Boston Children's Hospital
Until every child is well

Protocol Deviation Log v.1

Principal Investigator		Protocol #	

Protocol Title	

BCH policy requires Principal Investigators (PIs) to report all protocol changes, deviations and exceptions to the IRB. Upon discovery, if the PI deems the event a significant deviation (affects subject safety, risks or benefits, data integrity and/or subject's willingness to participate), the PI must complete a **Significant Deviation Form** to be submitted to the IRB within 72 hours.

Otherwise, all other minor deviations should be documented, filed with study records, and a copy submitted to the IRB with the next continuing review application. The following form is a template that may be used to document minor deviations for study purposes, and/or to submit to the IRB with the next continuing review. This form is not required by the IRB.

→ PROTOCOL DEVIATIONS

1.	**Date of Deviation:**	
	Is this a significant deviation?	☐ No ☐ Yes → complete Significant Deviation Form, and submit to IRB within 72 hours.
	Description of Event: *If available, please include:* 1. Explanation of why the event occurred, and 2. Description of any follow-up or corrective actions	
	PI Signature	

2.	**Date of Deviation:**	
	Is this a significant deviation?	☐ No ☐ Yes → complete Significant Deviation Form, and submit to IRB within 72 hours.
	Description of Event: *If available, please include:* 1. Explanation of why the event occurred, and 2. Description of any follow-up or corrective actions	
	PI Signature	

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PROTOCOL DEVIATION DOCUMENTATION LOG

#		
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	Is this a significant deviation?	☐ No ☐ Yes → complete Significant Deviation Form, and submit to IRB within 72 hours.
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