

IX. Oversight Monitoring

The Columbia HRPP assures oversight monitoring of human subjects research by various means, such as:

- 1) continuing review of the research by the IRB and brief inquiries with investigators or research records following concerns raised by IRB review;
- 2) IRB review of unanticipated problems involving risks to subjects or others;
- 3) data and safety monitoring by either an internal or external committees;
- 4) compliance oversight initiatives including for-cause and not-for-cause investigations;
- 5) additional reviews, investigations or monitoring by the Research Pharmacy, Radiation Safety Office (RSO) or Institutional Biosafety Committee (IBC); and
- 6) additional reviews conducted by either the Clinical Trials Office (CTO) or Research Administration (RA).

Furthermore, quality improvement efforts provided by the IRB office, as described in [Section XI](#), serve as additional mechanism to provide oversight monitoring of human subjects research.

A. Continuing Review

As described in Section VI.C.6, continuing review serves a key role in oversight monitoring of all human subjects research that is not exempt. By reviewing the progress of the study during the past approval period, the IRB receives information and insights to the risks associated with the study and the quality of study management. Through these insights the IRB is often able to make determinations that additional oversight monitoring may be necessary and in such cases, may refer a given study to the Compliance Oversight Team for further investigation or audit.

IRB staff and members are mindful of IRB expiration dates during the review process, particularly when subjects are actively participating and an interruption in the conduct of study procedures may pose an increase in risk to those subjects. While the IRB may not extend the IRB approval period without additional review, consideration may be given to allowing the continued participation of enrolled subjects to prevent harm or an increase in risk of harm. Investigators are advised to submit renewal requests sufficiently in advance of the expiration date to ensure sufficient time for review.

B. Review of Unanticipated Problems Involving Risks to Subjects or Others (including Adverse Events)

The review of adverse events and other unanticipated problems provides an important role in the oversight of human subjects in research. The process for IRB review of unanticipated problems is described in sections [VI.A.4](#) and [VI.C.2](#). Timing of and action subsequent to IRB review of unanticipated problems depends on the severity, relationship to the test article, and whether the

event occurred under the auspices of Columbia or at another site that relies on another IRB for review of the event(s). Depending on these criteria, the CU IRBs review the events either promptly or at continuing review.

C. Data and Safety Monitoring

The IRB will review a data and safety monitoring plan for certain research studies as described in Section VI.B.6. During the course of studies conducted by Columbia (either at Columbia or elsewhere), the IRB will review and/or solicit information from the applicable data and safety monitoring board or committee to address any relevant IRB concerns. The IRB will also rely on the data and safety monitoring boards and/or the sponsor to provide assessments of the adverse events or other unanticipated problems involving risks to subjects or others that may occur during the study.

D. Reviews or Monitoring by the Research Pharmacy, Radiation Safety, or Institutional Biosafety Committee

For monitoring of human subjects research providing specific risks from radiation, hazardous materials (including research with human organs, tissues, or fluids), or investigational drugs and devices, the IRB may also rely on additional oversight provided by the Research Pharmacy, the Joint Radiation Safety Committee (JRSC), the Radioactive Drug Research Committee (RDRC), Radiation Safety Office (which provide administrative support to both committees) or the Institutional Biosafety Committee. The Columbia HRPP provides for effective partnering and communication between each of these committees or offices and the IRB as appropriate. The IRB may rely upon either compliance oversight or oversight monitoring by these other groups either in lieu of, or as an adjunct to the oversight monitoring provided by the IRB.

To enhance the oversight of human subjects research/clinical investigations involving ionizing radiation, communication between the IRB and radiation safety committees (i.e., JRSC and RDRC) will include:

- 1) For any study involving human subjects and an investigational radiopharmaceutical that is not conducted under an IND, the IRB will forward a copy of the IRB approval to the RDRC.
- 2) For any study involving human subjects and an investigational radiopharmaceutical that is conducted under an IND or a radiographic procedure that is not standard practice (or the frequency of the procedure is greater than standard practice), the IRB will forward a copy of the IRB approval to the JRSC.
- 3) For continuing review of any study covered in items 1 or 2 above, the IRB will forward a copy of continuing review (i.e., renewal) IRB approval to the RDRC or JRSC, as appropriate.

- 4) For any unanticipated problem involving risks to subjects or others (UP) related to an investigational radiopharmaceutical, radiation therapy or a radiographic procedure, the IRB will forward the UP report along with the IRB review of the event to the RDRC or JRSC, as appropriate.
- 5) Any IRB approval of a modification or amendment to a protocol that involves or affects procedures involving ionizing radiation will be forwarded to the RDRC or JRSC, as appropriate.

E. Reviews by Clinical Trials Office or Research Administration

The Clinical Trials Office, Research Administration (at CUMC) and Office of Sponsored Programs (at CU-MS) each provide additional oversight of human subjects research during their routine review of contracts or grants. Each of these offices will communicate with the IRB office to resolve issues regarding IRB review of human subjects research. Issues commonly addressed range from assuring IRB review of grants as appropriate, review of subcontracts by the appropriately designated IRB, resolution of conflicts of interest issues, payment for research related injuries, and miscellaneous issues that could be identified during their routine review of contracts or grants.

F. Compliance Oversight

Compliance oversight procedures cover two types of Noncompliance: Research Noncompliance and IRB Noncompliance.

“Research Noncompliance” means Noncompliance by anyone other than the ED or any member of the IRB staff or the IRB (in his/her capacity as such).

“IRB Noncompliance” means Noncompliance by the ED of the IRB or any member of the IRB staff or the IRB (in his/her capacity as such).

For purposes of IRB policy, “Noncompliance” means a failure to comply with University policy or applicable federal and state laws, regulations and policies governing the protection of human subjects in research.

A response to an allegation of Noncompliance consists of three phases, each of which is explained in more detail in the CU “Noncompliance with Human Subject Regulations” policy (Working Practice Document #89):

Inquiry: the gathering of preliminary information and fact-finding to assess whether an allegation has substance and, if so, whether an Investigation is warranted (an “Inquiry”); this phase should be brief and not involve a substantive analysis of any information, but should determine whether the PI is actually conducting, or has conducted, the study, whether the information presented in the allegation appears to be potentially relevant, affiliation of the source of the allegation with the University, and whether any documents should be sequestered;

Investigation: following an Inquiry, the further investigation of facts with respect to whether Noncompliance has occurred (an “Investigation”); and

Outcome: following an Investigation, the determination as to whether Noncompliance has occurred and what corrective actions, if any, are required (an “Outcome”).

Related concepts of appeal, reconsideration, and notification to regulatory agencies are also addressed in the CU “Noncompliance with Human Subject Regulations” policy (Working Practice Document #89), as are guidelines for safeguards for the complainant and respondent, and measures to ensure confidentiality, preserve evidence, and sequester documents.