



July 6, 2004

ROWAN POLICY REGARDING THE REVIEW OF HUMAN SUBJECT RESEARCH

In accordance with Rowan University policy governing the use of human subjects in research, the Multiple Project Assurance (MPA) maintained with the U.S. Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP), all human subjects research conducted by or under the auspices of Rowan University will be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (45 CFR 46). In addition, the actions of Rowan University will also conform to all applicable federal, state and local laws and regulations.

All research involving human subjects that is conducted by anyone affiliated with Rowan (i.e., all faculty, staff, undergraduate, and graduate students) must be reviewed and approved by the Institutional Review Board for the Protection of Human Subjects in Research (IRB) prior to such studies being undertaken. The IRB is the body at Rowan charged with reviewing all projects that use human subjects. This policy applies to any work whether new, ongoing, or proposed for funding, whether conducted at the University or elsewhere.

Research is defined in 45 CFR 46 as, "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Human subject is defined in 45 CFR 46 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."

Individuals who plan to conduct research that involves human subjects must complete an Application Form to Request IRB Review of Human Research, which is available on the web, with instructions, at: In addition, all principal investigators and key personnel must successfully complete the "Human Participant Protections Education for Research Teams" from the National Institutes of Health.

ASSURANCE TO OHRP (FEDERAL AUTHORITY)

Anyone wishing to receive a copy of the Multiple Project Assurance should contact the Office of the Associate Provost for Research (ORSP), The assurance number is FWA00007111 and is required on many grant applications.

FEDERAL REQUIREMENT: EDUCATION IN THE PROTECTION OF HUMAN SUBJECTS

All principal investigators and other individuals who are responsible for the design and/or conduct of a research protocol that involves human subjects ("key personnel") must complete the "Human Participant Protections Education for Research Teams" training program which is available on the web at <http://www.rowan.edu/research>.

Before a Notice of Approval (Initial, Continuation, or Amendment) or Exemption will be issued, the principal investigator must successfully complete the education program. If the principal investigator has obtained the certification, but key personnel have not, the Notice of Approval or Exemption will be issued with a condition attached that those individuals who have not completed the program may not participate in the conduct of the research until certification is obtained.

CATEGORIES OF IRB REVIEW (AS PRINTED IN THE FEDERAL REGISTER)

There are three types of IRB review. The principal investigator is responsible for making the initial determination of the type of review that a protocol requires, and requesting such review on the HUMAN RESEARCH REVIEW APPLICATION form.

A. Full Committee Review

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

B. Expedited Review

Research activities that present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the following categories, may be reviewed by the IRB Chair or one or more experienced IRB reviewers designated by the Chair through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are noted on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Applicability:

- a. The categories in this list apply regardless of the age of subjects, except as noted.
- b. 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.
- c. The expedited review procedure may not be used for classified research involving human subjects.
- d. The standard requirements for informed consent (or its waiver, alteration, or exception) apply

regardless of the type of review, either expedited or convened, utilized by the IRB.

e. Categories one through seven pertain to both initial and continuing IRB review.

The categories of research that may be reviewed by the Institutional Review Board (IRB) through an expedited review procedure are as follows:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. NOTE: Children are defined in the DHHS regulations 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." 45 CFR 46.402(a).

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures [not involving general anesthesia or sedation] routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. For example: (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; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring

radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. 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. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. 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 for the protection of human subjects 45CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

C. Exemption

Research activities in which the only involvement of human subjects is in one or more of the categories listed below, and present no more than minimal risk to subjects, may qualify for a claim of Exemption from full IRB review.

In order to fulfill the federal requirement for the proper review of research, investigators cannot "self exempt" from IRB review. Nor does a claim of exemption necessarily exempt investigators from the requirement of gaining written informed consent from subjects. The following exempt categories do not apply to research involving:

a. deception of subjects where the investigator does not describe the true purpose of the research and /or the results of the subjects participation in the study;

b. sensitive behavioral research, or research involving pregnant women, in vitro fertilization, prisoners, the mentally disabled, or other vulnerable populations.

Individuals who plan to initiate studies involving human subjects in one or more of the six exempt categories described in the Federal Regulations must submit an Application Form to Request IRB Review of a Research Protocol Involving Human Subjects, along with appropriate documentation, prior to the start of the project. An IRB subcommittee will determine whether or not a given project needs to be reviewed on a continuing basis; however, the IRB may ask to reconsider a protocol if it deems it necessary. When this happens, the investigator will be asked to provide additional information for IRB review, and the full Board will determine whether the initial exempt ruling should be reversed. It is also an investigator's responsibility to report to the IRB any changes in an exempt protocol. The IRB subcommittee will review the changes and rule on the continuing exempt status of such projects.

Applications for IRB Review of a Research Protocol Involving Human Subjects that request exemption are reviewed as they are received, however, those unsure of whether their projects will qualify for an exemption are advised to adhere to the deadline schedule set forth in this memorandum. Then, if an exemption request is denied, the project can be referred to the full IRB in a more timely fashion. The categories of potential exemption are as follows:

1. Research may be exempt if it is conducted in an established or commonly accepted educational setting and involves normal educational practices such as research on regular and special education instructional strategies or 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 may be exempt, unless 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. NOTE: This exemption does not apply to research with children except for research involving observation of public behavior where the investigator does not participate in the activities being observed.
3. Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that would not exempt under paragraph (2) 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.
4. 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 Rowan students, the project is not exempt and must be reviewed by the IRB. Such research must conform with the Family Education Rights and Privacy Act of 1974, a copy of which may be obtained from the Assistant Director, Research Subjects Administration.

5. 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 public changes in or alternatives to those programs or procedures or 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 may be exempt if wholesome foods without additives are consumed or a food is consumed that contains a food ingredient at or below the level and for a use 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.

Information regarding Rowan's current submission procedures may be found at http://www.rowan.edu/open/provost/research/Integrity_and_compliance/Irb/Irb.cfm under Applicant Information and Forms/Submission Procedures.