

Defining and Reporting Protocol Deviations	Effective:	06.01.2007
	Revised:	1.21.2019

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to define protocol deviations to approved human research and identify how those protocol deviations are reported to the IRB.
- 2.0 Person's Affected:** Any of the following who become aware that there has been a deviation from the IRB approved protocol and/or procedures:
- 2.1 The Principal Investigator
 - 2.2 Research staff/study team members
 - 2.3 Other individuals who might be familiar with the protocol
 - 2.4 Research participants
- 3.0 SOP:** Deviations to an UMCIRB-approved protocol must be reported to the UMCIRB when such deviations result in the real or potential of increased risks or harm to participants or others. It is the responsibility of the Principal Investigator to report such a deviation to ensure that the UMCIRB is given appropriate opportunity to take into account any risks or harm caused by the deviation and to ensure that appropriate actions have been taken to minimize those risks. Other deviations also need to be reported as described below.
- 4.0 Definitions:**
- 4.1 Protocol Deviation: any action taken in the implementation of an approved research protocol that does not match the approved research procedures that were provided to the IRB at the time of its last review.
 - 4.2 Reportable Deviation: any action taken in the implementation of an approved research protocol that does not match the approved research procedures provided to the IRB at the time of its last review that poses a real or potential risk to participants or others.
 - 4.3 Non-Risk Reportable Protocol Deviation: the occurrence of five or more protocols deviations that when viewed separately do not appear to pose any risks to participants or others but collectively may indicate a problem with implementing the study as approved. The reported protocol deviations will be reviewed by the UMCIRB to determine the level of risk, if any, and whether a change in procedures is required to bring the study back into compliance.
- 5.0 Responsibilities:**
- 5.1 Principal Investigator (PI): is responsible for evaluating and then reporting deviations involving risks or potential risks to participants or others on UMCIRB-approved protocols to ensure that the UMCIRB is given appropriate opportunity to take into account those risks caused by the deviation, and to ensure that appropriate actions have been taken to minimize those risks from occurring again.
 - 5.1.1 The PI is required to take whatever action necessary to minimize or remove risks to participant or others and/or protect the integrity of the data that results from a deviation from the approved protocol. These actions should be described in the report submitted to the IRB for review.
 - 5.1.2 Unless discovered by the sponsor (or their affiliates) the PI is required to notify the sponsor of any deviations, for those studies that are externally funded.
 - 5.1.3 The PI is responsible for implementing any determinations of the UMCIRB regarding the deviation(s) reported.

- 5.1.4 The PI is responsible for notifying the risk management office of the respective institution where the deviation occurred if the inclusion or exclusion criteria have been violated, or if the deviation occurs during the study and leads to an untoward event.
- 5.1.4.1 The PI should determine whether notifications to other appropriate institutional offices are warranted (e.g., Risk Management, Pharmacy, etc.).
- 5.2 Coordinators and research staff: are responsible for notifying the PI of any deviation from the approved protocol, regardless of level of risk or potential for risk.
- 5.3 UMCIRB Office Staff: are responsible for evaluating the deviation reported and notifying the Chairperson immediately if, in the staff person's opinion, risks outweigh potential benefit, other participants may be at risk, or risks have not been appropriately minimized; all other deviations will be forwarded for review and acknowledgement by the IRB Chairperson (or designee).
- 5.3.1 The UMCIRB office staff will place those deviations that have potential to or have caused increased risks or harm to participants on the next available agenda for review at a convened IRB meeting.
- 5.3.2 The Principal Investigator will be provided with the UMCIRB determinations, in writing, **within two business days** of the convened meeting or when the Chairperson takes action on behalf of the UMCIRB.
- 5.3.3 Agenda and minutes are immediately available to all members, ex-officios and institutional administrators via the electronic IRB system. The pertinent section of the minutes will be provided to the PI, the sponsor, or Clinical Research Organization (CRO) upon request.
- 5.4 IRB Chairperson (or designee): will review the protocol deviation(s) submitted and has the authority to:
- 5.4.1 Request additional information;
- 5.4.2 Request a change to the corrective action plan before taking further action or making a final decision;
- 5.4.3 Request a copy of any correspondence sent to or received from a sponsor, FDA, CRO, or other agency regarding this deviation;
- 5.4.4 Require full IRB review of the deviation;
- 5.4.5 Take any action necessary to protect human participants;
- 5.4.6 Suspend enrollment or implementation of the study until the convened UMCIRB has had an opportunity to review the deviation; or
- 5.4.7 Notify appropriate ECU or Affiliate officials if immediate action is required to protect participants
- 5.5 UMCIRB: is responsible for evaluating the deviation reported, the actions taken by the PI to alleviate any real or potential risks and take whatever actions necessary to protect participants and others. The UMCIRB has the authority to:
- 5.5.1 Request additional information or further investigations by other institutional offices or committees;
- 5.5.2 Request a change to the corrective action plan before taking further action or making a final decision;
- 5.5.3 Request a copy of any correspondence sent to or received from a sponsor, FDA, CRO, or other agency regarding this deviation;
- 5.5.4 Require revisions to the currently approved protocol;
- 5.5.5 Place restrictions on the PI, coordinator or any research personnel that may have been responsible for the deviation;
- 5.5.6 Suspend or terminate the study or any portion of that study which may increase risks to participants or others;

- 5.5.7** Require changes in procedures to eliminate or reduce deviations that are occurring consistently and with risk to the participant.

6.0 Procedures:

- 6.1** Any deviation that involves real or potential risks to participants or others or which can negatively impact the integrity of the data must be reported to the UMCIRB within 5 working days.
- 6.2** When instances of 5 or more unanticipated changes in the UMCIRB approved protocol including but not limited to procedures, data collection methods, or following-up visits, that do not pose risks to participants or others and does not negatively impact the integrity of the data occur, they must be submitted to the UMCIRB for review within 10 working days of notification of the fifth (5th) deviation. This review will help determine if these deviations indicate that some action needs to be taken to ensure that the study can be carried out as approved or that additional training might be required by research personnel.
- 6.3** If the research study **requires** Continuing Review, and the number of deviations remains below five (4 or fewer than 4) and none of these deviations, in the opinion of the Principal Investigator, involve risk or potential risk to the participant or others or do not negatively impact the integrity of the data, they can be reported to the UMCIRB at the time of the scheduled Continuing Review Report
- 6.3.1** A brief description of these deviations should be provided along with justification for why the PI decided these events did not involve increased risks to participants or others or negatively impacted the integrity of the data.
- 6.3.2** The Continuing Review reports are reported in the UMCIRB minutes and are electronically available to all IRB members, ex-officios and institutional administrators for review.
- 6.4** If the research study **does not require** Continuing Review, the deviations need to be reported at the time of discovery as a Reportable Event.

Revision History:

Date	Change	Reference Section(s)
2.4.2009	Updated to stand-alone document.	All
10.8.2014	Updated office name from OHRI to ORIC and modified font for consistency; updated information about agenda/minutes being available electronically to applicable individuals, added Procedures section.	All
9.17.2015	Revisions to update and clarify information	1.0, 2.2, 5.1.2, 3.0, 4.1, 4.2, 5.1.2, 5.1.4.1, 5.3.1, 5.3.2, 5.3.3, 5.4.2, 5.4.6, and 5.5.2.
1.21.2019	Clarification of reporting for studies with no required continuing review; update office name to UMCIRB Office	6.4