

Eastern Michigan University
University Human Subjects Review Committee (UHSRC)
REQUEST FOR HUMAN SUBJECTS APPROVAL

Use this form for initial approvals and major protocol modifications.
For minor changes, please use the *Minor Modification* form.
To renew an approval after one year, please use the *Continuation Form*.

CHECK ONE

FACULTY/STAFF DOCTORAL MASTER'S UG Student

PROJECT TYPE – STUDENTS

Dissertation Master's Thesis GR Project Honor's Thesis UG Project

FACULTY/STAFF/DOCTORAL researchers should submit this completed form and the proposal with all required elements as email attachments to human.subjects@emich.edu. Also, send one hard copy of signed original approval form with proposal and all required elements to: Human Subjects Review Committee, 200 Boone Hall, Eastern Michigan University, Ypsilanti, MI 48197 (734.487.0042).

MASTER'S AND UNDERGRADUATE STUDENT researchers conducting minimal risk undergraduate or graduate theses/projects should submit them to the appropriate college-level committee for the CHHS, 206 Marshall; COB, 473 Owen; COE, 310 Porter; COT, 150 Sill or see the colleges' websites for submission details. **College of Arts and Science** projects should be sent by email attachment to human.subjects@emich.edu with paper copy going to CAS, 411 Pray Harrold. **Master's level research that is above minimal risk should be submitted to the college committee and then it will be directed to the UHSRC for review.**

Date Submitted: _____

Title of Project _____

Principal Investigator _____

Department _____

Phone _____ Fax _____ Email _____

Co-PI/Project Director _____

If a **student project**, list faculty _____

Signature of faculty sponsor _____

Student number _____

Program and status/year _____

Mailing address _____

If an **external grant** is being sought for this project, state the funding source and submission deadline:

Funding Source: _____

Submission Deadline: _____

If you have not already completed human subjects research training, you are strongly encouraged to visit <http://www.rcr.emich.edu/index.html>. Module 1 of the training program, entitled *Protection and Use of Human Subjects in Research*, is likely to be particularly helpful to you if you have not previously been through the UHSRC review process.

Have you completed EMU's Responsible Conduct in Research Human Subjects Training?

- Yes (Office of Research Development will confirm training date)
- No (You are strongly encouraged, but not required, to do so).
- Check here if you completed similar training elsewhere, and indicate...

Where: _____

When: _____

Is this application New (If yes, skip to Section I)
 Major modification of previously approved study (NOTE: If changes are minor and do not appreciably change the Risk-Benefit ratio, you may instead complete the UHSCR Minor Modifications form, available at: <http://www.ord.emich.edu/downloads/downloads.htm>)

If Modification:

- a. Date of last approval by this Committee _____
- b. Protocol number _____
- c. Principal Investigator of previously approved protocol _____
- d. Describe any modifications to the previously approved protocol:

- e. Were any Human Subjects problems encountered in previous research? No Yes
If yes, how were they addressed?

I. **If you are requesting an exemption from HSRC review**, explain the statutory basis for the requested exemption (see attached list of exempt project types):

II. **Briefly describe the purpose and importance of the study.**

Attach a brief summary of the study's primary goals/hypotheses.

III. **Information on Projects Using Pre-existing Data**

Check here and skip to Section IV if this project does **NOT** use pre-existing data. Pre-existing data includes retrospective medical chart reviews, public data sets, etc. Sometimes it is referred to as secondary data or archival data.

IMPORTANT NOTE: If you are obtaining medically-related information from a "Covered Entity" (a health plan, health care clearinghouse or a health care provider who bills health insurers – e.g., hospitals, doctor's offices, dentists, the EMU Student Health Center, the EMU Speech and Hearing Clinic, the EMU Psychology Clinic), the HIPAA Privacy Rule may apply. If so, check here and attach the UHSRC HIPAA Summary Form (<http://www.ord.emich.edu/downloads/downloads.htm>)

A. Name(s) of existing data set(s) [Include any ancillary data sets you might be linking the main data set(s) to]:

B. Source(s) of existing data set(s):

C. Please provide a brief description of the content of the data set(s):

D. When you obtain the data, will the individual records be anonymous or will they have identifiers/codes attached?

Anonymous (*i.e., no identifiers or codes attached to any records in any of the listed data sets*)

If your project also involves direct data collection, please go to section IV and complete the rest of the application. Otherwise, please complete from section VII to the end.

