



Research Education Improvement Program (REIP) Newsletter

August 08; Issue 2

Welcome!

This issue of the *REIP Newsletter* includes research review risk trends, what the research community can do to be in compliance with the regulations, helpful tools accessible to the research community, and what to do in case your lap top is stolen.

If there are topics you wish to see included please contact the Research Review Monitor (RRM) at 545-8376 or kjennings@ccmckids.org

What Have We Learned So Far?

The Research Review Monitor has reviewed 12 research studies. Below is an outline of risk trends identified from those reviews:

- Unable to locate signed consent forms
- Incomplete consent forms
- No documentation of the consent process
- In-eligible patients enrolled

Let's look at risk trends to see what can be done to be compliant:

- Keep copies of all consent forms in a separate binder. The binder should be kept in a locked cabinet.
- Review the consent forms prior to families and/or patients leaving CCMC. This will ensure that consents have been signed and dated properly.
- As per CCMC policy the consent process needs to be documented. To comply with this policy you can create a template that states the informed consent process has been completed, all questions answered, and copy given to whom. Include lines for the date and time consent was obtained. A template can be found on the G: drive under CCMCDOC/RESEARCH/REIP Program.
- To ensure all eligibility criteria is met, create an eligibility checklist. Any questions regarding eligibility discuss with the PI.

Where To Find Helpful Tools/Information For The Research Community:

Located on the G: drive/CCMCDOC/RESEARCH/REIP Program. The REIP folder contains the following information:

- REIP Program Manual – describes the research review process
- Templates for a Research Study Binder – information and templates to use for a complete Research Study Binder
- Templates for data capture forms/case report forms – templates that can be downloaded and amended for your clinical trial

Helpful Websites:

FDA Main website

<http://www.fda.gov/>

FDA Code of Federal Regulations

<http://www.fda.gov/cdrh/devadvice/365.html>

Department of Health and Human Services

<http://www.hhs.gov/>

HIPAA Information

http://privacyruleandresearch.nih.gov/clin_research.asp

Did You Know?

Lap top theft is a growing problem not only in the general public, but in the research realm as well. Many researchers have lap tops stolen that contain personal information about research subjects.

Who do you contact if your lap top is stolen?

- If lap top is stolen that is non-research oriented, call the Director of Risk Management, Elizabeth Starr or Security Manager, Phil LeClair.
- If a stolen lap top contains research information call, the Research Review Monitor, Kim D. Jennings and the IRB Department.
- Note – if the stolen laptop contains personal information, state and federal regulations related to informing affected individuals of the theft must be followed.

What steps can you take to prevent stolen lap tops and research data?

- Lock your lap top in a cabinet at the end of the day
- Do not leave your lap top unattended at airports or in cars
- Download your research data onto a flash drive and keep this separate from the lap top