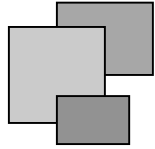


Please Fax or Mail to:



Ethical Review Committee, Inc.

14400 E. 42nd St., Suite 240
Independence, MO 64055
Phone: 816.421.0008 ♦ Fax: 816.356.2227

Study Complaint Form - Completed by the Site

Section A: Study Site Information	
Principle Investigator (PI):	Phone: () -
Primary Research Facility:	Fax: () -
Street Address:	City, State, Zip:
PI E-Mail:	

Section B: Study Status
<input type="checkbox"/> Open to enrollment: Recruitment, enrollment and/or subject interventions are ongoing.
<input type="checkbox"/> Closed to enrollment, but _____ (#) subjects still receive drug/biologic.
<input type="checkbox"/> Closed to enrollment: Long-term follow-up or data / specimen analysis only.
<input type="checkbox"/> Terminated: New information may affect previous subjects.

Section C: Complaint Description		
Subject #:	Date of Occurrence:	Date Complaint Filed:
1	Who lodged the complaint? (Example: subject, family member, other)	
2	What was the nature of the complaint?	
3	What is the impact of the complaint on other study subjects?	
4	What corrective action does the PI propose?	

Principal Investigator Original Signature

_____/_____/_____
Date

Typed or Printed Name