



**YALE UNIVERSITY SCHOOL OF MEDICINE
YALE NEW HAVEN HOSPITAL
HUMAN INVESTIGATION COMMITTEE**

Report of Adverse Event(s) Under Yale PI Form 6A

HIC #		Submission Date:	
Title of Research Project:			
Principal Investigator:			
Study Sponsor:			
Campus Address:			
Campus Phone:	Fax:	Pager:	E-mail:
Protocol Correspondent Name & Address:			
Campus Phone:	Fax:	E-mail:	

Adverse Event: _____
Several word description

Date: _____ **Date:** _____
Onset of AE *PI notified of AE*

Brief description of the adverse event:

(Include severity, duration, action taken, outcome, and plan. Describe how this AE meets the criteria for a serious and unexpected and related event.)

PI's opinion regarding relation of AE to study:

(Please note, if the AE is not possibly, probably or definitely related to the subject's participation in research, then it does not need to be submitted to the IRB.)

PI's opinion as to whether this AE changes the overall risk to subjects or the risk/benefit ratio as stated in the Yale protocol:

Modification of protocol or consent form needed?

Yes (copy of revised form(s) and amendment request attached)

No (why not?)

Single occurrence of the event does not warrant modification of the protocol/consent at this time

Other (please explain):

Report sent to sponsor and/or DSMB for consideration?

Yes

Date Sent

No (why not?)

Please explain:

Signature: _____
Principal Investigator