



GUIDANCE DOCUMENT - ESSENTIAL ELEMENTS OF A RESEARCH PROTOCOL

Writing a Research Protocol

According to 45 CFR 46.111, certain elements must be included with each 'new' IRB submission in order to ensure an effective review by the IRB Committee. The protocol (study design) should address certain areas in detail. The format below is suggested when writing a protocol.

Purpose of the Study and Background

Purpose of the Study

State the specific scientific objectives (aims) of the research. Brief references to literature and a statement of problem. The question and hypothesis of research study.

Background

This paragraph should support the purpose of the study. [Note: References should be cited in the Background.]

Study Design

Type of study design and principle variables or outcome measure.

Characteristics of the Research Population

Number of Subjects

State the total number of subjects expected to participate. In the case of multicenter protocols (performance sites in addition to those for which the IRB has jurisdiction) also include the overall total. Explain the reason for choosing this sample size. Include information regarding how subjects will be identified for study inclusion (e.g. through medical records, hospital database, office charts etc.)

Gender of Subjects

Describe the intended gender distribution of the subjects. If there are any gender based enrollment restrictions, explain the nature of the restriction(s) and provide justification. Equitable inclusion of both men and women in research is important to ensure that both receive an equal share of the benefits of research and that neither bears a disproportionate burden. Therefore, subjects of both genders should be included in the study unless there are appropriate medical and/or scientific reasons. [Note: Women of childbearing potential may not be routinely excluded from participating in research.]

Age of Subjects

State the age range of the subjects. Provide the rationale for selecting this age range. Participation of adult subjects in research should not be age-restricted unless there is scientific and/or medical justification. [Note: The age of majority in New York is 18 and special considerations apply to research with children. If you are conducting research with children, please take into account issues relating to consent/assent detailed below]

Racial and Ethnic Origin

Describe the intended racial and ethnic distribution of the subjects. If there are any enrollment restrictions based upon race or ethnic origin, explain the nature of the restrictions and provide justification. [Note: Within the limitations imposed by the population of the study site(s), research should include sufficient enrollment of persons of diverse racial/ethnic backgrounds to ensure that the benefits and burdens of research participation are distributed in an equitable manner.]

Inclusion Criteria

List the inclusion criteria. These should be based on scientific rationale and should define who will be eligible for the study.

Exclusion Criteria

List the exclusion criteria. These should be scientifically valid and help further define the subject population.

Vulnerable Subjects

If vulnerable subjects (e.g., those with limited autonomy or those in subordinate positions) are included, justification must be provided. Children, pregnant women, fetuses, and prisoners are considered vulnerable populations in the federal regulations. However, the elderly, students, employees, and persons with decisional incapacity are also generally considered vulnerable subjects in need of greater protection.

Methods & Procedures

Methods & Procedures

Summarize the research design and list procedures to be used to accomplish the specific aims of the project. Procedures/tests/interventions that are considered experimental and/or procedures performed exclusively for research purposes must be identified and differentiated from those that would occur regardless of the research (i.e., standard of care). Point out any procedures, situations, or materials that may be hazardous and the precautions to be exercised to minimize the risks. The outline must identify routine procedures performed solely for research purposes and any procedure that may extend a subject's length of stay. Identify and address potential biases or problems. If subjects are to be randomized please detail randomization procedures.

Data Analysis and Data Monitoring

If the study is designed to test a hypothesis, explain sample size derivation and address appropriate power issues. Summarize the statistical/analytical methods. For trials that involve interventions that entail potential risk to subjects, a data monitoring committee may be considered to protect the safety and/or welfare of subjects. If you will employ a data monitoring committee, please provide a detailed description of its operation (i.e., membership, function, frequency of review, stopping rules).

Data Storage and Confidentiality

Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data; including coding data and choosing an appropriate and secure data storage mechanism that will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person(s) or agency to whom the information will be released and the purpose of the release (e.g., routine verification of case report forms).

Risk/Benefit Assessment

Risk

Detail the risk that the research presents. (A risk is a potential harm associated with the research that a reasonable person would likely consider injurious.) Describe the potential risks associated with the study. Keep in mind, risks are not only physical, but psychological, sociological, economic and legal as well. This includes any specific toxicity data noted in the investigator's brochure. If possible, estimate the probability that a given harm may occur and state its potential reversibility.

