

NEUMANN UNIVERSITY
Aston, Pennsylvania

Guidelines for the Preparation of Research Proposals for IRB Review

These guidelines govern the preparation of all research proposals submitted to the Neumann University Institutional Review Board (IRB). Proposals must contain the information specified herein. If a proposal has been prepared in a format required by an external agency, there is no need to rewrite the proposal; information required herein that does not appear in the proposal as written may be included in an attachment.

1. The Proposal Face Sheet

A copy of Neumann University IRB Form 001, latest revision, **Research Proposal Face Sheet**, (see Appendix A, attached to this document) must accompany any research proposal submitted for IRB approval. The face sheet is available for download on the IRB web page. Please provide all information requested on the form, including all signatures. All information is to be typed, except for signatures. If additional space is needed for information on the face sheet, attach additional sheets, mark the check box on the bottom of the face sheet, and indicate the number of additional sheets attached.

1.1 Principal Investigator/Additional Investigators

The **principal investigator** is the contact person for all formal communication with the individuals involved in a research project. The principal investigator is the researcher when only one researcher is involved in a research project; when a group of researchers is involved in a research project, the group is to designate one of their members to serve as the principal investigator; the remaining individuals are the **additional investigators**. This information should be included in all correspondence with the IRB.

1.2 Title of Research Project

The title should be brief but inclusive and descriptive.

1.3 Duration

The starting date is when the research proposal is finalized (including IRB approval) and sample selection and data collection may begin. The ending date is the anticipated date of completion of the research project.

1.4 Location

Provide the specific name and location of any and all facilities at which data collection will take place.

1.5 Other Institution(s)

If the research proposal must be submitted to another institution or institutions for their internal review procedure, indicate the name of the institution and its location.

1.6 Type of Study

Provide a brief description of the type of research project, e.g. “Qualitative, participant observer,” “Randomized clinical trial,” “Interrupted time series,” “Experimental, double blind,” “Telephone survey,” “Medical record search,” “Combined therapeutic-experimental,” etc.

1.7 Sampled Population

Provide a brief description of the population that you propose to sample and an estimate of the total number of human subjects that will be involved, including all experimental and control groups. If the proposed research is a qualitative and / or quantitative study involving surveys or observation, estimate the numbers of persons you expect to survey or observe.

1.8 Safety Items

If the proposed research project involves any of the items listed, mark the appropriate check box. If the proposed research project involves any other items that have the potential of posing a threat to the safety of either the subjects of the research project or the researchers themselves, attach an additional sheet indicating those items. Make certain that any safety items indicated on the face sheet are addressed under the risks section of the proposal narrative.

1.9 Resources

If the proposed research project is being submitted to an organization for consideration for financial and/or equipment support, indicate the name of the organization and the grant or funding program to which application for support will be submitted.

If a company and/or organization is lending, donating, or otherwise supplying at less than market value, equipment or supplies for the research project, identify the company or organization and the items in question. If the research project involves the testing of prototype equipment, identify the manufacturer and the equipment.

1.10 Certification

A proposal for a research project is not approved until all the signatures indicated on the face sheet have been obtained, i.e. signatures of the following individuals must appear on the face sheet of the proposal:

- Principal investigator;
- Additional investigators (where applicable);
- Department Chair or Program coordinator.
- Division Chair

2. The Proposal

2.1 Abstract

On a separate sheet, include an abstract of the project of no more than 500 words. The abstract should address the following:

- Purpose of the research project;
- Type of research design employed in the project;
- Subjects, if any, involved;
- Procedures for data collection;
- Measurement instruments to be employed in the project;
- Anticipated type of data analysis to be employed; and,
- Relevance of the research project.

2.2 Narrative Description

A narrative description of the proposed research project should be brief, but should provide sufficient information to permit the IRB reviewers to judge if the problem chosen is significant or important, if the research question and design are adequate to address the problem, and whether the investigators have the knowledge, funding, and access to any equipment and/or subject populations necessary to complete the proposed project.

The narrative description shall be prepared in accordance with the following outline (except as noted in the opening paragraph of this document):

2.2.1 Purpose

State the overall purpose of the research project and, if appropriate, hypotheses to be tested. Briefly explain what you feel is the potential significance of the research project.

