**Methodist University Institutional Review Board Submission Form**

***INSTRUCTIONS:***Please complete all sections of this document. Should you require additional space for a particular section of this document (e.g., additional collaborators etc.), submit an appendix for each and note it in the additional documents section of this document. Please use the same title or heading as is utilized in the IRB form. Submit all appendices with final submission.

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| **INVESTIGATOR INFORMATION** |

1. **Primary Investigator** *(Main Contact)*

First Name: Click here to enter text. Last Name: Click here to enter text.

Phone: Click here to enter text. Email: Click here to enter text.

1. **What are the qualifications of the principle investigator and/or faculty collaborators for conducting the study?**

Click here to enter text.

1. **All Collaborators** (If there are **more than 6 collaborators** attach an appendix titled **Appendix\_Collab** that provide the first name, last name, status, email, and roles for additional collaborator.)

First Name: Click here to enter text. Last Name: Click here to enter text. Status: Choose an item.

Email: Click here to enter text.

Role in Project *(check all that apply)*:

[ ]  Co-investigator

[ ]  Subject recruitment

[ ]  Data collection

[ ]  Data reduction/analysis

[ ]  Authorship

[ ]  Other (Please Specify): Click here to enter text.

First Name: Click here to enter text. Last Name: Click here to enter text. Status: Choose an item.

Email: Click here to enter text.

Role in Project *(check all that apply)*:

[ ]  Subject recruitment

[ ]  Data collection

[ ]  Data reduction/analysis

[ ]  Authorship

[ ]  Other (Please Specify): Click here to enter text.

First Name: Click here to enter text. Last Name: Click here to enter text. Status: Choose an item.

Email: Click here to enter text.

Role in Project *(check all that apply)*:

[ ]  Subject recruitment

[ ]  Data collection

[ ]  Data reduction/analysis

[ ]  Authorship

[ ]  Other (Please Specify): Click here to enter text.

First Name: Click here to enter text. Last Name: Click here to enter text. Status: Choose an item.

Email: Click here to enter text.

Role in Project *(check all that apply)*:

[ ]  Subject recruitment

[ ]  Data collection

[ ]  Data reduction/analysis

[ ]  Authorship

[ ]  Other (Please Specify): Click here to enter text.

First Name: Click here to enter text. Last Name: Click here to enter text. Status: Choose an item.

Email: Click here to enter text.

Role in Project *(check all that apply)*:

[ ]  Subject recruitment

[ ]  Data collection

[ ]  Data reduction/analysis

[ ]  Authorship

[ ]  Other (Please Specify): Click here to enter text.

First Name: Click here to enter text. Last Name: Click here to enter text. Status: Choose an item.

Email: Click here to enter text.

Role in Project *(check all that apply)*:

[ ]  Subject recruitment

[ ]  Data collection

[ ]  Data reduction/analyisis

[ ]  Authorship

[ ]  Other (Please Specify): Click here to enter text.

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| **PROJECT OVERVIEW** |

1. **Nature of Project** *(Select all that apply)*

[ ]  Faculty led research

[ ]  Student led research

[ ]  Staff led research

[ ]  New Project

[ ]  Ongoing project with no changes List previous IRB Project Number and date of approval:

Previous IRB #: Click here to enter text.

Previous Date of Approval: Click here to enter a date.

[ ]  Ongoing project with changes. List Previous IRB Project Number and date of approval:

Previous IRB #: Click here to enter text.

Previous Date of Approval: Click here to enter a date.

List changes from question 13: Click here to enter text.

1. **Research Subject/Title:**

Click here to enter text.

1. **In a brief statement, describe the purpose of this study.**

Click here to enter text.

1. **Does your project utilize a survey instrument?** *Please label your consent form as Appendix\_Survey and include in the list of attached documents, see Question 30.*

[ ]  Yes

[ ]  No

*If no, then skip to question # 8 (Methods and Procedures).*

* 1. **How will you collect the survey data?**

Click here to enter text.

* 1. **If someone begins your survey and does not complete it or does not answer all of the questions, what will you do with the data?**

[ ]  Include what has been inputted

[ ]  Delete the data

[ ]  Do not know

* 1. **If you are collecting survey data, where will you get the distribution list or e-mail addresses for your survey?** *(Select all that apply)*

[ ]  Office of Institutional Research

[ ]  Specific Department or Program (Identify): Click here to enter text.

[ ]  Students from a set of classes (e.g., ENG 1010, etc).

Identify the classes: Click here to enter text.

[ ]  I will use information from my work setting to distribute the survey.

Identify the workplace: Click here to enter text.

[ ]  Other: Specify Click here to enter text.

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| **Methods and Procedures** |

1. **Describe, in detail, your research methodology. The methodology must be detailed enough so that it can be replicated from your description. The description should include the study design, all procedures (sequentially), and devices (by name) to be applied to participants, and tools to be used during the analysis of the data**.

Click here to enter text.

1. **Proposed Data Collection Start Date** *(mm/dd/yyyy format)* Click here to enter a date.

*Reminder - You may not begin collecting data until the IRB has given a final designation for this project.*

1. **Proposed Data Collection End Date** *(mm/dd/yyyy format)* Click here to enter a date.
2. **Briefly describe expected and/or possible outcomes and a statement regarding the potential significance of this research project**

Click here to enter text.

