

# **HUMAN RESEARCH PROTECTION PROGRAM**

## 1. Purpose

The purpose of this policy is to describe the mission, scope, authority, and components of the Human Research Protection Program (HRPP or Program) for ensuring that the rights and welfare of all human subjects participating in research at The Ohio State University are protected. The requirements of the HRPP apply to all research involving human subjects conducted on behalf of The Ohio State University, irrespective of funding.

# 2. Overview

The core purpose of The Ohio State University is to advance the well-being of the people of Ohio and the global community through the creation and dissemination of knowledge. The areas of priority focus in the university's academic plan include providing distinctive education for its students, facilitating cutting-edge interdisciplinary research, and supporting 21st-century outreach and engagement.

Ohio State is a leader in research expenditures among U.S. public research universities and in industry funding among all research universities. Research programs in the health sciences, arts and social sciences, and education intended to improve the health and economic well-being of society are supported by federal, state, and industry funding. The Human Research Protection Program of The Ohio State University is charged with the overall responsibility for the protection of human subjects in these research endeavors, regardless of funding source.

#### 3. Mission Statement

The mission of the Human Research Protection Program is to protect the rights, dignity, welfare, and privacy of the human subjects in all research conducted on behalf of the university (regardless of funding) by adhering to the principles outlined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled, *Ethical Principles & Guidelines for the Protection of Human Subjects of Research* ("Belmont Report") and the regulations of the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and other applicable agencies. The Program is committed to advancing the ethical treatment of research participants, promoting the responsible conduct of research, and ensuring and protecting the rights of every human research volunteer. The HRPP achieves its mission by:

- Ensuring that all research involving human subjects receives required approvals before research activities are initiated
- Creating an environment at the university of respect for, and understanding of, the rights and welfare of research participants
- Providing professional administrative support to the university's Institutional Review Boards (IRBs or IRB)
- Educating the university community about federal, state, and university research regulations, policies, and practice pertaining to human subjects protection
- Conducting activities to enhance compliance with the requirements of the HRPP.



## 4. Governing Principles

The Ohio State University HRPP adheres to the ethical principles and guidelines for the protection of research participants summarized in the Belmont Report, complies with federal regulations, guidance, and state laws related to human subjects protection, and for federally-sponsored research maintains a Federalwide Assurance of Compliance (FWA) with the Office for Human Research Protections (OHRP). The ethical and regulatory requirements of the HRPP apply to all research involving human subjects conducted on behalf of The Ohio State University and to all individuals and components of the Program.

## A. Ethical Principles Governing Human Research

The primary ethical principles guiding research for which the HRPP has overall responsibility, including protocols that are "exempt" from federal regulations pertaining to research involving human subjects, are provided in the Belmont Report.

Three basic principles of the Belmont Report are central to the ethics of research involving human subjects and guide the IRBs in ensuring that the rights and welfare of research participants are protected. These are:

- Respect for persons applied by obtaining informed consent, and considering privacy, confidentiality, and additional protections for vulnerable populations
- Beneficence applied such that the potential benefits of research are maximized and possible risks are minimized to the persons involved
- **Justice** evidenced in the equitable selection of research participants.

## **B.** Regulatory Requirements

The Ohio State University's human research policies, guidelines, and operating procedures are intended to comply with applicable federal regulations, guidance, and state laws governing human subjects research, including, but not limited to:

- Code of Federal Regulations (CFR) Title 45 Part 46 (45 CFR 46), Protection of Human Subjects
- 21 CFR Part 56, Institutional Review Boards
- 21 CFR Part 50, Protection of Human Subjects
- 21 CFR Part 312, Investigational New Drug Application
- 21 CFR Part 812, Investigational Device Exemptions
- 34 CFR Parts 50 and 56, Disability and Rehabilitation Research
- 34 CFR Part 98, Protection of Pupil Rights Amendment (PPRA); Student Rights in Research, Experimental Programs, and Testing
- 34 CFR Part 99, Family Educational Rights and Privacy Act (FERPA)
- 45 CFR Parts 160 and 164, Standards for Privacy of Individually Identifiable Health Information; Security Standards for the Protection of Electronic Protected Health Information (HIPAA Privacy and Security Rules)
- Additional federal requirements, as applicable (e.g., DOD Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research)
- Applicable Ohio laws.