2.2.2 Duration

Provide an estimate of the duration of the entire research project. The starting date is when the research proposal is finalized (including IRB approval) and sample selection and data collection may begin. The ending date is the anticipated date of completion of the research project. Note that IRB approval is required every 12 months (in some cases more often) while a re- search project involving human subjects continues.

2.2.3 Location

Provide the specific name and location of any and all facilities at which data collection will take place.

2.2.4 Background

Briefly review the most significant previous work done in the topic area and the specific problem area and describe the current status of work in this topic and problem area. Document this review with appropriate references using the APA style. Describe any preliminary work that the principal investigator, additional investigators, or others have done which led to this research project.

2.2.5 Methods

The methods section of the proposal should describe the:

- Type of study or research design that will be employed in conducting the project;
- Methods and instrumentation to be used for sample selection and for data collection;
- Data to be collected;

- Procedures used for data collection and analysis;
- Projected timetable of the study (all major steps in the study with approximate dates for initiation and completion).

2.2.6 Resources

- Describe the facilities, special equipment, consultative services, and other relevant resources available for the project. If any of these are to be secured through collaborative arrangements with institutions other than that which might be indicated in the address(es) of the investigator(s), attach letters from each such source confirming their willingness to provide these resources.
- Identify any supplies, equipment, or other resources that are required for completion of the project.

2.2.7 Subject Recruitment and Selection

- Summarize the process of obtaining subjects for the proposed research project. Specify the sample size needed for the level of significance desired in your proposed data analysis. If a larger sample is desired because attrition is expected, so state and state the additional number of subjects desired. If your design uses experimental and control groups, specify the number of subjects to be assigned to each experimental group and each control group. If your sample is to be generated by inviting m persons to participate, from which you shall select a sample of size n ($n < m$), specify the number m .
- If potential subjects are to be excluded because of age, gender, economic status, or race, the reasons for the exclusion must be documented.
- Describe any inducements that will be offered to subjects, such as cash payments, free hospitalization, medication, treatments, testing, etc.
- For research projects using patient populations, attending or referring physicians must have a reasonable opportunity to affect the manner in which their patients are invited to participate. If a patient has not previously given consent to the disclosure of his/her name as a candidate for research, the patient should first be contacted by his/her physician with the principal investigator's request.

- Include sample copies of all correspondence that will be presented or sent to subjects or prospective subjects, and any intermediaries involved.
- Indicate all special categories of subjects to be included in the research project, e.g. mentally retarded or disabled, minors, pregnant women, prisoners, etc.

2.2.8 Potential Risks

Describe and assess any potential risks – physical, psychological, social, economic, monetary, legal, or other – to the subjects involved in the research project and assess the likelihood and seriousness of such risks. If the research methods proposed create potential risks, describe other methods, if any, that were considered and provide the reasons why they were rejected.

2.2.9 Consent Procedures

Describe the procedures to be followed in obtaining informed consent from subjects, including how, when, where, and by whom informed consent shall be obtained.

2.2.10 Protection of Subjects

Describe the procedures, including confidentiality safeguards, that will be employed to protect against or minimize potential risks to subjects, and provide an assessment of the likely effectiveness of these procedures.

The following issues must also be addressed:

- If there is a point at which the collection of data from subjects may be discontinued prior to the end of the data collection phase of the research project, state how monitoring of the data collection is to be performed and the criteria for determining the discontinuation point.
- Include a description of any measures that will be taken to handle side effects or problems identified during the research that are associated with or resulted from the procedures used.
- Include one (1) copy of any questionnaires or rating scales that will be employed in the research project.
- If drugs are to be administered or devices are to be used in the research project, the packaging brochure or other informational literature regarding the drug or device must be attached to the

research proposal and the following questions must be answered:

- ▯ What is the name of the drug or device?
 - ▯ Does the drug or device have FDA approval?
 - ▯ What is the name of the manufacturer of the drug or device?
 - ▯ If drug or device is investigational, does it have an FDA investigational new drug or device exemption?
 - ▯ What is the exemption number?
- Proposals for research projects involving clinical drug or medical device trials should have a copy of an indemnification clause, signed by appropriate parties, attached to them. An indemnification form is usually available at the institution where the trials will take place.

2.2.11 Potential Benefits

Assess any potential benefits that may be gained by individual subjects involved in the research project and any benefits that may accrue to society in general as a result of the proposed research.

2.2.12 The Risk/Benefit Ratio

Analyze the possible benefits that may be gained by the subjects involved in the proposed research in light of the risks involved. *Minimal risk* means that the risks of harm anticipated in the proposed research are not greater than, with respect to both probability and magnitude, the risks encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.3 Informed Consent

Any research project that involves the use of human subjects requires implementation of procedures for obtaining the informed consent of the subjects. The research proposal must address how informed consent will be obtained and must provide copies of the actual consent form(s) that will be employed by the researchers. **If these form(s) are not submitted with the proposal, the proposal will be rejected.**

Consent forms must be prepared in accordance with Section 3 of this document and in accordance with the requirements contained in the Neumann University IRB's document IRB-101, *Policies and Procedures Governing the Formation and Operation of the Neumann University Institutional Review Board*.

2.4 Budget

Each proposal must contain a budget summary page which provides a breakdown of expenses in the following categories:

- Equipment purchase/rental;
- Supplies;
- Clinical site fees;
- Personnel/consultant fees;
- Participant support costs;
- Other.

The IRB is interested in budget information that has the potential to affect the safeguarding of human subjects involved in the research.

3. Consent Forms

The consent form should be a succinct statement (no more than three pages) providing information about the research project including (but not limited to) its purpose, procedures, benefits, risks, duration, and (where applicable) alternative therapies that are available. The document should bear the title **Consent Form** and immediately beneath the title should bear the title of the research project, the name and address of the principal investigator, and the names of any additional investigators. The consent form should identify the institution(s) represented by the investigator(s) and the institution(s) where the research project is to be carried out. The document should contain a footer identifying the date of the latest revision; only the form approved by the IRB may be used in the research project.

The consent form should be written in clear, understandable English. If the population to be sampled speaks another language, the investigators may attach to the English language version a certified translation of the consent form and have subjects sign both versions. A certified translation is one that has been approved by the IRB after consistency with the English language version has been certified by an IRB member or consultant to the IRB who is fluent in the language used in the non-English version of the consent form.

The consent form must provide adequate information to enable a prospective subject to decide whether or not to participate in the research project and may not include language by which a subject is made to waive, or appear to waive, any of his/her legal rights or to release the investigator(s), or the sponsoring institution(s) or its (their) agents, from liability for negligence. Each adult subject and each legal guardian who signs consent for a subject who is a minor must receive a copy of the signed consent form. Please note that in the event the protocol includes adolescents and / or children under the age of 18, there needs to be an assent consent form – an affirmative agreement by the adolescent / child (individuals under the age of 18) to participate in research. Mere failure to object by the adolescent / child should not be construed as assent without an affirmative agreement.

The principal investigator must retain in his/her confidential files copies of consent forms signed by each subject in the study for at least five years after completion of the research project or such longer period as may be specified by program requirements. In the case of subjects who are minors, the above rule on retaining copies of signed consent forms applies or the signed copies must be retained until the subject reaches his/her majority, whichever period is longer.

In preparing the consent form, it is recommended that the document be written in the same person throughout, that scientific terminology be defined in plain language, and the document be carefully edited for errors in fact, grammar, spelling, and typing.

The following information must be included in the consent form:

- **Invitation to Participate:** Provide a brief statement inviting participation as a subject in the research project. Basically, this section should state, “You are invited to participate in a research study ...” and continue with an amplification

of the title of the research project.

