

**Faculty & Staff Operating Guidelines
AU IRB Applications**

**Akamai University Institutional Review Board
Updated 2021 - 2025**

What is an IRB?

There is a Public Law Governing Research with Human Subjects. Akamai has established a process to abide by this federal law: [Title 45, Public Welfare, Department of Health and Human Services, PART 46, Protection of Human](#). HHS.gov Office for Human Research Protections Document [Link Here](#).

An IRB approval is required for our graduate research proposals (and faculty proposals).

Using decision charts, appointed IRB faculty members examine decisions related to whether an activity may be waived by an IRB preliminary reviewer, or whether the review must be performed by **expedited or full review procedures**, and whether it may be waived.

Step #1: Gathering the Student's IRB Application Materials

Staff begin processing IRB applications at the time a Thesis or Dissertation Committee provides approval of a DRAFT Proposal and instructs the student to submit the application and complete the IRB process. The student's IRB application materials sent via email attachment, must include:

- ✚ The signed and completed IRB Application form.
- ✚ The approved DRAFT of the student's thesis or dissertation proposal.
- ✚ The \$300 Preliminary IRB fee, in full.

Step #2: Send the Student's Application to IRB Chair

The student should immediately be issued the fee receipt. Once the funds have been dispatched and copies of the receipts are on file, staff immediately email the IRB application and draft proposal to the IRB Chair via AU President. Once these items are received and the student has been issued the fee receipt, the IRB application and draft proposal are submitted by email to the current AU IRB Chair via the AU President through the AU Administrative Office.



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Step #3: Guide IRB Chair to Identify Preliminary Reviewer

The following message should be included in a cover email when sending the application to the current AU IRB Chair:

Dear ...,

The attached documents are for your records and for use in sending to your selected preliminary reviewer of the attached research proposal. Attached or linked are the following:

- *Approved IRB application for research to be accomplished by [applicant name]*
- *The research proposal for review*
- *IRB Initial assessment report blank for reviewer completion The process from this point on is the following:*
 1. *You, as the IRB Chair shall select a preliminary reviewer from the IRB Committee membership.*
 2. *You, as the IRB Chair notifies the selected member by email, providing a copy of the approved proposal and the Reviewer Report Form with a link the following instructions.*
 3. *Upon receipt of the confirmation from the preliminary reviewer, please notify the Akamai headquarters with that message.*

Regards,

Your name and title

Step #4: Make the IRB Faculty Payments

The IRB Chair and the selected Preliminary Reviewer are provided their fee up front (\$100 USD each) prior to the onset of any review activities.

Once the Preliminary Reviewer has been identified and, and immediately following the deposit of the funds in the AU bank account, the IRB Chair provided their fees up front (\$100 USD each) prior to the onset of any review activities.

Step #5 Get the Preliminary Review Started?

The appointed IRB Preliminary Reviewer should start to review the research proposal, adhering to the IRB Decisions Charts and the standards published online:

[.https://www.akamai.university/au-research--scholarship.html](https://www.akamai.university/au-research--scholarship.html)

Staff in communication with AU Vice President of Academic Affairs should monitor the process, at this stage to see that activities for the review have started. Actually write or telephone

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the assigned Preliminary Reviewer and ask how things are going. Be sure there is a reply to your outreach. When needed contact the AU President for any questions.

Step #6 What Can be the Results of the Preliminary Review?

There are three possible outcomes of the preliminary review.

✚ **It can be approved as is.**

If the proposed project can be accepted as effective as it stands, the Preliminary Reviewer can complete, sign, and submit by email attachment to the University President and IRB Chair, the IRB Initial Assessment Report with initials to the right of the item stating *The research project is exempt from IRB review*

✚ **It may need further review.**

If the proposed project needs further review but is deemed appropriate for an expedited review, the Preliminary Reviewer shall complete, sign, and submit by email attachment to the University President and IRB Chair, the IRB Initial Assessment Report with initials to the right of the item stating: *The research project is appropriate for an expedited review by one member or a subcommittee of the IRB (notes attached).*

