IRB Review Fees

Effective: 03/16/2015 Reviewed: 01/2/2019

Policy Statement
To establish a fee schedule for the federally mandated responsibility to protect human subjects involved in research. Institutional Review Board (IRB) review fees will be charged to maintain the expertise and efforts needed to perform the numerous components of appropriate review, assessment and approval of research protocols. The IRB fee must be included as part of the IRB review proposal at the time of submission.

DEFINITIONS

1 Adverse event: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events encompass both physical and psychological harms.

2 Institutional Review Board (IRB): An administrative body composed of scientists and nonscientists established to protect the rights and welfare of human subjects recruited to participate in research.

3 Investigator: An individual having the background and training in scientific and administrative oversight to conduct and manage research activities. Investigator includes principal investigators and sub/co-investigators. The Food and Drug Administration (FDA) uses the term sub-investigators. For purposes of these policies the term co-investigator will be used.

4 Principal Investigator (PI): The individual ultimately responsible for oversight of all research activities. He/she is ultimately responsible for all communication with the IRB (via
IRB Review Fees

the Office of Research Administration) regarding that research. The principal investigator accepts responsibility for training all personnel associated with the study in compliance with the human subject regulations of 45 CFR 46.

5. Unanticipated problem involving risks to subjects or others (Unanticipated problem):

Any incident, experience, or outcome that meets all of the following criteria:

5.1. Unexpected (in terms of nature, severity, or frequency) given:

5.1.1. the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol, and any applicable investigator brochure, the current IRB-approved informed consent document, and other relevant sources of information, such as product labeling and package inserts; and

5.1.2. the characteristics of the subject population being studied or the expected natural progression of any underlying disease, disorder, or condition of the subject experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event;

5.1. Related or possibly related to a subject’s participation in the research (possibly related means there is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research); and

5.1. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

POLICY SPECIFICATIONS

1. Protocol Processing Fee Structure

<table>
<thead>
<tr>
<th>Types of Review</th>
<th>Full Board</th>
<th>Expedited</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review</td>
<td>$2500.00</td>
<td>$1500.00</td>
<td>$500.00</td>
</tr>
<tr>
<td>Facilitated Review</td>
<td>n/a</td>
<td>$500.00</td>
<td>n/a</td>
</tr>
<tr>
<td>(One time fee)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuing Review</td>
<td>$500.00</td>
<td>$250.00</td>
<td>n/a</td>
</tr>
<tr>
<td>Amendment</td>
<td>$250.00</td>
<td>$150.00</td>
<td>$100.00</td>
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1.1. The initial IRB protocol review fee is a one-time non-refundable charge. Investigators submitting applications for new industry-sponsored clinical trials need to include a line item in the budget that reflects these charges.

1.2. The continuing review, modification and adverse event fee is incurred at the time of the submission.

1.3. Palmetto Health IRB requires payment at the time of submission.

1.4. Payment of IRB fees are the responsibility of the Principal Investigator. It is expected that Investigators will incorporate and negotiate the applicable IRB fees into the research contract.

2. Approved/Tabled/Denied
IRB Review Fees

2.1. The review process and timetable for submissions will remain the same. The IRB review fee is payable regardless of approval and is used to offset costs associated with the review process.

2.2. The IRB review fee will be incurred even if subjects are not enrolled, the study terminates, expenditures exceed revenue, desired results or expectations are not met, and/or contract has not reached finality. If there is uncertainty as to contract finality, the sponsor, and PI may wish to delay incurring these charges until all plans are final.

3. IRB Fee Review

3.1. The fee amounts will be reviewed periodically and are subject to change at the discretion of Palmetto Health.

4. Fee Exclusions

4.1. The following submissions are not subject to this policy:

4.1.1. Protocols sponsored by Federal, State, County, and Local government, or not for profit organizations.

4.1.2. Investigator initiated protocols without sponsorship.

4.1.3. Protocols sponsored by funding agencies that prohibit payment of IRB fees.

4.1.4. Applications for a non-research use of a Humanitarian Use Device.

4.1.5. Applications for emergency use of an investigational drug or device.

5. Checks should be sent to the Palmetto Health IRB office. Checks should be made payable to “Palmetto Health IRB”, referencing “IRB Fee” and the assigned Palmetto Health IRB number or Pro number, to the attention of the Business Analyst. Electronic payment arrangements can be coordinated through the Business Analyst.