

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)  Serous 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: