

HUMAN RESEARCH PROTECTION POLICY

I. General Policy

It is the policy of Rice University to protect the rights and safety of human participants involved in research and to comply with relevant ethical or legal standards related to human participants in research. The Human Research Protection Policy applies to all research activities involving human participants conducted by, or on behalf of, Rice University or using Rice University facilities or equipment, irrespective of funding source.

This HRPP policy is established to help ensure compliance with applicable laws such as the Common Rule (45 CFR Part 46) and FDA regulations related to human participants (21 CFR Parts 50 and 56) and adheres to ethical standards set forth in the Belmont Report.

All research involving human participants conducted by Rice faculty, staff, post-doctoral students or students or conducted in Rice facilities or on Rice property by those with joint appointment or visitor status, shall be undertaken only after an Institutional Review Board (IRB) has reviewed and approved the research.

While federal regulations contain exemptions from IRB review for certain types of research, only the IRB or designated IRB personnel can determine whether a specific activity is exempt, based on review of a formally submitted research application. Upon initial review of submissions, the IRB Administrator will determine the type of review required: either 1) Exempt; 2) Expedited; 3) Full Board; or 4) Not Human Participant Research.

II. Roles and Responsibilities

The Vice Provost for Research has the authority and responsibility to establish, maintain and oversee the HRPP. The primary administration of the HRPP for daily operations lies with the Office of Sponsored Projects and Research Compliance (SPARC) and the IRB.

All researchers have an obligation to ensure that any research involving human participants has appropriate IRB approval, and to notify the IRB of significant changes in previously reviewed research plans.

The Vice Provost for Research is responsible for designating an individual as the IRB Chair to review and expedite protocols or exemptions.

III. Definitions

Human participant is a living individual about whom a researcher obtains (1) data through intervention or interaction with the individual and/or (2) identifiable private information about the individual.

Identifiable bio specimen is a bio specimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the bio specimen.

Interaction includes communication or interpersonal contact between the investigator and the participant.

Institutional Review Board (IRB) is a committee having authority and responsibility to formally approve, monitor, review, or curtail any research involving human participants.

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

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). In research involving human participants, 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), as determined by the IRB.

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Researcher is someone who conducts research involving human participants (1) on the premises of Rice University, (2) off-campus in the capacity of a Rice University affiliate or a collaborator thereof, or (3) targeting staff or students of Rice University as research participants.

Significant Change is any change to the research should be submitted to the IRB for review. These change are not limited to but could include revisions to the study design, survey/interview questions, consent forms.

IV. Elaboration of Policy

A. Goal and Objectives of the Human Research Protection Policy (HRPP)

The purpose of the HRPP is to protect the rights and welfare of human participants and enable research that abides by the applicable law and the principles of respect for persons, beneficence, and justice. The HRPP requires Rice to:

- exercise oversight of research involving human participants;
- establish a formal process to monitor, evaluate and improve the protection of human participants involved in research at Rice University; and
- educate investigators and research staff about their ethical responsibility to protect human participants.

B. Affiliated Organizations

The HRPP applies to all human participant research done at Rice University, or by Rice employees at affiliated organizations when an agreement is in place to provide such services related to the HRPP.

C. Role of the IRB

The IRB will conduct an initial and a continuing review and monitoring of human participant research. The IRB plays a primary role in the HRPP through ensuring that all research involving human participants meets approval criteria outlined in 45 CFR 46.111, including :

- conduct prospective and ongoing reviews of each project submitted to it that involves human participants, including an evaluation of the project's risks and benefits to human participants;
- review the adequacy of the informed consent process and documentation of consent as required by 45 CFR 46.116 and 46.117 particularly as to its description of the risks and benefits; and
- receive, evaluate, and conduct reviews concerning reports of unanticipated problems, possible non-compliance, and other applicable matters that may affect the approval of the project or the safety of the study participants.

