Frequents Errors When Completing an IRB Application

This guidance document is designed to help investigators prepare an IRB application by providing insight into common mistakes that often increase review time and require protocol revisions. By incorporating these recommendations into your application and assuring the errors mentioned are not present, the review and approval of your research will be quicker with fewer required revisions needed. The intent of this sheet is to use beside the application at the time the application is completed.

Errors Encountered with the Over All Application

Incomplete Responses

- Take time to ensure your response addresses the question's required content. Incomplete responses will result in the application being returned to you for more information and clarity. This means the start of the research project will be delayed.

Congruency

- Many applications lack congruency across all materials.
- Compare your materials prior to submission. All materials should consistently describe the study. Make sure the application, consent form and recruitment materials consistently describe all elements of the study including time of participation, risks, compensation, and interventions. For example, if the application states that time to complete a questionnaire is 15 minutes, then the consent form must state the same duration.

No Response

- No response – questions are unanswered. If you read a question on the application and it does not apply, type "N/A" to indicate you have read and considered the question.

Supporting Materials

- Supporting materials are often omitted – it is important to submit all recruitment and consent materials, appendices, and any other document that is relevant to IRB review.
- Supporting materials include advertisements including templates of emails that are being sent to recruit subjects.

Incomplete Sentences, Spelling Error, Missing Words, etc.

- Use complete sentences and proper spelling and punctuation in your protocol.
- An application that is sloppy, unorganized, and full of errors leaves the impression that this is how the actual research will be conducted. An IRB Application (protocol) represents a contract with the University (and the federal agencies that oversee human subjects research) of how the research will be conducted and must be exact, clear, and free of errors.

Students as Investigators and their Mentor PI

All student-investigators or non-PI research team members who are completing the application must have the PI carefully read through the document before submission and sign. It is the PI's responsibility to have all materials and details in place before submission.

Consultations and Guidance

The IRB will provide consultations and guidance through online and in-person meetings or through emails, however it is not to be used for purposes of simply checking through application drafts or editing your work; all application materials must be formally submitted through the IRB office for review; reviews will not be done via consultations.

Application Errors by Section
Section Order as Appearing on the Application Form

INVESTIGATOR INFORMATION SECTION

CITI Training

Error: CITI training is often not current or is incomplete or date of training is not listed for all individuals listed.

- The IRB cannot approve a new protocol or continuing request if anyone listed here does not have current training with the completion date listed. CITI is the only training accepted by the NEOMED IRB. Applications which list expired or no completion dates will be returned and not reviewed.

You must complete all columns for all persons listed:

PERSONNEL **(Name, Degrees)** **-List PI first** **-List everyone engaged in the research***	***EMAIL***	***PHONE***	***NEOMED DEPARTMENT*** **(Institution or agency if outside of NEOMED)**	***DATE OF HUMAN SUBJECT TRAINING***	

Application Signature

Error: Many applications are received without the PI's signature and the application must be returned. All applications and subsequent revised protocols must be signed by the study's PI and dated with the current date.

Principal Investigator Signature:

I verify that the information provided in this IRB Application is accurate, complete and an appropriate activity for submission to the IRB. Please be reminded the NEOMED IRB's only authority is to review, approve, and provide oversight of activities that meet the federal definition of human subject research and does not include projects conducted for the purpose of class, course, or program evaluation, quality improvement, or institutional effectiveness. For information on these types of projects, please contact the Office of Institutional Research at 330-325-6333.

Principal Investigator: ___ _____ Date:_____ _____If this is a student project, signature of student: _____ _____ Date: _____

APPLICATION CHECKLIST SECTION

Error: The Application Checklist section is often left blank.

- Complete the checkboxes in this section to indicate which materials are included with the application form. This helps the reviewer know that the materials have been included and to look for them when they are reviewing your application.

PERSONNEL SECTION

Error: Individuals are missing in this section

- Many times individuals listed in section 1 do not appear in section 2. Explain the role of all personnel listed in section 1 in section 2.

PROTOCOL SUMMARY SECTION

5. Hypothesis and Supporting Questions

Error: Many times investigators formulate a weak or no hypothesis in this section. Use the definitions and examples below to help formulate a true scientific hypothesis supported by relevant research question:

- A hypothesis should always:
  -be a statement and not a question.
  -Explain what you expect to happen in your study
  -Be clear and understandable
  -Be testable
  -Be measurable
  -Contain an independent and dependent variable

An example of a good hypothesis:

"The incidence of low birth weight in babies of mothers who are anemic is higher than those mothers who are not anemic." (This hypothesis contains one dependent variable (low birth weight) with one independent variable (anemia).

