



Project: _____

Date: _____

Investigator: _____

Patient #: _____

GCP and PROTOCOL
Irregularities / Non-Compliance

Check all of the following that apply:

- Informed Consent Document signed after patient started study procedures
- Safety labs not collected as specified by the protocol
- Inclusion/Exclusion criteria violated
- Patient in simultaneous interventional trials
- Required source data documentation could not be obtained
- Serious Adverse Event not reported appropriately to sponsor (see operations manual)
- Serious Adverse Event not reported appropriately to IRB (see local IRB guidelines)
- Drug accountability issue
- Patient took excluded medication
- Patient did not return study drug
- Patient did not take medication as directed or received wrong drug
- Patient was seen outside the allowed visit interval
- Required study procedure not completed
- Other

Description of irregularity or non-compliance:

Study Coordinator: _____
(Signature)

Date: _____