# Monmouth University Institutional Review Board

Office of the IRB/IACUC• Library, 006

Phone: 732-263-5726 • Fax: 732-263-5728

E-mail: **irb@monmouth.edu**

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

1. **ALL APPLICATIONS DO NOT REQUIRE** [**FULL COMMITTEE REVIEW**](http://www.monmouth.edu/resources/IRB/reviewtypes.asp)**-BIGGEST MISCONCEPTION.**
2. **DO NOT CHANGE THE FORMATTING ON THIS FORM.**
3. **If you have additions/revisions to a previously approved application, please submit an** [**addendum**](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_Addendum_2009.doc)**.**
4. For new applications, please take a moment to review the “Monmouth University Institutional Review Board Guidelines for Submitting Applications for IRB Review” available on the [IRB website](http://www.monmouth.edu/resources/IRB/default.asp).
5. Download and save this form into Microsoft Word. Place cursor on the gray boxes and type. The box size will expand as you type. Examples and instructions for individual questions appear in italics. The application MUST be completed using the Microsoft WORD program. NO handwritten versions of applications will be accepted. Please be sure to delete this instruction page before submitting.
6. Be sure to complete EVERY question in the application or it will be returned as incomplete. It is important to note that applications will not be sent to the IRB for review until the application is deemed complete. The application submission date is the date on which the IRB Administrator deems the application complete. Primary Investigators are strongly encouraged to plan their research accordingly to allow sufficient time to carry out the project allowing the IRB adequate time to process the application, 7-21 business days—depending on the level of review.
7. Please use all applicable templates and directions for relevant forms such as [Informed Consent](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_InformedConsentTemplateDirections_2010.doc), [Debriefing](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_DebriefingTemplateDirections_2010.doc), etc. These forms can be found below [Resources + Forms](http://www.monmouth.edu/university/faculty-and-staff/resources-and-forms.aspx).
8. For student research, the faculty advisor/supervising professor **MUST** review the protocol prior to submission to ensure that it is complete, and that it is scientifically and ethically sound. Supervising professors should consult “[Best Practices of a Supervising Professor](http://www.monmouth.edu/uploadedFiles/Content/University/faculty-and-staff/IRB/IRB_BestPractices_SupervisingProfessor.pdf)” and are required to complete the “[Supervising Professor Consent and Checklist](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_SupervisingProfessorConsentChecklist_2010.doc)” (both can be found on the [IRB website](http://www.monmouth.edu/resources/IRB/default.asp)). **At all times, but PARTICULARLY when professors are supervising groups of students submitting applications, please be vigilant about checking your students’ applications for completeness, appropriate forms and consistency within the application to facilitate prompt review.**
9. Signatures: You can sign the signature page then scan it into Microsoft Word or as an Adobe PDF document. Electronic copies help us process applications more quickly. **Alternatively**, the signature page can be photographed with a smartphone or digital camera and then you can email it to yourself. Once you have saved the signature page file, you can right click the saved document and then paste it to the signature page of your completed IRB application using Microsoft Word.
10. The completed application and supporting materials must be emailed as a single attachment to the IRB (irb@monmouth.edu). Please include your last name and the date in the title of the file attachment, such as “Save as” “Smith\_IRB\_Application\_9\_01\_2016”. 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 revisions are requested from the IRB.
11. Please email irb@monmouth.edu with any questions that you might have about submitting your IRB application.
12. Copy and paste all documents associated with your research to the end of the IRB application template.
13. If an area of the application does not apply to your study, you may answer N/A for not applicable. N/A is only acceptable for some areas such as E.11-12, G.2 or G.3, I.3, L.1-2
14. Please do not use the term “anonymous”. Rather, use the term “confidential”.

*Note: Links to relevant documents/information are provided here, but can also be found on the* [*IRB website*](http://www.monmouth.edu/resources/IRB/default.asp)*.*

**This page MUST be deleted prior to submitting your application.**

Application#\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (IRB USE ONLY)

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**Application for Review of Human Subjects Research**

 **\*IRB USE ONLY BELOW\***

# Category of Review:

# Date of Original Submission: Response Date:

# *Suggestions for Revision/Mandatory Revisions:*

|  |
| --- |
|  *.* |

## Date of Revised Submission: (Please attach this page along with revision) Response Date:

# [ ] Approved [ ] Not Approved (Reason application did not receive approval: )

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**A. IDENTIFYING INFORMATION**

# 1. Principal Researcher’s Contact Information:

|  |  |
| --- | --- |
| Name(s): . |  Address: . |
| Phone Number: . |  E-mail: . |

