**Marietta College Human Subjects Committee**

**PROPOSAL FORM FOR RESEARCH INVOLVING HUMAN PARTICIPANTS**

**Project Title:**

**Contact Information**

 Principal Investigator(s):

 E-mail:

Phone:

List Any Co-Investigators with their Contact Information:

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

[ ]  Faculty Project

[ ]  Graduate Student Project; please list your faculty supervisor(s):

[ ]  Capstone Project; please list your major and faculty supervisor(s):

[ ]  Undergraduate Student Project; please list your faculty supervisor(s):

[ ]  Class Project; please list the course name, number, and instructor(s):

[ ]  Other (specify):

**\*In order to check boxes within this form: double click on the box, select “Checked”, and click “Ok”.**

**Date Submitted:** **Anticipated Start Date:**

\*\*Allow at least 2 weeks for review and revisions process\*\*

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

[ ]  **New:** If you are submitting a new application, please append a brief proposal (outlined on Page 3 for a short review or Page 4 for a long review, please consult the submission guidelines on Page 2 to determine whether you should submit a short or long review). All items must be addressed in order for the proposal to be reviewed.

[ ]  **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 HSC website.

Please submit an electronic copy as a **Word document** and 1 hard copy with signatures to Jaclyn Schwieterman (sj004@marietta.edu) Sports Medicine Department, DBRC 16). Signatures are NOT required on the electronic copy.

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Primary Investigator(s) Signature(s)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

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Faculty Advisor Signature DEPT Date

|  |  |  |
| --- | --- | --- |
| **Does the proposed research involve:** | **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?
 | [ ]  | [ ]  |

**If you answered YES to any of the above, follow the instructions for a LONG REVIEW on Page 4.**

**If you answered NO to all of the above, follow the instructions for a SHORT REVIEW below.**

**INSTRUCTIONS FOR A SHORT REVIEW**

The following are categories of research involving human subjects that may be submitted for review using the **SHORT REVIEW**. Place a check mark next to 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 **subjects cannot be identified**, directly or through identifiers linked to the subjects |
| [ ]  | **Tests and surveys that are not anonymous, interviews, and/or focus groups:** Research involving surveys or interview procedures, where the subjects are legally competent. However, if **both** of the following conditions exist, then submission of the **Long Form** is required: * Responses are recorded in such a manner that the subjects can be identified directly, or through identifiers linked to the subjects
* The subjects’ responses, if they became known outside of the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing or employability; or the research deals with sensitive aspects of the subjects’ 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 human subjects 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 **subjects cannot be identified**, directly or through identifiers linked to the subjects |
| [ ]  | **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 subjects can be identified directly, or through identifiers linked to the subjects
* The observations recorded about the subject, if they became known outside of the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing or employability; or the research deals with sensitive aspects of the subjects’ 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. Will your subjects read AND SIGN an Informed Consent Document? ❒YES ❒NO**

If the answer to #1 is **YES**, follow the guidelines for an Informed Consent document on Page 5 and append a draft.

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

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

* Project objectives, design, hypotheses, and how the project relates to previous research in the area. 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.
* For any methods that are replicated/derived from another source, the original source must be cited.
* What is required of the participants (include **daily time frame & overall time frame**)?
* Details of all procedures and/or tests used for data collection methods during the investigation (please append **all surveys, test examples, and pictures of equipment**).
* Include procedures for any audio and/or visual recordings as necessary.
* How and where recruitment will occur (please append copies of all flyers, handouts, emails, or social media postings).
	+ Specify on- or off- campus recruitment.
	+ Include **how many subjects** will be recruited and who will be recruited.
	+ Include any inclusion and/or exclusion criteria (including an **age range** and other pertinent demographic information) for potential subjects. If you plan to include individuals **under the age of 18 years**, then you must complete the long 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.
* How and when informed consent will be obtained.
* Where data collection and/or testing will take place. Specify on- or off- campus locations and append letters of permission to use a space for research, as needed.
* 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 in your proposal and within your informed consent document.
* Any procedures or precautionary measures that will be employed to minimize the aforementioned risks or dangers.
* 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.**

**3. Will this study involve deception or misleading information to your participants? ❒YES ❒NO**

 If the answer is **YES**, please include the following information:

 •The nature of the deception & rationale for the deception

 •The expected reaction or consequences (immediate or long term) that the deception may have on participants.

 •The manner in which participants will be informed of the deception (i.e. debriefing procedures)

**4. Append the certificate(s) for every researcher** from theNational Institute of Health (NIH) “Protecting Human Research Participants” online web course & modules: <https://phrp.nihtraining.com/users/login.php>.

**INSTRUCTIONS FOR A LONG REVIEW**

**1. For New Applications, please include a brief but descriptive proposal that includes the following information:**

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**GUIDELINES FOR INFORMED CONSENT DOCUMENTS**

* No investigator may involve a human being as a subject in research unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative, or unless the investigator has been granted permission from the HSC to omit informed consent.
* If **minors** are subjects in the research project, **both parental consent and the minor’s assent are required**, when in the judgment of the HSC the children are capable of providing assent. In determining whether children are capable of assenting, the HSC 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 of the document “Informed Consent Document”, and the title of the research study. 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. 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 Human Subjects Committee.
* 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 subject’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 subject 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 subject (when appropriate).
* A statement describing the extent to which confidentiality of records identifying the subject 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 subject is otherwise entitled.
* A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
* Information about whom to contact for answers to questions or concerns about the rights of research subjects: Jaclyn Schwieterman, Marietta College Human Subjects Committee Chairperson, at sj004@marietta.edu or 740-376-4773.
* Spaces in which the subject will both print and sign their name, and write the date.

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

* Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.
* Any additional costs to the subject 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 subject’s willingness to continue participation will be provided to the subject.
* The approximate number of subjects 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.**