# Monmouth University Human Research Protections Program

# Institutional Review Board

**INSTRUCTIONS: Application for Review of Human Subjects Research**

1. Copy and paste all documents associated with your research to the end of the IRB application template. Documents that should be included, as applicable are:

* **Informed Consent Document(s)** -See forms and templates tab at [www.Monmouth.edu/irb/hrpp/new-submission-forms-and-templates/](http://www.Monmouth.edu/irb/hrpp/new-submission-forms-and-templates/) for templates to be used for these document
* **Study Materials** (*Please include everything that a participant will see or experience such as: recruitment material, manipulations, questionnaires, surveys, interview questions, demographics, etc.*)
* **Debriefing Materials**-see forms and templates tab at [www.monmouth.edu/irb/hrpp/new-submission-forms-and-templates/](http://www.monmouth.edu/irb/hrpp/new-submission-forms-and-templates/) for the debriefing template
* **IRB Approval from participating institutions or** [**organizations**](https://www.monmouth.edu/irb/hrpp/new-submission-forms-and-templates/) **other than Monmouth University**
* [**Off campus research/contact verification form**](https://www.monmouth.edu/irb/hrpp/new-submission-forms-and-templates/)
* **CITI Certificate:** All PIs, Co-Is and research assistants must have completed human research protections training in order for applications to be approved. Individuals must complete the CITI training requirement and attach the completion report to the application. See current CITI training requirements at <https://www.monmouth.edu/irb/training-requirements/>.

2. The completed application and supporting materials must be emailed as **a single attachment and as a Word document** to the IRB ([irb@monmouth.edu](mailto:irb@monmouth.edu)). Please include the PI’s last name (and Co-I last names, if applicable) and date in the Subject line of the email, such as Subject: **“(Merckx) (Diana) IRB Application 01.25.2021”.** It is important to include the date in the title of your document since most researchers have several versions of the IRB application. It is also a helpful way to stay organized throughout the process, especially if the IRB requests revisions. A friendly suggestion is to save the version number and date in the footer of the application. For example “(v.1 01.25.2021)”

3. **Please note that PIs must be a full-time faculty member or administrator. Undergraduate students and graduate students cannot serve as PI. They are permitted to serve as Co-Investigators with a full-time faculty members as PI. Adjuncts or visiting faculty may serve as a Co-Investigator only if the Department Chair and School Dean agree and there is a full-time faculty member as PI. Individuals not affiliated with MU may serve as Co-I with a full-time faculty member or administrator serving as PI.**

4. For Classroom Projects (including Activities for Student Scholarship Week) **that do not include undergraduate thesis, honors’ thesis, master’s thesis, dissertation or doctoral capstone projects,** please submit the **Determination of Human Subjects Research Checklist for Institutional Review** to the IRB for further guidance on whether an IRB application needs to be submitted to the IRB for review and approval.

5. Please email [irb@monmouth.edu](mailto:irb@monmouth.edu) with any questions about completing/submitting your IRB application.

**Please delete this page prior to submitting your application.**

# Monmouth University Human Research Protections Program

# Institutional Review Board

E-mail: [**irb@monmouth.edu**](mailto:irb@monmouth.edu)

**Application for Review of Human Subjects Research**

**V.01.27.2023**

**A. IDENTIFYING INFORMATION (Note: PI must be full-time faculty member or administrator.)**

# Principal Investigator Contact Information:

Name(s):  Address:

Phone Number: E-mail:

1b**.** Co-Investigator(s) Contact Information:

Name:  Address:

# Phone Number: E-mail:

2. a. Research Assistants (this may be students or other personnel):

Name:  E-mail:

Name:  E-mail:

Name:  E-mail:

# 3. Department and School of Principal Investigator:

# 4. Title of the Study:

5. Research Category: (Please check all that apply)

# Faculty research Undergraduate Thesis Research from another institution

Dissertation Undergraduate student research Graduate Thesis

Honors thesis Undergraduate independent study Graduate Student Research

Doctoral Program Capstone Project Other, please specify: \_\_\_\_\_\_\_\_\_\_\_

\*If this is dissertation research, please provide the name and email of the Chair of your dissertation committee:

Name:  Email:

6. Please provide information concerning the funding sources for this research.

N/A (un-funded)

Federal Government\*             Other Government (State, Local)

Foundation                               Departmental/Unit Funds

Other:  

Grantor/Sponsor Name:

\*If Monmouth University is the awardee of a federal grant that supports this research, a copy of the grant must be included with your submission.

