# FEES FOR EXTERNALLY FUNDED STUDIES

The infrastructure that supports the IRB is funded by the indirect (F&A) return on expenditures. That cost is not captured when the funding is run outside of UC (e.g. if the contract runs through UCHealth or CERV). If studies are receiving funding external to UC and are using UC's IRB, the following fees apply:

## INITIAL REVIEW of the research - \$2,500

Initial review encompasses the review of the research protocol, qualifications of the investigator, associated consent forms, protocol-related advertisements, questionnaires, screening scripts, and other submitted materials.

## FAST-TRACK REVIEW of the initial protocol submission - \$5,000

Fast-track review requires:

- A. Evidence from the sponsor indicating deadline/closure date for enrollment
- B. Evidence that approval delay would cause inability to enroll appropriate subjects for special requirement of a clinical trial
- C. Evidence of competitive enrollment by the sponsor

Other requirements for fast-track review can be obtained by contacting the HRPP office (513)558-5259. Fast track submissions will go before the board within 2 weeks of the office receiving **AND ACCEPTING ALL** of the required documents and signatures.

## EXEMPT REVIEW of the initial protocol submission - \$625

Included in the one-time fee:

- A. Initial review of the research protocol
- B. Qualifications of the Investigator and Staff
- C. Studies that meet exempt review categories

### CONTINUING REVIEW - \$1,250\*

The IRB must review ongoing research at least annually and that review must be substantive and at least comparable to the initial review. The protocol is reviewed annually, or more frequently as directed by the Board.

### CHANGES TO RESEARCH - \$300\*

Modifications to research such as protocol amendments, revised protocols, updates to consent forms, and new recruitment or retention materials, change of principal investigator or Co-Principal Investigator incur a fee. The change in research fee applies **EACH TIME** Board review and preparation of regulatory documentation is required for a research site.

### RELIANCE ON COMMERCIAL IRB - \$625

UC has contracts with the following commercial IRBs: Western Institutional IRB (WIRB), Advarra (formally Schulman Associates), and Quorum Review. The UC HRPP office will charge a handling fee for each new submission. Please contact the commercial IRB for further billing information.

\*For submissions with a combined continuing review and modification, invoices will reflect combined charges as described above.

There is no charge for administrative modifications (i.e., study personnel changes) or submission of reportable events (i.e., unanticipated problems, adverse event/serious adverse event, protocol deviation).

For fees when relying on UC IRB, please contact the IRB Office.