

Cornell University
Institutional Review Board for Human Participants

CHARGE

AUTHORIZATION

In accordance with its Federalwide Assurance on file with the Department of Health and Human Services, Cornell University has an Institutional Review Board for Human Participants (IRB). The IRB is a standing committee of the University Faculty. Its activities are overseen by the Vice Provost for Research Administration.

CORNELL'S COMMITMENT TO PROTECTING HUMAN PARTICIPANTS

In order to protect the rights of all human participants involved in research at Cornell University, the University operates its human participant research programs under a Federalwide Assurance (FWA) with the Office of Human Research Protection (OHRP) within the Department of Health and Human Services. The FWA represents a fundamental commitment to the protection of human participants and applies to all Cornell University research involving human participants, regardless of the location of the research or its sources of funding, be they governmental agencies, nonprofit organizations, industry, or University funds. In addition, the FWA applies to all research that is conducted at Cornell University or using Cornell resources regardless of whom is conducting the research.

As part of its mission, Cornell University maintains a Human Research Protection Program that adheres to the principles outlined in the Belmont Report, the Declaration of Helsinki (as amended in 1989), and the Nuremberg Code as well as with the federal regulations, outlined in 45 CFR 46 and its Subparts A, B, C, and D, and the FDA regulations, outlined in 21 CFR 50 and 21 CFR 56. In addition, the University complies with New York State Public Health Law 24-A §2444 and New York State regulations concerning the use of human participants in research. When research activities are being proposed to be conducted in other states and/or countries by Cornell faculty, staff, and/or students, the research activities will be approved in compliance with the regulations for those specific research locations.

DEFINITIONS

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge¹. Activities which meet this definition constitute research for purposes of this policy, whether or not they are

¹ Generally defined as publication, presentation, or requirement for a degree

conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities and they would be included in this definition of Research.²

*Human participants*³ means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes. Intervention includes communication or interpersonal contact between investigator and participant.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.^{4, 5}

Investigator - The individual(s) designated to have the appropriate level of authority and responsibility to direct the research project and/or activity.

ORGANIZATIONAL ROLES

1. Without exception, all human participant research conducted by Cornell University investigators, students, and staff, and any others conducting research at Cornell or utilizing Cornell resources, must receive prior approval of Cornell University's Institutional Review Board for Human Participants (IRB). The IRB for Human Participants has the authority to review, approve, disapprove or require changes in

² 45 CFR 46.102(d)

³ For purposes of this document, "Human Participants" is equivalent to "Human Subjects"

⁴ 45 CFR 46.102(f)

⁵ Private information includes: name; address; elements of dates related to an individual (e.g. birth date, marriage date, date of death, etc.); numbers (telephone, fax, social security, medical record, health beneficiary/health insurance, certificate or license numbers, vehicle numbers; account numbers (e.g. credit card), device identification numbers, serial numbers, and/or any unique identifying number, characteristics, or codes); email address; Web URLs; Internet Protocol addresses [IP]; biometric identifiers (e.g., voice, fingerprints); full face photographs or comparable images; or biological samples or genetic material.

research or related activities involving human participants. Research reviewed by the IRB may also be subject to other review and approval or disapproval by officials at Cornell University. However, those officials may not approve research that has not been approved by the IRB for Human Participants.

2. The IRB for Human Participants has the final determination as to what constitutes Research and the use of Human Participants. The IRB for Human Participants makes the final determination as to whether or not activities meet the definition of Research and if the activity needs to be reviewed and/or approved by the IRB for Human Participants. Investigators cannot exempt themselves and their activities from IRB review and approval. The approval by the IRB for Human Participants cannot occur after the data for a research activity has been collected.
3. The Vice Provost for Research Administration serves as the Institutional Official for the Federal-Wide Assurance with OHRP. As such, the Vice Provost for Research Administration, in consultation with the Provost and appropriate Deans, has oversight responsibility of the University's Human Research Protection Program.

CHARGE

The IRB shall ensure the protection of human participants as subjects of research at Cornell University. The IRB shall:

- (a) Determine what activities constitute research and the use of human participants.
- (b) Review, approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy prior to the commencement of the research.
- (c) Require that information given to participants as part of informed consent is in accordance with appropriate law, regulations, and international standards.⁶ The IRB for Human Participants may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.
- (d) Require documentation of informed consent or waive documentation in accordance with federal and New York State laws and regulations. When research activities are being proposed to be conducted in other states and/or countries by Cornell faculty, staff, and/or students, the research activities will be approved in compliance with the regulations for those specific research locations.⁷
- (e) Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it

⁶ 45 CFR 46.116

⁷ 45 CFR 46.117

shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(f) Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and have authority to observe or have a third party observe the consent process and the research.

(g) Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional official, and the department or agency head.

MEMBERSHIP

The IRB for Human Participants shall consist of twelve to eighteen members. It shall consist of (a) at least one physician representing the Gannett Health Services, (b) at least two members not otherwise affiliated with Cornell University; (c) a representative from Cornell Environmental Health and Safety, and (d) other members of the University faculty to be able to review and approve research conducted by Cornell University. All members shall be appointed by the President upon recommendation of the Dean of the Faculty in consultation with the Vice Provost for Research. Members will serve terms of one to three-years and should provide representation primarily from the social, behavioral, and biological sciences. The Committee Chair shall be appointed from among the faculty members by the President upon recommendation of the Dean of the Faculty in consultation with the Vice Provost for Research. The Chair will serve for a term of one to three years after which time the Dean of the Faculty, in consultation with the Vice Provost for Research; will make a recommendation to the President concerning the appointment of a new Chair or the reappointment of the present chair.

ADMINISTRATIVE SUPPORT

The Office of Research Integrity and Assurance (ORIA) provides the administrative support for the Human Research Protection Program and the IRB for Human Participants. Initial contact with the Committee should be made through ORIA.

Persons requesting a decision on whether research or scholarly activity is subject to the University's Human Research Protection Program must contact ORIA. The ORIA staff will make the decision based on the following factors: (1) whether or not the activity is subject to Cornell University's FWA, (2) when the activity represents Research and involves Human Participants, and (3) whether or not Cornell University is "engaged" in the research activity.

Determination requests made in writing (e-mail, fax, or hard copy), must include sufficient documentation of the proposed research to allow a fully informed determination. ORIA staff or the IRB will respond to these written requests with a written determination. The submitted

materials and a copy of the determination letter will be kept on file.

ORIA, acting for the IRB and any subcommittees, shall maintain minutes of all meetings and shall record their findings and recommendations as part of these minutes. These records shall be maintained in ORIA.

ANNUAL REPORT

The IRB shall submit an annual report to the President on its activities for the year and shall make its report available to the Faculty Senate. The Chair of the IRB shall also submit an annual report of IRB activities and deliberations to the Institutional Official and the Dean of Faculty.

The basic formulation and structure of this committee was embodied in a report from the Committee on Research Policy and Personnel, Faculty Council Minutes, June 6, 1967; amended November 18, 1970. Amended by the FCR, December 9, 1987, Records, pp. 6530-44C, Appendix B; October 11, 1989, Records, pp. 6769-70C. Changes in nomenclature from FCR to Faculty Senate and to reflect amendments to Organization and Procedures of the University Faculty, October 1995. Amended to increase the number of members from twelve to eighteen on October 10, 2001. Amended to change the composition of the committee on February 13, 2002. *Amended to (1) change the name of the committee to the Institutional Review Board for Human Participants, (2) clarify the charge to the Committee, (3) change the number of members from eighteen to 12-18, and (4) provide for rotating terms of Committee members, on*
