News from the Cornell IRB office: March, 2009

Ethicspoint: A new resource for reporting a concern or complaint

For human participant studies conducted at Cornell University or using Cornell University resources, participants in a study have always had the option to report concerns or complaints regarding their rights as subjects in the study. This could be done by contacting the Cornell Institutional Review Board (IRB) at 607-255-5138 or accessing the IRB website. Now concerns may also be reported anonymously through Ethicspoint or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured. A link to Ethicspoint can also be found on the IRB website.

Additional verbiage required on Consent forms

With the addition of Ethicspoint as a resource for participants to report their concerns and complaints, **all new submissions and continuations will need to include this language on the consent forms, effective March 1, 2009**. The exact verbiage can be found on the Consent template. In order to avoid delays in obtaining protocol approval from the IRB, please make sure that the new verbiage is incorporated in your consent forms.

Please note that PIs do not need to submit an amendment to update consent forms for current, approved protocols.

Standard Operating Procedures for IRB

In early 2007, the IRB and ORIA began revising the formal standard operating procedures (SOPs) that describe how the policies for Cornell's Human Research Protection Program (HRPP) are implemented. Among the newer SOPs, there are three that are especially noteworthy for investigators and research personnel: SOPs 9, 11 and 12.

- SOP 9 addresses the options and requirements involved in the informed consent process. This SOP is the most broadly applicable and contains a number of clarifications and new elements relevant to researchers:
    - Processes for obtaining informed consent, including training for research personnel and when waivers of signed consent may be appropriate.
    - Requirements in documentation of informed consent, including when oral consent or other alternative procedures are used.
    - Requirements for obtaining consent from non-English speaking research participants.

- SOP 11 addresses the considerations and requirements of involving children in research projects. Included in this SOP are the categories of permissible research involving children, and requirements for the informed consent process (assent, parental permission, and when waiver of parental permission may be appropriate).

- SOP 12 addresses the considerations and requirements of involving prisoners in research, including requirements for additional IRB and/or federal review, investigator responsibilities, informed consent, and circumstances when a participant becomes a prisoner during a research project.

Please consult these SOPs when developing or modifying your research protocols. For details on these and other SOPs, please visit the IRB website

* SOP 10 – which will address issues of research participation and consent processes for cognitively impaired individuals – is in process.

Some tips for researchers engaged in International Research

As the conventional academic year begins to come to a close, a number of students and faculty develop plans for travel and research abroad. We advise investigators to keep in mind some of the additional steps that factor into IRB approval of international research.

- International research must meet Cornell's ethical research standards as well as those of the host country. Some countries have comparable formal review requirements, while others do not. Nevertheless, investigators must provide the IRB with some form of documentation that their planned research meets local ethical standards. Having an independent representative from a local university, non-governmental organization, or other appropriate institution provide a letter indicating that the study design meets such standards is a good method, and one that is not difficult for most investigators.
- In some instances (such as anthropological research in smaller tribal communities) investigators should also plan to establish local contact and be invited into the community. Investigators should provide the IRB with an explanation of how they will be invited into the community.
- Plan ahead for variation in the consent process (see SOP 9, sections 9-11) and try to allow for time in getting translations for informed consent, when appropriate. The consent process should be designed in light of what is likely to be in the best interest of research participants.

Planning ahead for extra time in the IRB review and approval process is highly recommended.

Students who are receiving Cornell funding for international travel/research may have additional responsibilities or university requirements. Please consult the International Gateway's Travel Resources page for information legal, procedural, and practical matters related to international student travel.