Compliance with Regulations for Protection of Human Research Subjects in Program Evaluation and Research

A Guide for Rutgers Cooperative Extension Faculty and Staff

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All research involving human subjects conducted by or under the auspices of Rutgers University must be performed in accordance with federal regulations, and also conform to all other applicable state and local laws and regulations. Since Rutgers Cooperative Extension faculty and staff regularly perform both research and evaluation with human subjects, this fact sheet is intended to clarify the two, indicate when approval is needed, and provide descriptions of the types of regulations that typically will affect RCE research involving human subjects.

Definitions - When does this apply?

Note: IRB review is ONLY required if an activity involves BOTH research AND human subjects.

Program Evaluation

- Do not need to apply to Rutgers Institutional Review Board (IRB, see below) if primary goal of the activity is program evaluation and/or improvement, and findings are intended for internal use or sharing in popular media for public relations purposes. Systematic, scientific research methods can be used to perform program evaluation, even if children are subjects.

- Must apply to IRB if the intent of the evaluation is for publishing in scholarly journals or giving scholarly presentations. If determining program impact, value, and success is primary and scholarly publishing later becomes a secondary outcome, IRB approval can then be sought to use “existing data” from the program evaluation for publishing.

Research

- Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (i.e., the investigation must be protocol-driven and designed to yield statistically-valid data. The activity must be designed to test a hypothesis and permit conclusions to be drawn from analysis of the data.)

- Research with human subjects that does not pose more than minimal risk to participants must be approved in advance by the IRB, even if the study would be considered “exempt” from IRB “full” or “expedited” review. A research project that poses more than minimal risk to human subjects will likely require IRB “full” review before receiving approval.

Examples of projects that would not be considered research according to the definition cited above:

- Using research methods for program evaluation without intent to distribute the results outside of the program. This may include the following examples.

- Administering surveys to youth in 4-H programs to determine whether the program was successful.

- Surveying potential program participants to learn their needs and interests for courses, programs, and training.
• Collecting financial data from participants in a money management program in order for attendees to improve their financial standing through participation in this activity, or to determine if the program was effective.

Minimal Risk

• A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Types of risk include physical, psychological, social and economic harm.

• Subjects may be at more than “minimal risk” if the information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, and 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. (There are also other ways that research subjects may be placed at greater than minimal risk. For example, if investigational drugs were administered.)

Human Subject

• 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.”

• For an individual to be considered a human subject, data ABOUT them must be collected, not just FROM them. For example, if employees of a lawn care company are asked to complete surveys about the type and quantity of products used by the firm for weed control, these individuals would not be considered to be human subjects because data was collected from them, but not about them. If the same employees were asked their opinion about the types of products that were used, then they would be considered to be human subjects.

To whom does this apply?

• All research involving human subjects that is conducted by anyone affiliated with Rutgers (i.e., all faculty, staff, graduate and undergraduate students, postdoctoral fellows) must be reviewed and approved by the Institutional Review Board for the Protection of Human Subjects (IRB) prior to such studies being undertaken.

• This policy applies to any work whether new, ongoing, or proposed for funding, whether conducted at the University or elsewhere.

Institutional Review Board

• The Institutional Review Board for the Protection of Human Subjects in Research (IRB) is the body at Rutgers charged with reviewing all projects using human subjects.

• All faculty, staff, students and others anticipating conducting research projects involving human subjects must complete an Application Form to Request IRB Review of a Research Protocol Involving Human Subjects.

• Before human subjects are involved in nonexempt research, the IRB will give proper consideration to:
  • Risks to the subjects
  • Anticipated benefits to the subjects and others
  • Importance of the knowledge that may reasonably be expected to result
  • The informed consent process to be employed

Three Types of IRB Review

• Exempt from full or expedited review (Submit a Request for Exemption form.)

• Expedited Review (Submit an IRB Application to Request IRB Review.)

• Full Review (Submit an IRB Application to Request IRB Review.)

Categories of Research that may Potentially Qualify for Exempt Status

• Research procedures in which the only involvement of human subjects falls within one or more of the following categories, and presents no more than minimal risk to participants, may potentially qualify for exempt status. Most research conducted by RCE faculty will likely be exempt.

• Research is screened for exemption by an IRB staff member in consultation with the IRB. The form for requesting a screening for exemption is an easy-to-complete checklist, and does not need to be reviewed by the full IRB. The Request For Exemption From Full IRB Review form can be downloaded from orsp.rutgers.edu/human.asp. Normally, a screening
for exemption can be completed in a matter of days if all essential information is clearly presented. Applications for exemption may be submitted at any time. They are not subject to the IRB meeting schedule.

- Research may be exempt if it is conducted in an established or commonly accepted educational setting and involves normal educational practices such as (a) research on regular and special education instructional strategies or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods. Extension classes & events, 4-H clubs, camps, etc. are considered “commonly accepted educational settings.”

- Research involving the use of [a] educational tests (cognitive, diagnostic, aptitude, achievement), [b] survey procedures, [c] interview procedures, or [d] observation of public behavior may be exempt.

- Research in this category may not be exempt if the information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, and 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.

- This exemption does not apply to research with children except for research involving observation of public behavior where the investigator(s) do not participate in the activities being observed. (Children are defined as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” In NJ, this is 18 years of age in most cases.)

- Such research may be exempt if the human subjects are elected or appointed public officials or candidates for public office, or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- Research involving the collection or study of previously existing data, documents, records, pathological specimens, or diagnostic specimens may be exempt if they are being obtained from publicly available sources 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.

- Note: If the records involved are those of Rutgers students, the project is not exempt and must be reviewed by the IRB.

- Research and demonstration projects may be exempt if they are conducted by or subject to the approval of Federal department or agency heads, and are designed to study, evaluate, or otherwise examine [a] public changes in or alternatives to those programs or procedures or [b] possible changes in methods or levels of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies may be exempt if [a] wholesome foods without additives are consumed or [b] 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.

Research that may be Reviewed by the IRB through an Expedited Review

- An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers of the IRB.

- Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. The categories in this list apply regardless of the age of subjects, except as noted.

- The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

- The expedited review procedure may not be used for classified research involving human subjects.

- The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review (expedited or convened) utilized by the IRB.
Selected Categories of Research (relevant to RCE) Eligible for IRB Expedited Review

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations.)

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.)

- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity, moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings in a nondisfiguring manner.

Research That Requires Full Review by the IRB

All proposals that do not qualify for expedited review or exemption will be reviewed at a convened meeting of the full membership of the IRB.

Multiple Project Assurance (MPA)

Although some categories of research that involves human subjects are not subject to the federal regulations codified at 45 CFR 46, the Multiple Project Assurance that Rutgers maintains with the Department of Health and Human Services (DHHS) through the Office for Human Research Protections (OHRP) extends those regulations to all research involving human subjects that is conducted by anyone affiliated with Rutgers. The MPA may be reviewed on the IRB website at: orsp.rutgers.edu/human.asp.

Form Availability and Submission

To download an Application Form to Request Review of a Research Protocol Involving Human Subjects or Request For Exemption From Full IRB Review, go to the Rutgers University Institutional Review Board page on the Rutgers University Office of Research and Sponsored Programs (ORSP) web page: orsp.rutgers.edu/human.asp

All completed materials are to be sent to the Institutional Review Board for the Protection of Human Subjects in Research, University Office of Research and Sponsored Programs, ASB III, 3 Rutgers Plaza, New Brunswick, NJ 08901. Fax: 732-932-0163.

Questions can be directed to Research Subjects Administration at (732) 932-0150, x2104.

References

Application Form to Request Review of a Research Protocol Involving Human Subjects, Rutgers University Office of Research and Sponsored Programs (ORSP)

Institutional Review Board page on the Rutgers University Office of Research and Sponsored Programs (ORSP) web page: orsp.rutgers.edu/human.asp


Approvals

This document was approved by the Rutgers Office of Research and Sponsored Programs (ORSP) and the Director of Rutgers Cooperative Extension.