

Cayuse IRB Application Instructions

This document provides instructions on completing the Cayuse IRB human subjects application. It is meant as a reference guide to explain each section in the application.

Click on the question marks next to the questions in the application for additional guidance.

Be sure to save your application frequently.

General Information Section

This section will always appear.

Affiliation: click on your affiliation with Eastern Michigan University. Students: additional questions will appear asking what type of student you are and what type of project you are conducting. You will also see questions about your faculty advisor (required).

Program Evaluation: If the study is a program evaluation, you do not need to complete this application. If you click “no,” additional application sections will appear.

Study Abstract and Summary Section

This section serves as your study protocol. A separate study protocol document is **not** required.

Abstract: Provide a brief, one-paragraph summary of the study, including your hypothesis.

Purpose: Explain the purpose of the study.

Study Procedures: Provide a step-by-step description of each subject’s experience in the study from beginning to end. Explain how many study sessions, the duration of each session, and what will occur at each session. Use clear, **non-technical language**.

Study Measures: Describe each assessment or measure you plan to use. All measures must be attached, using the attachment button.

Drugs/Biological Products: If your study uses drugs or biological products, contact [Sonia Chawla](#).

Medical Devices: If you check “Yes,” additional questions will appear asking if the device is FDA approved, how the device will be used, and if FDA approval will be

sought for non-FDA-approved devices. All FDA documentation and labeling must be attached.

Exemption Section

This section contains Exempt criteria. **All study procedures must fit into at least one of the criteria for the study to qualify as Exempt.** If all of your research criteria do not fit into at least one of the Exempt criteria, click “None of the above.”

If you click criterion 4 only, the Pre-Existing Data section will appear (see below).

If you click on criteria 1, 2, 3, 5, or 6, additional questions will appear at the bottom of the page:

Exempt Documents: Attach your consent/assent forms, recruitment materials, and any study measures. Documents can be batch uploaded.

Consent Process: Describe how you plan to obtain consent or permission from your subjects prior to their participation.

Data Storage: Explain how and where you plan to store your data. Include confidentiality information.

Compensation: If subjects will be compensated, a follow-up question will appear asking you to describe how subjects will be compensated.

These questions are the entirety of the Exempt application. Once these questions have been completed, you can continue your submission (scroll below to **Continue Submission** section).

If you click “None of the above,” indicating that your study does not qualify for Exempt review, additional application sections will appear in the blue menu on the left.

Pre-Existing Data Section

If you are using pre-existing data, the following questions will appear:

Publicly Available: If your data are not publicly available, a button will appear at the bottom of this section requiring the attachment of all Data Use Agreements or other documentation of permission to use the data.

Source: Where or from whom will you obtain the data?

Storage: How will you store the data and protect confidentiality?

Risks to Subjects Section

Potential Risks: Check all that apply. There is no such thing as a no-risk study, so at least one option must be checked.

Risk Mitigation Procedures: Explain the study procedures in place to minimize each risk checked.

More than Minimal Risk Designation: Click the question mark for the definition of minimal risk.

Benefits Section

Benefits are measurable improvements in health, welfare, or quality of life. Compensation, self-discovery, and experience as a research participant are not benefits to participation.

Benefits to Subjects: 99% of the time, subjects do not directly benefit. It is fine to say that there is no direct benefit to subjects.

Benefits to Science: Explain the contribution to knowledge that will result from your research.

Sample Size and Description Section

Enrollment Total: The UHSRC is required to approve a **maximum** number of subjects. We suggest that you overestimate your subject total in order to account for attrition.

Group Affiliation: If you are randomizing or purposely enrolling distinct groups of people, you will see a follow-up question asking for the number of subjects in each group.

Eligibility Criteria: List the criteria or qualifications that are required for someone to participate in your study. Be as specific as possible.

Screening: If you plan to screen subjects to determine eligibility, you will see follow-up questions asking about your screening process and to attach a screening questionnaire.

Recruitment: Be as specific as possible explaining how you will inform people about your study. Do not use generic terms, such as snowball sampling and purposive recruitment.

Special Populations: Select all that apply. If you plan to enroll minors, prisoners, or pregnant women, fetuses, or neonates (nonviable or of uncertain viability), additional sections will appear in the blue menu on the left. Describe the study procedures in place to protect those subjects in the text area following the checklist.

Recruitment Materials: The UHSRC is required to review all materials (fliers, email texts, social media texts, in-person scripts, phone scripts, etc.) that are used to inform individuals about your study.

Privacy and Confidentiality Section

Privacy: This refers to the individual. Explain procedures to protect individual privacy during study participation.

Data Collection: This question is frequently answered incorrectly. Anonymous data mean that there is effectively no way to identify subjects from the data set. Coded data mean that there is a study ID field in the data set where each subject is assigned a study ID and a key linking study ID to name or other identifiable information is kept in a separate document. Identifiable data mean that there are fields in the data set that are unique identifiers (e.g., name, social security number, EID number, phone number, etc.).

Confidentiality: Explain how you will protect the data.

Dissemination: Where will results be published or presented? How will results be used?

Data Monitoring Plan Section

Data Monitoring: If you choose yes, additional questions will appear asking for a data monitoring plan and to attach any information distributed to subjects. Data monitoring plans are only required for studies in which there is a reasonable risk of physical injury, psychological injury, trauma, or severe distress. Click on the question mark in the application for additional information.

Informed Consent Section

Legal Consent: Competent adults age 18 or older in Michigan can legally consent for themselves. Minors (under age 18) or individuals who are decisionally or cognitively impaired cannot give informed consent, and consent is required from a parent or Legally Authorized Representative (LAR). A LAR is a person authorized by law to provide consent on behalf of the subject. If you are conducting your research in a different state or country, you must adhere to the laws of that state/country regarding the age of majority.

