

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.

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## Changes to IRB Website and Forms

The University of Minnesota Institutional Review Board (IRB), which is also Fairview's IRB, recently redesigned their [Website](#) to assist researchers in finding the information and forms they need. The site is reorganized into the following content areas:

- Forms
- Meetings & Deadlines
- Does My Research Need IRB Review?
- IRB Review Process
- Training
- Guidance & FAQs (frequently asked questions)

In addition, in March and April the IRB revised some of their forms to reflect the most current points of emphasis in human research subjects' protections, federal guidance, and University of Minnesota policies. Revised forms include:

- Health & Biological/Medical Application
- Appendix B – for federally funded research involving pregnant women, human fetuses and neonates
- Appendix E – for research involving the use of drugs or biological products
- Scientific Review Forms
- UPIRTSO Form (unanticipated problems involving risks to subjects or others)

Changes include added questions in Appendix E for [Treatment Investigational New Drug \(IND\)](#) and the dispensing and storage of study medication. In addition, the IRB's definition of a UPIRTSO has been revised to replace the criterion "serious" with "reflects new or increased risk to the subjects." The IRB has also added guidance (FAQs) for researchers about reporting unanticipated problems.

Please be sure to visit the [IRB's Download Forms Page](#) to use the most current version of IRB forms. If you have any questions, please contact the IRB at 612-626-5654.

## New Fairview Research Operations Manager

We want to welcome Phillip Hanlon, MBA, who recently joined Fairview Research Administration as the new Operations Manager. In this role, Mr. Hanlon oversees research business operations and staff, including coverage-analysis, account set-up, pricing, and billing. You can reach him directly by phone at 612-672-7667 or email at [phanlon1@fairview.org](mailto:phanlon1@fairview.org).

## Treatment Investigational New Drug (IND)

The University of Minnesota Institutional Review Board (IRB) recently revised Appendix E for new study applications involving use of drugs or biological products in research. Specifically, the IRB now asks whether the study involves use of a treatment Investigational New Drug (IND) and who is responsible for paying for the medication.

The FDA defines Treatment INDs as a way to make promising new drugs available to desperately ill patients as early in the drug development process as possible. The FDA permits an investigational drug to be used under a treatment IND if there is preliminary evidence of drug efficacy and the drug is intended to treat a serious or life-threatening disease, or if there is no comparable alternative drug or therapy available to treat that stage of the disease in the intended patient population. In addition, these patients are not eligible to participate in ongoing clinical trials.

The FDA passed a rule change last year amending its investigational new drug (IND) application regulation relating to charging for investigational new drugs (21 CFR Parts 312). Historically, drug companies provided the investigational drug to the treating institution free of charge for treatment IND uses. Under the FDA's new rule, drug companies may charge the treating institution for the cost of the investigational drug. However, many insurance companies and Medicare will not pay for these medications so it is presumed that the institutions will absorb the cost or pass the charge through to the patient bill.

Therefore, if you plan on using a treatment IND at a Fairview facility and the medication is not provided free of charge by the drug maker/sponsor, you need to indicate this to the IRB (via Appendix E) and notify Fairview Research Administration. Before a treatment IND can be used, Fairview's Treatment IND Committee must review a researcher's requested use of the medication and determine whether it is:

- 1) Approved with no restrictions on use
- 2) Approved with restrictions on use (e.g., number of patients, timeframe, dollars expended)
- 3) Additional information is needed (with a deadline for response before rejection)
- 4) Not approved

For further guidance and information, contact the Research Regulatory Affairs Officer at Fairview, Mike Rugani, JD, CHRC. He manages Fairview's treatment IND review process and is available by phone at 612-672-7680 or at [mrugani1@fairview.org](mailto:mrugani1@fairview.org).

## FDA Guidance on Statement of Investigator (1572) form

The Food and Drug Administration (FDA) recently issued a final information sheet to answer frequently asked questions about Form FDA-1572, also called the Statement of Investigator form.

Although much of the information provided in this guidance document is not new, it is the first time this information has appeared in a single, final document. It provides general information about the 1572 form such as the form's purpose and the minimum qualifications for investigators and sub-investigators, along with detailed information about completing each section of the form.

The final guidance document is available on the FDA's website at the following link: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>