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.

I. REQUIRED COMPONENTS OF A COMPLETE RESEARCH PROPOSAL

A complete research proposal consists of:

1. Research Proposal Face Sheet
2. Research Proposal Narrative
3. Proposal Attachments (including Consent Forms)
4. Proof of Human Subjects Protection Training

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. Research Proposal Face Sheet

A copy of Neumann University IRB Form 001, latest revision, **Research Proposal Face Sheet**, must accompany any research proposal submitted for IRB approval. It is available for download on the NU IRB web page (https://www.neumann.edu/about/irb.asp).

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. Proposals for which the Face Sheet is missing or incomplete will not be reviewed by the IRB until this form is submitted.

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.

The following is provided to guide investigators in the preparation of the Research Proposal Face Sheet (IRB-001).

1.1 Principal Investigator/Additional Investigators
Provide information for the principal investigator including name and address and if relevant, names of additional investigators.

The **principal investigator** is the contact person for all formal communication with the individuals involved in a research project as well as correspondence with the IRB. The principal investigator is the researcher when only one researcher is involved in a research project.

The **additional investigator(s)** are the remaining individuals on the research project if there is more than one researcher involved. The group is responsible for designating one of their members to serve as the principal investigator. If a student is conducting the research, the additional investigator(s) should include the student's faculty advisor to the project.

1.2 Title of Research Project
The title should be brief but inclusive and descriptive.

1.3 Duration
The proposal should include an anticipated starting date that is no sooner than two weeks prior to when the research proposal is finalized and submitted to IRB. 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. Indicate "online" for any online data collection (virtual interviews, online surveys). Indicate data collection that will take place at various locations with "various" and explain further in section 2.4 of proposal narrative.

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
Indicate whether the study is biomedical research or social behavioral research. Briefly indicate the methodology and/or design (for example: correlational study of secondary data; randomized control trial; qualitative interview study, 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, interviews, or observation, estimate the numbers of persons you expect to survey, interview, 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

Indicate resources required for the research project, such as supplies, equipment, materials, or software.

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 investigator(s) (where applicable, and for student investigators, must include faculty advisor signature)
- Department Chair (and/or Dean or Program Director when applicable)

2. RESEARCH PROPOSAL NARRATIVE

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.

2.1 Abstract

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 Purpose

State the overall purpose of the research project. Include the research questions to be answered, and, if appropriate to the research methodology, hypotheses to be tested. Briefly explain the potential significance of the research project.

2.3 Duration

Provide an estimate of the duration of the entire research project. The anticipated starting date must be no earlier than two weeks prior to the date when the research proposal is finalized and submitted to IRB. Only after IRB approval is received may sample selection and data collection begin. The ending date is the anticipated date of completion of the research project. Note that projects with a duration of more than 12 months may be subject to continuing review (and in some cases, continuing review may be required more often).

2.4 Location

Provide the specific name and location of any and all facilities at which data collection will take place. Describe any online data collection that will occur (virtual interviews or online surveys). Describe if various locations will be used (for example, if interview participants will have the option to choose the location). Describe any relevant details about the location of data collection that impact the protection of human subjects.

2.5 Background

Briefly review the most significant previous research done in the topic area and the specific problem area and describe the current research in this topic and problem area. Following APA style guidance, document this review with appropriate in-text citations in support of statements and include a list of all cited references (also in the APA style).

Describe any preliminary work that the principal investigator, additional investigators, or others have done which led to this research project.

2.6 Methods

The methods section should describe:

- 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)

2.7 Resources

Identify and describe the supplies, materials, software, facilities, special equipment, consultative services, and other relevant resources that are necessary to carry out 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.

2.8 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 way 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.
- Indicate all special categories of subjects to be included in the research project, e.g. mentally retarded or disabled, minors, pregnant women, prisoners, etc.

2.9 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.

If the research involves potentially sensitive topics such as substance use/abuse, family violence/abuse, mental health issues, sexual behavior/preferences, or illegal behaviors, the researcher should consider any necessary procedures to handle the possibility of a subject

becoming upset during and/or after participation in the research and include this information in the IRB application. This may require that additional information is provided during consent procedures (and noted in section 2.10) and/or additional protections and safeguards for subjects (noted in section 2.11).

2.10 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.

Include information about how participants will be informed if the research includes sensitive topics.

2.11 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:

- Include information about additional protections if the research includes sensitive topics.
- Include a description of how data will be handled in the case that a subject withdraws from the study.
- 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 (for example, if survey will be closed when goal sample size is met; if qualitative data collection will be discontinued when saturation is reached), 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.

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.

2.12 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.

2.13 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.

2.14 Budget

The IRB is interested in budget information that has the potential to affect the safeguarding of human subjects involved in the research. Each proposal must contain a budget summary which provides a breakdown of expenses in the following categories:

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

3. PROPOSAL ATTACHMENTS

The following guidance describes commonly required proposal attachments. Investigators should include all those attachments relevant to the proposed study.

3.1 Instruments and Protocols

Include one (1) copy of any questionnaires, interview protocols, or rating scales that will be employed in the research project.

