

## Protocol Principal Investigator Responsibilities

1. All Cornell investigators **must** complete training in the use of human participants **before** submitting applications to the IRB for review. **In addition, any research staff - including undergraduate and graduate students - who will be working with human participants or the data collected on human participants must also complete this training.** This requirement may be fulfilled in one of three ways:
  - o Complete the IRB on-line tutorial at: <http://www.irb.cornell.edu/training> You must obtain a score of 90 or higher on the test. When prompted, enter your name and email address, and this information will be forwarded directly to the IRB. No additional action is needed on your part.
  - o Complete the NIH on-line tutorial at: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>. After completing the training, you will be prompted to print out a certificate of completion. Send a copy of this certificate to the IRB with the protocol application.
  - o Document completion of a course in which the protection of human participants is thoroughly addressed. A syllabus of the course must be provided. There must be an indication that the topic of human subject protection in particular was covered -- general ethical discussions would not be deemed sufficient.
2. Read [The Belmont Report](#) to familiarize yourself with the ethical principles guiding the protection of human participants. Read [OHRP's Terms of Assurance](#) to understand Cornell's obligations to comply with [45 CFR 46](#). Read [Cornell's FWA registration](#) for details on FWA administration. Refer to the U.S. Dept. of Health & Human Services' [Office of Research Integrity](#) (ORI) for details on promoting integrity in biomedical and behavioral research. For an excellent overview of Responsible Conduct of Research (RCR), please refer to the informative booklet, "[On Being A Scientist: Responsible Conduct In Research](#)," from the National Academies Press.
3. Research investigators may **not** make the final determination of exemption from applicable Federal regulations or provisions of this Assurance. **Only ORIA or the IRB Administrator can designate a research project as "exempt."** All research involving human participants must therefore be submitted to the IRB for review.
4. Research investigators are responsible for providing a copy of the IRB-approved and signed [informed consent document](#) to each participant at the time of consent, unless the IRB has specifically waived this requirement. **All signed consent documents are to be retained for three years.**
5. **Prior to initiating changes/additions to a previously-approved study** using human participants, research investigators must submit an [Amendment Form](#). The proposed changes/additions may **not** be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants. ([Clarification](#) on when to submit an amendment.)
6. **Any injuries or other unanticipated problems** involving risks to participants and others must be immediately reported to the IRB. For projects involving student investigators, both the student and the faculty supervisor must file [Unexpected Event Management Reports](#). ([Clarification](#) on Unexpected Events.)
7. Read [Suspension/Termination of Approval to Use Human Participants](#)
8. Human participant review includes review of the analyses and creation of [certain kinds of survey data](#). **Analyses involving restricted, non-public use datasets and datasets with community or census level data merged into individual records must now be reviewed by the IRB.**
9. Faculty responsible for supervising student researchers, **including teaching assistants and students in classes that perform research as instruction**, will provide assurance that all Cornell human participants procedures are followed, including completion of the

- [IRB educational training program](#), or a similar course of instruction appropriate to the practices of the academic discipline represented in the class.
10. Research investigators are responsible for reporting progress of approved research to the IRB, as often as and in the manner prescribed by the IRB on the basis of risks to subjects, but not less than once a year. Upon final completion of the research project, investigators are responsible for completing and submitting the [IRB Project Closure Form](#).

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