## SOP 4: Reporting Protocol Deviations

### Overview:

A protocol deviation is any noncompliance with the study design and/or procedures of a Division of Cancer Prevention (DCP) and Institutional Review Board (IRB)/Central Institutional Review Board (CIRB)-approved protocol. Protocol deviations may result from the actions of the study participant, the investigators, or the clinical staff conducting the study.

Investigators, Site Coordinators, and designees at Consortium Lead Organizations (CLOs) and Participating Organization (POs) are responsible for recording and reporting to DCP protocol deviations as soon as they are identified.

DCP does not allow any protocol waivers or exceptions for the enrollment of a participant in violation of protocol inclusion/exclusion criteria.

### Responsibilities:

Investigators, Site Coordinators, and designees at each enrolling site will report protocol deviations using the electronic, fillable form (handwritten forms will not be accepted) as follows:

1. Use the [DCP Consortia Protocol Deviation Form](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/Protocol-Deviation-Notification-Form_0.pdf) to report a protocol deviation as soon as it is identified:
   * + 1. In general, only one protocol deviation per PID should be recorded on a single form.
       2. When the same deviation is identified for more than one participant per study per site:

* These deviations should be recorded and reported on one deviation form.
* Each PID and associated deviation date must be noted on the form.
* DCP does not require prior approval or Note to File.

1. For protocol deviations occurring at a PO:
   1. The PO completes fields 1 through 19 per the deviation form instructions, and then emails the completed electronic form to the CLO Study Coordinator.
   2. The CLO Study Coordinator or designee verifies the accuracy and completeness of fields 1 through 19, based on the referenced protocol. If any information needs to be corrected or clarified, the CLO Study Coordinator or designee will send a query to the form originator for resolution. The form originator must revise the form accordingly and return it to the CLO.
   3. Once all queries have been addressed, the CLO forwards the completed form to the DCP Medical Monitor and Nurse Consultant for review, with a copy to the DCP Help Desk. The PO must comply with all institutional and/or IRB/CIRB requirements related to reporting protocol deviations.
2. For protocol deviations occurring at a CLO:
   1. The CLO completes fields 1 – 19 and then emails the completed form to the DCP Medical Monitor and Nurse Consultant for review, with a copy to the DCP Help Desk.
   2. The CLO must comply with all institutional and/or IRB/CIRB requirements related reporting protocol deviations.
3. **IRB-/CIRB-Reportable Deviations**
   1. Studies for which a local IRB is the oversight body (i.e., non-CIRB studies): For potential IRB-reportable deviations (i.e. deviations that may be a Potential Unanticipated Problem/Potential Serious or Continuing Non-Compliance) the site where the deviation occurred must submit to the local IRB all IRB-reportable protocol deviations. The site must also copy the CLO on the IRB protocol deviation correspondence and retain a copy of the correspondence in the study binder. The CLO will forward a copy of the IRB correspondence to DCP staff and the DCP Help Desk.
   2. Studies for which the CIRB is the oversight body: The CLO is responsible for submitting to the CIRB all potentially reportable protocol deviations (i.e. deviations that may be a Potential Unanticipated Problem/Potential Serious or Continuing Non-Compliance) occurring at the CLO or PO. The CLO must copy DCP study staff, the DCP Help Desk, and the PO, if applicable, on the CIRB correspondence; and retain a copy of the correspondence in the study binder.

The DCP Medical Monitor and/or Nurse Consultant will review and submit protocol deviations as follows:

1. The DCP Medical Monitor or Nurse Consultant completes fields 20 through 23 and submits the electronic, fillable form via email to the DCP monitoring contractor via the DCP Help desk.

The DCP monitoring contractor will distribute protocol deviations as follows:

1. The DCP monitoring contractor distributes the completed form that includes the assigned protocol deviation grade and DCP comments to the protocol-specific contact list via the DCP Help Desk.

### Documentation Requirements:

1. Each enrolling site will retain in their study files a copy of the completed protocol deviation form and communications related to the reporting of the protocol deviation.
2. Each site will establish and maintain a protocol deviation tracking system.
3. The DCP Help Desk can be contacted with questions related to the status of a completed protocol deviation form or, with prior DCP approval, a request for a summary of all completed forms on file.

### Additional Information:

Refer to the [DCP Acronym List](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-Acronym-List.docx) to see the description of commonly used acronyms in this SOP.

**Please send questions and comments to the DCP Help Desk at:**

**1-844-901-4357 or** [**dcphelpdesk@dcpais.com**](mailto:dcphelpdesk@dcpais.com)