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Research Integrity and Assurance

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News from the Cornell University IRB office
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Congruence between IRB Approved Protocols and PHS Funded Grant Proposals

The U.S. Department of Health and Human Services (HHS) regulations (45 CFR 46.103(f)) require that each proposal for HHS-funded research involving human participants must be reviewed and approved by the Institutional Review Board (IRB). Therefore, investigators must ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IRB.

A typical method to prevent inconsistencies between the information submitted to HHS funding agencies and that on the IRB protocol is to conduct a direct comparison. At Cornell University, this responsibility is delegated to the Office for Research Integrity and Assurance (ORIA).

ORIA performs a comparison of the grant proposal with the approved IRB protocol(s) referenced in the Office of Sponsored Programs (OSP) Form 10 and on the protocol application. Investigators should ensure that they provide the correct OSP number on their IRB protocol applications to facilitate this review. Verification of grant and protocol consistency concentrates on research activities involving human participants and **does not** include a judgment of scientific merit. Common areas of non-congruence between grants and protocols include:

- data collection procedures that are proposed in the grant application but are not described in the IRB protocol;
- descriptions of the study population(s) and number of participants to be recruited;
- co-investigators and/or research personnel listed in the grant application but not in the IRB protocol (or vice-versa).

These discrepancies may come about from revisions to the grant, post protocol approval, either due to grant reviewer comments or due to the different time cycles in preparations of the protocol and the grant proposal documents.

If the comparison identifies material discrepancies, OSP cannot accept the award until those discrepancies have been resolved either by clarification or an amendment to the IRB protocol or the grant proposal, as appropriate to the research project. The IRB office will work with the Principal Investigator to facilitate and expedite the process so that the funding opportunity is not jeopardized. However, significant discrepancies between the two can lead to delays. Please contact Matthew Aldridge in the IRB office at 255-6182 or ma354@cornell.edu if you have any questions about this process.

Use of Online Survey Vendors

Computer- and Internet-based methods for collecting, storing, analyzing and transmitting data are becoming increasingly popular in research with human participants, and the use of online survey vendors has become an especially popular option for investigators. While many online survey vendors offer convenient, versatile services for distributing and collecting survey data over the Internet, not all services offer effective levels of protection for survey respondents.

In an effort to help investigators identify survey vendors who provide appropriate levels of protection to participants' privacy and confidentiality, the IRB has reached out to several service providers currently used by Cornell researchers. Based on the information provided in writing by these companies, the IRB has created a list of approved vendors. This list is available on the IRB website at www.irb.cornell.edu/internetsurveys.

Please note that the IRB does not, in any way, promote the use of these service providers. Inclusion in this list simply means that – based on the written statements and policies concerning security, privacy and confidentiality of data these companies have provided to the IRB – investigators may consider using their services for Internet surveys in research with human participants.

The IRB also welcomes suggestions for companies to consider adding to this approved list. ORIA will periodically evaluate the written statements, policies and terms of use of the vendors included in the list and update it accordingly.

New IRB policies/SOPs

The IRB recently approved two new Standard Operating Procedures (SOPs) that provide guidance on topics that are of significant interest to Cornell researchers. Please refer to the IRB Policy page for the full text of these SOPs.

- **Protocol Principal Investigator Roles and Responsibilities.** A Protocol Principal Investigator (PI) is defined as "the scientist or scholar with primary responsibility for the design and conduct of a research project." This SOP describes the eligibility criteria and

the roles, and responsibilities of a PI at Cornell University. Some salient features of the policy are:

- Only one person can be named a Principal Investigator (PI) on a protocol
- Only a person affiliated with Cornell University, Ithaca can be a PI on an application to the Cornell Ithaca IRB.

- **New York State Laws Related to Human Participant Research.** In all research with human participants, state law takes precedence before the requirements of federal regulations and University policies. This SOP addresses the New York State laws relating to human participant research activities.

The full SOPs can be found on the IRB website at http://www.irb.cornell.edu/policy.

If you have any questions or comments regarding these or any other topics relevant to the IRB, please contact the IRB office at irbhp.cornell.edu. Please visit the IRB website for updates and other information pertinent to conducting research with human participants at Cornell University.