

DEPARTMENT: Yale University YSM HIC
POLICY NUMBER:
SECTION: IRB Policy on Protocol Deviations
REVIEW RESPONSIBILITY: HIC Administration
ORIGINAL CREATION DATE: March 24, 2004

Yale University School of Medicine HIC Policy Regarding: HIC Policy on Protocol Deviations

I. Purpose: The HIC recognizes that deviations to approved protocols may occur. It is the responsibility of the Principal Investigator to notify the HIC if the deviations may expose subjects to increased risk or fewer benefits, or if the deviation compromises the integrity of the study.

II. Policy Statement:

A protocol deviation or violation occurs when there is a variance in a research study between the protocol and the activities being performed. Protocol deviations may be minor or major as defined below.

III. Definitions:

Minor protocol deviations:

The deviation has no substantive effect on the risks or benefits to the individual research subject, AND

The deviation has no substantive effect on the value of the data collected, AND

The deviation did not result from willful or knowing misconduct on the part of the investigator(s) or study staff.

Major protocol deviations (protocol violations):

The deviation has harmed or posed a significant risk of substantive harm to the individual research subject and increased the risk/benefit ratio, OR

The deviation has compromised the scientific integrity of the data collected for the study, OR

There is evidence of willful or knowing misconduct on the part of the investigator(s) or study staff, OR

The investigator(s) or study staff demonstrated other serious or continuing noncompliance with federal, state or local research regulations.

IV. Policy:

Investigators are required to report **major** protocol deviations that occur only at Yale's research site(s) to the HIC within five (5) working days of their occurrence or within five (5) days of the investigator becoming aware of their occurrence. Investigators are also required to report results of audits or inspections conducted by sponsors or other external entities such as the Food and Drug Administration (FDA), which involve a major protocol violation as defined above.

Investigators are not required to report deviations from other sites unless a Yale investigator serves as the managing investigator for a multi-centered study. The HIC reserves the right to request more frequent reporting and/or the submission of an action plan, depending on the nature of the violations. Major protocol deviations will be reviewed by the HIC Chair or Vice Chair who will determine whether full Committee review is required.

V. Procedure:

Completion and filing with HIC of Protocol Deviation Report Form.



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

Protocol Deviation Report Form

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. Deviation description:

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

2. Explain why the deviation occurred:

3. What was the outcome of the deviation?

4. Were the subjects adversely affected by the deviation?

If so, please explain.

5. Please state below what will be done to prevent future occurrences:

Investigator's Signature

Date