IRB Guide for Students Conducting Research with Human Participants

This set of guidelines is intended to assist students and other first time applicants with the Institutional Review Board (IRB) application.

What is the IRB?

The MCLA Institutional Review Board (IRB) was established to protect the rights of human participants of research. The IRB exists as a safeguard to promote the ethical and responsible treatment of those research participants.

MCLA policy requires that *all research involving human participants must be reviewed and approvedby the IRB before any research may be started*. Guiding the review process is the application of federal and state laws and regulations outlined in the Code of Federal Regulations Title 45 Part 46(45 CFR 46)and the ethical principles of the Belmont Report as the criteria for the review of all research studies.

How do I know if I should submit an application to the IRB?

The IRB reviews proposals that constitute research, as defined by the U.S. Department of Health and Human Services, Code of Federal Regulations. Research is "a systematic investigation designed to develop or contribute to generalizable knowledge." (45 CFR.46.102(d).

Certain research proposals may be exempt from review. *The determination of whether the research isexempt is made by the IRB. Different rules apply to research with children and other special populations.* Students should contact the IRB if they have questions about whether their projectswould be exempt or require expedited or full review.

You may be planning to survey members of the community, conduct a behavioral study with otherstudents, or interview teachers. Why does that research need approval?

Research with human participants is research in which a person (or groups of persons) is being studied.Interviewing an expert about public policy is not human subject research just because it involves a person. When you collect information about a person, then protections for the person as a researchsubject needs to be taken.

For example, if a researcher wanted to collect information about the health of college students and askedyou for details about your visits to a doctor, your medications and your medical history, it is important that the researcher protects your information against unintended use. This information may be delicate and could cause you great embarrassment and harm if it was made public without your consent. Before that research is approved, the IRB needs to know how the confidentiality of that information will be safeguarded so that it remains private, but can still be used to advance the research.

Research projects that involve little risk go through an **expedited review.** Those that pose more risk require **full review** from the IRB. Research that may be exempt, because the risks to the participants are very small, still needs to be registered with the MCLA IRB. It is better to err on the side of caution. If you are not sure what kind of review your project needs, ask your faculty advisor, or contact the IRB directly (see below for contact info).

How do I go about submitting an application?

Step One

All researchers must complete the online CITI certification program https://about.citiprogram.org/en/homepage/. Uponsuccessful completion of the training course you will be given a certificate of completion with a Record ID number. This number is required on the application form.

Step Two

Complete an application form. The form must be filled out and signed by the research applicant and faculty advisor. When research is being done at a location other than MCLA, a letter from the responsible individual (e.g., the principal of a school) giving access to participants must beincluded with the application.

Step Three

Complete a protocol for your proposed research. The protocol is a detailed description of your researchprocess which consists of:

Abstract – Describe your project. Remember that the IRB reviewers are not as familiar with your project as your faculty advisor. Include enough details to provide an accurate and complete description for them.

Description of Research Participants–Who will the participants will be. Will they be minors? Fellow students? Community members? The IRB needs to determine if the level of protections for your research participants is appropriate. Research with children, for instance, requires that additional safeguards be put in place.

Statement of Risks – What are the risks for the research participants? Are they minimal, such as they might encounter on any given day? Most research done by students involves little risk. Still, students tend to underestimate possible risks. Could the research participants suffer a physical injury, emotional trauma, public embarrassment or loss of a job if their answers became known? What might the short term, or long-term consequence be? All these possibilities should be taken in to account, and addressed as needed.

Statement of Benefits – Every study worth doing has benefits. Benefits may be for the researcher (knowledge, course credit, etc.), the participants (insight into a condition, a prize for participating, etc.) or to the field/public (deeper understanding of a medical condition, new knowledge about effective learning strategies, etc.). Most research will benefit all three.

Consent form – A research participant must be fully informed about the research, its risks, benefits andhow the information will be stored and used in order to make a fully informed decision about whether to participate or not. IRB approved research almost always requires informed consent. If a

waiver or modification of Consent is requested, the researcher must detail the reasons in the protocol. Research that presents little risk requires only a short consent form, butresearch that poses more risk should utilize the extended consent form. If participation in research is a course requirement, students must be informed of non-research alternatives.

Assent Form - When the research participants are minors (under 18), and the IRB has determined that the research is not exempt, the research application requires two additional steps. An extended consent form must be signed by a parent/guardian. In addition, the minor must be given an assentform. This is similar to a consent form, but written in language appropriate for the minor's age.

Statement of Confidentiality– Taking precautions to guard confidentiality of the research participantsminimizes risks that might result if their identity could be matched with the research data. The protocol needs to explicitly describe how confidentiality will be safeguarded.

Debriefing Statement – After the study is completed, it is important to recap the purpose of the research for the participants, ask if they have any questions/concerns, and provide your contact information for their reference. If the study involved asked particularly personal questions, the researcher should be aware that the participants may have strong emotional reactions. These may be obvious ornot, but given that possibility, the researcher should also provide the participants with contact information for counseling or other appropriate follow up, should they need it. The debriefing can be oral or in writing, but a statement of what will be said/mailed needs to be included in the application.

Step Four

Be sure to include any survey instruments or interview questions with your application packet.

Step Five

Assemble all the necessary parts of the application packet:

1. Completed application form (don't forget to include your CITI number, the CITI numbers of yourco-applicants and signatures)
2. Completed Protocol (abstract, description of participants, risk, benefits, statement of confidentiality, consent/assent forms, debriefing statement)
3. Research instruments (include any interview questions, surveys)
4. Copy of off-site letter (if applicable)

Be sure that your application packet has all the necessary parts and submit them together. The IRB willnot begin its review until all the elements of the application packet are completed.

Step Six

Submit an electronic version of the application to **institutionalreview@mcla.edu**. The IRB acceptselectronic signatures.

AND

Provide a hard copy of the application to the IRB, Office of Academic Affairs, Bowman Hall, B219.

What happens next?

The IRB reviews the application and generally provides responses within two weeks. Please note that applications received just prior to holidays, school breaks or near finals may require additional timefor review. Sometimes, the IRB needs additional information from researchers in order to make itsdecision. Build in extra time in case you need to submit additional information for review.

It is up to the research applicant to plan ahead and allow for enough time to assemble the applicationand to allow for the IRB to review the application.

You will receive an email from the IRB stating whether your application was approved without changes,approved with changes or rejected. If it is approved with no changes, you can proceed. If it is approved with changes request, complete those and send the revisions to the IRB. The revisions can usually be reviewed with a few days.

Do I really need to wait for approval before I begin?

Yes. Research projects that are begun prior to the receipt of written approval from the IRB will bedisapproved (see policy).

Do I need to let the IRB know the results of my research?

No. But if any harm, accident, or an adverse event occurs, you do need to report that immediately. The IRB may ask you to cease your research until it has a chance to review the incident.

What happens if I want to change my research project after my proposal has been approved by the IRB?

In general, any change which alters the risk or modifies the informed consent in some way, requires IRBapproval. Prior to making any changes, contact the IRB for information on how to proceed.

What if I have questions about my application?

Your faculty advisor will be able to guide you through the process. You may also contact either Ann Billetz at 662-5345, a.billetz@mcla.edu or Stacy Gagne at 662-5525, stacy.gagne@mcla.edu.