**Note-To-File:**  Project: Date:

Investigator:

Subject # (if applicable):

**EXPLANATION OF IRREGULARITY**

Check all that apply:

Patient Consent issue

Inclusion/Exclusion criteria not met

Patient in simultaneous interventional trials

Adverse event not reported to Sponsor as required

Adverse event not reported to IRB as required (see local IRB guidelines)

Drug or Device accountability issue

Patient seen, or procedure performed, outside the allowed visit window

Required study procedure not completed

Other

(1) Description of irregularity:

(2) Remedy for this event (if applicable):

(3) Steps to prevent recurrence (if applicable):

Study Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***File this with the study document or documents related to the event or issue that prompted this note.***