

## Purpose and Scope

### Introduction:

The mission of the University Hospitals Case Medical Center (UHCMC) Human Research Protection Program (HRPP) is to promote growth in clinical and translational research programs for the continued advancement of public health through academic medicine and to protect the rights, dignity, welfare and privacy of human research participants.

The UHCMC research program is guided by the ethical principles regarding research involving human participants as set forth in the [Belmont Report](#). The UHCMC assures that all of its research involving human participants will comply with the Terms of Assurance for Protection of Human Subjects for Institutions within the United States ([http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html)). This fundamental commitment to the protection of human participants applies to all UHCMC research involving human participants, regardless of the funding source and regardless of the location of the research.

### Definitions:

**Research:** As defined by DHHS any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under FDA regulations activities are “research” when they involve:

- a. Use of a drug other than the use of an approved drug in the course of medical practice ([21 CFR 312.3\(b\)](#)).
- b. Use of a medical device other than the use of an approved (means approved by the FDA for marketing) medical device in the course of medical practice (Food, Drug and Cosmetic Act 530(g)(3)(a)(i)).

Gather data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, including a dietary supplement that bears a nutrient content claim or a health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product. ([21 CFR 50.1\(a\)](#) or [21 CFR 56.101\(a\)](#)).

**Clinical Investigation:** Any experiment that involves a test article and one or more human subjects, and that is subject to the FDA regulations. FDA regulations consider the terms “clinical investigation” and “research” to be synonymous. The following are considered experiments subject to FDA regulations:

- Any use of a drug, other than the use of an approved drug in the course of medical practice.

- Any use of a medical device to evaluate safety or efficacy of that device.
- Any activity where data are being collection to submit to FDA or to be held for inspection by FDA.

**Test article:** Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.

**Human Subject (or Participant):** As defined by DHHS: a human subject is 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 ([45 CFR 46.102\(f\)](#)). If the research involves a medical device, individuals are considered “subjects” when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control ([21 CFR 812.3\(p\)](#)).

As defined by FDA: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient [21 CFR 56.102\(e\)](#). If the research involves a medical device, individuals are considered “subjects” when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control ([21 CFR 812.3\(p\)](#)).

**Research Activities Involving Human Subjects:** Activities that **either** (1) meet the DHHS definition of “research” and involve “human subjects” as defined by DHHS **OR** (2) meet the FDA definition of “research” and involve “human subjects” as defined by FDA. The definition of research and human subjects must consistently reference the **same set of regulations** (i.e., DHHS or FDA) and cannot reference the definition of research from one set of regulations, and the definition of a human subject from the other. **Anyone who plans to engage in an activity that qualifies as “research involving human subjects” requires Institutional Review Board (IRB) review and approval prior to commencement of the research.**

**Federalwide Assurance (FWA)** is a written agreement that establishes standards for human subjects’ research as approved by the Office for Human Research Protections and is executed by the institutional official.

**Department of Health and Human Services (DHHS)** is the United States government's agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

**Identifiable.** Federal regulations define identifiable to mean that the identity of the individual subject is or may readily be ascertained by the investigator or may be associated with the information.

**Institutional Review Board (IRB)** is an administrative body established by a local institution to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution.

**Interaction:** Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant or their private identifiable information.

**Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.

**IRB of Record** is a term utilized when an institution assumes the IRB responsibilities for a human subject research protocol conducted at another institution. An IRB Authorization Agreement signed by institutional officials at both institutions is required.

**IRB Authorization Agreement** is a formal agreement between UHCMC and another institution that allows the UHCMC IRB to serve as the IRB of Record for protocols at that institution.

**Office for Human Research Protections (OHRP)** is the division of DHHS responsible for providing leadership on human research participant protections and implementing a program of compliance oversight for DHHS ([45 CFR 46](#)).

**Private Information:** Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to be considered information to constitute research involving human participants.

**Department Review Committees** are committees within each academic and clinical Department at Case and UHCMC responsible for scientific review and approval of human subject research protocols prior to IRB review.

**Institutional Biosafety Committee (IBC)** is the Case committee that is responsible for the review and approval of all human subject research protocols involving recombinant DNA.

