SOP#: PM-16	**Protocol Deviation Tracking**
Version #: 1.0	**Next Review Date: 08/2024**
Approved Date: 08/2022	**Review Interval Period: Biennial**

NCI Clinical Director Signature/
Effective Date:

POLICY

All protocols, both observational and interventional, will have protocol deviations tracked in the Protocol Deviation Tracking System (PDTS). Both major and minor protocol deviations will be collected to help monitor protocol compliance and identify potential training needs. All major deviations will also be reported to the IRB per NIH Policy 801 Reporting Research Events. The PDTS also assists in summarizing protocols deviations as part of the continuing review (CR) reporting requirements. At the study closeout the final deviation spreadsheet will be maintained in the study regulatory file.

Definitions (as defined per NIH Policy 801 Reporting Research Events)**:**

- Deviation: Any change, divergence, or departure from the IRB-approved research protocol.
- Major: Deviation from the IRB-approved protocol that have, or may have the potential to, negatively impact, the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study.
- Minor: A Deviation that does not have the potential to negatively impact the rights, safety, or welfare of subjects or others, or the scientific integrity or validity of the study.

PURPOSE

To describe the process of tracking protocol deviations using the PDTS.

RESOURCES

- PDTS User Guide
- PDTS Login
- NIH Policy 801 Reporting Research Events

PROCEDURES

- Protocol deviations may be identified by the research team or a monitor/auditor.
- All deviations are to be entered into the PDTS as they occurred or are identified.
  - See the PDTS user manual for entry instructions including how to update a deviation.

  Note: For CCR-held INDs/IDEs, PDTS allows non-adherence events that are not deviations (e.g., issues related to Informed Consent) to be entered with some fields not needing to be entered. See user manual for specifics.

- The PDTS can generate reports including a continuing review report. See manual for instructions.

  Note: If the study sponsor provides a deviation log, the deviations are also to be captured in PDTS for tracking purposes including CR summary. It can be discussed with the sponsor to use the PDTS in place of their deviation log as a cumulative spreadsheet can be sent to the sponsor as needed.

- At the time of study closure, a final protocol deviation spreadsheet should be generated from PDTS and saved in the study regulatory file.