News from the Cornell IRB office: June, 2009

Addition to the IRB Administrative Support Team:

We are pleased to announce that Matthew Aldridge has been appointed as the Senior IRB Administrator for the IRB program at Cornell University, Ithaca campus. Until recently, Matthew served as the Education Coordinator for the Research Compliance program at Cornell. In that capacity, Matthew worked with researchers and compliance committees, providing guidance and training, particularly concerning research with human participants.

As the research community has learned more about human research requirements over the last three years, the workload of the IRB has increased significantly. In his new role, effective June 3, 2009, Matthew will be able to focus exclusively on providing the IRB and the research community guidance regarding institutional policy, IRB requirements, and best practices in the conduct of research with human participants.

Susan Lewis will continue in her role as the IRB Administrator and will continue to be the point of contact for questions relating to expedited protocols and the status of protocol applications submitted to the IRB.

Matthew can be contacted at 5-6182, and Susan at 5-5138. The IRB mailbox is irbhp-mailbox@cornell.edu.

Applications for Continuing Review of Approved Protocols:

In order to insure that their protocol may be reviewed and approved for a new time period, researchers should submit their applications for Continuing Review at least three weeks in advance of the expiration date of their initial approval. The volume of applications has grown by 100% over the past year alone. The reviewers and the administrative staff, therefore, need a minimum of three weeks to complete the review process. Please refer to IRB SOP#3 at http://www.irb.cornell.edu/policy for details on the policy and procedures for submitting continuing review applications.

Additionally, be sure to check the IRB website for any changes or new requirements and to download the latest forms. For example, consent forms are now required to include a statement regarding the use of Ethicspoint for participants to report concerns or complaints anonymously. Also, the IRB officially changed its name from the University Committee for Human Participants (UCHS) in the spring of 2007. Updating consent forms prior to submission for continuing review will help ensure a smoother approval process.

Submitting a Complete Protocol Application:

One of the easiest ways to expedite the review and approval of your IRB application is to submit all required documents, training and signatures with the application. This will reduce the need for revisions, email exchanges and last minute scrambling for information. Following a standard checklist when submitting protocol materials to the IRB, may be helpful when preparing submissions. For example: the following checklist of items should accompany every Initial Approval Request to the IRB:

1. The initial approval request form with signatures: If the project is led by an undergraduate or graduate student, the faculty supervisor must also sign the approval form;

2. The appropriate consent form (written consent form, assent form, information sheet, or consent/assent script) to obtain informed consent of the human participants. *See SOP 9: Informed Consent Options, Processes, and Documentation;*

3. External funding research proposal, if applicable;

4. Thesis or dissertation proposal, if applicable;

5. A copy of all recruitment materials;

6. All other study instruments including, but not limited to: (a) blank interview forms, (b) questionnaires or surveys, (c) sample contact letters, (d) instructions to interviewers and Research Assistants, (e) focus group guides, and (f) debriefing text;

7. Permission letters from the appropriate authorities of all non-Cornell organizations from which the Protocol PI will be recruiting participants;

8. Completion of human participant training by all members of the research team, including any study personnel, even if they are external to Cornell; *and*

For formal documentation requirements for a Continuing Review or Amendment, please review IRB SOP #3 at Institutional Review Board - Policy & Standard Operating Procedures

International Research involving Human Participants:

The IRB has seen a substantial increase in the number of human research studies being conducted outside the United States with members of the local population. The IRB will issue an SOP formalizing the policies and procedures concerning such research in Q3, 2009. In the meantime, researchers are encouraged to consult the ORIA staff, the Tips for International Researchers, provided on the IRB website, at http://www.irb.cornell.edu/news/#intlTips, and OHRP's guidance on international research, at http://www.hhs.gov/ohrp/international.

New SOP:

In April 2009, the IRB approved *SOP 13: Informed Consent, Enrollment, and Other Considerations for Research Involving Normal, Healthy Participants, available at* http://www.irb.cornell.edu/policy.