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Owner	Susan Kornetsky: Manager
Department	Research
Applicability	Boston Children's Hospital- Policies & Procedures

IRB Emergency Preparedness and Response Policy/ Procedure

Internal Approval

SVP, Research

EVP and Chief Scientific Officer, Research

Scope

This policy applies to all Boston Children's Hospital (BCH) Research department and the respective staff.

Policy Statements

The purpose of this policy is to ensure sustainability of Boston Children's Hospital IRB and the continued protection of research participants in response to emergencies/disasters that impact the human research protection program (HRPP), such as disease outbreaks, extreme weather events, natural disasters, and man-made disasters. Assessment of the damage and impact to IRB operations and human research protections requires consideration of the nature and scale of the emergency.When writing definitions, make reference to other documents that may contain similar terms to assure that common definitions are used.

This policy will be used as an information source for the BCH IRB staff, IRB Chairs and members, as well as BCH investigators and others within the human research protection community in the event of an emergency. This plan establishes IRB specific emergency planning and is intended to supplement, not replace, emergency response planning by Institutional leadership and/or Institution-wide response measures. The IRB will fully cooperate and coordinate with Hospital leadership assigned responsibility for responding to emergency preparedness plans. These IRB-specific emergency response plans and measures are limited only to those functions of the IRB not otherwise covered by institution-level plans.

This plan is invoked once the Institutional Official (IO) has indicated an emergency has occurred or preparations are needed for an imminent emergency, and human research at Boston Children's Hospital, including the IRB or IRB office operations, is or is likely to be adversely impacted.

These procedures may be modified as appropriate to be in accordance with other Institutional emergency plans, as no advance planning can address all possible emergencies.

It is the responsibility of the BCH Senior Director and the IO to periodically evaluate the Emergency Preparedness and Response Policy to ensure that the plan is updated as required and in accordance with institutional policies. Any changes to the policy may also require approval by other institutional officials to make sure it consistent with other institutional emergency response and preparedness plans. If any changes are implemented the IRB staff, members and research community will be notified of the changes through town hall meetings, newsletters, and/or webinars.

Procedures

1. Emergency Notification:
    a. Boston Children's Hospital maintains an Emergency Management website for all information pertinent to emergency preparedness and response. The hospital also maintains an alert system to notify staff and faculty when emergencies exist. Any additional requirements and instructions for research investigators and research participants will be coordinated with the relevant institutional emergency preparedness or response plan.
    b. IRB Staff, IRB chairs and IRB Members
        i. BCH IRB staff, Chairs and board members may receive additional notification and guidance on implementing emergency preparedness plans from the IO, IRB Senior Director or designee in the event of an emergency. In the event these individuals are not available, the Chief Scientific Officer or the Chief Executive Officer will designate alternate leadership during the emergency.
        ii. IRB staff work remotely and will continue to work remotely, as permissible, during an emergency or disaster.
        iii. The majority of IRB meetings are held remotely via zoom (or its equivalent) and will continue to be conducted remotely unless the issue impacts remote capabilities. In that situation an in-person meeting will occur either on site or another location. A conference call may be utilized if an in-person meeting is not feasible. If Board meetings cannot be held remotely via zoom, in person or through conference call, BCH may formally rely on an external IRB for review of human research.
        iv. Investigators will be instructed on procedures regarding their human subject research activities during an emergency or disaster. They may be notified through an institutional emergency response system, the IO or Senior Director of the IRB. All plans will be reviewed, coordinated and

consistent with relevant institutional procedures and directives.

v. Research Participants: Investigators will be instructed on messages to inform their research participants about what to do if their participation is affected by and during an emergency. Documentation of research participant contact should be kept in the research files

2. Emergency Training
    a. IRB Staff: The Senior Director will educate and train IRB staff, on expectations during emergencies/disasters on an ongoing basis and as necessary. Information in this policy will be covered, as well as other institutional information received that would be helpful if such an emergency/disaster occurs.
    b. IRB Chairs and members will receive information regarding this policy at board meetings and be updated via email or phone calls as needed. IRB chairs and members will continue to be advised during actual emergencies and disasters regarding expectations.
    c. Investigators: Investigators will be educated about expectations during emergencies on an ongoing basis through emails, newsletters and other institutional mechanisms. This BCH IRB policy is also available on the IRB website.
3. Advance Preparation for IRB Decisions and Determinations
    a. Actions the IRB and institutional leadership may take during emergencies and disasters, short of stopping all research, include identifying:
        i. Types of studies which should be halted entirely.
        ii. Types of studies for which recruitment or enrollment should be halted but all or some research activities may continue for existing participants.
        iii. Types of studies that can continue to enroll new participants via alternate mechanisms, such as the use of remote study visits, conference calls, or video conferencing.
        iv. The following criteria may be used to identify studies which may continue:
            - The study presents a likelihood of direct benefit to participant.
            - The study requires continued assessment and monitoring for safety issues.
            - The study involves direct interaction or intervention but procedures can continue with risk minimization by conducting study procedures via alternate mechanisms, including the use of remote study visits, conference calls, or video conferencing.
        v. The following criteria may be used to identify studies which will be entirely or partially halted:
            - Continuing research interventions/interactions will adversely impact risks for participants.
            - Continuing the study will have an adverse impact on resources required to address the emergency.