### **Policy:**

UHCMC requires that all human research projects in which UHCMC is *engaged* must be reviewed and approved by the UHCMC IRB or an appropriate IRB within the Case HRPP prior to initiation. UHCMC becomes *engaged* in human research when its employees (1) intervene or interact with living individuals for research purposes; (2) obtain individually identifiable private information for research purposes; or (3) all projects involving patients, personnel or resources (property or services) of UHCMC. “Human research” means any activity defined under the DHHS or FDA regulations that meets the definition of “research” and that involves “human subjects” (see definitions below). The definition of research and human subjects must consistently reference the *same set of regulations* (i.e., DHHS or FDA) and cannot reference the definition of research from one set of regulations, and the definition of a human subject from the other.

The UHCMC IRB has the authority to review, approve, disapprove or require changes in research or related activities involving human subjects. As stated in [45 CFR 46.109](#), the IRB has the authority to:

- Review and approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- Require that information given to subjects as part of informed consent is in accordance with [45 CFR 46.116](#).
- Require documentation of informed consent or waive documentation in accordance with [45 CFR 46.117](#).
- Notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modification required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision; however, a detailed critique of the protocol is not provided. The investigator may rewrite and submit the study as a new protocol.
- Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.
- Have authority to observe or have a third-party observe the consent process or the research and to review the research documentation.

The IRB also has the 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 subjects ([45 CFR 46.113](#)). Any suspension or termination of approval will include a statement of the reasons for the IRB’s action and will be reported promptly to the investigator, appropriate institutional officials, and the Department or

agency head ([IRB Policy, Non-Compliance with Human Subjects' Regulations](#) and [IRB Policy, Reporting to Regulatory Agencies, Department Heads and Institutional Officials](#)).

The IRB does not have the authority to grant retroactive approval should a research study be initiated without prior IRB review.

No institutional official at UHCMC or Case can reverse IRB decisions that involve disapproval, deferral, suspension, or termination of a research study. However, the UHCMC Institutional Official (UHCMC President and CEO or UHCMC Chief Medical Officer as designated by the UHCMC President and CEO) can disapprove an IRB approved protocol for activation or continuation at UHCMC.

The UHCMC IRB reviews all human research projects that originate from:

- Members of the UHCMC staff.
- The Case clinical and academic departments housed in the School of Medicine.
- The Case Frances Payne Bolton School of Nursing, Case School of Dentistry, Case School of Engineering, and any other Case School if the protocols involve patients, personnel, or resources of UHCMC.
- All projects involving patients or personnel of UHCMC.
- Other selected proposals as requested by the Case Behavioral Sciences IRB.
- Other selected proposals as outline under a fully executed IRB authorization agreement.

The IRB operates under the rules set forth under DHHS FWA00003937 for Protection of Human Subjects and the Code of Federal Regulations ([45 CFR 46](#)) as well as FDA regulations for the performance of all research activities that involve human subjects ([21 CFR 50](#) and [56](#)).

The responsibilities of the Institutional Review Board are:

- To protect human subjects from undue risk and deprivation of human rights and dignity.
- To disapprove studies of no scientific merit ([Belmont Report](#) – Respect of Persons).
- To ensure that participation by subjects is voluntary, as indicated by a voluntary and fully informed consent.
- To ensure equitable selection of subjects ([Belmont Report](#) – Justice).
- To maintain an equitable balance between potential benefits of the research to the subjects and/or society and the risks assumed by the subject ([Belmont Report](#) – Beneficence).
- To determine that the research design and study methods of a protocol are appropriate to the objectives of the research and the field of study.
- To assist the investigator by providing peer review and institutional approval.

- To ensure compliance of protocols with the regulations of the FDA, DHHS, and other funding agencies when appropriate.

### **A) Human Subject Research/Non-Human Subject Research Determination**

The UHCMC IRB has the sole authority to determine whether an activity meets the definition of “Human Subject Research”. When activities are conducted that might represent “Human Subject Research”, the activities must be submitted to the IRB for a determination. Investigators do not have the authority to make an independent determination and must submit a “Request for Determination of Non-Human Subject Research” to the IRB. An Investigator may request a determination that an activity is “Non-Human Subject Research,” but the final determination will be made by the IRB. The IRB will make a determination whether an activity is “Human Subject Research” by considering whether the activity either:

1. Meets the regulatory definitions of “research” that involves “human subjects,” or
2. Meets the regulatory definition of “clinical investigation.”

#### Non-Research

Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. Examples of systematic investigations include, but are not limited to observational studies, interviews (including those that are open-ended) or survey studies, group comparison studies, test development; or program evaluation. Examples of activities that would not normally be considered systematic investigations include, but are not limited to training activities (e.g., human subjects being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques) and classroom exercises involving human participants or human participant data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.

