

University of Southern Maine
Office of Research Integrity and Outreach
Request for Determination of Research Involving Human Subjects

Protocol # [automatically generated](#)

Investigator Information

1. Principal Investigator (PI) Name:
2. PI Last Degree Completed:
3. PI Student/Employee ID Number: [University of Maine System](#)
4. PI Email Address:
5. PI USM Affiliation: [Faculty, Staff, Graduate Student, Undergraduate Student, or Other](#)
6. PI Department: [\(Spell out acronyms.\)](#)

If applicable, Co-Investigator Information

7. Co-Principal Investigator (PI) Name:
8. Co-PI Last Degree Completed:
9. Co-PI Student/Employee ID Number: [University of Maine System](#)
10. Co-PI Email Address:
11. Co-PI USM Affiliation:
12. Co-PI Department:

If applicable, Advisor Information

13. Advisor Name:
14. Advisor Last Degree Completed:
15. Advisor Employee ID Number: [University of Maine System](#)
16. Advisor Email:
17. Advisor Department:

All student-conducted activities require a Faculty or Staff Advisor. The roles and responsibilities of an Advisor can be found on the ORIO website.

Start Date: [Estimated start date. Data collection cannot start prior to approval.](#)

End Date:

Background Information

18. What is the title of your project?
19. What is the purpose of the activity? [Please write a paragraph providing enough information for a reviewer to discern the activity. What is your hypothesis? What are you trying to prove/disprove? What are you trying to accomplish?](#)
20. What are the activities being conducted? [eMail supporting documents to USMORIO@maine.edu](#)
21. Who are the intended subjects?
22. Who is the intended audience?
23. Funding Source:
24. If there is a Business Associate Agreement (BAA), with which healthcare provider?
25. Are you using Maine Integrated Youth Health Survey (MIYHS) data?
<https://usm.maine.edu/sites/default/files/orio/IRB%20MIYHS%20data%20request.pdf>
26. Are you requesting a determination in order to fulfill W-9 form requirements?

W-9 Information - for Employees of University of Maine System

27. Who will be responsible for obtaining, securing, and disbursing compensation?
28. If participants were required to complete a W-9 form, how would it negatively impact your study?
29. How will you be compensating your study participants?
30. What is the total amount of compensation per participant?
31. On how many separate occasions throughout the study will a participant receive compensation?
32. How will you ensure a participant does not obtain more than \$600 in a calendar year resulting from participation?
33. How will compensation to participants be distributed?
34. Where will compensation be stored until it is dispersed?
35. What security provisions will be in place to prevent theft?

Is the activity Research?

According to the regulations at 45 CFR 46.102(l), research is "a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (Protection of Human Subjects 2017).

36. Is the activity an investigation? [Yes/No](#)

Investigation means a searching inquiry for ascertaining facts or a detailed or careful examination.

37. Is the activity systematic? [Yes/No](#)

Systematic means having or involving a system, method, or plan. (including the selection of subjects, decisions about what observations to record, and an interview process)

38. Is the activity designed to develop or contribute to knowledge? [Yes/No](#)

Designed means done with purpose or intent. Develop means to elaborate or expand in detail. Contribute means to be an important factor in. Knowledge means truth, facts, or information.

39. Is the knowledge generalizable? [Yes/No](#)

Generalizable means relevant beyond the population or program from which it was collected.

[If yes to any of the above, please elaborate:](#)

Is the Activity Non-research?

40. Is the activity scholarly or journalistic? [Yes/No](#)

Examples include oral history, journalism, biography, literary criticism, legal research, and historical scholarship.

41. Is the activity a public health surveillance activity? [Yes/No](#)

These activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

42. Is the activity a collection and analysis of information for a criminal justice agency?

[Yes/No](#) 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.

[If yes to any of the above, please elaborate:](#)

Does the Research involve Human Subjects?

This section will help to determine if the research is human subject research as defined in 45 C.F.R. 46.102(e).

43. Does the research involve obtaining information (or biospecimens) about a living individual? **Yes/No**

About means the information concerns the individual whose information is collected; the focus of the investigation is the opinions, characteristics, or behavior of the individual.

Biospecimen means material such as urine, blood, tissues, cells, DNA, RNA, and proteins.

If yes, please elaborate:

44. Does the research involve intervention with individuals? **Yes/No**

Intervention includes both physical procedures by which information or biospecimens are gathered and manipulation of the subject or the subject's environment that are performed for research purposes (for example, having subjects listen to music and then having them perform memory tasks in order to investigate the effect of music on memory).

If yes, please elaborate:

Intervention OR Interaction = Yes

45. Does the research involve interaction with individuals? **Yes/No**

Interaction includes communication or interpersonal contact between investigator and subjects.

If yes, please elaborate:

46. Does the research involve obtaining, using, studying, analyzing, or generating private information? **Yes/No**

Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

- 42.a Is the private information identifiable? **Yes/No**

Identifiable means the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

If yes, please elaborate:

47. Does the research involve obtaining, using, studying, analyzing, or generating identifiable biospecimens? **Yes/No**

Identifiable biospecimens means the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Other Information

48. Please include any additional information you would like to provide.

eMail any relevant documents to usmorio@maine.edu, such as:

Questionnaire/Survey

List of variables collecting

Introductory script/consent language

Recruitment materials

Obligations

49. PI Obligation: By checking the box below, I, **Primary Investigator** named above accept responsibility for the information provided. I understand that if it is determined that my project constitutes research involving human subjects I will be notified in writing and I am REQUIRED to submit an application for review with the IRB. The USM Assurance for the Protection of Human Subjects prohibits the start of any research involving human subjects (including recruitment of subjects) that has not been reviewed and approved or exempted by the IRB or its designee.

☐ I agree

50. **Advisor Obligation:** If applicable, by checking the box below, the Advisor named above attests that (s)he has read the information contained in this submission. The Advisor agrees to share with the student the responsibility for the ethical conduct of the project, to take an active role in the student activities, and to provide supervision for the duration of the project.

☐ I agree

How easy was it to use this Google Form? 1=Difficult 5=Easy

Any comments about the use of this Google Form?