Guidelines for Research Projects:

The IRB Process

Media & Information Studies

College of Communication Arts & Sciences

Michigan State University

M&I Master's Program IRB Application Guide

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Introduction

In order to maintain the highest levels of integrity and professionalism in our research, Michigan State University has instituted a Human Research Protection Program Institutional Review Board (IRB) that evaluates all proposed research at MSU to assure that it is ethical and protects research participants. This guide is to help students, instructors and faculty in our department to better understand the process and be able to submit applications that will be evaluated accurately and smoothly.

In this guide are the basic steps for most of the typical research projects in our department. If you go through the guide and don't see where your research fits, please discuss it with your advisor or the graduate director. This guide is not a comprehensive document but meant as a guide and checklist to avoid common errors that may delay the evaluation of your application.

As a world class institution, we want to promote high quality research that brings new insights and knowledge to our areas of impact. Learning how to prepare documentation for IRB review and carry out research is a major milestone in your accomplishments.

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What research needs IRB review?

Evaluating if a research project is exempt from IRB supervision is the responsibility of the IRB team. If a project meets the definition of research, it must be submitted to the IRB for review. The IRB team goal is to complete review of exempt research in 3-5 days once submission is complete. Delays are common if applicants do not complete the application accurately, or from communication delays because of how the CLICK system handles messages. Please see the Click Processing section for more information.

Excerpt from HRPP Manual Section 6-9-A
(full policy at https://hrpp.msu.edu/help/manual/6-9-A.html)

Student Classroom Research

In some courses students collect data from human subjects by using professional research methods, even though the student's work is not designed to develop or contribute to generalizable knowledge. For those student classroom activities that do not meet the federal definition of "research" (see definition below) because they are not designed to develop or contribute to generalizable knowledge, Institutional Review Board (IRB) review is not required. In these instances, the instructors are responsible for assuring that participants involved in the activity are protected. However, if such activities meet the definition of research involving human subjects, the activity must be reviewed and approved by the IRB or determined exempt prior to initiation of the activity.

If at the conception of the student classroom activity the instructor or student is aware or expects that the data gathered by the student is designed to develop or contribute to generalizable knowledge (note: theses & dissertations are by definition 'research'), the activity must be reviewed and approved by an MSU IRB prior to initiation. Failure to obtain IRB approval is noncompliance. Such noncompliance will be reviewed pursuant to HRPP Manual 9-2 "Noncompliance."

If a student collects data for non-research purposes and would subsequently like to use the data for research, IRB review may be required. The instructor or student should contact the IRB to determine if IRB review is required. When an IRB application is required, it should include an explanation of how the data were collected and why IRB approval was not sought prior to data collection. When appropriate, the consent process should be explained and a consent form attached.

When classroom activities not subject to IRB review are undertaken, instructors have primary responsibility for assuring that the rights and welfare of participants in the

activity are protected. To fulfill this responsibility, it is recommended that instructors communicate to students the ethical principles for the protection of human subjects, review student classroom activities involving humans, and monitor classroom activities and reports of findings to assure that participants are protected.

Please see the full policy for guidance for instructors & recommendations for instructor review of such project.

Definition of Research

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Some additional guidance on the definition of research:

To be considered a "systematic investigation," the concept of a research study must:

- Attempt to answer research questions (hypothesis)
- Is methodologically driven, (collects data or information in an organized way)
- Data or information is analyzed in some way, (quantitative or qualitative analysis)
- Conclusions are drawn from the results

To be considered "generalizable knowledge," the activity would include the following:

- Knowledge contributes to a theoretical framework of an established body of knowledge
- Results are expected to be generalized to a larger population beyond the site of data collection or population studied
- Results are intended to be replicated in other settings.

Overview of IRB

Everyone participating in human subjects research must first take HRPP/IRB training and be certified. You must complete both the-

- Overview of Human Research Protection at MSU, and
- Ethical and Regulatory Considerations sections.

