

Non-Compliance/Complaint Investigation Form
(Form Date: 2/2007)

Preliminary Investigation – Conducted by the CHS CIRB office

Date of event:

Date investigation initiated:

Name of Investigator:

Name of study:

Description of event:

Is sponsor notification of the event required? Yes No If yes, notify sponsor

Suspension Not Merited/Suspension Merited Determination – Within two (2) days of receipt of the allegation, the CHS CIRB office will consult with Chair or Co-Chair to confirm determination.

Suspension not merited: The issue will be resolved between any combinations of the following individuals; Human Protections Administrator, Chair, Co-Chair, and Principal Investigator (PI). Further action will be based on nature of non-compliance/complaint.

Suspension merited: Notice of suspension effective immediately will be sent to: PI, Co-Investigators, Institutional Signatory Official, Department of Medical Staff Services, Study Sponsor, required federal regulatory agencies and the CHS CIRB at its next regularly scheduled meeting. Proceed with investigation.

Non-Serious/Serious and Non-Continuing/Continuing Determination – Within five (5) days of the initial receipt of the allegation, a meeting will be called with any combination of the following individuals: Human Protections Administrator, Chair, Co-Chair, Principal Investigator, Institutional Signatory Official, a representative of Corporate Compliance to discuss the nature of the situation and to determine if the situation merits a designation of serious or continuing non-compliance.

The PI will be required to produce all records related to the study in question for auditing purposes to make a determination of serious or continuing non-compliance.

Non-serious and/or Non-continuing: Incident appears to be isolated, of a non-serious and/or non-continuing nature, the incident will remain internal. The CHS CIRB Office will issue a letter to the PI summarizing the audit. If a Corrective Action Plan was required, a response from the PI describing the corrective actions taken will be required within two (2) weeks. Suspension of study activities will be lifted upon receipt of the PI's response.

Serious and/or Continuing: Incident has been determined to be of a serious and/or continuing nature, the Office for Human Research Protection (OHRP) will be notified. A preliminary phone call will be placed to apprise them of the incident followed by a letter.

The letter will briefly describe the incident, the preliminary investigation and indication of plans for further investigation. A full report will follow, including the Corrective Action Plan for this specific incident and for the research program and/or CHS CIRB structure to ensure incidents will not occur in the future.

Additional Documentation:

Corrective Action Plan:

Attach report of audit, all correspondence, Corrective Action Plan, PI's response, etc. Copies of file will be placed in the study binder under the Quality tab and in the CHS CIRB office. The incident will be tracked in the Non-Compliance Data Base by the CHS CIRB office.

Participants in the investigation:

Signature	Title	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Required Follow-up Documentation

- Response to Corrective Action Plan
 - Date sent: _____
 - Date due: _____
 - Date received: _____