## C. Federalwide Assurance of Compliance

The Ohio State University maintains and supports a Federalwide Assurance of Compliance with the OHRP that outlines processes by which the university protects research participants in federally sponsored research. Three internal IRBs (IRB 00000294, IRB 00000295, and IRB 00003096) are designated under the FWA for review of human subjects research. Additionally, in specific circumstances, the university designates and relies on external IRBs for the review of Ohio State research involving human subjects. The university routinely relies on Western IRB (WIRB) for review of its industry-sponsored, industry-initiated clinical trials and on Central Institutional Review Board (CIRB) for NCI-sponsored clinical trials. The university also relies on the IRB of Nationwide Children's Hospital (Columbus, Ohio) for review of research conducted by Ohio State faculty in the Department of Pediatrics and Ohio State pediatric research conducted by the university wholly or in part at Nationwide Children's Hospital.

## 5. Research Subject to the Human Research Protection Program

Research is subject to the HRPP, regardless of funding or exempt status, when it includes activities that are either of the following:

- Research involving human subjects as defined by DHHS regulations
- Research (clinical investigation) involving human subjects as defined by FDA regulations.

**Research** is defined by DHHS regulations as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

**Human Subject** is defined by DHHS regulations as "a living individual about whom an investigator (whether professional or student) conducting research obtains either a) data through intervention or interaction with the individual or b) identifiable private information.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between investigator and subject.

**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 (for example, 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 for obtaining the information to constitute research involving human subjects."

**Clinical investigation** is defined by FDA regulations as "any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g)



of the Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms **research**, **clinical research**, **clinical study**, **study**, and **clinical investigation** are deemed to be synonymous..."

**Human subject** is defined by FDA regulations as "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. Subject [also] means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control."

Ohio State becomes "engaged" in human subjects research – and therefore bears responsibility for protecting participants involved in the research – when its employees or agents<sup>1</sup> intervene or interact with living individuals or obtain individually identifiable private information for research purposes. The university is also engaged in human subjects research whenever it receives a direct DHHS award to support the research.

The Ohio State University Human Research Protection Program is responsible for all Ohio State research involving human subjects, including the following:

- Research sponsored by The Ohio State University
- Funded or unfunded research conducted by or under the direction of any employee, staff member, or agent of the university in accordance with HRPP policy [Principal Investigator Status Appointments]
- Funded or unfunded research performed at university-approved performance sites in accordance with HRPP policy [<u>Research Performance Sites and Collaborative Off-Site Research</u>]
- Funded or unfunded research involving the use of private information held by the university, including that used to identify or contact prospective participants.

In accordance with HRPP policy [Research Involving Human Subjects], the Program is ultimately responsible for determining when an activity constitutes research involving human subjects.

## 6. Authority, Responsibility, and Independence of the Institutional Review Boards

All research involving human subjects overseen and conducted by The Ohio State University irrespective of funding must be reviewed by the IRB, unless the research has been determined to be exempt in accordance with HRPP policy [Exempt Research].

To fulfill its responsibilities, the IRB has the authority to:

- Ensure that research is designed and conducted in an ethical manner that protects the rights, dignity, welfare, and privacy of research subjects
- Approve, require modifications to secure approval, or disapprove all research involving human subjects

IRB Policy Committee

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<sup>&</sup>lt;sup>1</sup> "Agents" include all individuals (including students) performing institutionally designated activities or exercising institutionally delegated authority or responsibility.



- Suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects
- Observe, or have a third party observe, the consent process
- Observe, or have a third party observe, the conduct of the research.

The IRBs may exercise the option to perform expedited review, under the conditions described by federal regulations. IRB Chairs or Vice-Chairs may exercise any of the authorities of the IRB that do not require the determination of a convened IRB.

Research that has been approved by the IRB may be subject to further review and approval (or disapproval) by officials of the institution (e.g., Institutional Official, Deans, College Research Officers, etc.). However, no one may approve human subjects research (i.e., and authorize it to proceed) that has not been approved by the IRB.