After a hypothesis is formed, develop your research questions to support your hypothesis. Below are examples of research questions that would support

-How many women with anemia in pregnancy have low birthweight babies?
-Do food choices during pregnancy effect low birth weight in anemic mothers?
-What is the incidence of anemic mothers that give birth to low birthweight babies that are also anemic?

6. Purpose of the Study

Error: Many times the study's objectives are not clear, leaving the purpose of the study unclear.

The research objectives represent the relevance of the research to be conducted. For example, with the research hypothesis stated above, a scientific objective could be:

- The objective of this investigation is to confirm the correlation between low birth weight in infants and anemia in mothers.
- The objective of this investigation is to find out the prevalence of anemia in mothers and their infants.

11. Procedures, Interactions, or Interventions

Error: Interactions/procedures/interventions are not detailed enough or are missing.

- All interactions/procedures or intervention which will occur with human subject must be described in the application and the consent form/information sheet.
- An intervention can be broadly defined as an activity that is designed to manipulate a behavior. Interventions include cognitive activities, environmental manipulations, learning tasks, and physical manipulations.

16. For Research with Surveys and Focus Groups

Error: The duration listed is incorrect (16d).

- Duration does not mean the length of your proposed study period, but the time it takes a subject to participate in the research methods you have described, e.g., time it takes to complete a survey or set of surveys.
- The duration needs to be described in both the application and the consent form.

17. Data Collection, Storage and Confidentiality

Error: The materials do not correctly describe the study as either anonymous or confidential.

- *Anonymous* – unidentified in that personally identifiable information was not collected or if collected, identifiers were not retained and cannot be retrieved; information that cannot be linked directly or indirectly by anyone to their source(s).
- *Confidential* – there is prospect of being able to identify a subject and subject identities are maintained in a manner that prevents inadvertent or inappropriate disclosure. Coded information is considered confidential because it would be possible to link the information back to its source.

The question of either "anonymous or confidential" data is asked in 15 (b)

18. Potential Risks and Discomforts

Error: The investigators lists "no risks" or N/A in this section.

- It is important to understand as a researcher that all studies come with some degree of risk. Even in the case of studies employing only surveys, the content and number of the questions asked my provoke uneasiness, boredom, and fatigue.
- In the case of confidential data collection, the possibility of a breech in confidentiality always exists.

20. Compensation for Participation

Error: Investigators state an incentive will be given to subjects for participation in the study.

- Research participants should not be given incentives to participate in research as to avoid coercion. It is acceptable to reimburse participants in some form for their time spent to participate or for travel costs if the reimbursement does not seem excessive considering the socioeconomic status of the research participants.

INFORMED CONSENT/ASSENT PROCESS SECTION

- It is important for all investigators working with human subjects to understand that gaining the consent of a participant in research is more than just having a person sign a form that has been placed in front of them. Consent involves an actual process of teaching the participant about the project and having them make a truly informed decision to participate. This usually includes a verbal explanation of the project in addition to written information which the participant acknowledges they understand with their signature. Sometimes, depending on the nature and degree of risk of the study, there is no requirement for a consent form to be signed by the subject and retained by the investigator. This is referred to as a "waiver" of signed consent. The consent process, or the teaching of the project to the participant, must always take place regardless if a signed form is used or a shorter "Information Sheet" is used. Templates for both a Signed Consent Form and Information Sheet may be found on the IRB webpage.
- Waivers of Written Consent are not to be granted by the IRB simply because it is easier than having participants sign a paper. There must be appropriate justification. The IRB Application lists the two only acceptable reasons for a signed consent form to be waived. Such waivers are not granted for vulnerable populations and/or Full Board applications.

OTHER SUGGESTIONS FOR A SUCESSFUL APPLICATION

- Ask a friend or co-worker or someone not involved in the project to read your materials prior to submitting them to the IRB. They should be able to easily understand your research, its purpose, aims, and procedures.
- If your study involves multiple compliance processes (external IRB agreements, HIPAA, FERPA, IBC, Radiation Safety) plan ahead. These processes may complement IRB processes, but are separate, and take time to coordinate.