

Rose-Hulman Institute of Technology

Human Research Protection Policy

I. Introduction

Rose-Hulman Institute of Technology (RHIT) contracts with Indiana State University (ISU) to serve as the Institute's designated Institutional Review Board (IRB) for all human subjects research activity conducted by faculty, staff and students. As part of the contractual arrangement with ISU, RHIT agrees to follow the policies and procedures outlined in *Indiana State University Policies and Procedures for the Review of Research Involving Human Subjects* located at the following url: http://osp.indstate.edu/forms/IRB_Manual.doc

Policies and procedures outlined on the following pages highlight procedures for RHIT personnel and are intended to complement the ISU policy. For the reader's convenience, references to policies, regulations, abbreviations and guiding principles appear throughout the text. For a quick reference to this information and contact information for RHIT human protections program administrators, please see section XV., "References".

II. Purpose

There are research endeavors in which human subjects are essential to the conduct of the research, enabling investigators to advance knowledge and make discoveries in various fields of study. Any time human subjects are incorporated in research design, it is imperative that the relationship between researcher and subject be based on accurate information, trust, and respect. These principles apply regardless of whether the research is federally funded, privately funded, or unfunded. RHIT has adopted the following policies and procedures to ensure the principles of respect for persons, beneficence, and justice as set forth in the *Belmont Report* are adhered to in all human subject research activities conducted by the Institute.

III. History

Scientific research has produced both substantial social benefits and some troubling ethical questions. In December 1946, 23 physicians and administrators, many of them leading members of the German medical hierarchy, were indicted before the War Crimes Tribunal at Nuremberg for their willing participation in the systematic torture, mutilation, and killing of prisoners in experiments during World War II. Despite the arguments of the German physicians that the experiments were medically justified, the Nuremberg Military Tribunals condemned the experiments as "crimes against humanity"; 16 of the 23 physicians were found guilty and imprisoned, and 7 were sentenced to death. In the August 1947 verdict, the judges included a section called "Permissible Medical Experiments." This section became known as the *Nuremberg Code* and has formed the basis for ethics codes internationally.

The first accounts of the United States Public Health Service's long-term study of black males at the Tuskegee Institute, designed to observe the natural history of untreated syphilis, appeared in the national press in 1972. The resulting public outrage led to the appointment of an ad hoc advisory panel by the Department of Health, Education and Welfare to review

the study and advise on how to ensure that such experiments would never again be conducted. The primary task of the National Commission was to identify the ethical principles that would guide all research involving humans. The report of this commission would become known as *The Belmont Report* which serves as the foundation for the regulations that guide ethical human subjects research today.

IV. Regulations

A. The Belmont Report

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

In 1979, the National Commission wrote *The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects*, which serves as the cornerstone of ethical principles upon which Federal regulations for the protection of human research subjects are based. The three ethical principles identified in this report form the foundation for the conduct of human subjects research, including guidelines for obtaining informed consent, respect for privacy and confidentiality, and risk/benefit assessment.

1. Key Points

Rose-Hulman has provided assurance to the government that all activities related to human subjects research, whether externally funded or not, will be guided by the ethical principles in *The Belmont Report*. This report identifies three principles as essential to the ethical conduct of research with humans. Following are excerpts from *The Belmont Report* definition of these principles:

- a) **Respect for persons** Subjects must enter into the research voluntarily and with adequate information. Respect also requires the protection of those subjects with diminished autonomy.
- b) **Beneficence** Beneficence for the purposes of the report is to be understood as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.
- c) **Justice** Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

B. Common Rule

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

In addition to ethical considerations, the Federal Government mandates standards for protection of human subjects in research. These standards are set forth in the Code of Federal Regulations, Title 45 CFR Part 46. Subpart A, the basic policy for protection of human research subjects, is referred to as the *Common Rule*. These regulations

were enacted in 1991 and apply to all human subjects research as defined in this rule. Among the topics addressed in the *Common Rule* are definitions, applicability for the rule, compliance assurance requirements, establishment and operational procedures for an Institutional Review Board (IRB), and required procedures for review and approval of human subjects research and informed consent. Subparts B, C, and D address additional protections for special populations of human subjects.