Activities are not research if they do not contribute to generalizable knowledge or if the results (or conclusions) of an activity are not intended to be extended beyond a single individual or an internal program (e.g., publications or presentations). Examples of activities that are typically not generalizable include: biographies and service or course evaluations, unless they can be generalized to other individuals; services, courses, or concepts where it is not the intention to share them beyond the UHCMC community; classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices; and quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share them beyond the UHCMC community. Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable and therefore, require IRB review and approval.

### Non-Human Subject

Activities do not involve humans as participants if they do not involve the process of obtaining specimens or data through intervention or interaction with individual participants or identifiable private information. Information is considered “not identifiable” if it includes none of the following:

1. Name;
2. Any geographic subdivisions smaller than a state, including street address, city, country, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of a ZIP code;
3. All elements of dates (except year) directly related to an individual (e.g., date of birth, admission);
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voiceprints;
17. Full-face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code.

Specimens/data that are received by the Investigator as de-identified stripped of all HIPAA identifiers as noted above. When the Investigator receives the private information or specimens with no code or link that would allow an Investigator to establish identity, this would not involve human subjects. For example, a publicly available, unidentifiable, non-linked cell line qualifies as not involving human subjects. The Investigator may receive coded private information or specimens and qualify for non-human subject if the following conditions are met:

1. The code is not derived or related to the HIPAA identifiers that must be stripped from the PHI (e.g. patient medical record # + last 4 digits of individuals Social Security Number);
2. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**
3. The Investigator cannot readily ascertain the identity of the individuals to whom the coded private information or specimens pertain, because:

- a. The key to decipher the code is destroyed before the research begins;
- b. The Investigator and the holder of the key enter into an agreement prohibiting the release of the key to the Investigator under any circumstances, until the individuals are deceased;
- c. The private information is received from an IRB-approved repository or data management center that includes written operating procedures that prohibit the release of the key to the Investigator under any circumstances, until the individuals are deceased; or
- d. There are other legal requirements prohibiting the release of the key to the Investigator until the individuals are deceased.

A cadaver is not considered to be a human subject. Research involving cadavers must be submitted to the UHCMC IRB and the IRB will determine which studies qualify as a “non-human subject.”

#### Amendments

Any change that might disqualify the activity from a “Non-Human Subject” or “Non-Research” status must be reported to the IRB for review and verification prior to implementation.

All “Non-Human Subject Research” is subject to all applicable institutional and IRB policies and procedures.

When activities are conducted that might represent “Human Subject Research”, the activities must be submitted to the IRB for a determination. Investigators must submit the “Request for Determination of Non-Human Subject Research” in its entirety to the IRB Office for processing. The form and corresponding instructions are located on the IRB website [IRB Forms and Templates](#). The Investigator will reply to all requests for revisions and/or clarifications requested by the IRB, when applicable. Investigators must submit any changes that might disqualify an activity from a “Non-Human Subject Research” status to the IRB using the “Protocol Addendum” checklist. Such changes must not be implemented prior to IRB review. If needed, the Chairperson or his/her Designee will be available to assist the IRB staff in determining whether an activity meets the definition of “Human Subject Research.” The IRB staff will review the proposed project to determine if the research qualifies as “Non-Human Subject Research” as defined above. The IRB staff may:

- Approve the request.
- Request minor revisions to the submitted documents in order to approve the request, and review and approve the revisions prior to granting final approval; or
- Disapprove the request.

The IRB staff will document the determination and its justification on the Reviewer Comment Form. If the IRB staff disapproves the request, the IRB staff will determine the appropriate level of review, communicate this to the Investigator, and guide the

Investigator with the re-submission. If the IRB staff disapproves the request, the IRB staff will sign and send a letter of final approval using the appropriate template. Appropriate database entries will be completed, including notification of approval on the next available agenda.

### **B) Institutional Oversight of Federalwide Assurance**

A complete copy of the current UHCMC Federalwide Assurance (FWA) is maintained in the office of the Vice-President of the Center for Clinical Research, and is available at the [UHCMC IRB website](#). The President and CEO of University Hospitals Case Medical Center (UHCMC) has ultimate responsibility for the institutional commitment made in the institution's Federal Wide Assurance (FWA); and is the designated Signatory Official for the Institution and the HRPP. The Institutional Officials: the Chief Medical Officer and the Vice-President for Research and Technology are appointed by; and report to the President and CEO of UHCMC. They have been authorized to act for UHCMC and assume, on behalf of the President/CEO and the UHCMC Board of Trustees, the obligations of its FWA and of the Federal regulations. Accordingly, the Chief Medical Officer and the Vice-President for Research and Technology are authorized to assure that UHCMC complies with the terms of the FWA and are ultimately responsible for the review and conduct of human subjects' research conducted or supported by UHCMC. They also serve as the central authority for the UHCMC HRPP.

