**Marywood University - Exempt Review Committee**

Immaculata Hall, 2300 Adams Avenue, Scranton, PA 18509

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

 **EXEMPTION REQUEST APPLICATION**

**INSTRUCTIONS: Complete this form and submit it with supporting documents at** [**www.irbnet.org**](http://www.irbnet.org)**.** Before review may begin, your submission must be complete and contain all required e-signatures. Students and unaffiliated investigators must identify a Marywood research advisor, who must e-sign the submission.

**DO NOT COVERT THIS OR ANY OTHER DOCUMENTS TO .PDF FORMAT.**

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| **TITLE OF STUDY** | Click or tap here to enter text. |

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| **PRINCIPAL INVESTIGATOR (PI)** |
| **Name** | Click or tap here to enter text. | **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 or tap here to enter text. |
| **Email** | Click or tap here to enter text. |
| **Department** | Click or tap here to enter text. |
| **Personal Mailing Address** | Click or tap here to enter text. |
| [ ]  | **HUMAN RESEARCH TRAINING (CITI):** Check if you have taken the course and downloaded your completion **REPORT** (with modules and grades) from [CITI](https://www.citiprogram.org/). Add your report into your IRBNet user profile (one time) or into your submission (with each new study). The Human Research course is required. The Responsible Conduct of Research course is only required for specific Federal funding. Additional courses may be required for certain activities. See [Mandatory Training](http://www.marywood.edu/irb/detail.html?id=256737&crumbTrail=Mandatory%20Training&pageTitle=IRB:%20Mandatory%20Training&title=Mandatory%20Training) policy. |

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| **MU RESEARCH ADVISOR – For student or unaffiliated investigators** |
| **Name** | Click or tap here to enter text. | **Business Address** | Click or tap here to enter text. |
| **Telephone** | Click or tap here to enter text. |
| **Email** | Click or tap here to enter text. | **University Status**

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| [ ]  | Faculty (FT) | [ ]  | Staff/Admin (FT) |
| [ ]  | Faculty (PT/Adjunct) | [ ]  | Staff/Admin (PT) |

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| **Department** | Click or tap here to enter text. |
| [ ]  | **HUMAN RESEARCH TRAINING (CITI):** Check if your advisor has added a completion **REPORT** (with modules and grades) to his/her IRBNet user profile. Requirements are the same as for investigators. See [Mandatory Training](http://www.marywood.edu/irb/detail.html?id=256737&crumbTrail=Mandatory%20Training&pageTitle=IRB:%20Mandatory%20Training&title=Mandatory%20Training) policy. |

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| **CO-INVESTIGATORS or RESEARCH PERSONNEL – Insert rows if necessary.** |
| **Name** | **Organization and Department** | **University Status**  | **Project Role** Provide a description of their activities later in application. | **Completed Required Training?** |
| Click or tap here to enter text. | Click or tap here to enter text. | Choose an item. | Choose an item. | [ ]  |
| Click or tap here to enter text. | Click or tap here to enter text. | Choose an item. | Choose an item. | [ ]  |
| Click or tap here to enter text. | Click or tap here to enter text. | Choose an item. | Choose an item. | [ ]  |
| **Thesis or Dissertation Committee Members (Other than Advisor):** Names are requested in case they also serve on the IRB, so that we do not assign it for their review. CITI training is not required unless they are engaged in research activities (recruiting, obtaining consent, collecting data, analyzing identifiable data, etc.). | Click or tap here to enter text. | [ ]  |
| Click or tap here to enter text. | [ ]  |