# 2. Co-Researcher(s) Contact Information:

|  |  |
| --- | --- |
| Name(s): . |  Address: . |
| Phone Number: . |  E-mail: . |

# 3. Department/School: .

# 4. Title of the Study: .

# 5. Research Category: (Please mark an X in the appropriate box)

|  |  |  |
| --- | --- | --- |
| [ ] Faculty research | [ ] Undergraduate Thesis | [ ] Research from another institution |
| [ ] Graduate student research | [ ] Undergraduate student research | [ ] Other, please specify: . |
| [ ] Honors thesis | [ ] Undergraduate independent study |

# Definition of research as per Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects [46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102), *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

6. Does your project fit into one of the categories above and fall under the definition of research? [ ] Yes [ ] No

 Please include plans for disseminating your research:  **.**

**B. Human Participant Protections Required Training**

### I have attached the [NIH Protecting Human Research Participants Training Certificates](http://phrp.nihtraining.com/users/login.php) for everyone on the research team: [ ] Yes [ ] No

###

## C. SUPERVISING PROFESSOR’S CONSENT (required only for student research)

1. I have attached my [supervising professor’s consent form](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_SupervisingProfessorConsentChecklist_2010.doc): [ ] Yes [ ] No [ ] N/A

**D. 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?*):

 .

1. **Brief Rationale for the Study (***Why is this study needed? How does it fit in with existing research? Provide citations for any referenced material*. *Please cite at least two references here to support D.1/purpose. What new knowledge will this study potentially add? Applications should be written in lay terminology so that a lay person can understand the study. IRB members represent a variety of disciplines.  This means that some reviewers may not be as familiar with the terminology as you are, so please use language that a lay person would understand.***)**

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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; etc.)*:

 .

1. **Plan for Data Analysis** (*What statistical test(s) will you use? If qualitative, please describe the planned data analyses, e.g. if content analysis, what method are you using? How will you determine reliability? Please describe)***:**

 .

### E. SAMPLING METHOD AND PARTICIPANT REQUIREMENTS

1. Sampling Method (*e.g., random, convenience, purposive, snowball, etc.*):

 .

1. Affiliation of Participants(*e.g., Monmouth students, institution, hospital, general public, members of a listserv etc.*):

 .

### Participant Characteristics (You must *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: .

1. Access to Participants (*How will you gain access to participants? Who is granting you access to them? Will you use the Department of Psychology participant pool? 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.) If you are an instructor collecting data in a class, it is important to note that the instructor cannot be present when students choose whether to participate or when data are being collected.*

*Initial here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to show that you will be out of the room during the process in which students agree to participate AND during data collection.*

 .

1. 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 boxes for all of the ways you will recruit.

 .

Please mark an X in the appropriate box(es). (*Please append any of these materials to this application*)

 [ ] Flyers/Posters [ ] Telephone

 [ ] Letter [ ] Internet

 [ ] E-mail [ ] Newspaper

 [ ] Participant Pool [ ] Radio

 [ ] Verbal script [ ] Other, please specify: .

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):

 .

1. **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). Please include how many participants will be interviewed, surveyed or tested at a time.*  .
2. **Participant’s Estimated Time Commitment:**

 .

1. **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****.***):**

 .

1. **Timeline for the Study (List *month and year; e.g., 9/2016 – 5/2017, the start date should generally be “upon approval”. If you have specific time sensitive issues please explain here*):**

Expected Start Date: . Expected Completion Date:  .

1. **Does this research involve the IRB approval of one or more participating institutions or organizations other than that of Monmouth University? If you are conducting research at an off campus location, this is required. Please append the** [Off-campus Research Verification Form](http://www.monmouth.edu/uploadedFiles/Content/University/faculty-and-staff/IRB/IRB_OffCampusResearchVerificationForm_2010.doc) **to this application**

**[ ] No**

**[ ] Yes**

**Contact Person:**

|  |  |
| --- | --- |
| Name/Title(s): . |  Address: . |
| Phone Number: . |  E-mail: . |

1. **Does this research involve the participation or sponsorship of an outside entity, agency or business?**

[  ]   No

[  ]   Yes  (Please include a signed agreement or memorandum of understanding 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.)

### F. INFORMED CONSENT/ASSENT PROCEDURES

1. Will this study seek consent from participants?

[ ] Yes

[ ] No

If consent will not be sought, please explain why and what procedure you will use to ensure the participant understands in order to guarantee his or her rights.

 .

1. 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.)*

 [ ] Signed consent form [ ] Parental Consent Form

 [ ] Letter of Consent [ ] Child Assent

 [ ] Electronic Consent Form (for online use) [ ] Other, please specify: .