In addition, the President and CEO of UHCMC possesses knowledge about the requirements of Federal regulations, applicable state law, the institution's Assurance, and institutional policies and procedures for the protection of human subjects. The Vice President for Research has full responsibility for leading the strategic planning, operational management, quality improvement, and development of all research conducted at, administered by or affiliated with UHCMC.

The UHCMC Assurance is based on the following principles in order to safeguard the rights and welfare of human participants in research and other research activities.

- UHCMC staff and Case faculty, staff, and students, which comprise its schools, departments, divisions, and facilities, are subject to the Assurance and this policy. This includes any research for which an Assurance or another formal agreement (e.g., IRB Authorization Agreement) identifies the UHCMC IRB as the IRB of Record.
- UHCMC agrees to uphold the ethical principles of the Belmont Report to all proposed research involving human participants. The ethical principles set forth in the Belmont Report are:
  1. **Respect for Persons:** Recognition of the personal dignity and autonomy of individuals and special protection for those persons with diminished autonomy.
  2. **Beneficence:** Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm.
  3. **Justice:** Fairness in the distribution of research benefits and burdens.

- UHCMC further agrees to apply additional regulations such as the U.S. Food and Drug Administration Human Subject Regulations ([21 CFR 50, 56, 312 and 812](#)), DHHS regulations ([45 CFR 46](#)), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants.

**UHCMC prohibits officials, investigators, employees, and sponsors from attempting to or using undue influence with the UH IRB, any of its members or staff, or any other member of the research team to obtain a particular result, decision, or action. “Undue influence” means attempting to interfere with the normal functioning and decision-making of the UH IRB or to influence a IRB member or staff, or any other member of the research team outside of established processes or normal and accepted methods, in order to obtain a particular result, decision, or IRB action.**

If a UH IRB Committee member, IRB staff, principal investigator, research participant, or other individual feels that he/she has been unduly influenced (e.g., coerced to participate, approve a study, or conduct a study), a report should be made to the UHCMC Chief Medical Officer (Office of Chief Medical Officer, 216-844-3695); or to the UH Compliance Officer through the Compliance Hotline (1-800-227-6934). The person receiving the report (i.e., the UHCMC Chief Medical Officer; or the UH Compliance Officer, Compliance & Ethics Department) will investigate the allegation and when appropriate, take corrective actions. Appeals related to IRB policies and procedures (including investigator concerns or suggestions regarding the review process) may be reviewed by the IRB Executive Committee and forwarded to the Clinical Council.

### **C) Responsibilities of the IRB under the Federalwide Assurance**

All information provided under the UHCMC Assurance must be updated at least every 36 months, even if no changes have occurred, in order to maintain an active Assurance approved by OHRP. Amendments to the Assurance must be reported promptly to OHRP. This includes changes to IRB rosters and the addition or deletion of an IRB Chair or legally recognized entity related to UHCMC.

Changes in IRB membership are reported to OHRP by the Vice-President for Research and Technology of the Center for Clinical Research. An IRB member can only be designated as “non-affiliated” if he/she and or his/her immediate family members do not have any affiliation (including past employment) with institutions within the Case HRPP.

#### UHCMC IRB Policy and Procedure Review and Approval

The UHCMC IRB will maintain policies and procedures reflecting the current practices of the IRB in conducting reviews and approvals under its Assurance. These policies and

procedures will be maintained and kept current by the UHCMC IRB and will be re-reviewed at least every 36 months.

As appropriate, policies and procedures are developed and revised by the IRB Executive Committee. All IRB policies and procedures are reviewed and approved by the Vice-President for Research and Technology, the IRB Chair, and the Boards at convened meetings. The approval date or last revision date (when applicable) will be listed on each policy and procedure along with the name of the person who reviewed and approved the policy and procedure. Current versions of all policies will be available from the [IRB website](#), and previous versions of policies will be kept in the IRB administrative office.

On an annual basis, the Vice-President for Research; the IRB Chair; IRB Manager; and the UHCMC Chief Medical Officer will evaluate whether the number of IRBs is appropriate to the volume and types of human research being reviewed, so that reviews are accomplished in a thorough and timely manner.

