

Review by the Convened Institutional Review Board	Effective Date	
	Revisions Date	9.11.2019

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to define and describe the process of review by the convened University and Medical Center Institutional Review Board (UMCIRB).
- 2.0 Persons Affected:**
- 2.1 Individuals engaged in human research activities
 - 2.2 UMCIRB Chairperson (or designees) and members
 - 2.3 UMCIRB staff and administrators
- 3.0 SOP:** Any study involving greater than minimal risk requires review by the convened IRB. Any member of the IRB has the authority to request a full review of any study that has previously received expedited review or been determined to meet exemption criteria. The IRB Chairperson (or designee) may also send research studies to the convened IRB for review in cases where the study does not definitively meet the criteria under an Expedited or Exempt category of research or studies where the UMCIRB Chairperson (or designee) is uncomfortable with an aspect of the study that affects risk. The PI is notified when the study is placed on the agenda for review by the convened UMCIRB.
- 4.0 Definitions:**
- 4.1 **Minimal Risk:** the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
 - 4.2 **Convened Institutional Review Board (IRB):** review of proposed human research activities in which a quorum of IRB members has been reached.
 - 4.2.1 The IRB membership is defined by Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations (see SOP, “Institutional Review Board Membership”).
 - 4.3 **Quorum:** a majority of IRB members ($\geq 51\%$) or their designated alternates present, which must include a scientist and non-scientist, on each vote during a convened IRB meeting.
 - 4.3.1 Quorum must also be composed of any additional members required, as dictated by the nature of the research study, such as a physician on biomedical research involving test items regulated under FDA jurisdiction, or a prisoner representative on studies involving prisoner research.
 - 4.3.2 Ex-officio IRB members are not eligible to vote because of his/her actual or potential conflict of interest.
 - 4.4 **Recuse:** a voting option used to manage an IRB member’s conflict of interest to document the individual did not count towards quorum or the vote on a particular study.
 - 4.5 **Abstain:** a voting option used when an IRB member genuinely does not feel able to render a “yes” or “no” vote.
 - 4.6 **Defer:** a voting option used when there are significant changes that need to be made to a research study or issues that need to be addressed before it can be reviewed again by the convened IRB for approval.
 - 4.7 **Approve with Expeditable Modifications:** an action taken by the convened IRB where the changes necessary to a research study before it can be approved are so minor and

prescriptive that the IRB Chair (or designee) is allowed to verify these changes are made by the study team prior to issuing final approval.

5.0 Responsibilities:

5.1 The PI and Research Staff will:

- 5.1.1 Provide accurate and complete information to the IRB within the electronic application and attach all supporting documents (protocol, informed consent form(s), recruitment materials, etc).
 - 5.1.1.1 Studies reviewed by the full convened IRB require the submission of a stand-alone protocol document clearly describing the science, objectives and ethics of the project.
- 5.1.2 Comply with all procedures and determinations as outlined in their approved application and IRB approval letter.
- 5.1.3 Ensure research does not proceed until all requested modifications are met and an IRB approval letter has been received.
- 5.1.4 Ensure research is conducted in an ethical manner and with only those procedures reviewed and approved by the IRB.

5.2 UMCIRB staff and administrators will:

- 5.2.1 Ensure meeting space is secured well in advance of the UMCIRB meetings.
 - 5.2.1.1 The Biomedical committee meets the 2nd and 4th Wednesdays of each month.
 - 5.2.1.2 The Behavioral/Social Sciences committee meets the 1st and 3rd Wednesdays of each month.
- 5.2.2 Reschedule IRB meetings accordingly to adjust around holiday schedules and other unexpected events.
 - 5.2.2.1 IRB members and study team members will be made aware of these changes within the electronic IRB submission system.
- 5.2.3 Cancel any meetings where nothing is scheduled to be reviewed or if other unavoidable circumstances arise and notify IRB members of this cancellation as soon as possible.
- 5.2.4 Prepare for any members or others that may need to engage in the meeting via a conference call/webex.
 - 5.2.4.1 These instances will be recorded in the minutes.
 - 5.2.4.2 The IRB member attending the meeting via conference call/webex must be available to hear the discussion during the presentation and deliberation.
- 5.2.5 Present the review of a member who has completed and submitted their review but was unexpectedly not able to attend the UMCIRB meeting.
 - 5.2.5.1 While this reviewer's recommendation will be read to the committee and documented in the minutes, the reviewer's recommendation is not counted in the total vote as proxy votes are prohibited.
- 5.2.6 Forward agendas to IRB members approximately 1 week before the scheduled meeting.
 - 5.2.6.1 All IRB members have access to all items submitted within the electronic submission system.
- 5.2.7 Prepare for any meetings that need to be called on an emergency basis.
- 5.2.8 Communicate the convened IRB's decision to the investigator in writing, within two business days of the meeting.

- 5.2.8.1 Recusals for conflict of interest are noted on the IRB approval letter.
- 5.2.8.2 Full or alternate IRB members that would have been recused from a vote if they had attended a meeting will also be indicated in the IRB approval letter as not participating in the deliberation and vote on the particular study.