**B. Required ETHICS Training AND COMMON RULE STANDARDS**

### I have attached a current CITI Training [Completion](https://www.monmouth.edu/irb/training-requirements/) Report for everyone on the research team: Yes No

2. Will participants under 18 years of age be studied?  Yes  No

3. Will information be recorded without identifiers (no participant identifiers or codes that can be used to re-identify subjects will be recorded)?  Yes  No

If No, provide a justification for recording identifiers:

4. Will information be recorded that could damage participants’ employability, reputation, financial standing, educational advancement, etc. or place them at risk for criminal or civil liability if it were to be known outside of the context of research (e.g., sensitive information?)  Yes  No

5. Is it possible that the topic of the investigation or content of research activities may be offensive or embarrassing or upsetting to the subjects?  Yes  No

6. Does this study involve any deception and/or withholding of information about the nature of the study?

Yes  No

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**C. RESEARCH PROJECT DESCRIPTION**

1. Purpose of the Study (*What is the central research question and/or hypothesis that this study examines? What is the goal/objective of this study?*). This should be no longer than 120 words.
2. **a. Brief Rationale for the Study (*This section is your opportunity to educate the IRB about your project since the IRB may not be familiar with your topic. W****hy is this study needed? How does it fit in with existing research? Provide citations for any referenced material*. *Please provide in text citations for at least two references here to support C.1/purpose. What new knowledge will this study potentially add? For Ed.D. students, or any research being conducted in the educational setting, please include the citation for curriculum standards here and include the standard as well-if applicable.***)** *Applications should be written in lay terminology so that those who may not be as familiar with the terminology as you can clearly understand the need for your study.*

2.b. References for Brief Rationale. Please put the references for the above cited material (at least two references)

1. Research Design/Method (*e.g., Experimental; Quasi-Experimental; Comparative (specify the number of groups); Correlational; Predictive Model; Psychometric Testing of an Instrument; Phenomenological; Ethnography; Grounded Theory; Case Study; Survey research; secondary data analysis etc.)*:
2. **Plan for Data Analysis** (*What statistical test(s) will you use (be specific)? If qualitative, please describe the planned data analyses, such as descriptive or inferential statistics used to test hypotheses, if content analysis, what method are you using? How will you determine reliability? Please describe)***:**

### D. SAMPLING METHOD AND PARTICIPANT REQUIREMENTS

1. Sampling Method (*e.g., random, convenience, purposive, snowball, etc.*):
2. Affiliation of Participants/ Sampling Frame(*e.g., Monmouth students, institution, hospital, general public, members of a listserv etc.*):

### Participant Characteristics (*i.e., list sex, age range, and projected number of participants. Please provide any inclusion/exclusion criteria. If vulnerable subjects are recruited, explain why their inclusion is necessary*):

1. What is the population from which you will select participants for the study?

Please mark an X in all appropriate box (es):

MU Students  Non-English Speaking Persons

MU Employees  Physically Disabled

General Public Mentally Disabled

Pregnant Women  Prisoners  
  Children/Minors  Economically Disadvantaged

Institutionalized Persons  Educationally Disadvantaged

Critically or Terminally Ill  Elderly

Other, please specify:

5.a. Access to Participants: *Describe how will you gain access to participants? Who is granting you access to the participants?*

5.b *Will you use the Department of Psychology (SONA) participant pool\*?*  *YES*  *NO*

*\*A participant pool is a system through which MU students participate in research projects being conducted by faculty and students in the Department of Psychology.*

5.c. Are you an instructor collecting data in your own class?  YES  NO

*It is important to note that the instructor cannot be present when students choose whether to participate or when data are being collected. Protections must be put in place to protect students from undue coercion of Instructors who have control over students’ grades. (i.e., instructor will not have access to who participated in the study until after grades have been submitted).*

Initial here: to show that you will be out of the room while students agree to participate AND during data collection.

