporary employees
- Ability to purchase emergency supplies

Resources: HRPP Specific Needs

- IRB membership structure that allows for use of alternates
- Flexibility to accommodate time sensitive reviews
- Agreements with other IRBs to enable transfer of review responsibility in an emergency
- HRPP Community- HRPP Colleagues may have solutions in place /be able to share ideas

Encourage Researchers to Have Emergency Plans

- Should research teams collect emergency contact information from participants?
- Should they have plans for common research interruptions, such as evacuations for hurricanes?
- Should they have specific SOPs for ensuring safe storage of biospecimens or data backups, including for regulatory binders

Leverage Regulatory Flexibility

- Consult with federal regulatory agencies or accreditation bodies about maximizing regulatory flexibility
- Consider what may be put in place for regulated vs. unregulated research
- Monitor for any situational flexibility or guidance issued by federal agencies

Consider Preservation of and Ongoing Access to Records

- How will you ensure continued access to IRB and other HRPP records, both paper and electronic?
- How will researchers ensure continued access to research and applicable clinical records for participants?

Consider Effects on Study Logistics

- Could there be supply chain interruptions that would affect availability of investigational articles or equipment needed to conduct the research or monitor participant safety?
- How will participant safety be monitored if treatment procedures or study visits must be delayed or stopped?

How Research Priorities will be Identified

- Should some research be paused or discontinued and what criteria will be used?
  - Should it depend on the preparedness of the researcher?
  - Should it depend on the type of research (clinical studies, studies involving records, social and behavioral interventional studies)?
- Who will make these decisions?
- When should you will you evaluate what research should continue and what criteria should be used to re-open research?

Modifications to Research Studies

- During extended emergencies, instead of stopping all research, might there be things researchers can do to continue some research activities?
  - Pause recruitment of new participants but continue with existing participants?
  - Use alternate approaches – instead of in-person visits, can researchers use remote study visits, or video interviews?
- Could you develop procedures for researchers in advance of extended emergencies in coordination with the IRB?
  - Can you define the types of changes that require prospective IRB approval?

Consider the Effect on Research Personnel

- Lay offs and furloughs can affect staffing
- Safety and other logistic concerns which prevent staff or research participants from traveling or accessing buildings
- Post-traumatic stress and other mental health challenges can affect how people respond and their availability

Partners

- Who might be available as partners to help you respond?
  - For clinical research – Local hospitals? Regional hospitals?
  - Other IRBs? Independent IRBs?
  - Government agencies? State regulatory agencies?
- What agreements may need to be established in advance of an emergency to enable these partnerships?
- Have liaisons in likely partners been identified?

Education and Training

- How will you provide education in advance of an emergency?
- Who needs to be educated and trained?
- Could education include exercises where people meet and test out the plan using different emergency scenarios? Could this help people experience the types of decisions they may face during an actual emergency?
  - Examples:
    - Mock Emergency IRB Reviews
    - Practice use of Emergency Communication Channels
    - HRPP Stakeholder Meeting to “Test” Emergency Preparedness Plan

Planning for and Learning from Emergencies

- Could your organization develop “draft” or “template” research protocols in coordination with the IRB in advance of possible future emergencies?
- How might you record what everyone has learned in a way that can inform research during future emergencies?
- What best practices for research administration and conduct can be adopted from what occurred in response to an emergency?
- Could you create working groups of researchers to develop strategies for alternate ways of conducting research during emergencies?

After the Emergency

- Who might be involved in evaluating your HRPP's response?
- How can you communicate what you have learned and retain organizational knowledge of your experiences?
- How often should you evaluate your emergency response plan?

