

### Clinical Research Fee Schedule<sup>1</sup>

Item Description	Fee
Study Initiation Fee <sup>2</sup>	\$8,529
Protocol Amendment	\$800 <sup>3</sup>
Protocol Amendment with Consent Change	\$950 <sup>3</sup>
Annual Re-approval Submission	\$1,500
SAE Report (per SAE occurrence)	\$400
Investigator Brochure Updates	\$325
IND Processing Fee	\$33
Monitoring Visit (per occurrence)	\$400
Record Retention (Document Archiving and Storage)	\$2,000
Study Close-Out	\$1,000

1. Line item fees may vary based on study specific characteristics. All fees listed are inclusive of overhead.

2. Average initiation fee. Initiation fees vary based on study complexity. All studies have a minimum initiation fee of \$4,500

3. Includes regulatory work and CTMS update

**Justification for Fees:** (all fees include 30% overhead):

**Study Initiation Fee** Our Site's Administrative Start-up Fees are a one-time, non-refundable fee, and includes variable and non-variable fees. These fees covers the costs associated with the many different processes involved in preparing a study to open such as:

- Feasibility Review
- Preparation of the Regulatory Submission
- Preparation and maintenance of the study in the Clinical Trial Management System
- Assessment of the study budget in collaboration with the Office of Clinical Research
- Site Initiation Visit

These fees do not include core research services such as Institutional Review Board and Investigational Pharmacy. UMass Worcester does expect payment of these fees by sponsor independent of contract execution.

**Protocol Amendment** Amendments may or may not be required in the course of the study. However, in the event they are required or requested by the sponsor, these are our site's standard fees. Amendments include, but are not limited to modifications to research which require board review, such as protocol amendments, revised protocols, updates to consent forms, and new recruitment or retention materials, which covers the cost of reviewing the materials, any updates to the CTMS system and associated calendar and the related administrative responsibilities of preparing review documents and updating the investigator file. **There is an additional IRB review fee for major protocol amendments.**

Examples of Amendment/Modifications include:

- Protocol Amendment Revisions (IRB Submission)
- Consent Form Modifications
- New or Updated Recruitment / Retention Materials
- Site Prepared Translations
- Other Changes to Research

**Annual Re-approval Submission** The Annual Re-approval Submission fee includes, but is not limited to the following activities

- Progress Report
- Consent updates / revisions
- IND Safety Report List

**There is an additional IRB review fee for annual review activities.**

**SAE Reporting** The standard SAE Reporting fee includes, but is not limited to the following activities

- Completing Sponsor SAE forms
- Printing all corresponding clinic notes, lab & other reports
- PI review & signatures
- Faxing
- Follow-up reports

**Investigator Brochure Update** The Investigator Brochure Updates fee includes, but is not limited to the following activities

- Consent revisions (if applicable)
- IRB submission

**If part of a major amendment (above) Additional IRB review fees will be charged to the amendment submission as a whole.**

**IND Processing Fee** The IND Processing fee includes, but is not limited to the following activities

- Printing, filing & adding each to IND list
- PI review & signatures

**Investigational Pharmacy Fee** All studies are assessed a start up fee, a per patient dispense fee, and a monthly maintenance cost. The start up fees and maintenance fees are fixed for all studies, and the per patient dispense fee is calculated according to the route of administration and complexity of the protocol.

**Monitor visits** Proper monitoring is necessary to assure adequate protection of the rights of human subjects and the safety of all subjects involved in clinical investigations and the quality and integrity of the resulting data. (FDA)

The monitoring visits consume a substantial amount of personnel time that is not captured elsewhere in the budget. The Monitor Visit fee includes, but is not limited to the following activities:

- Arranging adequate space and equipment.
- Providing the external party with accurate and complete study records (case report forms (CRFs)/data collection verification), appropriate documentation of the consent process, site issue resolution.
- Meeting with the Investigator to discuss the study and other aspects of the study that may require the monitor's attention.
- Meeting with the Research Pharmacist, Regulatory team, etc. if necessary.

**Record Retention (Document Archiving and Storage)** Record archiving fee covers the site's expenses to pack, ship, store, and retrieve study and patient-related documents at an off-site location, after required time period of on-site storage ends.

**Study Close-Out** Study Close-Out cost covers query resolution to close database, sponsor's close-out visit, pharmacy close-out and fiscal payments reconciliation.