

Form 10 Protocol Deviation

Participant ID (participantid)

Date Form Completed: (pd_fdate)

(mm-dd-yyyy)

Date of Protocol Deviation: (pd_date)

(mm-dd-yyyy)

Deviation Code: (pd_code)

- Participant was enrolled but did not meet inclusion criteria (1)
- Participant was enrolled but met exclusion criteria (2)
- Participant did not sign Informed Consent (3)
- Research activities prior to consent (4)
- De-identification broken (5)
- Other (6)

Other, specify: (pd_codeoth)

Provide details of deviation (i.e., how deviation occurred, etc.): (pd_details)

Was this protocol deviation reportable to the IRB?
(pd_report)

- Yes (1)
- No (2)

If yes, provide name and signature date of key personnel completing the form: (pd_desc)

Name of key personnel completing this form: (pd_sig)

Date: (pd_sigdate)

(mm-dd-yyyy)

Study Personnel Initials (pd_init)

Date data entered (pd_edate)

(mm-dd-yyyy)