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| **FUnding** |

1. **Describe any funding sources for this project including MU grants** *(e.g., MU Journey, Center for Research and Creativity, Leadership Fellow, Study Abroad)*

[ ]  Non-Funded Project (3)

[ ]  MU Grant: Identify all grant sources below (2): Click here to enter text.

[ ]  External Grant: Specify all grant sources for this project below (1): Click here to enter text.

1. **What is the status of the funding for this project?**

[ ]  Pending

[ ]  Recevied

1. **Does this project fall under the purview of any other Institutional Review Board or similar agency?**

[ ]  No

[ ]  Yes, Please identify the agency / institution below: Click here to enter text.

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| PARTICIPANTS AND RISK |

1. **Are you specifically studying or collecting data from any of the following groups:** *(Select all that apply)*

[ ]  MU students

[ ]  Incarcerated Individuals

[ ]  Individuals under 18 / minors

[ ]  Individuals with mental disabilities

[ ]  Pregnant Women

[ ]  Illegal Behaviors

[ ]  Fetuses

[ ]  Educationally disadvantaged individuals

[ ]  New drugs or medical devices

[ ]  Economically disadvantaged individuals

[ ]  Abortuses

[ ]  Vertebrae animals

[ ]  Other: Specify in the box below

Click here to enter text.

1. **What are additional inclusion criteria for participation in this research project?** *(e.g., gender, age range, surgical history etc.)*

Click here to enter text.

1. **What are exclusion criteria that would prohibit participation in this research project?**

Click here to enter text.

1. **What is the nature of the risk to individuals participating in your study?**

[ ]  Minimal risk - meaning that the risk of harm anticipated in the proposed research is not more likely than those risks encountered in daily life, or during routine physical or psychological examinations/tests

[ ]  More than minimal risk - risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life.

1. **Describe any potential risks to the participants in this research project? Describe the seriousness of these risks (risks could be physical, psychological, social, legal etc.) that may result from your experimental procedures or methods of obtaining, handling or reporting of data.**

Click here to enter text.

1. **Describe your emergency action plan** *(if applicable)*

Click here to enter text.

1. **Describe the procedure for post-study debriefing of participants** *(as applicable)***.**

Click here to enter text.

1. **Identify the nature of information to be deliberately withheld from participants and provide justification for the non-disclosure.** *(e.g., blinding of the participants etc.)*

Click here to enter text.

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| **SECURITY, COMPENSATION, AND CONFIDENTIALITY** |

1. **Describe all data security protections you propose to implement. Examples include: Encryption of data, separation of master list from data, password protection for computer, locked file cabinet, locked office door.**

Click here to enter text.

1. **Describe any potential benefits expected from this research project. Benefits can be direct or indirect to the participant or to the community.**

Click here to enter text.

1. **Describe any compensation (monetary or other forms of compensation) which will be provided to participants, and any conditions which must be fulfilled for participants to receive compensation.**

Click here to enter text.

1. **If the participants are to receive academic credit for research involvement, describe the alternative(s) available to them to earn equivalent academic credit if they choose not to participate.**

Click here to enter text.

1. **Describe explicitly how confidentiality of data will be maintained. If you plan to share your data this must be reflected in your methodology. According to federal regulations, all data must be retained for at least three years. Include a statement here acknowledging that data collected will be retained for at least three years in compliance with federal regulation.**

Click here to enter text.

1. **Please provide a list of names of experts in your field that can provide insight into the risk/benefits of this research project.**

Click here to enter text.

1. **Do you have a consent form for this project?** *Please label your consent form as Appendix\_Consent and include in the list of attached documents, see Question 30.*

[ ]  Yes

[ ]  No

**If yes, please e-mail a copy of the participant consent form (Appendix A) you plan to use to** **irb@methodist.edu** **along with this submission form. Note e-mail surveys should have a message that contains the same elements as a consent form. Please see the MU IRB website for further information.**

1. **If your project is a survey, please email a copy of your survey to the IRB AND your instructor. Copy of survey e-mailed to IRB and faculty supervisor (if student led research).**

[ ]  Yes

[ ]  No

1. **Do you have any brochures, flyers or other materials that you intend to use for participant recruitment?** *Please label your consent form as Appendix\_Recruit and include in the list of attached documents, see Question 30.*

[ ]  Yes

[ ]  No

**If yes, please e-mail a copy of any brochures, flyers, or other material that you intend to use to recruit participants to IRB. This includes letters, email messages, electronic communication of any sort and any other form of communication. Also send (email) a copy of recruitment materials to your faculty supervisor if student led research.**

1. **Please list and e-mail the IRB all relevant documentation that you feel the IRB will need to make a complete review of your project including; required appendices, literature review/background information, and methodology and/or protocol support documentation)**

**Documents:**

[ ]  Appendix\_Survey (if applicable)

[ ]  Appendix\_Consent

[ ]  Appendix\_Recruit

[ ]  Appendix\_Collab

**Other Documents** (list file name and brief description) *Example: Appendix\_Protocol, this document includes information that supports the methodology for the treatment group*)

Click here to enter text.

**FINAL STEP:**

**Save and email this IRB Project Submission and all required documents to** **irb@methodist.edu** **to begin the review process. Please plan ahead as the review process takes a minimum of 7-10 days even for exempt items. The review process can be much longer depending on the nature and expertise needed to review the project.**