POST-APPROVAL REPORTS: CHAIR / DESIGNEE 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.	INITIAL PASS		YES	NO	N/A
	1.	More information needed before preliminary determinations	☐	☐	
	2.	Referral to others needed before any IRB review (e.g., Compliance re HIPAA)	☐	☐	

- ***If <u>both</u> are "No," proceed to the next section***
- ***If <u>either</u> is "Yes," skip rest of sheet and mark as Additional Information Required in webIRB***

B.	PRELIMINARY DETERMINATIONS- UAP		POSSIBLY	NO	N/A
	1.	The event or information is unexpected in terms of nature, severity or frequency	☐	☐	☐
	2.	The event or information is related or possibly related to participation in the research	☐	☐	☐
	3.	The event or information suggests greater risk of harm to subjects **<u>or</u>** others	☐	☐	☐

- ***If <u>all 3</u> are checked "Possibly," this must be referred to the Convened IRB. Complete Sections C & D.***
- ***If <u>any</u> are checked "No" or "N/A," this is not an Unanticipated Problem. Proceed to Section C.***

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C.	PRELIMINARY DETERMINATIONS- NON-COMPLIANCE		POSSIBLY	NO	N/A
	1.	*If report includes an allegation of non-compliance*: allegation has a basis in fact • ***If "Possibly" continue in this section, otherwise proceed to Section D or E***	☐	☐	☐
	2.	The event, information **<u>or</u>** the timing of the report is Non-Compliance • ***If "Possibly," answer Questions 3-6 below.*** • ***If "No" <u>and</u> this is not a possible UAP, skip to Section E.***	☐	☐	
	3.	The non-compliance has a significant adverse impact on rights or welfare of subjects	☐	☐	
	4.	The non-compliance has a significant adverse impact on the integrity of the data	☐	☐	
	5.	There is a pattern of non-compliance that indicates unwillingness to comply	☐	☐	
	6.	There is a pattern of non-compliance that indicates inability to comply	☐	☐	
• ***If any of 3-6 are checked "Possibly," this must be referred to the Convened IRB. Complete Section D.*** • ***If all of 3-6 are checked "No," this is not Serious or Continuing Non-Compliance. If also not a UAP, skip to Section E.***					

D.	REFERRAL TO CONVENED IRB		YES	NO	N/A
	1.	Is any information needed before the next Board meeting?	☐	☐	
	2.	Are interim measures needed for immediate safety concerns before the next Board meeting?	☐	☐	
• ***If either is "Yes" notify staff in webIRB about your determinations and what information and/or measures are needed.***					

E.	CLOSEOUT STEPS		YES	NO	N/A
	1.	Are any actions needed to correct a problem?	☐	☐	
	2.	Are any actions needed to prevent recurrence?	☐	☐	
• ***If either is "Yes" notify staff what actions are needed and what deadline to impose.***					