**MU ERC Informed Consent Form Template and Guide**

**INSTRUCTIONS: Use of this template is mandatory for exempt research involving informed consent.**

1. Remove ALL instructions on pages 1-2, including the above header. Begin document with ERCInformed Consent Form.
2. Remove ALL instructions within the body of the form, appearing in orange text (as keys) or in brackets. Retain page numbers.
3. Read the below chart. If the left column applies to your study, include what is indicated in the right column.
4. Do not include exculpatory language, which waives legal rights or releases anyone from liability for negligence.
5. Proofread your document, using your software’s spellcheck and readability statistics features. See [Readability Tips](http://www.marywood.edu/irb/consent-form-readability-tips.html).
6. Save the document in DOC format (no PDFs please).
7. If you are asked to make changes after IRB review, enable the track changes feature in your word processing software before making the changes. If you do not have this feature in your software, visit a campus or satellite campus’ computer lab. See [Track Changes Instructions](http://www.marywood.edu/dotAsset/0c826373-3df3-4764-9a6e-0bdca04e3a96.pdf).

 **If any items in the left column apply to your research, add what is indicated in the right column.**

|  |  |
| --- | --- |
| **ACTIVITY or POPULATION** | **ADDITIONAL LANGUAGE OR DOCUMENTATION REQUIRED** |
| 1. **Amazon Mechanical Turk (M-Turk or AMT)**
 | **Confidentiality**: * Your worker ID will only be used to pay you. It will not be stored with your responses.
* Your worker ID may potentially link you to your Amazon public profile page. This depends on the settings you chose for your profile. However, the investigator(s) will not access information from your public profile.
* Amazon may disclose worker information according to its Participation Agreement.

**Voluntary Nature:** If you wish to stop, you must return the HIT so that your work will not be rejected.**M-Turk Website:** To make sure that no penalty is made if they do not complete the procedures in the allotted time, add more time to your estimate. |
| 1. **Audio/Video Recordings**
 | **Procedures:** Mention that audio or video recording will take place, under what method (e.g. digital audio recorder, tape recorder), and who will transcribe, if applicable (e.g. the investigator, a transcriptionist). **Confidentiality:** If someone else is transcribing, include (1) who will access any recordings, and (2) when you will destroy recordings (e.g. recordings will be destroyed after they are transcribed). |
| 1. **Deception or Incomplete Disclosure** When giving incomplete or false information about purpose or procedures to obtain unbiased results
 | **Purpose:** Deception or incomplete disclosure may only be exempted with brief and benign behavioral interventions with adults if the subjects are informed that they will be unaware of or misled regarding the nature or purposes of the research. Therefore, add this to the purpose section and also state that they will be debriefed at the end of their participation.If this isn’t included, it cannot be exempted. |
| 1. **Funding**
 | **Top Section of Form:** Include the name of the entity providing funding.**Confidentiality:** State if you will share data with the funding entity, and to what extent (i.e. de-identified or aggregate data, etc.). |
| 1. **Internet or Web-based Transmissions** About 3rd Party Access
 | **Confidentiality:** Add, “No web-based action is perfectly secure. However, reasonable efforts will be made to protect your transmission from third-party access.” |
| 1. **Non-English Language**
 | After the English version is cleared, submit (1) the translated version and (2) a completed ***Translation Certification*** form. Review our [Non-English Speaking policy](http://www.marywood.edu/irb/detail.html?id=260746&crumbTrail=Non-English%20Speaking%20Participants&pageTitle=IRB:%20Non-English%20Speaking%20Participants&title=Non-English%20Speaking%20Participants). |
| 1. **Mandatory Reporting Requirements** (e.g. Abuse or Public Health)
 | **Confidentiality**: Add, “We may share your information with appropriate authorities if we learn \_\_\_ .” [requirements or plans for abuse or public health reporting]. |

 **REMOVE pages 1-2 entirely, including the header. Begin your form with the words “Exempt Informed Consent Form” as shown on the next page.**

**Exempt Informed Consent Form**

Title: [*Insert title of Research Project*]

**Principal Investigator (PI):** [Name and institutional affiliation - e.g. John Hu – Staff at Marywood University]
**Principal Investigator Contact Information:** [Phone number and email address]
**Co-Investigator(s):** [Name and institutional affiliation – Remove entire line if not applicable.]
**Research Advisor:** [Name and institutional affiliation – Remove entire line not applicable.]
**Research Advisor Contact Information:** [Phone number and email address – Remove entire line if not applicable.]
**Provider of Study Funding:** [Name of Funder – Remove entire line if not applicable.]

 **Invitation for a Research Study**

You are invited to participate in a research study about **\*** . You were chosen because you \_\*\*\_. Please read this form. Ask any questions you may have before agreeing to take part in this study.

[Only if applicable, include \*\*\* from the key below, here as a separate paragraph.]

[PLEASE DELETE THIS “KEY” SECTION, AND ALL BRACKETED OR KEY SECTIONS THROUGHOUT THE FORM BEFORE UPLOADING IT TO IRBNET.]

\* [Insert a simple statement about the study.]

\*\* [Insert how or why the person was identified - e.g. “because you are 18 years of age or older. You are also a student at Marywood University.” Be specific. Do not use “because you meet study criteria.”]

\*\*\* [If you have any specific inclusion or exclusion criteria, list them. Bullets are suggested.]

**Purpose – About the Study**

The purpose of this study is to \* .

\* [Insert a short purpose statement in clear and concise language. One to two sentences are usually sufficient.]

**Procedures - What You Will Do**

You will \* .

\* [Insert a simple explanation of all procedures involved, in a layperson’s terminology. If applicable, identify any procedures which might be experimental. Include the (1) location of procedures (2) duration - total subject time commitment (3) frequency, if more than once, and (4) assignment to groups, if applicable. If you are performing more than one procedure (e.g. interview and also records), state each. If using a control group, include a description. You may use bullets or a table if the procedures are complex.]

**Risks and Benefits**

The risks are no greater than the risks in daily life or activities. [Remove this if it doesn’t apply.]

A risk may be that \* . [Remove this if it doesn’t apply.]

\* [Insert any reasonably foreseeable risk/s or discomfort/s. Risks may be physical, psychological, social or economic. If there are risks, explain how they will be minimized. For example, if there’s a risk of slight distress, you might provide a counseling resource with contact information.].

A benefit may be that \_\*\*\_.

\*\* [Insert any benefits to the field of study or general knowledge. If applicable, insert any to the subject or others that may reasonably be expected from the research. Note that there does not need to be a direct or individual benefit to subjects. Do not include payments or incentives here, since they must not be weighed against risks.]

**Payment or Other Rewards**

You will receive \* . [Remove this statement if they will not receive a payment or reward.]

You will not receive a payment or reward. [Remove this statement if they will receive a payment or reward.]

\* [Include any specific payment or incentive. If offering a raffle award, name the award type (e.g. VISA, Amazon) and explain if it is a physical card or an electronic code. If awarding course credit, state how many, and also state an alternative means to earn the credit, such as an assignment arranged with their professor. If the study involves multiple visits, include a disbursement schedule which is prorated, in case someone withdraws before completing all visits].

**Confidentiality**

The records of this study will be kept private. Information used in any written or presented report will not make it possible to identify you. Only \_\*\_ will have access to the research records. Records will be kept in a locked file. Records will be kept for \_\*\* years. Then they will \_\*\*\*\_.

\* [Insert who will have access to records, such as the investigator(s), research advisor, transcriptionist, etc. If sharing data with another entity, state that in a separate sentence, and indicate whether or not identifiers will exist when shared or if you will remove them.]

\*\* [There is no minimum retention period for exempted studies, but you should still indicate a time period. If keeping indefinitely, state so.]

\*\*\* [Insert how they will be destroyed (e.g., deleted, shredded, etc.). If they are being kept indefinitely, delete this sentence, and instead explain if they will be de-identified (unless you never had identifiers).]

**Taking Part is Voluntary**

Participation is voluntary. Your decision whether or not to participate will not affect your current or future relationship with the investigator[s]. It will not affect your relationship with Marywood University. \_\*\_ You may withdraw at any time \_\*\* .There will be no penalty. To withdraw, \_\*\*\*\_. Your information will be \_#\_.

\* [If applicable, add any other affiliated entity, such as a recruitment site or site providing data, as another sentence.]

\*\* [If the information you collect will be anonymous to you, such as at a survey site, add “until you submit your answers” or something similar, so they know they cannot withdraw afterwards.]

\*\*\* [Insert how they may withdraw, such as “tell the investigator” or “close your web browser.” Do not make it difficult to withdraw. For instance, they should not have to write a letter.]

# [Insert if their information will still be use or if destroyed, and if destroyed, how.]

**Contacts and Questions**

If you have questions about this study at any time, contact the principal investigator or the advisor [Remove advisor if not applicable.]. His [Her/Their] contact information appears at the top of page one.

If you have questions related to the rights of research participants or research-related injuries (where applicable), please contact the Institutional Review Board at (570) 961-4782 or irbhelp@marywood.edu.

You Choose an item. a copy of this form to keep for your records.

**Statement of Consent**

By proceeding:

* You understand what the study involves.
* You have asked questions if you had them.
* You agree to participate in the study.