

INSTITUTIONAL REVIEW BOARD

OVERVIEW AND INSTRUCTIONS

People who participate in research have rights that must be understood and upheld by researchers. This is an ethical and legal obligation. 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.

1. A RESEARCH PROTOCOL AND ACCOMPANYING MATERIALS MUST BE SUBMITTED BY

- a. Any student, faculty member, or staff member of Cardinal Stritch University performing research involving human participants, regardless of where these participants are from and regardless of whether the data have already been collected (archival data).
- b. Any individual or institution performing research in which students, faculty, or staff at Cardinal Stritch University are participants. This also applies to archival records belonging to the university.
- 2. DETERMINE IF YOUR STUDY QUALIFIES AS RESEARCH (as defined by the Federal Government) that must be reviewed by the IRB.
 - a. The definition of research can be found in Definitions of Research.
 - b. Certain classroom activities may require IRB review.
 - Most classroom activities are not regarded as research and thus IRB review and approval are not needed.
 - However, if there are potential risks to the participants of this research, if the research deals with sensitive issues, or if the results of classroom research will be presented outside of the classroom, the research might need IRB approval.

- Refer to <u>Definitions of Research</u> to determine which classroom activities or studies must be reviewed.
- c. If you are not certain if your research must be reviewed by the IRB, contact Dr. Terry Steele 414-410-4474 tlsteele@stritch.edu
- 3. READ <u>Standards for the Protection of Human Participants of Research</u>. This document provides detailed information on policies and the review process.

4. COMPLETE REQUIRED FORMS

- a. The following forms must be submitted by ALL researchers
 - <u>Human Participants Research Protocol (HPRP)</u>
 This form provides the details of the study and is submitted to the IRB.
 - <u>Informed Consent (Participant Information)</u>: This form describes the study and is given to each participant. One of three forms will be required.
 - Online IRB Ethics Training
 All researchers must be ethics-certified and submit a copy of an ethics training certificate.
- b. The following forms may be required by SOME researchers
 - <u>Affiliation Agreement</u>
 This form must be completed by any researcher recruiting participant's not affiliated with Cardinal Stritch University.¹
 - <u>Cooperative Research Agreement</u>
 This form must be completed by any researcher conducting research in partnership with another institution.¹
 - Surveys, interview questions, etc.
 - Copies of recruitment flyers or invitations to participate on social networking sites.

5. PRIOR TO SUBMITTING THE FORMS

- a. Please read forms carefully and fill them out completely.
 - Answer *each* question in the space following that question. If you do not believe the question applies to your study, put in NA for not applicable.

¹ Certain institutions or organizations require Stritch IRB approval before they will sign documentation. In these cases, provide a sample of the document. The IRB will give "conditional approval", meaning the protocol is in order and only signatures are needed for final approval.

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- Sample forms can be found on the IRB website.
- NOTE: PROTOCOLS THAT ARE INCOMPLETE, MISSING SIGNATURES, OR MISSING THE ETHICS TRAINING CERTIFICATE WILL NOT BE REVIEWED. Although we will attempt to contact you about missing materials in a timely manner, you will still be required to submit completed materials seven days prior to the scheduled IRB meeting.

• Use as much space as necessary, but do not submit a complete thesis or full proposal.

b. Course instructors, thesis advisors, and doctoral advisors: Please review protocols carefully. Poorly written protocols that are not reviewed by faculty are the primary reason why approval is delayed.

6. SUBMITTING THE FORMS

- a. To facilitate review of protocols, the IRB has a two-tiered structure (see IRB Members).
 - There are four College Research Advisory Committees (RACs), one for each college. These committees are the first to review a research protocol.
 - The Central IRB must also review any research that recruits protected populations, involves sensitive issues, or presents risk to the participant (see THE REVIEW PROCESS below). 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.
- b. Collate your materials in the following order.
 - Human Participants Research Protocol (HPRP)
 - Informed Consent & Participant Information
 - Affiliation Agreement (if needed)
 - Cooperative Research Agreement (if needed)
 - Surveys, interview questions, etc. (if applicable)
 - Copy of your ethics training certificate
- c. Submit three typed and signed hard copies and one e-copy (pdf) as ONE DOCUMENT to the appropriate IRB College Research Advisory Committee (RAC) chair.

College of Arts & Sciences	Terrance Steele	Box 358	tlsteele@stritch.edu
College of Business & Management	TBA	Box 422	
College of Education & Leadership	Darnell Bradley	Box 103	djbradley@stritch.edu
College of Nursing	Donald Miller	Box 442	ddmiller@stritch.edu

d. Protocols must be received by the above individual by noon seven days before the scheduled IRB meeting (see Scheduled Meetings at the bottom of Stritch's IRB homepage)

- e. A research protocol that has been approved by another institution can often be substituted for Stritch's IRB materials.
 - However, those IRB materials, including evidence that the protocol was approved, must be submitted to Stritch's IRB.
 - Any materials required by Stritch's IRB that were not included in the other institution's materials must be submitted.

