



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

**Protocol Deviation or Unanticipated Problem Involving Risks to Subjects or Others
Report Form**

Reporting of (please check one); Protocol Deviation Unanticipated Problem

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:	

1. Description of the Deviation or Unanticipated Problem:

Please describe the nature of the deviation/problem. Include the date(s) when the deviation/problem occurred.

2. Explain why the deviation/problem occurred:

3. What was the outcome of the deviation/problem?

4. Were the subjects adversely affected by the deviation/problem?

If so, please explain.

5. Please state below a description of any changes to the protocol that are required as a result of this deviation/problem and what corrective actions will be taken to prevent future occurrences:

(If necessary, please submit a revised protocol and/or consent form along with the request for approval of amendment form found on the website).

Investigator's Signature

Date