



Office of Public Safety and Emergency Management

Developing an EM Plan

Bob Chamberlain

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Tools we have:

- University EM Guidelines
 - Appendices and Operational Annexes
- Safety.pitt.edu
- Pitt Business Continuity Plan



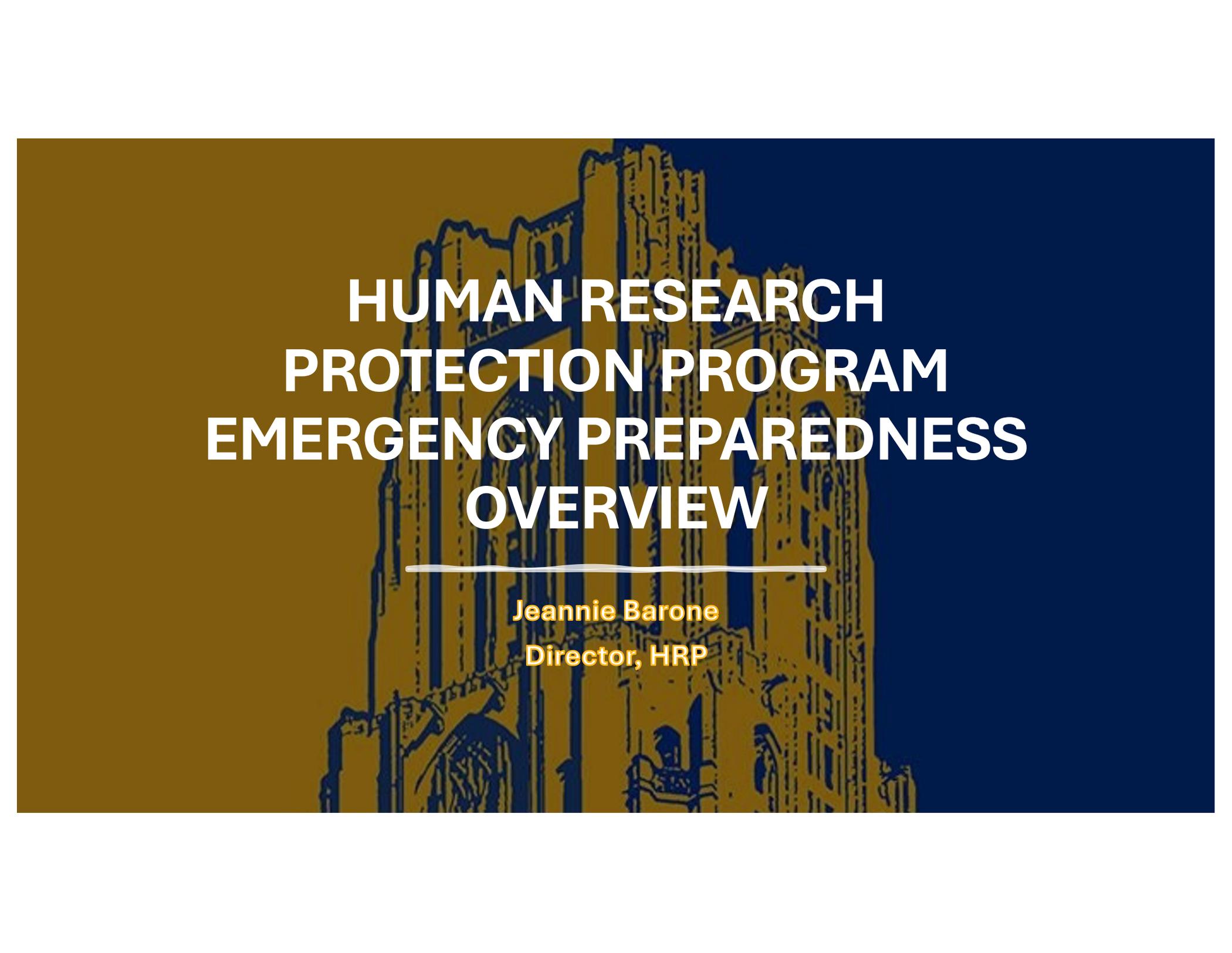
Where do we start? (Prep)

- Assemble a Team (Key People)
- Review the Pitt EM Guidelines
- What is our goal? Guidelines, SOP, or Execution Matrix
- What level are we addressing? Strategic or Operational
- Can we reach out to other research institutions?
- Are there any internal plans or templates we can use? Business Continuity Plan?
- AI Options
- Who will manage the plan?