5.d. Are you using emails or social media platforms to recruit participants?  YES  NO

If YES, *how, where, from who are you getting emails from or gaining access to social media groups? Please explain how you have access to the email list or social media platforms. Is it publicly available? Have you been granted access through site administrators? If so, supplemental documentation is needed in D.12.*

6. a. Participant Recruitment (***How*** *will you recruit participants?* ***Who*** *will do the recruiting?* ***How*** *will participants initially learn what the study is about?*):

Please check the box (es) that you have attached recruitment materials for all of the ways you will recruit. (*Please append all materials used to recruit to the end of the application. The IRB must see all documents that the participant will see to grant approval*)

Flyers/Posters  Telephone

Letter  Internet

E-mail  Newspaper

Participant Pool  Radio

Verbal script  Other, please specify:

Social Media platforms please specify:

6.b. For SONA participants in the Department of Psychology Pool, please include the information you will use to recruit participants here (i.e., any information about your study that you give to participants prior to participation):

6.c Will you be sending out the recruitment more than one time if you do not reach your target sample size?

YES  NO

If yes, please label and attach the secondary recruitment documentation for review (email, letter, etc.)

**7.a Steps in Procedure (***Here, please generally describe a typical participant’s experience from the beginning until the end of the study from recruiting to debriefing (as applicable). If you are providing incentives, please describe in this section how that will be implemented. If you are conducting any follow-up assessments, please include that process in this section as well. Please be linear in describing the participants’ experience.*

7.b. How many participants will be interviewed, surveyed or tested at a time? How will you protect the participant’s personal information, privacy and confidentiality*?*

*7.c. If you are collecting any other data for the study (i.e. data from medical records or school records of participants etc.) please describe what you are collecting, how and when you are collecting/getting access to this information, and how you will ensure compliance with any applicable regulations. For example, medical records (protected health information) are protected under HIPAA (see* [*https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html*](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html)*) and educational records are protected under FERPA (see* <https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>)*.*

7c.i - Are these records accessible to the public?  YES  NO

**7.d. What steps will be taken to protect subjects’ privacy interests? (Check all that apply)**

**Identification and recruitment of potential subjects follows procedures consistent with privacy**

**standards**

**Consent discussion and research interventions will take place in a private setting**

**Limiting the information being collected to only the minimum amount of data necessary to**

**accomplish the research purposes**

**Limiting the people with access to the identifiable research data to the minimum necessary as**

**specified in the application and consent process**

**Other – Specify:**

**8. Participant’s Estimated Time Commitment to the research components of the study. Please be sure to include time needed for any follow up assessments. If you are conducting an evaluation of a program which the participants are already participating in regardless of whether or not they agree to participate in your research, please do not include the time to be in the program as part of the research.**

**9. Setting for Data Collection (***e.g., school, hospital, clinic, home, lab, online setting-so any electronic device that has access to the internet.* ***Please be specific****.***):**

**10. Timeline for the Study (List *month and year; for example: 02/2021 – 5/2022, the start date should generally be “upon approval”. If you have specific time sensitive issues please explain here*):**

Expected Start Date:  Expected Completion Date: 

**11. Does this research involve the IRB approval of one or more participating institutions or organizations other than that of Monmouth University? Please append the** [Off-campus Research Verification Form](https://www.monmouth.edu/irb/hrpp/new-submission-forms-and-templates/) **or IRB approval notice to this application.**

**No**

**Yes**

**Contact Person:**

**Name and Title:** **Address:**

**Phone Number:** **E-mail:**

**12. Does this research involve the participation or sponsorship of an outside entity, social media account, agency, school district, school, institution, or business? If you are conducting research at an off-campus location, this is required.**

   No

   Yes  (Please include the [Off-campus Research Verification Form](https://www.monmouth.edu/irb/hrpp/new-submission-forms-and-templates/)or a memorandum of understanding, if applicable, about the arrangement and explain the nature of this relationship including the way the organization or business would use information from this research. If you have received a grant, please include the amount and the grantor and attach the appropriate paperwork as requested above.) If you are using another agency/social media account etc. to get access to participants, please provide documentation (letter, email, etc.) indicating the partnership and that the organization is willing to provide you access to their members/participants.