5.3 IRB Members will:

- 5.3.1 Identify any conflicts of interest they have with an assigned review as soon as possible to the UMCIRB staff so the study may be re-assigned.
- 5.3.2 Be encouraged to contact the investigator to clarify any questions that will facilitate review at the convened meeting, improve efficiency and foster a collaborative environment.
- 5.3.3 Utilize reviewer checklists, in addition to the study application and documents, to assist in making a determination that a research study meets (or does not meet) the criteria for IRB approval.
- 5.3.4 Make recommendations during convened IRB meetings regarding the outcome and vote of the study.
 - 5.3.4.1 The convened UMCIRB has the authority to approve, request modifications to, defer, or disapprove human research.
 - 5.3.4.2 The UMCIRB may vote to authorize the Chairperson (or designee) to approve the response submitted by the PI when minor, prescriptive modifications are requested as a requirement for final approval.
 - 5.3.4.3 Should the Chairperson (or designee) feel the response is not adequate or requires review by the fully convened IRB, the study will be added to the next available agenda for the committee to review.
- 5.3.5 Make recommendations during convened UMCIRB meetings on the required frequency of review, which may be more frequent than the required annual review.
- 5.3.6 Raise issues that may be outside of the UMCIRB jurisdiction for communication to the investigator or appropriate institutional official.
- 5.3.7 Recuse from voting on any research study for which they have a conflict of interest and inform the UMCIRB staff of that decision for the purpose of documentation within the minutes.
 - 5.3.7.1 The Chair (or designee) may also recuse a member from the vote if he/she judges that there is a potential conflict of interest.
 - 5.3.7.2 The recusing member should leave the IRB meeting room for the deliberation and vote.

6.0 Procedures:

- 6.1 The IRB Chair or designee will certify a quorum at the start of the IRB meeting; the meeting cannot be called to order until quorum is established. A quorum is required and must be maintained at all times in order to conduct the business at the convened IRB meeting.
 - 6.1.1 The UMCIRB committee may take no action on a research study at any time there is a loss of quorum.
 - 6.1.2 An unaffiliated member is not required to be in attendance in order to call a meeting to order, however, it is expected that unaffiliated members will have regular attendance habits
 - 6.1.3 Only full members, or their designated alternate as identified on the OHRP roster, are eligible to count towards quorum and participate in voting.

- 6.1.4 While meetings are generally always “in-person”, members can attend remotely by speaker phone/webex.
- 6.2 The IRB Chair or designee will indicate the members or their alternates who will be voting during the meeting (including those members who may be calling in or attending via webex).
- 6.3 Initial review of human research at a convened IRB meeting is conducted under a primary/secondary reviewer system. Two IRB members are assigned to review the entire study submission and report any issues that need to be addressed.
 - 6.3.1 Once the study is discussed at the IRB meeting and recommendations made, the committee votes and outcomes are recorded in the minutes.
- 6.4 Continuing reviews, amendment and reportable events that require review and approval by the convened IRB will have a primary reviewer only.
- 6.5 Each research study action will be discussed and voted on separately. The vote will be obtained by calling for a verbal yes vote, no vote, abstentions, and recusals.
- 6.6 Only IRB members participating in the entire presentation, discussion, and deliberation are eligible to count towards quorum and place a vote.
 - 6.6.1 Members that join the meeting after a discussion is underway on a study or that leave during the discussion on a study may not be counted towards quorum on that study, will be recused from the vote, and the reason for their recusal will be documented in the minutes.
 - 6.6.2 Members participating in the presentation, discussion and deliberation who are unable to render a “yes” or “no” vote will be counted in the vote as an abstention.
 - 6.6.2.1 Because an abstention is counted towards quorum, the member will be reflected in the total number of votes.
 - 6.6.2.2 Committee members may abstain from voting without revealing the nature of his/her abstention; however, he/she should not abstain in the place of a “no” vote.
- 6.7 An action will be carried if it gains the majority of the total number of votes, for example, there must be $\geq 51\%$ of total votes recorded as “yes” to approve an action.
 - 6.7.1 If the majority of the total number of attending members abstains on a particular vote, then there will be an insufficient number of “yes” votes to approve the action at that time.
- 6.8 The approval period on human research can be no greater than one year and will extend from the date approval is granted (even if minor modifications eligible for review by the IRB Chair or designee are required by the IRB committee) for the frequency set by the convened IRB, which may be based on a number of factors including:
 - 6.8.1 Studies with significant risk medical devices
 - 6.8.2 Early phase studies such as Phase I and II
 - 6.8.3 Investigator experience or mentor oversight
 - 6.8.4 Evidence of previous or current noncompliance
 - 6.8.5 Greater than minimal risk studies that target extremely vulnerable populations
 - 6.8.5 Non-externally sponsored research studies
 - 6.8.6 Rate of proposed enrollment or proposed sample size
 - 6.8.7 Proposed study location
- 6.9 Study team notification of IRB approval will generally be sent within two business days of the IRB meeting and will include approval and expiration dates.
 - 6.9.1 Modifications required for IRB approval will also be communicated to the study team generally within two business days of the IRB meeting.

- 6.9.2 Once the study team submits corrections for the requested modifications, the study will be forwarded back to the IRB Chair or designated reviewer (for confirmation that minor modifications are complete) or placed on the next IRB committee meeting agenda (for deferred studies that needed more significant modifications which require convened IRB review).
- 6.10 Study team notification of disapproval of a research study or amendment will be communicated within two to five business days of the IRB meeting along with the rationale and instructions for study team response.

Revision History:

Date	Change	Reference Section(s)
10.29.14	Updated to stand-alone document.	All
8.1.2018	Minor clarifications to definitions and responsibilities, procedures updated to describe reviewer system and communication after the IRB meeting.	4.0, 5.0, 6.0
9.11.2019	Added clarification on the requirement of a separate written protocol document for studies reviewed by the full convened IRB. Changed ORIC to UMCIRB.	2.0, 5.1, 5.3

References:

DHHS, OHRP. Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

FDA. Code of Federal Regulations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>