

Study and IRB Number:	Site Number:
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NonCompliance Log

Incident Description: (include date of incident and subject number if applicable)	<i>Does the noncompliance meet any of the following required reporting?*</i> Mark all that apply	<i>PI Assessment: Does the noncompliance meet any of the following?*</i> Mark all that apply	IRB notification date, if applicable	Sponsor notification date, if applicable	PI Initials and Date
	<input type="checkbox"/> Failure to obtain informed consent or re-consent <input type="checkbox"/> Modifying the protocol without IRB approval <input type="checkbox"/> Conducting research without IRB approval <input type="checkbox"/> None	<input type="checkbox"/> Affected subject rights and welfare <input type="checkbox"/> Affect integrity of the research data <input type="checkbox"/> Subject(s) experience actual harm <input type="checkbox"/> Increase the risk of harm for one or more subjects <input type="checkbox"/> None			
	<input type="checkbox"/> Failure to obtain informed consent or re-consent <input type="checkbox"/> Modifying the protocol without IRB approval <input type="checkbox"/> Conducting research without IRB approval <input type="checkbox"/> None	<input type="checkbox"/> Affected subject rights and welfare <input type="checkbox"/> Affect integrity of the research data <input type="checkbox"/> Subject(s) experience actual harm <input type="checkbox"/> Increase the risk of harm for one or more subjects <input type="checkbox"/> None			
	<input type="checkbox"/> Failure to obtain informed consent or re-consent <input type="checkbox"/> Modifying the protocol without IRB approval <input type="checkbox"/> Conducting research without IRB approval <input type="checkbox"/> None	<input type="checkbox"/> Affected subject rights and welfare <input type="checkbox"/> Affect integrity of the research data <input type="checkbox"/> Subject(s) experience actual harm <input type="checkbox"/> Increase the risk of harm for one or more subjects <input type="checkbox"/> None			

*if any boxes other than None checked, complete NonCompliance Reporting Form (<https://redcap.kumc.edu/surveys/?s=8AYJCWNW4F>)