**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.***