**Marywood University – Institutional Review Board and Exempt Review Committee**

Immaculata Hall, 2300 Adams Avenue, Scranton, PA 18509

Phone: (570) 348-6211, x.2418 or Email: irbhelp@marywood.edu

 **DETERMINATION REQUEST** To determine if official IRB or ERC review is required

**INSTRUCTIONS: Complete this form and submit it at** [**www.irbnet.org**](http://www.irbnet.org)**.** The principal investigator must e-sign in IRBNet.

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| **TITLE OF STUDY** | *Click here to enter title.* |

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| **PRINCIPAL INVESTIGATOR (PI)** |
| **Name** | Click here to enter name. | **University Status**Select all that apply. If you are a student or unaffiliated investigator, identify a MU research advisor in the next section.

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| ☐ | Faculty (FT)  | ☐ | Undergraduate Student |
| ☐ | Faculty (PT/Adjunct) | ☐ | Doctoral Student (Ph.D.) |
| ☐ | Staff/Admin (FT) | ☐ | Doctoral Student (Psy.D.) |
| ☐ | Staff/Admin (PT) | ☐ | Unaffiliated |
| ☐ | Graduate Student |  |  |

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| **Telephone** | Click here to enter phone #. |
| **Email** | Click here to enter email. |
| **Department** | Click here to enter department. |
| **Personal Mailing Address** | Click here to enter address. |

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| **MU RESEARCH ADVISOR – For student or unaffiliated investigators** |
| **Name** | Click here to enter name. | **Email** | Click here to enter email. |
| **Telephone** | Click here to enter phone #. | **Department** | Click here to enter dept. |
| **University Status**  | ☐ Faculty (FT) ☐ Faculty (PT) ☐ Staff/Admin (FT) ☐ Staff/Admin (PT) |

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| **CO-INVESTIGATOR or RESEARCH PERSONNEL – Insert rows as necessary**  |
| **Name** | **Organization and Department** | **University Status**  | **Project Role**  |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. |

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| 1. **DETERMINING FIT WITHIN RESEARCH DEFINITION OR CLASSROOM GUIDELINES**

***Research*** is Federally defined under 45 CFR 46.102 (d) as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. |
|  | **YES** | **NO** |
| 1. **Is the proposed activity a systematic investigation?**A systematic investigation involves a prospective plan for examining a topic with intent to answer a specific question, testing a specific hypothesis, or developing a theory. The prospective plan incorporates quantitative or qualitative data collection and data analysis to answer the question. Examples may include, but are not limited to, observation, surveys, interview techniques, group comparisons, test development, etc.
 | ☐ | ☐ |
|  | **YES** | **NO** |
| 1. **Is the proposed activity designed to develop or contribute to generalizable knowledge?**Such projects are designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program, often through dissemination of results. The intent is to expand the knowledge base of a scientific discipline or other scholarly field of study. Results do not have to be published or presented to qualify an investigation as research. The intent to contribute to scholarly knowledge makes an activity research, regardless of what happens later.
 | ☐ | ☐ |
| 1. **Is the activity part of a dissertation, thesis, professional contribution, independent study, or other culminating experience that is typically referred to as research?**
 | ☐ | ☐ |
| 1. **Is the activity an assigned classroom project?** If yes, also answer letters a through c.
 | ☐ | ☐ |
| * 1. Will you share the results outside of the classroom setting (e.g., publish, present at a forum, or professional conference, etc.)? If yes, explain where. Click here to enter text.
 | ☐ | ☐ |
| * 1. Will you involve any individuals who are vulnerable to coercion or undue influence (e.g. children under 18, prisoners, those with impaired decision-making capacity, economically or educationally disadvantaged, etc.) or from a population that itself might pose increased risk?
 | ☐ | ☐ |
| * 1. Will you recruit anyone on campus through large, campus-wide list-serves (e.g. UG, Grad, Commuter, Resident, Faculty, MWAdmin, etc.)?
 | ☐ | ☐ |
| 1. **Does the activity involve journalism or documentary activities?**Such projects are limited to investigations and interviews that focus on specific events, opinions, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.NOTE**:** An application is required when journalists conduct activities normally considered to be scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys and/or interviews that are intended to test theories or develop models).
 | ☐ | ☐ |
| 1. **Does the activity involve oral history activities?**Such projects are limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings. NOTE**:** An application is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models or theories).
 | ☐ | ☐ |
| 1. **Does the activity involve quality improvement or assurance activities?**Such activities are specifically designed to assess or improve performance within a department, hospital or classroom setting. The intention is not to reach conclusions that can be applied universally, outside of the immediate environment where the project occurred, and the intention is also not to add to the field of study. While such results may be shared, any resulting publication or presentation should make it clear that it is QI/QA and not research.
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| 1. **DETERMINING INVOLVEMENT WITH HUMAN SUBJECTS**

***Human subject*** is a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. ***Interaction*** includes communication or interpersonal contact between investigator and subject. It may be online or via telephone rather than in person.***Private information*** includes 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).***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An ***identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. |
|  | **YES** | **NO** |
| 1. **Does the activity involve collection of information about living individuals?**
 | ☐ | ☐ |
| 1. **Does the activity involve** **an intervention, interaction, or observation of individuals, and use, study, or analysis of the obtained information or biospecimens?**  If yes, also answer a.
 | ☐ | ☐ |
| * 1. If yes, will you or your research team record information in such a manner that subjects can be identified by you or your team, directly or indirectly through links to them (includes deductive associations)?
 | ☐ | ☐ |
| 1. **Does the activity involve obtaining, using, studying, or analyzing existing information, records or biospecimens (secondary research)?**  If yes, also answer a and b.
 | ☐ | ☐ |
| * 1. If yes, will it be recorded in such a manner that you or your research team can identify subjects, directly or indirectly through links to them (includes deductive associations)?
 | ☐ | ☐ |
| 1. If yes, who will access it and record information?

☐ The PI, co-investigator, research assistant or research advisor☐ A 3rd party not affiliated with the project (not part of the research team with completed CITI training) |
| 1. **Will any activities involve identifiable use of private health information held by a covered entity and therefore subject to** [**HIPAA**](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html)**?** Note that HIPAA also covers decedents, and there are [18 HIPAA identifiers](https://cphs.berkeley.edu/hipaa/hipaa18.html).
 | ☐ | ☐ |

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| **PROJECT DESCRIPTION** |
| **Please provide a description of the planned activity.**Click here to enter a summary. |