Monmouth University Institutional Review Board
Guidelines for Submitting Applications for IRB Review

Introduction

This document is meant to supplement (not replace) the instructions that accompany the Application for Review of Human Subjects Research. If you have any questions regarding the instructions, please contact the IRB Coordinator at irb@monmouth.edu.

Role of the IRB

The Institutional Review Board (IRB) is responsible for safeguarding the interests of persons who participate as subjects in research projects conducted by faculty or students of Monmouth University. (Mission Statement) In carrying out that duty, the IRB must examine and evaluate all research proposals to determine whether certain guidelines for the protection of the welfare of human subjects have been met, as set forth in the federal regulations. Approval is required for all research that is to be conducted by a faculty member, or by a student under the guidance of a faculty member, prior to the initiation of contact with human subjects.

Required Training

Prior to completing the Application for Review of Human Subjects Research (IRB Application), each applicant is required to complete the necessary training as set forth by the federal regulations. The IRB educational training requirements can be located here. A Certificate of Completion is available at the completion of the training module which is to be printed out and submitted with the application to the IRB.

Completing Your Application

In planning your research and preparing your IRB application, the investigator should think carefully about potential avoidable harm to human subjects, for example keeping in mind the ethical guidelines of the American Psychological Association and considering the need for cultural sensitivity in approaching subjects. Potential harm will be weighed against potential gain on each application reviewed by the IRB.

When completing the IRB application, be sure to provide all information requested in a clear and concise manner and attach any necessary information. Be sure to provide information regarding the procedures and methodology and attach any necessary information, as appropriate.

If your research includes obtaining personal information or videotaping or voice recording of participants, the application should include a description of the planned disposition of that information, which should also be clearly stated in the consent for (i.e. How will the participant's identity be kept confidential?)

It is important to note that the risks to participants must be clearly detailed in both the IRB application and the consent form. Risks may include physical, psychological, legal or social distress. Although the range of vary from the risk of physical injury to boredom and fatigue, the idea that the research has no risk will not be deemed as appropriate.

Keep in mind this is your chance to describe your research to the IRB. Failure to provide sufficient detail regarding your project may result in the application being returned to you as incomplete and will require resubmission, thereby causing a delay in the inception of your research.

Submitting Your Application

The completed application and supporting materials should be emailed as a single attachment to the IRB (irb@monmouth.edu). You should sign the signature page then scan it into Microsoft Word or as a .pdf document, and email it to irb@monmouth.edu. Alternatively, the signature page can be hand delivered to the IRB office (Library Room 006, Lower Level), during regular hours (Monday – Friday 9am-5pm). Prior to submitting your application, be sure to review the Checklist below to verify that the application is complete.

Upon receipt of the IRB application and supporting materials, the IRB Coordinator will perform a "Completeness Check" to determine if the application is neat, organized, free of obvious content or grammatical errors, and that all necessary information is included with the application. The IRB Coordinator will email the application back to the Principal Investor with a list of changes necessary to consider the application complete. Upon completion of the requested changes, the PI should re-submit the application to the IRB Coordinator via at irb@monmouth.edu. The Completeness Check and request for changes will be repeated by the IRB Coordinator until the application is complete.

It is important to note that applications will not be forwarded to the IRB for review in any form until the application is deemed complete. The application submission date is the date at which the application is deemed complete by the IRB Coordinator.

Application Checklist

Prior to submitting your application, please review the checklist below to ensure your application is complete. For specific instructions on completing any of the items below, refer to the IRB website for templates and directions.

- ☐ Completed IRB Educational Training Requirement / Certificate (Click here)
- ☐ Application – Please be sure to follow directions and complete each section.
    - For research involving children, please review Additional Protections for Children Involved as Subjects in Research
- ☐ Study Materials (as applicable):
    - Ex. Surveys, questionnaires, interview questions, measurement tools, and/or study materials used for experimental manipulations
- ☐ Informed Consent Documents (as applicable)
    - Ex. Informed Consent, Letter of Consent, Parental Consent, Child Assent
- ☐ Debriefing Script (as applicable)
- ☐ Additional Forms & Documentation (as applicable)
    - Ex. Research in Schools Form, Off Campus Research Verification Form
- ☐ Signed and dated Researcher Responsibilities Form (Section M in the Application)
- ☐ Signed and dated Supervising Professor's Consent Form and Checklist (Student Research Only)

IRB Review Process

Once the IRB Coordinator has deemed the IRB application as complete, the application is assigned the necessary review category based on federal regulations. The IRB Chair will determine the review category to which each application will be assigned.

However, it is strongly recommended that Principal Investigators review these categories, as well as the associated timelines for each type of review. Principal Investigators are strongly encouraged to plan their research accordingly so that there is sufficient time to carry out the project upon completion of the IRB review process.

If the research involves an outside institution, the IRB Chair or Coordinator will get in touch with the Contact Person listed in the application to confirm that he or she has given his or her approval for this study to be conducted. This can also be verified by utilizing the contact verification form. Any questions about the appropriateness of study procedures for vulnerable populations will be addressed at this time.

Regardless of the category of review, members of the IRB will evaluate each application based on the Criteria for IRB Approval of Research. Additional guidance on IRB assignment of research to review categories can be found here.

1. **Exempt:**
   - Information about a research applications that qualifies for an *Exempt Review* can be found here.
   - The IRB Chair (or a designate) reviews the application.
   - Within 7 calendar days of receiving the complete application, the PI will be informed via email of the Outcome of IRB Review.

2. **Expedited:**
   - Information about a research applications that qualifies for an *Expedited Review* can be found here.
   - The IRB Chair (or a designate) reviews the application along with a second reader.
   - Within 10 calendar days of receiving the complete application, the PI will be informed via email of the Outcome of IRB Review.
   - Note: If the application is not favorably reviewed by either reader, it will go to a Full Review.

3. **Full Review:**
   - A research application qualifies for a *Full Review* if it does not fall in either the *Exempt* or *Expedited* category, OR if a reader of an expedited review does not review it favorably, OR at the discretion of the chair or chair designate.
   - Members of the IRB review the application and discuss it at the upcoming IRB Meeting. Principle Investigators file a complete application at least 21 days before an IRB meeting to facilitate a review at the upcoming meeting.
   - Within 30 calendar days of receiving the complete application, the PI will be informed via email of the Outcome of IRB Review.

Potential Outcomes of IRB Review

After the appropriate level of IRB review, there are three possible outcomes for an application:

a) **Approval** – Upon final approval the IRB Coordinator will notify the PI via email and send a paper-copy of the official approval notice. The research may proceed as stated in the application. IMPORTANT: Research can not start until the application receives final approval.

b) **Revise and Resubmit** – Based on a review by members of the IRB, certain revisions may be necessary which will require the application to be resubmitted prior to final approval. The IRB Coordinator will email the PI with a list of the required revisions. The research as described in the application can not begin until revisions are made, the application is re-submitted, and final approval is given by the IRB. PI's are encouraged to discuss any questions about the necessary changes with the IRB Chair.

c) **Denied** – Based on a review, the research as described in the application cannot receive approval due to the risk involved. PI's are encouraged to discuss any questions about the IRB's decision with the IRB Chair.

Research Follow-Up

a) 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.

b) Submit the Annual Review Form at least one year from date of Approval Notice to the Office of the IRB.

c) If you have additions/revisions to a previously approved application, please submit an addendum.

Questions and Assistance

For questions, please consult the FAQ page, ask the IRB Chair, or feel free to stop into the IRB office during open consultation hours Monday – Friday 3:30pm-5pm.