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| **Messiah College** **Institutional Review Board***Check* [*www.messiah.edu/irb*](http://www.messiah.edu/irb) *for the latest version.***Request for IRB Review of Research Involving** **Human Subjects** | **LEAVE BLANK – FOR IRB USE ONLY** |
| **IRB Number:** | **Date Received:** |
| **Review Board Action:****[ ]  Certified as Exempt from Review (by Chair)****[ ]  Approved under Expedited Review (by Chair)****[ ]  Approved by the Full Board****Date:** |
| **IRB Representative Signature:** |

Messiah College institutional policy and federal regulations require that research projects involving human subjects be reviewed to consider:

1. the rights and welfare of the individual(s) involved
2. the appropriateness of the methods used to secure informed consent
3. the balance of risks and potential benefits of the investigation.

*Research* as defined in 45 CFR 46.102(d) consists of a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *Human subject* is defined in 45 CFR 46.102(f) as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

With the exception of classroom projects and research approved by an IRB at another institution, all research involving human subjects should complete this application.

**Please send this form with any supporting documentation in one combined electronic document to** **provost@messiah.edu****. Questions may be directed to** **provost@messiah.edu** **or to the current IRB Chair.**

# Section A: Applicant Information and Assurances (Please TYPE ALL SECTIONS)

|  |  |
| --- | --- |
| Title of Proposed Research |  |
| Researcher’s Name |  |
| Anticipated Start Date of Project |  | Anticipated Ending Date |  |
| Department |  | Box Number |  |
| Email |  | Phone |  |
| Co-Researcher(s), if applicable |  |
| Faculty Advisor, if applicable |  |
| Source of funding, if applicable |  |

Researcher Assurance:

I certify to the following:

 1. The research will not be initiated until written approval is obtained from the IRB.

 2. I have completed the appropriate training for human subjects protection through the NIH Office of Extramural Research (<http://phrp.nihtraining.com/users/login.php>) and a copy of my certificate is on file in the Provost’s Office. (Note other certification may be acceptable).

 3. The proposed research includes only those activities described in this application.

 4. I will obtain prior written approval for modifications to this project, including but not limited to changes in procedures.

 5. I will report to the IRB any unanticipated problems and adverse effects, as well as my findings during the course of the study that may affect the risks or benefits to the subjects.

 6. I agree to keep records of IRB approved documents and to retain research data with appropriate confidentiality.

 7. I understand that this research is subject to continuing review and approval by the IRB.

 8. The information on this application is correct.

 Date

Researcher #1 (signature)

 Date

Researcher #2 (signature)

Faculty Advisor Assurance: *(Student research only)*

I have examined the proposal, and I assume the roles and responsibilities required to oversee the conduct of this research, prevent harms and foster benefits to the subjects. I will report any significant and relevant changes in the research proposal, adverse events, or incidents to the IRB. The students and I completed the appropriate training for human subjects protection through the NIH Office of Extramural Research (link on MC IRB), and provided documentation of training to the IRB.

Faculty Advisor

 Signature Date

|  |  |
| --- | --- |
| Course # and Name (if applicable) |  |
| Faculty Advisor(s) |  |  |
| Student Researchers |  |  |
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**SECTION B: Checklist**

Please be sure that you have included all of the following material *before* you submit this form to the IRB. **Incomplete applications will be returned to the researcher before the IRB will review them.**

1. **[ ]** Completed and typed Form 20: Request for IRB Review of Research Involving Human Subjects
2. **[ ]** All researchers have signed form (as well as Faculty Advisor, if applicable)
3. **[ ]** Certificates for all researchers from NIH indicating completion of the *Protection of Subjects* training is included at the end of this protocol
4. **[ ]** Copies of all instruments used in data collections and/or statements directions given to participants
5. **[ ]** A copy of any recruitment material (include e-mail requests with subject line and body, letters, flyers, etc.)
6. **[ ]** A copy of the Consent Form (or rational for a waiver of written consent)
7. **[ ]** A copy of the Child Assent Form (if applicable)
8. **[ ]** A copy of the Parental/Legal Guardian Consent Form (if applicable)
9. **[ ]** Documentation of support for project if applicable (e.g. approval for usage of equipment, approval by appropriate personal at site for collaboration, etc.)
10. -The readability index of the informed or online consent has been checked and determined to be at the 8th grade level or below based on the Flesch-Kincaid readability index. The Flesch-Kincaid readability index for the informed or online consent is: \_\_\_\_\_\_\_\_\_\_

Note, guidance on how to determine the Flesch-Kincaid readability level and also on how to reduce it can be found in the document “Tips on Adjusting Readabiltiy” on the IRB web site.

1. -The anticipated start date is at least 30 days from the date of submission for Expedited Reviews (60 days for Full Board Reviews and International Research).
2. -For student researchers, faculty mentor has carefully reviewed the application to ensure that it is of professional quality and meets all the guidelines and expectations for a properly completed application based on the guidelines, comments, and FAQs provided on the IRB site.
3. -The faculty mentor has provided at least one round of detailed feedback on the application based on the adherence to the guidelines presented on the IRB website, the student researcher has made revisions based on such feedback, and the faculty mentor has reviewed those revisions.

