Deviations and Violations
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Executive Director
Objectives

• Define violations and deviations
• Clarify reporting requirements
• Inform of policy change

Protocol Deviation

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.

Example: Potential subject has lab value slightly outside range; sponsor prospectively approves inclusion.
Protocol Violation

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*).

Example: Subject has lab value outside range and was enrolled without approval of sponsor or IRB.

*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.
Major or minor?

Major violation:

• Violates the rights or welfare of subjects
• Negatively affects the integrity of the study
• Requires a change to protocol or consent form
• Example: errors in the consent process; many minor violations that lead to a change in the protocol

Minor violation:

• Violations that are not UPs and do not meet criteria to be considered major violations
• Example: out of window study visits that do not affect safety; use of a consent form with approved content but without an IRB stamp
Violation = Noncompliance?

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.

Examples of violations that would not be considered noncompliance:

- participant driven events (e.g. failure to show up for an appointment)

- safety concern (e.g. failure to complete a study stress test because the participant isn’t healthy enough)
Reporting

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.
Submitting to the IRB

<table>
<thead>
<tr>
<th>Type</th>
<th>Submit as</th>
<th>Time-sensitive?</th>
<th>Consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deviation</td>
<td>Modification</td>
<td>If need arises shortly before subject visit, email IRB manager</td>
<td>Does protocol need to be revised?</td>
</tr>
<tr>
<td>Minor violation</td>
<td>Log with renewal</td>
<td>N/A</td>
<td>Appropriate corrective action</td>
</tr>
<tr>
<td>Major violation</td>
<td>Modification</td>
<td>Submit promptly</td>
<td>Appropriate corrective action</td>
</tr>
<tr>
<td>Violation=UP</td>
<td>UP report</td>
<td>Submit w/in 5 days</td>
<td></td>
</tr>
</tbody>
</table>
Medication Misadministration

Report in accordance with general violation guidelines

Should not be submitted as UP, if criteria are not met*

*Change in guidance

Unanticipated Problems Policy:

Include in the Rascal submission:

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 should be attached.
Also…

For major violations that are not UPs:

• Include the assessment of the PI that the event does not suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized, and that it did not meet the UP reporting criteria.
Additional IRB Updates:

- The agreement with IRBshare has been finalized
  - If you are interested in using IRBshare – call the HRPO Office first!

- Combined consent forms and HIPAA Authorizations are encouraged
  - Privacy Office must still approve the HIPAA language at this time

- Rascal Upgrade to the IRB Module is currently being programmed

- Planning for the Rascal Upgrade to the Consent Form Builder will begin in the Fall
Staffing changes

Promotions:

• Alan Teller, Associate Director for IRB Operations
• Rachel Lally, Associate Director for IRB Management
• Challace Pahlevan, Senior Manager, IRBs 1 and 2
• Laurence Butaud-Rebbaa, Senior Manager, IRB 4

New Staff:

• Maryanne McGinn, Auditor
• Ellie Hernandez, QA/Float Person
• Rui Ferreira, Investigator Liaison/Central IRB Specialist
Columbia IRB Websites:

-CUMC  http://www.cumc.columbia.edu/dept/irb/

-CU IRB  http://www.columbia.edu/cu/irb/