The Magnifier

Fall 2010 ***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.

IN THIS ISSUE

New Fairview Research Administrative Coordinator

We want to welcome Katherine (Katie) van Meurs who recently joined Fairview Research Administration as the Administrative Coordinator, the position previously held by Tiffany Walker. Katie will continue to provide help with IRB submissions, protocol development, and regulatory compliance for all Fairview employees. You can reach her directly by phone at (612) 672-7647 or email at kgleaso1@fairview.org.

NIA Clinical Research Investigator's Toolbox

The NIH has several guidelines and lists of required documents for clinical trials. The National Institute on Aging (NIA) took all those recommendations and created a helpful and easy-to-use website. This toolbox is an information repository for all aspects of a clinical research trial. Though focused on NIA grants, it contains templates and sample forms, as well as guidelines and information on regulations and compliance in clinical research in any field. It is a valuable resource for the development and execution of a successful trial.

NIA Toolbox

IRB Expedited & Exempt Review Submission Tips

In June, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) released data collected from its group of 196 accredited organizations. The data included types of reviews and review times, among other metrics. The University took these metrics and compared them to their own HRPP office, implementing changes where necessary to remain with the national average. For more information, please see the OVRP Research News article.

The IRB also released tips for expedited and exempt IRB submissions based on the most common hold ups.

For Medical Record Chart Review:

- When a link to protected health information (e.g., the patient names or medical record numbers) is maintained separately from the data, it should be noted that the IRB still considers a link to exist.

- The Medical Record Chart Review application allows the researchers to select the level of review appropriate for the research. If the Principal Investigator thinks their research will qualify for expedited review, initially selecting the most accurate category of review will assist in a more expedient approval (e.g., “Research including a retrospective and prospective chart review” is considered expedited).

For All Projects:

- Electronic applications need to be sent to irb@umn.edu using an official University of Minnesota email account; email providers such as Gmail, Hotmail, or Yahoo! cannot be accepted.
- Remember to cc your advisor and any co-Investigators associated with the research application using their official University of Minnesota email account.
- Submit any surveys, questionnaires, recruitment materials, supporting documents, and consent forms with the application.
- Indicate completion of Human Research Subjects’ Protection training in the appropriate portion of the application.

Revised IRB Medical Review Requirements

The IRB has modified **3 components** of the IRB Medical new application submission *in response to revised regulatory guidelines and requirements*. The information below must be provided before the IRB can begin its review process:

1. Section 3.1 of the application, scientific review, Fairview researchers would fall under Method C, and the Fairview Research Scientific Review Committee Approval Memorandum must be attached with your submission;
2. If the study is funded by a federal agency, such as NIH, one copy of the entire grant application must be provided along with Appendix A;
3. Please note that Appendix A has been revised to include required information regarding federal grants, and a TASCS Billing Grid must be submitted with coverage analysis completed if applicable per Section 3.2 of the application.

If these components apply to an application and are not included, review by the full IRB panel will be delayed. Questions should be directed to the IRB at irb@umn.edu or 612.626.5654.