**Request for Human Subject Research Determination**

**What is the purpose of the activity? text**

**What are the activities being conducted? text**

**Who are the intended subjects/participants? test**

-If your project includes a specific group or population, please elaborate in narrative.

**Who is the intended audience? text**

-How will the results be shared, with whom, and in what form?

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**If there is a Business Associate Agreement (BAA), with which healthcare provider? text**

**Are you using Maine Integrated Youth Health Survey (MIYHS) data? Y/N**

**Has this been reviewed by another IRB? Y/N**

 **If this project been reviewed by an IRB, provide context: text**

**Are you requesting a determination in order to fulfill W-9 form requirements? Y/N**

*-Incentive/payment to UMS employees.*

**If yes W-9**

Who will be responsible for obtaining, securing, and disbursing compensation? **text**

If participants were required to complete a W-9 form, how would it negatively impact your study? **text**

How will you be compensating your study participants? **text**

What is the total amount of compensation per participant? **text**

On how many separate occasions throughout the study will a participant receive compensation? **text**

How will you ensure a participant does not obtain more than $600 in a calendar year resulting from participation? **text**

How will compensation to participants be distributed? **text**

Where will compensation be stored until it is dispersed? **text**

What security provisions will be in place to prevent theft? **text**

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**Is the Activity Non-research?**

**Is the activity scholarly or journalistic? Y/N**

- *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.*

**Is the activity a public health surveillance activity? Y/N**

-*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. Such 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 (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).*

**Is the activity a collection and analysis of information for a criminal justice agency? Y/N**

-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.

**Is this activity Non-Research? Y/N**

***-****Did you answer yes to any of the 3 previous questions?*

**Does the project meet definition of "Research"?**

As defined by 45 CFR 46, **research** is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

**Is the activity an investigation? Y/N**

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

**Is the activity systematic? Y/N**

-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)

**Is the activity designed to develop or contribute to knowledge? Y/N**

-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.

**Is the knowledge generalizable? Y/N**

-Generalizable means relevant beyond the population or program from which it was collected, or universally applied/accepted, to other contexts or situations.

**Is this activity Research? Y/N**

*- Did you answer yes to any of the 4 previous questions?*

**If the project is research, does it meet the definition of "Human Subject" research?**

As defined by 45 CFR 46, a human subject is "a living individual, about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

**Does the research involve obtaining information (or biospecimens) about a living individual? Y/N**

-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.

**Does the project involve interaction with individuals? Y/N**

-Interaction includes communication or interpersonal contact between investigator and participant.

**Does the research involve intervention with individuals? Y/N**

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

**Does the project involve obtaining, using, studying, analyzing, or generating private information? Y/N**

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 (e.g., a medical record).***Consider***: If the project only involves data and/or specimens that were pre-existing, or collected for some purpose other than this project, consider the original source of the data/specimens, how they are provided to investigators, if the data/specimens are identifiable in any way to investigators, etc.

If yes, is the private information identifiable?

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

**Does the research involve obtaining, using, studying, analyzing, or generating identifiable biospecimens? Y/N**

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

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**HIPAA**

* *The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies to projects where Protected Health Information (PHI) is being obtained, used, or released/disclosed by a* [*Covered Entity*](https://privacyruleandresearch.nih.gov/pr_06.asp)*for the purposes of Research.*
* *Even if your project is Not Human Subject Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a* [*Covered Entity.*](https://privacyruleandresearch.nih.gov/pr_06.asp)
* *Protected Health Information (PHI) = health information + one or more of the* [*18 identifiers*](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#protected)

**Does this project involve obtaining, using, or releasing/disclosing identifiable PHI by a Covered Entity? Y/N**

See [HIPAA](https://usm.maine.edu/orio/wp-content/uploads/sites/361/2023/05/Cayuse-HIPAA-Section.pdf) Caysue form

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**Please include any additional information you would like to provide. Text box**

**Attach recruitment material(s), questionnaires or surveys, and consent language document(s), etc.**

*-Word or pdf copies are best. Links, such as Google or SharePoint cannot be accessed by external reviewers.*