Develop the plan

- Simple is best
- CONTACT INFO!
- If this is a campus wide emergency, where do we fit in regarding priorities?
- Criteria to activate this plan



HUMAN RESEARCH PROTECTION PROGRAM EMERGENCY PREPAREDNESS OVERVIEW

Jeannie Barone

Director, HRP

AAHRPP Element I.1.H

What does the Element require?

- The organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency

Why is it important?

- Emergency preparedness & response should be an integral part of the entire HRPP
- Ensuring the safety & wellbeing of research participants is paramount
- A risk-based emergency preparedness and response plan should exist to ensure sustainability of the HRPP to ensure the rights & welfare of research participants are protected



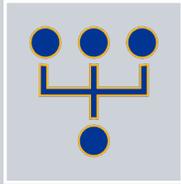
The University of Pittsburgh HRPP has been accredited since 2005

AAHRPP Element I.H

The Element includes four essential requirements:

1. The HRPP has an emergency preparedness plan, appropriate to the size and complexity of the HRPP
2. The plan is periodically evaluated and, when necessary, adjusted to ensure continuity of operations
3. Organizations provide education about their emergency response plan for IRB members, staff, researchers, and other members of the HRPP
4. Persons in the HRPP are knowledgeable about the organization's expectations during emergencies

Applicability and Scope of HRPP Plan



The HRPP consists of individuals, administrative units, and committees with responsibilities for human research protection



The HRPP Emergency Preparedness Plan is a component of the University's Institutional Emergency Plan



The emergency preparedness and response plan will be followed when a situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent

Who is Responsible for the Plan?

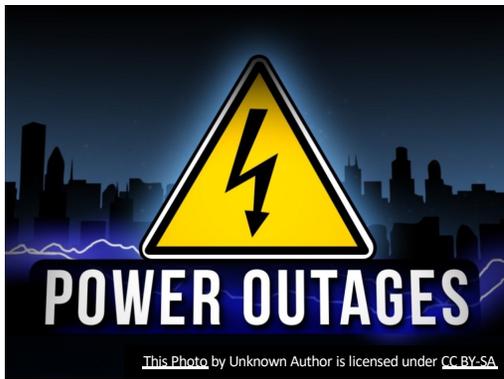
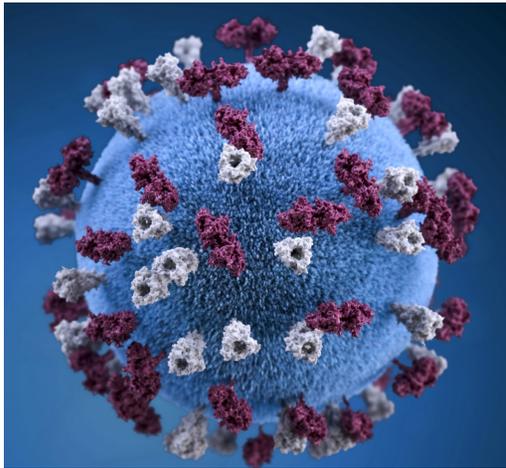
HRP Leadership

Institutional Official – Bill Yates, PhD, Vice Chancellor for Research Protections

Senior Vice Chancellor for Research

Senior Vice Chancellor for Research, Health Sciences

Office of Public Safety/Emergency Management



Identifying Potential Emergencies/Disasters

There are a number of emergency scenarios that could affect research. The HRPP identifies and prepares for a wide range of emergency scenarios that could impede the normal conduct of human subject research, each requiring tailored response mechanisms.

Purpose and Scope of the HRPP Emergency Preparedness Plan

1

Ensuring protections for participants enrolled in research

2

Ensuring the ability of the HRPP to continue to function

3

Ensuring the ability of the IRB Committees to continue to operate

4

Ensuring a coordinated emergency response across the University



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Considerations for the HRPP

Risk Based Assessment

Office Operations

IRB Functions

Responses to Emergency

A risk-based approach will determine how and when studies may continue

Consideration will be given to types of research that may continue and the types of research that may need to be temporarily postponed:

- Permitting studies which present a likelihood of direct benefit to participants or those where stopping study interventions may be harmful
- Postponing studies which may have an adverse impact on resources required to address the emergency

HRP Operational Concerns



HRP Staff is remote and would continue to work as threats & hazards allow



PittPRO and other electronic systems are hosted at a facility with state-of-the-art back up systems, technical capabilities & redundant power sources



Use of flexibilities for non-federally funded studies



IRB meetings will continue to be held via Zoom or other teleconference.



