Boston Children's Hospital
Until every child is well

Protocol Deviation Log v.2

Principal Investigator _____ Protocol # _____

Protocol Title _____

BCH policy requires Principal Investigators (PIs) to report all protocol changes, deviations and exceptions to 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),), a **Significant Deviation Form** must be completed and 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 each 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.

#	Description of Deviation	Date of Deviation	PI: Significant or Minor?	PI Signature and Date
1.			☐ Significant **notify CCI within 72 hours*	
			☐ Significant **notify CCI within 72 hours*	
			☐ Significant **notify CCI within 72 hours*	
			☐ Significant **notify CCI within 72 hours*	
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			☐ Significant **notify CCI within 72 hours*	
			☐ Significant **notify CCI within 72 hours*	
			☐ Significant **notify CCI within 72 hours*	

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#	Description of Deviation	Date of Deviation	PI: Significant?	PI Signature and Date
			☐ Significant *notify CCI within 72 hours	
			☐ Significant *notify CCI within 72 hours	
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