**Definition**

A **Protocol Deviation** is any noncompliance with the clinical trial protocol, Good Clinical Practice (GCP), or protocol-specific Manual of Procedures requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff.

**DMID Reporting Requirements**

- All protocol deviations must be reported **within 5 working days of identification of the protocol deviation**, or within 5 working days of the scheduled protocol-required activity.

- If study data is captured via the Emmes Internet Data Entry System (IDES – known also as AdvantageEDC™), protocol deviations will be submitted via IDES. No other reporting is required. IDES will automatically notify DMID of the reported protocol deviation.

- If a clinical trial is being coordinated by a **Central Unit or Coordinating Center**, protocol deviations will be reported as specified in the respective study protocol and/or the Manual of Procedures (MOP). The Central Unit will be responsible for reporting of the protocol deviation information to DMID-CROMS.

- For those studies **not utilizing Emmes IDES (AdvantageEDC™) and not coordinated by a Central Unit**, protocol deviations must be reported to the **DMID Clinical Research Operations and Management Services (CROMS)** contractor.

**How to report Protocol Deviations to DMID-CROMS**

There are three different ways you may submit protocol deviation reports:

1. **Via the DMID-CROMS website web-based report form.** To request access to the website, please submit a request using the **Systems Access Request Form**.

2. **Via email to protocoldeviations@dmidcroms.com.** Attach both the **Protocol Deviation form** and **Transmittal cover sheet**.

3. **Via Fax to 215-789-9587.** Print and Fax the **Protocol Deviation form and Transmittal cover sheet**.

**Protocol Deviation Report Flow**

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Site --> IRB (per requirements)
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 EMMES (if applicable) --> DMID-CROMS --> Central Unit (if applicable) --> DMID
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**Questions:**

Contact the Protocol Deviation Team members via email at **protocoldeviations@dmidcroms.com**.