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Office of
Research Integrity and Assurance

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News from the Cornell University IRB office
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Contents

Required Training for Research with Human Participants

In May 2010, the Office of Research Integrity and Assurance (ORIA) began using the Collaborative Institutional Training Initiative (CITI) Program for web-based training in the ethical conduct of research with human participants. **Beginning June 1, 2011, all investigators named on an IRB protocol will be required to have completed the CITI Program within the past three years, as a condition of approval of their protocols that are subject to IRB review.**

Investigators and research personnel can access the training through the IRB website (www.irb.cornell.edu/training/citi). Cornell users can log in with their NetID and password. Instructions for individuals without NetIDs (e.g., collaborators not affiliated with Cornell) are provided on the training's webpage. Please contact Susan Lewis at irbhp@cornell.edu or 255-5138 with any questions related to the training or problems that you may have in accessing the training.

Confidentiality Agreements for Research with Existing Data/Specimens

Cornell University's requirements for IRB review and approval extend to all human participant research projects that Cornell-affiliated researchers are engaged in. However, in some limited cases, a Confidentiality Agreement may be used to consider the Cornell-affiliated researchers *not to be engaged in human participant research*. In such cases, a review by the Cornell IRB is not required. All of the following criteria must apply for the research to eligible:

- Investigators must be working with existing datasets or analyzing human biological specimens that have already been collected;
- The Cornell researcher(s) will receive coded private information and/or human biological specimens from another researcher/institution involved in the research;
- The other researcher/institution has a key/link to individually identifying information; and

- The Cornell researcher(s) and the holder of the key/link enter into a confidentiality agreement specifically prohibiting the release of the key/link to the Cornell researcher(s) under any circumstances.

When these criteria apply, the IRB office encourages investigators to download the Confidentiality Agreement template from the IRB website – www.irb.cornell.edu/forms – and revise the template to fit the needs of their project. (Note: be sure to specify that Cornell researchers will not have any access to identifiers.)

Please contact Matthew Aldridge (ma354@cornell.edu) if you have questions about use of Confidentiality Agreements.

Withdrawal of Participants from Research

Recently, the Office for Human Research Protections (OHRP) – the federal agency that provides regulatory oversight for research with human participants – issued new guidance for investigators on the withdrawal of participants from research projects.

The new guidance reiterates some basic information – if a participant says they no longer want to be involved in a research project, investigators should discontinue data collection (active intervention, obtaining private identifiable information, or observing private behavior) – but also offers some helpful perspectives about retention and use of data that investigators have already collected. Specifically, OHRP indicates that investigators can keep and continue to analyze data they have already collected.

While this is not a complete change in direction in thinking about voluntary participation in research, it does bring up questions about the expectations and obligations for researchers conducting social/behavioral science research. The IRB office continues to encourage researchers to be considerate in honoring the wishes of participants who want to withdrawal from a study, but also recommends that researchers think carefully about the language they use in informed consent forms. If the consent form indicates that when a participant withdraws from a study, all data collected during their participation will also be omitted, then the investigator must abide by that pledge. However, if the consent form does not specify this option, or if it indicates that the investigator will retain data collected, then the data may remain in the investigator's research records.

Further information about OHRP's guidance on participant withdrawals from research can be found on their website - http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html.

New Form for Requests for Exemption from IRB Review

Earlier this month the IRB office released a new version of the Request for Exemption from IRB Review form. The new version of the exemption request is a dynamic, interactive PDF form, and it is being rolled out as a Beta version to allow investigators to test the functionality and provide feedback to the IRB office regarding ease of use and clarity of questions asked.

As with the new Initial Approval Request and Amendment forms, the new Request for Exemption from IRB Review form has checkboxes and reminders to assist investigators in providing the information commonly needed for review, and to prompt investigators to answer questions that are applicable to their research. For example, an investigator only using existing data sets will not be asked questions about data collection procedures.

The new form is available on the IRB website (www.irb.cornell.edu/forms) in addition to the current form, and we strongly encourage investigators to use the new form as we believe it will assist in determining if their protocol is eligible for exemption from IRB review. We expect to phase out the older version of the form by June 2011. Please contact Matthew Aldridge (ma354@cornell.edu) for questions about Exemptions and the Exemption form.

IRB Approval Stamp on Informed Consent Forms

For research protocols that receive IRB approval, ORIA has begun putting approval stamps – indicating the IRB approval and expiration dates – on the informed consent forms. The expectation is that investigators will use consent forms with IRB approval stamps when enrolling participants in their research projects.

One minor complication that has emerged with this new procedure is that older versions of the informed consent templates had investigators write the approval date into the consent forms themselves, but the new approval stamps make this a redundant step. To help minimize any potential administrative delays (and awkward text/information in the consent form) ORIA has updated the informed consent templates on its website – www.irb.cornell.edu/forms. Investigators are encouraged to use the forms and template from the IRB website with each new application to be sure they are using the forms with the most current information.

Amendment Requirements – Changes to Research Protocols

As a reminder to investigators, all changes to human participant research protocols – whether IRB-approved or exempt from IRB review – must be submitted for review and approval prior to implementing the change(s) into the research study. Please visit the FAQs page on the IRB website (www.irb.cornell.edu/faq) for further information on amendment requirements. To request approval for changes to a protocol, investigators must use an Amendment Request form (www.irb.cornell.edu/forms).

If you have any questions or comments regarding these or any other topics relevant to the IRB, please contact Matthew Aldridge (ma354@cornell.edu) or Susan Lewis (irbhp@cornell.edu) for assistance. Please visit the IRB website for updates and other information pertinent to conducting research with human participants at Cornell University.