

RASCAL Study Description Help Text
August 22, 2009

Provide a detailed description of your proposed study here. You may copy and paste from a word processor file; if you use this method, please select “View Study Description” before submission, to evaluate the pasted text for conversion errors, and correct any that are found.

Please structure this description using headings 1 through 11 below. If an element is not applicable, include the heading, followed by “Not applicable”.

ABBREVIATED REQUIREMENTS: If this is a **multicenter, industry sponsored trial, or a study that is sponsored by a national cooperative group** (e.g., ACTG, NCI Cooperative Oncology Group), this field may be limited to items #7, 8, 9, and 10, provided that all other items are addressed, in detail, in the sponsor’s protocol and related documents.

1. Study Purpose and Rationale .

Include pertinent background description with references that are related to the need to do this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.

2. Study Design and Statistical Procedures .

Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations based on the number of participants to be entered into the study.

3. Study Procedures

Describe the procedures in sufficient detail so that a reviewer who is not familiar with them can comprehend what is to be done and can evaluate any risks. Delineate procedures that are already being performed for diagnostic or treatment purposes from those that are being done for research, i.e., clearly identify those procedures that would be occurring whether or not the individual was participating in this research.

4. Study Drugs or Devices

If this is a drug, device, or biologic study, describe how the drug or device works and past experience. [Be sure to complete the Investigational Products section for each applicable article.]

5. Study Instruments (e.g., Questionnaires, Interview Outlines, Focus Group Guides)

Describe any study instruments that will be used, and identify which are standardized instruments. Attach a copy of each in RASCAL

6. Study Subjects .

Give detailed inclusion and exclusion criteria and number of patients to be enrolled based on the statistical description and any other considerations. This information should relate to the background information provided above, and must be consistent with information entered in the Subjects section. If this is a clinical trial, this should include a description of the disease and the goals of therapy.

7. Recruitment

Describe in detail how participants will be recruited including type (e.g., newspaper advertisements, posters) and location (e.g., CUMC or NYPH, private practices, clinics). Attach a copy of each written advertisement, and the script for each recruitment media or method that is verbal (e.g., video, telephone script).

If this is a CUMC study, remember that it is a CUMC policy that researchers **generally** cannot directly approach a patient for recruitment until that patient has been informed of the study by their physician who has ascertained and documented that the patient is willing to discuss the study with the investigators.

8. Informed Consent Process

Describe how consent will be obtained, including by whom (i.e., list one or more titles, roles, or names), when, and by what method (e.g., use of consent form requiring signature, verbally in-person, verbally by telephone). Be sure to describe means of communicating if non-English speaking, illiterate, or other vulnerable persons will be included among study subjects. Also if necessary, describe any visual aids or devices that may be used to help explain a complicated procedure or process.

9. Confidentiality of Study Data

Describe how this will be maintained (if it is to be maintained) locally, and during transmission to another site, if applicable. Include a clear description of how data will be stored, specifically indicating whether data will contain direct or indirect identifiers. Describe protections related to accessing the study data, whether in an electronic or paper form.

Please note that “deidentified” means that identifiers have been removed and no one (research team or others) can identify from whom the data or sample was collected. “Coded” means that the data/specimens are labeled with a code number, and there is a link between the respondent/donor and the data/specimen, i.e., someone can identify from whom the data/sample was collected if they have the link to the code. For any coded data/samples, indicate who, if anyone on the research team has access to the identifiable data.

10. Privacy Protections

Describe how subject privacy will be protected, and the limits to protection. Privacy protection may be summarized as safeguarding an individual’s expectation that the information they offer will be held in confidence. Protections should cover (e.g.,) screening activities, HIPAA provisions, forums such as focus groups where private information may be shared, and recordings of research activities, as applicable. Limitations such as compelled disclosure and mandatory reporting should also be described.

11. Potential Risks

Describe risks including data on risks that have been encountered in past studies. That is, if the occurrence of a certain adverse event was 20%, include those data in this description.

12. Data and Safety Monitoring

Describe how data and safety will be monitored locally to identify unanticipated problems (i.e., events, outcomes, or occurrences that are unexpected, at least possibly related to the research, and suggest an increase in risk of harm to subjects or others).

13. Potential Benefits

This description should also be based on accrued data from related studies that have been completed. There should be a rational description of why such benefits are expected based on current knowledge. If there is unlikely to be direct benefit, describe benefits to society.

14. Alternatives

If this is a clinical trial involving therapy, describe alternative therapies providing data to support their efficacy or lack of efficacy. An important alternative is also not to participate in this research.

15. Research at External Sites

If CU investigators will be conducting research at one or more non-CU site(s), additional information is required. This includes, but is not limited to, plans for authorization and/or IRB approval at each site, explanation of funding and organizational relationships, description of procedures at each site, and plans for data and safety monitoring. Details, as applicable to the various types of situations that may occur, are provided in the CU IRB Standard Operating Procedures, Section V, which are available on the Policies and Guidance pages of the IRB websites.

16. Columbia as Lead Institution

If CU will serve as the lead institution for a multicenter study, specific information about management of information related to safety of subjects must be provided. This includes, but is not limited to: 1) obtaining and maintaining IRB approval at each site; 2) ensuring that each site follows consent procedures and utilizes consent documents approved by the designated IRB (if the designated IRB is not the CU IRB, then the IRB-approved consent document must be similar to the CU IRB-approved consent document with regards the content and style of the document); and 3) plans for data and safety monitoring. Additional information is provided in the CU IRB Standard Operating Procedures, section 5, on the Policies and Guidance pages of the IRB websites.