

Advocate Aurora Health (AAH) IRB Review Fees

[Implementation date: 11/1/18]

Studies where the Advocate Aurora Health (AAH) IRB does not cede to an external IRB

Study Risk Level #	Initial review	Annual review fee (charged one year from the date of the initial approval even if there is more than one continuing review in a given year or if continuing review is not required by regulation)
Full/Convened Board Review (GTMR = greater than minimal risk)	2500	1500
Expedited Review (NGTMR = no greater than minimal risk)	1500	750
Exempt Review	1000	NA

Any modification that changes the approval category (full, expedited, or exempt) of an approved study will require a new submission. That new submission will incur the initial review cost noted above for the new submission category. For example, should an exempt study be modified such that it no longer fits the exempt criteria, but instead requires review as a NGTMR study, the submitter will need to submit a new application to the IRB, and this new application will incur an initial review fee for a NGTMR research study (as well as NGTMR annual review fees should the study remain open for longer than one year).

No review fees will be charged for Human Subject Research (HSR) Determinations in order to not discourage such submissions. An HSR Determination may be requested of the IRB/RSPP office when a formal decision is necessary to determine whether an activity constitutes human subject research per system policy and federal regulations.

Waivers of IRB fees will be considered on a study by study basis. Waiver criteria are listed below. An IRB review fee waiver will be requested in the IRB submission application.

Studies where AAH cedes IRB oversight to an external IRB

A one-time fee of \$1500 will be assessed for any study ceded for IRB oversight to an external IRB. **Note: the external IRB/IRB of Record may assess its own review fees in addition to this Aurora IRB review fee.** Waivers of this IRB Review Fee will be considered on a study by study basis. Waiver criteria are listed below. A fee waiver may be requested in the ceding application.

Fee payment

IRB Review fees are charged for IRB administrative and review considerations. Payment is due in full **60** days after receipt of invoice.

- IRB review/administrative fees are due in full even if the IRB does not approve the study, participants are never enrolled, or the study is terminated/withdrawn before enrollment begins or research objectives met.
- Fees are not-refundable.
- Delinquent payment of the above fees may result in researcher/sponsor being deemed ineligible to participate in future research projects at AAH.
- 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/RSPP Office, in consultation with the Advocate Aurora Compliance Department and Advocate Aurora Research Institute. Researchers/sponsors will be notified of such decision.

Fee waiver criteria

A waiver of the established IRB fee will be granted if the research aligns with AAH mission (as determined through the research pre-authorization process), and is one of the following:

- unfunded research conducted to fulfill specific or general academic or accreditation requirements of students or training programs affiliated with Advocate Aurora Health (e.g., residents, fellows, nursing students) or research by other students (e.g. Aurora or Advocate employees obtaining an advanced degree) that aligns with AAH's mission;
- investigator-initiated research led by an Advocate Aurora Health team member that is not funded either internally or by an external organization
- research funded by a federal, state, or local government entity that doesn't allow inclusion of IRB fees or the amount of funds granted is so limited that paying for IRB review services would not allow the research to go forward;
- an activity requiring IRB review but conducted for clinical, non-research purposes (i.e., Emergency Use, Compassionate Use, Expanded Access, HUDs)
- an activity funded solely by a not-for-profit group/entity and the group/entity either does not allow the charging of IRB fees or the amount of funds granted is so limited that paying for IRB review services would not allow the research to go forward

In the event that 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 for reasons not listed above must be submitted in writing to the Advocate Aurora Research Compliance Office. **Approval by Compliance must be included with the initial IRB application.**