1. PURPOSE
   1. This procedure establishes the process that the IRB will follow to develop a response to an emergency/disaster that impacts the human research protection program (HRPP), such as:
      1. Disease outbreaks
      2. Extreme weather events
      3. Natural disasters
      4. Man-made disasters
   2. The process begins when the IRB manager, Institutional Official or designee determines that an emergency/disaster will impact HRPP operations.
   3. The process ends when the event no longer impacts the HRPP.
2. REVISIONS FROM PREVIOUS VERSION

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| --- | --- | --- |
| Version | Date | Revisions |
| R00 | 12/12/22 | Original issue |
| R00 | 11/14/23 | Annual review, no changes. |

1. POLICY
   1. The office of Research Compliance (ORC), which oversees the HRPP operations will work with the University at Buffalo Emergency response team to develop a response to an emergency that affects the program.
   2. This plan will be reviewed at least annually by a member of the HRPP for potential revision as part of the HRPP annual document review (HRP-060-R02 - SOP - Annual Evaluations of the HRPP).
   3. This plan may also be reviewed if important updates/ revisions will improve the plan.
   4. This plan will be communicated to the IRB staff and members as an annual educational item during convened meetings
      1. At least annually or when significant revisions are made to the plan.
   5. This plan will be communicated to the investigators as educational material via investigator LISTSERVs upon initial approval, and anytime significant revisions that may affect the investigators ability to carry out human research during an emergency incident are included
2. RESPONSIBILITIES
   1. The Institutional Official, IRB manager, or their designee will carries out these procedures.
3. PROCEDURE
   1. If an emergency/disaster occurs or is imminent, the effects upon the HRPP operations will be identified.
   2. If the effects involve areas outside of the ORC, but critical to HRPP operations, work with institutional leadership to identify appropriate contact persons for each critical area. These might include
      1. Information technology
      2. Communications
      3. Maintenance
      4. Facilities
      5. First responders
   3. If the event will affect IRB committee meetings, from convening in person or virtually:
      1. Develop a communication plan for IRB staff and members to provide information and updates.
      2. Rescheduling of the meeting
      3. Developing an alternative method to hold the meeting such as:
         1. Relocating the site of the meeting
         2. Developing a method to hold the meeting virtually, such as via zoom or conference call
         3. Cancellation of the meeting
         4. If changes to the meeting will result in currently approved studies having their approval lapse, the investigators will be notified and instructed to cease all study related activities that are not necessary for subject safety, and a reportable new information submission will be initiated by the investigator and/or IRB describing the reason for the lapse and what procedures were undertaken to mitigate any risks.
         5. Enter a reliance agreement to allow another IRB to review and approve protocols.
   4. If the event will affect the ability of IRB staff to review and approve protocols:
      1. Develop a communication plan for IRB staff and members to provide information and updates.
      2. A process will be developed to allow reviewers to perform their reviews remotely:
         1. Utilize remote computers to access the electronic submission system for review
         2. Reassign studies to other reviewers who are still able to perform reviews
         3. Delay the review of protocols
         4. If changes to the review process result in currently approved studies having their approval lapse, the investigators will be notified and instructed to cease all study related activities that are not necessary for subject safety, and a reportable new information submission will be initiated by the investigator and/or IRB describing the reason for the lapse and what procedures were undertaken to mitigate any risks.
         5. Enter a reliance agreement to allow another IRB to review and approve protocols.
   5. If the event affects normal communications, alternative communications strategies will be identified
      1. Telephone
      2. Email
      3. Mobile telephone
      4. Text messaging
      5. Social media platforms
   6. If the event may impact the ability of investigators to effectively carry out human research:
      1. The ORC will consult with appropriate institutional leadership of parties affected to develop guidance for investigators to carry out or suspend Human research:
         1. Short term guidance
         2. Long term guidance
         3. Define what processes would require IRB approval, and which would not.
         4. Define when the event is over, and how normal operations can resume.
      2. File the approved new or revised document in the standard operating procedure files.
      3. Post the approved procedure on the Human Research Protection Program Web site.
      4. File the old document, if any, in the archive files.
      5. Notify affected individuals informing them of the change.
   7. If the event is deemed to be a long term event that affects HRPP operations, work with appropriate institutional leadership:
      1. Develop a plan to use alternative processes to review and approve protocols
      2. Develop an effective communications plan
      3. Provide updates and guidance to IRB staff
      4. Provide updates to investigators
4. MATERIALS
   1. HRP-060-R02 - SOP - Annual Evaluations of the HRP
5. References
   1. AAHRPP Element I.1.H Tip sheet