To effectively ensure the protection of research participants, the IRBs' decision-making must be independent from coercion or undue influence. Any attempt to inappropriately influence the IRBs or ORRP staff in the performance of their duties will not be tolerated and should be reported immediately to the appropriate IRB Chair and/or the Institutional Official (IO).

The performance of research involving human subjects without IRB approval or exemption is noncompliance with human subjects protection requirements and will be handled as described in HRPP policy [Noncompliance].

## 7. HRPP Organizational Structure

The components comprising the HRPP and their responsibilities, ethical obligations, and authorities for carrying out the mission of the Program are described below.

#### A. Office of Research

The Office of Research (OR) provides oversight for all human, animal, and laboratory research conducted at The Ohio State University. The Institutional Official for the university's Human Research Protection Program is the Senior Associate Vice President for Research, who reports to the Senior Vice President for Research. The Senior Vice President for Research, assisted by the Senior Associate Vice President for Research and Associate Vice Presidents for Research, reports to the university Executive Vice President and Provost. Administrative units with distributed responsibility for human subjects research reporting to the Senior Vice President for Research include the Office of Responsible Research Practices (ORRP), Office of Research Compliance (ORC), and Office of Sponsored Programs (OSP).

The Senior Vice President for Research has responsibility for the development of overall research policies and operating procedures and for providing advice and assistance to college research administrators in the development of research programs within the colleges under the Bylaws of the Board of Trustees for the Administration of the University [Ohio Administrative Code § 3335-1-03(M)].



## B. Institutional Official for the Protection of Human Subjects

The Senior Associate Vice President for Research serves as the IO for the Human Research Protection Program at The Ohio State University and bears the ultimate responsibility for the following activities:

- Communicating the importance of human subjects protection across The Ohio State University and regularly demonstrating the institutional commitment to human subjects protection at Ohio State
- Assuming the obligations of the Federalwide Assurance of Compliance for the Protection of Human Subjects on behalf of The Ohio State University
- Supporting the implementation of Program decisions and taking administrative actions to ensure compliance
- Ensuring that the HRPP at the university is provided the resources necessary to conduct the activities under its jurisdiction and adjusting resource allocation as needed
- Appointing individuals acting on behalf of the university to review research
  proposals involving human subjects and policies, procedures, and operations of
  the HRPP, and ensuring that these individuals are protected from coercion or
  undue influence while serving in this capacity
- Serving as a point of contact for OHRP and other federal agencies sponsoring research
- Communicating with and advising other senior administrative officials on human subjects protection issues as necessary
- Ensuring that HRPP personnel provide effective, institution-wide communication of and access to human subjects protection policies and other information
- Ensuring that key HRPP personnel, including investigators, research staff, students, administrators, IRB members, and staff possess adequate knowledge of the federal, state, and local requirements pertaining to human subjects research
- Encouraging participant outreach activities to further the understanding of and support for human subjects research on and off the university's campuses.

## C. IRB Policy Committee

The IRB Policy Committee (IPC) is authorized by the Senior Vice President for Research and appointed by the Senior Associate Vice President for Research to:

- Develop, review, and approve policies and procedures for the university's Human Research Protection Program
- Receive input from the university community regarding HRPP operations, including the activities of the Office of Responsible Research Practices and the IRBs
- Provide input to the IO regarding operations of and resources allocated to the HRPP, including the composition and number of the IRBs and staff devoted to support Program activities
- Support the educational, quality improvement, and outreach activities of the HRPP
- Enhance strategies for recruiting and retaining IRB members
- · Review and approve new HRPP initiatives.



The IRB Policy Committee derives its authority from and reports its activities to the IO and Senior Vice President for Research. The IPC receives administrative support from the Office of Responsible Research Practices.

The IPC is comprised of the IRB Chairs and Vice-Chairs, at-large faculty members representing the investigator community, and the ORRP Director. Other individuals representing the HRPP (i.e., designees from OR, OSP, and ORRP) serve as ex-officio advisory members.

