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| **Study Stage:** Start-up, Conduct, Termination  |



**Purpose:** This template lists all of the protocol deviations from a particular study. The template may also be used to submit accumulated deviations to the IRB at the time of a continuing review for a study.

**Useful to:** Principal Investigators, Co-Investigators, Project Managers, Research Coordinators and study team members.

**Instructions:**

* Complete each column of the log as thoroughly as possible, documenting all study protocol deviations on the study.
* See the IRBMED website for a definition of protocol deviations and when to report (see in Reference section below).

**Best Practice Recommendation:**

* If a sponsor (funding entity of the study; NIH, Industry, coordinating site etc.) provides a Protocol Deviation Log, complete as instructed. Otherwise, the log should be completed throughout the study, as protocol deviations occur.
* File in an appropriate location to be easily accessible for monitoring visits, internal auditing and in order to have complete study records. It is recommended to update this log using an excel spreadsheet.
* It is recommended to have a section in the regulatory binder to place sponsor correspondence and CAPA (corrective action and preventative action) plans in response to deviations.

**Template History:**

**Last updated**: 6/07/2022

**Version**: 2.5

**Reference(s)**

**Protocol Deviations Definition**:ICH GCP 10.2 pg.13 https://database.ich.org/sites/default/files/E6\_R2\_Addendum.pdf

**Reporting Protocol Deviations** to the IRBMED -

<https://az.research.umich.edu/medschool/guidance/protocol-deviations-exceptions-violations>

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| --- | --- |
| **Study Name:**  | **IRB HUM #:** |
| **Principal Investigator:**  |  |

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|  | Participant ID or N/A | Date of Deviationa | Date Identified | Type of Event or Information  | Descriptionb | Date Reported to IRB  | Date IRB Acknowledged | Date Sponsor Notified |
| **1** |  |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |  |

1. Protocol Deviation IRB submissions are reported within 7 calendar days or as part of the Scheduled Continuing Review

[res\_irbmed 2021.06.04 ORIO reporting for approved studies requiring CR.pdf (umich.edu)](https://az.research.umich.edu/sites/default/files/res_irbmed%202021.06.04%20ORIO%20reporting%20for%20approved%20studies%20requiring%20CR.pdf)

b. Here are examples of protocol deviation categories:

**Protocol Deviations/Violations**

* Deliberate Procedural Deviations (including “protocol exceptions”)
* Accidental Procedural Deviations
* Appointment/ Visit Deviations
* Dosage/Intervention Errors or Deviations
* Breach of Confidentiality or Privacy
* Consenting/Assenting Process Deviations or Problems