

Yale University Institutional Review Boards

700 CH1 Noncompliance and Unanticipated Problems Checklist

DATE: _____	IRB#: _____		
PI: _____	REVIEWER: _____		
Title of Study: _____			
Brief Description Of Problem:			
	YES	NO	NA
FUNDING SOURCE:			
Is this study federally funded? If yes, state source and grant #:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is this study FDA regulated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DETERMINATION:			
<p>Represents Serious Noncompliance, defined as: Any behavior, action or omission in the conduct or oversight of human research that has been determined to affect the rights and welfare of participants, increases risks to participants, decreases potential benefits, or compromises the integrity or validity of the research. Examples of serious noncompliance include, but are not limited to:</p> <ul style="list-style-type: none"> • Conducting non-exempt research that requires direct interaction or interventions with human subjects without first obtaining IRB approval; • Enrolling subjects who fail to meet the inclusion or exclusion criteria in a protocol that involves greater than minimal risk and that in the opinion of the IRB Chair, designee, or convened IRB, places the participant(s) at greater risk; • Failure to report serious, unanticipated, and related adverse events, unanticipated problems, or major proposed protocol changes to the IRB or • Serious protocol deviations that place, or have the potential to place, participants at increased risk from the research. 	<input type="checkbox"/>	<input type="checkbox"/>	
<p>Represents Continuing Noncompliance, defined as: A pattern of noncompliance that, in the judgment of the IRB Chair, designee, or a convened IRB:</p> <ul style="list-style-type: none"> • Indicates a lack of understanding of or disregard for the regulations or institutional requirements that protect the rights and welfare of participants • Compromises the scientific integrity of a study such that important conclusions can no longer be reached • Suggests a likelihood that noncompliance will continue without intervention • Involves frequent instances of minor noncompliance • Continuing noncompliance may also include failure to respond to a request from the IRB to resolve an episode of noncompliance 	<input type="checkbox"/>	<input type="checkbox"/>	

Represents Unanticipated Problem Involving Risks to Subjects or Others , defined as: Any incident, experience or outcome that is:			
<ul style="list-style-type: none"> • Unexpected in terms of nature, severity, or frequency • Places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) <i>than was previously known or recognized</i> and • Is possibly or probably related to participation in the research project. 	<input type="checkbox"/>	<input type="checkbox"/>	
If event meets any of the above criteria it MUST go to Committee. Meets criteria?	<input type="checkbox"/>	<input type="checkbox"/>	
Send to Committee?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	YES	NO	NA
If event does NOT meet any of the above criteria, is further action required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, check ALL that apply			
CORRECTIVE ACTION PLAN			
Was a Corrective Action Plan provided by the investigator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are changes required to the Corrective Action Plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is Corrective Action Plan acceptable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
POSSIBLE IRB DETERMINATIONS:			
Determination that additional records or information is required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Determination that the event does not meet criteria for SAE/UPIRSO/Noncompliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Determination that the event does meet criteria for SAE/UPIRSO/Noncompliance and that further action is necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
POSSIBLE IRB ACTIONS (Pick ALL that apply):			
Remediation or educational measures required of the research team	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Restrictions on the investigator’s research practice, such as limiting the privilege to minimal risk or supervised projects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Monitoring of research activities by appropriate person(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Monitoring of the informed consent process by appropriate person(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Notification of past or current research participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Requiring re-consenting of subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Modification of the research protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased reporting by the researcher of his/her human research activities to the IRB	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Requiring a more frequent continuing review schedule	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Requiring periodic audits by the Compliance Manager or other quality assurance/quality improvement auditors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Suspension of approval for one or more of the researcher’s studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Termination of approval for one or more of the researcher’s studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (describe):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CORRESPONDENCE (note if direct letter or cc) If federally funded and meets the criteria on page 1, the federal agency(ies) MUST be notified.			
Letter to PI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter to IO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter to Department Chair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter to OHRP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter to Funding Agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter to FDA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

INVESTIGATOR RESPONSE:			
Is a response required from the investigator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was investigator's response reviewed? Date Reviewed: ___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was investigator's response acceptable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
STATUS:			
Is this matter closed? Date Closed: ___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

COMMENTS:			

The official version of this information will only be maintained in an on-line web format. Any and all printed copies of this material are dated as of the print date. Please make certain to review the material on-line prior to placing reliance on a dated printed version.