### D. Institutional Review Boards

All Ohio State research involving human subjects that requires IRB review will be reviewed by one of three university IRBs, WIRB, CIRB, Nationwide Children's Hospital IRB, or an external IRB of record through an Institutional Authorization Agreement. IRB members of the three university IRBs are appointed by the IO and/or Vice President for Research. The scope of review of these IRBs and any exceptions are described below.

- The Behavioral and Social Sciences IRB reviews investigator-initiated (funded or unfunded) research that does not involve medical procedures, drugs, or medical devices, originating from a variety of disciplines including the arts, humanities, business, communication, education, music, nursing, political science, psychology, sociology, and social work. The Behavioral and Social Sciences IRB does not review FDA-regulated research.
- The Biomedical Sciences IRB reviews investigator-initiated (funded or unfunded) biomedical research, excluding cancer research. The Biomedical Sciences IRB does not review industry-initiated, industry-sponsored clinical trials (see below).
- The Cancer IRB reviews investigator-initiated (funded or unfunded) research involving cancer surveillance, etiology, diagnosis, early detection, prevention, treatment, symptom control, and survivorship studies, including quantitative, observational, and interventional study designs. The Cancer IRB does not review industry-initiated, industry-sponsored cancer clinical trials (see below).

Ohio State research that is industry-initiated and industry-sponsored is reviewed by Western IRB. WIRB provides review and oversight for research that meets all of the following conditions:

- The project is a controlled study involving human subjects, designed to prospectively evaluate the safety and effectiveness of new drugs or devices or of behavioral interventions
- The only sponsor of the project is a for-profit entity/company
- The project was designed and written by the sponsor
- The sponsor holds all INDs/IDEs for the project.

Sub-studies or extension studies (e.g., pharmacokinetics, registries) associated with clinical trials reviewed by WIRB are also sent to WIRB for review.

Research involving any the following, regardless of funding source, is reviewed by a university IRB and is not sent to an external IRB for review:

- Planned emergency research
- Xenotransplantation
- Gene transfer



- Embryonic stem cell research
- Any other research requiring review and approval by The Ohio State University Institutional Biosafety Committee (IBC).

Except for research that meets the conditions for review by an external IRB or the exceptions noted above, research conducted by Ohio State faculty in the Department of Pediatrics and Ohio State pediatric research conducted wholly or in part at Nationwide Children's Hospital is reviewed by Nationwide Children's Hospital IRB.

Only the IRB designated by The Ohio State University may approve Ohio State research involving human subjects, unless the research is covered under a cooperative agreement (or other similar agreement) authorizing the research to be reviewed by another appropriate IRB serving as the IRB of record. The full authorities and responsibilities of the IRBs are described in Section VI above.

## E. Privacy Board

The Privacy Board reviews requests for waiver of HIPAA authorization in human subjects research involving protected health information (PHI) that has been determined to be exempt. For human subjects research that involves PHI requiring IRB review, the IRBs act as the Privacy Boards for requests for waiver of HIPAA authorization.

## F. Office of Responsible Research Practices

The Office of Responsible Research Practices, in conjunction with the IRBs, comprises the research review unit of the HRPP. ORRP's activities include the following:

- Providing administrative support for the university's IRBs and the IRB Policy Committee
- Determining and documenting when activities constitute research involving human subjects and when research is exempt from IRB review
- Providing education on human subjects protection and the ethical and responsible conduct of research to faculty, staff, and students
- Maintaining the university's FWA and cooperative agreements (or other similar agreements) for IRB review
- Serving as a resource for the university and external community for HRPP policies and other information relating to the protection of human subjects
- Assisting the IPC with evaluation of HRPP operations and resources
- Supporting the quality improvement, outreach, and compliance activities of the HRPP.

In addition, ORRP staff provide administrative support to the Institutional Biosafety Committee and Privacy Board. The Office of Responsible Research Practices is also responsible for coordinating ancillary reviews performed by other components of the HRPP (e.g., Conflict of Interest Advisory Committee) with IRB review.

