Continuation Review… & HIPAA too

If your research is subject to the Health Insurance Portability and Accountability Act (HIPAA) you may have noticed an additional requirement on your IRB Continuation Review Request. If the study has an IRB approved HIPAA Authorization and subjects have been enrolled since the previous continuation review, investigators are now asked to include two copies of the entire signed HIPAA Authorization form for the last two subjects enrolled.

A HIPAA Authorization Form describes how the researcher will use, disclose and secure the participant’s protected health information. For applicable studies, it can be an effective means of demonstrating compliance with the HIPAA regulation and avoiding any associated penalties from the federal government. Review of the last two signed HIPAA Authorizations, ensures the IRB that research participants are being enrolled with the current IRB approved document. Any modifications made to the form during the course of the study must be reviewed and approved by the IRB prior to implementation.

If you have any questions on this requirement or other continuation review issues, see the continuation review website for sample forms and tips lists or contact the following ORI Professional Associates:

♦ Continuation Review for Medical IRB # 1 & 2
  Gail Cadwallader   email: gcc@uky.edu   phone: 859-257-6071

♦ Continuation Review for Medical IRB # 3 & 6
  Karen Larson   email: Karen.larson@uky.edu   phone: 859-257-9819

♦ Initial and Continuation Review Nonmedical IRB
  Tiffany Adler     email: tiffany.adler@uky.edu   phone: 859-257-6072
2010 VA Medical Center Research Update

Investigators and staff conducting research at the VA are encouraged to attend one of several upcoming education sessions to learn about regulatory updates, and issues including VA requirements for tissue banking and adverse event reporting.

Training date options:
- Monday, August 23, 2010 10:00 am—12:00 noon
- Wednesday, August 25, 2010 2:00 pm—4:00 pm
- Tuesday, August 31, 2010 12:00 noon—2:00 pm
- Thursday, September 2, 2010 8:00 am—10:00 am

RSVP to VA Research Compliance Officer, Candace Foley
e-mail: Candace.Foley@va.gov phone: 233-4511 x4275

UK Human Subject Protection Regional Conference
Thursday, October 7, 2010
Northern Kentucky Convention Center

Presentation Topics:
- Surviving the Angel of Death’s Auschwitz Twins Experiments
- FDA IRB Inspections & the FDA Commissioner’s Enforcement Initiative
- What Participants are owed in Genetics & Genomics Research
- Children as Research Subjects
- IRB and the Internet
- Continuing Challenges for IRB Review

Full Conference Brochure and Registration Form for UK staff and faculty is available at:
http://www.research.uky.edu/ori/upcoming_events.htm

Co-Sponsors:

🌟 Attendance at the regional conference satisfies the U.K. human subject protection 3 year continuing education requirement.