Cornell University
Office of
Research Integrity and Assurance

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News from Your IRB: April 2018

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FERPA issues when using student work, grades: When using student work or grades, researchers may be limited by the Family Education Rights and Privacy Act (FERPA), which protects the privacy of student education records. FERPA even applies to records developed in a class that *you* teach. The best way to ensure compliance with FERPA is to get prior student consent to use their grades and/or class work, including papers, journals, projects, and tests, in your research. If obtaining consent is not practical, contact the IRB to discuss options. See IRB SOP 15: Considerations for Research Involving Cornell Students.

Single IRB requirements for multi-site NIH studies: Recent policy changes greatly impact NIH-funded research with human participants. One notable change affects proposal preparation, since researchers must now include in their application a plan to use a Single IRB (sIRB) for ethical review of non-exempt, domestic, multi-site research. At this time, Cornell is unable to act as the sIRB. If you are or hope to be NIH-funded, please read our message on this and other NIH changes (click and scroll to "Message to Researchers about New NIH Policies") or contact Guilaine Senecal at 255-8994.

You may be conducting a clinical trial: The NIH definition of "clinical trial" now includes not just medical research, but some social and behavioral research. If you answer yes to each of the 3 questions below, NIH considers your study to be a clinical trial:

1. Are the participants prospectively assigned to an intervention?
2. Is the study designed to evaluate the effect of the intervention on the participants?
3. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Your study can still considered a clinical trial even if: you are studying healthy participants; there is no placebo or control group; or you are using only a behavioral intervention. Please note that many NIH Funding Opportunity Announcements (FOAs) are now specifically for either clinical trials or non-clinical trials, so it is important that you make the assessment in order to select an appropriate FOA. NIH-funded clinical trials must register at ClinicalTrials.gov and researchers must complete Good Clinical Practice (GCP) training (others are not required to, but are encouraged to do both). When the IRB staff reviews a new study or renewal, they will tell you if your study is a clinical trial.

Is written consent your best option? Researchers must inform potential participants about the research they are being invited to participate in so that they can make an informed, voluntary decision about whether or not to participate. But the consenting process can and should vary depending on the complexity of the study and the risk involved. The following options are available:

Written Consent

- Participants sign a hard copy consent form to indicate that they agree to participate
- Can be used for any type of study, but study is not "anonymous" if written consent is used
- Typically used for higher risk or complicated studies or when it is important to have written documentation of consent

"Verbal" or "Online" Consent (aka, Waiver of Documentation of Consent)

- Verbal: Consent language is read aloud, and participant signals desire to participate orally, but does not sign a form (an information sheet is often provided to take home). Note that in this case, the researcher must record that the participant gave consent
- Online: Participant reads a consent document on a screen explaining key information about the study, and clicks a box or arrow to signal consent before proceeding with the study. This should be a data field that is recorded to indicate positive consent
- Used for minimal risk research, and more than minimal risk studies where a signed consent form would be the only document identifying study participants

Get in touch with your IRB Team

During Office Hours

Alternating Wednesdays (10 am–1 pm), and Tuesdays (1-4 pm).

See detailed schedule here, click the "IRB Office Hours (New times!)" link.

In person: East Hill Office Building, Suite 320 (accessible via 82 bus)

By phone: 254-5162, 255-5138, or 255-8994

At other times

Via email: irbhp@cornell.edu. Expect a response within 1 business day.

By phone: Vanessa McCaffery, 254-5162, Janet Jayne, 255-5138, or Guilaine Senecal 255-8994

Comments or suggestions? Please contact us: irbhp@cornell.edu