Continuity of Operations Plan (COOP)

Major events and emergencies may disrupt programs and essential operations of the Boston Medical Center (BMC) and Boston University Medical Campus (BUMC) Human Research Protection Program (HRPP) and the human subject research overseen by the BMC/BUMC HRPP. Disruptions may occur with varying scope, severity, and duration and may be caused by circumstances such as, but not limited to:

- an infectious disease epidemic; or
- extreme weather event; or
- natural disaster; or
- man-made disaster

Disruptions may occur with varying scope, severity, and duration. The scope of the disruption may be effects on personnel, records, or both. The severity of the disruption may be partial or complete unavailability of personnel and/or records. The duration of the disruption may be hours, days, weeks, or months.

Personnel Disruptions:
A personnel disruption occurs when there is an unexpected lack of availability of some or all HRPP staff. Causes can include multiple resignations, epidemic diseases, natural disasters preventing personnel from traveling to work, and interruptions in electricity and/or internet service to work and/or home. If the IRB is subject to administrative actions [by FDA under 21 CFR 56.120 or 56.121 or by OHRP under 45 CFR 46.103(e) prior to January 21, 2019 or 46.103(c) on or after January 21, 2019] that include limitations on the IRB's authority to provide oversight, this would also be considered a personnel disruption for the purposes of this contingency plan, but would be likely to be known farther in advance than other personnel disruptions.

In the specific instance where the disruption results from the inability of IRB staff and members to travel to the IRB office location, as long as electricity and internet access are available, they may use the electronic system from home and participate in convened meetings via teleconference.

To obtain external resources for responding to personnel disruptions, the HRPP will utilize the services of one or more commercial IRBs which already provide oversight for some research at Boston Medical Center and Boston University Medical Campus (see Section 7.2.2.18). For disruptions limited in scope, severity, and duration, the role of the commercial IRB will be to provide services on behalf of the BMC/BUMC HRPP, following the HRPP Policies and Procedures, which would not constitute transfer of oversight to the commercial IRB. Otherwise, the transfer of oversight, either temporarily or for the life of the study, will follow the FDA recommendations for transferring research oversight.

The IRB Director is responsible for identifying and responding to personnel disruptions involving IRB staff and IRB members, and the HRPP Director is responsible for identifying and responding to personnel disruptions involving other HRPP staff performing educational and compliance activities. In the situation where one of the Directors is unavailable, the other Director has both responsibilities. In the situation where both Directors are unavailable, these responsibilities transfer to the HRPP Assistant Director, Institutional Officials, Chairs, and IRB Administrators, in that order.

As soon as a personnel disruption is identified, the responsible individual will:

- Determine the services needed to maintain oversight of research given the scope, severity, and likely duration of the disruption, including, if necessary, services needed for restoration of the electronic system; and
- Assess whether or not existing internal resources will be sufficient to provide these services; and
- If external resources are necessary:
    - Consult with the IOs to determine the funding available for obtaining external services; and
    - Contact one or more commercial IRBs to enter into an agreement for the commercial IRB to provide the necessary services; and

    - If appropriate, communicate to investigators and research staff any necessary actions on their part associated with use of the services of the commercial IRB (or include such communication in the services provided by the commercial IRB); and
    - If appropriate, communicate to OHRP, FDA, and sponsors about transfer of oversight (or include such communication in the services provided by the commercial IRB); and
- Monitor the response to the disruption to assess the impact on research oversight and adjust as necessary; and
- Determine when the disruption has resolved and as appropriate terminate any responses.

Record Disruption:
One key component of the COOP is availability of HRPP records. For IRB functions, the electronic system is used as the system of record, and no records that are essential to IRB oversight are maintained only in paper or only in other forms such as email correspondence.

The electronic system (both the software and the data) is backed up on a daily basis in the main Boston University Information Services & Technology (IS&T) data center on the Boston University Charles River Campus (CRC) ("local backup"). Another backup of both the software and the database is also made on a daily basis on disk at the Massachusetts Green High Performance Computing Center (MGHPCC) ("remote backup"). The electronic system would be restored within the one-week goal.

For disruptions where the local backup has not been compromised, the process will be to have the IRB Director make the determination that restoration from the local backup is required and to have IRB staff coordinate with Boston University IS&T for the restoration of the electronic system and reconstruction of any records that were added to the system after the time of the backup.

For disruptions where backup from the remote copy on disk is required, the responsible individual at Boston University will make the determination that a disaster requiring recovery has occurred, and the IRB Director and IRB staff will coordinate with Boston University IS&T for restoration of the electronic system as well as reconstruct any records of IRB actions after the time of the backup.

Timing of Recovery:

In considering the timing of recovery from a disruption, the goal is to be able to return to normal operations within a week of the beginning of the disruption. The one-week goal is appropriate for most HRPP operations (IRB review, education, and compliance).

