1. PURPOSE

To standardize the fees charged for Clinical Research Office (CRO) support of clinical research activities:

- Review and initiate clinical research supervised by Creighton faculty, fellows, and residents.
- Provide ongoing regulatory support for the research study through study termination.
- Provide Research Coordinator support of active clinical studies, including Study Participant (SP) visits, interaction with study sponsors, subject screening, sponsor monitoring, and audit support.

Ensure that the activities related to research study performance/management and patient safety/welfare are completely and accurately documented in a timely and legible manner.

2. SCOPE

Applies to externally sponsored clinical trials that receive funding.

3. RESPONSIBILITIES

It is the responsibility of the CRO to review the fee schedule with the Principal Investigator (PI) for each study, and, where necessary, review with Department/Division financial advisors.

4. BACKGROUND

The CRO requires compensation for the initial start-up of sponsored clinical trials and compensation for ongoing activities related to the trial.

5. PROCEDURE

5.1. Start-Up Fees

5.1.1. The CRO charges $1,800 to the PI's research fund.

5.1.2. The fee is negotiated into the contract with the study sponsor, and the reimbursement request includes applicable indirect cost rate for sponsored projects.

5.1.3. The fee is charged to the PI by means of a Journal Entry form completed by the CRO and approved by the Department/Division as applicable.

5.2. Regulatory Support

5.2.1. Regulatory support for the project is funded through the recovery of indirect costs from reimbursements received from the study sponsor.

5.2.2. The CRO must notify the Office of Grants Administration of each fund for which indirect costs should be transferred to the CRO.

5.2.3. 50% of the indirect costs from reimbursement are directed to the CRO operating fund by the Controller's Office.

5.3. Study Coordinator (SC) Support

5.3.1. SC support for the project is funded through the billing of hourly study activity related to each clinical trial.

5.3.2. The SC must track each hour, down to the quarter hour, for all activities related to a clinical trial.

5.3.3. The SC must submit Journal Entry forms to the PI each month demonstrating the hours worked on each project for review and signature approval. Signed Journal Entry forms must be submitted to the CRO Director for processing.

5.3.4. The CRO Director will provide signature approval for each Journal Entry form and forward the Journal Entry to the Associate Vice President for Research and Compliance.

5.3.5. The SC will charge $60 per hour. This fee may be subject to change annually, but will not vary within the term of a clinical trial.

5.3.6. The SC should compare the hours billed for protocol-specific study visits with the number of hours estimated during the study budgeting process and notify the CRO Director. This process is meant to keep the SC costs within budget for a specific clinical trial.

5.4. Reduction in Fees/Fee Waiver

5.4.1. Unfunded clinical research projects are eligible for a waiver of CRO fees:

5.4.1.1. Faculty, fellow, and resident projects not supported by external sponsorship and funding.

5.4.1.2. Internally funded projects, including Health Future Foundation awardees and LB 692-funded projects.

5.4.2. Funded projects that were not granted funds to support CRO activities are not eligible for CRO support.

5.4.3. Funded projects for which contract and budget negotiations are directed by the CRO: a reduction in start-up fees is allowable if the study sponsor does not approve the start-up cost request.

6. TERMS & ABBREVIATIONS

CRO Clinical Research Office

PI Principal Investigator

SC Study Coordinator

7. REFERENCES

None

8. ATTACHMENTS

None