

**What is the IRB Looking For?**

**a. Study Background and Purpose**

Explain the clinical and scientific aspects of what has led historically to this study and explain the purpose of this study specifically. State the study hypothesis.

*IRB reviewers will be looking for the following*

* *Are the specific aims clearly specified?*
* *Is there adequate preliminary data to justify the research?*
* *Is there appropriate justification for this research protocol?*

**b. Study Design**

* Note the number of subjects and controls and any identifiable subsets (eg, gender or age groups. If no controls, explain why.
* Note the full-time commitment for each subject (eg, a one-year study).
* Note eligibility screening criteria – best shown as inclusion/exclusion lists.
* Note who will perform the consenting process and when
* Note location and duration of research

*IRB reviewers will be looking for the following*

* *Is the scientific design adequate to answer the question?*
* *Are the objectives likely to be achievable within a given time period?*
* *Is the scientific design (i.e., randomization; placebo controls; Phase 1, 2, or 3) described and adequately justified?*
* *Are inclusion and exclusion criteria clearly specified and appropriate?*
* *Are the rationale and details of the research procedures accurately described and acceptable?*
* *Is there a clear differentiation between research procedures and standard of care?*
* *Are the individuals performing the procedures appropriately educated?*
* *Is the location of where the procedure will be performed acceptable?*
* *Are there adequate plans to inform subjects about specific research results if necessary (clinically relevant results, risk of depression, risks of suicide, incidental findings, etc.)?*

**c. Subject Population (who, what, where)**

* Identify the source of subjects (elementary school, TCNJ, Capital Health Hospital etc.).
* Note the total number of subjects to be enrolled
* Note the population included in research

*IRB reviewers will be looking for the following*

* *If women, minorities, or children are included or excluded, is this justified?*
* *Is the choice of subjects appropriate for the question being asked?*
* *Are the methods for recruiting potential subjects well defined?*
* *Are the location and timing of the recruitment process acceptable?*
* *Is the individual performing the recruitment appropriate for the process?*
* *Are all recruitment materials submitted and appropriate?*
* *Are there acceptable methods for screening subjects before recruitment?*

**d. Data Collection and Analysis**

* Note what data will be collected in detail. (Best shown as list or attach an investigator created data collection form/spreadsheet) Include an explanation of identifiers and how they will be used or not or at what point they will be stripped from the database.
* Explain how the data will be protected and who will have access to it and in what manner (eg, data will be entered by research coordinator on password-protected PC in her personal office).

*IRB reviewers will be looking for the following*

* *Is the rationale for the proposed number of subjects reasonable?*
* *For high risk studies, are there adequate provisions for monitoring data, e.g., a data safety monitoring board (DSMB)?*

**e. Risks**

* Identify the potential risks to subjects and include their degree of possibility.

Explain how risks will be minimized (eg, screening for contraindications).

*IRB reviewers will be looking for the following*

* *Are the risks adequately identified, evaluated, and described?*
* *Are the potential risks minimized?*
* *Is the risk/beneﬁt ratio acceptable for proceeding with the research?*
* *If children are involved, which regulatory category of risk/beneﬁt does the protocol fall within, and are all criteria within the category adequately addressed?*

**f. Benefits**

* List the potential benefits to the subject personally.
* If no personal benefits exist, explain the global benefits to the field.

*IRB reviewers will be looking for the following*

* *Are the benefits adequately identified, evaluated, and described?*
* *Are the potential benefits maximized?*
* *Is the risk/beneﬁt ratio acceptable for proceeding with the research?*
* *If children are involved, which regulatory category of risk/beneﬁt does the protocol fall within, and are all criteria within the category adequately addressed?*

**g. Confidentiality**

* Note what personal health information (PHI), if any, will be collected (attach data collection form)
* Note how specimens will be labeled; will any PHI be recorded on sample
* Note at what point information will be de-identified.
* Note how data will be protected (e.g. de-identified, password protected electronic data base, locked office etc.)
* Note where data will be analyzed and by whom.
* Note where data will be stored, how will it be kept secure and by whom
* Note if the data will be transferred out of TCNJ, how it will be securely transferred, and to whom
* Note if the transferred data will be returned to TCNJ and if not, how will it be securely stored at the transfer site
* Note where the master key will be kept, how it will be kept secure and by whom

*IRB reviewers will be looking for the following*

* *Are there adequate provisions to protect the privacy and ensure the confidentiality of the research subjects?*
* *Are there adequate plans to store and code the data?*
* *Is the use of identifiers or links to identifiers necessary, and how is this information protected?*
* *Is the amount or type of compensation or reimbursement reasonable?*
* *Are there adequate provisions to avoid out-of-pocket expenses by the research subject, or is there sufficient justification to allow subjects to pay?*
* *If children or adolescents are involved, who receives the compensation, and is this appropriate?*
* *Are all the elements of informed consent contained in the consent document?*
* *Is the process of obtaining consent adequately described?*
* *Is assent required?*
* *Is waiver or modification of consent possible?*