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| **EXEMPTION CATEGORIES** |
| Based on activities, select **all** categories involved. Since this list is condensed, review our [Exemption Policy](http://www.marywood.edu/irb/detail.html?id=260244&crumbTrail=Exempt%20Review&pageTitle=IRB:%20Exempt%20Review&title=Exempt%20Review). While there are eight exemptions, categories 5 and 6 are uncommon. Categories 7 and 8 concerning broad consent are not shown because they are not being implemented at this time.  |
| **Category 1**[ ]  | Research conducted in established or commonly accepted educational settings that **specifically involves normal educational practices** that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| **Category 2**[ ]  | **Interactions involving** **educational tests** (cognitive, diagnostic, aptitude, achievement), **surveys, interviews or observation of public behavior** (including visual or auditory recording), if **(i)** recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **OR** **(ii)** any disclosure of responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. |
| **Category 3**[ ]  | **Benign behavioral interventions** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and if **(i)** recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, **OR** **(ii)** any disclosure of their responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. |
| **Category 4**[ ]  | **Secondary research (existing data)** **for which consent is not required** (i.e. no other laws require permission/consent) and which uses identifiable private information or identifiable biospecimens, but which: is recorded by the investigator in such a manner that subjects’ identities cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR which is conducted by, or on behalf of, a Federal dept. or agency using government-generated or collected information obtained for non-research activities, with additional, specific stipulations (review [Exemption Policy](http://www.marywood.edu/irb/detail.html?id=260244&crumbTrail=Exempt%20Review&pageTitle=IRB:%20Exempt%20Review&title=Exempt%20Review)) |
| **Category 5** [ ]  | Research and demonstration projects Federally- conducted or supported and designed to examine public benefit or service programs | **Category 6**[ ]  | Taste and food quality evaluation and consumer acceptance studies |

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| **SCREENING QUESTIONS** |
| **Will you include…?** | **YES** | **NO** | **N/A** |
| 1. Activities which pose more than minimal risk, where the anticipated probability and magnitude of harm or discomfort to subjects is greater than the risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?
 | [ ]  | [ ]  | **---** |
| 1. [Prisoners](http://www.marywood.edu/irb/detail.html?id=261733&crumbTrail=Prisoner%20Research&pageTitle=IRB:%20Prisoner%20Research&title=Prisoner%20Research) or those involuntarily confined or detained in an institution?
 | [ ]  | [ ]  | **---** |
| 1. Children – those under the age of majority in the activity’s jurisdiction, usually under age 18 (19 in NE and AL or 21 in MS)?
 | [ ]  | [ ]  | **---** |
| **IF YES**, will you employ surveys, interviews, observations where you participate in the observation or behavioral interventions (if no, exemption might be possible in certain circumstances)? | [ ]  | [ ]  | [ ]  |
| 1. Anyone located in the [European Economic Area](http://www.marywood.edu/irb/detail.html?id=bf39ee4c-826a-4660-8232-cbeaba794869&crumbTrail=General%20Data%20Protection%20Regulation&pageTitle=IRB:%20General%20Data%20Protection%20Regulation&title=General%20Data%20Protection%20Regulation) at the time of the research, along with yourrecording information in a manner considered identifiable under the [GDPR](http://www.marywood.edu/irb/detail.html?id=bf39ee4c-826a-4660-8232-cbeaba794869&crumbTrail=General%20Data%20Protection%20Regulation&pageTitle=IRB:%20General%20Data%20Protection%20Regulation&title=General%20Data%20Protection%20Regulation)’s parameters?
 | [ ]  | [ ]  | **---** |

