Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: **2023-035.0**
Policy Title: HSPP Emergency Preparedness Plan

Purpose

The HSPP Emergency Plan is intended to ensure sustainability of the HSPP and continuing protection of research participants during emergencies.

Definitions

Policy

It is the policy of the HSPP to have an emergency preparedness plan in place, to ensure human subjects research decisions during an emergency will be conducted in conjunction with the University of Connecticut Health Center and John Dempsey Hospital Emergency Operations Plan and in accordance with AAHRPP Element I.1.H. The emergency preparedness plan will go into effect when the safety of all HSPP employees involved in carrying out the plan can be ensured.

The Director of the HSPP (DHSPP) is responsible for ensuring the HSPP has an emergency preparedness and response plan, that key personnel are educated about the plan, and that the plan is evaluated at least annually (e.g., tabletop emergency exercises). The plan focuses only on human subjects research and is a supplement to the University of Connecticut Health Center and John Dempsey Hospital (JDH) Emergency Operations Plan. Any conflicts with the organization's Emergency Operations Plan will be resolved by the Institution Official (IO) and DHSPP.

The IO and DHSPP will review this policy at least annually as part of the HSPP evaluation.

On an annual basis, the IO/DHSPP will engage in an emergency preparedness tabletop exercise where the key personnel in the HSPP respond in real-time to a scenario and evaluate the emergency preparedness plan based on the exercise and suggests revisions where needed.

Emergencies may occur at the national, state, local, or institutional level. The types of emergencies that the Institution may see can be defined as minor emergencies, limited and potential emergencies, or major disasters.

- **Minor emergencies** are events that are short in duration and may impact a small number of research protocols and may be managed through HSPP policy#2009-001.0, "Reporting Unanticipated Problems to the Institutional Review Board," as applicable. Examples of minor emergencies may include but are not limited to, brief and localized power outages, website/webpage outages, lab equipment failures.
- **Limited and potential emergencies** are events that may be short in duration but may require an extended mitigation plan and may impact more than one research team or group of research protocols, such as weather or storm events which may lead to localized flooding, destruction or disruption to infrastructure, or lengthy power outages, as well as threats posed by chemical, biological, radiologic and nuclear hazards from external or internal events. Limited and potential emergencies are managed according to the severity of the event and specific to the needs of the research group in conjunction with the Institution.

- **Major Disasters** are events which pose a major threat to continual care of research subjects and communication with research subjects. The events may be short in duration, but response and recovery efforts are significant and outside of the standard operations of the HSPP. Examples of Major Disasters include, but are not limited to: Institutional Fire, Institutional Power outage, Institutional Cybersecurity Threats, and Pandemic/Infectious Disease events.

The possible impact of such emergencies, in relation to human subjects research, will be considered in determining the extent of emergency preparedness planning and implementation needs at the time of the emergency categorization.

Responsible Parties

Planning and emergency preparedness procedures shall include and take into consideration the Institution's existing emergency procedures. The Institution Official (IO) shall be knowledgeable of and involved in the Institution's processes and procedures in order to determine appropriate emergency actions to ensure protection of human subjects. The IO is responsible for activating the emergency preparedness plan in response to an event; the DHSPP shall assume responsibility in the absence of the IO. The IO may elect to convene an ad hoc committee of representative members of research administration and the research community to address special considerations related to the nature of the emergency (e.g., IRB, IT, Pharmacy, Environmental Health & Safety).

Emergency Actions

Emergency actions shall be implemented as necessary based on the following designations of research:

1. **Research for which recruitment and/or enrollment should be halted but research activities may continue with existing participants**, such as:
    - Research that has direct benefit for research subjects (a direct benefit does not include subject incentives or financial compensation).
    - The research presents a likelihood of direct benefit to participants (or conversely, studies which include study interventions which may be harmful to subjects if discontinued) shall not be postponed, to the extent possible.
    - Research that meets the definition of a clinical trial as defined in HSPP policy #2011-007.0, "Definitions Applied to Policies" and registered as a clinical trial.
2. **Research that can continue via alternate mechanisms**
    - use of remote study visits, conference calls or video conferencing.
3. **Research that should be postponed**
    - for example, studies with no direct benefit to participants and unable to safely continue through alternative mechanisms.

Based on the type of research as described above, the Principal Investigator may be required to provide a research protocol-specific emergency plan (as a modification request or part of the initial IRB review if emergency actions are in effect or anticipated).