Identifiers/codes attached (*examples would include, but not be limited to, record numbers, subject numbers, case numbers, etc.*)

E. If the **records have identifiers or codes attached**, can you readily ascertain the identity of individuals to whom the data pertain (*e.g., through use of a key that links identifiers with identities; linking to other files that allow individual identities to be discerned*)? (Check here if not applicable)

Yes, I can ascertain the identity of the individuals.

Please explain in the box below how you will protect the confidentiality of subjects. UHSRC is concerned about two dimensions of confidentiality: (1) that the researcher has legitimate access to the records, i.e., the records are not protected by any special confidentiality conditions, and (2) that the researcher will not reveal individual identities unless permission has been granted to do so.

No, I cannot readily ascertain the identity of the individuals.

Please describe in the box below, the provisions in place that will PROHIBIT you from ascertaining identities (e.g., key to decipher the code/identifier has been destroyed, agreement between researcher and key holder prohibiting the release of the key).

If your project also involves direct data collection, please go to section IV and complete the rest of the application. Otherwise, please complete from section VII to the end.

F. Are the data from a public data set? (A public data set is data available to any member of the public through a library, public archive or the Freedom of Information Act. Data obtained from private companies, hospital records, agency membership lists or similar sources are not usually public data.)

Yes No

Are you requesting permission to conduct multiple research projects with these data?

Yes No

G. If you are obtaining access to non-public information, please explain in the box below how you will obtain access to the information (e.g., permission from the CEO, permission from the Board of Education, agency/hospital director, etc.). Note: a condition for UHSRC approval will be written documentation of this permission – this can be hard copy or an email from the relevant authority.

H. Before the data were collected, did respondents give their permission for the information to be used for research purposes? Yes No Unsure

If no or unsure, please explain how human subjects will be protected in the absence of this explicit permission:

I. Are you recording the existing data in a manner that will allow you to identify subjects, either directly or through identifiers linked to the subjects?

Yes No

If your project also involves direct data collection, please continue completing the rest of the application.

If your project does **not** involved direct data collection, please complete sections VI and beyond, as appropriate.

IV. Numbers, Types, and Recruitment of Subjects

A. Numbers and characteristics of subjects (e.g., age ranges, gender, ethnic background, health status, disabilities, etc.):

B. How are the individual participants to be recruited for this research? Is it clear to the subjects that participation is voluntary and that they may withdraw at any time without negative consequences?

C. Special Populations

1. Does the research involve subjects from any of the following categories?

Yes **No**

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | a. Under 18 years of age as the target population
(If “yes” signed, active parental consent is required unless a waiver is granted by the UHSRC.) |
| <input type="checkbox"/> | <input type="checkbox"/> | b. Over 65 years of age as the target population |
| <input type="checkbox"/> | <input type="checkbox"/> | c. Persons with a physical or mental disability as the target population |
| <input type="checkbox"/> | <input type="checkbox"/> | d. Economically or educationally disadvantaged as the target population. |
| <input type="checkbox"/> | <input type="checkbox"/> | e. Unable to provide their own legal informed consent |
| <input type="checkbox"/> | <input type="checkbox"/> | f. Pregnant females as the target population |
| <input type="checkbox"/> | <input type="checkbox"/> | g. Victims of crimes or other traumatic experiences as the target population |
| <input type="checkbox"/> | <input type="checkbox"/> | h. Individuals in institutions (e.g., prisons, nursing homes, halfway houses) |

2. If yes to any of the above, please explain the rationale for the use of participants from vulnerable population(s).

3. If individuals from vulnerable populations are to be included, explain the steps you are taking to ensure that their rights are protected.

V. Informed Consent

A. To what extent and how are the subjects to be informed of research procedures before their participation?

B. Attach a copy of the written "Informed Consent" form or a written statement of the oral consent or assent. (See attached checklist for essential elements of informed consent).

Consent/assent documents attached

Not applicable (Explain why: _____)

Yes **No**

 1. Are you seeking consent/assent from all relevant parties?

If "No", explain why not in the box provided below.

Yes **No**

 2. Are you having your participants physically sign consent/assent form(s)?

If "No," you are requesting a waiver of signed informed consent. Provide justification in the box below.

C. If deception or emotional or physical stress is involved, subjects must be debriefed about the purposes, consequences, and benefits of the research and given information on procedures they can follow or resources that are available to them to help them handle the stress. Please attach a copy of all debriefing materials, if applicable.

Is debriefing form attached? Yes No Not Applicable

- D. Explain below the procedures you will follow to protect the confidentiality of your subjects. Include considerations associated with data and/or consent form collection and storage, and dissemination of results. Explain whether or not the study is anonymous. *(Note: It is not always necessary to protect the confidentiality of your subjects, but they must be informed if you plan to quote them directly or reveal their identities in any way.)*

- E. Describe what participants will be asked to do or have done to them from the time they are first contacted about the study until their participation in the study ends. **Note:** A summary of this information should be included in information provided to the subjects as part of the consent process.

VI. Risks Involved in the Research

- A. Describe potential risks involved in project/research participation. What procedures will be in place to minimize any risks to subjects?

- B. Does the research involve any of the following procedures?

- | | | |
|--|-----------------------------|------------------------------|
| 1. Deception of the participant? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 2. Punishment of the participant? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 3. Use of drugs/medications in any form? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 4. Electric shock? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 5. Deliberate production of anxiety or stress? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 6. Materials commonly regarded as socially unacceptable? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 7. Use of radioisotopes? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 8. Use of chemicals? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 9. Drawing of blood? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 10. Handling of any other bodily fluid? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 11. Sexually explicit materials or questions ? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 12. Questions about drug and/or alcohol use? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 13. Questions about sexual orientation, sexual experience,
or sexual abuse? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 14. Physical activity, stress, or strain? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |
| 15. Administration of substances to subjects? | No <input type="checkbox"/> | Yes <input type="checkbox"/> |

- (e.g., food, medications, vitamins, etc.) No Yes
16. Any other procedure that might place subjects at risk? No Yes
17. Systematic selection or exclusion of any group. This includes the selection or exclusion of any group based on age, gender, race, ethnicity, etc. No Yes
18. Any other procedure that might be regarded as inducing in the participant any altered state or condition potentially harmful to his/her personal welfare? No Yes
19. Any other procedure that might be considered to be an invasion of privacy? No Yes
20. Any other physically invasive procedure? No Yes
21. Disclosure of the name of individual participants? No Yes

If the answer to any of the above is "Yes," please explain this procedure in detail and describe procedures for protecting against or minimizing any potential risk.

C. Please answer the following additional questions about potential risks.

- Yes** **No**
1. In your opinion, does the research involve more than minimal risk to subjects? ("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.") If the answer is "yes," explain in the box below and provide an explanation of the **benefits (in Section X)** of the research to the subjects and to society.)

- Yes** **No**
2. Can any **emergencies or adverse reactions** (physical, psychological, social, legal, or emotional) be anticipated as a result of the research? (If "yes," then explain the measures to be taken in case of emergency in the box below.)

- Yes** **No**
3. Will participation in this research result in any appreciable negative change in the subject's emotional state? (If "yes," explain the nature of the change and the process for assisting subjects in the box provided.)

VII. HIPAA

If you answer “Yes” to either of the following questions in section VII, your project is subject to Federal regulations under the Health Insurance Portability and Accountability Act (HIPAA), and you must complete the UHSRC HIPAA Summary Form (available at <http://www.ord.emich.edu/downloads/downloads.htm>) and include it with your application.

Yes No

A. Will health information (*information relating to the past, present, or future physical or mental health or condition of an individual*) be obtained from a covered entity (*a health plan, health care clearinghouse or a health care provider who bills health insurers – e.g., hospitals, doctor’s offices, dentists, the EMU Student Health Center, Speech and Hearing Clinic, Psychology Clinic or COE Counseling Clinical Suite*)?

B.1 Will the study involve the provision of health care by a covered entity?

Yes No

B.2 *If yes*, the study does involve provision of health care: Will a health insurer or billing agency be contacted for billing or eligibility?

VIII. FERPA

If you answer “Yes” to any of the following questions, your project is subject to Federal regulations under the Family Educational Rights and Privacy Act (FERPA).

Yes No

A. Will you be requesting access to **EMU records related to** student grades, class schedules, course instructors, financial aid, student financial accounts, social security numbers, EID numbers, transcripts, courses attempted/completed, ethnicity/residency/visa type, selective service/VA status, or names with contact information, etc.? Note: if yes, your project will be forwarded to the Office of Records & Registration for an additional level of review.

Yes No

B. Will you be requesting access to **K-12 student records related to** student grades, class schedules, teachers, ID numbers, transcripts, courses attempted/completed, ethnicity or names with contact

information, etc.? Note: if yes, this will require both school and parent/guardian permission.

If “yes” for A or B, explain the nature of the records you are seeking to access in the box provided below.

IX. Confidentiality

A. To what extent is the information confidential and to what extent are provisions made so that subjects are not identified?

B. What are the procedures for handling and storing data so that confidentiality of the subjects is protected (particular attention should be given to the use of photographs, video and audio recordings)? Will separate permission be sought for audio/video taping? If recordings will be transcribed, who will do this so as to protect confidentiality?

C. How will the results of the research be disseminated? Will the subjects be informed of the results? Will confidentiality of subjects or organizations be protected in the dissemination? Explain.

X. Benefits

Describe any anticipated benefits to subjects from participation in this research. Note that compensation should not be framed as a “benefit,” although it is important to include mention of any compensation in your consent form (simply as compensation).

XI. Submitting Your Protocol -- CHECKLIST

- If this is a Doctoral dissertation, Master's or Honor's thesis, please attach your **Committee Approval form**. Check here if not applicable .
NOTE: Master's and Honor's thesis that are not beyond minimal risk should be submitted to College committees.
- If available, attach a full copy of your research proposal (grant, thesis, dissertation proposal, etc.) Check here if not available
- Regardless of whether or not a full research proposal is available, attach a concise summary (2-5 pages) that includes:
- A brief summary of the background literature stimulating this research
 - Rationale for the proposed study, including goals, research questions or hypotheses
 - A description of the participants and how they will be recruited
 - A detailed description of study methodology
- NOTE: You may "cut-and-paste" as needed from your full proposal, if available, and the committee may refer to the full proposal for clarification.
- Consent Agreement(s) -- (Check here if not applicable).
See attached checklist of required elements to include in these consent documents.
NOTE: Please add the following statement to the final copy of your Informed Consent Agreement: **"This research protocol and informed consent document has been reviewed and approved by the Eastern Michigan University Human Subjects Review Committee for use from _____ to _____ (date). If you have questions about the approval process, please contact Dr. Deb de Laski-Smith (734.487.0042, Interim Dean of the Graduate School and Administrative Co-chair of UHSRC, human.subjects@emich.edu)."**
- Copies of all instruments, questionnaires, or tests to be used (if instruments are not fully developed yet, attach drafts, and so indicate).
- For studies that are to be conducted in agencies, hospitals/clinics, schools, churches, or community programs, include a copy of the approval letter (or email) from agency/hospital/school/program administrator. (Check here if not applicable).
- If your research constitutes EMU institutional or departmental assessment, you are strongly encouraged to contact the appropriate program officers for advising on how to streamline the UHSRC approval process. (Check here if not applicable).
- For consultation on Institutional Assessment projects, Dr. Denise Reiling (dreiling@emich.edu) is available to assist you. For example, Dr. Reiling might be consulted about projects that involve surveys regarding student exit interviews, and student or employee satisfaction measures.
 - For consultation on Academic Assessment projects, Dr. Jean McEnergy (jmcenery@emich.edu) is available to assist you. Academic assessment projects include learning outcomes evaluations such as assessments of the effectiveness of rubrics, portfolios, standardized tests, or comprehensive, certification, or licensing exams.
- Please note that Drs. Reiling or McEnergy will review the application and send their input to you as well as to the UHSRC. This consultation process will not slow down the review

of your application at the UHSRC level because both Drs. Reiling and McEnery also serve on the UHSRC. For more information about Institutional Assessment, please see <http://www.emich.edu/strategicplanning/ia.htm>.

Flyers to be posted on campus

NOTE: These must be stamped with Committee Approval prior to posting.

For clarification on human subjects procedures at EMU, please see this webpage:

http://www.ord.emich.edu/federal/federal_comp_subdir/humansubjects/human.html

Principal Investigator:

(Signature)

Date:

Master's or undergraduate projects from the Colleges of Business, Education, Health and Human Services, and Technology go to the college committee at the dean's office.

Faculty/staff/doctoral student studies and ug/gr College of Arts and Science research are submitted as email attachment to human.subjects@emich.edu. Also, send one hard copy of signed original form with proposal and all required elements to: Human Subjects Review Committee, 200 Boone Hall, Eastern Michigan University, Ypsilanti, MI 48197 (734.487.0042), or CAS, 411 Pray-Harrold.

Listed below are elements that the UHSRC reviewer will look for in your subject consent or assent agreement. To save valuable time in the review process, please be sure to devote attention to each item in your informed consent agreement document(s) before submitting your proposal. Provide a brief explanation for any item not checked off.

Checklist of Required Elements of Informed Consent

- A statement that the study involves research
Comments: _____
- Purpose of the research
Comments: _____
- Duration of subject's participation
Comments: _____
- Description of the procedures followed
Comments: _____
- Means of public dissemination
Comments: _____
- Description of foreseeable risks or discomforts to subject
Comments: _____
- Description of benefits to subject or to others
Comments: _____
- Disclosure of appropriate alternative procedures or courses of treatment
Comments: _____
- Statement of extent to which confidentiality of records identifying subject is maintained
Comments: _____
- Statement of how participant confidentiality is maintained in public dissemination
Comments: _____
- For research that poses greater than minimal risk, information regarding medical treatments or counseling should personal injury or problems occur
Comments: _____
- List of contacts who can answer questions about the research and subjects' rights and respond to research-related injury to subjects. Include the paragraph above regarding how to contact the UHSRC, in addition to information about how to contact the investigator(s).
Comments: _____
- Statement that participation is voluntary
Comments: _____
- Statement that refusal to participate will involve no penalty or loss of benefits
Comments: _____
- Statement that the subject may discontinue participation at any time
Comments: _____
- Statements of significant new findings developed during the course of research that may relate to subjects' willingness to continue participation
Comments: _____

Rationale for Exclusion of a Required Element:

Comments: _____

Exempt Activities

Investigators may not determine their own research to be exempt from HSRC review. Exemption decisions are made through the expedited review process.

Activities that are not research are exempt from HSRC review. Research is defined as: “A systematic investigation designed to develop or contribute to generalizable knowledge.”

Research that does not involve human subjects is also exempt from HSRC review. A human subject is defined as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be determined to be exempt from UHSRC review. Requests for exemption must cite the statutory basis for the requested exemption from the categories listed below:

I. Research

- A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - 1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND
 - 2. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

NOTE: This exemption does not apply to research involving children, unless the investigator is a non-participant observer of behavior.

- C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Criterion 2, above, if:
 - 1. The human subjects are elected or appointed public officials or candidates for public office; OR

2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- E. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
1. Public benefit or service programs;
 2. Procedures for obtaining benefits or services under those programs;
 3. Possible changes in or alternatives to those programs or procedures; or
 4. Possible changes in methods or levels of payment for benefits or services under those programs.
- F. Taste and food quality evaluation and consumer acceptance studies, if:
1. Wholesome foods without additives are consumed, or
 2. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

II. Program Review

- A. **Federal Regulations Exemptions.** Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs.
- B. **EMU Program Review Data.** Data collected for the purpose of the evaluation, review, and improvement of EMU academic and extra-curricular programs is exempt from review under the Federal Regulations exemptions listed above *unless* these data are collected: 1) for use beyond program review, and/or 2) for publication beyond the review process for EMU programs administered by EMU, by its associated accrediting agencies, and by other related educational bodies. Program Review proposals that meet the criteria for exemption from review do not need to be sent to the EMU HSRC.

Note: The above exemptions do not apply to research involving prisoners as subjects.