Protection Against Risks

Describe how the study design will prevent and/or minimize any potential risks or discomfort. Potential risks and discomforts must be minimized to the greatest extent possible by using procedures such as appropriate training of personnel, monitoring of subjects, withdrawal of the subject upon evidence of difficulty or adverse event (clearly define the exit criteria); and referral for treatment, counseling or other necessary follow-up. State who will pay for treatment, counseling or follow-up.

Potential Benefits to the Subjects

Describe potential benefit(s), if any, for subjects participating in the research. If there are no anticipated benefits, this should be stated. [Note: Payment to subjects is not considered to be a benefit of research (see Payment section below)].

Investigator's Qualifications & Experience

Your IRB Submission must include one copy of C.V./resume and medical license for each investigator. All key research personnel are required to complete CITI training – you may contact the IRBCo. Office to obtain these instructions.

Subject Identification, Recruitment and Consent/Assent

The information detailed in the protocol will provide a base for the information that will be included in the consent document. If the information is not detailed in the protocol the IRB will not have been provided with accurate information regarding the consent process or the detail that should be included in the process or the document. Hence, it is important to consider the categories in this section because investigators have a legal and ethical obligation to ensure that prospective subjects/subjects' representatives have sufficient knowledge and comprehension of the elements of informed consent. The information presented to subjects must be clear in order to enable subjects to make an informed and enlightened decision whether or not to participate or allow participation in research.

Please note: if recruitment and consent are not applicable such as in certain emergency medicine research or studies of existing data/specimens, you may address only the first item below (study population identification) and explain why recruitment and consent are not applicable.

Method of Subject Identification and Recruitment

Describe the method(s) that will be employed in the identification and recruitment of prospective subjects. Note: The identification and recruitment of subjects must protect privacy and be free of undue influence. Recruitment of an investigator's own staff, employees and patients may be considered potentially coercive and steps should be taken to minimize undue influence. These should be outlined in the protocol.

Process of Consent

Describe who will obtain consent and how the process of informed consent will be structured to be conducive to rational and thoughtful decision making by the subject/subject's legally authorized representative. Individuals who are authorized to obtain consent must be listed on the protocol (or FDA form 1572) and consent form document. If necessary to use 'Auditor/Witness' and/or translator, these roles would be described in this section.

Subject Capacity

If not all subjects will have the capacity to give informed consent, describe how capacity will be assessed. Describe the anticipated degree of impairment relative to their ability to consent to participate in research. Research with persons who have diminished capacity is allowed only for minimal risk or direct benefit studies.

Subject/Representative Comprehension

In this section, describe how it will be determined that the subject/subject's authorized representative understood the information presented. This section should clearly document that the investigator has an adequate plan in place to assure an acceptable level of comprehension before consent is obtained. If children and/or decisionally impaired adults will be subjects, this section should also include a specific plan to assess comprehension during assent (the subject's agreement).

Debriefing Procedures

In psychological studies where any information will be purposely withheld from the subject, state the information to be withheld, justify this non-disclosure and describe the post-study debriefing of the subject.

Consent Forms

Consult the IRBCo's Guidance Document, titled, Required Elements of Informed Consent for specific sections required for consent documents. The first page of the consent form must be printed on letterhead of the department or institution.

Documentation of Consent

The PI is responsible for ensuring that valid consent is obtained and documented for all subjects. If not already addressed in item above (Process of Consent) specifically describe how consent will be documented and how/where documentation will be stored.

Costs to the Subject

Describe and justify any costs that the subject will incur as a result of participating in the study. This section should clarify who will pay for procedures associated with the study (e.g., sponsor of the research, etc). Normally, subjects should not have to pay for research procedures without direct benefit. No charge may be made to subjects if the costs are covered by a grant, contract, or other payment method.

Payment for Participation

Describe any reimbursements or payments such as cash payments, coupons and gift certificates that the subjects will receive for participation. List the prerequisite condition(s) that must be fulfilled by subjects to receive these payments. The amount must be justified and not constitute undue inducement of the subject to participate in the research or to continue beyond a point that they would have otherwise withdrawn. Note: The IRB requires a prorated system for financial payments. This means that payments are accrued as the study progresses and that subjects do not have to complete the entire study to be eligible to receive a payment. This is to protect the subject's right to withdraw without penalty.