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|  | **YES** | **NO** | **N/A** |
| 1. Deception or withholding or any study details from subjects to eliminate bias in the results? **NOTE**: Exemption allowed for Cat. 3, benign behavioral intervention with adults, but only w/ prospective agreement to the deception or withholding and debriefing afterward.
 | [ ]  | [ ]  | **---** |
| 1. Drugs, supplements, ingested items or foods, investigational devices, or biologics?
 | [ ]  | [ ]  |  **---** |
| 1. Collection of biological specimens (e.g., tissue, blood, plasma, urine, saliva, etc.)?
 | [ ]  | [ ]  |  --- |
| 1. Physical activities (exercise, muscular strength testing, etc.) or any procedures routinely employed in clinical practice (e.g. sensory testing, activity trackers, heart rate monitors, EEG, ultrasound, body composition, etc.)?
 | [ ]  | [ ]  |  --- |
| 1. **FOR** [**CATEGORY 2**](#Category2) or [**CATEGORY 3**](#Category3) **activities** in which you are also able to readily ascertain identities (directly or indirectly), will any disclosure of subjects’ responses outside of the research reasonably place them at risk of criminal or civil liability, or be damaging to their financial standing, employability, educational advancement, or reputation?
 | [ ]  | [ ]  | [ ]  |
| 1. **FOR** [**CATEGORY 4**](#Category4) **activities (secondary research / existing information or records):**
 |
| * 1. Will you record information in such a way that subjects will be directly (e.g., names, SSN,addresses, etc.) **OR** indirectly (e.g. key, client #, demographics, etc.) identifiable?
 | [ ]  | [ ]  | [ ]  |
| * 1. Willany student records be included?NOTE: Exemption prohibited when [FERPA](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html) requires written permission (consent) for release.
 | [ ]  | [ ]  | [ ]  |
| * 1. Are records health-related and held by a covered entity? If collecting any of [18 identifiers](https://cphs.berkeley.edu/hipaa/hipaa18.html), it might not be exempt if subject authorization is required. NOTE: See [HIPAA](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html).
 | [ ]  | [ ]  | [ ]  |
| **If you have checked YES to any of the above questions, STOP HERE.** Your project mostlikely does not qualify for exemption. Instead, apply to the IRB using an IRB application. |

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| **FUNDING AND CONFLICTS OF INTEREST** |
| 1. **Will your study receive funding?**

[ ]  Yes [ ]  No (Skip to letter F.) | 1. **If Yes, indicate type:**

[ ]  External – Federal [ ]  External – Private Grant [ ]  Other[ ]  External – State [ ]  Internal – Student/Faculty Award  |
| 1. **Funder Name**
 | Click or tap here to enter text. | 1. **Award Name**
 | Click or tap here to enter text. |
| 1. **Who or what organization will take responsibility for the project’s fiscal matters?**
 | Click or tap here to enter text. |
| 1. **Do you or any co-investigators, research assistants or advisors have a conflict of interest** (e.g. personal considerations which may or appear to compromise your professional judgment, financial stake in the research, etc.)?
 | [ ]  Yes [ ]  No  |

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| 1. **PURPOSE and LITERATURE REVIEW**
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| **In this section:**1. Clearlystate your study’s purpose.
2. Clearly describe your overall research question(s) or hypothesis.
3. Clearly describe the results of your review of existing literature. Include in-text citations when you reference, summarize, paraphrase, or quote from another source, e.g. (Smith & Jones, 2012) or “Smith & Jones (2012) found xxx.”
4. Providea complete reference list for any works cited for C.

Click or tap here to enter text. |
| 1. **SECONDARY RESEARCH – Use of existing records or materials to be collected for non-research purposes (e.g., medical records) – SKIP if not applicable.**
 |
| 1. **Record Holder Name** Attach Permission Letter
 | Click or tap here to enter text. | 1. **Approximate number of records or materials to be included**
 | Click or tap here to enter text. |
| 1. **Record Format**
 |  [ ]  Paper [ ]  Electronic [ ]  Biospecimen [ ]  Audio/Visual [ ]  Other |
| 1. **Are the records or specimens** **publicly available, meaning that anyone can easily access them without special assistance, payment, passwords, etc.?**
 | [ ]  Yes [ ]  No  |
| 1. **Will the record holder remove all identifiers before providing records or information to you or your research team, such that you can never re-identify them?**
 | [ ]  Yes [ ]  No  |
| 1. **If E is No, will YOU (or a co-investigator or RA) have access to the identifiable records or specimens yourself, but record your data without any identifiers or codes that link back to or may be associated with specific individuals?** NOTE: Secondary research cannot be exempt if directly or indirectly identifiable.
 | [ ]  Yes [ ]  No  [ ]  N/A  |
| 1. **Exact Location** In hard copy files, in provider’s computer database, on a website, etc. NOTE: If on a website, provide a URL to the site, and if available, an exact URL to the actual dataset
 | Click or tap here to enter text. |
| 1. **Describe the records or materials in more detail, such as:**
2. How you will decide which ones to include or exclude
3. What data points you or the record holder will extract. Attach a data collection sheet or spreadsheet.
4. A description of your relationship to those whose records you are accessing (e.g., case worker, teacher, etc.)

