FROM THE DEPARTMENT OF
Internal Medicine
Academic Research Services (ARS)
Medical Sciences Building (MSB) Room 6111
Email: imresearch@ucmail.uc.edu

UNIVERSITY OF Cincinnati

FEE SCHEDULE

Industry/Sponsored Study		
Description		
	Initial Fee	**Renewal Fee**
Complete compliment of IM Regulatory services	**$4200**	
IM Regulatory services -annual maintenance		**$2100**

Investigator-Initiated Study/Federally Funded/Grant Funded		
Description		
	Initial Fee	**Renewal Fee**
Complete compliment of IM regulatory services	**$2400**	
IM Regulatory services -annual maintenance		**$1200**

Effective 01Jul2022:

The above rates for ARS Regulatory Services **will be billable once an ARS intake form is submitted for services.** ***The signed intake form will now serve as the PIs approval of these fees.*** **A separate MOU is no longer needed.** At the end of each fiscal year, ARS will send each PI a list of current studies that will be billed the renewal fee as they are renewed. **No other notification of charges will be sent, unless specifically requested.**

- **Initial fees** are billed in the month that we begin regulatory work.
- **Renewal fees** are billed in the month that we submit the continuing review to the IRB of record.

- **Amendments** are included in the Initial and Renewal fees for most studies*, **unless they are due to insufficient information** from the PI or delegate regarding study teams and facilities that require a complete revision to all study regulatory documentation. These types of amendments **may result in an additional bill** for the number of hours required at the current hourly rate for time incurred for the CRP to revise all documentation.

  *Studies that are expedited or exempt and do not require continuing review submissions may be billed an hourly rate for modifications submitted and time utilized for study maintenance. This includes time to make required updates to regulatory documentation such updating the delegation log, collecting credentials for new staff adds, training logs, etc., as no renewal fees are charged for these types of studies.

  Studies that are submitted to UCIRB by ARS IM Regulatory that eventually receive **NHSR** determinations will be billed the Investigator Initiated startup fee in the month that ARS IM Regulatory begins work. Once the determination is received, you will receive a credit of that initial fee minus 10 billable hours at the current hourly rate.

  (example: Billed $2400 in July for the submission. Credited $2000 in August if deemed NHSR by UCIRB – total billed = $400 for the initial submission – based on a current hourly rate of $40.00/hr)

- **Multi-site research studies**- 1st two sites (UC site + 1) are included in standard fee schedule above. Each additional site will be $600 for initial setup, $300 annually.

- Regulatory support **fees waived for *projects designed by trainees for academic objective*** (student, residents, fellows, grad students). Trainee **must obtain division level approval of protocol prior to submission to**

the IRB and must be listed as PI with a faculty Co-PI. (The scientific pre-review form must be signed, CITI training completed, FDA training completed (if applicable), current CV, license (if applicable) and writing sample on file with ARS IM Regulatory before we can begin work.)

- **All investigator-initiated protocols** must be accompanied by a scientific pre-review form -with a division level approval signature to initiate the IRB submission.

- **All investigator-initiated protocols** must be submitted using the IRB required protocol template format (HRP-503); Consents must be submitted using the IRB required consent format (HRP-502M).

- **Complion electronic regulatory documentation platform:**
  - Studies that receive NHSR or quality improvement determinations from the IRB should not be entered into Complion. Once these determinations are established, ARS Regulatory services are no longer needed.
  - All other **IRB approved human subject research**, including retrospective, observational, and trainee research are to utilize Complion electronic regulatory documentation system. This includes exempt studies, and studies that do not require continuing reviews.

- Please note, **projects with identifiable data** need to remain open at the IRB throughout data analysis.

Contact IMRegulatory@uc.edu to initiate services or with questions.

You may also reach out to Gina Shelton directly at sheltohn@ucmail.uc.edu or 513-558-7183 for more information.