

# The Magnifier

**Spring 2011**

**Fairview Research Administration**

*The Magnifier* is a quarterly newsletter providing information and announcements pertaining to the conduct of research within Fairview Health Services. Please share our newsletter with others who may be interested and [contact us](#) to be added or removed from the mailing list. You can also view this and previous editions of our newsletter on the Research web page.

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### Welcome Mike Nordberg!

Mike Nordberg joined FRA this week as a Research Administrative Coordinator. He will be the lead on the cardiovascular service line collaboration and investigational devices, among others, and will work closely with Katie van Meurs and Mike Rugani. He brings a wealth of research experience to our department from his time at UMN, and we're excited for this new perspective. His phone number is (612) 672-6737, and email [mnordbe2@fairview.org](mailto:mnordbe2@fairview.org).

### Southdale Radiation Safety Committee Review

The Southdale Radiation Safety Committee (FSH- RSC) is formalizing their review process, and all applications will be reviewed at their quarterly meetings. This will allow the committee to have a discussion about the project instead of relying on email communication alone for reviews. The meetings are scheduled in February, May, August, and November. Exact dates are not set until the previous meeting.

The committee requests that all applications are submitted with a cover letter that provides the following: the name of the research study, a brief explanation of the purpose of the study, and what additional radiation patients will receive (what type of radiology exam, how many per patient, and over what length of time). Dian Finn is the Manager of Radiation and Imaging at FSH, and has agreed to be the contact for questions about the FSH-RSC (952-924-5254; [dfinn2@fairview.org](mailto:dfinn2@fairview.org)).

### Changes to IRB Process for Fairview Researchers

Fairview Research Administration (FRA) has revised the IRB submission process to allow better enforcement of Fairview policies, and a more streamlined process for Fairview Researchers. The main change is that investigator training and conflict of interest disclosures will be confirmed by FRA *before* the IRB will review an application.

### 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

### *FRA as a study correspondent*

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

Name (Last name, First name MI): <b>Fairview Research</b>	Highest Earned Degree:
Mailing Address: <b>2344 Energy Park Drive Saint Paul, MN 55108</b>	Phone Number: <b>612 672 7647</b>
	Pager or Cell Phone Number:
	Fax: <b>612 672 7691</b>
U of M Employee/Student ID:	Email: <b>research@fairview.org</b>
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:	
Should This Person Be Copied on All Correspondence? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Human Subjects Training (one of these must be checked--refer to training links at the end of this section): <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. We recently submitted a request to the IRB to convert all Active Studies listing Adrienne Baranauskas, Katherine Gleason/van Meurs, and Tiffany Walker to this correspondent.

The reason behind this process change is to allow more efficient communications between the IRB and FRA, and to allow FRA backup in the case the staff member listed on the IRB is unavailable at the time of a question. We feel it more accurately captures the administrative function of including FRA on IRB applications.

### *Confirmation of Human Subjects Protection Training*

Current human subjects protection training will be confirmed at the time of initial review and continuing renewal. From this time forward, 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. No other training documentation is necessary.

FRA will review the training records of all 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 Katie van Meurs ([kvanmeu1@fairview.org](mailto:kvanmeu1@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.

The reason behind this process change is to eliminate inefficient communication and follow up between FRA and the researcher. Currently, FRA attempts to enforce the training requirement. This new process will allow the PI a greater role in either enforcing the training requirement or removing the ineligible researcher from his/her study.

### *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 form. 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 all 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.

The reason behind this process change is to help FRA maintain an accurate record of COI's. Financial conflicts are becoming an increasingly high compliance issue within research regulations. We hope that closely tying them to IRB submissions will help to remind both researchers and FRA when COI disclosures are due.

### *Payments to the IRB*

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. Both expedited and full review of studies sponsored by business and industry cost \$2,500. FRA will no longer create invoices for IRB payments. The reason behind this process change is to exclude unnecessary steps. The IRB will manage the incoming checks.

### **A Note on Individual Investigator Agreements (IIAs)**

Please note that an IIA is required for all external researchers only once. External researchers include researchers who are NOT: an employee of Fairview Health Services; a University of Minnesota Physicians' physician; or a faculty member or student of the Academic Health Center at the University of Minnesota, with the exception of adjunct appointments.