

IRB Fee Policy

The Office of Research Compliance (ORC) has instituted an IRB review fee of \$1,500 to be charged on all industry-initiated clinical studies. The fee will cover the review of the protocol and consent form for a study, as well as any subsequent amendments. A fee of \$400 is charged for each continuing review. These fees are applied only to those studies that have been developed and prepared by an industry or corporate sponsor. There will be no charge for studies developed by University investigators, 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 patient" costs. The IRB fee 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-patient cost. The IRB fee should be excluded from the calculation of indirect costs (i.e. When calculating indirect costs, do not include the IRB fee in the Total Direct Costs.)

Billing and payment will be handled in one of two ways: 1) ORC will invoice the sponsor upon accepting the study for IRB review and checks will be made payable to an IRB revenue account or 2) funds will be transferred from the project account to the appropriate IRB revenue account.

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 Tommy Coggins at 777-4456.