- **Basis of Subject Selection:** Provide a brief explanation of how the sampled population was determined, i.e. explain the defining criteria that determined who was invited to participate. For example, individuals with a certain specific condition were sought for an experimental group while those without the condition were sought as controls.
- **Purpose:** The purpose of the research project, and the potential significance of the research, should be explained without using jargon or undefined technical terms.
- **Procedure:** All subjects must be informed of what, exactly, their participation in the study will involve. All tests and procedures should be explained, and any that are experimental in nature should be clearly identified as such.
- **Potential Risks and Discomfort:** It should be clearly stated that participation in the study may involve risks or discomfort, and the known risks and discomforts should be clearly delineated. Participants should also be apprised of the potential for unknown or unforeseeable risks or discomforts. The disclosure of includes the implications of randomization procedures and of the experimental design – such as in a double blind experiment neither the investigator nor the subject knows who is receiving genuine treatment and who is receiving a placebo.
- **Potential Benefits:** The benefits of the research to the subject or to society in general are to be explained. If no benefit to the subject is foreseeable, this should be clearly stated.
- **Inducements:** Any inducements being offered to subjects, such as cash payments, free hospitalization, medication, treatments, testing, etc. must be clearly explained as well as the mechanism for obtaining or availing oneself of the inducement.
- **Financial Obligations:** In addition to any inducements offered, prospective subjects should be told which expenses involved in participation are the investigator's or sponsoring institution's responsibility and which expenses are the participant's responsibility. For example, the investigators are responsible for the cost of all tests and procedures performed and the only cost to the participant is transportation to the facility where testing and treatment takes place.
- **Alternatives:** In therapeutic studies, alternative treatments, including their risks and benefits, should be described.
- **Confidentiality:** When the research project involves the acquisition or use of personal information, subjects must be informed of the steps that will be taken to

safeguard that information and assure confidentiality.

Subjects must be informed of who will receive information derived from the study. *Research subjects involved in clinical trials involving drugs or devices under the jurisdiction of the FDA must be told in the consent form that representatives of the manufacturer of the drug or device and representatives of the FDA may review data collected during the study and that the information will be kept confidential except as may be required by law.*

- **Non-participation or Withdrawal:** It must be made clear that those invited to participate are free to consent or decline. In the case of those consenting to participate, assurance must be given that they are free to withdraw from the study at any time. Assurance must be given that a decision not to participate in, or a decision to withdraw from, the research project will not prejudice future interactions between the person involved and the investigator(s) or the sponsoring institution(s).
- **Complications or Injuries:** Prospective subjects should be advised of the availability or non-availability of medical treatment or compensation for complications or injuries incurred as a result of participating in biomedical or behavioral research.
- **Subjects' Questions and Rights:** Subjects must be provided with an opportunity to ask questions regarding the study and their participation in the study, or to request an elaboration of any of their rights as subjects of research. Subjects must be provided with the name and method of contacting a person who can answer their questions or requests for additional information.
- **Consent:** An affirmation should appear at the end of the consent form immediately above the line for the subject's signature and should read,

"I have read and received a copy of this consent form. I voluntarily consent to participate in the research project described herein. My rights as a subject of this research have been explained to me."
- **Signatures:** Lines for required signatures should be provided at the end of the consent form. All signature lines on the consent form should contain a printed or typed version of the signer's name and space for the date of signing. A person may not participate as a subject of the research unless they, or their legally authorized representative, have signed the affirmation. If the prospective subject is a minor, signature lines for both the subject and a relative or legal guardian must be provided. In the case of prospective subjects whose capacity or competence to give consent is limited for any reason, the signature of their legally authorized representative must be obtained. There must also be signature lines for the principal investigator and any required witnesses.

4. Proposal Submission

The face sheet, form IRB-001, must be completed in its entirety, including all signatures, or the proposal will not be accepted for review. See the document, IRB-100, *Policies and Procedures Governing the Formation and Operation of the Neumann University Institutional Review Board*, latest revision, if you need clarification of who must sign the research proposal face sheet and the procedures to follow in the case where an investigator for the proposed research project is one of the pre-submission reviewers. For research projects involving personnel from more than one department, approval must be obtained from the requisite individuals from each department.

4.1 Submissions for Full Review

The original hard copy and an electronic submission of the proposal must be delivered to the Office of the Director of Institutional Research, at which time the proposal will be stamped with the date received, assigned a Proposal ID Number, and logged into the IRB records. While every effort will be made to review research proposals in a timely manner, no guarantees can be made as to when a particular proposal will be scheduled for review by the IRB. At grant application deadline times, the number of proposals submitted to the IRB may increase dramatically. Only a limited number of proposals can be placed on the agenda for a meeting of the IRB, and proposals are assigned to the agenda on a first-come, first-served basis. Investigators are urged to submit their proposals well ahead of any deadlines they are facing in order to ensure completion of IRB review prior to those deadlines.

4.2 Submissions for Expedited Review

In some instances a research proposal may qualify for expedited review. This occurs if there is minimal risk to human subjects involved in the proposed research, or if minor changes are being made in previously approved research. Investigators should check the list of categories of research that qualify for expedited review that is maintained in the Office of the Director of Institutional research. If the investigators are requesting an expedited review for the initial submission of a proposal, the original hard copy and an electronic submission of the proposal must be delivered to the Office of the Director of Institutional Research, at which time the proposal will be stamped with the date received, assigned a Proposal ID Number, and logged into the IRB records.

5. The Review Process

5.1 Full Review

The IRB will attempt to review any research proposal and respond with a decision within thirty (30) days of receipt of the proposal. However, the IRB is required to meet only once a month and, although more frequent meetings may be scheduled when a large number of proposals have been submitted for review, only a limited number of proposals can be considered at each meeting of the IRB. Delays may also occur if the IRB must request clarification from the investigators, or must consult persons not on the IRB who have expertise in the area of research in question and can provide input to the members of the IRB that will help them to better understand a proposal and its implications.

When a proposal is submitted, it is checked for completeness. If not complete, it is returned to the principal investigator. If complete, it will be circulated to the members of the IRB and placed on the agenda for an IRB meeting. At the meeting of the IRB, the proposal will be evaluated for the extent to which it provides for the protection of human subjects involved in the proposed research. If the research proposal is approved by the IRB, the chairperson of the IRB shall forward the proposal to the President for institutional approval.

5.2 Expedited Review

The expedited review process is the same as the full review process except that the research proposal will be considered by the chairperson of the IRB or by one or more experienced reviewers designated by the chairperson from among the members of the IRB. If the decision of the reviewer(s) is not to approve the proposal, the proposal must then move onto the agenda of the IRB for a vote to disapprove.

6. IRB Response

The IRB reviewer/s will determine “Category I Requirements” and/or “Category II Recommendations” based upon the following criteria:

- Category I Requirements – Category I requirements are substantive changes necessary to “eliminate apparent immediate hazards to the subject population.”¹ They may also identify deficiencies which prevent accurate determination of the risks and benefits, and therefore require significant clarification or modification. As such, Category I requirements will be cited when there is a degree of uncertainty regarding¹:
 - the nature of the study or risks posed
 - the vulnerability of the subject population

- the use of novel therapies or interventions
- verification of information from a source other than the investigator
- the experience of the investigator
- previous compliance issues by the investigator

The substantive concerns of the IRB must be addressed for further consideration for approval. A full review may be necessary and / or the principal investigator may be asked to attend an IRB meeting in order to clarify the proposal.² The principal investigator must revise the protocol, consent and other documents and submit the entire study for reconsideration. An attached document highlighting the clarifications is recommended. If the full IRB determines the risks continue to outweigh the benefits and disapproves the study, the study must be entirely rewritten and resubmitted as a new study.²

- Category II Recommendations – Category II recommendations are defined as, “explicit conditions which recommend minor changes or simple agreement of the PI.”² In short, a Category II recommendation is simply a recommendation or minor non-obligatory modification presented to the PI in an effort to enhance the study’s content.

If the research proposal is not approved by the IRB, a response will be prepared by the chairperson of the IRB and sent to the principal investigator. The response will include an explanation of the IRB’s action.

If the proposal is approved by the institution, the chairperson of the IRB will notify the principal investigator of the approval.

Adapted, in part, from:

1. www.hhs.gov Office for Human Research Protections. Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018)
2. www.research.utexas.edu The University of Texas at Austin. Office of Research Support and Compliance. IRB Policies and Procedures Manual