



FORM 10: PROTOCOL DEVIATION LOG

Participant ID: _____ - _____

Date: ___/___/___
MM DD YYYY

Date of Protocol Deviation: : <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Deviation code: _____ (from list below)
Deviation Code
1. Participant was enrolled but did not meet inclusion criteria
2. Participant was enrolled but met exclusion criteria
3. Participant did not sign Informed Consent
4. Research activities prior to consent
5. De-identification broken
6. Other:
Provide details of deviation (i.e., how deviation occurred, etc.)
Was this protocol deviation reportable to the IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, provide name and signature date of key personnel completing the form
Name of key personnel completing form: _____
Signature: _____ Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/>