

A. REPORTING INSTITUTION

INSTITUTION:

DATE OF THIS REPORT

B. STUDY IN WHICH THE AE OR IMMINENT THREAT OF AN AE IN RESEARCH OCCURRED:

1. STUDY TITLE

1A. STUDY NUMBER

1B. IND/IDE NUMBER

1B. SPONSOR

2. STUDY PRINCIPAL INVESTIGATOR (PI)

2A. PHONE NUMBER

2B. E-MAIL ADDRESS

 3. IS THIS A MULTI-SITE TRIAL? YES (*NOTE: Submit report only if AE occurred at your site*) NO

3A. IF YES, OVERALL PRINCIPAL INVESTIGATOR

3B. PHONE NUMBER

C. INFORMATION ABOUT THE AE OR IMMINENT THREAT OF AN AE IN RESEARCH

 1. DESCRIBE INCIDENT (*Diagnosis, event, outcomes etc.*)

Continue in Comments Section on page 2.

2. CHECK ALL THAT APPLY

AE IN RESEARCH RESULTED IN SUBSTANTIVE CORRECTIVE ACTION BY IRB

TYPE OF AE IN RESEARCH

PHYSICAL

PSYCHOLOGICAL

SOCIAL

ECONOMIC

IMMINENT THREAT OF AE IN RESEARCH RESULTED IN SUBSTANTIVE CORRECTIVE ACTION BY IRB

TYPE OF AE IN RESEARCH

PHYSICAL

PSYCHOLOGICAL

SOCIAL

ECONOMIC

UNEXPECTED DEATH OF A RESEARCH PARTICIPANT

3. DATE OF INCIDENT

3A. DATE PI BECAME AWARE OF INCIDENT

3B. DATE IRB INFORMED OF INCIDENT

 3C. DATE OF IRB ACTION (*If any*)

4. PARTICIPANT STATUS

- RECOVERED/RESOLVED NOT RECOVERED/NOT RESOLVED DEATH
 RECOVERING/RESOLVING RECOVERED WITH SEQUELAE

 5. HAVE OTHER AEs IN RESEARCH BEEN REPORTED IN THIS STUDY? YES NO

D. SUBSTANTIVE ACTION(S) TAKEN

1. CHECK ALL THAT APPLY

MAJOR CHANGE IN PROTOCOL

TERMINATION OF STUDY

MAJOR CHANGE IN CONSENT FORM

RESTRICTION OF INVESTIGATOR PARTICIPATION

MAJOR CHANGE IN CONSENT PROCESS

SUSPENSION OF INVESTIGATOR PARTICIPATION

ADDITIONAL INFORMATION PROVIDED TO ENROLLED SUBJECTS

TERMINATION OF INVESTIGATOR PARTICIPATION

ADDITIONAL MONITORING OF STUDY

ACTIONS TAKEN TO PREVENT FUTURE AE

RESTRICTION OF STUDY

 OTHER (*Describe below*)

SUSPENSION OF STUDY

D. SUBSTANTIVE ACTION(S) TAKEN(Continued)

2. DESCRIBE ACTION(S) TAKEN (Append IRB minutes in which the substantive actions were discussed, ratified, and /or summarized.)

3. ARE OTHER ENROLLED SUBJECTS POTENTIALLY EXPOSED TO THIS RISK?

YES

NO

IF YES, HAVE THEY BEEN INFORMED ABOUT THIS RISK? YES NO

4. NAME OF IRB
and
IRB CHAIR

4A. PHONE NUMBER

4B. E-MAIL ADDRESS

E. REPORTING INFORMATION

1. REPORTER

1A. POSITION

1B. PHONE NUMBER

1C. E-MAIL ADDRESS

1D. MAILING ADDRESS

2. OTHER REPORT(S) OF THIS INCIDENT

REPORTED TO	REPORTED BY			DATE
	IRB INSTITUTION	PI	OTHER (Name/Title)	
MANUFACTURER/SPONSOR				
FOOD AND DRUG ADMINISTRATION				
OFFICE FOR HUMAN RESEARCH PROTECTIONS				
OTHER (Identify)				

COMMENTS