TULANE UNIVERSITY
HUMAN RESEARCH PROTECTION PROGRAM

EMERGENCY PREPAREDNESS AND CONTINUITY OF RESEARCH FOR INVESTIGATORS

Roxanne R. Johnson, Director, MSPH, CHRC
Objectives

- To assist research investigators in protecting continuity of FDA regulated studies where drugs or devices are involved.
- To assist research investigators in keeping subjects informed about what to do in a disaster with their research drug or device when an evacuation or other disaster has occurred that disrupts normal operations.
- To encourage research investigators to maintain good communications with the HRPO.
Pre-disaster event

- PIs should gather updated emergency contact numbers and emails annually at study visits prior to the hurricane season.
- PIs should give an IRB approved Emergency/Evacuation Card for research subjects to all subjects in their studies who are taking study drugs or have study devices implanted.
- Prior to hurricane season, the HRPO Director or designee will send out a memo or IRB newsletter to all PIs requiring that the PI maintain an updated list of subjects and contact information for all drug/device protocols.
- This memo was recently communicated via IRB and SPA listservs on June 3, 2020 and is sent to the research community, annually.
- PIs should have this list with them if and when they have to evacuate. In addition, the disaster research call-in phone number and HRPO email address is shared in the communication and throughout this presentation.
- PIs should be informed on how to contact essential personnel in the IRB, SPA, and University Research Compliance Office (URCO) in a disaster situation when normal means of communication are not working due to an evacuation or major disaster.
- Contact with the HRPO and IRB will be via the disaster research call-in phone number provided by the IRB, should other alternatives fail.
Pharmacy Plans

- For studies involving investigational drugs that require an emergency evacuation pharmacy plan, please contact Dr. Hamada Rady, Investigational Research Pharmacist, at 504-930-9654.
Modifications to research

■ 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).

■ 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.
For studies (industry sponsored or otherwise) where implementing safety measures might impose additional concerns resulting in failure to meet study milestones, missed visits that would result in protocol deviations, etc., this should be reported to the IRB as soon as possible and no later than 10 working days as described in the “Reportable Event” section of the Tulane University Policies and Standard Operating Procedures for its Human Research Protection Program.

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.
Human Subjects Research SOPs

- In the event of an emergency or disaster (e.g., public health or weather-related), 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

- As informed in the Annual Summer Newsletter, 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.


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