

Protocol Deviation Reporting Form (Clinical Research)

Site ID

Protocol Title

Protocol Number

Subject ID

Date of Deviation

Reported By

Description of Deviation

Type of Deviation

Detected By

Impact/Consequence (e.g., on subject safety or data integrity)

Immediate Corrective Action Taken

Preventive Action (to avoid recurrence)

Notified to (Sponsor, Ethics Committee, etc.)

Date of Notification

Signature

Date Signed