Initial Review of Human Research Activities	Effective Date	8.1.2018
	Revisions Date	6.10.2021

1.0 Purpose: The purpose of this standard operating practice (SOP) is to describe the process of initial review of human research applications by the University and Medical Center Institutional Review Board (UMCIRB). The initial review process must be completed and IRB approval granted for each research study before any human research activities begin.

2.0 Persons Affected:

2.1 Individuals engaged in human research activities

2.2 UMCIRB Chairperson (or designees) and members

2.3 University and Medical Center Institutional Review Board (UMCIRB) staff and administrators

3.0 SOP: The UMCIRB is responsible for reviewing and approving human research activities which meet the criteria outlined in the federal regulations, state and local laws and institutional policies and procedures. The application process for the UMCIRB is electronic with access to the electronic system available from the UMCIRB website. The research application and submission process includes the Departmental and Ancillary Review, as applicable for each study.

Anyone transferring research studies from their previous place of employment, or performing ongoing research from an educational experience (i.e. thesis, dissertation work) from an institution other than ECU, must seek advice from the UMCIRB regarding initial review and approval before implementing any aspect of the research at ECU.

4.0 Definitions:

4.1 Initial Review: the first time a research study is reviewed by the fully convened UMCIRB or the IRB Chairperson (or designee).

4.2 Departmental Review: Certification by the Department Chairperson ensuring the study application and protocol have been reviewed and meet departmental standards. Departmental review also ensures:

4.2.1 There are adequate resources, including space and support personnel, available to the PI to conduct this study in the manner proposed,

4.2.2 The PI has the appropriate expertise and/or knowledge to conduct the research

4.2.3 The proposed research is scientifically sound,

4.2.4 Contributes to the scope and mission of the Department, and, therefore, to that of ECU.

4.2.5 This review would be applicable to human research studies initiated at ECU only.

4.3 Ancillary Review: Certification by applicable resource areas required for the conduct of the research that indicates the representative of that area is aware of and supports the research procedures that utilize their service areas.

4.4 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.

4.5 Full Board Review: Review of proposed human research activities by the fully convened IRB as defined by Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations which do not meet the federal criteria for expedited,

limited or exempt review. (See SOP, "Review by Convened IRB")

4.6 **Exempt Review:** Review of human research activities determined to be exempt under federal regulations and guidance which do not require review and approval by the convened IRB. (See SOP, "Certified Exempt Research")

4.7 **Limited IRB Review**: Review of human research activities determined to qualify for exempt categories 2(c), 3(a) and 3(c) under the federal regulations. Ensures there are adequate provisions for protecting privacy and maintaining confidentiality and provides privacy safeguards to reduce the chances that the disclosure of identifiable private information will occur and lead to harm.

4.8 **Expedited Review**: Review of human research activities that involves no more than minimal risk and meets one or more of the categories authorized in the federal regulations. (See SOP, "Expedited Review Procedures")

5.0 Responsibilities:

5.1 **Principal Investigators** are responsible for:

5.1.1 Allocating adequate time to complete the human research submission process.

5.1.2 Providing accurate and well thought out details of the proposed research plan within the UMCIRB application and other supporting material.

5.1.3 Ensuring all required documents are accurate and included with the submission.

5.1.4 Assessing and disclosing any potential Conflict of Interest (COI) with regard to the research study.

5.1.4.1 The investigator should seek guidance from their institutional representatives regarding COI determinations and management plans for disclosed conflicts.

5.1.5 Providing any additional information or clarification requested by the UMCIRB, convened IRB or IRB Chairperson (or designee) in a timely fashion (or as indicated in the IRB correspondence) to assist in the determination of approval.

5.1.6 Securing any additional required approvals outside of the IRB related to the research study (i.e., approval from an outside facility to conduct research there, approval from a professional organization to send a research recruitment email to its members, etc.)

5.1.7 Ensuring no research procedures begin before the receipt of a letter stating the UMCIRB has approved the research study.

5.1.8 Requesting an appeal of the decision made by the UMCIRB if the investigator questions that decision.

5.1.8.1 This appeal must be made in writing.

5.1.8.2 No other body or individual may override the UMCIRB's decision to disapprove, suspend or terminate a research study.

5.2 **UMCIRB Staff** are responsible for:

5.2.1 Pre-reviewing research submissions for determining whether the projectconstitutes human research activities and, if so, verifying the type of review required.

5.2.1.1 More than minimal risk studies require review by the convened UMCIRB.

5.2.1.2 Studies submitted requesting exempt certification, limited review or expedited approval may be placed on the agenda for the convened UMCIRB if the Chairperson (or designee) is uncomfortable with an aspect of the study that affects risk or when the study does not definitively fit under exempt or expedited criteria.

