DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

HRPP Emergency Preparedness Procedures & Guidance

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The Duke University Health System (DUHS) Human Research Protection Program (HRPP) maintains procedures to ensure the protection of the rights, safety, and welfare of research participants during emergencies and to maintain continuity of HRPP operations when normal institutional functions are disrupted.

This document supplements the DUHS Emergency Preparedness Plan and the Duke University School of Medicine Emergency Preparedness Supplement by addressing considerations specific to human subjects research and IRB oversight.

The Institutional Official and the Executive Director of the IRB are primarily responsible for evaluating this plan, with IRB leadership and other HRPP leadership (e.g., Conflicts of Interest, Research Integrity, Privacy) participating as applicable. The plan will be reviewed at least every three years and following substantive revisions to the DUHS Emergency Preparedness Plan or the Duke University School of Medicine Emergency Preparedness Supplement. The plan may also be evaluated following an emergency event or other evaluation that affects human subjects research operations. Evaluation findings will be used, as appropriate, to revise this document to support continuity of operations, protection of research participants, and compliance with applicable requirements.

Evaluations will include documentation of findings using a DUHS-approved emergency preparedness evaluation form, SBAR tool, or other comparable assessment instrument. Where deficiencies are identified, a root cause analysis will be conducted and a corrective and preventive action plan implemented, and this document will be revised as appropriate.

The IRB will be trained on these procedures at least once every three years or after a major revision or event, whichever comes first.

This document applies during emergencies that may disrupt research operations, including but not limited to:

- Natural disasters
- Public health emergencies
- Infrastructure failures (power, IT systems)
- Institutional closures
- Security incidents
- Widespread staff unavailability

During emergencies the following priorities guide HRPP actions:

- Protection of research participants
- Continuity of critical research interventions

- Regulatory compliance
- Communication with research participants
- Continuity of HRPP oversight
- Coordination with institutional emergency management

The HRPP Emergency Preparedness Plan operates within the broader DUHS emergency management structure. During emergencies the institutional command will operate under the DUHS emergency operations framework. The HRPP will coordinate with:

- Institutional leadership
- Clinical operations
- Research administration
- Information technology
- Environmental health and safety
- The Institutional Official and Executive Director of the IRB will serve as the primary liaisons between emergency command structures and human research oversight functions.

Investigators and study personnel must prioritize participant safety above research objectives. During emergencies investigators may:

- Modify study procedures to eliminate immediate hazards
- Delay or cancel research visits
- Transition to remote assessments when feasible
- Provide medical referrals if needed

Emergency protocol changes may be implemented immediately if necessary to eliminate hazards to participants and must be reported to the IRB as soon as possible. Investigators do remain responsible for communicating with participants, and when possible using IRB approved mechanism. If the research involves investigational drugs or devices, investigators must ensure:

- Continuity of essential treatments when possible
- Secure storage of investigational products
- Documentation of any deviations caused by emergencies

If necessary, investigators may coordinate with sponsors for:

- Alternative distribution methods
- Temporary treatment interruptions
- Protocol modifications

The IRB will maintain oversight functions during emergencies through:

- Remote IRB meetings
- Expedited reviews, as appropriate when necessary
- Prioritize review of:
    - Studies involving vulnerable populations
    - Studies involving significant risk
    - Emergency protocol changes

To maintain HRPP functionality during emergencies, operational continuity strategies include:

- Remote work capabilities for HRPP staff
- Electronic IRB submission systems

- Redundant communication platforms (e.g., zoom, teams, jabber, outlook)
- Backup data systems centrally by the institution
- Delegation of Institutional Official responsibilities and cross training of staff as appropriate.

If system access is disrupted, HRPP staff will work with the OASIS-IRIS team to retrieve and download available copies of critical IRB records, including when feasible:

- IRB meeting agendas
- Board review documents and protocol materials
- Approved protocols and consent forms
- Investigator submissions and amendments
- IRB determinations and approval letters

These records may be temporarily stored in secure institutional locations to allow continued review and oversight to allow for alternative IRB Review Procedures

- Distributing review materials to IRB members through secure institutional file-sharing systems
- Accepting investigator submissions through secure email or designated shared drives
- Documenting determinations using interim tracking logs until systems are restored

Once normal systems are restored, all records and determinations will be uploaded or reconciled in the official IRB system.