In addition, the IRB administrative personnel and budget will be reviewed on an annual basis by the Vice-President of the Center for Clinical Research, the IRB Chair, and the UHCMC Chief Medical Officer. Modifications in space, facilities, and staff will be made as necessary to accommodate the volume and types of research reviewed.

#### **D) Research Conducted at Multiple Sites**

Affiliated IRBs of the Human Research Protections Program (HRPP) may rely upon one another via the executed IRB Authorization Agreement (or Inter-Institutional Amendment) in effect between the collaborating institutions (MHS, Case, UHCMC). The decision of which IRB to rely on for review of a particular protocol is made jointly by the Chairpersons and/or IRB Administrators of the collaborating institution's IRB, and is determined primarily by the place of primary appointment of the PI or place of primary interactions for study-related activities. Both parties must agree that it is acceptable to rely upon the respective IRB for initial and continuing review of the research in accordance with the terms and conditions of the IRB Authorization Agreement. When acting as the IRB of record, the IRB sends the site PI and designated institutional representatives' copies of IRB correspondence. Copies of relevant IRB Minutes are provided to the designated institutional representative, upon written request.

Institutions external to UHCMC may rely on the UHCMC IRB if there is an executed IRB Authorization Agreement in effect between the institution and the UHCMC IRB. The decision of whether to rely on the UHCMC IRB for review of a particular protocol is made jointly by the Vice-President for Research and the Chairperson; and the Chairperson/Administrator of the collaborating institution's IRB. Both parties must agree that it is acceptable to rely upon the UHCMC IRB for initial and continuing review of the research in accordance with the terms and conditions of the IRB Authorization Agreement. When acting as the IRB of record, the UHCMC IRB sends copies of IRB

correspondence to the responsible PI and designated institutional representatives at the external site. Copies of relevant IRB Minutes are provided to the designated institutional representative, upon written request.

When research, which plans to include research activities at external sites is reviewed and approved by the UHCMC IRB and the external site does not have an IRB, investigators must provide documentation that the external site has agreed to host the research activities and also must provide relevant contact information for the external site.

The IRB submission materials should capture the following:

- Whether the site has an IRB
- Whether the site has granted permission for the research to be conducted
- Contact information for the site
- If the site has an IRB, whether the IRB has approved the research or plans to defer review to the organization's (UHCMC) IRB.

### **E) Case Affiliations**

The Office of Sponsored Projects Administration is an administrative office of Case responsible for ensuring that all research grants and studies awarded to Case are in compliance with the regulations and guidelines of various granting agencies. Within the Case Office of Sponsored Projects Administration is an Office of Research Compliance and IRB administrative office. The IRB at Case is a behavioral research IRB and Case relies on its affiliated hospital IRBs for review and approval of medical research protocols. The UHCMC IRB reports to the Office of Sponsored Projects for issues of compliance and research integrity for Case faculty members, and for protocols funded and administered through Case.

The Case Office of Sponsored Projects has established an Institutional Review Board Advisory Committee (IAC) composed of IRB Chairs and IRB administrators from MetroHealth Medical Center, Cleveland Veterans Affairs Medical Center, Cleveland Clinic Foundation, UHCMC, and Case. It is primarily a coordinating and communicative body that does not exercise any oversight activities with respect to individual IRB activities. The IAC has established educational and auditing programs related to human subjects' protections and responsible conduct of research.

### **F) Institutional Review Board Advisory Committee (IAC)**

#### Communicating Changes and New Information

The Case Office of Research Compliance (ORC), in conjunction with the UHCMC IRB Advisory Committee (IAC) members, will identify new information that might affect the HRPP, including laws, regulations, policies, procedures, and emerging ethical and scientific issues. UHCMC IAC members will disseminate this information to their HRPP administrators, investigators and their research staff, and the IRB members and staff through written communication (i.e., IRB websites) or verbal presentations. The IAC

will also determine whether the required Continuing Research Education Credit (CREC) Program should be revised based on any new information. Investigators are encouraged to monitor the IRB, CREC and HRPP Web sites for new postings.

### **References and/or Regulatory Citations:**

[45 CFR 46](#)

[21 CFR 50, 56, 312, and 812](#)

[Belmont Report](#)

[UHCMC Website for Federalwide Assurance](#)

[OHRP Assurance Information](#)

[OHRP IRB Registration](#)

[OHRP Policy Guidance](#)

### **Related Policies:**

[IRB Policy, Non-Compliance with Human Subjects' Regulations](#)

[IRB Policy, Department Review of Protocols](#)

[IRB Policy, Membership](#)