7. THE REVIEW PROCESS

- a. The College RAC will make one of four decisions
 - 1) Approve the protocol
 - 2) Conditional approval (certain clarifications, revisions, or signatures are needed)
 - 3) Need more information (aspects of the protocol cannot be fully understood as written)
 - 4) Send to Central IRB
 - Research involving protected populations, physical or psychological risk, sensitive issues that could impact a participant's social or legal standing, significant deception, or funded by the federal government will automatically be sent to the Central IRB. Note that this adds time to approval.
 - The only exception is K-12 classroom research that does not involve protected populations (e.g., children with disabilities), risk, sensitive issues, or federal funding. These protocols can be approved by the College RAC.
 - All additions and/or revisions required by the College RAC must be completed before your protocol will be forwarded to the Central IRB.
 - The Central IRB must receive the College RAC approved protocol by noon seven days prior to a scheduled meeting.
 - Central IRB meeting dates can be found at *Scheduled Meetings* at the bottom of Stritch's IRB homepage.
- b. If forwarded, the Central IRB will make one of four decisions
 - Approve the protocol
 - Conditional approval
 - Need more information
 - Disapprove (though rare, this usually occurs if the rights of participants cannot be protected)
- c. The Chair of the College RAC will contact you
 - Confirming receipt of your protocol (this will be done no less than 3 working days after *all* of your materials were submitted).
 - Giving the College RAC's decision (within 3 working days after the committee meeting).

8. COLLECTING DATA

- a. The principal investigator and advisor (if applicable) will receive an electronic copy of the IRB's decision followed by a signed hard copy that will be sent in the mail. DO NOT BEGIN RECRUITMENT OF PARTICIPANTS OR DATA COLLECTION until you receive an approval letter or e-mail from the IRB.
- b. Note that the principal investigator, other identified investigators, and the major advisor are the only individuals who may work with participants or have access to data containing the names or identities of the participants. IRB approval is needed for others to have access to this information.
- c. Requested changes in the protocol that are needed during the data collection phase must be sent to and approved by the College RAC chair prior to making those changes.
 - Minor changes (for example, adding participants) will most likely be approved via email or letter.
 - Substantial changes in terms of participant involvement must be submitted in writing (Changes in Research).
 - Changes must be approved before they can be initiated except when necessary to eliminate apparent immediate hazards to the participants.
 - Promptly report, using a **Changes in Research** form
 - o Unanticipated problems involving risks to participants or others.
 - Complaints made by participants that might require a change in research procedures.
 - o Serious or continuing non-compliance with IRB regulations.
- d. IRB approval is for a period of 12 months. In the event that participant involvement has not been completed within the 12-month period, the protocol must be resubmitted to the IRB. First send an e-mail to the Chair of the College RAC to determine the extent of information that must be submitted.
- e. Under certain circumstances you may be asked to submit a progress report prior to your 12-month deadline. For example, a study in which participants may be exposed to physical or psychological risk may require intermittent reviews.

9. AFTER PARTICIPANT INVOLVEMENT IS COMPLETED

a. The IRB must be informed, in writing, once all data have been collected (Research Completion).

b. Data and *Informed Consent* statements from research involving protected populations, physical or psychological risk, sensitive issues that could impact a participant's social or legal standing, or funded by the federal government, must be kept in a secure location for at least 3 years. This is required by the Federal Government. Other data may be kept or destroyed at the researcher's discretion.

10. SUGGESTIONS

- a. 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.
- b. ADVISOR APPROVAL: Make sure your research proposal has been approved by your instructor or thesis/doctoral advisor *before* submitting an IRB protocol.
- c. 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 required.

d. PLAN AHEAD

- People who submit protocols at the last minute frequently have them returned due to incomplete information or having significant errors. In many of those cases, the principal investigator must wait until the next scheduled meeting to have their protocol reviewed.
- Protocols submitted after deadlines are reviewed at the next meeting. This can cause a delay of a month or more.
- e. RESEARCH INVOLVING MINORS (17 years of age or younger) can be very difficult to get approved. This is especially true if the participants are recruited from a school system. Determine the probability that you will be given permission by a school district or parents *before* submitting a protocol to the IRB.
- f. ASK QUESTIONS. The IRB members are here to help.
- g. MAKE SUGGESTIONS. If you believe there are ways to improve the process, please contact an IRB member.

Although the above steps may appear time-consuming and complicated, be assured that the IRB will work with you so that your research can be approved in a timely manner.

If you have any questions about the IRB process, whether or not your activities require IRB review, how to fill out forms, or if you cannot meet deadlines, feel free to contact any one of the IRB RAC members listed above or visit the government's OHRP website (http://www.hhs.gov/ohrp/).

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