

IRB Protocol Deviation/Violation Report Form

Protocol Information

Protocol Title

Protocol Number

Principal Investigator Name

Contact Information

Deviation/Violation Details

Date of Deviation/Violation

Date Discovered

Describe the Deviation/Violation

Location (if applicable)

Personnel Involved

Subject(s) Involved (if applicable)

Type



Impact Assessment

Potential Impact on Subject Safety/Data Integrity

Is this deviation/violation reportable to the sponsor or regulatory authorities?

Corrective and Preventive Action

Corrective Actions Taken

Preventive Measures to Avoid Recurrence