vi. The BCH IRB may exercise additional flexibility in oversight when research is not covered by regulations (for example, unfunded research) by extending continuing review dates, and/or allowing minor changes to be reported after implementation. Major changes may undergo expedited review when full board review would normally have been required. Depending on the nature of the emergency, additional flexibility may be identified and promptly communicated to investigators.

4. Disruptions to CHeRP and/or Electronic Communications
    a. BCH IRB relies upon CHeRP (an online IRB application and management system) and may depend on video conferencing systems entirely to operate during emergency or disaster. Since 2012 all IRB records have become electronic. In some limited circumstances protocols that were initiated before 2012 may have initial paper files. If the BCH IRB cannot access these systems during an emergency, including cyber-attack, disaster or emergency, the Senior Director in consultation with the Institutional Official and other required institutional leadership (information technology) will identify other ways to operate during the emergency/disaster and notify staff, board members, and investigators.
    b. Research Administration, in accordance with Research Computing, has developed response plans for all information technology systems necessary to operate the IRB. This includes security, support and back up required to maintain the integrity and access to the system. The plan includes the CHeRP application, describes what will be done in an event of an emergency and puts a mechanism in place to secure the system on an ongoing basis. There will be an annual assessment of the CHeRP emergency preparedness plans.
5. Utilizing Another IRB During an Emergency
    a. If it is deemed appropriate to rely upon another organization for IRB review, the BCH may utilize a reliance agreement to formally cede IRB review to an external IRB. Consideration for selection of the external IRB include:
        i. Accreditation Status: The IRB must be accredited.
        ii. Signatory to the SMART IRB Relance Agreement or other fully executed reliance agreement: Preference will be given to institutions that are signatory to the SMART IRB Reliance Agreement or to independent IRBs with whom BCH has an existing reliance agreement.
    b. The BCH IRB will work directly with the appropriate external IRB to discuss arrangements for IRB review. The BCH will support communication to BCH investigators on the process to submit protocols, changes, and other reportable activities requiring IRB review and approval. When the BCH IRB can function, IRB review documentation and approved materials will be transferred to BCH IRB via secure methods and updated in CHeRP by IRB staff, with assistance from investigators as determined necessary.
6. Investigator Considerations:
    a. The need for a response plan is based on the type of research conducted and degree of risk in the event the study could not continue. The plan should address if specific

treatments or assessments need to be interrupted/delayed/changed and whether follow up visits and assessment may be performed remotely or in other locations.

b. Investigators need to have emergency response plans contemplated for the types of research they perform, and the location utilized for research. This will be dependent on whether the research or components of the research are conducted at the hospital (inpatient or outpatient), in the community or remotely.

c. Investigators should be prepared to develop alternate mechanisms for safety monitoring. If trial participants may not be able to come to the investigational site for protocol specified visits, the IRB will evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible and would be sufficient to assure the safety of trial participants.

d. In some studies, investigators may ask the IRB for a waiver of informed consent documentation during a disaster or emergency. The IRB has guidance for remote and electronic consent, and this may be utilized in the event of an emergency or disaster when it is not possible to get in person consent or when new information needs to be presented to those who have already provided written consent.

e. Investigators should consider whether the establishment of an approved research protocol would be helpful in the event of an emergency/ disaster. For example, drug protocols anticipating a public health pandemic or protocols that can be implemented quickly to collect research samples during a infectious disease outbreak may be helpful if they are fully developed and ready for use. IRB review may be obtained in advance, when possible, for safety plans

f. If there are organization wide changes that impact clinical care and research in similar ways, these do not require IRB review. Examples of changes that do not require IRB review include screening procedures mandated by the health care system in which a clinical trial is being conducted.

g. Investigators should collect and update participants' emergency contact information annually if their health, safety, or welfare could be jeopardized during an emergency. Investigators must be able to access/retrieve this information under emergency conditions. (for example, if computer systems are down)

h. Investigators should make sure participants are aware of alternative methods of contacting the research team during an emergency (as necessary).

References/Citations

AAHRPP Element I.1.H

AAHRPP Tip Sheet – Emergency Preparedness and Response

Related Content

FDA Guidance entitled "Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency" will be used to set guidelines to ensure the safety of research participants.
https://www.fda.gov/media/136238/download

Boston Children's Hospital Emergency Management website ***http://web2.tch.harvard.edu/em/index.html***

Approval Signatures

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Applicability

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