OFFICE OF RESEARCH AND SPONSORED PROGRAMS
Institutional Review Board-Downers Grove
Dr. Arthur G. Dobbelaere Support Services Hall, Suite 305
Phone: (630) 515-6395
FAX: (630) 515-6430
ilorsp@midwestern.edu

REQUEST FOR DETERMINATION OF HUMAN SUBJECTS RESEARCH

Investigators who are unsure whether a proposed study is subject to oversight by the MWU IRB should complete and submit this form. The IRB Chair or a Designated Member Reviewer will review the responses and provide documentation that the project is not subject to MWU IRB oversight or request completion of Form A (Application for Review).

PRINCIPAL INVESTIGATOR INFORMATION

Name and Degrees:	
Title:	
College:	
Department or Program:	
E-mail:	
Office Phone:	
Alternate Phone:	

Project title:	

REASONS FOR REQUEST

Check the applicable categories below that represent the reason(s) you believe the proposed study may not require IRB review. For each reason checked, complete the appropriate sections.

Category	*Sections to Complete*
Quality improvement, program evaluation or other studies not meeting the definition of human subjects research	☐ → ***Complete Sections A and D***
Engagement of MWU in the activity	☐ → ***Complete Sections B and D***
Case study, case series, or case report	☐ → ***Complete Sections C and D***

AFFIRMATION AND SIGNATURE

By signing and submitting this Request for Determination of Human Subjects Research, I affirm the following:

- **The activities associated with this study have not been initiated.**
- **The information provided here is complete and correct, including any necessary attachments.**
- **If this study is determined to be human subjects research and/or subject to oversight by the MWU IRB, Form A (Application for Review) must be submitted and an approval or qualification for exemption must be provided by the IRB before the study can begin.**
- **If subsequent changes to the proposed study may change the determination related to human subjects research and/or oversight by the MWU IRB, I will immediately suspend all study-related activities and contact ORSP staff.**

Signature:	Date:

SECTION A: DEFINITION OF HUMAN SUBJECTS RESEARCH

1. Does the proposed project involve a systematic investigation?
   "Systematic investigation" refers to an activity involving a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer one or more pre-specified questions or objectives. This includes activities related to research development, testing, and evaluation.
   - ☐ Yes
   - ☐ No

2. Are the findings obtained from this study intended to develop or contribute to generalizable knowledge?
   "Generalizable" means that the findings are intended to apply to populations or situations beyond those involved in the proposed project.
   - ☐ Yes. The findings will be universally or widely applicable
   - ☐ No. The applicability will be limited in scope to the local setting or context where the study is conducted (medical practices within one health-system, one organization providing rehabilitation services, a course in one educational program, etc.)

3. Will information or biospecimens be obtained from living individuals?
   - ☐ Yes
   - ☐ No

4. Will any member of the research team have direct, personal communication or interpersonal contact with participants?
   - ☐ Yes
   - ☐ No

5. Will the activities involve physical procedures or manipulations of the environments of participants?
   - ☐ Yes
   - ☐ No

6. Will the project involve collection of information or biospecimens that are individually identifiable?
   - ☐ Yes (subject identities are associated directly or indirectly through codes or can be readily determined by the information/biospecimens collected)
   - ☐ No

7. a. Will the project involve the secondary use of information or biospecimens?
      - ☐ Yes
      - ☐ No

   b. Which best describes the data that the investigator will access or receive for the project?
      - ☐ Data obtained without restrictions from a publicly available site or source.
      - ☐ De-identified data (all potential identifiers have been removed)
      - ☐ Directly identifiable data
      - ☐ Coded data → ***Answer 7c***

   c. For coded data, does the research team have access to the key that would allow linking the code to an individual's identity?
      - ☐ There is a written agreement or existing IRB-approved written policies and/or procedures that prohibit release of the key to the decipher code to MWU investigators under any circumstances. *A copy of this agreement or relevant policies/procedures **must** be included with this submission.*

☐ There are other legal requirements exist (such as HIPAA) prohibiting release of the key. (Explain: Click or tap here to enter text.)
☐ The investigators have access to the key.

d. Certain activities are specifically excluded from the federal definition of research (see 45 CFR 46.102(l)).

8. Check one or more of the following if all of the study-related activities fit into that category.
☐ Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
☐ Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
☐ Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
☐ Authorized operational activities (as determined by each federal agency) in support of intelligence, homeland security, defense, or other national security missions.

9. Is the project limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from or about students as part of routine class exercises or assignments and will not be disseminated or used outside of the particular course?
☐ Yes
☐ No

SECTION B: MWU ENGAGEMENT IN THE STUDY

1. Has another institution's IRB (or similar body) approved the study, determined that it qualifies for an exemption, or determined that it does not meet the definition of human subjects research?
☐ Yes → ***Attach documentation of the approval or determination***
☐ No

2. Will MWU receive direct federal funding through a grant, contract, or cooperative agreement for the proposed study?
☐ Yes
☐ No

3. As part of study-related activities, will MWU faculty, staff, or students interact or intervene with participants or with identifiable information or specimens?
*This includes, but is not limited to, such activities as performing invasive or noninvasive procedures, manipulating the environment, analyzing identifiable information or identifiable biospecimens, engaging in protocol-dictated communication or interpersonal contact, conducting interviews, or administering questionnaires. This does **not** include situations where subjects are only provided with or referred to prepared recruitment information or study materials (e.g., a MWU faculty, staff, or student provides a potential participant with a study information sheet or refers them to a website).*
☐ Yes
☐ No

4. Will MWU faculty, staff, or students obtain informed consent from participants for the proposed study?
☐ Yes

☐ No

5. Will MWU faculty, staff, or students obtain identifiable private information or identifiable biospecimens from any source for the purposes of the proposed study, even if there is no other direct interaction or intervention with subjects?
   ☐ Yes
   ☐ No

6. Will MWU faculty, staff, or students' interactions with participants be limited only to one or more of the following categories?

	Yes	***No***
Conducting activities that would be provided as part of routine care in a study where MWU is selected as a control site and does not administer any study intervention	☐	☐
Informing prospective participants about the availability of research	☐	☐
Providing prospective participants with information about the research but do not obtain consent or otherwise act as representatives of the investigators	☐	☐
Seeking or obtaining permission from prospective participants for investigators to contact them	☐	☐

SECTION C: CASE REPORTS, CASE STUDIES, OR CASE SERIES

Projects involving a limited number of subjects may be classified as a case report, case study, or case series and may not be human subjects research. Select all of the following that apply to the proposed study.

☐ The project is examining no more than 3 subjects.
☐ The project is a case report, case study, case series, or multi-chart review reporting patient condition, treatment outcome, or presentation that draws conclusions only about that participant or group and only in that specific context.
☐ The project does not involve investigation of a project currently regulated by FDA (including drugs, biologics, or medical devices).
☐ The project does not include data manipulation or include the use of statistical methods, such as subgroup comparison or compilation of observations in such a manner that might allow for generalization to a larger population.
☐ The project does not involve experimental intervention or a case series that incorporates statistics.
☐ The project does not offer incentives to participants (compensation, free treatments or diagnostic work, etc.).
☐ The project does not include any added interventions to enhance the case study (additional treatments beyond the standard of care, diagnostic work, etc.).

SECTION D: BRIEF STUDY PROPOSAL

1. Provide the name, degrees, e-mail address, and role of all additional individuals who will participate in this project. This includes participant recruitment, obtaining consent/assent, data collection, or data analysis.

Name and Degrees	***E-mail***	***Affiliation*** *(MWU college and department/program, or organizational name)*	***Role*** *(Co-investigator, student investigator, study coordinator, etc.)*

2. State the research objectives, questions, specific aims or hypotheses guiding the proposed study.

3. Briefly describe the background and significance of the proposed study.

4. Describe the study design and research procedures.
Include a description of the setting(s) in which the proposed study will take place. If applicable, include a description of procedures being performed for other non-research purposes (e.g., for diagnosis or treatment). If existing data are being obtained, include a list of all variables being obtained and used for research purposes. This list can be attached separately.

5. Briefly describe procedures that will be used to analyze data collected for the proposed study.
It may be helpful to discuss the analysis plan in relation to the research objectives, questions, specific aims, and/or hypotheses noted in Question 1 of this section.

6. Indicate the anticipated duration of the proposed study.

Start month/ year:
End month/year:

7. Describe the size and expected demographic make-up of the study sample (age, gender, race, etc.).
Include a description of any potentially vulnerable populations, such as children, pregnant women, human fetuses, neonates, prisoners, or cognitively impaired individuals, that may be included, as well as an explanation of the rationale for their inclusion.

8. Describe procedures for participant recruitment
Describe procedures for the recruitment of subjects including: (1) how potential subjects will be identified (school personnel, health care professionals, etc.), (2) how you will get the names and contact information for potential subjects, (3) who will make initial contact with these individuals (if relevant) and (4) how that contact will be done. If vulnerable subject groups, such as children, pregnant women, human fetuses, neonates, prisoners or cognitively impaired individuals, will be recruited describe any special recruitment procedures for these populations. Explain how you will access individuals for recruitment. If any special support, approval, or agreement will be needed to access specific populations (local medical practice, a school, etc.), explain how you will obtain those. ***Documentation of these must be submitted with this form (e.g., a letter of support from a medical office)***.