**Contact Person:**

**Name and Title:** **Address:**

**Phone Number:**  **E-mail:**

### E. INFORMED CONSENT/ASSENT PROCEDURES

1. Will this study seek consent from participants?

No - please explain why:

Yes- Please describe the circumstances under which consent will be obtained, including

(a) who will obtain consent, along with their qualifications and experience in obtaining research consent (or the plan to train and supervise the individual):

(b) where the consent process will take place:

(c) How you will ensure that the subjects have sufficient opportunity to consider whether to participate? Check all that apply:

Subjects will be provided the consent form to take home for consideration prior to signing it.

Subjects will be allowed a waiting period of at least  to consider their decision.

Other (describe): 

2. How will the subject express understanding of the information presented within the informed consent? (Check all that apply):

Subjects will be asked open-ended questions about the research (purpose, procedures, risks, voluntary nature)

Other, describe:

Not applicable (e.g., Researchers will only have access to de-identified data). Describe:

3. What type of document(s) will be used to obtain consent? *(Please append a copy to this application. It is important to note that informed consent materials should be at an appropriate reading level and should be adjusted accordingly to fit the population.)* Templates are available for each of these documents on the IRB website.

Signed consent form  Parental Consent Form  Electronic Consent Form (for online use)

Child Assent  Other, please specify:

Letter of Consent/Information Letter-Please justify the need for not obtaining participant signatures:

**F. MANIPULATIONS, INTERVENTIONS, MEASURES, AND QUALITATIVE DATA COLLECTION**

1. Intervention/Manipulation Information: Will this study be testing/evaluating a program, intervention, treatment, manipulation, such as an educational program etc. (This would be your independent variable)? If yes, this independent variable must be described.

No

Yes

Please describe in detail the intervention/program/manipulation being used. *(Please append a copy of the relevant materials—what participants will see or experience—to the end of this application.)*

1. Measure Information (Please include citations for all materials, even if you as the researcher created it for the purpose of the study. Provide the name of any instrument(s) being used and a citation/reference. Please copy and paste all relevant materials—such as tests, questionnaires, surveys, stimuli such as pictures, videos-including links, as applicable, any materials participants will see— to this application.) Be vigilant about proof reading all materials that participants will see and note reading level where appropriate for test materials for participants not expected to read at the adult level, depending upon the population. If there will be materials in multiple languages, all versions must be attached.
2. Qualitative Data Information (What method of data collection will you use? e.g., Focus groups, individual interviews, observations) (Please append a copy of relevant materials e.g. A focus group script, an interview protocol, a plan for recording observations or taking field notes, all data collection forms)

1. Feedback (*What information will be provided to participants concerning the results?) (Note this is usually “none” - if information will be shared explain the qualifications of the person sharing individual results*):

G. DATA COLLECTION AND CONFIDENTIALITY

1. Please indicate if you will use any/all of the following:

N/A  Audio recording  Video recording  paper worksheets/data collection forms

Electronic files  Other, please specify:

2. Will information or research records that subjects or others might reasonably consider to be sensitive in nature (e.g., social security numbers, genetic test results, communicable disease status, substance abuse, mental health information, illegal activity, etc.) be  accessed,  used, or  disclosed for the research?

No  Yes-Explain what sensitive information is included and why it is needed:

3. Will direct identifiers (e.g., name, email address etc.) be replaced with a subject code on research records other than the key to the code, and the consent form?  Check one:

N/A - I am not getting documented consent (i.e., signatures) and the data being collected is completely anonymously.

Yes - describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.) and indicate whether a linking file (key) will be created and, if so, how it will be protected/where it will be stored:

No *-*explain which direct identifiers will be included, on what records, and why they are needed:

4. Describe the provisions that will be taken to protect the confidentiality of subjects’ information and research data (e.g., storage of research data in a locked file cabinet located on campus at Monmouth University, separate storage of a key to code that allows re-linking of data, password protections, encrypted files, etc.):

5. Where, how, and for how long will the data from the study be stored? (*All research records must be stored for a minimum of three years after closure of the study on a Monmouth University password protected computer. Informed Consent forms must be filed separately from the data. Describe how you will ultimately dispose of your records after this time. If you do not plan to destroy research records, please provide a justification and how you will ensure confidentiality. In what form will data be stored, paper or digital or both.* ***Please be specific.***)

