IRB Standard Operating Procedures
Version 4 June 12, 2012
Summary of Changes

Cover
Name
Version date (as each section is updated, the overall version date will change, e.g., when Section IX was revised in July 2012, the version date of the overall SOP document was revised to 4.1, and when another section is revised, the version date will become 4.2) (In regards to the footer, each page will show the section number and page number within the section, the page number within the overall SOP document) (Appendix III-SOP tracking will show the history of sections that have been changed since)
Revisions since Version 4 was released on June 12, 2012: Version 4.1 July 9, 2012 Section IX only

Introduction
Reorganization, incorporating information from various sections of the prior SOP version; also some new information throughout:
A – Institutional Leadership;
B – Institutional Culture;
C – Standard Operating Procedures (previously its own section);
D – Requirement for Submissions;
E – Definitions of Research and Human Subject;
F – Rascal.
(Reference Documents, cited throughout the SOPs, are auxiliary documents such as policies and guidance. They will soon be accessible by Document number from the IRB websites. Most are already listed there, although not listed by Document number.)
(Many abbreviations are used in the SOPs. Appendix I-Abbreviations provides a complete list.)

Section I: Human Research Protection Program
New section resulting from reorganization of other sections:
A – Institutional Review Boards and IRB Office (organization, duties, education/training; COI/confidentiality; committees);
B – Privacy Board;
C – Office of Sponsored Projects Administration;
D – Clinical Trials Office (Research Pharmacy, IND/IDE Assistance Program, Clinical Trials Monitoring Assistance Program, Spanish Translation Center);
E - Office of Research Compliance and Training;
F - Joint Radiation Safety Committee, Radioactive Drug Research Committee, and the Radiation Safety Office;
G – Institutional Biosafety Office;
H – Protocol Review and Monitoring Committee;
I – Irving Institute for Clinical and Translational Research;
J – NYP Pharmacy;
K – NYP Patient Services Administration;
L – Center for Bioethics;
M – Department Chairs, Investigators, and Departmental Administrators
(Researchers should note the scope of the HRPP. The HRPP is accredited by the Association for the Accreditation of Human Research Protection Programs. Columbia is in the process of being reaccredited, which includes a site visit that

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involves interviews with institutional officials, IRB staff, IRB members, researchers, and staff of other Research Administration offices and other units that are part of the HRPP, e.g., Clinical Trials Office, Radiation Safety Office, Sponsored Projects Administration, Research Pharmacy, NYP Pharmacy.)

**Section II: Institutional Review Boards**

Reorganization and important new information:
A - Columbia IRBs and Administrative Review Committee (principles/regulations/statutes/standards/policies, structure, scope of authority, autonomy, research conducted by CU faculty/staff/students, constitution, appointments/terms);
B – Role of Non-Columbia IRBs (reliance agreements, research conducted at CU by non-CU researchers).

(Due to the significant increase in number of reliance agreements over the past year or two, it is important that researchers have a basic understanding of the various types of agreements and their respective requirements, as well as being aware that extra time is needed to complete the review of a protocol when an agreement is involved.)

**Section III: Preparation of Submissions to the IRB**

Expansion of information previously included (extremely important information that is necessary to be aware of, in order to prepare complete submissions):
A – Preparation of Event Submissions (explain “event”);
B – IRB Abbreviated Submission Process (e.g., industry-sponsored, student-initiated, grant-funded);
C – Personnel (PI eligibility and responsibility for determination of research/human subject, roles and responsibilities, training);
D – Documents/Information Needed for Each Type of Event (new protocol, modification, renewal/continuing review, unanticipated problems, termination/closure, deviations/violations, emergency use report);
E – Material Needed for Review of Particular Types of Research or Situations (drug, biologic, or device research, planned emergency research, research involving pregnant women/fetuses/neonates, prisoners, children, other vulnerable adults, non-English speaking individuals, employees/students as subjects, international research, substudies, collaborative research not conducted under an IRB Authorization Agreement, collaborative research conducted under an IRB Authorization Agreement, domestic research at non-CU or external sites, transfer of research when PI is leaving Columbia)

**Section IV: Processing of Submissions to the IRB: Pre- and Post-IRB or –ARC Review**

Extensive reorganization and revision of information previously included:
A – Preliminary review of submitted events;
B – Routing of submissions to IRB per level of review required (Not Human Subjects Research, Exempt determination; Expedited review, Facilitative/Administrative/118, Full Board);
C – Primary Reviewer system;
D – Post-Review Procedures;
E – Notification to Researcher;
F – Documentation of Review and Approval

**Section V: IRB Pre-review and Review Criteria**

Extensive reorganization and new information:
A – Pre-review of Submitted Events (for each type of event);
B – IRB Criteria for Review (new info: requirement for clinicaltrials.gov statement; guidance for additional consent situations; need to know IT policies; DISCOVERY; SSN release; combined consent/authorization okay; acceptable recruitment; treatment relationship explained; reference to new COI policy)
Section VI: IRB Review of Specific Types of Events, Types of Research, and Types of Documents

Extensive reorganization:
A – IRB Review of Specific Types of Events (by event) (Rascal labeling of event YM; explanation of expiration date calculation for February in leap years; deviations/violations including misadministration of drug; IRB initiated closure);
B – Review of Specific Types of Research (need for SI to consult with IAP; expedited review of renewals for HUD studies in some situations; clarification of requirements if subject becomes incarcerated; approval for advocates if wards are involved; effective communication throughout study when non-English speaking subjects are involved; altered consent procedures may be okay in some research if cultural norms differ; requirement for back translation and verification by local IRB; IIAs; approval from OHRP for some planned emergency research; death of subject in planned emergency research; review of research conducted by students) (Note that the PI should be copied on all communications to the IRB that are related to submissions, if the PI is not personally sending the message; for student projects, the IRB will direct communications about submissions to the faculty member who is the PI);
C – Review of Specific Types of Documents (stamping exceptions; stamping on exempt research material; facility requirements; recruitment tips; clarification of compensation vs reimbursement; consideration of payments to children; consent reference to payments and IRS requirements).

Section VII: IRB Convened Board Meetings: Organization and Management

Mostly about IRB operations, i.e., information is more relevant for IRB staff than for researchers.
A – Schedule of Meetings;
B – Agenda Preparation;
C – Primary Reviewer Assignments;
D – Voting Requirements;
E – Minutes (IOs; clarification of approval emails) (Researchers must be sure to READ approval correspondence thoroughly because it may include restrictions, requirements for future action, or other qualifying information!)

Section VIII: Record Retention and Documentation
(Who has access to IRB records; required retention terms; procedures regarding records if PI leaves Columbia.)

Section IX: Oversight Monitoring (V4.1, July 9, 2012)
(Closures, when involve ionizing radiation, will be reported to Radiation Safety)

Section X: Education and Training
Updated requirements for IRB staff, IRB members, and research personnel
(Researchers are advised that they should refer to this information frequently so that review of submissions will not be delayed for completion of training requirements, and participation of research personnel will not be restricted because training requirements have not been satisfied!)

Section XI: Quality Assurance and Improvement
IRB activities related to assessing and improving quality of operations. (Metrics related to IRB operations are calculated on a regular basis and evaluated by institutional officials and IRB management.)

Section XII: Subject Outreach
A – Information for Potential Subjects;
B – Information from Research Subjects and the Community;
C – Compliance Hotline (Everyone who is involved in or exposed to research activities should be aware of the hotline.)