

## IRB Fee Policy

The Office of Research Compliance (ORC), an administrative office that supports the University of South Carolina Institutional Review Board, has instituted an IRB review fee of \$2500 to be charged on all industry-sponsored studies. The fee will cover the review of the study. A fee of \$500 is charged for each continuing review, which includes study close outs. A continuing review is required for study close out. These fees apply to all industry-funded human subjects research conducted by USC, including sponsor-initiated and investigator-initiated studies. The fees apply to industry-sponsored studies regardless of review type or reliance on external IRB. There will be no charge for internally-funded studies, government-funded studies or studies sponsored by not-for-profit organizations.

Sponsors, and specifically pharmaceutical companies, consider IRB costs an essential part of their budget and generally do not include them in the “per subject” costs. The IRB fees should be included as a separate line item in the budget. It should appear as a flat fee and not as part of the per-subject cost. The IRB fees should be excluded from the calculation of indirect costs (i.e., when calculating indirect costs, do not include the IRB fees in the Total Direct Costs). It is the responsibility of the Principal Investigator’s department to ensure the appropriate fees are included in the contract. If a contract is executed without inclusion of the fees, the fees must be paid by the department.

Billing and payment will be handled in the following way: ORC will send an invoice to the Principal Investigator’s department for the fees to be transferred from the project account to the appropriate IRB revenue account (CL049 210000 E1016 456) per internal university procedure such as Journal Entry (JE).

Fees are assessed whether or not a study is approved or whether subjects are ever enrolled. Future charges will be assessed at the time of subsequent reviews.

The Office of Research Compliance and the IRB will use these fees to:

- Offset some of the costs associated with increasing regulatory requirements;
- Appropriately allocate and recognize the total costs of clinical trials;
- Provide continuing education and training to IRB members and investigators with respect to federal regulations and ethical guidelines for conducting research on human subjects.

Questions regarding the IRB fee policy should be directed to:

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