Title: Reporting Protocol Deviations

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.0	AUG-17-2020	Original version of document.

1. PURPOSE AND INTRODUCTION

A protocol deviation is any noncompliance with the study design and/or procedures of a Division of Cancer Prevention (DCP) and 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 Lead Academic Organizations (LAOs) and Affiliated Organizations (AOs) are responsible for recording and reporting DCP protocol deviations as soon as they are identified.

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

2. SCOPE

This document details the responsibilities of the LAO and AO Investigators, Site Coordinators, and designees regarding the reporting of deviations, as well as the DCP Medical Monitors and DCP Nurse Consultants for reviewing and submitting deviations to the DMACC.

3. RESPONSIBILITIES FOR REPORTING DEVIATIONS

Investigators, Site Coordinators, and designees at each enrolling site report protocol deviations using the electronic, fillable CP-CTNet Protocol Deviation Notification Form as soon as a deviation is identified. Handwritten forms will not be accepted.

1. **Complete the CP-CTNet Protocol Deviation Notification Form following the instructions on the form:**

   1.1. In general, only one protocol deviation per Participant Identification Number (PID) should be recorded on a single form.

   1.2. 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.

2. **For protocol deviations occurring at a LAO:**

   2.1. The LAO completes the first section of the CP-CTNet Protocol Deviation Notification Form, and then emails the completed form to the DCP Medical Monitor and DCP Nurse Consultant for review, with a copy to the DMACC.

   2.2. The LAO must comply with all institutional and CIRB requirements related to reporting protocol deviations.

3. **For protocol deviations occurring at an AO:**

   3.1. The AO completes the first section of the CP-CTNet Protocol Deviation Notification Form, and then emails the completed form to the LAO Study Coordinator.

   3.2. The LAO Study Coordinator or designee verifies the accuracy and completeness of the CP-CTNet Protocol Deviation Notification Form, based on the referenced protocol. If any information needs to be corrected or clarified, the LAO Study Coordinator or designee sends a query to the form originator at the AO for resolution. The form originator must revise the form accordingly and return it to the LAO.

3.3. Once all queries have been addressed, the LAO forwards the completed form to the DCP Medical Monitor and DCP Nurse Consultant for review, with a copy to the DMACC.

3.4. The AO must comply with all institutional and CIRB requirements related to reporting protocol deviations.

4. The DCP Medical Monitor and/or Nurse Consultant reviews the LAO or AO-completed deviation forms, assigns the deviation grades by completing the second section of the form, and submits the form via email to the DMACC

5. The DMACC distributes the completed form that includes the assigned protocol deviation grade and DCP comments to the LAO and/or AO and DCP study staff.

4. CIRB REQUIREMENTS FOR REPORTING DEVIATIONS

The LAO is responsible for reporting all required deviations to the CIRB, including deviations that occur at an AO. The following deviation categories must be reported to the CIRB via the IRB Manager (https://nci.my.irbmanager.com/):

- Serious or continuous noncompliance

  Further details regarding whether a deviation is reportable as a serious/continuous noncompliance may be found on the NCI CIRB webpage:

  https://ncicirb.org/institutions/institution-quickguides/managing-study/algorithm-to-assess-noncompliance

- Unanticipated problem

Further details regarding whether a deviation is reportable as an unanticipated problem may be found on the NCI CIRB webpage:

https://ncicirb.org/institutions/institution-quickguides/managing-study/algorithm-to-assess-a-potential-unanticipated-problem

Notify the DCP study staff and the DMACC that you have reported the serious or continuous noncompliance/unanticipated problem to the CIRB.

In addition to CIRB requirements, deviations (including those not reportable to the CIRB) must be reported to the site's local IRB as per local requirements.

5. DOCUMENTATION REQUIREMENTS

1. Each enrolling site retains a copy of the completed Protocol Deviation Notification Form and all communications related to the reporting of the protocol deviation in their study files. Note that these materials will be reviewed during audit.

2. Each site establishes and maintains a protocol deviation tracking system.

3. The DMACC can be contacted with questions related to the status of a completed protocol deviation form.

6. ADDITIONAL INFORMATION

Refer to the CP-CTNet Acronym List to see the description of commonly used acronyms in this SOP.

Please send questions and comments to: DataManagement_CP-CTNet@frontierscience.org

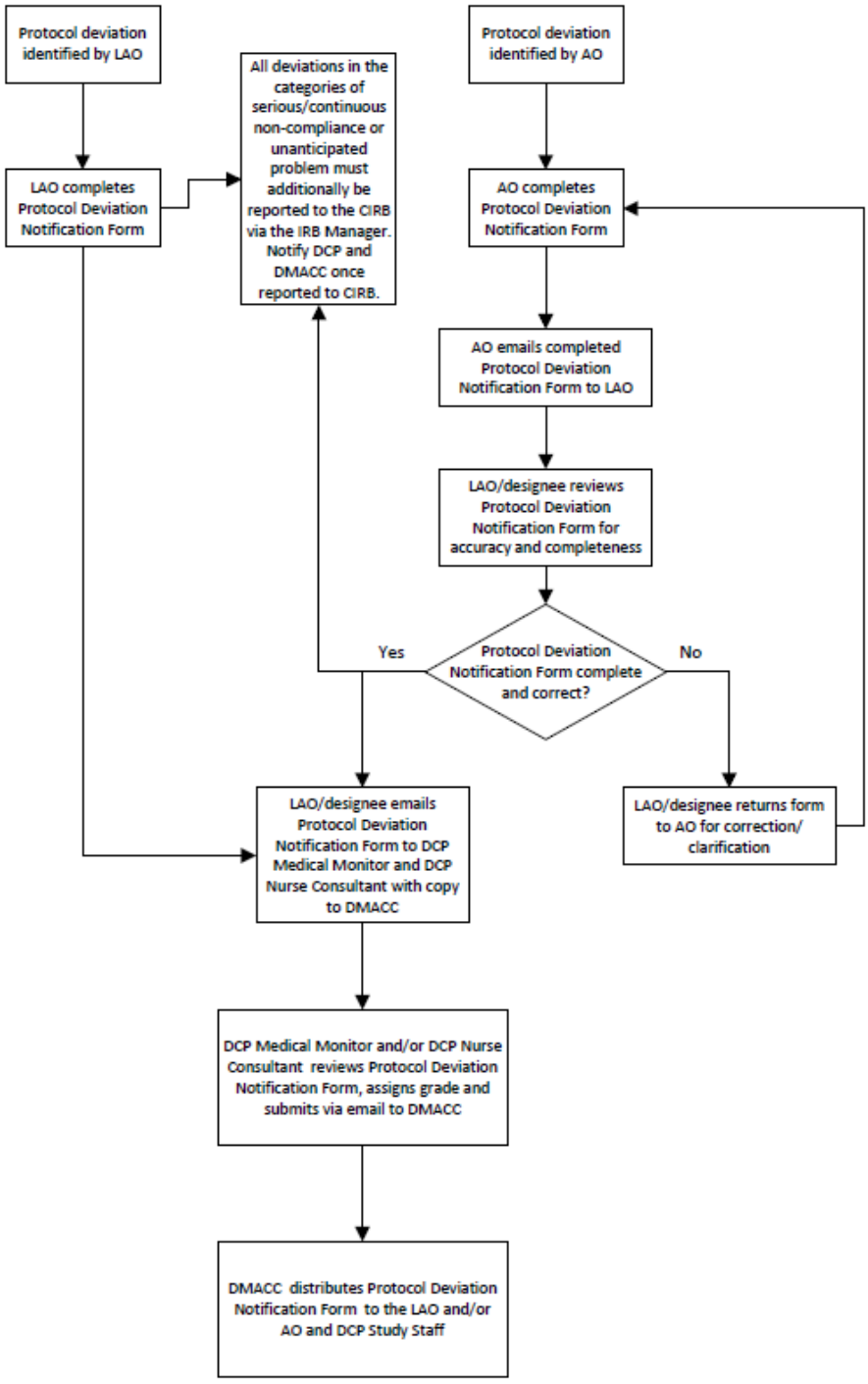
REFERENCES

- None

APPENDICES

- Appendix I - Protocol Deviation Notification Process

Appendix I
Protocol Deviation Notification Process



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