

IRB Process for Fairview Researchers

Fairview Research Administration (FRA) is responsible for ensuring three things for all IRB applications:

1. The application is complete
2. Human subjects' protection training (e.g. CITI) was completed by all researchers; and
3. Conflict of interest disclosures were completed by applicable researchers.

We manage this by embedding application review into the IRB submission process.

Definition of a Fairview Researcher

First, we would like to define a *Fairview Researcher* for easy identification of who needs to follow this process. Fairview Researchers include all medical staff appointees, students, physicians privileged to practice at Fairview, and employees of Fairview who participate in research involving human subjects at any Fairview facility.

This definition specifically excludes University of Minnesota faculty and students.

If you are not performing research at Fairview or using Fairview records, and you are not a Fairview employee, then you do not have to follow this process. Please note, though, that in this case you may not be able to use the UMN IRB as the IRB of record for your research. Please contact FRA if you have questions about whether or not your study must follow this process, or may use the UMN IRB.

IRB Submission Process

Selecting 'Fairview Researcher' as the Occupational Position

Every researcher that meets the above definition of a Fairview Researcher should select Fairview Researcher as the 'Occupational Position' on the IRB application.

Occupational Position: <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input checked="" type="checkbox"/> Fairview Researcher <input type="checkbox"/> Gillette Researcher <input type="checkbox"/> Other:

FRA as a study correspondent

When you are submitting your initial application, please include Fairview Research as a study correspondent, as listed below:

Name (Last name, First name MI): Fairview Research	Highest Earned Degree:
Mailing Address: 2344 Energy Park Drive Saint Paul, MN 55108	Phone Number: 612 672 7690
	Fax: 612 672 7691
U of M Employee/Student ID:	Email: research@fairview.org
Occupational Position: <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/> Fairview Researcher <input type="checkbox"/> Gillette Researcher <input checked="" type="checkbox"/> Other: correspondent	
Human Subjects Training <input checked="" type="checkbox"/> CITI , <input type="checkbox"/> Investigator 101, <input type="checkbox"/> NIH training (EXCEPT for 5/8/06 to 2/29/08), <input type="checkbox"/> UM/RCR (between 1994-2003) <input type="checkbox"/> Other - Indicate training received, when and from which institution:	HIPAA Training (Required if Data Contains PHI): <input checked="" type="checkbox"/> HIPAA

No individual staff member from FRA needs to be listed. This will allow more efficient communications between the IRB and FRA, and to allow FRA backup in the case a staff member listed on the IRB is unavailable at the time of a question. We feel it accurately captures the administrative function of including FRA on IRB applications.

Director of Fairview Research as Department Head

The System Director of Fairview Research should be listed as the Department/Division Head for all applications from a Fairview Researcher.

As Department/Division Head or Dean , I acknowledge that this research is in keeping with the standards set by my department and I assure that the Principal Investigator has met all departmental requirements for review and approval of this research.	
Adrienne Baranauskas, System Director of Fairview Research	
Typed Name of Dept. Head, Director of Research Fairview, or Director of Gillette Research Administration	
Original Signature of Department, Fairview, or Gillette Official	Date

Submitting a New Study to the IRB

The initial submission for each study must be sent by FRA.

Paper Submissions: For submissions that are too large to fit in one email, a paper copy of the completed submission should be sent to FRA. The submission should include the original signatures of all investigators. FRA will review for completeness, and Adrienne Baranauskas will sign as the System Director of Fairview Research. FRA will attach a cover letter that attests they reviewed the application, and list the contents.

Email Submissions: For submissions that may be sent in one email, the complete submission should be emailed to FRA. The documents do not require signatures in this case. FRA will review for completeness, and submit to the IRB on the researcher’s behalf. The investigators will be cc’ed on the email submission to signify their signatures.

Submitting Other Information to the IRB

All further documentation to the IRB can be submitted by the researcher directly. FRA should receive a copy of all correspondence.

Please note that there are two ways to submit to the IRB:

Paper: Paper submissions must include original signatures where needed. The researcher should make copies of the submission for their own records and for FRA.

Email:

Without signatures: Signatures are not required on emailed applications as long as it is sent from the PI’s institutional email address. If other investigators’ signatures are required on the submission, they should be cc’ed. This signifies the PI’s and investigators’ signatures on the application.

With signatures: Signed applications can be scanned and submitted via email by study staff.

Confirmation of Human Subjects Protection Training

Current human subjects' protection training will be confirmed at the time of initial review and continuing renewal. CITI training is the only acceptable form of training, and must be renewed every three years. FRA must have a copy of each researcher's CITI completion report. If the researcher affiliated with Fairview on the CITI site, FRA will automatically receive a copy of this report once the training is completed. No other training documentation is necessary.

FRA will review the training records of all Fairview personnel listed on the application or renewal when the IRB sends the 'Application Received' email. If a researcher's training has lapsed, FRA will 'Reply All' to this email with a request for the IRB to hold review of the application. We will then follow up with the researchers directly to resolve the issue. Once all requirements are met, FRA will again 'Reply All' to release the submission for IRB review.

We recommend confirming with FRA (research@fairview.org) that all Fairview Researchers listed on your application are up-to-date with training requirements before submitting to the IRB. This will avoid unexpected delays in review.

Confirmation of Conflict of Interest Disclosures

Conflict of Interest (COI) reporting is due at the time of initial submission and continuing renewal for all sponsored studies. All investigators, including co-investigators, must submit a COI disclosure. The original signed forms must be received by FRA before the application can be reviewed by the IRB.

FRA will confirm the receipt of COI forms for investigators listed on the application or renewal when the IRB sends the 'Application Received' email. If all COI's have not been received, FRA will 'Reply All' to this email with a request for the IRB to hold review of the application. We will then follow up with the researchers directly to resolve the issue. Once all COI requirements are met, FRA will again 'Reply All' to release the submission for IRB review.

Payments to the IRB

There is an IRB fee of \$2,500 for all expedited and full review studies with Business and Industry sponsors. Please send your IRB payments directly to the IRB, attention Linnea Anderson. Be sure to include the PI name and IRB# on the check, and on a cover letter attached to the check.