**Marietta College Institutional Review Board**

**PROPOSAL FORM FOR RESEARCH INVOLVING HUMAN PARTICIPANTS**

1. **Project and Author Information**

**Project Title:** Click or tap here to enter text.

**Contact Information**

 **Principal Investigator(s):** Click or tap here to enter text.

 **E-mail:** Click or tap here to enter text.

**Phone:** Click or tap here to enter text.

**List Any Co-Investigators with their Contact Information:** Click or tap here to enter text.

**Co-Author 1 Name:** Click or tap here to enter text.

**Co-Author 1 Email:** Click or tap here to enter text.

**Co-Author 2 Name:** Click or tap here to enter text.

**Co-Author 2 Email:** Click or tap here to enter text.

**Co-Author 3 Name:** Click or tap here to enter text.

**Co-Author 3 Email:** Click or tap here to enter text.

**Co-Author 4 Name:** Click or tap here to enter text.

**Co-Author 4 Email:** Click or tap here to enter text.

**Type of Project (check one and provide the necessary information):**

[ ]  Faculty Project

[ ]  Graduate Student Project

If Graduate student project, please list your faculty supervisor(s): Click or tap here to enter text.

[ ]  Capstone Project

If Capstone Project, please list your major and faculty supervisor(s): Click or tap here to enter text.

[ ]  Undergraduate Student Project

If Undergraduate Student Project; please list your faculty supervisor(s): Click or tap here to enter text.

[ ]  Class Project;

If Class Project, please list the course name, number, and instructor(s): Click or tap here to enter text.

[ ]  Other (specify):

**Date Submitted:\_\_\_\_\_\_\_**

**Anticipated Start Date (***\*Note:* Allow at least 2 weeks for review and revisions process):\_\_\_\_

**This Research Proposal is (check one):**

[ ]  **New:** If you are submitting a new application, first consult the checklist on Page 3 to determine whether you should submit a short or full review. Then, follow the directions on the appropriate form (full review form or the short review form).

[ ]  **Addendum** (additional factors or information need to be added to a previously approved submission): If you are submitting an addendum application, please include any additional information, surveys, or other paperwork that need approval, in addition to a brief explanation for the reason these additions are necessary.

[ ]  **Revision** (Changes have been made to a previously approved submission): If you are submitting a revision application, please include any changes to be made to the previously approved proposal and the reason the changes are necessary.

[ ]  **Renewal** (Project needs to extend past the approved expiration date): If you are submitting a renewal application, please complete this form and the renewal form found on the IRB Website.

Please submit an electronic copy as a **Word document** and one (1) hard copy with signatures to Alicia Doerflinger (ad001@marietta.edu), Mills Hall 405. Please sign the electronic copy with your initials.

Primary Investigator(s) Signature(s)

Author 1 Click or tap here to enter text.

Author 2 Click or tap here to enter text.

Author 3 Click or tap here to enter text.

Author 4 Click or tap here to enter text.

Date\_\_\_\_\_\_\_\_

Date\_\_\_\_\_\_\_\_

Date\_\_\_\_\_\_\_\_

Date\_\_\_\_\_\_\_\_

Author 5 Click or tap here to enter text.

Date\_\_\_\_\_\_\_\_

Click or tap to enter a date.

Date

Click or tap here to enter text.

DEPT

Click or tap here to enter text.

Faculty Advisor Signature

1. Please Answer the following questions to determine if you need a short review or a full review:
2. If you answer YES to ANY of the items, your proposal will undergo a FULL REVIEW. This means that the entire IRB committee will review the proposal.

If you answer NO to ALL of the above, your proposal will undergo a SHORT REVIEW. This means that 3-4 IRB members will review the proposal.

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| * person(s) under 18 years of age?
 | [ ]  | [ ]  |
| * prisoner(s) or person(s) awaiting trial?
 | [ ]  | [ ]  |
| * known pregnant woman/women?
 | [ ]  | [ ]  |
| * any other person(s) who are vulnerable to risks or are possibly not capable of giving informed consent (e.g., elderly, individuals with disabilities)?
 | [ ]  | [ ]  |
| * potentially painful or purposefully stressful activities/procedures?
 | [ ]  | [ ]  |
| * the extraction of blood or other bodily fluids?
 | [ ]  | [ ]  |
| * procedures which might be considered an invasion of privacy (e.g., questions about sexual orientation or sexual experience, drug/alcohol use, history of abuse, medical or psychological health history)?
 | [ ]  | [ ]  |
| * procedures that involve physical contact between researchers and participants?
 | [ ]  | [ ]  |

1. The following are categories of research involving human participants that may be submitted for review using the **SHORT REVIEW** process. Check the box for the category that best describes your planned research project.

