Columbia University IRB
Guidance for Protocol Deviations and Violations
October 29, 2013

All deviations from and violations of Columbia IRB policies or IRB determinations, including departures from the requirement for adherence to the approved protocol, must be reported to the IRB.

- A protocol deviation is defined as a variation from the approved protocol for one subject or to address a temporary situation that is identified by the research team and approved by the IRB before implementation.
- A protocol violation is defined as a variation from the approved protocol that was implemented without prospective approval by the IRB (and was not implemented to avoid or minimize imminent harm*). Protocol violations may be considered as noncompliance with the federal regulations and institutional policies for the protection of human subjects. If the violation is noncompliance, the provisions of the IRB Noncompliance Policy will apply.

Requests for Protocol Deviations should be submitted to the IRB via the Modification module in Rascal as soon as the study team becomes aware of the need for the deviation. When applicable, the sponsor’s concurrence, e.g., that an individual who does not meet eligibility criteria may be enrolled, should be provided with the submission. The IRB recognizes that some deviations regarding inclusion/exclusion criteria are identified shortly before the subject is scheduled for randomization or entry into the study and that a quick review by the IRB is important for the study. In time-sensitive situations, the investigator should follow his/her submission to the IRB with an e-mail outside of Rascal to the Manager of the IRB that approved the study. Please note that repeated Protocol Deviation requests related to eligibility suggest that the investigator should revise the protocol to reflect more appropriate eligibility criteria for the study consistent with research participant safety and preserving the scientific integrity of the data.

If a Protocol Violation is unanticipated, at least possibly related to the research, and involves risks to subjects or others, it should be reported to the IRB within one week (5 business days) as an Unanticipated Problem (UP) Report in Rascal. The UP policy can be found at: www.cumc.columbia.edu/dept/irb/policies/documents/UnanticipatedProblemsPolicy_FINALVERSION.012408.pdf. Protocol violations related to medication dose errors should also be submitted as an Unanticipated Problem, whether the error involves an over- or under-administration of medication. If the error occurred within NYP, the situation should be discussed with the subject, in accordance with the underlying philosophy of NYPs Disclosure Policy (Policy #E145); discussion with the subject may also be appropriate for medication dose errors that occur outside of NYP in clinical studies under the purview of the Columbia IRBs.

Violations other than UPs that violate the rights or welfare of subjects, negatively affect the integrity of the study, or require a change to the protocol or consent document(s) are considered to be Major Violations and require prompt reporting to the IRB as a Modification.

Modification submissions to report Major Violations should include the Principal Investigator’s assessment that the event does not suggest that the research places subjects or others at a greater
risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized and that they did not meet the Unanticipated Problem reporting criteria.

Minor violations are violations that are not UPs and do not meet the criteria to be considered major violations. These should be reported to the IRB at the time of continuing review, in a list or log that includes all UPs, deviations, and violations. The log should reflect when individual submissions of each UP, deviation, or major violation were made.

Scheduling delays due to state or federal holidays, inclement weather, or circumstances that are beyond the control of the research team and/or the subject, and do not meet either the UP or major violation criteria are considered minor violations but they do not constitute noncompliance. A summary of situations such as these should be submitted at the time of renewal as long as these do not involve risks to subjects. (If the scheduling delay involved risks to subjects, e.g., if administration of a drug that had to be administered on a specific day for safety reasons was delayed, a UP Report should be submitted.)

When the Columbia Principal Investigator is the Sponsor-investigator (SI), and a sub-site has requested a Protocol Deviation, this request must be submitted by the Lead Principal Investigator to the CUMC IRB for review and approval. Once approval is obtained, the Principal Investigator at the sub-site must also submit to their IRB in accordance with their institutional policies. If the protocol involves an Investigational Device Exemption (IDE), FDA approval is required prior to submission for IRB approval. If the protocol involves an Investigational New Drug (IND), documentation that the FDA has been notified should be submitted to the IRB at the time of renewal. In addition, when the Columbia PI is also the Sponsor, the IND/IDE Assistance Program (IAP) must be notified of deviation or violation, for both IDE’s and IND’s.

Information to provide to the IRB for Deviations and Violations

The description of the circumstances surrounding the deviation/violation should be clearly stated in the Unanticipated Problem Report, in the summary section of the Modification Information form, or in the Renewal Form, as applicable.

The following information should be included:
  a. a complete description of the deviation/violation;
  b. an explanation of why the deviation is necessary, or why the violation occurred;
  c. whether the deviation affects, or the violation affected, the risk/benefit ratio for subjects, integrity of the research data, and subjects’ willingness to continue study participation; and
  d. for protocol violations, a description of the corrective measures that will be taken to prevent a recurrence of the same or similar violations.
  e. for protocol deviations, a plan to inform the subject if the deviation may change the subject’s willingness to participate in the research study.

Supporting documentation may be attached electronically, and should be provided whenever available or pertinent.
*At any time during the conduct of a study, if it is discovered that there is the potential for imminent harm to subjects, the investigator should implement any change(s) necessary to reduce or remove such harm and subsequently submit a report of the situation via the Modification module so that such change(s) are documented and acknowledged by the IRB.

This information will replace the Protocol Deviation and Violation information in the version 4.2 (Nov. 2, 2012) version of the IRB Standard Operating Procedures.