

Hurricane Preparedness for Clinical Research

Practitioner Considerations

- Complete as many study activities as possible prior to the event (i.e. bring study participants in for any visits that can be completed early, ensure that they have enough study drugs to last through the storm and following days, etc.)
- Notify sponsors and stakeholders to discuss any potential impacts on the protocol
- If biological samples are being kept through the storm, consider the integrity of those samples and take the necessary steps to secure them (i.e. back-up generator or move to a safer location)
- Coordinate an alternative site to conduct study visits or cancel appointments taking place during the time of the event
- Establish a process to un-blind studies in the case of a disaster
- Ensure clear procedures exist to secure and access investigational drugs and devices during a disaster
- Keep a list of IRB Chairs and HSRO staff available to address approvals needed for revisions to study plan

Research Participant Considerations

- For clinical trials, issue wallet cards to subjects that includes:
 - Protocol Title
 - Information about test article
 - Cell phone number for study team
 - Sponsor contact information
- Contact the study participants to properly inform them of the storm and determine if they need anything from you (contact information, Investigational Product)
- Consider implications of subject lack of access to study drug
 - Should provisions be made for subjects to taper dose?
 - Should additional test article be provided prior to the storm?
 - Should alternative treatment be recommended?
- Ensure that the study participants contact information is current; moreover, if there is an evacuation, is there an alternative means of contacting them?
- Do not allow research to take precedence over the welfare of your study participants
- Secure all clinical trial research records, both paper and electronic format. Document the process and inform the study team of the method and location

Preservation of Research

Please keep the following items in mind as you prepare to preserve your research.

- Do you need to ship or relocate samples and test article to a safer location?
- How long does it take to prepare a shipment?
- Where are they going?
- Who will be moving the samples and test article?
- Does the residing location meet all the security and physical needs of the research study?
- Who will verify that the shipment was received and in what condition?

- How will the samples and test article be maintained under required storage conditions?
- Document the chain of custody.
- When will the shipment be returned?
- Back up sensitive data files that have no replacement

Data Preservation/Protection

- The University provides faculty, staff, and students access to several cloud-based services
- Data Storage Best Practices: 3-2-1 Rule
 - Have at least **3** copies of your data
 - Keep these backups on **2** different media
 - Store **1** backup offsite

After the Storm-Study Recovery Phase

- Contact the study participants to determine if they need assistance and reschedule visits, if needed
- Verify the stability of the study participant's samples, study drug, data, etc. and make arrangements for their return. Inform your supervisor of any damages
- Contact the study-sponsor to discuss any impact on the protocol
- Resume the protocol timeline as soon as practical.
- Facilitate transfer of subjects to other investigators, as needed.