|  |  |
| --- | --- |
| [ ]  | **Research within a classroom setting:** Research conducted in established or commonly accepted educational settings, **involving normal educational practices**, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods |
| [ ]  | **Anonymous tests or surveys:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or questionnaires, if information obtained is recorded in such a manner that participants **cannot be identified**, directly or through identifiers linked to the participants |
| [ ]  | **Tests and surveys that are not anonymous, interviews, and/or focus groups:** Research involving surveys or interview procedures, where the participants are legally competent. However, if **both** of the following conditions exist, then submission of the **Full Review Form** is required: * Responses are recorded in such a manner that the participants can be identified directly, or through identifiers linked to the participants
* The participants’ responses, if they became known outside of the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing or employability; or the research deals with sensitive aspects of the participants’ own behavior, such as illegal conduct, drug use, sexual behavior, or underage use of alcohol.
 |
| [ ]  | **Public officials:** Research involving survey or interview procedures, where the participants are **elected or appointed public officials or candidates for public office** |
| [ ]  | **Retrospective study of existing data or specimens:** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are **publicly available** or if the information is recorded by the investigator in such a manner that participants **cannot be identified**, directly or through identifiers linked to the participants |
| [ ]  | **Observation of public behavior:** Research involving the observation of public behavior in places where there is a recognized expectation of privacy. However, if **both** of the following conditions exist, then submission of the **Long Form** is required:* Observations are recorded in such a manner that the participants can be identified directly, or through identifiers linked to the participants
* The observations recorded about the participant, if they became known outside of the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing or employability; or the research deals with sensitive aspects of the participants’ own behavior, such as illegal conduct, drug use, sexual behavior, or underage use of alcohol
 |
| [ ]  | **Taste and food quality:** Research involving taste and food quality evaluation and consumer acceptance studies, when the following conditions exist: * Wholesome foods without additives are consumed, or
* A food is consumed that contains a food ingredient at or below the level and for use found to be safe by the FDA or approved by the EPA or the USDA, or
* Agricultural chemical or environmental contaminant is consumed at or below the level found to be safe by the FDA or approved by the EPA or the USDA
 |

1. **1. Will your participants read AND SIGN an Informed Consent Document?**

[ ]  **YES** [ ]  **NO**

1a. **If the answer is YES, follow the guidelines for an Informed Consent document.**

1b. **If the answer to #1 is NO, please provide a brief explanation:**

Click or tap here to enter text.

1. **INSTRUCTIONS FOR IRB PROPOSAL FOR RESEARCH INVOLVING HUMAN PARTICIPANTS**

**A. For new applications, please append a brief but descriptive proposal that includes the following information:**

*\*Note:* Please use LAYPERSON’S TERMS, as the committee is made up of a group of researchers, non-researchers, and community members with diverse backgrounds and expertise. Any technical terms must be explained.

1. **Project background (this is a brief literature review/foundational information on which your research project is based). You should address how the project relates to previous research in the area.**

 Click or tap here to enter text.

1. **Project objectives (what are the goals of this project? What outcomes will be achieved?)** Click or tap here to enter text.
2. **Project design (Is this qualitative research? Quantitative? Experimental?)**

Click or tap here to enter text.

*\*Note:* For any methods that are replicated/derived from another source, the original source must be cited

1. **State your hypotheses**

Click or tap here to enter text.

1. **In 5a-5c you will describe, in full, your methods. *\*Note:* please append** **all surveys, test examples, and pictures of equipment**.

5a. **List all materials you will use (this includes software, equipment, stimulus tasks, surveys, and tests; cite sources where relevant.):­**

Click or tap here to enter text.

5b. **Give details of all procedures and/or tests used for data collection methods during the investigation:**

Click or tap here to enter text.

5c. **Describe procedures for any audio and/or visual recordings as necessary:**

Click or tap here to enter text.

1. **What is required of the participants (include** **daily time frame & overall time frame**)?

Click or tap here to enter text.

1. In parts 7a-7d you will describe how and where recruitment will occur. *\*Note:* append letters of permission to use a space for research, as needed.

7a. **Specify on- or off- campus recruitment. *\*Note*: please append copies of all flyers, handouts, emails, or social media postings with your other testing materials and tasks.**

 Click or tap here to enter text.

7b. **If it is off campus, where will the research take place?**

Click or tap here to enter text.

7c. **If it is online, what software and platforms will be used to collect data?**

Click or tap here to enter text.

7d. **Include** **how many participants** **will be recruited and who will be recruited.**

Click or tap here to enter text.

1. **Include any inclusion and/or exclusion criteria (including an age range and other pertinent demographic information) for potential participants.**

Click or tap here to enter text.