Lessons Learned from Developing a Plan through the COVID Emergency: The Johns Hopkins Medicine Experience

- Prior to COVID relied on organizational emergency preparedness planning efforts
  - Dedicated team members participated in standardized exercises and were point persons for the office
  - Systems were able to accommodate remote work but work was primarily conducted in person
- Complex University system with three distinct IRB offices
- HRPP includes research locations in Maryland, DC and Florida
- Planning was largely office and function focused rather than emergency focused

What worked

- “Command Team” for decisions related to research with human participants
  - Initially met daily and then less frequently as the pandemic proceeded
- Close integration to critical stakeholders
  - Hospital Infection Control, COVID Prioritization Committees, COVID Steering Committee
- Centralized web presence on IRB website where all new COVID-related information could be found

What worked

- Nightly Notifications to IRB Staff
  - Pointed out “new” information released that day
- Emergency Response IRB
  - First met in March 2020 and met daily
    - 129 meetings held since March 2020
    - 553 new COVID-related protocols reviewed
- Flexibility in requesting and securing approval for additional resources
  - Zoom accounts
  - Temporary part-time employees to assist with research restart
  - Support for Emergency Response IRB

What worked

- Regular Assessments of COVID impact
  - “Pulse” surveys of investigators throughout the process of Research Restart
  - Research Participant Satisfaction Survey for COVID-related research
  - Availability to address stakeholder concerns

What didn’t work as well

- Terminology mattered- Began with a “tiered” approach to research ramp-down and eventually had to change to “phases” to align with state guidelines and university terminology
- Systems could not easily identify types of studies that should be paused/eligible for restart
- Communication channels became less effective over time as many systems were using similar channels

Considerations for Future Planning

- Emergency planning will be incorporated into regular HRPP evaluation/planning activities
- HRPP emergency preparedness is distinct from general emergency preparedness activities- there are unique HRPP considerations that must be addressed
- Stakeholders in emergency preparedness will be constantly reevaluated- new HRPP partners were created through the COVID emergency

Disaster Planning for Research

- Emergency preparedness and response includes four steps, sometimes referred to as the "4 Rs:"
  - *Reduction (mitigation) of risks*: develop preemptive measures to protect people and property.
  - *Readiness (preparedness)*: create and refine emergency operation plans, establish an emergency communications infrastructure, and train public employees and response volunteers (emergency research institutional plans).

Disaster Planning for Research

- *Response*: provide emergency medical assistance, shelter, and other critical services. It is important to have a command center for coordination of information and resources. For example, for Katrina, the Ochsner command center was located in Baton Rouge.

- *Recovery*: efforts should focus on rebuilding affected communities. It is important to engage with municipal, county, and state emergency agencies, as well as the Federal Emergency Management Agency (FEMA) and other governmental agencies to make sure the research community has the resources, including financial, to continue to study and conduct research until the organization is back up and running.

Some Lessons from Hurricane Katrina

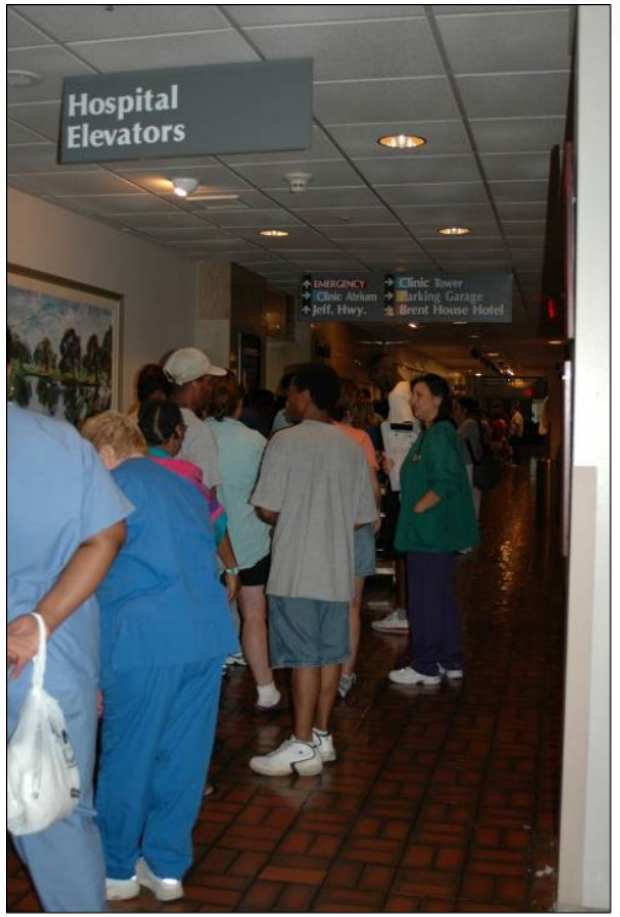
- Be mindful of paper record storage
  - Some records destroyed due to flood water
  - Other records affected by mold and mildew
- Decentralize record storage and create a plan for backing up records
  - Use electronic records when possible (but other types of emergencies might encourage paper record back ups)

1. The Katrina Experience

The Katrina Experience

August 26-29, 2005

- Friday 8/26: Katrina on path to Florida
- Saturday 8/27: Katrina turns west toward LA and MS
- Sunday 8/28: Mandatory evacuation of NOLA and Gulf Coast Region
  - Team A ordered to report to the Ochsner Main Campus in New Orleans
  - Team B ordered to report to the Baton Rouge facility



The Katrina Experience

From the National Hurricane Center:

- “While the intensity of Katrina was Category 3 as the center of the eye made its closest approach (about 20 n mi) to the east of downtown New Orleans, the strongest winds corresponding to that intensity were likely present only over water to the east of the eye. The sustained winds over all of metropolitan New Orleans and Lake Pontchartrain likely remained weaker than Category 3 strength.”

http://www.nhc.noaa.gov/pdf/TCR-AL122005_Katrina.pdf

The Katrina Experience

The Katrina Experience

The Katrina Experience

The Katrina Experience

The effects on institutions, government infrastructure:

- The Federal Government could not mobilize and be very useful for weeks within the disaster zone
- Parts of the State of Louisiana and all of the local government infrastructure was destroyed: communications, police, water, sewage, electricity – weeks to months to return. Many years for housing to recover.
- Local institutions were on their own
  - Ochsner: their own independent trunk lines for communications, water wells, generators, armed security = could continue to operate
  - Most other local institutions had to abandon ship

The Katrina Experience

- At Ochsner, a virtual IRB was up and running within a week with ability to have convened meetings
  - Baton Rouge Research Command Center (RCC)
  - IRB Chair on campus in New Orleans
  - Communications with sponsors, Feds, research staff, subjects
  - But…research staff were scattered and months to be ready to submit CRs and reports to the IRB

- Most other local IRBs were part of an institution that collapsed for months, and they were not able to function adequately till their institution was able to

The Katrina Experience

- Subjects scattered around the country with significant risk investigational devices implanted, or on investigational drugs
  - Not knowing how to reach their investigator
  - Missing all the windows for next visit and monitoring
  - Subject safety issues in many SOC + agent trials
- Clinical investigators with
  - Subjects' home and cell phone numbers that do not work, no way to contact their subjects
  - BR Research Command Center Clearing House

HRPP Emergency Preparedness

- Before an emergency event…
  - ✓ Ensure up-to-date list of research subjects is maintained with all contact information
  - ✓ Provide research participants with a contact number for study personnel
  - ✓ Update the contact list for all research study staff and distribute to all study personnel
  - ✓ Coordinate an alternative site to conduct study visits, if feasible
  - ✓ Have a pre-arranged plan with the study Sponsor for securing study samples, investigational product and research data
  - ✓ Ensure clear procedures exist to secure and access investigational drugs and devices

HRPP Emergency Preparedness

- Before an emergency event…
  - ✓ Establish a process to un-blind studies and to provide investigational drugs for treatment purposes, if appropriate
  - ✓ If possible, establish partnerships with other academic institutions so collaborative emergency sites are available
  - ✓ Secure all clinical trial research records, both paper and electronic format
  - ✓ Backed up and retrievable from a remote location
  - ✓ Paper records in a safe and dry location

