

Institutional Review Board - Protocol Deviation/ Violation Report Form -

NOTE TO RESEARCHERS:

Please complete this form to report a:

- **Protocol deviation or violation*:** A protocol deviation or violation is an unanticipated or unintentional change to the approved protocol. These changes are usually procedural in nature and are sometimes implemented in order to mitigate risks to the participants' safety. Deviations differ from amendments or modifications to the study in that they refer to a one-time occurrence and do not usually warrant an amendment to the entire protocol.

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* the terms deviation and violation are used interchangeably.

Principal Investigator:

Study Title:

IRB Study Number:

Date of event:

Location:

DESCRIPTION OF EVENT (provide as much information as possible) _____

Does this event compromise the scientific integrity of the study? **Yes** **No**

How will the PI follow-up on the event?:

- Revising the protocol and/or consent/assent forms (provide an amendment form) _____
 - No further action required _____
 - Other (please describe) _____
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SIGNATURE

Principal Investigator

Date