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| Fees for IRB Review | Effective Date | 3.01.2008 |
| | Revisions Date | 10.1.2019 |

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to outline the fees associated with research involving humans reviewed by the University & Medical Center Institutional Review Board (UMCIRB) at East Carolina University (ECU).
- 2.0 Persons Affected:** Any of the following who plan to conduct research involving humans:
- 2.1 Non-ECU Investigators submitting human research protocols to the UMCIRB for review
 - 2.2 ECU and its Affiliate Investigators submitting human research protocols to the UMCIRB for review
 - 2.3 UMCIRB office staff
- 3.0 SOP:** This procedure establishes the fee schedule applicable to the UMCIRB review of any proposed human research. The fees will apply to both expedited and full committee review of protocols. The fees will apply to initial reviews, continuing reviews, sponsor requests for revisions that require full board review, and PI requests for revisions that require full board review, originating from the University and affiliate users as well as non-ECU users of the UMCIRB services.

There may be contracts with affiliate sites that outline IRB fee expectations that would be separate from this SOP.

- 4.0 Definitions:**
- 4.1 Fee Schedule for submission to UMCIRB:
 - 4.1.1 \$2,000, Initial Reviews
 - 4.1.2 \$1,000, Continuing Reviews
 - 4.1.3 \$500, Sponsor-generated amendments requiring review by the convened IRB
 - 4.1.4 \$500, PI generated amendments (where there is sponsorship) requiring review by the convened IRB
- 5.0 Waivers:** The following human research activities will have fees waived when applying for IRB review:
- 5.1 Human research sponsored by federal, state or local governments;
 - 5.2 Human research originating from ECU students as part of a course-related project, thesis or dissertation;
 - 5.3 Human research designated by the UMCIRB as “exempt” (see Certified Exempt Research SOP);
 - 5.4 Human research supported or sponsored by ECU or other academia;
 - 5.5 Human research that is PI-initiated and not externally funded projects;
 - 5.6 Clinical investigations for which the only support provided is the test article (drug, device, biologic);
 - 5.7 Implementation of a Humanitarian Use Device, which requires full IRB review but is not considered research;
 - 5.8 Emergency use of a test article, which requires full board review;
 - 5.9 Human research activities in which an ECU or affiliate faculty, staff or student is subcontracted to carry out part of the research and which will not have funding dollars flow through ECU;

- 5.10 The report of study closures, deviations, unanticipated problems, or non-compliance in a human research activity; and
- 5.11 Human research receiving limited external monies and the IRB fees would equal 40% or more of the total monies offered by the sponsor (requires submission of the budget for verification).

6.0 Procedures:

6.1 New Full and Expedited Submissions for IRB Review

6.1.1 Fees are payable as part of the protocol submission process.

6.1.1.1 Non-ECU protocols: a check made payable to East Carolina University must be forwarded to the UMCIRB office at the time the study is submitted. While the IRB fees should be included in the agreed upon budget, if a sponsor or funding agency requires a separate invoice, the UMCIRB office can provide a template invoice for use by the study team.

6.1.1.1.1 The UMCIRB office will deliver the check and a copy of the IRB approval letter to the ECU Cashier's Office for processing.

6.1.1.1.2 If, after payment processing, it is determined that the IRB fees can be waived, the payment will be returned

6.1.1.2 University submissions: the PI/Department must indicate the account number to which the charges are to be made at the time of submission to the UMCIRB. This information needs to be provided for initial review, continuing review, and full board review of applicable amendments. An appropriate fund number (full FOAP) must be provided in the UMCIRB application. The UMCIRB office will process a cost transfer, charging the designated fund for the fee.

6.1.1.2.1 The UMCIRB office will forward the appropriate paperwork for processing according to the fund from which the IRB payment is coming. A copy of the IRB approval letter will also be attached.

6.1.1.2.2 If, after payment processing, it is determined that the IRB fees can be waived, the cost transfer will not be processed or will be reversed.

6.2 Studies with existing IRB Approval and those for which funding is subsequently secured: Studies for which IRB approval is currently in place will have fees assessed and an account charged accordingly. The Principal Investigator is responsible for notifying the sponsor or funding agency and amending the budget to incorporate any and all charges for IRB review. The Principal Investigator can, in certain cases, provide a fund/FOAP number other than that specifically related to the current study in cases where the fund/FOAP account has not yet been set up to cover IRB fees. In these cases, the Principal Investigator should contact their departmental administrator to initiate transfer of funds for IRB services.

6.3 PI Procedures for Recuprating IRB Charges: To ensure the investigator or his/her department is not ultimately held responsible for UMCIRB fees, the cost for IRB review should be included as a line item in any proposed budget for research involving humans. In cases where the UMCIRB review is prior to establishment of a sponsored fund, the PI may charge the fee to a non-sponsored account and the charge may be transferred to the sponsored fund, once the award has been established in the financial system. However, the fee cannot be charged to a different **sponsored** fund.

- 6.4 Failure to submit the appropriate fee or account number with an IRB submission may result in:
- 6.4.1 New submissions' approvals being held in the IRB office or suspension of the Principal Investigator's ability to submit new studies until the fees have been paid.
 - 6.4.2 Continuing review reports will be processed but failure to provide the appropriate fee or account number will result in the suspension of the Principal Investigator's ability to submit new studies until the fees have been paid.
 - 6.4.3 Submission of amendments will be processed but approvals may be held in the IRB office unless the IRB deems that the action of the requested revision is required to protect the rights and/or welfare of the participants enrolled in the study. In such cases, the ability of the Principal Investigator to submit new studies may be suspended until the fees have been paid.

7.0 Responsibilities:

- 7.1 Principal investigator:
 - 7.1.1 Ensure the sponsor or funding agency is aware of the ECU UMCIRB fee schedule and adequately addresses these fees (Initial, Continuing, Amendment reviews) in the proposed budget.
 - 7.1.2 For Non-ECU initiated research, it is the responsibility of the principal investigator to provide a check covering the fee or, when required, notify the UMCIRB office when a separate invoice is required for the sponsor or funding agency to issue a check.
- 7.2 UMCIRB office staff:
 - 7.2.1 Ensure fund transfers and payments for IRB fees are appropriately processed monthly.
 - 7.2.2 Track and manage all outstanding fees and develop a reminder system for those whose fees have not been paid.

Review History

| Date | Change | Reference Section(s) |
|------------|---|--|
| 10.15.2008 | Revision of format Specific details added Clarification of qualifying waivers | All Sections |
| 12.2.2013 | Clarify processes since commencement of electronic IRB submission; verify name of office; clarify timing of fee processing in ORIC office; font change | All Sections |
| 5.7.2014 | Remove waiver of fees for non-profit or charitable organizations; indicate that fees could be received from more than just industry (for profit) sponsors | Section 5.0 and all sections to clarify. |
| 10.1.2019 | Change name of office from ORIC to UMCIRB. Description of UMCIRB office responsibilities. | All sections; Section 7.2 |