

Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) Event Form Descriptions:

HSREB Annual Renewal Form	This form can only be used to renew your ethics clearance annually. Ethics Clearance from the HSREB must be renewed at least once per year (TCPS2, Article 6.14). If you would like to close your ethics file, submit the HSREB Study Closure Form in TRAQ.
HSREB Study Closure Form	This form is to be used to request closure of the ethics file. Study closure is defined as having no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed. The HSREB recommends that all studies remain open until a manuscript has been accepted for publication in the event that further follow up with respect to data collection is required. Once an ethics file has been closed, no further data collection, query resolution, data clarification, primary data transfer or contact with participants is permissible. If you require an active ethics clearance, delete this draft and submit the HSREB Annual Renewal Form in TRAQ.
HSREB Change in Study Team Request Form	This form is to be used to request changes to the study team members ONLY. If study team members will be performing significant study-related duties, have access to study data, or require access to the ethics files/correspondence in TRAQ, they must be listed as a study team member within the study files and/or be listed on the ethics file. A confidentiality agreement may suffice for some roles (e.g., transcriber, statistician).
HSREB Amendment Form	This form should be used to communicate all changes to the ethically cleared research with the exception of adverse events and protocol deviations. Annual renewals will NOT be processed on this form. Submit the HSREB Annual Renewal Form or HSREB Study Closure Form to provide an update regarding study status.
HSREB Serious Adverse Event (SAE) Form - Local	This form should be used to submit LOCAL adverse events that meet the definition of an unanticipated problem (is unexpected and related or possibly related to research participation) per HSREB SOP 410 HSREB Adverse Event Reporting. Refer to HSREB's website under 'Application Form Resources' to find the SAE Multi-Event Reporting Form if you are reporting multiple adverse events. The HSREB will no longer be accepting adverse event report submissions that do not meet the HSREB reporting criteria.
HSREB Serious Adverse Event (SAE) Form - Non-Local	This form should be used to submit NON-LOCAL adverse events that meet the definition of an unanticipated problem (is unexpected and related or possibly related to research participation) per HSREB SOP 410 HSREB Adverse Event Reporting. Refer to HSREB's website under 'Application Form Resources' to find the SAE Multi-Event Reporting Form if you are reporting multiple adverse events. The HSREB will no longer be accepting adverse event report submissions that do not meet the HSREB reporting criteria.
HSREB Protocol Deviation Form	This form should be used to report protocol deviations which are unanticipated or unintentional divergences or departures from the ethically cleared research/protocol on part of the research team. Deviations that result from participant non-compliance (i.e. they did not take medication, did not show up for a visit) do not need to be reported to the REB. Form created April 2016.

General Research Ethics Board (GREB) Event Form Descriptions:

GREB Annual Renewal Form	This form can only be used to renew your ethics clearance annually. Ethics Clearance from the GREB must be renewed at least once per year (TCPS2 Article 6.14). If you would like to close your ethics file, submit the GREB Study Closure Form in TRAQ.
GREB Study Closure Form	This form is to be used to request closure of the ethics file. Study closure is defined as having no further participant involvement at the site and all new data collection is complete. GREB recommends that all studies remain open until a manuscript has been accepted for publication in the event that further follow up with respect to data collection is required. Once an ethics file has been closed, no further data collection, data clarification, primary data transfer or contact with participants is permissible. If you require an active ethics clearance, delete this draft and submit the GREB Annual Renewal Form in TRAQ.
GREB Change in Study Team Request Form	This form is to be used to request changes to the study team members ONLY. If study team members will be performing significant study-related duties, have access to study data, or require access to the ethics files/correspondence in TRAQ, they must be listed as a study team member within the study files and/or be listed on the ethics file. A confidentiality agreement may suffice for some roles (e.g., transcriber, statistician).
GREB Amendment Form	This form should be used to communicate all changes to the ethically cleared research with the exception of adverse events and protocol deviations. Annual renewals will NOT be processed on this form. Submit the GREB Annual Renewal Form or GREB Study Closure Form to provide an update regarding study status.
GREB Adverse Event (AE) Form - Local	This form should be used to submit adverse events which include, but is not limited to, a complaint from an individual about your research study (participant, potential participant, community member, researcher, etc.), a privacy breach, or an unanticipated event that adversely affects participants and/or research staff. A serious adverse event is one that has had a significant impact upon participants and/or research staff in terms of physical, psychological, and/or emotional discomfort or distress.
GREB Protocol Deviation Form	This form should be used to report protocol deviations which are unanticipated or unintentional divergences or departures from the ethically cleared research/protocol on part of the research team. Deviations that result from participant non-compliance (i.e. they did not show up for a visit) do not need to be reported to the REB.