

POST-APPROVAL REPORTS: BOARD REVIEW

Unanticipated Problem (UAP): An incident, experience, or outcome that meets all of the following criteria:

1. unexpected (in terms of nature, severity or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (possibly related means that there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Non-Compliance: Failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB.

Serious Non-Compliance: Non-compliance that has a significant adverse impact either on the rights or welfare of participants or on the integrity of the data.

Continuing Noncompliance: A pattern of noncompliance that indicates an inability or unwillingness to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.

A.	DETERMINATIONS- UAP		YES	POSSIBLY	NO	N/A
1.		The event or information is unexpected in terms of nature, severity or frequency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.		The event or information is related or possibly related to participation in the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.		The event or information suggests greater risk of harm to subjects <u>or</u> others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • If <u>all 3</u> are checked "Yes" or "Possibly" this is or may be an Unanticipated Problem. Complete Sections B & C. • If <u>any</u> are checked "No" or "N/A," this is not an Unanticipated Problem. Proceed to Section B. 						

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B.	DETERMINATIONS- NON-COMPLIANCE	YES	POSSIBLY	NO	N/A
1.	The event, information <u>or</u> the timing of the report is Non-Compliance <ul style="list-style-type: none"> • <i>If "Yes" or "Possibly," answer Questions 2-5 below.</i> • <i>If "No" <u>and</u> this is not a possible UAP, skip to Section D.</i> 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.	The non-compliance has a significant adverse impact on rights or welfare of subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	The non-compliance has a significant adverse impact on the integrity of the data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	There is a pattern of non-compliance that indicates unwillingness to comply	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	There is a pattern of non-compliance that indicates inability to comply	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> • <i>If any of 2-5 are "Yes" or "Possibly," this is or may be Serious/Continuing Non-Compliance. Complete Section D.</i> • <i>If all of 2-5 are "No," this is not Serious or Continuing Non-Compliance. If also not a UAP, skip to Section D.</i> 					

C.	UAP AND/OR SERIOUS/CONTINUING NON-COMPLIANCE	YES	NO	N/A
1.	Is any additional information needed (especially if definitive determination not made)?	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Are additional corrective actions needed?	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Should IRB approval be Suspended or Terminated?	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> • <i>If any are "Yes" describe what information/actions are needed and what deadlines/conditions to impose.</i> 				

D.	NEITHER UAP NOR SERIOUS/CONTINUING NON-COMPLIANCE	YES	NO	N/A
1.	Are any actions needed to correct a problem?	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Are any actions needed to prevent recurrence?	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> • <i>If either is "Yes" describe what actions are needed and what deadline to impose.</i> 				