✚ **It may need a full review.**

If the proposed project needs a full; review, the Preliminary Reviewer shall complete, sign, and submit by email attachment to the University President and IRB Chair, the IRB Initial Assessment Report with initials to the right of the item stating: *The research project is subject to full review by the IRB (notes attached)*

Step #7: How To Handle Follow-up of the Preliminary Review

There are three options for follow-up to the results that come from the Preliminary Reviewer:

✚ **Follow-Up ---If it can be exempted as is.**

Upon receipt of the report from the Initial Reviewer, if it can be **exempted** as it, the President may prepare and issue to the researcher, the IRB Chair, and Committee Chair, the Approval Form for Research with Human Subjects.

✚ **Follow-Up ---If it needs an Expedited Review**

Upon receipt of the report from the Initial Reviewer, if an expedited review is needed, the staff should request the IRB Chair to appoint a Reviewer to conduct the Expedited Review

✚ **Follow-Up ---If it needs a full review.**

Upon receipt of the report from the Initial Reviewer, if a full review is required, the staff should request the IRB Chair to appoint an IRB Sub-Committee to conduct the Full Review.

Step #8: Handling an Expedited Review, if Needed

When determined that an expedited review is required, the IRB Chair will designate an IRB Expedited Reviewer to evaluate the proposal further. Staff should monitor that this activity is initiated and completed in a timely manner. If the Reviewer has questions concerning the proposal, he or she will consult with The IRB Chair to determine whether or not full review is required. After a detailed inspection, if the research project can be determined exempt by the IRB Expedited Reviewer, such can be indicated on the written report to be sent to the IRB Chair with copy to the University President.

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If determined to be exempt, the IRB Exemption Report will be signed by the IRB Chair and returned to the researcher immediately with copies sent by email to the Committee Chair and University Administration for the archival record.

Step #9: Handling a Full Review, if Needed

If the IRB Expedited Reviewer determines, in consensus with the IRB Chair that the research project will require a Full Review, the IRB Exemption Report is marked *Not Exempt* and signed by the IRB Chair and returned to the researcher immediately with copies sent by email to the Committee Chair and University Administration for the archival record.

If. Full IRB Committee Review is required; a copy of the research proposal will be assigned to a voluntary IRB Full Review Preliminary Committee of two- three faculty members, in good standing, appointed from among the IRB Membership, for a detailed preliminary assessment and written report, initiated at least fifteen days before convening a meeting of the Full IRB Committee. A summary report of the findings from the preliminary reviewers will be prepared by the IRB Chair and distributed to the Full IRB Committee at least three days prior to the scheduled meeting date.

The Full IRB Committee meeting shall be conducted via audio conference arranged by the IRB Chairperson. At the Full IRB Committee meeting, a majority quorum of the IRB Committee members must be present at the meeting for a full review of any proposal to take place. The principle investigator shall be invited to attend the meeting to answer questions about the research. A majority of the quorum present may approve or disapprove the research. Members of the IRB who vote to disapprove a proposal must submit their reasons in writing to the IRB Chairperson.

Step #10 Procedures Following Approval by IRB Full Review Committee

If the IRB Full Review Committee determines, in consensus with the IRB Chair that the research Project is approved, the IRB Full Review Committee Report is marked “approved” and signed by the IRB Chair and dispatched to the researcher immediately with copies sent by email to the Committee Chair and University President for the archival record.

Step #11 Procedures Following Disapproval by IRB Full Review Committee

If the IRB Full Review Committee determines, in consensus with the IRB Chair that the research project is disapproved, the IRB Full Review Committee Report is marked “DISAPPROVED” and signed by the IRB Chair and dispatched to the researcher immediately with copies sent by email to the Committee Chair and University President for the archival record.

Further, together with the report of disapproval, the researcher will be notified in writing, with clearly itemized reasons for the disapproval, and will be given an opportunity with complete instructions, to respond in writing and make requisite changes, corrections and upgrades to the research proposal and re-submit for review within a designated period not to exceed 90 days, with a deadline date provided.