- Emergency plans will be required to be submitted as part of the initial IRB application and/or protocol materials if the project provides direct benefit and is considered an essential need for everyday life.
- Emergency plans shall be written in a manner that takes into account any unique and extenuating circumstances that may impact research and/or external persons. Emergency plans may also

include information in protocols and informed consent form(s) regarding emergency preparedness and the alternative mechanisms that may be utilized to communicate with participants and continue the research study in the event of an emergency.
- A requirement to include emergency plans in any project beyond the scope described in this policy must be approved by the Institutional Official, HSPP Director, and/or the IRB Chairperson.

The IO and DHSPP have the authority during an emergency to transfer existing studies to an external or independent IRB for review. Preference will be given to those IRBs with which UConn Health has pre-existing reliance agreements and which are AAHRPP-accredited. The DHSPP is responsible to ensure reliance agreements are in place with AAHRPP-accredited external IRBs including at least one independent IRB outside of the immediate geographic area in advance of an emergency.

Training and Education

The Education Specialist will have the primary responsibility to develop and implement educational opportunities to the research community, HSPP staff and IRB members on the emergency plan, which may include brown-bag lunch sessions, newsletter articles, broadcast announcements, and training at IRB meetings and HSPP staff meetings. Examples of information that may be covered in these training sessions include conducting consent procedures, remote study visits, alternate mechanisms of delivering investigational drugs, remote monitoring and providing or arranging for the provision of care in the event of a research-related injury.

The Education Specialist will provide education at least annually for the research community on the emergency plan, making recordings of the session available on the HSPP website. Investigators will have access to emergency preparedness planning information through the HSPP website. Principal Investigators are responsible to ensure that all members of their research teams are informed about activation of the HSPP Emergency Preparedness Plan and any study specific emergency preparedness plans, as necessary.

The education plan shall be evaluated annually in coordination with the overall evaluation of the emergency plan.

Procedure

When an emergency is identified, the Institution Official shall:

1. Assess the nature of the risk and the potential impact to the HSPP.

Determine the response based on the nature of the event. Contact the appropriate Institutional personnel to determine whether there are Institutional plans already in place to address the event. If institutional plans are activated, proceed in accordance with those plans and determine whether the HSPP Emergency Preparedness Plan is to be activated. When the HSPP Emergency Preparedness Plan is activated, the IO will notify the HSPP Director/designee, who will notify the HSPP/IRB staff, membership and research community through email, IRIS and website announcements.

2. Assess whether the emergency may impact HSPP operations.

- IRB Meetings:

    - If the emergency may prevent one or more IRB meetings from occurring, determine whether to cancel or reschedule the meetings.
    - Identify currently approved human research which may expire prior to IRB review. If research will expire, follow HSPP policy #2011-009.13.pdf – Institutional Review Board – Lapse in IRB Approval. For minimal risk research, consider whether to grant an extension of expiration dates due to the emergency.
- IRB Staff submission processing and review:
    - If staff will be unable to complete submission processing and review responsibilities, or if capacity will be limited, the DHSPP/designee shall work with the staff to prioritize reviews.
    - If research will expire, follow policy # 2011-009.13 – Institutional Review Board – Lapse in IRB Approval. For minimal risk research, consider whether to grant an extension of expiration dates due to the emergency.
- Data and records:
    - For emergencies impacting computer systems, consult IT to ensure backup data is secure.
    - If electronic records and submission systems are or will be unavailable, consult with Information Technology (IT) support to ensure alternative procedures are implemented to access backup data and systems.