The Ability training system helps record and track certifications. You can log in here-

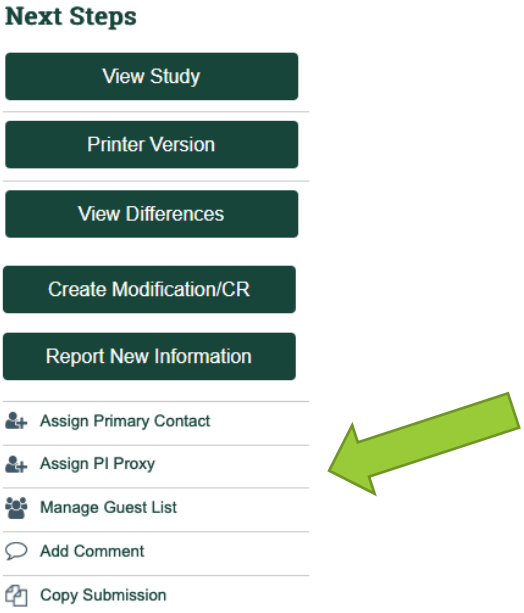
For more details please go to this page--

CLICK processing

MSU uses the Click™ system. This data management system tracks the submission through the review process.

Please note that it is very "territorial" and if the researcher submits a question and doesn't fully submit it and check "to the attention" box, it won't be seen. Also, if the IRB staff member sends a question back to the researcher they can't do anything else until the researcher fully responds and sends it back. More details later- but the communication process is often where there are delays.

A faculty member needs to start the submission as PI. Once it is started, they can assign a PI proxy. This allows the student, or designated member of the research team to answer messages and make changes to the submission.



To start the process you will need:

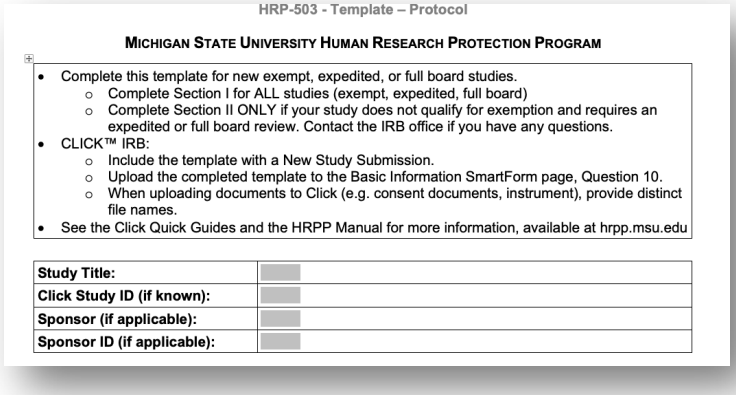
1. Title of study
2. Short title
3. Brief description

4. What kind of study is this?
5. If there is an external IRB (e.g., from another university or business) act as the IR of record for this study?
6. The name of the local principal investigator (this must be an associate professor, assistant professor, or a professor)
7. If the investigator have a financial interest related to this research (yes/no)
8. Is the activity a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge? (yes/no)
9. Does the activity involve a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information?
10. Is this project being conducted to fulfill the requirement of an education/training program? (list of options)
11. Attach protocol (see more details in next section- templates are in application)
12. Attach consent form,

Exempt Research

To determine if a project is exempt the IRB team needs enough information to clearly identify that it is exempt. This would include: consent form, solicitation information, applicable protocol forms, and clear description of activity.

The first template form that most UX/ games/ policy research will use is HRP 503 it is downloadable in the Click interface. Fill in all the relevant areas.

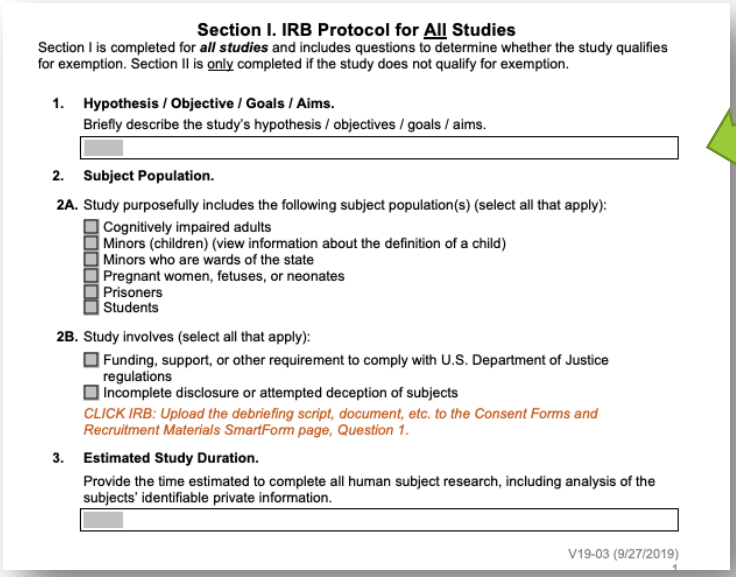


HRP-503 - Template – Protocol

MICHIGAN STATE UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM

- Complete this template for new exempt, expedited, or full board studies.
  - Complete Section I for ALL studies (exempt, expedited, full board)
  - Complete Section II ONLY if your study does not qualify for exemption and requires an expedited or full board review. Contact the IRB office if you have any questions.
- CLICK™ IRB:
  - Include the template with a New Study Submission.
  - Upload the completed template to the Basic Information SmartForm page, Question 10.
  - When uploading documents to Click (e.g. consent documents, instrument), provide distinct file names.
- See the Click Quick Guides and the HRPP Manual for more information, available at hrpp.msu.edu

Study Title:	
Click Study ID (if known):	
Sponsor (if applicable):	
Sponsor ID (if applicable):	



Section I. IRB Protocol for All Studies

Section I is completed for ***all studies*** and includes questions to determine whether the study qualifies for exemption. Section II is only completed if the study does not qualify for exemption.

1. **Hypothesis / Objective / Goals / Aims.**
   Briefly describe the study's hypothesis / objectives / goals / aims.

2. **Subject Population.**

2A. Study purposefully includes the following subject population(s) (select all that apply):

- ☐ Cognitively impaired adults
- ☐ Minors (children) (view information about the definition of a child)
- ☐ Minors who are wards of the state
- ☐ Pregnant women, fetuses, or neonates
- ☐ Prisoners
- ☐ Students

2B. Study involves (select all that apply):

- ☐ Funding, support, or other requirement to comply with U.S. Department of Justice regulations
- ☐ Incomplete disclosure or attempted deception of subjects

CLICK IRB: Upload the debriefing script, document, etc. to the Consent Forms and Recruitment Materials SmartForm page, Question 1.

3. **Estimated Study Duration.**
   Provide the time estimated to complete all human subject research, including analysis of the subjects' identifiable private information.

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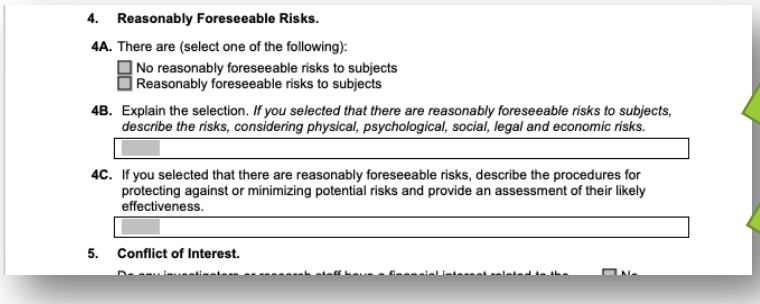
Having clear objectives or hypothesis is essential for successful research.



4. **Reasonably Foreseeable Risks.**

4A. There are (select one of the following):

- ☐ No reasonably foreseeable risks to subjects
- ☐ Reasonably foreseeable risks to subjects

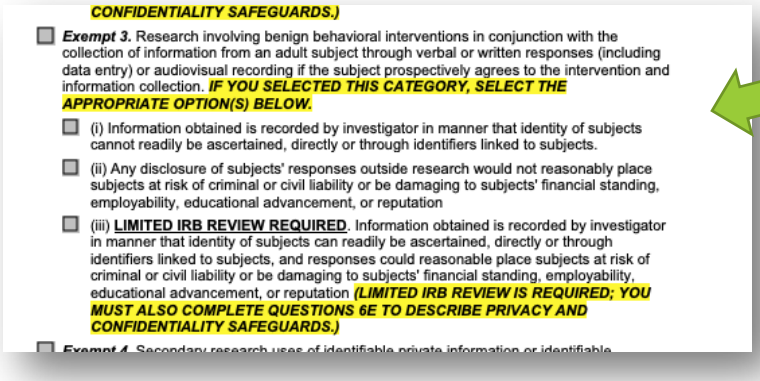
4B. Explain the selection. *If you selected that there are reasonably foreseeable risks to subjects, describe the risks, considering physical, psychological, social, legal and economic risks.*

4C. If you selected that there are reasonably foreseeable risks, describe the procedures for protecting against or minimizing potential risks and provide an assessment of their likely effectiveness.

