
MEMORANDUM

TO: DEPARTMENT CHAIRS, CENTER DIRECTORS, AND RESEARCH COORDINATORS
FROM: PAUL DELUCA, PH.D.
ASSOCIATE DEAN FOR RESEARCH AND GRADUATE STUDIES
SUBJECT: FEE FOR HUMAN SUBJECTS COMMITTEE PROTOCOL REVIEW
DATE: DECEMBER 1, 2001

Over the last few years, the Health Sciences Human Subjects Committee (HSC) has experienced tremendous growth in the number of research protocols that it is being asked to review. Not only has there been a substantial increase in new submissions (and correspondingly, continuing reviews), requests for exemptions from review, changes of protocol, and expedited review of administrative changes are also on the rise. In addition, the effects of medical records research and the reporting of serious adverse events are just beginning to be felt by the HSC, but are expected to have a huge impact in the near future. Finally, federal regulators have dramatically increased their oversight and expectations for documentation and compliance with every detail of the regulations, with the threat of shutting down all of our research activities if we are found to be in non-compliance. These increased demands on the HSC require more staff and equipment as well as the development and implementation of new policies and procedures, systems, and business practices, all of which costs money.

To deal with this increased cost of clinical research almost all major academic medical centers have established a fee for review of clinical protocols. It is my recommendation that, the Medical School institute such a fee. Outlined below are the details of how such a fee for service enterprise will be applied and collected.

Fee structure

\$2500 Initial Review

\$750 Annual Re-review

1. Protocols requiring a fee for review

Protocol review and annual re-review fees will not be required of all clinical protocols. Federal and non-industry sponsored investigator-initiated protocols submissions will receive a waiver of review fees. Review fees will be applied to all other submissions. We do anticipate that DHSS will soon allow IRB fees to be included in grants and contracts. At that point we will include such awards.

2. Collection of fees

Protocol review fees will be added to the contracted budgets of all clinical trial agreements from applicable sponsors. The Office of Clinical Trials will generate the invoices for these activities as part of the clinical research budgeting process. Payment of this fee will be required in the first trial installment from the sponsor, deposited into the investigators 133-research account. Upon receipt of this deposit on the institutional transmittal form, a fund transfer will be initiated.