A review fee will be assessed by the Prisma Health Institutional Review Board (IRB) for sponsored studies requiring full board review, as well as for all externally reviewed studies. Fees will be assessed at the time of the initial study review, annual continuing reviews, and any amendment reviews. These fees will cover the expenses for IRB operations and administration related to the submission and review of the study. The fees are retained by the IRB and are neither available to the Principal Investigator (PI) or clinical department, nor are they intended to compensate the PI or regulatory staff’s time related to IRB preparation, submission, and/or maintenance.

**The attached fee structure is applied to studies submitted to the IRB after September 30, 2019.**

**Fee Payment**

* IRB review/administrative fees are due in full once the protocol is reviewed by a convened IRB Committee. The fees are applied whether or not the study is approved, participants are enrolled, or the study is withdrawn/terminated before enrollment begins or research objectives met.
* Fees are non-refundable.
* Decisions about how to address non-payment of IRB review fees that are not granted a waiver will be made on a case-by-case basis by the IRB, in consultation with the Prisma Health Clinical Research Management Office (CRMO).

**Fee Waiver Criteria**

* Unfunded research conducted to fulfill specific or general academic or accreditation requirements of students or training programs affiliated with Prisma Health (e.g. residents, fellows, nursing students, medical students, and allied health students);
* Investigator initiated research that is not funded by an external organization;
* Research funded by a federal, state, or local government entity that either does not allow inclusion of IRB fees or the amount of funds granted is so limited that paying the IRB review fee would be prohibitive;
* An activity requiring IRB review but conducted for clinical, non-research purposes (i.e. sIND, Emergency Use, Compassionate Use, HUDs);
* An activity funded solely by a non-profit organization that either does not allow the charging of IRB fees or the amount of funds granted is so limited that paying the IRB review fee would be prohibitive; or
* Determination of request for waiver will be made by the Institutional Official or their designee.

**Waiver of IRB Fees**

If a study does not meet any of the above criteria, a waiver of or reduction in the amount of the established IRB review fee may occur under other extenuating circumstances. A request to waive or reduce the established IRB fee must be submitted in writing to the Prisma Health Office of Human Research Protection Director prior to the submission of the actual IRB application.

*\*Request for Waiver of Institutional Review Board Fees attached below.*

**IRB Fee Schedule**

Initial IRB Review ……………………………….………………………………………………… $2500

Annual Continuing Review\*…………………………………………………………………… $1000

Amendment Review ……………………………….…………………………………………… $1000

External IRB Review (one-time fee) …………………….………………………………. $1000

*\*The annual continuing review fee will only be assessed annually. Some IRB determinations may require review more frequently; however, only one fee will be assessed based on the initial review date every twelve months.*

**Request for Waiver of Institutional Review Board Fees – DO NOT COMPLETE THIS FORM UNLESS SPECIFICALLY DIRECTED TO BY THE IRB.**

|  |  |
| --- | --- |
|  | **PROTOCOL INFORMATION** |
| Study Title  | Click or tap here to enter text. |
| Principal Investigator | Click or tap here to enter text. |
| Sponsor *(governmental, NPO, investigator initiated, internal funding)* | Click or tap here to enter text. |
| **Principal Investigator’s Statement and Signature**  |
| I request a waiver of the normal IRB administrative fee(s) due to the nature of this study. Please provide justification and/or documentation as appropriate.  |
| Click or tap here to enter text. |
| **Principal Investigator’s Signature** | **Date of Signature** |
| Click or tap here to enter text. | Click or tap to enter a date. |
| **Response to additional information request:**Click or tap here to enter text. |
| **This Section is for IRB Administrative Use Only**  |
| Request Approved [ ]  | Institutional Official or Designee: |
| Additional Information Requested [ ]   | Click or tap here to enter text. |
| Request Denied [ ]  | Date: Click or tap to enter a date. |