

Protocol Deviation Report Form

Joint CUHK-NTEC Clinical Research Ethics Committee

Protocol Deviation: A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the CREC. The Principal Investigator is responsible for reporting any protocol deviation(s) promptly to the CREC using this reporting form.

Background Information

Study Title:

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CRE – Ref. No :		Name of Principal Investigator (PI)		Email of PI	
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Protocol Deviation(s) Report Summary

Subject No:	Date of Occurrence (DD-MMM-YYYY)	Description of Protocol Requirement	Description of Protocol Deviation	Type of Protocol Deviation##	Any action to avoid similar deviation in the future?	Increase the risks to subject?	Did the deviation cause AE / SAE?	Was the deviation due to:
				<input type="checkbox"/> Major Deviation <input type="checkbox"/> Minor Deviation	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> Investigator error <input type="checkbox"/> Subject error <input type="checkbox"/> Others, Please Specify:
				<input type="checkbox"/> Major Deviation <input type="checkbox"/> Minor Deviation	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> Investigator error <input type="checkbox"/> Subject error <input type="checkbox"/> Others, Please Specify:

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				<input type="checkbox"/> Major Deviation <input type="checkbox"/> Minor Deviation	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> Investigator error <input type="checkbox"/> Subject error <input type="checkbox"/> Others, Please Specify:
				<input type="checkbox"/> Major Deviation <input type="checkbox"/> Minor Deviation	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, Please specify:	<input type="checkbox"/> Investigator error <input type="checkbox"/> Subject error <input type="checkbox"/> Others, Please Specify:

Name of Principal Investigator / Designee	Signature of PI / Designee	Date

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-Major Deviation: Major change, divergence, or departure from the study design or procedures of a research protocol that affects the subject's right, safety, or well being and/or the completeness, accuracy and reliability of the study data constitutes. If a protocol deviation occurs which meets this definition, the deviation should be submitted to CREC within one month of awareness.

-Minor Deviation: Deviation does not affect the scientific soundness of the plan or the rights, safety, welfare of human subjects, or affect the value of the data collected. If a protocol deviation occurs which meets this definition, the deviation should be submitted to CREC within three months of awareness.