5.2.2 Detecting problematic and sensitive issues that may require further explanation or clarification by the research team.

5.2.3 Answering questions researchers have about the submission process.

5.2.4 Assigning new research reviews to IRB members (or their alternate) based on the reviewers' availability, experience, training, or the special needs of the study, andvia consultation with the UMCIRB Chair (or designee) if needed.

5.2.5 Ensuring there is adequate expertise, including special representatives (such as a prisoner representative) present to review the research at the convened meeting or obtaining review by a consultant, if necessary.

5.2.6 Arranging investigator attendance at an IRB meeting in which the investigator's study will receive review, whether by invitation by the IRB or request by the investigator.

5.2.6.1 The investigators and other research team members are prohibitedfrom being present during the vote on the research study.

5.2.7 Providing written correspondence to the investigator regarding UMCIRB review determinations.

5.2.8 Preparing meeting minutes for all convened IRB meetings.

5.3 **<u>UMCIRB Members and Chairpersons (or designees)</u>** are responsible for:

5.3.1 Reviewing all applications according to the DHHS "Common Rule" published at 45 CFR 46 Subpart A, along with Subpart B (pregnant women, human fetuses, neonates), Subpart C (prisoners) and Subpart D (children), the Belmont Report and those sections applicable to the IRB included in the International Conference on Harmonisation, Good Clinical Practices (section 3: Institutional Review Board/Independent Ethics committee, section 4.8: Informed Consent of Trial Subjects, and all other relevant portions), federal, state and applicable local laws, and institutional policies.

5.3.2 Reviewing FDA regulated human research according to 21 CFR Parts 50, 56, 312, 600 and 812 as applicable.

5.3.2.1 While DHHS and FDA mirror the majority of regulations contained in DHHS Subparts A and D, there are additional regulations that are unique to each regulatory body.

5.3.2.2 When appropriate, the IRB shall apply requirements set forth by the Department of Justice, Department of Defense, Department of Education and any other applicable federal or state funding agencies.

5.3.3 Raising any issues outside of the UMCIRB jurisdiction and communicating those issues to the investigator or appropriate institutional official for further review as needed.

6.0 Procedures:

6.1 The PI completes and submits the electronic IRB application.

6.2 The application must first receive Departmental review (if the principal investigator is associated with ECU).

6.3 A second level of review is conducted by all applicable Ancillary areas (as indicated in the application).

6.4 The application is then available for IRB review and the staff at UMCIRB conduct a

preliminary review to identify areas of inconsistency, incompleteness, and to identify ethical issues that may need further attention or clarification.

6.4.1 Research studies will not be forwarded for IRB approval until anyoutstanding questions or corrections to the application have been addressed

6.5 IRB review occurs after the Departmental and Ancillary review due to the fact that the institution has the authority to disapprove a study from the outset, for any number of reasons.

6.6 Once all pre-review issues have been resolved, the research application is forwarded to the UMCIRB Chair (or designee) for Exempt and Expedited reviews, and any research studies requiring approval by the convened UMCIRB committee will be placed on the nextavailable agenda.

6.6.1 Meeting agendas for the convened UMCIRB meetings will be distributed approximately one week in advance of the meeting so that all UMCIRB members have adequate time to review the agenda items and their primary/secondary reviewer assignments.

6.6.2 Investigators are prohibited from selecting or assigning reviewers for either full committee or expedited review procedures.

6.7 Questions or clarifications that arise from the review of the research study will be forwarded to the PI and research team via the electronic submission system.

6.8 Responses received from the PI and research team will be forwarded for further IRB review.

6.9 UMCIRB approval letters will be forwarded to the PI and research team via the electronic submission system.

6.9.1 If an investigator has an expired study(ies) (including those studies which expire while in the UMCIRB queue), the UMCIRB office will not release new study approvals for that PI until the requirements set forth in the "Expiration of IRB Approval" SOP are met.

6.10 IRB approval letters are generated by the electronic IRB submission system and therefore will not contain a signature from the IRB Chairperson (or designee).

6.10.1 If applicable, consents will be watermarked with the approval dates on eachpage. This stamped consent should be used to consent research participants.

Revision History:

Date	Change	Reference Section(s)
10.29.14	Made SOP a stand-alone document	All
8.1.2018	Minor clarifications to procedures	6.0
6.10.2021	Updated office name; Added new footer format; Added language about limited IRB review; Added language about not releasing approval letters for PIs with expired studies; Updated ICH to most recent FDA accepted version.	Throughout; 4.0; 6.0; References

References

FDA. Code of Federal Regulations:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

DHHS, OHRP. Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Comparison of FDA and HHS Human Subject Protection Regulations

The Belmont Report: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

ICH INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2), Current *Step 4* version, dated 9 November 2016
https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf