

OFFICE USE ONLY:

Determination #:

Received:

Determination Form

Determination of whether an activity constitutes Human Subjects Research as per the federal regulation (45CFR46).

INSTRUCTIONS:

1. **Faculty** should complete this form and submit with any applicable attachments to the Human Research Protection Office (HRPO) at humansubjects@ora.umass.edu.
2. **Students** should provide the completed application to their Faculty Sponsor for review and approval. The Faculty Sponsor should submit the form along with endorsement of the project or activity to the HRPO.
3. The HRPO will send you a notice of determination or will contact you, if needed, within three business days.

1. PROTOCOL DIRECTOR(S) (PD) INFORMATION:

PD Name:	Faculty Sponsor Name:
Department:	Department:
Affiliation:	Affiliation:
Email:	Email:

2. LOCATION:

Please state the location where this study will take place (i.e., online study, UMass Amherst, etc.):

3. COLLABORATION:

Please list collaborating institutions, if any, and describe their role:

4. PROJECT FUNDING:

Does external funding support this project?:

- No
- Pending * Please identify your anticipated funding source:
- Yes * Please identify your funding source:

** If funded, please attach a copy of any associated grant proposal(s).*

5. PROJECT INFORMATION:

Project Title:

Project Purpose:

Project Procedures:

Please describe how you plan to use the study results (overall intent i.e., publication, presentation at conferences, etc.):

Please describe the participant population (e.g., age range, gender, ethnic background, type of participant such as student, faculty, health care professionals, etc.), and approximate number of participants:

Please describe your recruitment procedures:

6. ATTACHMENTS

I have included copies of any project proposals (e.g., Honors or MA Theses, DNP projects, Dissertation Prospectus, etc.), as well as surveys/questionnaires, interview questions, etc. with this form **OR** this is Not Applicable to this project.

7. PD RESPONSIBILITIES AND ASSURANCES:

- I certify that the information provided in this determination form and all attachments is complete and accurate.
- I certify that the proposed project has not yet been done, is not currently underway, and will not begin until IRB determination and/or approval has been obtained.

8. PD SIGNATURE(S):

Name:

Date:

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The project does NOT need IRB review.

Date: _____ Initials: _____

Project DOES need IRB review.

Date: _____ Initials: _____

Not Human Subjects Research (NHSR)

Determination based on the following rationale:

1. The proposed project does not involve research that obtains information about living individuals [45 CFR 46.102(f)].
2. The proposed project does not involve intervention or interaction with individuals OR does not use identifiable private information [45 CFR 46.102(f) (1), (2)].
3. The proposed project does not meet the definition of human subject research under federal regulations [45 CFR 46.102(d)].

Human Subjects Research

Review Type:

Category:

1. Full Board _____
2. Expedited _____
3. Exempt _____

University of Massachusetts, Amherst (UMA) Faculty/staff/students NOT engaged in Human Subjects Research.

Determination based on all criteria below being met:

- UMass Amherst faculty/staff/students will not be involved in a direct intervention or interaction with human subjects of research.
- UMass Amherst faculty/staff/students will not obtain identifiable private information for the research.
- UMass Amherst faculty/staff/students will not be involved in the consent process.
- All data will either be de-identified (no-one is able to link the information back to identifiers) OR coded (key linking participant data/specimen exists but the key to the code will never be released to UMass Amherst Faculty/Staff).

NOTES: