

Procedure for Conducting IRB Business in the Event of a Pandemic or Other Significant Emergency

The Office for Human Research Protections (OHRP) does not offer specific guidance on how an institution's IRB is to continue to conduct business during such an event. IRB's are required by HHS regulations to review research at a convened meeting at which a majority (or quorum) of the members of the IRB are present. A quorum consists of regular members or their alternate and includes at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.

A. IRB Meetings.

1. **Requirement:** The UMBC IRB will review proposed research that requires full board review as well as discuss pertinent policy issues at scheduled meetings at which a quorum is present. A majority of members present at the meeting must vote in favor of an action for that category of action to be accepted by the IRB.
 - i. **Contingency:** OHRP strongly recommends that meetings take place with all participating IRB members physically present. The UMBC IRB may institute alternatives to face-to-face meetings such as teleconference (see below)

B. Protocol Review.

1. **Requirement: Full Board Review:** The UMBC IRB will review proposed research that requires a full board review at scheduled meetings at which a quorum is present. The UMBC IRB meets every other month during the academic year. The IRB may use the teleconference contingency to conduct a full board reviews.
2. **Requirement: Expedited Review:** The expedited review procedure is used when a primary reviewer is selected to perform the protocol assessment. The primary reviewer is expected to perform an in-depth review of all pertinent documentation, including the protocol application, the proposed informed consent document, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects. Secondary review and approval is performed by the IRB Chair. Complete documentation is also available on the IRB Blackboard site to all members for review. Approvals will be documented in the minutes of the next scheduled meeting.
 - i. **Contingency:** The UMBC IRB will continue to use the currently established the primary reviewer system whereby protocols are electronically (via email) forwarded to the primary and secondary reviewer for consideration.
3. **Requirement: Continuing Review:** Continuing review of research must be substantive and meaningful. The expedited review procedure is also used when a primary reviewer is selected to perform the assessment of the continuing review. The primary reviewer performs the review of all pertinent documentation. Secondary review and approval is performed by the IRB Chair. Complete documentation is also available to all members for review. Approvals will be documented in the minutes of the next scheduled meeting.

- i. **Contingency:** The UMBC IRB will continue to use the currently established the primary reviewer system whereby protocols are electronically (via email) forwarded for review and consideration.
 4. Minor changes and amendments as well as applications for exempt review will continue to be reviewed and approved by the IRB chair. Documents will be forwarded electronically to the Chair; email approval from the Chair will be stored in the protocol file.
- C. HARPO response during event
 1. Investigators will follow protocol submission procedures found on <http://www.umbc.edu/research/HARPO/IRB/IRBprotdevelop.html>. These procedures require the electronic submission of protocol applications and related documents to a central email address, irbsubmissions@umbc.edu.
 2. In the event UMBC campus is closed and HARPO staff cannot come to campus, staff will review email during the campus downtime period. Staff will have the ability to connect to protocol databases and IRB correspondence on the UMBC mainframe drives using remote access. All applications will be processed following the standard HARPO protocol processing procedures. Communication with investigators will be accomplished using email or telephone follow-up.
 3. Protocol applications and reviewer checklists are forwarded electronically via email to all members of the IRB
 4. Questions, concerns and requests for more information from IRB members will be dealt with using the expedited review method or full committee review using the teleconferencing method. HARPO has established an account with a conference service to conduct full meetings via the telephone.
 5. Requests for more information will be sent electronically to investigators. Responses to these inquires will be forwarded to IRB members.
 6. Final approval documentation will be sent to investigators via email.

Guidance on IRB meetings Convened via Telephone Conference Call

(adapted from <http://www.hhs.gov/ohrp/references/irbtel.pdf>)

The IRB chairperson, as the appointed leader of the committee, bears some responsibility for holding committee meetings in a manner that encourages participation and facilitates interaction among members.

Methods of telecommunications (e.g., telephone or video conferencing) are acceptable for the conduct of official IRB business requiring a quorum, provided the following criteria are met:

- All members are given notice of the meeting. **Notice of this meeting will be forwarded to IRB members no less than two (2) weeks prior to the meeting**
- Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting. All members have access to the documents and the technology necessary to fully participate. **All documents will be available via myUMBC on Blackboard (Institutional Review Board organization link)**
- A quorum of voting members is convened when required by HHS regulation.
- The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication). **HARPO will set up conference call with members who are available to participate in a teleconference.**
- If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. To allow for appropriate discussion, all members must be connected simultaneously for a conference call to take place – “telephone polling” (where members are contacted individually) will not be accepted as a conference call.
- Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IRB members but may not be counted as votes or considered as part of the quorum.
- Written minutes of the meeting are maintained in accord with 45 CFR 46 §46.115 and will clearly document that all members have received all pertinent information prior to the meeting and that actively and equally participated in the discussion of all protocols.