3.2 Subject Correspondence

Include sample copies of all correspondence that will be presented or sent to subjects or prospective subjects, and any intermediaries involved.

3.3 Letters of Support from Outside Institutions or Organizations

Include one (1) copy of any letters of support on organizational letterhead for each outside institution or organization that is providing resources to the project.

For example, if proposal entails: observational research that will take place in an outside organizational setting (i.e. schools, hospitals, community organizations, outside Neumann University), recruitment of research subjects that will be facilitated by an outside organization, retrieval of secondary or administrative data that will not be collected by the researcher but furnished by an outside organization (i.e. student achievement data, customer satisfaction data, employee retention data).

If your project uses an instrument created by another researcher or organization, include a copy of correspondence granting permission for use of the instrument.

3.4 Consent Forms

Include one (1) copy of any consent forms (for participants over 18 years of age) and/or assent forms (for participants under 18 years of age). The proposal must include 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.

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 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. It is recommended that the consent form be written in the same person throughout (for example, “you”), that scientific terminology be defined in plain language, and the document be carefully edited for errors in fact, grammar, spelling, and typing.

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 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 / Participant 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 told of the potential for unknown or unforeseeable risks or discomforts. This disclosure 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 who consent 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 of medical treatment or compensation for complications or injuries incurred as a result of participating in biomedical or behavioral research.

Subjects' / Participants' 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. PROOF OF HUMAN RESEARCH PROTECTION TRAINING
Per IRB policy I.R. 1.00 #14) All members of the IRB and individuals conducting research at the University are expected to complete Human Subject Assurance Training from the Office for Human Research Protections (OHRP), every three years, and submit their training certificate to the administrative liaison upon completion.

This policy applies to all individuals listed on an IRB proposal for research (Primary and Additional Investigators). Specific programs may require training that meets and supersedes this requirement. Refer to your school or program. For example, the DPT program requires students to complete a competency-based training course administered by the National Institutes of Health | Protecting Human Subject Research Participants (PHRP).

The minimum required training is five modules of the Office of Human Research Protections, Human Research Protection Training (Human Research Protection Training | HHS.gov). Required modules: When HHS Regulations Apply (Lesson 1); What is Human Subjects Research (Lesson 2); What are IRBs (Lesson 3); IRB Review of Research (Lesson 4); Institutional Oversight of Human Research (Lesson 5). At the completion of each module a certificate is provided. Retain all five certificates for your own records and submit them to your administrative liaison.

If an investigator has submitted certificates to an administrative liaison, they will be asked to provide their name, school or program, and e-mail address. If the investigator does not have a school or program administrative liaison who retains training certifications, they must submit proof of their training to IRB directly to NUIRB@neumann.edu to retain on file. Proof of training is considered current for up to three years from the date the training was completed.

II. PROPOSAL SUBMISSION AND REVIEW
Information about the steps for proposal submission is posted and maintained on the NU IRB web site (https://www.neumann.edu/about/irb.asp). Investigators should follow the steps as outlined on the web site for submission of each of the four components of a complete research proposal.

In some instances, a research proposal may qualify for exempt/limited review or expedited review. Investigators should check the list of categories of research that qualify for exempt/limited review and expedited review that is maintained by the Office of Human Research Protections when preparing their proposals. While the IRB makes the determination of review type, investigators may wish to submit a screening for exemption.

5. The Review Process

The IRB will attempt to review any research proposal and respond with a decision within thirty (30) days of receipt of the proposal. Delays may occur if the IRB must request clarification from the investigators, or if the IRB must consult individuals not on the IRB who have expertise in the 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.
- The IRB determines whether the proposal qualifies under the criteria for exemption based on federal guidance. Investigators may review these criteria and request IRB screening for an exemption. Additional charts are available through the Office for Human Research Protections to aid those who need to decide if an activity is research involving human subjects may be determined Exempt.
- If a proposal does not qualify as exempt under the criteria, it will either undergo expedited review and be circulated to members of the IRB or undergo full review (convened committee) and placed on the agenda for discussion at an upcoming IRB meeting.

The proposal will be evaluated to assess 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.

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 (convened committee) for a vote to disapprove.

6. IRB Response

6.1 Category I Requirements and Category II Recommendations

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

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 regarding:

- 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
- confidentiality

In the case of Category I Requirements, 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 to clarify the proposal. The principal investigator must revise the protocol, consent, and other documents and submit it for reconsideration. An attached document highlighting the clarifications is recommended. If the full IRB determines the risks continue to outweigh the benefits and disapproves of the study, the study must be entirely rewritten and resubmitted as a new study.

Category II Recommendations are defined as, “explicit conditions which recommend minor changes or simple agreement of the PI.” In short, a Category II recommendation is simply a recommendation or minor non-obligatory modification presented to the PI to enhance the study’s content. In the case of Category II Recommendations, the principal investigator may agree to the recommendations without revising the study as previously submitted. Examples of Category II Recommendations may include clarifications about the details of the research that do not meet the criteria of a Category I Requirement listed above; grammatical corrections; and minor formatting modifications.

