Suspension/Termination of Approval to Use Human Participants

Cornell University's responsibilities regarding the protection of human research participants are articulated in the Federalwide Assurance (FWA) we hold with the Office of Human Research Protections (OHRP) at the Department of Health and Human Services. The FWA is a legally-binding contract that **requires** Cornell University to comply with the ethical principles of *The Belmont Report* and the federal regulation for the protection of human participants (45 CFR 46). The Institutional Review Board – Human Participants (IRB) is Cornell's IRB charged (per 45 CFR 46) with developing and enforcing the policies/procedures required for Cornell University to remain in compliance with its FWA.

The IRB's policies/procedures on the use of human research participants apply to all faculty, staff, extension personnel, and students who conduct research involving 1) interactions with human participants, 2) identifiable data on living humans, and 3) human biological materials. All such research projects **must** be reviewed and approved by the IRB before the investigator may commence the research, regardless of the funding source of the study. In addition, 1) revisions to previously-approved study protocols must be reviewed by the IRB before they can be implemented; 2) only the IRB can designate a study as exempt from the federal regulations protecting human participants; and 3) investigators must promptly report all unexpected events involving human participants to the IRB.

In cases of non-compliance with the IRB's policies/procedures, the federal regulation (45 CFR 46.113) stipulates that the IRB "...shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with serious harm to participants." In addition, "Any suspension or termination. . . shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head." ("Department or Agency head" refers to the federal agency sponsoring the research, where applicable.)

Cornell's FWA additionally requires that OHRP receive reports of the following: 1) any injuries to human participants or other unanticipated problems involving risks to participants or others, 2) any serious or continuing noncompliance with the regulations or requirements of the IRB, and 3) any suspension or termination of IRB approval for research.

In summation, if an investigator's research is suspended and/or terminated by the IRB, the following parties shall receive written notification from the IRB Chair:

1) the investigator
2) the investigator's college dean
3) Sponsored Program Services (when applicable)
4) the sponsoring federal agency (when applicable)
5) OHRP

Investigators who receive written notification to suspend or terminate a research study involving human participants must **immediately cease all interactions with human participants** (including recruitment) on that project.

Potential Reasons for Suspension of IRB Approval

1) Non-compliance with IRB policies/procedures:

- Conducting research using human participants without IRB review and/or approval

- The project is not being conducted in accordance with the protocol submitted by the investigator and approved by the IRB
- Approval period expires, and the investigator continues using human participants, but does not submit a continuation application to the IRB
- Failure to use IRB-approved consent forms
- Evidence that students conducting research are not trained in proper procedures

2) ORIA or the IRB receives complaint from a participant

3) Unexpected event

IRB Investigation and Potential Termination of Approval

ORIA and/or the IRB investigates all occurrences/reports of non-compliance, complaints received from participants, and unexpected events. In the case of unexpected adverse events, ORIA and the IRB will review reports and the investigator's plan to minimize risk for subsequent human participants. If the adverse event is sufficiently serious or if the plan to minimize risk in the future is not adequate, ORIA will issue a suspension notice to the investigator. In the case of non-compliance with IRB policies/procedures, or the receipt of a participant complaint, ORIA and/or the IRB will issue a suspension notice pending further investigation.

At the next convened meeting of the IRB, the Chair and members of IRB will discuss the situation and recommend a plan of action. Many situations may be resolved by discussion between the investigator and ORIA/ IRB on ways to minimize risks to participants or to effect compliance with all applicable policies and regulations. If the problems are serious enough to warrant termination of the project, the IRB will notify, in writing, the five parties listed above.

Until the investigator receives written notification from the IRB that approval has been reinstated following a suspension notice, the investigator may not use human participants (including analyzing identifiable data, or working with human biological materials) in the effected study.