### G. Office of Sponsored Programs

The Office of Sponsored Programs coordinates sponsored research at The Ohio State University to support the university's educational and research objectives and the academic plan. OSP staff provide oversight of sponsored projects to ensure compliance with all governing policies, including government, sponsor, and university policies



dealing with allowable costs, time and effort, and classified materials. The Office of Sponsored Programs also works with the Office of Responsible Research Practices and Office of Research Compliance to ensure compliance with governing policies concerning conflicts of interest, scholarly misconduct, human subjects and animal research, and research involving recombinant DNA.

OSP staff in the Office of Grants and Contracts (OGC) act as the interface between Ohio State investigators and sponsors and are responsible for ensuring that proposals, budgets, and contracts comply with federal and state laws, sponsor guidelines, and university policy. OGC staff work with the ORRP staff and the IRBs to ensure congruence and consistency between sponsored research agreements and IRB approved research.

## H. Office of Research Compliance

The Office of Research Compliance supports and promotes ethical research practices at The Ohio State University. The Office of Research Compliance serves the Ohio State research community by coordinating institution-wide research compliance policy and procedure development and by partnering with researchers so that the university is compliant with federal, state, and local laws and regulations, as well as university policies. ORC staff also provide support to the IRBs and ORRP staff in instances and investigations of noncompliance and maintains the university's anonymous reporting line for anonymous or confidential reports of activities that may involve unethical or otherwise inappropriate activity or behavior in violation of the university's established policies, including those of the HRPP.

### I. Conflict of Interest Advisory Committee

The Conflict of Interest Advisory Committee (COIAC) is comprised of a minimum of six faculty members, two from colleges in the health sciences, two from colleges in the arts and sciences, and two from the professional colleges (Business; Education and Human Ecology; Engineering; Food, Agricultural and Environmental Sciences; Law; Social Work). COIAC members are appointed by the Senior Vice President for Research. The COIAC meets regularly to review conflicting interests that are disclosed through annual reports and during the IRB submission and review processes, discuss potential management plans for eliminating or managing such conflicts, and to address conflict of interest related issues, policies, and procedures.

Recommendations resulting from COIAC review of conflicts involving human subjects research are communicated in writing to the appropriate IRB, including any proposed management plans. The IRBs have final authority regarding approval of research involving a conflict of interest. Following its evaluation, the IRB will inform the investigator and COIAC of its determination.

# 8. Additional Components Supporting the HRPP

### A. Office of Legal Affairs

The Office of Legal Affairs provides the IRBs, Office of Responsible Research Practices, and other components of the HRPP with counsel on an as needed basis, primarily on



matters related to state laws, cooperative agreements, noncompliance, conflicts of interest, and contractual issues in human subjects research.

## **B. Institutional Biosafety Committee**

The Institutional Biosafety Committee is charged with ensuring that all Ohio State research involving recombinant DNA, regardless of funding source, is registered with the IBC and is conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules. The IBC is further charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals. This review is conducted pursuant to the Centers for Disease Control and Prevention/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories*. ORRP staff provide assistance with IBC registrations and applications and coordinate IBC and IRB review of research involving human subjects requiring approval from both Committees.

The IBC, in conjunction with the Office of Environmental Health and Safety (EHS), also provides guidance to the Ohio State research community regarding proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.

## C. University Radiation Safety Committee

The EHS University Radiation Safety Committee (URSC) has the following responsibilities:

- Review and oversight of human subjects research involving radiation for research purposes (including x-rays, nuclear medicine studies, DEXA scans, CT scans)
- Oversight of and ensuring compliance with the radiation safety program
- Establishment of university policies consistent with Ohio Department of Health and federal regulations.

The URSC has three subcommittees: Medical Use, Audit, and Crisis and Monitoring. The Medical Use Subcommittee provides recommendations to the URSC regarding applications for the use of radioactive materials in humans.

The Medical Use Subcommittee also serves as the Human Subject Radiation Committee (HSRC), which provides review of research uses of radiation in human subjects research to facilitate IRB review as described in HRPP policy [Research Involving Radiation]. The HSRC also provides suggested language that can be used to communicate radiation exposure dose, provide comparison to other sources of radiation, and estimate the level of risk to potential participants in human research involving radiation.

