Studies Conducted Without IRB Approval

Federal regulations and guidelines do not allow for review and post hoc approval of studies that have already been conducted involving human participants, human biological materials, or identifiable data that can be connected to any living individual. Cornell's Federalwide Assurance (FWA) with the federal government states that the IRB must review and approve data collection procedures and protocols **before** the study begins. The FWA is a legally binding contract that the university has signed with the U.S. Office of Human Research Protections (OHRP), and it obligates Cornell to comply with the ethical principles of *The Belmont Report* and the federal regulations for the protection of human participants.

The IRB has adopted the following procedures regarding studies conducted without prior IRB approval.

1. We ask that all investigators (faculty, staff, students) who have conducted studies involving human participants *since July 1, 2000* without prior IRB approval report their project to IRB promptly. We also suggest that investigators inform relevant department/center/office personnel that the report has been made. For a faculty member, the appropriate person is the department chair; for a graduate student, the committee chair and director of graduate studies; for an undergraduate, the director of undergraduate studies; and for staff, the office supervisor.
2. The IRB administrator and ORIA will investigate why the investigator did not have the project reviewed by the IRB.
3. The reporting investigator will be required to pass the IRB educational program on the web if he or she has not done so previously.
4. Depending upon the circumstances leading to the lack of compliance as well as the type of study conducted, ORIA and/or the IRB may require the following corrective actions. These will apply only to research that requires formal approval by the IRB (i.e., non-exempt research).

- If the data are intended for publication, the investigator must disclose to the publication editor(s) that the data were collected without the approval of the Cornell University's Institutional Review Board. Some journals and disciplinary fields now require such disclosure as a condition of publication.
- If the study is on-going, interaction with human participants must cease until the IRB has reviewed and approved all study procedures.
- In some cases, the IRB may require that investigators inform participants of the investigator's lack of compliance with the IRB procedures, and solicit permission from the participants to use the data or biological materials collected.
- When there are multiple instances of lack of compliance in a unit, the IRB will ask the unit to take extra steps to assure that its investigations comply with human participant regulations.
- When the lack of compliance has resulted in risk of harm to participants, the IRB will report the situation to OHRP and appropriate university officials, as required by the FWA. In addition, the IRB **may** forbid publication of the results of the study.
- If, after the IRB has intervened to take corrective action, the investigator undertakes a second study without human participant review and approval, the procedures outlined in Suspension/Termination of Approval to Use Human Participants will be applied.

The IRB is fully aware that there are many datasets involving human participants and numerous human biological samples on campus that were collected without prior IRB review and approval. Federal regulations allow the IRB to review the use of pre-existing data and biological samples for

future uses. Please consult the IRB if you have concerns about use of data or human biological material currently in your possession.