Obtaining Consent from All Subjects: If you will not obtain consent from all subjects, you will see questions asking you to justify why you will not obtain consent and about your debriefing process.

Debriefing: You will only see this question if you respond “no” to the question about obtaining informed consent from all subjects. If you will debrief subjects, you will see follow-up questions asking about your debriefing process and to attach a debriefing script or form. If you will not debrief subjects, you will see a follow-up question asking for justification.

Consent Process: Describe your consent process. Note that consent is an ongoing process and not always a one-time thing.

Signature: If subjects will not sign a consent form, do not include signature lines on the form. If subjects will not sign a consent form, you will see a follow-up question asking you to select one of two options. These options are regulatory criteria for waiving the required signature. One of these two options must be selected and accurate to the study procedures.

Consent form: The UHSRC website contains additional information about [developing a consent form](#). We strongly recommend that you use our consent template or one of our sample forms in developing your consent form.

Minors Section

You will only see this section if you selected that you plan to enroll minors in the Sample Size and Description section.

Assent: Assent is permission from the child. The process must be age- and mental-age appropriate, but there are no regulatory requirements regarding how and in what form assent should be obtained. The [UHSRC website](#) has sample assent forms/scripts for different developmental ages. If you plan to obtain assent from your subjects, you will see follow-up questions asking about the assent process and to attach your scripts/forms. If you will not obtain assent, you will see a follow-up question asking for justification. Note that it may be inappropriate or impossible to obtain assent from very young children.

Parental Consent: This should be described in the Informed Consent section of the application. If you do not plan to obtain parental consent, you will see a follow-up question asking for justification.

Consent for Subjects who Turn 18: If a subject turns 18 during the course of the study, they must provide consent for themselves once they turn 18 (parental consent is no longer valid). If this is the case in your study, you must provide a process for obtaining consent on or very close to the subject's 18th birthday.

Wards of the State: Wards are the State are minors for whom the State is the legal guardian. There are additional regulations governing research using wards of the state. If you will enroll wards of the state, you will see a follow-up question asking about your research.

Research with Wards of the State: This is a follow-up question only seen if you indicate that you are enrolling wards of the state. If you select "None of the above," you cannot use wards of the state. If you select either other option, you will see a follow-up explanation of the requirement of an advocate and questions asking to list the advocates and to attach their credentials.

Prisoners Section

You will only see this section if you selected that you plan to enroll prisoners in the Sample Size and Description section.

Research Purpose: Research can only be conducted using prisoners in very specific cases. If you respond “None of the above,” you will not be permitted to enroll prisoners into your study.

Advantages: Prisoners cannot experience any advantages that would be coercive to participate or that affect the sentencing or prison term.

Selection: What are the eligibility criteria within the prison. Eligibility must be equitable.

Parole Decision: Participation cannot be used by parole boards to influence parole decisions. You must explain how this is achieved through your study procedures.

Pregnant Women, Fetuses, and Neonates Section

You will only see this section if you selected that you plan to enroll pregnant women, fetuses, and neonates in the Sample Size and Description section. Pregnant women can be incidentally enrolled in studies that carry no physical risk to the woman or the fetus (e.g., survey or interview studies). This section only applies to nonviable neonates or neonates of uncertain viability. For studies enrolling viable neonates only, please complete select “minors” in the Sample Size and Description section and complete the Minors section.

Determination of Potential Risks: This question asks for the results of previous research on humans and animals that can be used to ascertain the specific risks to the pregnancy and/or fetus, and/or neonates.

Risk Determination: If your study constitutes greater than minimal risk, you must contact the Office of Research Compliance via [email](#) or by phone at 734-487-3090.

Involvement: You will see relevant follow-up questions based on your response. Contact the Office of Research Compliance via [email](#) or by phone at 734-487-3090.

Costs and Payments Section

Costs: If your subjects have to pay in order to participate in your research, you will see a follow-up question asking to explain the cost. Transportation, parking, etc. are not research costs. Research costs are for the cost of treatment or the research intervention, specifically.

Payments: If you plan to compensate subjects for participation, you will see a follow-up question asking for an explanation of the payment. Food, drink, or other

refreshments offered are not compensation. The UHSRC has [guidance](#) about compensating research subjects.

HIPAA Section

The Health Insurance Portability and Accountability Act (HIPAA) requires protections of Protected Health Information (PHI) from covered entities. EMU is a hybrid covered entity. The departments on campus that are covered by HIPAA are University Health Services, Human Resources – Benefits, Counseling and Psychological Services (CAPS), and the Autism Collaborative Center. Faculty, staff, and students conducting who are conducting research that is **not** under one of these four departments, are not subject to HIPAA regulations.

Collecting Identifiable PHI: If you are collecting identifiable PHI directly from subjects and your research is conducted in one of the four HIPAA-covered departments at EMU, you must include HIPAA-authorization language in your consent form.

Obtaining PHI: If a HIPAA-covered entity is providing you with a data set containing PHI, you will see a follow-up question asking to attach the data use agreement or HIPAA authorization.

FERPA Section

The Family Educational Rights and Privacy Act protects students' educational records.

EMU Records: If you will access EMU records, you will see follow-up questions asking to attach documented permission from the Office of Records and Registration, to explain what information you want in the educational record, and to describe how you will obtain permission for the records.

K-12 Records: If you will access K-12 records, you will see follow-up questions asking you to attach documentation that you have permission from the K-12 institution to use the records, to explain what information you want from the educational record, to describe how you will obtain student permission to use the records, and to describe how you will obtain parent permission to use the records.

Attachments Section

This section lists the attachments to the application. It is a purely administrative section. If you have already attached your supporting documents throughout the application, they will be carried over to this section.