

Note-To-File:

Project: _____

Date: _____

Investigator: _____

Participant # (if applicable): _____

EXPLANATION OF IRREGULARITY

(1) Description of irregularity:

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

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

Record of parties notified (as applicable):

	Individual	Date	How notified
<input type="checkbox"/> Sponsor			
<input type="checkbox"/> IRB/CIRB			
<input type="checkbox"/> RCO			
<input type="checkbox"/> Research Office			
<input type="checkbox"/> Privacy Officer			
<input type="checkbox"/> Other			

Study Coordinator: _____ Date: _____
(Signature)

Investigator: _____ Date: _____
(Signature)

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