



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

**Report of External Adverse Event(s) Under Non-Yale PI
Form 6B**

HIC #		Date AE reported to PI: Date Submitted to HIC:	
Title of Research Project:			
Yale Principal Investigator:			
Study Sponsor:			
Campus Address:			
Campus Phone:	Fax:	Pager:	E-mail:
Protocol Correspondent Name & Address:			
Campus Phone:	Fax:	E-mail:	

After evaluating the AE, the Yale PI determined that the adverse event report(s) _____ meets criteria for submission to HIC. (If yes, submit the AE report(s) with the analysis or summary of the event performed by the sponsor or DSMB. The summary must explain the significance of the event or series of events.)

_____ does not meet criteria for submission to HIC. (If not, keep report(s) for study file but do not submit to the HIC.)

PI's assessment of how the Adverse Event(s) meet the criteria (Serious AND unanticipated AND related) for reporting to HIC:

Yale PI's assessment of whether this AE changes the overall risk to subjects or the risk/benefit ratio as stated in the Yale protocol and need for protocol and/or consent form changes:

Signature: _____
Principal Investigator

HIC Form #6B (6/07)