All research involving human participants must be submitted to the IRB for review, including:

- research conducted by Rice faculty, students, or staff on or off campus; and
- research conducted on Rice campus by any non-Rice personnel in collaboration with or formally approved by Rice University.

D. Training Concerning the HRPP

Rice University requires documentation of appropriate training regarding the type of research in which the individual will be involved for all individuals who will be engaged in human participant research. This includes, but is not limited to, all investigators, research staff, faculty, students, IRB members and IRB management staff. Protocol submissions must be accompanied by a certificate of human participant training that is not more than three years old, and issued by CITI (Collaborative Institutional Training Initiative) or another equivalent program approved by the Vice Provost for Research. At the three (3) year renewal period, a Basic Refresher for the CITI IRB (or equivalent) module must be completed in order for the researcher to continue human participant research. Research staff, students, IRB members and IRB administrative staff must also complete a Basic Refresher for the CITI IRB (or equivalent) module every three (3) years.

Appropriate training for investigators and others is determined by the IRB, and is based on the research protocol and the role of the individual. Investigators should contact the IRB administrator early in the process to determine what training will be required based on the specific protocol.

In addition to the training requirements above, Researchers may also be required to attend laboratory specific or other Environmental Health and Safety training if the scope of the research involves blood, tissue, or other potentially infectious materials.

E. Conflict of Interest

Conflict of Interest is governed by [University Policy 216](#) (*Conflict of Interest and Commitment for Faculty (Including Faculty Fellows and Investigators)*). Faculty Members, Faculty Fellows, and Investigators must identify conflicts of interest related to the research. This would include researchers involved in the design, conduct and/or reporting of the research. No IRB member may participate in the review or vote of any initial, continuing review, revision, or any other matter involving research in which he or she has a conflict of interest.

F. Health Insurance Portability and Accountability Act (HIPAA) and Privacy

The HIPAA Privacy Rule establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes. In the event Rice personnel access PHI for

the use of research, under the Privacy Rule, covered entities are permitted to use and disclose PHI for research with (i) the individual's authorization; (ii) without the individual's authorization, under limited circumstances – if the IRB grants the researcher a waiver of authorization; or (iii) if an exception applies.

HIPAA applies to research when:

- The researcher is part of a covered entity and will use health or member information for research purposes.
- The researcher is conducting research at Rice University and will use health data from a covered entity or a covered entity business associate. This includes identifying or recruiting research participants who are patients of a covered entity.

G. Non-Compliance and Reporting

Anyone who knows of, or has reason to believe that human participant research is being conducted in a manner that is not in compliance with the HRPP must report the matter. If any member of the Rice community has any questions regarding the HRPP or wishes to make a report related to human participants in research they should contact the IRB administrator, Assistant Vice Provost of Sponsored Projects and Research Compliance, Office of General Counsel, or the Ethics Hotline. .

Non-compliance with the HRPP, research protocol deviations that impact human research, or violations of applicable local, state and federal regulations may have serious consequences and may result in administrative, civil, or criminal penalties against individuals and the organizations participating in the HRPP. Disciplinary action may include, but is not limited to, termination of the research project, reprimand, loss of research privileges, or termination from Rice University.

V. Cross References to Related Policies

Policy for the Submission and Administration of Sponsored Projects – [Policy No. 301](#)

Laboratory Safety – [Policy No. 313](#)

Research Misconduct - [Policy No. 324](#)

Conflict of Interest - Policies [No. 838](#) and [No. 216](#)

Whistleblower Protection- [Policy 813](#)

VI. Responsible Official and Key Offices to Contact Regarding the Policy and its Implementation

Responsible Official: Vice Provost for Research

Key Offices: Office of Research
Office of Sponsored Projects and Research Compliance
Institutional Review Board

VII. Procedures and Forms

<http://sparc.rice.edu/irb>

VIII. Links to Additional Information

<http://www.hhs.gov/ohrp/>

www.fda.gov

Signed David W. Leebron

David W. Leebron

President

Policy History

Revised: April 6, 2018; January 15, 1998

Issued: 1989