Protocol Deviations

A protocol deviation is ANY departure from the defined procedures and treatment plans outlined in the protocol version or application version submitted and approved by the IRB.

Deviations are generally unplanned and/or unintentional events that require review and documentation from the Principal Investigator (PI).

Examples of Protocol Deviations

- Performance of an unapproved research procedure
- Failure to adhere to inclusion/exclusion criteria
- Failure to consent on the most current, IRB approved ICF, PPF, Assent version found in ERICA
- Incorrect or missed research lab assessment or procedure
- Participant visits missed or outside permissible windows outlined in the approved IRB research protocol
- Participant non-compliance with research requirements
- Use of prohibited medications
- Incorrect investigational drug dosing, administration or missed dose