



Human Research Participant Protection Program

Policy 19: USE OF PHYSIOLOGICAL DEVICES, BIOMEDICAL PROCEDURES OR BIOLOGICAL SAMPLES IN RESEARCH

Note: The IRB strongly encourages PIs to contact IRB staff well in advance for advice and assistance in preparing protocol applications involving physiological or biomedical research.

1. Subject

Research involving the collection of biological specimens, the use physiological or biomedical devices, or other biomedical procedures with human participants requires additional considerations regarding participant protections, handling of genetic and biohazardous material, use of biomaterials for future research, and other research-related activities. Since research on Cornell's Ithaca campus is conducted in non-clinical settings, the physiological and biomedical procedures that are allowed to be conducted on this campus are limited in nature. This policy describes the types of procedures that can be conducted on the Ithaca campus, the additional considerations for those procedures, the conditions under which those considerations apply, and how they will be implemented to assist Principal Investigators (PIs) in planning these studies.

2. Policy statements

- The Institutional Review Board (IRB) review and approval of a research protocol involving biomedical or physiological procedures must be concurrent with any of the University's medical oversight requirements.

Commensurate with the risk of the procedures to the participant population, these requirements may include:

- Review of the protocol application by medical oversight personnel, [Occupational Medicine](#) staff, and/or the [Biosafety staff in Environmental Health and Safety \(EH&S\)](#);
- Written standard operating procedures for conducting physiological or biomedical procedures;
- Documentation of credentials of all research personnel, their training and competence in conducting the research procedures;
- Appropriate safety and material handling precautions;
- Appropriate response procedures for emergencies or unexpected outcomes that could impact the health or safety of participants;
- Procedures for the handling and disclosure of any unanticipated or adverse findings in the research;
- Procedures for complying with New York State laboratory requirements;
- Procedures for providing research participants with medically relevant information and referrals to a physician;
- Procedures for obtaining informed participant consent for retention and use of biological materials or data for future research;

- Detailed information and specifications for research devices;
- Appropriateness of the physical facilities where procedures are being conducted (considerations of privacy, sanitation, access to safety equipment if needed, etc.); and
- Other factors important in ensuring the safety of research participants and staff.
- Research activities may not commence until the PI receives a written notice of approval from the IRB.
- Researchers are responsible for ensuring full and continuing compliance with all University and IRB policies in the conduct of their research.

3. Procedures for IRB Review

3.1. Application Materials

IRB requirements for application materials – a completed application form, informed consent forms, participant recruitment materials, data collection instruments, etc. – are no different for studies involving physiological or biomedical devices/procedures. However, PIs should be aware that studies involving physiological or biomedical procedures may require additional documentation to assure adequate protections for human participants, such as:

- Written SOPs describing training of personnel, cleaning and sanitization of devices, steps for data/specimen collection and handling procedures;
- Credentials, qualifications and/or experience of co-investigators and research personnel conducting procedures;
- Literature on devices being used in the research; and
- Information about the lab facilities where research activities will take place.

As noted above, the level of documentation needed is commensurate with the types of study procedures and levels of risks posed to participants. If you are unsure of the extent of documentation the IRB may request, please contact the IRB office for guidance.

3.2. Evaluation of Procedures

In evaluating the research procedures, the IRB may consult with other University offices that have responsibilities and expertise in related areas. Specifically, the following offices are likely to play a role in these evaluations:

- Occupational Medicine staff at Gannett Health Services:
- Biological Safety staff in Environmental Health and Safety:

IRB staff can assist investigators in identifying and contacting the appropriate individuals for consultation and advice in planning the research activities so that the IRB review and approval can occur without delay.

Researchers should note that a very limited set of physiological and biomedical procedures are allowed to be conducted on the Ithaca campus. The remainder of this section lists categories of research activities and the factors that are important in IRB review. The list is not meant to be all-inclusive; rather it is meant to provide guidance in designing research projects and preparing materials for review.

A. Use of existing human specimens/biological materials

- Examples
 - Serum from blood banks
 - Residual tissue from surgical procedures (e.g., discarded tumor specimens)
 - Placenta specimens

- Factors in review
 - The biological safety issues in handling, shipping, storage and disposal of the materials
 - Whether there are individual identifiers linked to the samples
 - The types of analyses being conducted – to understand whether the research is likely to identify clinically significant findings or communicable diseases;
 - Information about the origin of the specimens – to understand how they were obtained and/or if there could be limitations on their use;
 - Location of the lab facilities – to determine if the space is suitable for the research procedures

B. Use of procedures ordinarily considered to be “no greater than minimal risk” or minimally invasive to collect physiological information or human specimens/biological materials.