**G. MANIPULATIONS, MEASURES, AND QUALITATIVE DATA COLLECTION**

1. Manipulation Information (Will this study include a manipulation?):

[ ] No

[ ] Yes

Please describe in detail the manipulation being used. *(Please append a copy of the relevant materials—what participants will see—to 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.

 .

1. 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*):

 .

H. DATA COLLECTION AND CONFIDENTIALITY

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

[ ] N/A [ ] Audio recording [ ] Video recording [ ] Other, please specify: .

1. Is confidentiality promised to participants? *(It is important to note that there are almost NO conditions under which anonymity is possible in the information age and only use this term if you can defend the extenuating circumstances that warrant it.)*

**[ ] Yes**

**[ ] No**

 **If no, please explain why retaining** identifying information is necessary. Also explain who will have access to this information (*e.g., a list that identifies participants and the assigned identification numbers*):

 .

1. Will identification numbers be assigned to each participant and used on data collection forms to protect the participant(s) responses?

[ ] Yes If Yes, who will assign the identification numbers? .

 [ ] NoIf *No, please explain*  .

1. 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. 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.***)

 .

1. Will signed informed consent forms be kept separately from the data? **[ ] Yes [ ] No [ ] N/A**

**I. RISKS TO RESEARCH PARTICIPANTS**

*Risks can be physical, psychological, legal, or social. No research has zero risk. Please describe even minor risks (e.g., potential embarrassment, anxiety, feeling left out, etc. If you cannot foresee any risk, “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, I.3 must be completed:

 .

1. Potential Long-Range Risks, if you include long range risks, I.3 must be completed:

 .

1. 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.)*

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## J. BENEFITS TO RESEARCH PARTICIPANTS

1. Describe any benefits participants may receive as part of volunteering in your study, including educational. *(If there is an expected benefit to a specific field of study, a possible answer could include: This study may add to the body of research on the topic of \_\_\_\_\_\_\_.”*)

 .

1. Will participants be compensated for their time?

[ ] No

[ ] Yes, please explain: .

**K. DECEPTION**

1. Will you be utilizing deception?

[ ] No (Please skip to section L.)

[ ] Yes (Please note, this automatically makes this application an expedited review.)

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*.)

 .

1. Why is this deception necessary?

 .

1. Deception Debriefing (*Describe the procedure you will use to debrief your subjects regarding the deception. How will you explain the deception to participants?*):

 .

**L. 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?*):

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M. 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 an Addendum Form (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. Store informed consents, and data in a secure place for a minimum of three (3) years.
5. Promptly report all undesirable and unintended, although not necessarily unexpected adverse reactions or events, that are the result of therapy or other intervention, within five (5) working days of occurrence. All fatal or life-threatening events or events requiring hospitalization must be reported to the MU IRB in writing within 48 hours after discovery.
6. Submit the [Continuing Review Form](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_AnnualReview_2010.doc) 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.

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Signature of Principal Researcher Date

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

Signature of Co-Researcher Signature of Co-Researcher

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

Signature of Co-Researcher Signature of Co-Researcher

N. Appendices Checklist

Please remember to attach copies of the following materials (where applicable), to the end of this document. The completed application and supporting materials should sent electronically via email as a **single attachment** to the IRB (irb@monmouth.edu). Please include your last name in the file attachment. Due to the volume of applications the IRB handles, these procedures help ensure the expeditious review of all applications. Failure to adhere to the submission protocol will delay the review of your application.

1. Informed Consent Document(s) *(Several types are available under the “Informed Consent” menu on*

 *the IRB website)*

1. Study Materials (*Please include everything that a participant will see or experience such as: recruitment material, manipulations, questionnaires, surveys, interview questions, demographics, etc.*)
2. [Debriefing Materials](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_DebriefingTemplateDirections_2010.doc)
3. [Supervising Professor’s Consent Form](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_SupervisingProfessorConsentChecklist_2010.doc) (Student Research Only)
4. IRB Approval from participating institutions or [organizations](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_OffCampusResearchVerificationForm_2010.doc) other than Monmouth University
5. [Contact Verification Form](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_OffCampusResearchVerificationForm_2010.doc)
6. [Research in Schools Form](http://www.monmouth.edu/uploadedFiles/Resources/IRB/IRB_ResearchInSchoolsForm_2010.doc)
7. [Certificate from NIH Protecting Human Research Participants Training](http://phrp.nihtraining.com/users/login.php)  (*Please insert below*

 *as a picture or PDF since it is a single page*)

**PLEASE COPY AND PASTE NIH CERTIFICATE BELOW:**

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