HRPP Emergency Preparedness

- Immediately before an emergency event…
  - ✓ Contact research participants and provide direction regarding any medications or study visits
  - ✓ Confirm participant contact information
  - ✓ Complete as much study activity as possible in advance of the event, within the constraints of the protocol
  - ✓ Follow the pre-arranged plan to securing study samples, investigational product and research data

HRPP Emergency Preparedness

- During the emergency event
  - ✓**<u>Be safe and take care of your family</u>**
  - ✓Ensure the safety of clinical trial staff and participants
  - ✓Follow the lead/direction of the Sponsor/other clinical sites in moving participants to other areas

HRPP Emergency Preparedness

- Following the emergency event
  - ✓Confirm the safety of clinical trial staff and participants
  - ✓Verify the stability of the study participant's samples, study drug, data, etc.
  - ✓Contact the Sponsor to discuss any impact on the protocol
  - ✓Resume the protocol and timeline as soon as practical

HRPP Emergency Preparedness

- The objectives of a HRPP disaster plan should include the following:
  - Protect the capability of carrying out expedited and convened board reviews.
  - Ensure business continuity in U.S. Food and Drug Administration (FDA)-regulated studies where drugs or devices are involved.
  - Safeguard the capability of communicating with regulatory authorities.

HRPP Emergency Preparedness

The objectives of a HRPP disaster plan (continued..):

- Inform research subjects and principal investigators about proper procedures during emergencies or natural disasters with regard to their research drugs or devices, especially if an evacuation has disrupted normal research operations.
- Inform principal investigators (PIs) and the research pharmacist about proper procedures to unblind studies, if applicable, in an emergency or natural disaster.
- Protect identifiable health information of participants in clinical research.
- Maintain good communication within the HRPP.

HRPP Emergency Preparedness

- Institutional Review Board (IRB) chairs and/or designees are available to carry out required expedited reviews.
- The HRPP manager performs the following duties and responsibilities:
  - Prepares an emergency communications list of IRB members and staff with alternate contact telephone numbers and email addresses should they need to be reached in the event of an evacuation.
  - Prepares a newsletter to IRB members and staff explaining procedures for telephone meetings if regular meetings are disrupted due to evacuations as a result of an emergency or natural disaster.

HRPP Emergency Preparedness

- Established procedures to conduct meetings by electronic means (by phone or internet phone connection).
- Inform PIs prior to any evacuations on details for participating in teleconferences, if needed.
- Provide special emergency telephone numbers and emergency website for post-emergency or disaster research operations to all IRB members, staff, and PIs on all meeting agendas.
- Confirm with informational technology (IT) personnel that electronic systems are backed-up at an off-site location.

HRPP Emergency Preparedness

- The Executive IRB Chair will notify the FDA and when applicable, the Office for Human Research Protections (OHRP), external IRBs of record, and research sponsors of the potential impact on the organization's research operations if there is a specific threat (within 72 to 120 hours of the potential event).

HRPP Emergency Preparedness

- PIs should obtain updated emergency contact information for research subjects at study visits on a routine basis.
- PIs should also provide research subjects on clinical drug or device trials with an IRB-approved emergency/evacuation wallet card. The wallet card contains contact information for the investigator or study coordinator, the study protocol number, the participant identification number, and the HRPP toll-free telephone number.
- This card should be approved by any/all external IRBs with oversight responsibility for the trial.

HRPP Emergency Preparedness

- Don’t forget about the Office of Sponsored Programs!
  - Contracts stored electronically and backed-up. Or hard copies are appropriately stored
  - Study visit information available in CTMS
  - Ability to contact Sponsor’s if extended evacuation
  - Confirm with informational technology (IT) personnel that electronic systems are backed-up appropriately
  - Maintain regular communication with OSP & other research leadership

HRPP Emergency Preparedness

- And don’t forget about Research Pharmacy!
  - Update and have available Pharmacy Research Staff, Research leadership and Pharmacy leadership contact information.
  - Designate Pharmacy Research staff on both team A and B
  - Review with CRC all subjects that may be exhausting medication supply during evacuation
  - Ensure all critical electronic devices are using emergency generator power supply outlet
  - Test temperature data logger to ensure working accordingly to monitor temperature for excursions
  - Lift medications to higher shelves where applicable
  - Shipping supplies on hand if medication transport required.

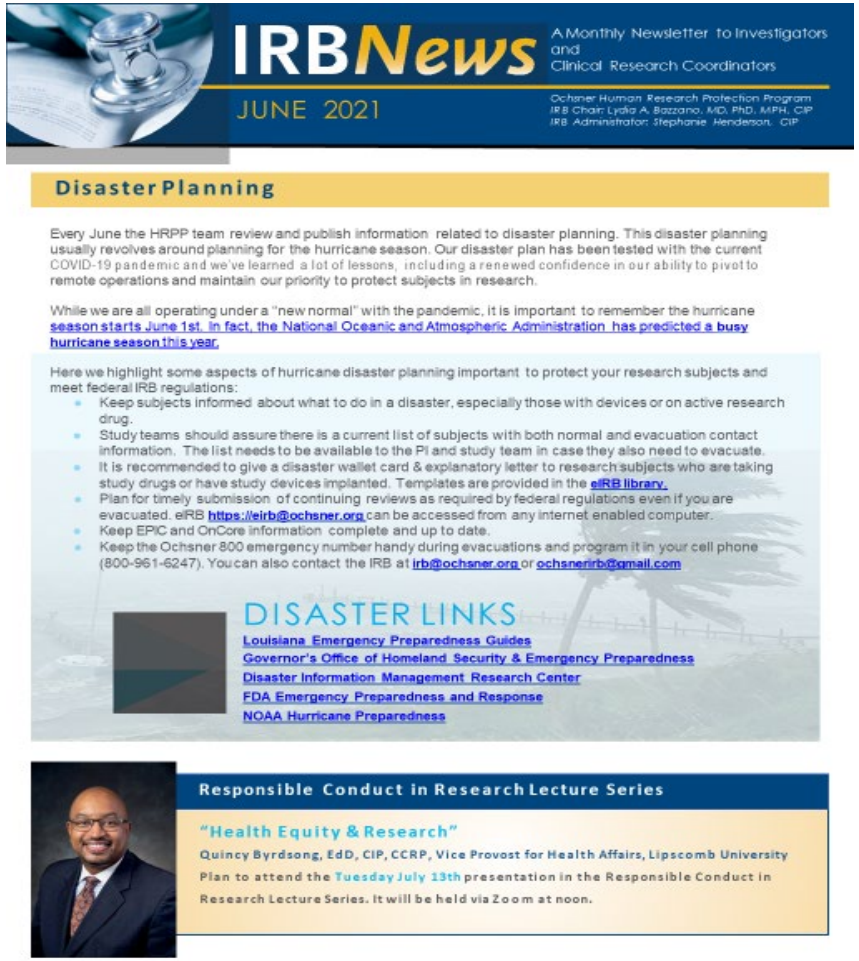
HRPP Emergency Preparedness

- Develop a disaster plan for your IRB/REC (RCC)
- **Integrate it with the institutional disaster plan**
- **Review it annually** with all stakeholders (HRPP, OSP, Pharmacy, Biosafety, etc)
- **Communicate it** well via an annual newsletter, memo, presentation
- Develop wallet cards & letters for subjects
- Develop checklists for investigators

HRPP Disaster Plan Resources

- http://www.getagameplan.org/index.htm
- Annual IRB Newsletter on Disaster Preparation - June
- Disaster wallet cards
- Disaster Subject Letters (drugs)
- Disaster Subject Letters (devices)

Annual IRB Newsletter



IRB*News*

A Monthly Newsletter to Investigators and Clinical Research Coordinators

JUNE 2021

Ochsner Human Research Protection Program
IRB Chair: Lydia A. Bazzano, MD, PhD, MPH, CIP
IRB Administrator: Stephanie Henderson, CIP

Disaster Planning

Every June the HRPP team review and publish information related to disaster planning. This disaster planning usually revolves around planning for the hurricane season. Our disaster plan has been tested with the current COVID-19 pandemic and we've learned a lot of lessons, including a renewed confidence in our ability to pivot to remote operations and maintain our priority to protect subjects in research.

While we are all operating under a "new normal" with the pandemic, it is important to remember the hurricane season starts June 1st. In fact, the National Oceanic and Atmospheric Administration has predicted a busy hurricane season this year.

Here we highlight some aspects of hurricane disaster planning important to protect your research subjects and meet federal IRB regulations:

- Keep subjects informed about what to do in a disaster, especially those with devices or on active research drug.
- Study teams should assure there is a current list of subjects with both normal and evacuation contact information. The list needs to be available to the PI and study team in case they also need to evacuate.
- It is recommended to give a disaster wallet card & explanatory letter to research subjects who are taking study drugs or have study devices implanted. Templates are provided in the eIRB library.
- Plan for timely submission of continuing reviews as required by federal regulations even if you are evacuated. eIRB https://eirb@ochsner.org can be accessed from any internet enabled computer.
- Keep EPIC and OnCore information complete and up to date.
- Keep the Ochsner 800 emergency number handy during evacuations and program it in your cell phone (800-961-6247). You can also contact the IRB at irb@ochsner.org or ochsnerirb@gmail.com

DISASTER LINKS

Louisiana Emergency Preparedness Guides
Governor's Office of Homeland Security & Emergency Preparedness
Disaster Information Management Research Center
FDA Emergency Preparedness and Response
NOAA Hurricane Preparedness

Responsible Conduct in Research Lecture Series

"Health Equity & Research"

Quincy Byrdsong, EdD, CIP, CCRP, Vice Provost for Health Affairs, Lipscomb University

Plan to attend the Tuesday July 13th presentation in the Responsible Conduct in Research Lecture Series. It will be held via Zoom at noon.

Disaster Subject Letter

Ochsner
Health System

Dear Research Participant:

Thank you for participating in a research study at the Ochsner Clinic Foundation. As a participant, we want to ensure that you are able to maintain communication with the research team in case an emergency or natural disaster causes an evacuation of your local area.

Should an evacuation be necessary, maintaining contact may allow the research team:

- to assist you in getting your study drug and/or managing your device
- to assist any health care provider caring for you at a distant location
- to provide you with answers to any questions you may have.

In order to help you contact your Research Team, **Ochsner has created an emergency information disaster line at 800-961-6247. Please call this number as soon as you safely reach your destination.**

Ochsner will make every effort to have a staff member available to answer these calls. If that is not possible, a voice mail system will answer and record your message. Please leave your name, the name of your research physician, and a contact number where you can be reached. Ochsner Personnel will contact you as soon as possible.

Please have this letter and/or the wallet-sized card with your study information handy. This will allow you to provide Ochsner personnel with the information needed to best assist you.

Principal Investigator:
Research Coordinator:
Study # (IRB#):
Sponsor Name:
Sponsor Phone #:
Protocol Title or #:
Subject ID #:

If you have any questions, please feel free to talk to your research physician or study coordinator.

Sincerely,

The Ochsner Research Team

Disaster Wallet Cards

- Give to each research subject
- Provide toll free number to the research command center
- Study title, PI, Sponsor
- Discuss with subjects ahead of time what to do in a disaster (letter given)
- Obtain evacuation contact information from each subject

Discussion & Questions

Thank You!

Contact AAHRPP with questions:

About the Webinar:

events@aahrpp.org

About the new Element:

accredit@aahrpp.org

Phone: 202-783-1112