When anticipating the occurrence of an emergency situation, the LSU Health – New Orleans Clinical Trials Offices recommend that Investigators and their study teams have a plan and procedures in place that address the following:

- Continuity of FDA regulated studies involving investigational drugs and/or devices.
    - Access to the investigational drugs and/or devices for research subjects, especially in the event an evacuation has disrupted normal research operations.
    - Consider evacuation situations not only for the research site but also for research subjects.
- Communication with regulatory authorities (IRB, FDA, NIH, NSF, etc) and sponsors.

Before an emergency event, consider…

1. Ensuring up-to-date list of research subjects is maintained with all contact information.
2. Providing research participants with remote contact information of the study personnel. See IRB Emergency Readiness for helpful tools and templates.
3. Updating the contact list for all research study-staff and distribute to each member.
4. Keeping a copy of the research contact list and study-staff in a secured off-site location.
5. Coordinating an alternative site to conduct study visits, if feasible.
6. Having a pre-arranged plan with the study Sponsor for securing study samples, investigational product and research data.
    - *Best practice would be to develop and share this plan with the sponsor at the site initiation visit.*
7. Establishing a process to un-blind studies in the case of a disaster and to provide investigational drugs for treatment purposes – this may require remote access by the research pharmacist or delegated unblinder who has the key to un-blind studies.
8. Ensuring clear procedures exist to secure and access investigational drugs and devices during a disaster.
    - *When sharing emergency response plan with the sponsor, confirm with the sponsor if they are able/willing to ship drugs directly to subjects in an emergency.*
9. Establishing partnerships with other academic institutions so collaborative emergency sites are available and ensuring approval is in place to utilize local laboratories for subject safety labs.
10. Securing all clinical trial research records, both paper and electronic format. Document the process and inform the study team of the method and location.
11. Ensure all electronic research records are backed up and retrievable from a remote location.
12. Ensure all paper research records are kept in a safe and dry location, away from potential water damage.
13. Securing any equipment provided by the Sponsor or that is specific to the conduct of the study.

Immediately before an emergency event, consider…

1. Study Coordinators/Investigators should contact study sponsors to inform them of potential protocol deviations due to unforeseen circumstances. Research patients with upcoming appointments should be contacted with updates regarding possible changes to their schedules. All communication with the sponsors and/or patients should be documented.
2. Confirming contact information with all participants.
3. Completing as much study activity as possible in advance of the event, within the constraints of the protocol.

4. Following the pre-arranged plan for securing study samples, investigational product and research data (ship specimens to the Sponsor or relocate to a more secure alternate location).

Following the emergency event, consider…

1. Confirming the safety of clinical trial staff and participants.
2. Verifying the stability of the study participant's samples, study drug, data, etc. and if necessary, arranging for their return.
3. Documenting any damages and informing your PI, Sponsor, Funding Agency.
4. Contacting the Sponsor to discuss any impact on the protocol.
5. Resuming the protocol timeline as soon as practical.