***\*Note:* If you plan to include individuals** **under the age of 18 years, then you must complete the full review, otherwise please state in your proposal and within your informed consent document that participants must be at least 18 years of age to participate in your research.**

1. **Describe How and when informed consent will be obtained.**

Click or tap here to enter text.

1. **In your best estimation, are there any risks to participants in your study? (Please address physical, psychological, social, economic, legal, ethical, and moral risks, as needed.) If there are no risks, simply state that there are no risks in your proposal and within your informed consent document. *\*Note:* Becoming bored is not a risk.**

[ ]  **YES** [ ]  **NO**

10a. **If you answered “Yes” above, please describe the risk from the list above (or other) and estimate the severity & likelihood of each risk:**

Click or tap here to enter text.

10b. **If you answered “Yes” above, please provide any procedures or precautionary measures that will be employed to minimize the aforementioned risks or dangers.**

Click or tap here to enter text.

1. Methods by which confidential information is **obtained, stored, protected, and disposed**. **Any persons who will have access to the confidential information or individual data must be listed as researchers or faculty advisors within your proposal and within your informed consent document.**
2. **Will this study involve deception or misleading information to your participants?** [ ]  **YES** [ ]  **NO**

12a. **If the answer is YES, please include the following information: The nature of the deception & rationale for the deception**

Click or tap here to enter text.

12b. **If the answer is YES, please include the following information: The expected reaction or consequences (immediate or long term) that the deception may have on participants.**

Click or tap here to enter text.

12c. **If the answer is YES, please include the following information: The manner in which participants will be informed of the deception (i.e. debriefing procedures) *\*Note:* Please append the debriefing statement.**

Click or tap here to enter text.

**B. Append the certificate(s) for every researcher** from Marietta College Participants Training Course.

**GUIDELINES FOR INFORMED CONSENT DOCUMENTS**

* No investigator may involve a human being as a participant in research unless the investigator has obtained the informed consent of the participant or the participant's legally authorized representative, or unless the investigator has been granted permission from the IRB to omit informed consent.
* If **minors** are participants in the research project, **both parental consent and the minor’s assent are required**, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved.
* In all cases where an informed consent document is used, a copy must be offered to each research participant.

**INFORMATION THAT MUST BE WITHIN YOUR INFORMED CONSENT DOCUMENT**

* Title the document “Informed Consent Document.” The second line should be the title of the research study.

*\*Note:* If the title on your informed consent document differs from the title on this proposal form in order to prevent participant bias, then your study involves **deception**.

* **Name and contact information** for all investigator(s) and, for student projects, faculty advisor(s).
* A statement that the study involves research and an explanation of the purpose(s) of the research.

*\*Note:* If you do not explain the purpose of your research in order to prevent participant bias, then your study involves **deception**.

* A statement that the research study has been approved by the Marietta College Institutional Review Board. For the proposal, leave a space for the approval number. Provide the approval number on the Informed consent once it is available.
* A brief description of the procedures to be followed. Include description of tests, surveys, or procedures for audio and/or visual recording information when necessary.
* Information about the expected duration of the participant’s participation (including both daily and overall time frames).
* A description of any dangers or risks to participants in your best estimation. Please address physical, psychological, social, economic, legal, ethical, and moral risks, as needed, and estimate their severity & likelihood. Becoming bored is not a risk. If there are no risks, simply state that there are no risks.
* Any procedures or precautionary measures that will be employed to minimize the aforementioned risks or dangers.
* For research involving more than minimal risk, an explanation of any compensation and/or medical treatments available if injury or illness occurs as a result of participation in the study.
* A description of any benefits to the participant or to others which may reasonably be expected from the research (including course credit, monetary compensation, etc.).
* A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant (when appropriate).
* A statement describing the extent to which confidentiality of records identifying the participant will be maintained, and that all data will be used for research purposes only.
* A statement that participation is voluntary and that refusal to participate will involve no penalty, or loss of benefits to which the participant is otherwise entitled.
* A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
* Information about whom to contact for answers to questions or concerns about the rights of research participants: Dr. Alicia Doerflinger, Marietta College Institutional Review Board Chairperson, at ad001@marietta.edu or 740-376-4975.
* Spaces in which the participant will both print and sign their name, and write the date.

**If the IRB deems it appropriate, additional elements of informed consent may be required as follows:**

* Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.
* Any additional costs to the participant that may result from participation in the research study.
* A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.
* The approximate number of participants involved in the study.
* **If any research participants will be minors, then both a parental consent document (similar to the informed consent document) and minor assent document will be required.**

*\*Note:*Please see the attached example of an Informed Consent and a Debriefing statement.