- Examples
 - Blood draw – heel stick, venipuncture
 - Blood pressure measurements
 - Bod Pod body composition measurements
 - Body measurements (various) – skin fold, waist circumference, height, weight
 - Cheek swabs
 - EEGs
 - Fecal sample collection
 - Hair sample collection
 - Heart rate monitoring
 - Urine sample collection (for screening or data collection)
 - Ultrasounds

- Factors in review
 - General device safety information (e.g., manufacturer literature), if a device is being used

- Inclusion and exclusion criteria and screening procedures for research participants – to ensure that individuals who are not eligible to participate are appropriately identified and excluded
 - Description of experience of or training for research personnel conducting the procedures
 - Cleaning and sanitizing procedures for reusable devices
 - Safeguards in place to assure the safety of study participants
 - Location of the lab/procedure facilities – to determine if the space is suitable for the research procedures
 - Any plans for storage and retention of biological materials
 - Plans for protecting the privacy of participants
- C. Use of biomedical or physiological procedures that are ordinarily considered greater than minimal risk or invasive in nature.
- Note: Research involving procedures that fall under this category will typically need a higher level of safety and medical oversight. PIs must consult IRB and Occupational Medicine staff well in advance of submission for IRB review to assure procedures are properly evaluated and information needed for review is available.**
- Examples
 - Biopsies (fat or muscle tissue)
 - DXA scans
 - fMRI/MRIs
 - Vaginal Ultrasounds
 - Factors in review
 - Level of invasiveness/risks of the procedures and the appropriate level of medical oversight needed to protect participant health
 - Device safety information (manufacturer literature)
 - Inclusion and exclusion criteria and screening procedures for research participants – to ensure that individuals who are not eligible to participate are appropriately identified and excluded
 - Description of experience of or training for research personnel conducting the procedures
 - Cleaning and sanitizing procedures for reusable devices
 - Safety precautions and emergency medical response procedures for study participants and research personnel and a contingency/medical assistance plan in the event that a participant experiences an unexpected physical reaction to a research procedure
 - Location of the lab/procedure facilities – to determine if the space is suitable for the research procedures

- Any plans for storage and retention of biological materials
- Plans for protecting privacy of participants

3.3. Training and Expertise of Personnel

It is the PI's responsibility to ensure that all personnel listed on an IRB application have the appropriate training and experience required to perform the research activities while ensuring the safety of research participants. All personnel who perform procedures/use devices on human participants must be appropriately trained in the use of devices; conduct of data collection, safety, and material handling procedures; and response to unexpected events.

For studies that involve increased potential risks – such as DXA scans, biopsies, etc. – documentation of competency must be provided. In some cases, a certification of training or correspondence from a clinical setting (e.g., hospital, clinical research center, etc.) indicating the number of years of recent and direct experience performing study-related procedures may be sufficient. In others, an onsite assessment of competence may be required, especially if the procedure being conducted is a non-standard procedure, for which no direct certification is available.

Information regarding training requirements can be provided in advance of submitting an application for IRB review. Please consult the IRB staff, the Occupational Medicine staff at Gannett Health Services (<http://www.gannett.cornell.edu/services/occupational/index.cfm>), or the Lab and Research Safety team in Environmental Health and Safety (<http://sp.ehs.cornell.edu/lab-research-safety/Pages/default.aspx>).

4. Regulations and Guidance Applicable to the Use of Physiological Devices or Biomedical Procedures in Research

4.1. Federal Regulations

- A.** Cornell has filed a Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP) of the U.S. Department of Health & Human Services guaranteeing its application of the federal policy for the protection of human participants in 45 CFR 46 when engaging in human participant research funded by the Public Health Service (PHS). According to institutional policy, the same standards apply to all human participant research, regardless of funding support.

4.2. State Laws and Regulations

- A.** New York State Law Articles 22 through 24
- B.** New York State laboratory requirements <http://www.wadsworth.org/labcert/regaffairs/clinical/title5.pdf>

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