Note, incomplete or unsuitably completed applications will be returned without further review until the application has been suitably revised and completed.

**Briefly, but completely, answer the following questions. *[Please type your information into this Word document.]***

**Section C: Project Description**

1. Provide a *brief* description (250 words or less) of the purpose of the study, hypothesis(es) if applicable, research question(s), and a description of the research procedures in lay language, paying special attention to what will happen to participants.
	1. Purpose of the Study:
	2. Hypothesis(es):
	3. Research Question(s):
	4. Summary of Study Procedures: (*This will be expanded in Section C-4*)

2. **BACKGROUND:** Briefly describe the rationale for the study from your literature review. Provide references at end of application.

1. **PARTICIPANTS:**
	1. Target Population: (*Check all that apply*)

**[ ]** Adults (18 years of age or older)

**[ ]** Minors (Less than 18 years of age)

**[ ]** Patients in health care facilities (inpatient or outpatient)

**[ ]** Pregnant women or fetuses

**[ ]** Non-English speaking subjects

**[ ]** Persons who may be compromised in their ability to make decisions. (For example: cognitively impaired, those with psychiatric disorders, organic impairment, such as dementia, developmental disorders, such as learning disabilities or mental retardation, persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps.)

**[ ]** Prisoners, parolees, or incarcerated persons

**[ ]** Students at Messiah College

**[ ]** Students at other schools: (identify schools)

**[ ]** Study will take place overseas: (country)

 **[ ]** Other (please identify):

* 1. Anticipated Sample Size: N =

[*If the sample is composed of groups, provide the anticipated number per group as well.*]

* 1. Inclusion Criteria: [*List criteria for participation in the study related to your target population. For example: sophomore college students, able to read and write in English*]
	2. Exclusion Criteria: [*List criteria for exclusion from study participation. For example: under age 18 years, certain medical conditions that would confound study results or increase risk.* ***If certain racial/ethnic groups, or genders will be excluded, the rationale for exclusion must be justified****.*]
	3. Recruitment: [*Discuss how participants will be recruited to be in the study. Include any recruitment materials, e.g.: posters, announcements, flyers, email communication- including subject line and body of text.*]
1. **STUDY PROCEDURES:** [*Describe each of the study procedures in detail, expanding on info from summary in 1.4. Please attach surveys, interview questions, focus group questions, or other instruments that will be used in the research.*]
	1. Study Design: Please identify the type of study design

**[ ]** True Experimental Design: Randomized Controlled Trial

**[ ]** Quasi-Experimental Design: Intervention study without randomization

**[ ]** Non-Experimental Design:

**[ ]** Case-Control

**[ ]** Comparative

**[ ]** Correlational

**[ ]** Descriptive

**[ ]** Survey

**[ ]** Qualitative Design:

**[ ]** Case Study

**[ ]** Ethnography

**[ ]** Focus Groups

**[ ]** Grounded Theory

**[ ]** Historical Analysis

**[ ]** Phenomenology

* 1. Type of Data: (*check all that apply*)

 **[ ]** Interviews

 **[ ]** Focus Groups

 **[ ]** Questionnaires or surveys

 **[ ]** Existing data banks, archives or documents not collected for research purposes

 **[ ]** Functional measurements, physiological measurements, blood samples

 **[ ]** Observations

 **[ ]** Public records

 **[ ]** Educational Tests (e.g.: Cognitive, Aptitude, Achievement)

 **[ ]** Other (list):

* 1. Study Instruments: [*List instruments and provide citation for instrument or indicate if researcher developed. Remember to attach a copy of all instruments*.]
	2. Study Procedures, including location, sequence of events, and time required for study procedures:
1. **POTENTIAL RISKS TO PARTICIPANTS**: [*select ALL of the potential risks involved in your study*]

**[ ]** Use of deceptive techniques

**[ ]** Use of private records (such as educational or medical records)

**[ ]** Manipulation of psychological or social state (such as psychological stress, sensory deprivation, social isolation)

**[ ]** Probing for personal or sensitive information in surveys or interviews (such as private behaviors or employer assessments)

**[ ]** Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading

**[ ]** Possible invasion of privacy of subject or subject’s family

**[ ]** Social or economic risk (reputational, cultural, employability, etc.)

**[ ]** Identification of child, spousal, or elder abuse

**[ ]** Identification of illegal activity

**[ ]** Risk of injury or bodily harm

**[ ]** Other risks (please specify):

**[ ]** There are NO identifiable risks to any participants enrolled in this study.

**All risks/harms must be disclosed in the consent form.**

* 1. Describe the steps that will be taken to minimize risks or harm to protect the welfare of study participants. [*Include a description of how you will handle an adverse or unexpected outcome that could potentially be harmful (eg: suicidal ideation);* *If any deception, i.e., withholding of complete information, is required for the validity of this research, explain why this is necessary, and attach debriefing statement - how and when the participants will be told the true purpose of the research and the reason for the deception.*]

