22.0 Emergency Preparedness Plan for the Human Research Protection Program (HRPP)

22.1 Scope

This policy establishes written procedures for initiating a response to an emergency/disaster impacting the PBRC Human Research Protection Program (HRPP) or HRPP operations.

This policy outlines emergency planning specific to the Human Research Protection Program (HRPP). It is designed to complement, not replace, the broader emergency response plans established by institutional leadership or institution-wide protocols. HRPP-specific emergency measures apply only to HRPP functions that are not already addressed by the institution's general emergency plans.

22.2 Purpose

The procedures outlined in this policy will be invoked when an emergency/disaster situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted.

22.3 Definitions

Emergency or disaster: may include but is not limited to natural disasters, extreme weather events, man-made disasters, and public health crises including infectious disease outbreaks.

22.4 Policy

HRPP leadership defers to the designated institutional authorities and institution-wide disaster and emergency response plans. HRPP-specific planning is limited to operational areas or human research protection activities that are not otherwise addressed by broader institutional plans.

The HRPP director or designee will periodically evaluate the emergency response plans and make changes when appropriate.

The HRPP Director or designee is responsible for carrying out these procedures.

22.5 Procedures

22.5.1 Assess the Nature of the Risk and the Potential Impact to the HRPP

Once an emergency or imminent emergency is identified, determine the response based on the nature of the event. HRPP leadership will contact the appropriate Institutional personnel to determine whether there are Institutional plans already in place to address the event. If these plans are activated, proceed in accordance with those plans and determine whether communication with the research community is necessary to alert them to the activation of the emergency preparedness plan.

22.5.2 Assess Whether the Emergency may Impact HRPP Operations

a. IRB Meetings
   - If the emergency may prevent one or more IRB meetings from occurring, determine whether to cancel or reschedule the meetings, being certain to identify currently approved human research which may expire prior to IRB review. If research will expire, follow IRB Policy 3.12 Continuing Review regarding lapses in continuing review. Because the IRB meets remotely, every attempt will be made to continue IRB meetings to the extent possible.

b. IRB Staff Processing and Member Reviews
   - If staff and IRB chairs will be unable to complete protocol processing and review responsibilities, or if capacity will be limited, IRB leadership will work with the staff to prioritize reviews. If research will expire, follow IRB Policy 3.12 Continuing Review regarding lapses in continuing review.

   - Because the IRB office staff, chair, and reviewers have the capacity to work remotely, every attempt will be made to continue/restore regular IRB office operations as quickly as possible.

22.5.3 Assess Whether the Emergency may Impact Investigators' Ability to Conduct Research

<u>In-person interactions with research subjects:</u> If studies involve in-person interactions with research subjects, organizational leadership will determine whether the studies may be conducted as written while adhering to emergency mitigation strategies.

a. Sponsored Research

   When studies have an external sponsor, ensure coordination with each sponsor to confirm mitigations plans.

b. Clinical Trials Unit

   If the emergency impacts clinical care standards which may in turn impact Research, clarify what does and does not require IRB review. For example, in the case of a public health crisis, screening procedures implemented by the Clinical Trials Unit where a clinical trial is being conducted would not require IRB review/approval of the screening procedures. Conducting research procedures at an alternate clinical care location may require prospective IRB approval. Patient safety will take priority above all other considerations; measures implemented immediately to ensure patient safety may be reported retrospectively. Emergency response plans must be considered for each existing research location.

c. Safety Monitoring

   If trial participants are unable to come to the investigational site for protocol-specified visits, alternative methods for safety assessments must be considered. This may include utilizing phone contact, virtual visits, and/or alternative locations for assessment (including local labs or imaging centers) to assure the safety of trial participants.

22.5.4 Consider Necessary Actions to Address the Impact of the Emergency

The HRPP, in coordination with PBRC leadership and Investigators will determine the actions to take during the emergency to minimize research disruptions. Possible actions include, but may not be limited to, the below.

a. Postponing New Study Implementation

   Consider delaying review and/or startup of new protocols that are non-interventional in nature, present no direct benefit to participants, and do not pertain to the current emergency.

b. Suspending Enrollment/Recruitment on Open Studies

   The institution may need to identify studies for which recruitment and/or enrollment should be suspended, but ongoing study interventions may continue.

c. Continuing Studies via Alternate Mechanisms

   Whenever feasible, adopt online or remote methods for conducting research activities such as recruitment, obtaining consent, data collection, debriefing, and follow-up. Identify additional procedures that can be carried out via telephone, video conferencing, or other digital platforms. If appropriate, consider adjusting the timing of visits and research procedures.

d. Relying on Another Organization to Provide IRB Oversight

Make arrangements (when possible, in advance of an emergency) as necessary to rely upon other organizations for IRB review. Identify the external IRBs and ensure reliance agreements are in place in accordance with IRB Policy 21.0 Collaborative Research.

e. Employing Strategies to Exercise Flexibility in Oversight

For studies not subject to federal regulations, organizations may implement alternative procedures that are equivalent in safeguarding the rights and welfare of research participants. For instance, during emergencies, the IRB may consider extending continuing review timelines for non-federally funded or supported research, and may permit minor protocol changes to be reported at the time of continuing review rather than in advance. Additionally, for most minimal risk studies, regardless of funding source, the IRB may more broadly apply waivers of documentation of consent, particularly when notifying participants of updates to consent forms.

22.5.5 Triage the Research that will be Subject to the Emergency Mitigation Strategies

The organization will consider the types of research that may continue and the types of research that may need to be temporarily postponed. This consideration may include:

a. Studies which present a likelihood of direct benefit to participants (or conversely, studies which include study interventions which may be harmful to subjects if discontinued) should not be postponed, to the extent possible.

b. Research involving direct interactions or interventions may continue if those activities can be conducted through alternative methods, such as remote visits.

c. Studies which may have an adverse impact on resources required to address the emergency must be postponed, if possible.

22.5.6 Develop Education, Training, and Communications on Expectations During an Emergency

Targeted communications and education/training will be developed and distributed based on roles/responsibilities within the HRPP. In particular, researchers and research staff, IRB Chairs and IRB members, IRB Staff, and departmental administrators may each have differing needs regarding effectively responding to emergency mitigation strategies.

PBRC will communicate research-related measures implemented in the event of an emergency via standard communication routes, such as email and web-based platforms, if available. If the standard routes are not available, consult the institutional plans in place to address communications. Ensure the communications include instructions and expectations for impacted personnel.