The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Response Plan for Emergencies or Disasters Impacting the HRPP

1.0 PURPOSE

This procedure establishes the process for initiating a response to an emergency or disaster situation impacting The Christ Hospital (TCH) Human Research Protection Program (HRPP) or its operations. Challenges to HRPP operations or the conduct of Human Research may arise, for example, from:

1.1 Extreme weather events
1.2 Natural disasters
1.3 Man-made disasters
1.4 Infectious disease outbreaks

2.0 POLICY

2.1 HRPP leadership defers to designated institutional leadership and institution-wide disaster and emergency response planning, and limits HRPP-specific disaster and emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans/policies.

2.2 The HRPP evaluates its emergency response plans at least every three years in accordance with the SOP 3.04 Policy Development and Communication for the Institutional Review Board (IRB) and Human Research Protections Program.

3.0 RESPONSIBILITIES

The IRB chairman or designee is responsible for carrying out procedures of this policy.

4.0 PROCEDURE

4.1 Initial Actions

If an emergency/disaster has occurred, or there is an imminent possibility of an upcoming emergency/disaster:

4.1.1 The nature of the event and the appropriate response will be assessed;

4.1.2 Any institution-specific emergency preparedness plans or other information already in place will be consulted;

4.1.3 The Institutional Official (IO) and/or designated institutional personnel responsible for institutional level emergency preparedness will be contacted to determine whether there are new or revised institution-level emergency preparedness plans relevant to the current or anticipated emergency;

4.1.4 Actions shall proceed according to any new or revised plans and the determination made whether further contact with, or notification to, the human research community is necessary.

4.2 Impact on HRPP/HRPP Operations

The determination of whether a current or anticipated emergency/disaster could impact the HRPP and/or HRPP operations will include the following assessments and actions:

4.2.1 Institutional Review Board

4.2.1.1 IRB Meetings

If the emergency/disaster will prevent any upcoming IRB meetings from properly convening in-person, determine whether the meeting can be conducted virtually, including via teleconference.

4.2.1.1.1 If yes, work with IRB members and staff to arrange a virtual meeting.

4.2.1.3.1 If a virtual meeting is also not feasible, determine whether the meeting should be canceled and rescheduled.

4.2.1.2 Protocol Processing/Review

If, during the emergency or disaster, the IRB will be unable to complete their responsibilities of processing and reviewing protocols, or if their capacity will be limited for a period of time:

4.2.1.2.1 Work with the staff to use any available capacity to prioritize protocol processing, pre-review, and review of continuing review submissions.

4.2.1.2.2 If currently approved Human Research has or will expire prior to IRB review due to IRB office capacity limitations, follow IRB SOP 2.07 Notice of Study Closure.

4.2.1.2.3 Work with the IO to notify the research community of the IRB Office's limited capacity to process and review study submissions.

4.2.1.2.4 When the emergency/disaster no longer presents a limitation to IRB Office functions, under the direction of the IO, the IRB chair will notify IRB members and staff and research community that normal business operations have resumed.

4.2.1.3 Reliance on External IRB

If impact to local HRPP operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required. If reliance on one or more external IRBs is required and the necessary reliance agreements are not currently in place, work with the IO to identify appropriate candidates for external IRB reliance and follow IRB SOP 1.21 - Establishing Authorization Agreements.

4.2.2 **Records and Data**

If records and/or data (paper or electronic) are unavailable during the current or anticipated emergency/disaster, consult with local IT support and or electronic system vendors to implement alternative procedures to access and back up records/data.

4.2.3 **Conduct of Research**

Assessment of whether the emergency/disaster could impact some or all investigators' ability to conduct Human Research and whether the impact necessitates additional flexibility in IRB review processes shall be made. If yes:

4.2.3.1 Notify the research community of the need for planning protocol-specific emergency/disaster risk mitigation.

4.2.3.2 If clinical care standards will be impacted which could, in turn, impact the research, develop guidance for researchers that clarifies what does and does not require IRB review (e.g., screening procedures mandated by the health care system in which a clinical trial is being conducted).

When the emergency/disaster no longer presents a limitation to Human Research activities, work with the IO to notify the research community that normal business operations have resumed.

4.3 **Evaluation of Additional Threats/Risks**

An evaluation of whether the nature of the emergency/disaster may pose additional threats or risks to specific aspects of the institution's research activities or facilities will be conducted. For example, man-made disasters, industrial accidents, or terrorist threats could potentially impact some research activities or facilities more than others. Under such circumstances, and if broader institution-level emergency/disaster preparedness measures do not already address actions or facilities specific to the emergency situation, the IRB chair will work with the IO and appropriate institutional leadership to escalate and address any additional threats or risks identified.

5.0 EDUCATION

The Emergency Preparedness Plan is made available to the human research community via

the TCH IRB website and SharePoint page. New information, revised materials, and opportunities for continuing education are communicated to the research community by way of various channels targeted to appropriate audiences to maintain awareness of IRB policies and procedures. IRB office staff will coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the organization. The organization is responsible for notifying research teams when the organization's emergency response plan is activated.

6.0 REFERENCES

6.1 **IRB Standard Operating Procedures**

- 6.1.1 SOP 3.04 Policy Development and Communication for the Institutional Review Board and Human Research Protections Program.
- 6.1.2 SOP 1.21 - Establishing Authorization Agreements
- 6.1.3 SOP 2.07 - Notice of Study Closure

6.2 **TCHHN Disaster/Emergency Plans/Policies**

- 6.2.1 1.01.143 - Emergency Management Program
- 6.2.2 1.02.100 - Emergency Operations Plan (Code Yellow)
- 6.2.3 1.02.101 - Emergency Recovery Plan (Continuity of Operations)
- 6.2.4 1.03.100 - Internal Emergency Response Plan
- 6.2.5 1.03.108 - Emergency Codes and Response Guidelines
- 6.2.6 1.03.111 - Terrorism Threat Response
- 6.2.7 1.03.114 - Emergency Notification Systems
- 6.2.8 2.21.131 - Pandemic Influenza and Other Severe Emerging Respiratory Viruses
- 6.2.9 7.3.101 - Cancer Center Disaster Plan

6.3 **AAHRPP Domains and Elements**: I.1.H