

CARDINAL STRITCH UNIVERSITY INSTITUTIONAL REVIEW BOARD

Overview

The following must be read by any student, faculty or staff member planning to conduct research involving human participants (subjects). This applies to both funded and non-funded research as well as to the use of certain existing or archival data. Note that some classroom activities may be regarded as research.

IRB Purpose

People who participate in research have rights that must be understood and upheld by researchers. The Federal Government requires that researchers follow specific guidelines to ensure these rights are protected. To guarantee guidelines are followed, the government requires each institution conducting human research to establish an Institutional Review Board (IRB) that approves and monitors this research. Cardinal Stritch University's IRB was thus established in 1987 and is registered with the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP). The following provides researchers with information and procedures necessary for meeting both Federal and University policies.

The University's IRB must approve all research performed by:

- Any student, faculty member, or staff member of Cardinal Stritch University that involves human participants, whether the participants are affiliated with Cardinal Stritch University or another institution.
- Any individual or institution not affiliated with Cardinal Stritch University desiring to use students, faculty, or staff at Cardinal Stritch University as research participants.

Documents to Read

An individual planning to perform research involving human participants must complete the IRB process. In addition, students, faculty or staff who will gather information from human participants, whether this occurs in the classroom or as part of a class project, must:

- **Determine if your activities are considered research** (as defined by the Federal Government). Not all activities involving human participants are classified as research. For example, many classroom activities are not regarded as research, and thus IRB review and approval are not needed. However, researchers, students, and classroom instructors **must** read *Definitions of Research* to determine whether or not federal and institutional guidelines apply to their classroom activities.
- **Read** *Standards for the Protection of Human Participants of Research*. This document provides detailed information on policies and the review process.

College Committees

Each college has an RAC comprised of two or three IRB members. Initial review of protocols is done by the appropriate college's RAC and thus all protocols must be submitted to your college's RAC. Send your protocol to one of the following RAC chairs:

College of Arts and Sciences – Terrance Steele – Box 518 – 414-410-4474 – tsteele@stritch.edu

College of Business – Elizabeth Regimbal – Box 422 – 952-835-6418 x 40 – eeregimbal@stritch.edu

College of Education and Leadership – Joan Whitman – Box 375 – 414-410-4343 – jwhitman@stritch.edu

College of Nursing – Sharon Garrett – Box 442 – 414-410-4696 – slgarrett@stritch.edu

Staff or administrators must send research protocols directly to the chair of the Central IRB:
Central IRB Chair - Joan Whitman - Box 375 - 414-410-4475 - jlwhitman@stritch.edu

Central IRB Committee

The Central IRB is composed of the chairs of the RACs and individuals not affiliated with the university (as required by federal policies). These additional members have expertise in ethics, specific populations, or related areas.

The Central IRB will make one of four decisions:

- Approve the protocol
- Conditionally approve the protocol contingent upon the completion of required changes
- Ask for clarifying information (the Central IRB will then review the protocol a second time)
- Disapprove the protocol

Suggestions

- **DESIGN YOUR STUDY CAREFULLY:** Although the IRB normally does not comment on the validity or design of a study, the Federal Government has mandated that “the study must be properly designed, scientifically sound and likely to yield valid results. Risks to participants are minimized by using procedures consistent with sound research design that will yield useful data and that do not unnecessarily expose participants to risk.” Thus, studies that are specious or, because of poor design, could subject participants to unnecessary risk, will not be approved.
- **PLAN AHEAD:** Protocols submitted after deadlines are reviewed at the next meeting. This can cause a delay of a month or more.
- **REVIEW YOUR DOCUMENTS CAREFULLY:** Protocols are often returned without approval due to sparse or missing information, improperly completed forms, or unclear writing. This will delay approval. In addition, since documents read by participants or cooperating institutions represent your university, proper spelling and grammar are essential.

IRB Definitions - Cardinal Stritch University

1. **Affiliation Agreement** is an agreement between the researcher and institution/agency where the researcher is employed and will conduct research with human subjects.
2. **Cooperative Research Agreement** is an agreement between two or more different institutions/agencies to conduct research with human subjects.
3. **Competence** involves the use of procedures and techniques used only by qualified and/or experienced researchers, with care being taken to protect the welfare of the participants.
4. **Dependent variable** means the variable, or event that is being measured; the variable that is affected by the manipulation of the independent variable (e.g., the number of correct answers on a test, the answers to a survey question).

5. **Deception** is involved when participants are not informed about the risks of research in order to gain cooperation from the subjects. (Note; care must be taken to identify research in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator).

- An alternative definition of deception** means that participants may not be fully aware that they are involved in the research. The deception by a researcher for the purpose of securing participant's cooperation and/or to prevent potentially biased reporting of data by the participant is allowable provided that all of the following conditions are met:
 - 1) Deception is necessary due to lack of alternative procedures for data collection not involving deception;
 - 2) The deceptive procedures will not place participants at significant financial, physical, psychological, or social risks;
 - 3) Careful debriefing whereby the participants are fully informed of the nature and purpose of the deception will follow the data collection/experiment.

6. **Exempt research** includes those activities in which there is minimal participation of human participants as defined in OPRR Report 455 CRF Section 46.101.

7. **Expedient research** is that which involves no more than minimal risk to the participant or for which a previously approved protocol requires minor changes. Approval is obtained from the IRB Chair or designated IRB member.

8. **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** protects against the misuse or disclosure of the participants health records and personal information.

9. **Human participant** means a living individual with whom an investigator (faculty, staff, or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102).

10. **Informed consent** is a statement of agreement to be signed by the participant and/or his/her parent or legally authorized representative in whom s/he expresses a willingness to participate in the experiment detailed in the document.

11. **Independent variable** means the variable, or treatment that is manipulated by the research (e.g., if the different tests are given to different groups of participants, the type of test would be the independent variable).

12. **Institution** means any public or private entity or agency including federal, state, and other agencies.

13. **Instrument(s)** is a measuring device for determining the present value of a quantity under observation. Examples of an instrument might be questionnaires or surveys.

14. **Interaction** includes communication or interpersonal contact between investigator and participant.

15. **Intervention** includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the participant or the subject's environment that are performed for research purposes.
16. **Legalized authorized representative** is an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to allow participation in the procedure(s) involved in the research.
17. **Minimal risk** means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
18. **Private information** includes information about the behavior of an individual that occurs in a situation and will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is available to the investigator or associated with the information) in order to obtain information to constitute research involving human participants.
19. **Protocol** is a plan for scientific experiment or treatment.
20. **Research** means a systematic investigation, including methodology development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of these regulations, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
21. **Research proposal** is a written plan for the proposed research investigation containing basic information related to the area being researched.
22. **Sensitive or protected population** includes minors (17 years of age or younger), persons with mental retardation, people with mental disabilities, persons with developmental disabilities, older people (65 and over), prisoners, pregnant women and fetuses, or any individual who might not be capable of making an informed decision concerning participation (e.g., persons with mental illness or psychiatric disability) as defined by the code of federal regulations 45.CFR.