

From Research Idea to IRB Review Elements of a Protocol

This template is being provided as guidance on how to develop and write a protocol that is being planned for IRB submission. While including each major section in your protocol is strongly recommended, depending on the type of research you are planning, you may or may not need each sub-section. Please feel free to contact your local IRB if additional guidance is needed.

Recommended Sections

- **Aim and Hypotheses**

- Begin with a brief introduction to describe the origin and importance of the study.
- Clearly state the aim(s) and hypothesis (es); listing them by number if there is more than one.

- **Background**

- Describe the facts, events, and thought processes leading to the currently proposed research project.
- Summarize any pertinent studies supporting this proposed project. Human studies are preferred; include animal studies only if human studies data are lacking.

- **Rationale**

- Explain how the background information from the literature supports the currently proposed hypothesis (es).
- Explain how the performance of this proposed project will advance knowledge in this field, and/or improve understanding of the disease or physiological condition being studied.
- Explain how this study, if the hypothesis (es) is (are) proven correct, might improve the diagnosis or treatment of the disease being studied (if applicable), or advance knowledge in the field.

- **Research Plan (THE MOST DETAILED AND TIME CONSUMING PART)**

- Indicate type of study (e.g. cross-sectional vs. longitudinal; multicenter, controlled, cross-over, randomized, etc.) and describe how the study is to be conducted.
- Describe the analytic and statistical methods to be used, including the method of randomization.

- If blinding is involved, describe the procedures, indicate who has the code to the blind, and the circumstances and procedures for breaking the code.
- State the maximum number of subjects to be enrolled in each group. If the research project needs to be pilot tested, state how many subjects will be enrolled in the pilot test and how the procedures for the pilot test will differ from those used in the research protocol.
- Subject criteria: Age, gender, disease, and stage of treatment. Justify excluding subjects based on race, gender, or age.
- Inclusion criteria: State the criteria for inclusion in the study.
- Exclusion criteria: State the criteria for excluding potential subjects from the study.
- Withdrawal/Termination criteria: Include the specific circumstances in which the subject's participation will be terminated by the investigator, including any necessary safety precautions to be applied to those who withdraw (tapering drug doses, evaluative x-ray, etc.)
- Clarity regarding whether a study subject may participate in another research study while participating in this research study.
- As appropriate, address the following parameters as each relates to the individual subject in the study. Be sure to include consideration of study assignment (Arm A, Arm B, placebo, active substance, etc.):
 - Physical risk
 - Psychological risk
 - Social risk
 - Economic risk
 - Potential benefit of participating in the study
 - to the individual subject and/or parent if any
 - to the population from which the subject is drawn
 - to science, society, and humanity in general
 - Laboratory tests: Indicate purpose, amount and timing of tests performed (e.g., blood tests, urine tests, CSF tests, EKGs, etc.).
 - Study Procedures: Describe imaging techniques including the instruments used, time required for each study, cognitive assessments)

- Clearly indicate which procedures, tests, visits, etc., are part of usual standard therapy and which are performed solely for research purposes. Make it clear which tests are routinely performed for clinical care but are providing data for the research (and are billable to insurance companies), and which tests are only performed for research purposes (not billable to insurance companies).
- Describe the fate of anybody component (blood, CSF, bone marrow, etc.) used in the study, emphasizing confidentiality of labeling of the sample and the sample's destruction or storage.
- **Subject Timeline: Consider attaching a study flow chart illustrating subject visits and tests or procedures to be performed at each visit.**
- Describe how adverse events will be ascertained and handled. Explain exactly which adverse events will be considered serious and reported to the IRB. The reporting timeframe should also be detailed.
- Describe how the severity of the adverse event and its relationship to the study protocol will be assessed and by whom.
- Explain exactly what will happen if a patient experiences an adverse event (for example, will discontinue study drug).
- Explain whether the study will be monitored by a Data and Safety Monitoring Board and if not, why a board is not necessary.
- Describe Accountability procedures as they relate to drugs, devices, and data including who on the research team will be accountable (in addition to the Principal Investigator), who will interface with the pharmacy (drugs) or sponsor (devices).
- Describe from where the subjects will be recruited and what arrangements have been made with other institutions (if applicable).
- Describe by whom and how the recruitment is performed.
- Attach a copy of advertisements and/or flyers and state where they will be placed.
- Indicate who will give subjects detailed and comprehensive information about the study and obtain their written consent.
- Indicate how the consenting process will be structured to ensure independent and thoughtful decision-making, and what steps will be taken to avoid coercion and guarantee confidentiality.

- Indicate how, and by whom, it will be determined whether the subject is able to give informed consent, or whether their legal guardian will give informed consent. For subjects whose ability to give informed consent may be compromised by cognitive and/or decisional impairment (examples may include individuals with a psychiatric disorder, an organic impairment, a developmental disorder, or those suffering from a terminal illness, degenerative disease, severe physical handicap or dependence on drugs or alcohol).
- Certificate of Confidentiality: a Certificate of Confidentiality should be obtained for research involving collection of information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. For more information, go to: <http://grants1.nih.gov/grants/policy/coc/index.htm>
- Explain how data will be coded, recorded, and stored to protect confidentiality
- Identify all parties who will have access to the data, including the key to the identity code.
- Identify all parties who will have access to research records, such as research staff, sponsor, monitor(s), DSMB(s), IRB(s), etc.
- Other logistics:
 - Study location(s)
 - Personnel: Who will do what?
 - Collaborations? If so, attach other IRB approvals to protocol if available.
 - Patient cost and/or remuneration for study participation or injury?
 - Tissue banking? If so, justify how it relates to context of protocol.
- **Appendices**
 - All appendices (e.g., recruitment flyers, data collection tools, patient education tools, etc.) MUST receive IRB approval before use.
 - Explain any vulnerable participants (e.g., children, pregnant women, prisoners, etc.)