1. Key Points

- a) **Human subject** is defined as 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.
- b) **Research** is defined as a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- c) **Identification of Exempt Research** Certain categories of research are exempt from the Common Rule. However, an individual investigator is **not** eligible to make this determination for his/her own research activity. RHIT has designated an Institute Reviewer (IR), approved by the ISU Institutional Review Board (ISU IRB) to review research procedures and determine if the activity meets exemption criteria. Researchers must receive an official “certification of exemption” letter from the IR on RHIT letterhead before beginning any human subjects research activity. The IR serves as an alternate member of the ISU IRB and receives his or her authority from the ISU IRB. For a detailed list of exemption categories see section IV. C., “To What Research Does this Policy Apply”? Procedures for human subjects protocol review and certification of exemption are outlined in section VI., “Process for Review and Approval of Human Subjects Research”.
- d) **Institutional assurance (Federalwide Assurance, FWA)** Each institution engaged in Federally-supported human subjects research is required to file an Assurance which formalizes the institution’s commitment to protect human subjects. In the FWA, RHIT assures:
 - (1) all activities related to human subjects research, regardless of funding source, will be guided by the ethical principles in *The Belmont Report*.

- (2) all activities related to federally-conducted or federally-supported human subjects research will comply with the *Terms of Assurance for Protection of Human Subjects for Institutions Within the United States*
- (3) the Institute will apply the *Common Rule* to all of its human subjects research regardless of source of support
- (4) Indiana State University Institutional Review Board (ISU IRB) is designated to review all human subjects research activity undertaken by RHIT faculty, staff and students

C. To What Research Does this Policy Apply?

RHIT, in filing its Federalwide Assurance has elected to apply the principles of *The Belmont Report* and the *Common Rule* to all research projects involving human subjects. The *Common Rule* stipulates that research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the rule, unless otherwise required by Department or Agency heads. Researchers are reminded that an individual may not make this determination for his or her own research activity. Please see section VI. A.2., “Certification of Exemption” for exemption certification process.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner

that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subjects to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

V. Responsibilities and Rights of Human Protections Program Administrators

A. The Signatory or Institutional Official:

- ensures implementation of the Federalwide Assurance terms
- designates an Institutional Review Board (IRB) to review and approve all nonexempt human subjects research covered by the Assurance
- appoints RHIT Institute Reviewer (IR) to be approved by designated IRB
- appoints RHIT IRB administrator
- ensures effective Institute-wide communication and guidance on human subjects research
- ensures researchers fulfill their responsibilities
- ensures faculty and staff participation in human subjects education activities
- serves as a knowledgeable point of contact for the Office of Human Research Protections (OHRP) or designates such a contact
- supports IRB and IR authority and decisions
- develops and/or revises policies and procedures for effective and efficient administration of the human subjects protection program at RHIT
- ensures appropriate oversight mechanisms to ensure compliance with regulations and effective administration of the human subjects protections program
- ensures prompt reporting of any unanticipated injuries or problems involving risks to subjects or others; any serious or continuing noncompliance with the regulations or requirements of the IRB; and any suspension or termination of IRB approval of research to the designated IRB, IRB administrator, OHRP, and any sponsoring federal department or agency head

B. Institute Reviewer:

- provides regulatory and ethical advice to researchers in human subjects research design, preparation of human subjects applications and forms, and preparation of human subjects section of grant proposals
- reviews human subjects application/protocol and determines if protocol meets exemption criteria
- provides researcher with certification letter for exempt research
- serves as an alternate member of the designated IRB and attends IRB meetings when RHIT protocols require full review
- ensures protocols requiring IRB are submitted to designated IRB
- ensures prompt reporting of any unanticipated injuries or problems involving risks to subjects or others to the IRB Administrator, Signatory Official, and designated IRB
- ensures prompt reporting of any serious or continuing noncompliance with the regulations or requirements of this policy to the IRB Administrator, Signatory Official, and designated IRB
- ensures prompt reporting to the IRB of proposed changes in a research activity, and ensures that such changes in approved research are not initiated without IRB review and approval except when necessary to eliminate apparent, immediate hazards to the subjects
- implements appropriate oversight mechanisms are implemented to ensure compliance with determinations of the IRB
- participates in any investigation of human subjects research at RHIT

C. The IRB Administrator:

- retains records for RHIT Federalwide Assurance
- provides access to copies of pertinent regulations, policies and guidelines related to the involvement of human subjects in research
- maintains records and log for new applications, modification requests, adverse event reports, continuation requests, completion reports, and other correspondence for each RHIT human subjects protocol
- provides designated IRB and authorized federal officials access to human subjects protocol records upon request
- ensures all grant and contract applications involving human subjects comply with regulations and provide certification of IRB approval or exemption to the sponsoring agency
- ensures all cooperating research sites in federally supported research have appropriate OHRP-assurances and provide certification of IRB approval of proposed research to the appropriate federal department or agency

- notifies researcher when continuation requests must be filed with the IRB
- oversees the training program on the ethical conduct of research involving human subjects and ensures faculty, staff, and students maintain certification
- educates members of the RHIT community about the ethical conduct of human subjects research
- ensures that cooperative designated IRB review arrangements are documented in writing in accordance with OHRP guidance
- ensures designated IRB receives all documents regarding human subjects research

D. Researcher or Principal Investigator:

- assumes primary responsibility for protecting the rights and welfare of human research subjects and is responsible for complying with all applicable provisions of the RHIT Assurance.
- consults with Institute Reviewer if unsure whether a study meets the definition of research with human subjects
- submits applications for research involving human subjects for review and **approval prior to initiating research**, in accordance with section VI., “Process for Review and Approval of Human Subjects Research”
- conducts human subjects research in accordance with the ethical standards described in *The Belmont Report*, the *Common Rule*, *Rose-Hulman Institute of Technology Human Research Protection Policy*, and *Indiana State University Policies and Procedures for the Review of Research Involving Human Subjects (ISU Policy)*.
- conducts research according to the IRB approved protocol and in compliance with all IRB determinations
- ensures that each potential subject understands the nature of the research and of the subjects’ participation
- promptly reports any unanticipated problems involving risks to subjects or others to the Institute Reviewer (IR) and ISU IRB Chair at 237-8217
- promptly forwards requests for proposed changes to IRB approved human subjects research activities to the IR and ensures changes to approved protocol are implemented **after** IRB approval
- attends the IRB meeting as requested by the IRB when a full review of the application is required
- maintains education and training certification for him/herself and others involved in human subjects research as prescribed in this policy, section VI. D., “Human Research Protections Training”
- makes accessible all records for inspection and copying by a designated IRB member or the department or agency supporting the research as required
- retains signed informed consent forms and research materials after the completion of the research project for a minimum of three years or in accordance with the funding agency’s requirement, whichever is longer.

E. Rights of Researcher or Principal Investigator

- Applications shall be reviewed by the IRB in accordance with the ethical principles described in the Belmont Report, federal regulations, and ISU policy.
- When protocols are submitted, the IRB shall review the application in a timely manner as specified in the policy, barring any unforeseen and insurmountable problems.
- All decisions of the IRB shall be conveyed to the researcher in writing.
- The researcher should consult with the Institute Reviewer if he or she is unclear about the rationale for IRB decisions or if any questions arise at any time.

VI. Process for Review and Approval of Human Subjects Research

A. New Applications for Human Subjects Research

- 1. Determination of Human Subjects Research** Please refer to the definitions of “human subjects” and “research”, section IV. B.1.a., b., “Key Points”. The Office of Human Research Protections also provides decision charts <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm> to assist with this determination. In order to ensure the protection of human subjects in research, RHIT strongly encourages researchers to contact the Institute Reviewer to discuss the particular research activity to properly determine if it meets the definition of human subjects research.
- 2. Certification of Exemption** Please refer to section IV.C., “To What Does Research Does this Policy Apply?” for categories of exempt research. Exempt research is still human subjects research, and therefore requires a researcher or principal investigator to answer “yes” to the question regarding the use of human subjects as a part of a research application. The researcher will also be asked to provide either an IRB approval date or certification of exemption category. **Please remember a researcher may not make the exemption determination on his/her own.**
- 3. Protocol Review** Researchers must complete a human subjects review application any time research plans call for use of human subjects. If the PI will be recruiting students to participate as research subjects, Form S must also be completed and included with the application. Applications are reviewed by RHIT Institute Reviewer (IR) and categorized either as “exempt” research, (exempt from further IRB review) or “require full or expedited IRB review”. If “requires full or expedited IRB review” is the determination, IR forwards entire packet to the designated IRB. During the review process, the designated IRB communicates directly with RHIT researcher to clarify procedure and resolve questions. IR and researcher attend designated IRB meeting during which the review is to occur when required. Researchers are notified of review outcome by official letter from the designated IRB or IR with copy to RHIT IRB Administrator. Human subjects protocols must be approved, official notification received, and human subjects training completed prior to initiating research. Contact RHIT IRB Administrator (x8454) to initiate review process.