In absence of an IRB meeting, IRB Chair determines continuance, if in subjects' best interest



Potential for transfer to alternate IRBs should an emergency be ongoing



Considerations for Research Teams

- Assessing Emergency Needs
- Contingency Planning
- Collaboration and Compliance
- Facility-Specific Considerations

Researcher Considerations: Planning

When might a study-specific plan be necessary:

- The study involves in-person interactions
- The study cannot be carried out as approved by the IRB while adhering to institutional emergency requirements

Plan Complexity:

- Consider emergency type, study type and associated risks
- Sponsor requirements for emergency management plans
- Institutional directives that are more restrictive than a sponsor's must be followed

Researcher Considerations: Participants

Recruitment and Enrollment

- Consider pausing recruitment or enrollment.
- Add or revise screening procedures (e.g., infectious outbreaks).
- Use alternate locations or remote enrollment when appropriate.

Communication Plans

- Maintain updated participant contact information.
- Develop participant communication plan: what, who, when, how to communicate changes.
- Update and distribute staff contact lists; store securely off-site.

Researcher Considerations: Safety

Alternative Operations

- Identify alternative sites for study visits.
- Shift to phone/virtual visits or local labs as needed.
- Coordinate secure handling of samples, investigational products, and data with sponsors.

Unblinding and Drug Access

- Establish unblinding procedures for emergencies.
- Confirm procedures for securing and accessing investigational products.
- Consider direct-to-patient shipping or home administration options.

Secure Records and Equipment

- Protect trial records; document processes.
- Back up electronic records; store paper records safely.
- Secure sponsor-provided or study-specific equipment.

Researcher Considerations: Administrative

Form Collaborative Partnerships

- Partner with other institutions for emergency sites.
- Ensure approvals for local labs and reliance agreements.
- Identify alternate locations for monitoring visits.

Research Records and Documentation

- Document changes in study conduct, duration, and participant impact.
- Document reasons for missing assessments due to EOD.
- Document FDA consultation for protocol changes where required.

IRB Notification and Approval

- If change eliminates immediate hazards: take action and notify IRB within 5 business days.
- Otherwise: submit amendment to IRB prior to implementation.

Final Thoughts

- Emergency preparedness is a shared responsibility across the entire research enterprise
- Consistent communication is key
- Research participant safety is a cornerstone of the response plan
- If everyone works together, we will get through the situation

Questions?

Resources:

- OHRP: [Effects of Disasters on Human Research Protections Programs Guidance](#)
- FDA: [Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies](#)
- Chapter 28 - [Response Plan for Emergencies-Disasters Impacting the Human Research Protection Program \(HRPP\)](#)
- University of Pittsburgh [Emergency Management Guidelines](#)



Disaster preparedness in animal facilities

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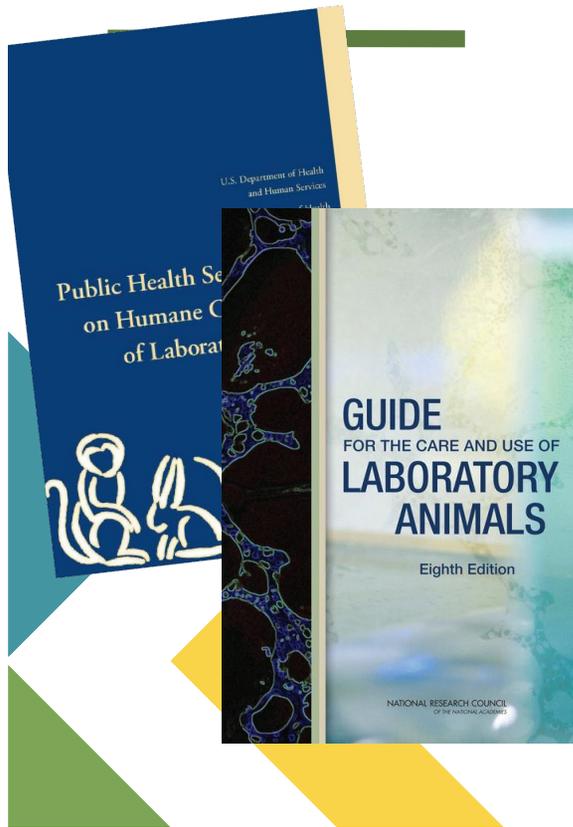
What researchers need to know about disaster preparedness