6. Will signed informed consent forms be stored separately from the data?  **Yes  No  N/A**

**H. RISKS TO RESEARCH PARTICIPANTS**

*Risks can be physical, psychological, legal, or social.*  ***If there is no foreseeable risk, you can state so (“No foreseeable immediate/long-range risks are expected”).*** *Include those aspects of the procedure that might cause unusual discomfort or inconvenience to the research participants, including the impact on their self-esteem or self-image. As****defined****by federal regulations, at 45 C.F.R. § 46.102(i), “****Minimal risk means****that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”*

*Please note –-any risks mentioned here MUST match up with the statement of risks on the informed consent materials.*

1. Potential Immediate Risks, if you include immediate risks, H.3 must be completed:
2. Potential Long-Range Risks, if you include long range risks, H.3 must be completed:
3. If there are immediate or long-term risks to the participant, how will you mitigate these risks? *(Be sure to include contact information for any counseling referrals you will list here and on the Informed Consent document as well. Please note that MU counseling services can only be included as a referral for MU students.)*

## I. BENEFITS/COMPENSATION TO RESEARCH PARTICIPANTS

1. **Benefits:** Describe any direct benefits participants may receive as part of volunteering in your study, including educational. If there are no direct benefits, so state (**note: payments or research credits to subjects are not considered benefits of research)**. If there is an expected indirect benefit to a specific field of study, also include such a statement *(e.g., This study may add to the body of research on the topic of \_\_\_\_\_\_\_.”*)
2. **Compensation:** Will participants be compensated for their time?

No

Yes, please explain:

*If yes, please make sure the process of compensation is described in D.7.a as well as here.*

**J. DECEPTION**

1. Will you be utilizing deception?

No (Please skip to section K.)

Yes

1. What is the nature of the deception involved? Will this be significant to participants? (*If possible, please provide citations for published research that has used similar methods*.)
2. Why is this deception necessary?
3. Deception Debriefing (*Describe the procedure you will use to debrief your subjects regarding the deception. How will you explain the deception to participants?*):

**K. DEBRIEFING**

1. Will you debrief participants?

Yes

No *(Please consider that it may be advisable that subjects receive a full debriefing for educational purposes, to answer any questions, and/or to provide an additional opportunity for participants reveal if the study caused any feelings of discomfort.)*

1. Debriefing Procedure (*How will debriefing take place? When? Where? Individually or in groups?*):

L. RESEARCHER RESPONSIBILITIES

As a researcher you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations imposed by the MU IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved application.
2. Adhere to ethical codes and applicable policies and procedures of the University, the sponsoring agency, relevant professional organizations and cooperating institutions (if any).
3. Do not implement changes in the approved study or consent form without prior MU IRB approval by completing a [Modification Request Form](https://www.monmouth.edu/irb/new-submission-forms-and-templates/) (except in a life-threatening emergency, if necessary to safeguard the well-being of human subjects).
4. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved [MU IRB consent form](https://www.monmouth.edu/irb/new-submission-forms-and-templates/).
5. Promptly report all deviations, violations, noncompliance, and unanticipated problems involving risks to subjects or others as soon as possible but within seven (7) working days after the investigator first learns of the event by completing the [Interim/Event Report Submission Form](https://www.monmouth.edu/irb/new-submission-forms-and-templates/) and sending it to [irb@monmouth.edu](mailto:irb@monmouth.edu)
6. Submit the Continuing Review Form located at <https://etcentral.monmouth.edu/#/form/170> at least one year from date of Approval Notice to the Office of the IRB.
7. Retain required records for a minimum of three (3) years from date of study closure.

**By signing my name and inserting the date on this application and required attachments, I acknowledge and agree that I am submitting an electronic signature indicating that I certify that the information provided in this application is complete and correct. I further acknowledge and agree that submitting this application shall constitute my signature hereto and shall be valid and have the full force and effect as an original signature.  I understand and agree that it is recommended that I print a copy of this application and required attachments for my file.  If I do not wish to submit an electronic signature, I may request that a paper copy be provided to me by the IRB for my signature.**

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Signature of Principal Investigator Date

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Signature of Co-Investigator Signature of Co- Investigator

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Signature of Co-Investigator Signature of Co-Investigator