Penn University of Pennsylvania | Human Research Protections Program

Emergency-Disaster Review Considerations

The purpose of this guidance is to provide IRB staff and members with additional considerations that may become relevant when reviewing Human Research during an emergency/disaster situation. These additional considerations may provide additional and necessary flexibility for study teams while continuing to assure research participant safety during the emergency/disaster.

1. More widespread use of waivers of documentation of consent for minimal risk research: Additional use of waivers of documentation of consent may be appropriate if the following items are true. (All four criteria must be met)

A. The research involves no more than Minimal Risk to the participants;
B. The research involves interactions and/or involves no procedures with participants for which written consent is normally required outside of the research context;
C. The emergency/disaster may create additional challenges in notifying participants of changes to consent documents; AND
D. The research meets one of the eligibility categories for waiver of written documentation of consent under 45 CFR 46.117.

2. Alternate mechanisms for safety monitoring. (All criteria must be met)

A. The research involves protocol-specified visits to the investigational site;
B. Research participants may not be able to come to the investigational site for protocol-specified visits due to the emergency/disaster;
C. Alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) are available;
D. Alternative methods for safety assessments can feasibly be implemented; AND
E. Alternative methods for safety assessments would be sufficient to assure the safety of trial participants.

3. Additional flexibility in oversight of research not subject to federal regulations. (All criteria must be met)

A. The research is not covered by federal regulations; AND
B. One or more of the following options is feasible and appropriate during an emergency/disaster to provide necessary flexibility for study teams while continuing to assure research participant safety:
    i. Extend continuing review dates during the anticipated period of an emergency; AND/OR
    ii. Allow minor changes to be reported to the IRB without requiring IRB or EC approval prior to implementation.

4. Other mechanisms for additional flexibility not described above. In addition to the options above, additional considerations in providing added flexibility to study teams during emergency/disaster situations may be appropriate where any of the following is true.

A. Additional institution-level information related to emergency/disaster planning (and not otherwise specified above) provides additional guidance in providing additional flexibility or support to study teams managing research during and emergency/disaster; AND/ OR
B. Federal guidance or communications related to managing research during the emergency/disaster is issued and provides additional flexibility or resources.