5. **Conflict of Interest.**

Think deeply about foreseeable risks. If there are any risks (e.g., images or game play that might be violent) describe how you will protect participants and how you can counter those risks.

Professors who are doing the same project over several semesters with different students can file one IRB application and just make sure additional participants are certified and added as needed to the project.



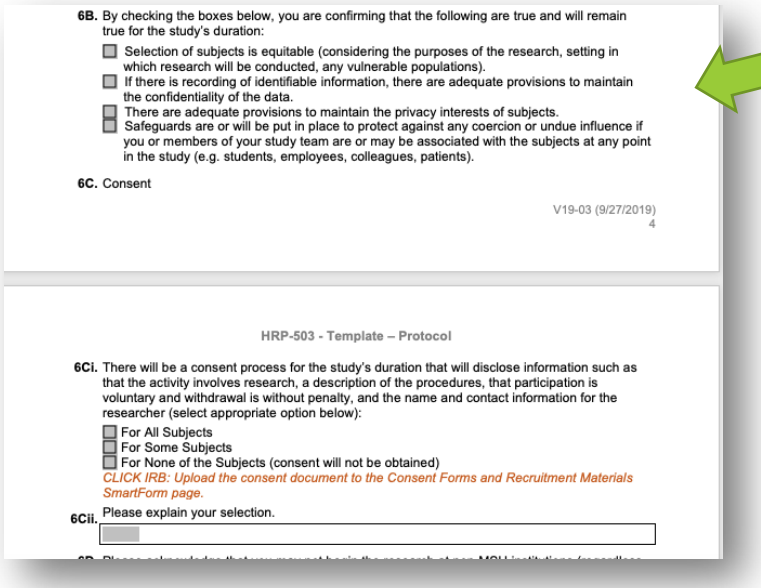
CONFIDENTIALITY SAFEGUARDS.)

☐ ***Exempt 3.*** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection. ***IF YOU SELECTED THIS CATEGORY, SELECT THE APPROPRIATE OPTION(S) BELOW.***

- ☐ (i) Information obtained is recorded by investigator in manner that identity of subjects cannot readily be ascertained, directly or through identifiers linked to subjects.
- ☐ (ii) Any disclosure of subjects' responses outside research would not reasonably place subjects at risk of criminal or civil liability or be damaging to subjects' financial standing, employability, educational advancement, or reputation
- ☐ (iii) **LIMITED IRB REVIEW REQUIRED**. Information obtained is recorded by investigator in manner that identity of subjects can readily be ascertained, directly or through identifiers linked to subjects, and responses could reasonable place subjects at risk of criminal or civil liability or be damaging to subjects' financial standing, employability, educational advancement, or reputation ***(LIMITED IRB REVIEW IS REQUIRED; YOU MUST ALSO COMPLETE QUESTIONS 6E TO DESCRIBE PRIVACY AND CONFIDENTIALITY SAFEGUARDS.)***

☐ ***Exempt 4.*** Secondary research uses of identifiable private information or identifiable

Most of our department's research will be exempt in category #3. If doing a survey, usually (i) would be the subcategory. If doing usability or game testing, usually (ii).



Make sure you check all the appropriate boxes. You should check all the boxes for section 6B and clearly describe how you will obtain informed consent.

The Next Pages

The next few pages include funding information and team members. Make sure all members are approved for human research. If there certification was recent, they might not be in the system yet so you can include a document that has a screen shot of the congratulations message when the student completed the training session. Answer the other questions about type of study until you get to the consent form.

The Consent Form

There are many sample consent forms that are recommended for different types of studies. You do not have to use these forms, but the consent form has four essential elements-

1. The participant must know this is research
2. The participant must know what they are being asked to do (include expected time)
3. They must know that it is voluntary, that they can skip questions or stop at any time
4. The consent form must have contact information, either the PI or the student if they are a proxy for PI in the forms

Upload your form in this section. It helps if you use the same title on all documentation for the application.

