JEFFERSON OFFICE OF HUMAN RESEARCH PROTECTION

EMERGENCY OPERATIONS PLAN

SCOPE

This plan applies to the Jefferson Office of Human Research Protection department, staff, and JOHRP IRB members. The purpose of this plan is ensure continued JOHRP operations and the continued protection of participants in TJU's clinical research during emergencies and disasters that may impact the TJU clinical research program. These emergency/disasters include but are not limited to extreme weather, disease outbreaks, as well as disasters of natural or human origin. The nature and scope of the disaster dictate the impact to JOHRP operations and human research protections.

This plan will serve as a resource for JOHRP staff, TJU IRB members, and the TJU clinical research community in the event of an emergency or disaster. This JOHRP Emergency Plan is intended to supplement rather than replace TJU emergency plans and will be invoked upon the declaration of an emergency or the need to prepare for an imminent emergency by the JOHRP Director or designee. The procedures in this plan may be modified as appropriate given the circumstances of the emergency/disaster and institutional or JOHRP needs. The JOHRP Emergency Operations Plan will be periodically evaluated by JOHRP leadership to ensure that the plan remains in accordance with TJU emergency plans, which take precedence. IRB members, JOHRP staff, and the TJU clinical research community will be notified of substantial changes to this plan through IRB continuing education (CE) programs, the JOHRP website, and other educational outreach programs such as newsletters and presentations.

PROCEDURES

1. Emergency Notification
    a. Thomas Jefferson University and all Enterprise facilities maintain a system (JeffAlert) to notify staff and faculty of emergencies or heightened concerns . The JeffAlert system sends notifications to the TJU community through texts, voicemail, and email. The Thomas Jefferson University Emergency Preparedness webpage provides information resources for the Center City, Methodist, and East Falls campuses. These systems work in conjunction with other communications systems such as the Jefferson Emergency Management application (MyEOP), Jefferson-wide broadcast emails, intranet, public address systems, and campus security notifications.
    b. JOHRP staff and IRB members may receive additional notification and guidance on implementing the emergency operations plan from the IRB Director or designee in the event of an emergency. In the event these individuals are not available, TJU leadership will designate alternative leadership during the emergency.

OPERATIONS

1. JOHRP staff
    a. JOHRP staff are equipped to work remotely and will continue to work remotely, as expedient, during an emergency or disaster unless the emergency impacts the ability to work remotely.
    b. All TJU IRB meetings are held remotely via Zoom and will continue to hold meetings, as expedient, unless the emergency impacts the ability to meet remotely. Other remote platforms, conference calls, or in person meetings may be held if the circumstances warrant. If meetings cannot through any means be held, JOHRP may relay on an external IRB for review of clinical research.
    c. The JOHRP Director or designee will instruct investigators and study staff on procedures regarding their clinical research activities during an emergency or disaster. These instructions may be communicated through the JOHRP websites and/or institutional emergency response systems. Instructions will be coordinated and consistent with relevant institutional procedures and directives. Instructions to investigators and study staff will include informing research participants regarding the impact of the emergency on their participation. Documentation of research participant contact information should be kept in research files and/or the electronic medical record.

2. Emergency Plan Education
    a. JOHRP staff will be trained on the Emergency Operations plan at routine staff meetings along with any significant updates to the plan.
    b. IRB members will receive training on this plan at CE sessions during regular board meetings. Any significant changes to the plan will be communicated either through additional CE sessions or through e-mail.
    c. Clinical research investigators will be informed of the emergency operations plan and any changes through the JOHRP website, emails, newsletters, educational programs, and other institutional mechanisms.

IRB DECISIONS

1. Potential decisions and determinations made by the IRB and institutional leader include:
    a. The suspension of all clinical research.
    b. The suspension of particular types of research studies.
    c. The suspension of enrollment of new participants
    d. Permissable alternative methods of research participation including such methods as remote informed consent, remote study visits or forgoing procedures which may not be feasible during the emergency including procedures which require in person visits or the availability of resources.
    e. Study continuation decisions may be made on a study by study basis.

2. The study characteristics taken into consideration during the emergency include:
    a. The study presents a likelihood of direct benefit to the participant

b. The study requires that participants receive continued assessment and monitoring for safety reasons
c. The nature of the study allows for conducting the study using alternative mechanisms such as remote study visits or visits in other locations.
d. Study procedures require resources that are needed to address the emergency.
e. Continuing the study may adversely impact the participants.
f. The consideration if a proposed or existing protocol may be helpful in the emergency e.g. investigational product studies that may address a public health emergency

The TJU IRB may exercise additional flexibility in oversight for studies not covered by FDA or other regulations (e.g. unfunded research) by extending continuing review dates or annual check-ins and/or allowing minor changes to the study required by the emergency to be reported after implementation. Additional flexibility may be required depending on the nature of the emergency.

3. Disruptions to Electronic Communciations. The TJU IRB relies on electronic IRB records through the iRIS system and may depend on video conferencing during an emergency or disaster. In the event that electronic systems may not be accessible during an emergency e.g. cyberattack or other circumstances impacting these systems, the Director in consultation with TJU leadership and/or other departments such as IS&T, will endeavor to identify other methods of operation and will notify JOHRP staff, IRB board members, and investigators.

4. Utilizing Another IRB During an Emergency If it is deemed appropriate to rely upon another IRB clinical research review, the TJU IRB may utilize a reliance agreement to formally cede IRB review to an external IRB. Consideration for selection of the external IRB include:
    a. Accreditation Status: The IRB must be accredited.
    b. Signatory to the SMART IRB Reliance Agreement or other fully executed reliance agreement: Preference will be given to institutions that are signatory to the SMART IRB Reliance
    c. Agreement or to independent IRBs with whom TJU IRB has an existing reliance agreement.

    The JOHRP will work directly with the external IRB to discuss arrangements for IRB review. JOHRP will support communication to TJU investigators on the process to submit protocols, changes, and other reportable activities requiring IRB review and approval. When the TJU IRB can function, IRB review documentation and approved materials will be transferred to TJU IRB via secure methods and updated in iRIS by IRB staff, with assistance from investigators as determined necessary.

5. The IRB may collaborate with investigators to assess research studies to determine:

a. The type of research they conduct and the degree of risk in the event the study cannot continue.
b. Consideration should be given to assessments that may need to be interrupted, delayed or changed and whether treatments or assessments can be conducted remotely or in other locations. This may be dependent on whether the research is conducted inpatient or outpatient, at the hospital or clinical office, in the community or remotely.
c. Alternative mechanisms for safety monitoring, it necessary. Alternative methods may include:
    i. Contacting participants by phone, telehealth visits, or at alternative locations
    ii. The use of locations such as alternative labs or imaging centers may be necessary.
d. If the adaptations proposed to the clinical research study will be sufficient and feasible for assuring the safety of participants.
e. If informed consent waivers or alternative processes e.g. remote consenting may be warranted during the emergency when in person consenting is not possible or new information needs to be presented to participants who have already given consent. TJU has procedures and applications for remote consenting.

INVESTIGATOR CONSIDERATIONS

1. Investigators should consider the nature of their clinical research studies and how any needed changes to their studies could be addressed in the event of various types of emergencies.

2. Investigators should collect and update participants' emergency contact information and maintain that information so that it is accessible in the event that electronic records cannot be retrieved.

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

This plan does not supersede any TJU institutional emergency plans. Institutional plans and policies will take precedence and do not require IRB review, e.g. screening procedures implemented by TJU throughout the healthcare system. This emergency operations plan should be assessed by JOHRP leadership routinely at the time of the Policy and Procedures Manual review to determine if any updates or changes are required.