Click or tap here to enter text. |
| 1. **PARTICIPANTS (SUBJECTS) and RECRUITMENT – SKIP if no interaction, interventions or observation is involved.**
 |
| 1. **Describe your participants’ characteristics and inclusion or exclusion criteria. Include age range.**Click or tap here to enter text.
 |
| 1. **What is your intended number of participants?** Include both recruitment # and enrollment #.
 | Click or tap here to enter text. |
| 1. **What entity is allowing recruitment?** Attach Permission Letter
 | [ ]  MU [ ]  Other  | **Entity Name (if MU, name exact unit)**Click or tap here to enter text. |
| 1. **What is your role at the location?** Choose an item.
 | **If other, explain:** Click or tap here to enter text. |
| 1. **Describe your relationship to the population (e.g., case worker, teacher, etc.), if any. If a relationship exists, explain how you will reduce undue influence to participate.**

Click or tap here to enter text. |
| 1. **Who is recruiting?**
 |  [ ]  PI or Co-Investigator [ ]  Research Assistant [ ]  Other (May require training) |
| 1. **Recruitment Method(s)**Attach Advertisements
 | [ ]  Email [ ]  Postal Mail [ ]  Social Media [ ]  Snowball Sampling [ ]  Other [ ]  In Person [ ]  Telephone [ ]  SONA Advertisement [ ]  Flyer Hanging  |
| 1. **Provide recruitment detail.** If using social media, explain where, settings, etc. For instance, on Facebook, are you purchasing an ad? Are you posting from your personal account or a “page” created just for the research? Are you posting a flyer or text? Are you posting to your own wall or to an existing group? Do you have permission to post according to the group’s rules or from a group moderator? Will you disable or otherwise monitor comments?

Click or tap here to enter text. |
| 1. **How many times** **will you send emails, make phone calls, post to social media, etc**.?
 | Click or tap here to enter text. |
| 1. **INFORMED CONSENT**
 |
| An ERC informed consent form (formerly participant letter) is required of subjects or their legally authorized representatives (LAR) for most exempted studies. This is typical of interventions or interactions. Under exemption, subject signatures are NOT typically required to be collected on the form. Attach copies of all forms.  |
| **In Person or Postal Mail Presentation** | [ ]  | I will present subjects or their LARs with a hard copy informed consent form and have uploaded a copy with my submission. |
| **Online Presentation** | [ ]  | I will present subjects or their LARs with an electronic copy of the informed consent form at the beginning of an online survey, or via other electronic means. I have uploaded a copy with my submission. **NOTE:** For online surveys (e.g., REDCap, SurveyMonkey), **please do not attach two versions** of the informed consent form. One, stand-alone, .doc formatted document is sufficient. Once approved, you will place it before the survey on the survey platform. |
| **Telephone Presentation** | [ ]  | I will orally present informed consent to subjects or their LARs. I have uploaded a copy with my submission.  |
| **Informed Consent Not Required** | [ ]  | I am not seeking informed consent because I am conducting research with existing records or information (secondary research) and will not be collecting identifiers, creating codes, or making associations, and no additional consent requirements apply (e.g., FERPA, HIPAA, GDPR). |
| 1. **PROCEDURES**
 |
| 1. **Method Type**
 |  [ ]  Qualitative [ ]  Quantitative [ ]  Mixed Methods (Both) |
| 1. **Check all data collection methods** (not to be confused with recruitment procedure)**.**

