FEE SCHEDULE

**Industry/Sponsored Study**

<table>
<thead>
<tr>
<th>Description</th>
<th>Initial Fee</th>
<th>Renewal Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete compliment of IM Regulatory services</td>
<td>$4200</td>
<td></td>
</tr>
<tr>
<td>IM Regulatory services -annual maintenance</td>
<td></td>
<td>$2100</td>
</tr>
</tbody>
</table>

**Investigator-Initiated Study**

<table>
<thead>
<tr>
<th>Description</th>
<th>Initial Fee</th>
<th>Renewal Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete compliment of IM regulatory services</td>
<td>$2400</td>
<td></td>
</tr>
<tr>
<td>IM Regulatory services -annual maintenance</td>
<td></td>
<td>$1200</td>
</tr>
</tbody>
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**Effective 01Jul2021:**

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 annual 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, unless they are due to insufficient information from the PI 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.

• Projects that do not require the full complement of regulatory services may be invoiced at an hourly rate. **The current hourly rate is $40.00/hr.**

• Studies that are submitted to UCIRB by ARS IM Regulatory that eventually receive **exempt or NHSR** determinations from the IRB will be billed the Investigator Initiated start up 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 hourly rate. (example: Billed $2400 in July for the submission. Credited $2000 in August if deemed exempt/NHSR by UCIRB – total billed = $400 for the initial submission)

• **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:
  • IRB exempt and NHSR quality improvement studies 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.

• 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.