

Non-Compliance Reporting Timelines

Reporting Party	Event	Report to	Timeframe	Supporting Information Required
Sponsor or delegate	Confirmed Serious Breach	HREC	7 Calendar days from when the Sponsor confirms a Serious Breach is confirmed	Complete and submit a Serious Breach Form via ERM ; include: <ol style="list-style-type: none"> 1. Details of the serious breach 2. Impact of the serious breach on any of: <ul style="list-style-type: none"> - Participant safety - Participant rights - Reliability and robustness of data 3. Details of any action taken to date: <ul style="list-style-type: none"> - Investigations conducted and their outcome - How the serious breach will be reported in publications - CAPA plan to be developed and implemented
Sponsor or delegate	Serious Breach which leads to site closure	HREC & TGA	As soon as reasonably possible	Complete and submit a Site Closure Report via ERM and include: <ol style="list-style-type: none"> 1. Reason for closure of site 2. Ongoing plan for site participants 3. Implications for other sites, if any
Site Principal Investigator	Suspected Breach	The Sponsor or delegate and RGO	Within 72 hours of becoming aware of the suspected breach	Complete a Non-Compliance Report Form [MCTC124] and email direct to the Sponsor. Include the following information in the form: <ol style="list-style-type: none"> 1. Deviation category 2. Description of the suspected serious breach 3. CAPA plans both taken and planned
Third Party (often the site)	Suspected Serious Breach where the Sponsor is in conflict (ie. the Sponsor disagrees with the site team's assessment, or is responsible for the breach)	HREC	Within 48 hours of receiving a negative response from the Sponsor	Complete a Third-Party Suspected Breach Report Form [MCTC109] and email direct to the reviewing HREC. Include the following information in the form: <ol style="list-style-type: none"> 1. Details of the suspected serious breach 2. Impact of the serious breach on any of: 3. Explanation of where, how, and when the suspected breach was identified