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| [ ]  Survey – In Person  | [ ]  Interview – In Person  | [ ]  Focus Group  | [ ]  Other Describe in Activity Detail.  |
| [ ]  Survey – Survey Website | [ ]  Interview – Online (e.g. Skype) | [ ]  Observation of Behavior  |
| [ ]  Survey – Postal Mail | [ ]  Interview - Telephone | [ ]  Psych Laboratory Procedure  |

If using a web-based survey platform (REDCap, SONA, etc.), name it. If using SurveyMonkey, state whether it’s your own or a professor’s account. MU library’s account may not be used.**Activity location and any other detail about procedures:** Click or tap here to enter text. |
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|[ ]  **Self-Created:** | Attach a professional review form signed by an individual with a Master’s or higher in the field and who is not affiliated with your study |
|[ ]  **Standardized:** | Provide reliability and validity information from scholarly literature and any intervention details (e.g., Psychology computer exams with photos) |

1. **Check the type of instruments or interventions you are using.** Attach all instruments (no Internet links). Include any extra demographic questions, if applicable.
 |
| Click or tap here to enter text. |
| 1. **State (1) how you will analyze data AND (2) who is performing analysis.** Click or tap here to enter text.
 |
| 1. **If offering an incentive or compensation, explain the method and rationale.** If using gift cards, explain the type (VISA, Amazon, etc.) and whether or not you will mail a physical card or email a code.

Click or tap here to enter text. |
| 1. **State the approximate time commitment expected for participants.**  Click or tap here to enter text.
 |
| 1. **RISKS, BENEFITS, CONFIDENTIALITY & RETENTION**
 |
| 1. **Identify potential benefits to your field of study.** Click or tap here to enter text.
 |
| 1. **Only if they exist, identify potential benefits to participants (do not include incentives or compensation).**

Click or tap here to enter text. |
| 1. **Identify risks (psychological, social, financial, legal or physical) or discomforts.** State if no greater than minimal. If slightly more than minimal, state what actions you will take to reduce risks (e.g., referral to counseling resources).

Click or tap here to enter text. |
| 1. **Describe the measures you will take to protect participants’ identities and responses, or data obtained from private records or specimens.** Examples are disabling IP address collection on web-based survey platforms, collecting minimal data points (demographics) in a small and familiar population, or not collecting any identifiers.

Click or tap here to enter text. |
| 1. **Indicate when you anticipate that data collection and analysis will end.**
 | Click or tap here to enter text. |
| 1. **Will you share your data with anyone other than your co-investigators, research assistants, or research advisor?**
 | Choose an item.**With Whom?** Click or tap here to enter text. |
| 1. **How and where will you keep your records** (e.g., locked file cabinet in home, password protected computer, password protected memory stick or folder, etc.)**?**

Click or tap here to enter text. |
| 1. **How long will you retain records after closure (e.g. one month, indefinitely)?**
 | Click or tap here to enter text. |
| 1. **How will you destroy records?**
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| [ ]  | N/A – Keeping  | [ ]  | Paper Burning | [ ]  | Electronic Deletion |
| [ ]  | Paper Shredding | [ ]  | Erasure of AV Recordings | [ ]  | Other |

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| [ ]  | **By checking this box and e-signing my IRBNet submission package, I agree to all policies and procedures concerning human research and exemption, including:** * Submitting a closure report form at the completion of my research
* Submitting a check-in form if my research is still active at its one-year approval anniversary
* Submitting any changes for review and approval before implementation (Revision Request)
* Reporting of deviations from what was proposed or reporting serious events or unanticipated problems
 |
| **I will NOT begin any part of the proposed research until final approval is issued, with the exception of obtaining site permission (recruitment or data access permission letter from the location).** |