

Preamble

The ethical conduct of research involving human subjects requires a balancing of society's interests in protecting the rights of subjects and in developing knowledge that can benefit the subjects or society as a whole.

...investigators should not have sole responsibility for determining whether research involving human subjects fulfills ethical standards. Others, who are independent of the research, must share this responsibility, because investigators are always in positions of potential conflict by virtue of their concern with the pursuit of knowledge as well as the welfare of the human subjects of their research.

Report of the National Commission for
the Protection of Human Subjects

Introduction

The stated policy of Union College with regard to human subjects research conducted by its employees and students is embodied in the Code of Federal Regulations, *Title 45*, Department of Health and Human Services (DHHS), Part 46, Protection of Human Subjects, as well as *Article 24A* of the New York State Public Health Law. Anyone contemplating human subjects research is required to familiarize himself/herself with these documents. The procedures for complying with certain aspects of these laws are detailed below. *The Vice President of Academic Affairs is legally required to stop all research not in compliance with these procedures.*

Procedures for Researchers to Follow

1. Any Union College staff or faculty member (full or part-time) or Union College student (full or part-time) who proposes to conduct research on human subjects, or who is currently doing so, under the auspices of Union College, is obliged to review the pertinent sections of the DHHS guidelines and Article 24A of the New York State Public Health Law.
2. All human subjects researchers must complete either the official *Statement of Intention* or the official *Statement of Exemption* form for each and every research project. Completed forms should be forwarded to the Office of the Dean of Arts and Sciences. The following categories of research are exempt from committee review, provided that a Statement of Exemption form is submitted.
 - (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 subject 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.

3. All researchers conducting nonexempt human subjects research must submit a Statement of Intention form. If all the answers to the questions are acceptable, the researcher may expect immediate, routine clearance from the committee. In all other cases, the review committee will give the completed statement careful consideration and will render a prompt judgment as to whether the guidelines have been met. If the committee concludes that any aspect of the proposed research is not in conformity with the guidelines, it will request that necessary modifications be made before extending its approval. Any research on human subjects carried out without the express approval of the Committee is in violation of state and federal law as well as the rules of Union College.

4. Following the recommendations of the Office for Human Research Protections (OHRP), the Chairperson of the Human Subjects Committee or designated reviewers may give expedited review without a meeting of the full committee for the following categories of research procedures provided that they present no more than "minimal risk" to human subject. The definition of "minimal risk" is that the probability and

magnitude of harm or discomfort anticipated in the 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. The activities listed should not be deemed to be of minimal risk simply because they are included 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.

Research Categories

(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.

(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 noninvasive 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

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; (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 DHHS 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 DHHS regulations for the protection of human subjects, 45 CFR 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 full Human Subjects Committee 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 that is not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the Human Subjects Committee has determined and documented that the research involves no greater than minimal risk and no additional risks have been identified.

5. In projects where subjects are judged to be at more than “minimal risk”, two copies of a voluntary informed consent (*sample copy* is provided) must be completed by each subject. One copy is to be given to the subject; the other should be retained by the researcher for at least seven years following completion of the research project, in the event that subsequent controversy or legal action develops. The general requirements for informed consent, including the criteria for waiving consent, can be found in the DHHS regulations for the protection of human subjects, 45 CFR 46.116 and 46.117.
6. Any significant changes in the conduct of previously approved research that might result in unanticipated potential injury to human subjects must be approved by the Human Subjects Research Review Committee.
7. Research conducted by Union College students in conjunction with faculty members (including independent studies and senior projects), or funded through the College’s Internal Education Foundation (IEF), must be approved by the Human Subjects Research Review Committee.
8. Departments that teach students how to do research on human subjects must develop a formal policy on human subjects research. The object of this policy shall be to make students aware of their ethical and legal obligations to protect human subjects against injury, and to obtain informed consent from their subjects.

Additional Comments

The DHHS Guidelines and N.Y. State regulations are taken to be the minimal standards for safe and ethical human subjects research. If a particular academic discipline has promulgated its own set of standards and principles that exceed the state and federal guidelines in their stringency, and if the researcher so chooses, he/she may of course adhere explicitly to these standards (e.g., the American Psychological Association’s *Ethical Principles in the Conduct of Research with Human Participants*). This in no way, however, relieves the researcher of the responsibility to complete and submit the official Union College Statement of Exemption or Statement of Intention form.

Finally, it should be clearly understood that neither the Human Subjects Research Review Committee nor the College intends that the establishment and implementation of these standards and procedures should be seen as an attempt to infringe upon academic freedom. The committee expects that the overwhelming majority of research projects undertaken by Union faculty and students fall outside our purview. In the small number of instances in which human research is involved, it is expected that hardly any will present any challenge or uncertainty. We believe that Union researchers will exhibit a high order of ethical sensitivity. Whatever files the Committee may have occasion to accumulate will be held in close confidence, although in the unlikely event of legal complications the records would necessarily have to be put at the disposal of appropriate college administrators and lawyers. The present system is designed both to meet unavoidable legal obligations and to afford a degree of protection to researchers and human subjects.