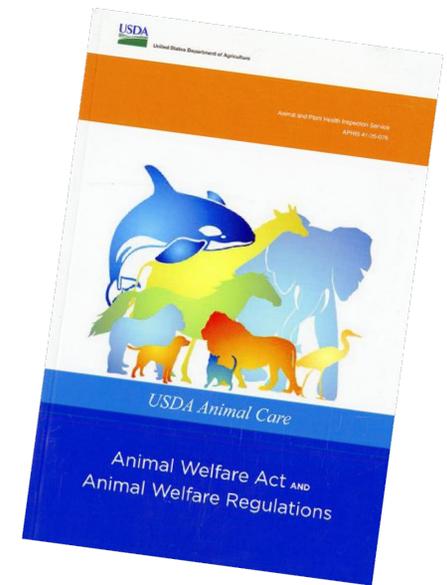
- **Emergency events:** natural, man-made, infrastructure failure
- **Goal:** protect
 - human safety,
 - animal welfare,
 - research integrity.
- **Core principle:** Proper preparation is more effective and less costly than reactive measures.



Regulatory & ethical mandates

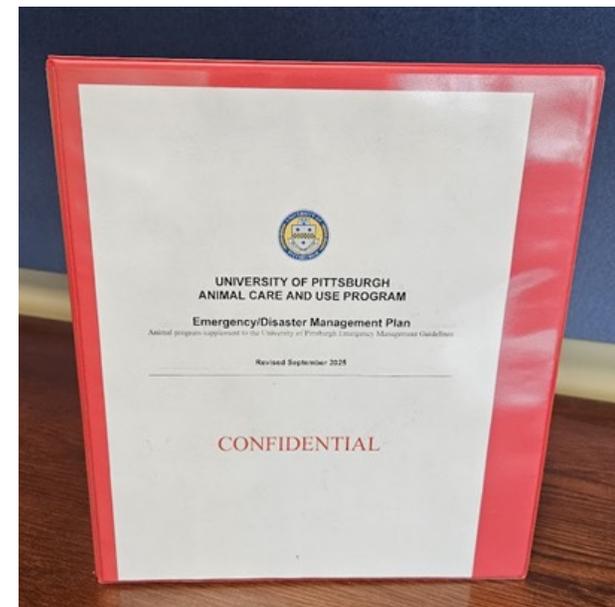


- **APHIS Regulation (effective 2022):** USDA-registered facilities must have written contingency plans, including training for employees on implementing those plans.
- **PHS Policy/OLAW:** Institutions must have emergency plans to address the care of laboratory animals, including identifying essential personnel.
- **The Guide:** Must outline actions to prevent pain, distress, and death due to loss of life-sustaining systems (HVAC, water).



Key components of an effective plan

- **Risk Assessment:** Identify likely threats (flood, fire, power failure)
- **Emergency Personnel:** Designate essential staff, ensure training, and provide access to the site during/after disaster
- **Essential Supplies:** Maintain 3–5 days of food, water, key supplies
- **Communication:** A clear chain of command & contact lists for staff, administration, & emergency responders



Protecting research continuity

Identify irreplaceable models: prioritize most critical lines/studies

Cryopreservation: store genetic material of unique lines

Fail-safe infrastructure: emergency power (generators) covers HVAC for critical housing systems, freezers, essential equipment

Triage system: establish clear criteria for evacuation vs. sheltering-in-place vs. humane euthanasia as a last resort



Super storm Sandy caused severe flooding in lower Manhattan. It also flooded the basement parking garage, killing thousands of laboratory mice crucial for scientific research. (Stan Honda / AFP/Getty)

Key takeaways for researchers



- **Safety first:** Human life/safety takes precedence over animal life.
- **Proactive vs. Reactive:** Planning before a crisis ensures research integrity.
- **Specific training:** Staff must be trained before an emergency occurs.
- **Institutional alignment:** Animal facility plans must align with the overall institutional disaster plan.

Final tips & takeaways

A well-thought-out plan saves animal and human lives, and helps to deal with the aftermath of a disaster.



Thank you

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