1. **POTENTIAL BENEFITS TO PARTICIPANTS:** [*Describe the potential benefits that may be gained by any individual participant, as well as benefits that may accrue to society in general as a result of the planned work. If “none”, state “none”.* ***Remuneration/compensation is NOT a benefit****.*]

1. **REMUNERATION/COMPENSATION:** [*Explain whether and/or how participants will be compensated for participation in the study, e.g.: cash, gift certificate, required course credit, extra course credit, etc.* ***If participation is required for a course, an alternate assignment for the same point value must be available for those students who choose not to participate.***]
2. **Anonymity and CONFIDENTIALITY:** [*Procedures to protect the identity and information of each study subject]*
	1. Will the identity of your study subjects be anonymous? [*The study subject gives no personal information about himself/herself and should not be asked for specific personal information that would give his/her identify away. Researcher CANNOT link individuals with the data they provided*.]

**[ ]** Yes

**[ ]** No

* 1. If not anonymous, will the identity of your study subjects be confidential? [*The study subject will need to provide some personal identifiers – see below- about himself/herself to whoever is conducting the test, project, or investigation.  This information is NOT to be given to anyone not involved in the project, testing site, or organization.* *Data CAN be linked to a specific individual, but this will not be revealed to anyone outside of the study.*]

**[ ]** Yes

**[ ]** No

How will you assure confidentiality?

* 1. Check any of the personal identifiers that the research team will collect or have access to:

**[ ]** Name

**[ ]** Date of birth

**[ ]** Mailing or email address

**[ ]** Phone or fax numbers

**[ ]** Social Security Number

**[ ]** Medical records

**[ ]** License, certificate or vehicle ID

**[ ]** IP address

**[ ]** Photos/images/audio recording

**[ ]** Other unique identifiers:

**[ ]** No member of the research team will have access to any personal identifiers.

* 1. How will data be stored to ensure privacy?

**[ ]** Electronic data:

**[ ]** Paper data:

**[ ]** Informed Consents/Assents/Parental/Guardian Permission forms:

**[ ]** Other: [please explain]

* 1. Who will have access to the data?

8.6 Under current Health and Human Services requirements, research records must be maintained for at least three years. Records may be preserved in hard-copy, electronic or other media form, and must be accessible for audit purposes. Records for completed projects should be stored in secure locations on campus with the same care used when the project was active.

How long will the data from this study be kept?

**[ ]** 3 years

**[ ]** Specify time frame if less than or greater than 3 years [please explain]

* 1. Destruction of human subjects research records should be performed in a fashion that protects the confidentiality of the research subjects. How will data from this study be destroyed?

**[ ]** Electronic data:

**[ ]** Paper data:

**[ ]** Informed Consents/Assents/Parental/Guardian Permission forms:

**[ ]** Other: [please explain]

1. **WITHDRAWAL FROM THE STUDY:** [*Include a statement allowing voluntary withdrawal from the study without prejudice. If remuneration/compensation is provided, discuss whether or not subjects will still receive this if they terminate before completion of the study. If course credit is awarded for study participation, identify if credit will still be given if the study subject withdraws. Discuss what will happen to the data from subjects who withdraw.*]
2. **INFORMED CONSENT**: [*If you are using a signed consent/assent/permission form, please attach a copy. If you request a waiver of documented consent, please indicate and explain how you will communicate participants’ rights and document their understanding. An internet-based survey may request a waiver of documented informed consent (completing the survey signifies consent), but attach a copy of the email or initial web page that indicates how you will communicate participants’ rights.* *Obtaining readability index is found on the MC Square IRB site.]*
	1. Will you use a written informed consent document?

**[ ]** Yes. Readability index:

Describe how the researcher will obtain the informed consent:

**[ ]** No, I am seeking a waiver of written informed consent. EXPLAIN:

* 1. Will you obtain a written assent for children and individuals under 18?

**[ ]** Not applicable

**[ ]** Yes. Readability index:

Describe how will you obtain written assent:

**[ ]** No, I am requesting a waiver of written assent. EXPLAIN:

* 1. Will you obtain written parental or guardian permission for children and individuals under 18?

**[ ]** Not applicable

**[ ]** Yes. Readability index:

Describe how you will obtain permission:

**[ ]** No, I am requesting a waiver of written assent. EXPLAIN:

**11.** **DISSEMINATION OF RESERCH FINDINGS**: [*Please check all that apply*.]

**[ ]** Classroom presentation at Messiah College

**[ ]** Other presentation/poster at Messiah College

**[ ]** Presentation/poster at a workshop or conference (outside Messiah)

**[ ]** Publication (please describe):

**[ ]** Other (please describe):

1. **FINANCIAL CONFLICT OF INTEREST DISCLOSURE:**

 Do faculty on this project, or their spouses or dependent children, have any significant financial interests that are reasonably related to this research?

**[ ]** No

**[ ]** Yes. Please describe: