

Overview

It is the investigators responsibility to learn and understand the rules governing ethical research and to ensure that ethical principles are carried out in all interactions with potential participants and research subjects. The following guidelines illustrate how Rutgers University ensures that investigators are qualified for conducting research with human subjects.

- A) [Qualification](#)
- B) [Assessment and reporting of unanticipated problems](#)
- C) [PI Oversight and delegation](#)
- D) [Data and safety monitoring](#)

REFERENCES:

AAHRPP Standard III-2. Investigators meet requirements for conducting research with human participants and comply with all applicable federal, state, and local regulations and Rutgers University's policies and procedures for protecting research participants.

A. Qualification

Under Rutgers University policy and the professional ethics of their respective fields, Rutgers University faculty and staff do not undertake research for which they are professionally unqualified. Graduate and undergraduate students performing human subjects research are required to be supervised by faculty sponsors. The following, from Vice President Flanagan's [memo announcing Student Research policy](#), May, 2000, specifies this requirement:

Current policy requires students submitting a protocol to have a faculty sponsor for the project. Faculty sponsors must certify that the student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct the particular study, in addition to having the faculty sponsor's approval of the study.

Before beginning research, faculty, staff and students complete the [Human Subjects Certification Program \(HSCP\)](#) which provides information regarding the history of human research protections, the principles governing research with human subjects, and the regulations supporting those principles.

Two alternative means of completing the HSCP have been offered:

- A) First, attendance at the showing of Human Subjects Certification Film (HSCF): This video-taped seminar is offered regularly to the University research community across all three campuses of Rutgers.
- B) Second, investigators and key personnel who have completed the training program for the protection of human subjects in research offered by the University of Medicine and Dentistry of New Jersey (UMDNJ) may submit a copy of their certificate to ORSP in lieu of completion of the HSCP. Likewise, completion of the HSCP is similarly recognized by UMDNJ.

Investigators are aware that they can address questions to the Sponsored Programs administrator, as well as seek guidance in developing applications for review and continuing review of their research. The Sponsored Program Administrator informs faculty and staff of new regulatory or procedural developments and opportunities for training by means of the *IRB Newsletter* distributed by email University-wide.

In addition to the training and reference material that the IRB staff provides, the Office of Research and Sponsored programs secured grants which funded a workshop series to increase the awareness and knowledge of the University research community about regulatory matters and compliance. In these workshops nationally recognized experts discussed major topics of interest to the research community. During the first half of 2003, for example, the following compliance workshops were held at central locations on Rutgers' New Brunswick campus:

Thomas Puglisi

Informed Consent and common areas of non-

	compliance
Heather Fields	HIPAA, and perspectives of the Act from the researcher's and administrator's stance
Joyce Iutovich	Conflict of Interest; Scientific misconduct; Scientific conduct in research methodology
Jeremy Sugarman	History and principles of the ethics of research with human participants; Informed consent of vulnerable populations; Privacy-confidentiality with respect to ethics in research design.

REFERENCES:

AAHRPP III-2.A. Investigators and research staff are qualified by training and experience for their research role, including knowledge of applicable federal, state, and local regulations; relevant professional standards; and Rutgers University's policies and procedures regarding the protection of research participants. Investigators understand the definition of human research and seek guidance when appropriate.

B. Assessment and reporting of unanticipated problems

It is the Investigator's responsibility to maintain close oversight of their research and data, and to report unanticipated problems to the IRB and, if appropriate, to the sponsor, their department and their research subjects. When the Investigator takes on the responsibility of conducting human subjects research, the Investigator is also taking on the responsibility of reporting all unexpected problems involving human participants to the IRB in a prompt manner. This information is part of the Human Subjects Certification Program, as well as in Guidelines, instructions and application forms for initial and continuing review. The IRB has procedures to handle adverse event reports (See Standard I-3.F.). An Adverse/Unexpected Event is defined as: (1) any medical, psychological or behavioral event that is undesirable and unintended, although not necessarily unexpected; (2) an event in which the outcome is fatal or life threatening, causes permanent disability, causes hospitalization or prolongation of hospitalization; (3) an overdose; or (4) a complaint by a research subject or family member of a research subject concerning the research or the protocol. An [Adverse/Unexpected Event report form and instructions](#) are available on the [ORSP Human Subjects website](#). All fatal or life-threatening events must be reported in writing *within 48 hours after discovery*. (If it is the opinion of the principal investigator that a fatal or life-threatening event is likely related to the protocol, research activity should stop until the IRB has reviewed the adverse event and consulted with the principal investigator.) All other problems regarding subject safety are required to be reported in writing as soon as possible, but *no later than 5 working days after discovery*. If an investigator is unsure whether an event qualifies as a reportable event, it is recommended that the investigator report it.

REFERENCES:

AAHRPP III-2.B. Investigators assess and report unanticipated problems occurring during a research study in accordance with applicable federal, state, and local regulations, and Rutgers University's policies and procedures.

C. PI Oversight and delegation

PIs are expected to maintain close oversight of the research activities under their direction. Their responsibility includes delegating research tasks and responsibilities only to members of their staff or other individuals who are qualified to perform them. It is the primary investigator's responsibility to ensure that the IRB approved protocol is adhered to and that no changes or amendments to the protocol are made prior to IRB review unless there is an apparent need to minimize risk to participants. Ultimately, it is the PI's responsibility that all members of their staff follow ethical principles for the protection of human participants and that all staff members accurately document and report any adverse/unexpected events. The IRB investigates allegations of problems associated with the research, including those associated with inadequate oversight, and is empowered to suspend or terminate the research if their findings so warrant.

What are investigator responsibilities when conducting research using investigational drugs?

Investigator's are responsible for the control of any investigational drugs they may be using in their studies. PI's must ensure that these drugs are only being used on research subjects and must document all uses and disposals of the investigational drug. This documentation should include dates, quantity, and how the drug was used. At the end of the study, the PI must either return the investigation drug to the sponsor or properly dispose of the investigational drug. The Investigator is also responsible for maintaining case histories of all research subjects taking the investigational drug and keeping these case histories available for a time frame of at least 2 years following marketing application of the investigational drug or discontinuation of the study.

REFERENCES:

AAHRPP III-2.C. Principal Investigators maintain appropriate oversight of their research protocols and research staff including recruitment, selection of study participants, and study conduct, and appropriately delegate research responsibilities.

D. Data and safety monitoring

The nature of the research reviewed by the Rutgers University IRB rarely requires formal data and safety monitoring. However, when it is appropriate, investigators work with the IRB to design and implement adequate procedures. More information about these procedures and about data and safety monitoring can be found in Standards II.8 and II.4.C.

REFERENCES:

AAHRPP III-2.D. The Investigator designs and carries out research studies with adequate data and safety monitoring during the research, when appropriate.

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