Recruitment Materials

How will participants be recruited? If you are doing a snowball sample, asking friends, or putting a message on a Twitch chat room, you need to specify how you will gather your subjects. Include a copy of the message you will share to recruit participants. Include how many participants you will be enlisting and any debriefing.

Supporting Documents

This is where you can clearly describe what you will do in the research. Include the entire process of research, describing how you will get their informed consent. Describe how long it will last and what participants will be exposed to.

- If it is an interview, include the interview protocol.
- If it is playtesting a game, describe what they will see and include screen shots.
- If it is testing a prototype of an app include images (even if low fidelity) to give the reviewers a clear idea of what you will be doing.
- If it is a survey, include the questions and any images they will see
- If it is a website, include what participants will see, even if it is lo-fidelity wire frames.

In the documentation- NO LINKS TO WEBSITES- or Google docs. Documentation must be fully in the application. The review boards needs this documentation as a record of what they used for their decision.

The IRB tries to process applications that are exempt in 3-5 days once they have cleared the pre-review check for errors in the application.

Expedited Research

Expedited Research means that there is limited risk to the participants and the research is conducted under IRB review. Data collection and storage must follow the guidelines promised in the application and there should be no substantive changes in any part of the protocol.

Minor changes, such as slightly changing the wording in a survey question do not need prior approval. Major changes, such as exposing the participants to anything that changes risk must be approved prior to the research starting.

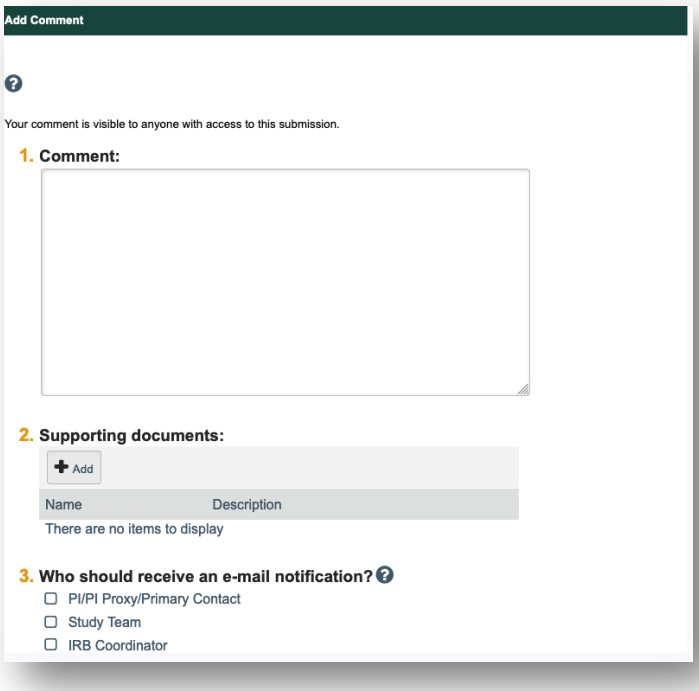
Full Review Research

If research is dealing with sensitive issues or using a vulnerable population (e.g., children) there is a full review where the IRB panel will meet with the PI and team members, usually on Zoom. They will ask any questions they have about the research and clarify expectations. Any changes in any part of the research must be submitted to the board before implementation.

Communication

As the IRB staff prepares the application for review, if they see any error if there is a missing point, the review stops at that point and the staff will send the application back to the PI or the PI proxy with comments on what should be done to resolve the issue.

The PI or PI proxy will log in and make changes and submit the corrected documents in the appropriate locations. Make sure to submit the reply and click who should receive an email notification. If you do not click the IRB coordinator, they will not receive a notification of the changes and it will take longer until they check the application.



The data management system is very "territorial" so once the IRB team sends a message out to the PI/ PI proxy, the IRB team can't see or alter the application until

the applicant sends it back to them completely. If there are any delays be sure to check the message center to see if any comments from the IRB team are replied and that the IRB coordinator is checked so they see the response.

If you have any questions, please contact the IRB staff person who is reviewing your account.