Principal Investigators are expected to submit progress reports for continuing review to the IRB well before the expiration date of the study; however, some Principal Investigators who submit less than a week before expiration may be required to cease study operations if a disruption occurs. Principal Investigators are also expected to submit well in advance of any need for IRB approval for funding purposes; however, a funding deadline may be missed if a submission was made less than a week before the deadline and a disruption occurs. Unanticipated Problems involving a fatal or life-threatening event may require actions sooner than one week after being reported to the IRB; however, the IRB response does not rely on the availability of electronic records and can be coordinated by a number of different personnel: the two IOs, the HRPP Director, the IRB Director, or one of the Chairs of the four panels. A disruption would be unlikely to render all of those individuals unavailable.

Disruption Process Responsibilities:
The goal is to ensure that essential operations and services continue while recovery efforts are underway. If a disruption has been identified, the HRPP Director will act as the COOP's Point of Contact and will coordinate with the HRPP Assistant Director, IRB Director, and relevant university offices to initiate the COOP and a response to the disruption. If the HRPP Director is absent, operational decisions may be led by the HRPP

Assistant Director, the IRB Director, or one of the Chairs of the four panels. A disruption would be unlikely to render all of those individuals unavailable.

The planning and activation of the COOP is overseen by the HRPP Director and the IOs.

COOP Plan Point of Contact will:

- Identify and respond to disruptions involving the HRPP; and
- Maintain a call tree to rapidly communicate with HRPP staff and IRB members. Multiple communication systems may be used including the use of personal cell phones and email addresses; and
- Determine the services needed to maintain oversight of research and to restore application systems, as applicable; and
- Coordinate with the HRPP Assistant Director, the IRB Director, the Institutional Official (IO), and/or other university officials, as appropriate, to assess the impact to human subject research both on and off campus; and
- Assess, if possible, the impact on active research projects and personnel; and
- Provide content expertise to university officials and assist in the development of procedural protocols appropriate for the given disruption; and
- Assist in drafting communications to IRB members, researchers, and study participants, as appropriate; and
- Provide support and guidance to impacted researchers and study participants, as appropriate; and
- Consult with the Marketing/Communications offices at BMC, BU Chobanian & Avedisian School of Medicine, BU School of Public Health, and BU Henry M. Goldman School of Dental Medicine, as applicable, to coordinate notifications of alerts, instructions, and guidance for the research community; and
- Identify any necessary external resources (such as utilizing the services of one or more commercial IRBs and/or consultants); and
- Consult with BU Information Systems and Technology (IS&T) department on access, back-up and/or restoration of electronic records and systems as described above; and
- Monitor the response to the disruption to assess the impact on research oversight and adjust the response as necessary; and
- Determine when the disruption has resolved and, as appropriate, terminate any responses to the disruption.

Principal Investigators (PIs) will:

- Continue to maintain full responsibility for the oversight of their research study, as outlined in Section 6.6.1, including during disruptions to human subject research; and
- Identify and respond to disruptions involving research staff, research site(s), systems, information technology and other resources that are critical to the operations of the research; and
- Provide prompt notification and instructions to impacted study participants; and
- Communicate promptly with the IRB office about any anticipated impacts to research subjects or project operations that may affect compliance during the disruption, and obtain IRB approval, if possible, prior to implementation of any necessary changes; and
- Continue to ensure that anyone delegated to conduct study-related tasks is appropriately qualified and trained; and
- Submit notification to the IRB of any changes to study procedures related to the disruption that were implemented without prior IRB approval; and
- Continue to submit Progress Reports or Status Check-in Reports prior to the expiration date or status check-in due date, when possible; and
- Continue to submit reports of Unanticipated Problems, major deviations, and safety monitors' reports with required changes or recommended changes involving subject safety within 7 days of becoming aware of the incident(s). The IRB's review and response does not rely on the availability of electronic systems and can be coordinated via telephone, video-conferencing, or email, and may be facilitated by several different personnel (e.g. IRB Director, IRB Chair, and/or Vice Chair).

COOP Training, Community Outreach and Evaluation
The process to maintain awareness about the HRPP's COOP includes notification during:

- IRB member and HRPP staff orientation meetings where the COOP will be distributed and discussed; and
- Institution-wide communication updates from the HRPP.

COOP Evaluation
The BMC/BUMC HRPP's COOP will be reviewed every two years to ensure that it addresses the evolving operational processes of the BMC/BUMC HRPP and the BMC/BUMC research community. This review will be conducted by the HRPP Director, the HRPP Advisory Committee, and the IO. Results from the biennial review of the COOP, when necessary, will be used to adjust the plan to ensure continuity of operations.

To enhance preparedness during a disruption, the IRB Director and INSPIR Application Administrator, in cooperation with Boston University's IS&T COOP Team will evaluate applications and technology critical to IRB operations to ensure availability during disruptions.