TULANE UNIVERSITY

HUMAN RESEARCH PROTECTION OFFICE

EMERGENCY PREPAREDNESS FOR INVESTIGATORS

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DIRECTOR

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OBJECTIVES

- To assist research investigators in protecting continuity of research, especially when drugs and devices are involved, in the event of an evacuation or occurrence of an emergency event that disrupts normal operations

- To encourage research investigators to maintain ongoing communications with their study participants and the HRPO

PRE-DISASTER EVENT

- PIs should gather updated emergency contact numbers and email addresses for study participants at study visits on an annual basis, and prior to the hurricane season.

- PIs should give an IRB approved **Emergency/Evacuation Card** to all subjects in their studies who are taking study drugs or have study devices implanted.

- Study specific Emergency/Evacuation cards should be reviewed to ensure that the 24 hour study team contact number and Principal Investigator name and email addresses are current.

PRE-DISASTER EVENT, CONT'D

- PIs should remove and maintain their regulatory binders, study records, participant contact lists, and any other files necessary to address the needs of study participants during an emergency evacuation.

- When normal means of communication are not working due to an evacuation or major disaster, PIs should utilize the disaster call-in phone number to contact the HRPO and IRB (**1-866-655-0014**).

- Study participants should also be encouraged to utilize this number, only if they are unable to make contact with the study PI during an emergency/evacuation event.

PHARMACY PLANS AND SPONSOR GUIDANCE

- PIs are reminded to keep subjects informed about what to do with their research drugs or devices, in the event of an evacuation or other emergency event disrupting normal operations.

- All studies involving investigational drugs should follow the guidance in their investigational pharmacy plans, in the event of an evacuation/emergency event.

- PIs should consult with study sponsors regarding contingency plans for studies involving investigational devices.

- If your study does not have an emergency evacuation pharmacy plan, please contact Dr. Hamada Rady, Investigational Research Pharmacist, at 504-930-9654 or hamada.rady@hcahealthcare.com.

MODIFICATIONS TO RESEARCH

- Modifications to research should be approved in advance by the IRB, except when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval.

- Should it become necessary to implement changes to eliminate immediate apparent hazards, please report the changes to the Tulane IRB as soon as possible and no later than 10 business days, as outlined in the **Reportable Event** procedures described in **Section 14** of the Tulane University Policies and Standard Operating Procedures for its Human Research Protection Program.

MODIFICATIONS TO RESEARCH, CONT'D

- Be certain to describe how any actively enrolled participants will be managed, particularly in regards to any safety monitoring/follow-up.
- If this affects more than one study, a separate Event Report must be submitted for each affected study. All communications to and from sponsors regarding halting or changing protocols should be submitted to the IRB as part of the Event Report, even if not received until after an emergency event.
- The Tulane HRPO staff are available for consultation on contingency plans for active research studies that may be disrupted as a result of an emergency event. Please contact the HRPO at irbmain@tulane.edu, 504.988.2665, or 1-866-655-0014 (during evacuations only).

ALTERNATIVE IRB PROCEDURES OR POLICY MODIFICATIONS

- In the event of an emergency or disaster, the procedures in the Tulane University Human Research Protection Program Policies and SOPs may be modified as appropriate for the situation.
- Such modifications may include alternative meeting procedures, alternative procedures for the submission and review of modifications, alternative procedures for prompt reporting, and any other changes necessary to ensure appropriate ongoing oversight and conduct of research.
- Because procedural modifications may vary based on the nature of the event, these cannot be anticipated and described in the SOPs. Instead, such procedural modifications will be recorded in an addendum to the SOPs, note-to-file, or other appropriate means of documentation and communicated to the research community.
- Continue to monitor the HRPO's website for new information.

POST-DISASTER EVENT

- Researchers have the responsibility to provide emergency contact information to TU Human Research Protection Office within 72 hours after an emergency threat is declared by the University.
- Email Ashanti Roberts, HRPO Assistant Director, aroberts1@tulane.edu with your emergency contact information. If email is unavailable, call 1-866-655-0014.
- Monitor the website for the Office of Research, https://research.tulane.edu.
- Monitor the website for the Human Research Protection Office, https://research.tulane.edu/hrpo.
- Monitor the University's Emergency Preparedness and Response website at https://emergencyprep.tulane.edu.

EMERGENCY CONTACT INFORMATION

Human Research Protection Office (HRPO)	1-504-988-2665
Emergency Number (only used during evacuations)	1-866-655-0014
HRPO email address	irbmain@tulane.edu
HRPO website	research.tulane.edu/hrpo
TULANE ALERT LINE	1-504-862-8080
(Outside of New Orleans)	1-877-862-8080