3. **Assess to what extent the emergency may impact the conduct of research and the extent of studies impacted** Depending on the nature of the emergency (minor, limited, major), the impact may be localized or widespread.
    - In-person interactions with research subjects: If studies involve in-person interactions with research subjects, the IO will determine whether such studies may be conducted as written while adhering to emergency mitigation strategies.
    - Sponsored research: When studies have an external sponsor, the Investigator will ensure coordination with each sponsor to confirm mitigation plans.
    - Clinical care and/or research facility considerations: If the emergency impacts clinical care standards, which may in turn impact research, the IO will clarify what does and does not require IRB review. For example, in the case of a public health crisis, screening procedures implemented and required by the institution where a clinical trial is being conducted would not require IRB review/approval of the screening procedures, whereas conducting research procedures at an alternate clinical care location may require prospective IRB approval. Emergency response plans must be considered for each existing research location.
    - Safety monitoring: If trial participants are unable to come to the investigational site for protocol-specified visits, the investigator must consider alternative methods for ensuring completion of safety assessments. This may include utilizing phone contact, virtual visits, alternative locations for assessment (including local labs or imaging centers) to assure the safety of trial participants.
    - Research laboratories, repositories and databases: The IO will identify impacted research laboratories, repositories and/or databases and work with the appropriate institution officials to establish mitigation plans (e.g., environmental health and safety, IT, biosafety officials).
    - Drug / Device storage and accountability: The IO will identify impacts to investigational drug/device (storage, dispensing, etc.). Investigators are responsible to consult with Research Pharmacy to ensure the safe storage, handling and control of drugs/devices during the emergency.

4. **Triage the research that will be subject to emergency mitigation strategies.** The Institution Official shall consider the types of research that may continue and the types of research that may need to be temporarily postponed.
    a. **Research for which recruitment and/or enrollment should be halted but research activities may continue with existing participants**, such as:
        - Research that has direct benefit for research subjects (not inclusive of subject incentives or financial compensation).
        - Research that meets the definition of a clinical trial as defined in HSPP policy #2011-007.0, "Definitions Applied to Policies" and registered as a clinical trial.
        - The research presents a likelihood of direct benefit to participants (or conversely, studies which include study interventions which may be harmful to subjects if discontinued) shall not be postponed, to the extent possible
    b. **Research that can continue via alternate mechanisms or should be postponed**,
        - Research involving direct interactions or interventions which can continue those interventions via alternate mechanisms.
            - When possible, implement online or remote strategies for research procedures such as recruitment, consent, data collection, debriefing, and follow-up. Identify any additional research activities that can be completed via telephone, video conference, or via online mechanisms. If possible, alter the timing of visits and procedures.
        - Studies which may have an adverse impact on resources required to address the emergency shall be postponed, if possible.

5. **Consider any additional necessary actions to address the impact of the emergency.** The Institution Official shall define the actions to take during the emergency to avoid stopping all research activities.
    - Postpone new study implementation: Consider whether to suspend accepting submissions of new protocols for IRB review for research which is non-interventional in nature, or which presents no direct benefit to participants.
    - Relying on another organization to provide IRB oversight: If needed, identify the external IRBs and reliance agreements in place in accordance with HSPP policy #2011-009.15.b – Institutional Review Board – Reliance on External IRB. Select with preference given to those IRBs with which UConn Health has pre-existing reliance agreements and which are AAHRPP-accredited.
    - Employ strategies to exercise flexibility in oversight: When studies are not federally regulated, examine whether different but equivalent procedures to protect the rights and welfare of research participants may be employed. For example, for non-federally funded research, the IRB may consider extending continuing review dates during the emergency, and/or allowing minor changes in research to be reported to the IRB at the time of continuing review versus in advance of the change. For most minimal risk research regardless of funding, the IRB may consider more widespread use of waivers of documentation of consent, particularly for notifying participants of changes to consent documents.

6. **Identify any new education, training, and communications needed specific to the emergency event.** Develop and distribute any targeted communications and education/training based on roles/responsibilities within the HSPP. Communications will occur via standard communication routes, such as email and web-based platforms, as available, and include instructions and

expectations for impacted personnel. Information will be made available in a designated area of the OVPR/HSPP website for researchers and research staff, IRB Chairs / Members and departmental administrators. If the standard routes are not available, the Institution Official will consult the institutional plans in place to address communications.

The Institution Official and DHSPP will convene on a routine basis during the emergency to assess mitigation strategies and reevaluate any restrictions imposed on research activity. When the emergency has ended, the IO/DHSPP will convene to debrief and evaluate the response to the emergency and make changes to the emergency plan as determined necessary.

Related Policies

2004-02 – Authority of the Human Subjects Protection Office (Institutional Policy)
11-052 - UConn Health John Dempsey Hospital Emergency Management Policy (Institutional Policy)
2009-003 – Imposing and Lifting Suspension of IRB Approval or Imposing Terminations of IRB Approval
2011-007.0 – Definitions Applied to Policies

Basis

AAHRPP Element I.1.H

Document Attributes

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