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Cornell University
Office of Research Integrity and Assurance

Human Participant Research Newsletter

35 Thornwood Drive, Suite 500
Ithaca, NY 14850
Telephone: 607 255-5138
Fax: 607 255-0758
E-mail: oria@cornell.edu

The Human Participant Research Newsletter is a publication of the Office of Research Integrity and Assurance (ORIA). This publication is intended to provide information on ethical standards and expectations, regulatory compliance, and other practical matters related to the Human Research Protection Program. Recipients are encouraged to share the Human Participant Research Newsletter with colleagues, students, staff and others in the research community at Cornell University.

In This Issue

Changes in the Human Research Protection Program

With the creation of the Office of Research Integrity and Assurance (ORIA) in February 2006, Cornell has underscored its commitment to ethical research standards and a culture of compliance at the university. One of ORIA's principal areas of focus is to assure the responsible conduct of research with human participants, and the first major step in this effort has been the renewal of the roles and responsibilities of the committee charged with the ethical review of such research.

In March of this year the Faculty Senate unanimously approved the committee's renewed, and somewhat revised, charge. Approval of the charge sets the groundwork for a variety of other updates, changes, and improvements to Cornell's current Human Research Protection Program. Among the changes the university community can expect to see, now and in the coming months, are a new name for the committee, major updates to its website, a new set of online training modules, and several revised policies and procedures.

New Name and Website

ORIA is pleased to announce the first change brought about by the the Faculty Senate's approval of the committee's charge: the adoption of a new name. What was formerly called the University Committee on Human Subjects (UCHS) has now become the Institutional Review Board for Human Participants (IRB).

The first portion of the new name – institutional review board – was adopted from the generic phrase used in the federal regulations for such committees and the term most frequently used at academic institutions. The latter portion was chosen after a recommendation from the National Human Research Protection Advisory Commission that the phrase "human participants" be used rather than "human subjects"

to reflect two fundamental ethical concepts: humans are participating in research and not simply the object of the research; and individuals give voluntary, informed consent to participate in research activities.

ORIA recognizes this change may be slightly inconvenient for investigators familiar with the former UCHS. However, it is our expectation that the IRB acronym will be more universally recognized by new faculty, will better serve student investigators when they move on to other institutions, and is in fact already in use by many faculty members. We anticipate that after a brief period of transition for the committee's long-standing users it will result in more consistent use by all concerned.

Of course, adoption of the new name requires updating the IRB's website and the various documents used for IRB review. Currently, ORIA is in the final stages of a major revision of the IRB's website, which should be published by late May.

The website will be reformatted to improve users' access to information. Improvements will include clarification of submission requirements, comprehensive information on regulations and research guidance, description of IRB responsibilities, and other useful materials. Additionally, it will be updated to meet Cornell University visual identity standards and have a new independent web address – www.irb.cornell.edu – with a forwarding link available for a limited time, for those needing to update their bookmarks.

Future Enhancements

The next several months will also see a number of other changes designed to clarify the scope of the Human Research Protection Program, specify the policies and procedures of the IRB, and improve the required training for research with human participants.

The IRB and ORIA are developing a new set of policies and procedures to assure compliance with university policy and federal regulations, and to maintain high ethical standards. A total of 16 policies and procedures have been identified for development. To date, three Standard Operating Procedures (SOPs) have been completed, and seven others are in progress. The three completed SOPs are

- SOP 1: Determining Human Participant Research;
- SOP 2: Requirements for Submission of Research Protocols for a Determination by ORIA of Exemption from IRB Review; and
- SOP 3: Expedited, Convened Committee and Continuing Review.

Additionally, in early autumn ORIA is expecting to implement a new online training program for the responsible conduct of research with human participants. The new training program is intended to provide more comprehensive coverage of ethical and regulatory issues of human participant research, as well as more Cornell-specific information on IRB policies and procedures, thus serving as both an educational tool and an ongoing resource for investigators. ■

Decision Tree for Projects that Do Not Need to be Submitted to the IRB

Often it can be difficult to determine if an activity requires review and approval by the IRB without significant discussions with someone who has extensive knowledge about the regulations and institutional policies. This can be particularly true for investigators newer to the research process or those using social and behavioral research methods as a smaller component of a project (e.g., use of pre- and post-activity surveys in an educational outreach program).

To help faculty, students and staff faced with such ambiguities, a decision tree has been designed to clearly identify activities and/or projects that *do not* fall under the purview of Cornell's Human Research Protection Program, and consequently *do not* need to be reviewed by the IRB. This approach is useful because a decision tree of what the IRB does need to review is much longer and more difficult to use, and requires more consultation with individuals within ORIA or the IRB.

ORIA's decision tree indicating what does not need IRB review is much shorter and easier for investigators (faculty, students and staff) to use.

The decision tree will be available on the IRB website. In the meantime, a copy can be requested from Sarah Demo at uchs@cornell.edu. If you have any questions with using the decision tree or need clarification on an issue, please contact ORIA. ■

Does Student Research Require IRB Approval?

The opportunity for experience in conducting research is an integral part of academic development, and Cornell encourages students in their pursuit of these opportunities. Nevertheless, university policy and federal regulations set the same requirements of all investigators conducting research with human participants, regardless of whether they are students, faculty, or staff.

That said, there are two exceptions to the requirement for IRB review and approval. One is called exemption, and is a formal concurrence that is given by ORIA. The other is when research is being conducted as part of a course assignment. In the latter circumstance, the instructor of the course must file a form (available on the IRB website) with ORIA describing the nature of the course assignment and indicating that all research activities will be used *exclusively* for class purposes.

When ORIA grants an approval in these circumstances, the students in the course are not required to submit individual applications for their own projects. However, it is critical to note that under such approvals students *cannot* use the data collected through these class assignments for theses, dissertations, articles, websites, or any public presentations. If students want to reserve the opportunity to use their activities for research purposes (publication, presentation, and/or use as part of the requirements for a degree), they must submit an individual application for IRB review and approval or apply for an exemption from IRB review. ■