B. Modification Requests

IRB approval is required for any proposed change to an approved protocol or consent/assent forms. Modifications must be approved by the appropriate reviewing body PRIOR to implementation. Changes to exempt research protocols may render the activity non-exempt in which case full or expedited IRB review is required. Changes to approved non-exempt protocols also require either full or expedited review and will in general follow the same review process as new applications. Researchers are directed to the IR to determine which level of review is required. It is imperative that all modifications to approved protocols are communicated to the IR so that he/she is able to ensure compliance with regulations and determinations of the designated IRB. If full IRB review is required due to a modification in a protocol, IR and researcher will attend IRB meeting during which review of proposed change is to occur.

C. Continuing Review

Human subjects protocols are approved for a specified period of time, not to exceed one year. Researchers will receive notice (and continuation form) in advance of the expiration date of their research protocol that a review of the protocol is required. If the research is to continue, researcher returns completed continuation form to RHIT IR for processing. If the research is complete, see section VI.,E., "Completion of Research". If continuation of study is not approved, or completion form is not received, researcher will receive a letter from the IRB terminating the study.

D. Human Research Protections Training

In order to ensure the Signatory Official, Institute Reviewer, IRB Administrator, and researchers engaged in human subjects research maintain continuing knowledge of ethical principles, federal regulations, and Office of Human Research Protections guidance regarding the conduct of human subjects research, RHIT requires training certification in accordance with designated IRB policy.

1. The Signatory Official, Institute Reviewer, and IRB Administrator will complete both the OHRP assurance training module and the modules recommended by ISU IRB. Each of these individuals will re-certify every three years.
2. Researchers engaged in exempt human subject research will be required to complete the RHIT Human Subjects Familiarization Exercise within Angel software prior to approval of a human subject protocol.
3. Researchers engaged in non-exempt human subject research will be required to complete training as outlined in designated IRB policy prior to approval of human subject protocol.
4. Upon submission of a completed human subjects review application, researchers will receive instructions from the RHIT IR to complete training requirements.
5. Re-certification will be required annually for as long as the researcher is involved in human subject research. RHIT IR will notify researchers no less than 30 days before the expiration of certification that re-certification is required.

E. Completion of Research

Upon completion of research, researcher contacts the RHIT IR to obtain appropriate forms for close-out procedure.

VII. Problems Involving Risk, Adverse Effects, and Noncompliance

Researcher must notify the IR and immediately following an incident of injury when risk is increased to human subjects, when an unanticipated risk arises, or when the subject(s) experience(s) any adverse effects. Researcher must also promptly report any incident of noncompliance with policy or approved protocol.

VIII. Conflict of Interest see ISU policy section H

IX. Cooperative Research see ISU policy section I

X. Informed Consent see ISU policy section J

XI. Protection of Confidential Information see ISU policy section K

XII. Human Subjects Protection in Field Research see ISU policy section M

XIII. Other Studies Involving Human Subjects see ISU policy section N

XIV. Students as Research Subjects see ISU policy section P

XV. References

Material derived and obtained from:

Office of Human Research Protections web site <http://ohrp.osophs.dhhs.gov/>

Human Participant Protections for Research Teams web site

http://69.5.4.33/c01/nih_intro_01.htm

The Belmont Report <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

Terms of Assurance for Protection of Human Subjects for Institutions within the United States

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm>

Code of Federal Regulations Title 45 Part 46

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

Indiana State University Policies and Procedures for the Review of Research Involving Human Subjects http://osp.indstate.edu/forms/IRB_Manual.doc

Indiana State IRB Information <http://osp.indstate.edu/irb/home.html>

Abbreviations

RHIT- Rose-Hulman Institute of Technology

ISU- Indiana State University

IRB- Institutional Review Board

IR- Institute Reviewer

OHRP- Office of Human Research Protections

Rose-Hulman Institute of Technology Human Subject Protections Administrators

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Questions regarding this policy or human research protections program may be addressed to the RHIT IRB Administrator (x8165).