

Abbreviated IRB Submission
For Multicenter, Sponsored Studies
June 16, 2009

The Columbia IRB has introduced a new abbreviated submission process for entry of multicenter studies sponsored by industry or NIH cooperative groups (e.g., ACTG, PACTG, HVTN, NCI Oncology Groups, etc.). All RASCAL fields that provide information regarding local implementation of the study will still need to be completed. However, the summary of the study will no longer be required, as the Columbia IRB will now rely on the sponsor's protocol for review by all of its IRB members). Item 3 below reflects the changes in the process from submission of all other types of studies.

The rationale for implementation of this abbreviated submission process is that the Columbia IRB generally finds that protocols developed by industry or the NIH cooperative groups are more consistent in their organization and content of information. As a result, IRB members will be able to rely on the sponsor's protocol better than the summary provided in RASCAL. Furthermore, this change eliminates the potential of discrepancies between the summary and the protocol or other errors that may have resulted in the creation of the protocol summary in RASCAL.

Abbreviated submission process

1. General Information screen: Complete all fields
2. Personnel screen: Add all study personnel
3. Research screen:
 - a. Enter Research Questions/Hypothesis(es) (from sponsor's protocol)
 - b. Enter Scientific Abstract (summary, from sponsor's protocol)
 - c. Enter Lay Abstract (description of study in non-technical language)
 - d. Study Description field: Enter the information described below
 - 1) Statements: "This is a multi-center, sponsored trial. Please see the attached sponsor's protocol (and *investigational drug brochure, or device manual*, as applicable) for scientific and procedural details."
 - 2) Description of recruitment procedures
 - 3) Description of the informed consent process
 - 4) Description of how data will be maintained and stored (e.g., identifiable, coded, de-identified, anonymous), and plans for maintaining confidentiality of identifiable data
 - 5) Plans for monitoring data and safety
4. Funding screen: Complete all fields
5. Location screen: Complete all fields

6. Subjects screen: Complete all fields with local information (i.e., # and demographics of subjects to be enrolled at CU); in the Subjects Justification field state the total number to be accrued for the study and the number of sites
7. Child Involvement screens: Complete, if children are included among subjects
8. Investigational Product screen: Complete, if a drug, device or biologic is involved
9. Human Specimen screen: Complete, if biological samples will be involved
10. Complete and attach any applicable Hazmat appendices
11. Complete and attach any applicable HIPAA forms
12. Attach all consent documents:
 - a. recruitment flyers, website or print advertisements
 - b. consent, assent, and parent permission forms
 - c. information sheets
13. Attach all study instruments
14. Attach sponsor's protocol, IDB (if applicable), and device documents (if applicable; e.g., device manual, instructions for use)