6.2 Approval and Disapproval of Research Proposals

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

In cases where the IRB determines that the study does not meet the federal definition of human subjects research, a "Not Regulated" determination correspondence is distributed.

In cases where the IRB determines that the study meets the criteria for exemption, an “Exempt” determination correspondence is distributed.

IRB correspondence on Approval or Disapproval to investigators contain important information, including, but not limited to:

- IRB decision date
- Review type determination (not regulated, exempt, expedited, full review)
- Approval expiration date for proposals under full review (automatically set one year from decision date
- Interim reporting requirements (for modifications in studies requiring limited review, expedited review or full review)

- A list of modifications (e.g., specific protocol changes, informed consent changes, etc.) to be met for full approval and a deadline for investigator response, if contingent approval is initially granted

After a research protocol has received initial approval through a limited review, expedited, or full review, the IRB has continuing oversight responsibilities for the conduct of the research, some of which will depend on the project's level of risk to participants and/or the stage of the research activity.

6.3 IRB Correspondence and Investigator's Responsibilities Following Approval

Investigator correspondence with IRB should always include the proposal number (assigned to approved proposals by IRB). Correspondence on approved proposals may include study closure, extension, modification, other report, or as required by continuing review.

To ensure ongoing compliance with the federal regulations, it is the investigator's responsibility to:

- Report any unanticipated problems, adverse events, or other reportable information or occurrences (ORIO) promptly to the IRB to initiate an evaluation of the impact. ORIO refers to any unexpected or significant events that happen during a research study that need to be reported to the Institutional Review Board (IRB), even if they aren't necessarily considered adverse events, and could include issues like protocol deviations, data integrity concerns, participant safety issues, or problems with study procedures or facilities.
- Submit any proposed changes to the research protocol and/or procedures to the IRB for review prior to implementing those changes by following the amendment process (Changes to Approved Protocols) below.
- Prevent a lapse in IRB approval for an active, non-exempt human research study by following the Continuing Review process, if required.
- Close the IRB application once the project is completed.

6.4 Retaining Research Records

Investigators should retain research records, including signed consent documents and IRB correspondence. Federal regulations require retention of study documents, including informed consent forms, **for a minimum of 3 years after study closure.**

Records may need to be kept longer if other requirements apply. For example, any research that involved collecting identifiable health information is subject to HIPAA requirements and records must be retained for a minimum of 6 years after each subject signed an authorization. Researchers must comply with the longest applicable standard that applies to their research.

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.

6.5 Changes to Approved Proposals

Any protocol or procedural change to an approved study must be submitted to the IRB for review through the Amendment process. Examples include changes to the:

- Recruitment procedures
- Participant inclusion/exclusion criteria
- Research procedures (methods, evaluation criteria)
- Informed consent document/process
- Data collected

The modifications must be approved by the IRB prior to their implementation, except in cases where necessary to ensure the immediate safety of the participants. In those cases, the investigator must notify the IRB as soon as possible after the event occurs, but no later than seven (7) calendar days per OHRP or five (5) working days if the study is FDA-regulated. An amendment may be reviewed either by the full committee or by the expedited review process depending on the original review path, on the magnitude of the change, and the effect of the change on the study's level of risk (risk/benefit ratio).

6.6 Scheduled Continuing Review (SCR) Process

IRB approval must be renewed at least on an annual basis for:

- Studies involving more than minimal risk;
- Research that is FDA regulated;
- Studies that do not meet the criteria for expedited review; or
- Studies that otherwise are required to be reviewed annually per federal regulations.

Continuing review (i.e., ongoing oversight) is the process investigators use to renew IRB approval for a study. For a Scheduled Continuing Review (SCR), the investigator provides information to the IRB for its review, including:

- The number of participants enrolled and enrollment status;
- The status of the research;
- Descriptions of adverse events and/or unanticipated problems;
- The reasons for any withdrawal of participants;
- Descriptions of any complaints; and
- A summary of relevant new information that might relate to an individual's continuing participation in the research.

In addition to the information provided by the investigator, the IRB reviews:

- The research protocol to determine that the initial requirements for approval (45 CFR 46.111 and 21 CFR 56.111) continue to be satisfied;
- Approved amendments to the study, as applicable; and
- A copy of the current informed consent document.

Continuing Review by an IRB is not required for:

- Exempt human research

- Most studies that qualify for the Expedited Review process (except for those that are FDA-regulated or have other requirements for annual review per a grant or contract)
- Studies (regardless of review path) that have completed participant interaction/ intervention procedures and in which activity is limited to:
- Data analysis, including analysis of identifiable private information or identifiable biospecimens; and/or
- Accessing follow-up clinical data from procedures that participants undergo as part of standard clinical care. Human research studies that have been completed or involve only the analysis of de-identified data where personally identifiable information has been destroyed, including any links to any identifying keys or codes, should be closed (i.e., terminated).

Sections of these guidelines have been 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*
3. *https://research-compliance.umich.edu/peerrs-portal University of Michigan PEERS (Program for the Education and Evaluation of Responsible Research and Scholarship).*