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Research Integrity and Assurance

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News from the Cornell University IRB office
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Contents

Alternatives to Written Informed Consent

The informed consent process is a core component in research with human participants. In its review of research proposals/protocols, the IRB expects a description of how written informed consent will be obtained from participants. However, the IRB may consider a request to waive this requirement if the principal investigator (PI) explicitly requests a waiver and provides justification that speaks to one of the following cases:

1. A signed consent document poses a risk of potential harm to the participant resulting from a breach of confidentiality. In this case, the IRB will expect researchers to give individuals the option to sign a consent form and allow the individual's wishes to govern.

2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context (e.g., observation of public behavior in a public place).

When the IRB grants waivers of signed consent, PIs must still provide participants with the same level of information regarding the research and detail how they will do this in their applications to the IRB. Some examples:

- give participants an unsigned copy of the consent form.

- use an "information sheet" (essentially a consent form without signature lines).
- provide oral consent, either exclusively as a verbal interaction or in conjunction with written documents.

The IRB may, on occasion, waive some or all of the elements of informed consent. The essential elements of informed consent, as well as the conditions when such a waiver may be considered, are detailed in SOP 10. The PI should study the requirements to determine if their research qualifies for the waiver, and provide a justification in the IRB application for consideration of the IRB.

Guidelines for Oral Consent Procedures

The IRB expects that the level of information provided in an oral consent process will be comparable to a written consent document, and would need to see a consent script or a summary indicating how the investigator will describe the research to participants. As with a written consent process, the IRB may also require investigators to include additional elements with oral consent, or may waiver some or all the elements of the consent, depending on the characteristics of the research.

For example, during phone interviews, where a script with all the elements of the informed consent could be considered arduous and unnecessary, an abbreviated script with the following information may be sufficient:

- name and nature of the study,
- voluntary nature of the study and the ability to withdraw at any time or to not answer a question,
- a note about confidentiality and,
- contact information for the PI if requested by the participant.

For oral consent, investigators should describe how they plan to document that participants have consented to participate (e.g., with audio or video recording, a third-party witness, in their field notes, etc.). Such procedures should always consider the welfare of potential participants first and the interests of the investigator and needs for the research design second.

If you have any questions about using an alternative to written consent or procedures for using oral consent in your research, please contact Matthew Aldridge (ma354@cornell.edu, 255-6182) or Susan Lewis (irbhp@cornell.edu, 255-5138) in the IRB office.

New IRB policies/SOPs

The IRB recently approved four 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.

- **Recruitment and Payment of Human Participants.** The methods and materials used by investigators to recruit potential participants to their studies are subject to IRB review

and approval. In its review, the IRB will consider (1) the degree of risk and likelihood of benefit to the participants and (2) the protections for participants from coercion or undue influence. Among other things, the SOP provides clarifications on content of advertisements, payment procedures, and responsibilities of the PI. The IRB will pay close attention when investigators seek to recruit and enroll themselves, students, employees, or members of vulnerable populations such as children, pregnant women, and educationally or economically disadvantaged persons.

- **International Human Research.** For Cornell researchers conducting research outside of the United States, the IRB review process can be particularly challenging. Both the U.S. and host country standards for protecting human participants must be respected during the IRB's review and approval process and the conduct of the research. Where the two sets of standards present a conflict, the research must meet the higher standard. The SOP describes the necessary steps for investigators who will be conducting research in countries outside of the United States and its national territories, such as documenting the local requirements (or lack thereof) for ethical review, explanations of how they will be invited into local communities when there are no established systems for research oversight, and informed consent requirements.

- **Research Involving Cornell Students.** While the IRB does not consider Cornell University students to be a vulnerable population, *per se*, the IRB, pays special attention to ensuring that the research protocol and associated recruitment methods and informed consent avoid coercion or the appearance of coercion especially in the context of the faculty-student relationship. This SOP describes the IRB's expectations as they relate to advertisements and recruitment, offering extra credit or other types of incentives or compensation to students, confidentiality, etc.

- **Computer- and Internet-Based Survey Research**. The use of computers – and more specifically the Internet – in survey research has increased significantly over the past several years, and this increase has raised the IRB's awareness of concerns with privacy of participants, confidentiality of participant data, and data security, among other things. This SOP explains the IRB's current standards for the use of computer-based technologies for survey research. Noteworthy components of the SOP include expectations when working with third-party survey vendors, data transmission and storage standards, recruitment and informed consent procedures, and a survey software checklist to help ensure appropriate protections for research participants.

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.