

## Guidelines for Writing a Research Protocol

The format below is suggested when writing a protocol.

### I. PURPOSE OF THE STUDY AND BACKGROUND

- 1 **Purpose of the study.** State the specific scientific objectives (aims) of the research.
- 2 **Background.** This paragraph should support the purpose of the study. [Note: References may be cited in the Background.]

### II. CHARACTERISTICS OF THE RESEARCH POPULATION

- 1 **Number of subjects.** State the total number of subjects expected to participate. In the case of multi-center protocols (performance sites in addition to those for which the RSRB has jurisdiction), also include the overall total.
- 2 **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.]
- 3 **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. Special considerations apply to research with children.]
- 4 **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.]
- 5 **Inclusion Criteria.** List the inclusion criteria. These should be based on scientific rationale and should define who will be eligible for the study.
- 6 **Exclusion Criteria.** List the exclusion criteria. These should be scientifically valid and help further define the subject population.
- 7 **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, the elderly, students, employees, fetuses, prisoners and persons with decisional incapacity are generally considered vulnerable subjects in need of greater protection.

### III. METHODS AND PROCEDURES

- 1 **Methods and Procedures.** Summarize the research design and all procedures (sequentially) to be used to accomplish the specific aims of the project. Procedures/tests/interventions which are considered experimental and/or procedures performed exclusively for research purposes must be identified and differentiated from that which 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. Identify routine procedures performed solely for research purposes (e.g., additional tests).
- 2 **Data Analysis and Monitoring -** Summarize the statistical/analytical methods to be used. For trials that involve interventions that entail potential risk to subjects, a data monitoring committee may be required to protect the safety and/or welfare of subjects. Provide a detailed description of its operation (i.e.,

membership, function, frequency of review, stopping rules).

Studies involving greater than minimal risk must have a *Data and Safety Monitoring Plan*: a plan established to assure that each research study has a system in place for appropriate oversight and monitoring of the conduct and progress of the study to ensure that: 1) important information that may affect the safety or welfare of subjects comes to light and is acted upon as quickly as possible, and 2) the validity and integrity of the data. Who is responsible for monitoring the data, and at what intervals, to ensure subject safety?

3 **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. This includes coding data and choosing an appropriate and secure data storage mechanism which 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).

#### IV. RISK/BENEFIT ASSESSMENT

1 **Risk Category.** State the risk that the research presents as one of the following: Minimal, Greater than Minimal. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. A risk is a potential harm associated with the research that a reasonable person would likely consider injurious.

2 **Potential Risk.** Describe the potential risks associated with the study. 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.

3 **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, withdrawal of the subject upon evidence of difficulty or adverse event; and referral for treatment, counseling or other necessary follow-up. State who will pay for treatment, counseling or follow-up.

4 **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).

5 **Alternatives to Participation.** This section should include a description of alternative courses of action which are available should the subject elect not to participate in the study. If the subjects are students who will receive academic credit for participation, describe the alternatives available to earn equivalent academic credit. Academic alternatives must be approximately equal in time and effort required.

#### V. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

*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.*

1 **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 students, employees and patients is considered as potentially coercive and the steps taken to minimize undue influence should be included.

2 **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 without any element of coercion or undue influence. Only individuals who are listed in this section are authorized to obtain consent. If used, 'Auditor/Witness' and translator roles would be described in this section.

3 **Subject Capacity.** If all subjects will not 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.

4 **Subject/Representative Comprehension.** All 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 to enable them to make an informed and enlightened decision whether or not to participate or allow participation in research. 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).

5 **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.

6 **Consent Forms.** Consult the RSRB consent form guidelines for specific sections required for consent documents. The first page of the consent form must be printed on letterhead of the department or institution.

7 **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 two above (Process of Consent), specifically describe how consent will be documented and how/where documentation will be stored.

8 **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., agency grant versus departmental funds). 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.

9 **Payment for Participation.** Describe any reimbursements or payments such as cash payments, coupons and extra class credit 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 RSRB 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.