#### D. Center for Clinical and Translational Science

The Ohio State University Center for Clinical and Translational Science (CCTS) is an NIH-supported program with resources facilitating research involving human subjects, providing financial, organizational, and educational support to biomedical researchers. Resources include dedicated clinical research space (Clinical Research Center), nursing and bionutrition services to support the execution of a study, biostatistics and data management support, core laboratory specimen analysis, and provision of a research subject advocate to enhance the safety of participants in human research.



Information regarding administration and approval of human subjects research is made available to CCTS Administration by the Office of Responsible Research Practices. Documentation of CRC Scientific Advisory Committee approval is required prior to beginning research involving human subjects in the CRC.

## 9. Activities/Resources that Enhance Quality and Compliance of the HRPP

In addition to the review and oversight responsibilities of the IRBs, several additional activities and resources support the university's overall efforts to protect research participants. These are described below.

# A. University Policies

University policy documents provide a statement of Ohio State's official position on requirements related to performance of research involving human subjects at The Ohio State University. These are supplemented by HRPP policies, ORRP desk procedures, and investigator forms and guidance. General university research policies are available on the OR and ORC websites.

#### **B. HRPP Policies**

HRPP policies provide investigators, IRB members, and ORRP staff with guidance on IRB-related processes and help to facilitate consistent decision-making among the different IRBs. These documents are accessible to all faculty, staff, and students via the ORRP website and serve as an educational resource for those involved in conducting or supporting human subjects research at The Ohio State University.

## C. ORRP Desk Procedures

ORRP desk procedures provide ORRP staff guidance on operations primarily related to the processing of protocol submissions for IRB initial and continuing reviews, amendment reviews, expedited reviews, exemption determinations, and IRB meeting administration. Desk procedures also serve to facilitate compliance with HRPP documentation and recordkeeping requirements.

# D. Quality Improvement Program

Quality improvement activities for the HRPP are coordinated by the ORRP Director and the HRPP Quality Improvement team. Activities include education, participant outreach, and post-approval monitoring. Data obtained from monitoring and compliance activities are used by the Quality Improvement Specialists to revise existing policies, guidance, and direct educational efforts.

### E. IRB Website

HRPP policies and forms are accessible to investigators, research staff, and IRB members from the IRB page on the ORRP website. In addition, links are provided to news and announcements, newsletters, applicable regulations and guidance, educational activities, and FAQs. A secure site for IRB members is maintained to facilitate sharing of IRB minutes, announcements, and reference materials, as well as to post protocol submissions for expedited IRB review.



#### F. Participant Outreach Activities

In order to involve and inform current and future research participants in accordance with the Belmont principle of *Respect for Persons*, the HRPP maintains a "Research Participants" page on the IRB website. This page provides resources for research participants, including links to university departments that maintain lists of active research projects seeking participants and educational links to websites related to research involving human subjects. In addition, research participants are invited via the website to contact ORRP staff to provide feedback and/or obtain information about human subjects research and HRPP activities.

## G. Education and Training

To ensure that all personnel involved in the conduct or review of human subjects research receive appropriate education on the ethical principles and regulatory requirements related to human subjects protection, all IRB members, ORRP staff, and investigators and research staff must complete the required modules within the webbased Collaborative Institutional Training Initiative (CITI) course. Such individuals must complete this training every three years. The HRPP regularly provides a variety of additional training and educational offerings related to human subjects research, including the following topics:

- Informed Consent
- Participant Recruitment
- IRB Review and Exemption Determinations
- Quality Improvement and Post-Approval Monitoring
- Requirements for Undergraduate and Graduate Researchers
- New Research Staff Orientation
- .
- "Office Hours" for Biomedical/Cancer Research and Behavioral/Social Science Research
- College/Department/Class specific topics (e.g., program evaluation, educational research, etc.).

#### H. Accreditation

To affirm that the Human Research Protection Program is in compliance with applicable federal regulations and state laws, as well as institutional and academic best practices, The Ohio State University will maintain accreditation of its Program through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP accreditation is renewed every five years.

### 10. History

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