

CONFIDENTIAL

Study Review: Principal Investigator Response Form

Principal Investigator:	_____
Protocol Number:	_____
Protocol Title:	_____
PI Response Due Date:	_____

Instructions:

- 1. The PI must review, address and respond to each Required Action and Recommended Action as outlined. PLEASE DO NOT INCLUDE ANY DIRECT IDENTIFIERS IN THIS REPORT. USE INITIALS OR STUDY ID NUMBERS.**

Part A. Required Actions: *all actions must be addressed promptly* to meet federal regulations, guidelines and Children's Hospital policies. If the required action is not possible or cannot be completed, please provide reason.

Part B. Recommended Actions: *consider all recommended actions*. While not mandatory, it is strongly encouraged to consider the recommendations, evaluate them in terms of your program/study procedures and to incorporate as deemed helpful.

Please respond to each recommendation with one of the following actions:

→ Accept Action	Recommendation deemed useful and action implemented. Please explain how.
→ Postpone Action	Recommendation deemed useful, but action will be implemented later in this study and/or will be applied to future studies.
→ Decline Action	Recommendation deemed impractical or unfeasible for this study as well as future studies.
→ Acknowledge	As applicable, an observation may be noted in which no follow-up action is necessary, but PI will be asked to acknowledge or clarify.

- 2. Once this form is complete, please sign below and return (PDF by email) to yvette.marts@childrens.harvard.edu by the due date noted above.**

This signature indicates the Principal Investigator has reviewed this report, shared findings and provided copies to appropriate research staff and addressed all *Required and Recommended Actions*.

Principal Investigator (Printed): _____

Principal Investigator Signature: _____ Date: _____



Part A. REQUIRED ACTIONS: *all actions must be addressed promptly*

Ref.	Required Action	PI Response	EXPLAIN RESPONSE		EQUIP Use Only
			COMPLETED:	If no changes, no response required	
A1	1.	<input type="checkbox"/> COMPLETED <input type="checkbox"/> OTHER/NO ACTION	Response: _____	OTHER/NO ACTION: Why alternative or no action taken	<input type="checkbox"/>
A2	1.	<input type="checkbox"/> COMPLETED <input type="checkbox"/> OTHER/NO ACTION	Response: _____	ACKNOWLEDGED: As applicable, acknowledge or clarify	<input type="checkbox"/>
A3		<input type="checkbox"/> COMPLETED <input type="checkbox"/> OTHER/NO ACTION	Response: _____		<input type="checkbox"/>



Part B. RECOMMENDED ACTIONS: consider all recommendations.

Ref.	Recommended Action	PI Response	EXPLAIN RESPONSE	
				EQIP Office Use Only
B1	1.	<input type="checkbox"/> ACCEPT <input type="checkbox"/> POSTPONE <input type="checkbox"/> DECLINE	Response: _____	<input type="checkbox"/>
B2		<input type="checkbox"/> ACCEPT <input type="checkbox"/> POSTPONE <input type="checkbox"/> DECLINE	Response: _____	<input type="checkbox"/>
B3		<input type="checkbox"/> ACCEPT <input type="checkbox"/> POSTPONE <input type="checkbox"/> DECLINE	Response: _____	<input type="checkbox"/>

This program is intended to help investigators meet and understand the regulations that apply to their research, as well encourage improvements that maximize the protection of human subjects. Your participation is appreciated and your input useful. Please provide any additional suggestions, concerns, and comments that you feel might help.
