

Pre-IRB Review Pediatric Human Subjects Checklist

Purpose of Document

This checklist is intended to facilitate Pre-IRB review for protocols involving pediatric human subjects as well as facilitate IRB submissions. It is being distributed to all divisions in the Department of Pediatrics and is also available to all researchers with studies involving pediatric subjects. This checklist seeks to incorporate both federal and CUMC guidelines.

This checklist is NOT intended to part of the RASCAL submission, but to be used by the Department of Pediatrics. NOT all sections will be relevant for all studies. PIs using the checklist should provide feedback to their Division Chiefs about the usefulness of the checklist. Divisions can modify the checklist and the scientific review process as needed.

The following is the website for the CUMC IRB:

<http://www.cumc.columbia.edu/dept/irb/index.html>

General

- Is this study:
 - Exempt?
 - Expedited?
 - Full review?

To be a study reviewed by expedited review, the study must involve no more than minimal risk (i.e. categorized as CFR "404"). In the "Child Involvement" section (which appears only if you select ""Children/Minors" in the "Subjects Section", categorize risk/benefit of the study according to Federal Regulations and explain your reasons for the category chosen. Please remember to provide the information that justifies this characterization in the descriptions below.

For additional descriptions, the following may be helpful:

<http://www.hhs.gov/ohrp/>

<https://www.rascal.columbia.edu/help/Irb/info/irbinfo262.html>

- Who sponsors this study (NIH, CDC, Pharmaceutical Co., etc.)?
- Is this a collaborative or multicenter study?

SIGN-OFF to ensure scientific review

- PI, Division Chief (must sign off before Department of Pediatrics Chair)
 - Chair, Department of Pediatrics
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Study Synopsis

Please note that this reflects the Rascal submission section entitled "Research". Be succinct. You can cut and paste from other documents.

1. Background: Study Purpose and Rationale.

Include pertinent background description which can include references that describe the need to do this study. The background should be *brief* and include both preclinical and clinical data.

2. Study Design and Statistical Procedures.

Describe the study design, e.g., randomized placebo controlled, observational epidemiology study, case-control, etc. Describe how you are going to analyze your data. The IRB needs to know that your study will provide meaningful information. Provide statistical procedures to be used including power calculations (if relevant) based on the number of participants to be entered into the study.

3. Study Procedures

Describe the study-related procedures (including a chart review) 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. For an intervention study, the IRB needs to understand exactly what is going to be done and how these procedures DIFFER from the standard of care.

Here are the Pediatric subject issues that must be addressed *if relevant* to your proposal:

- Sequence of testing mapped out:*** This would describe the sequence of testing to minimize multiple sticks or avoid repeated sedations.
- Medications:*** If experimental or standard medications are to be used, explain how doses are adjusted for body size or justify why not adjusted. If doses are adjusted for body size, describe the stable pediatric formulation to be used to allow precise dosing based on body size. Address if the effects of different doses will be studied. Describe Pediatric specific issues for investigational compounds, e.g., effects on growth and fertility.
- Blood drawing:*** Please include precise details about volume of blood drawing and how often blood will be drawn. Current guidelines for *no more than minimal risk* which could be applicable for an expedited review are: ≤ 3 cc/kg per 8 weeks, ≤ 50 cc total, and ≤ 2 draws per week. Increased amounts of blood drawing must be described precisely for the IRB to understand in the review process.
- Pediatric sedation/ pain management:*** If sedation to be used, describe who will administer and address if study team is approved for administration of sedation.
- Radiation exposure:*** This includes the use of any ionizing radiation (e.g., CT scan or chest x-ray) that is not part of the standard of care. You must submit an application to the Joint Radiation Safety Committee [<http://jrsc.cumc.columbia.edu/>]
- Pediatric developmental and psychosocial issues are addressed.***

4. Study Drugs or Devices [<http://www.fda.gov> to determine if an IND or IDE are needed]

If this is a drug study, *briefly* describe how the drug works and past experience in human subjects.

If this is a device study, *briefly* describe how the device works and past experience in human subjects.

5. Study Questionnaires

Briefly describe what will be asked. Highlight any potentially sensitive areas that will be explored, e.g., sexual activity, drug use. Attach a copy of the questionnaire to the Rascal proposal.

6. Study Subjects.

Give detailed inclusion and exclusion criteria and the number of patients to be enrolled. Include the ages of the subjects.

7. Recruitment

Remember that researchers cannot directly approach a patient or patient's parent for participation in a study until the patient's physician has been told about the study and agrees that the patient is appropriate for the study and gives permission to the investigator to approach the patient and their parents.

The IRB needs to understand the process by which patients/ families are recruited to be certain that they are not coerced or in vulnerable situations which could affect their ability to give true informed consent. Describe in detail how participants will be recruited. Include who will contact the families, when and where, e.g., private practices, clinics, etc. Attach any recruitment flyers or advertisements to the Rascal proposal.

8. Confidentiality of Study Data

Describe how confidentiality of personally identifiable study data will be maintained. This could include unique study ID #'s, password protected computer with access only by study personnel, locked file cabinet.

9. Potential Risks

Describe the reasonably foreseeable risks to the subject as a result of participating in the study. These may include risks encountered in past studies. When available, provide estimates of likelihood of risk. Risks could include loss to confidentiality. A description of the risks associated with the treatment of the underlying disease should NOT be included.

10. Potential Benefits

Potential benefits could be to the individual, to the patient's group, or to society. Potential benefits could reflect accrued data from related studies.

11. Alternatives

Describe alternative therapies with data to support their efficacy or lack of efficacy.

CONSENT ISSUES

- Have you determined the level of risk for the subject and described it in the consent?
 - Is this study NOT greater than minimal risk (probability of harm and magnitude of harm or discomfort NOT greater than those encountered in daily life or during routine physical/psychological exams or tests)? 45 CFR 46.404/21 CFR 50.51; i.e., Section 404.
 - Is this study GREATER than minimal risk with prospect of DIRECT benefit to subject (potential for medical benefit justifies risks AND anticipated benefit at least as favorable as available alternatives)? 45 CFR 46.405/21 CFR 50.52; i.e., Section 405.
 - Is this study GREATER than minimal risk with NO direct benefit to subject (MINOR increase over minimal risk AND intervention or procedure is: reasonably consistent with subject's medical, social, educational situations; AND will yield generalizable knowledge about subject's disorder or condition; AND is VITAL to understanding or ameliorating disorder or condition)? 45 CFR 46.406/21 CFR 50.53; i.e., Section 406.
 - Complete CFR designation in the "Child Involvement" section.
- Have you put the correct number of signature lines for parents in the CONSENT?
 - Not greater than minimal risk - 1 parent sufficient
 - Greater than minimal risk with direct prospect of benefit - 1 parent sufficient
 - Minor increment over minimal risk, no prospect of benefit - 2 parents needed
- Have you completed all CONSENT sections requested in Rascal?
- Did you print out the CONSENT and read it aloud to be certain it is comprehensible to a person with an 8th grade education?
- If you are asking for a waiver of documentation of consent, did you complete that section in Rascal to ensure your protocol meets Federal guidelines?

- Issues related to children in foster care should be discussed with the IRB regulatory team prior to submission.

ASSENT ISSUES

Seeking assent is generally suggested for all children 12 years of age or older, and those 7-11 years of age when appropriate.

- Have you completed the ASSENT section on RASCAL?
- Have you completed the relevant sections on the ASSENT form itself?
- Have you read the ASSENT aloud to be sure it would make sense to a child?

TRANSLATION ISSUES

- Translations can be provided either by a certified translator or the ?
- Do not translate documents until IRB approval of English documents.
- Remember to translate anything patients see (e.g. consents, assents, surveys, diaries).

<http://www.cumc.columbia.edu/dept/irb/policies/index.html#irb>

http://www.cumc.columbia.edu/dept/irb/policies/Nonenglish_Speaking_Subjects.rtf

TIPS to avoid having your proposal sent back and/ or approval delayed.

- Did you attach the entire grant and/or protocol?
- Did you attach the sponsor's full protocol?
- Did you attach the Investigator's brochure, if applicable?
- Did you attach the instructions for use for devices?
- Did you attach all study related documents that a subject or potential subject would see including study advertisements, diaries for adherence measures, questionnaires, etc.?

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- Did you complete HAZMAT for study personnel coming into contact with any potentially infectious materials, e.g., blood, sputum, etc.?
- Did you attach the HIPAA form?
- Did you submit an application to the Radiation Safety Committee, if applicable?
- Did you describe any payments to be made to the subjects in the compensation section of Rascal?
- Are all study personnel certified for research HIPAA?
- Are all study personnel certified for Good Clinical Practices?
- Are all study personnel certified for CITI (pediatric human subjects)?
<http://www.cumc.columbia.edu/dept/irb/education/documents/CITInstructions121307.doc>

If you aren't sure about these certifications, you can check in the "data sheet" section of your Rascal proposal for personnel on your protocol.
