

Guidelines for Faculty and Students Engaged in Human Subjects Research at Union
College Revised July, 2020

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 *Application to Engage in Research Involving Human Subjects* or the official *Statement of Exemption* form for each and every research project. Completed forms should be forwarded to the Human Subjects Review Committee (HSRC) chair. More information, including specific guidelines, are posted on the HSRC website.
3. All researchers conducting nonexempt human subjects research must submit a full application. 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. 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.

5. 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.

6. 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 HSRC.

7. 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.

8. Researchers conducting HSRC-approved research projects in which unanticipated problems involving risk to subjects or others arise are responsible for reporting the problems to the HSRC chair as soon as possible after the researcher is made aware of them.

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 HSRC 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 majority of research projects undertaken by Union faculty and students fall outside our purview. In the 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.