| **Trillium Health Partners (THP) Research Ethics Board (REB) Application Forms** | **Purpose and Use** |
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| 1. **Main Research Ethics Board Initial Application Form** | To be completed for all research studies. |
| 1. Additional Study Team Information Form | To list additional study team members not included on the Main Research Ethics Board Initial Application form. |
| **Appendices: All appendices (listed below) that are relevant to the research study being conducted, should be completed and submitted with the main REB initial application form.** |  |
| 1. **Appendix A**: Interventional Studies | Regulated/non-regulated clinical trial or any other interventional study. |
| 1. **Appendix B:** Retrospective Chart Review, Retrospective Biological Sample Analysis and Secondary Analysis | Studies with a retrospective (no new data being collected) component to the research study. |
| 1. **Appendix C:** Prospective Research Study (Non-Interventional Study) | Any study being conducted prospectively (new data will be collected as part of the research) that does not involve a research intervention (e.g. Qualitative, Observational, Epidemiological, Genetic, Descriptive Survey, Registry studies). |
| 1. **Appendix D:** Genetic / Biobank Research Study | Any study that involves examining a person’s genes, genetic variation, heredity, or involves storing biological samples in a biorepository. |
| 1. **Appendix E:** Waiver of Consent Consideration | Requesting waiver for a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirement to obtain informed consent (e.g. consent to contact, consent for screening, etc.). |
| 1. **External Research Advertisement/Recruitment Application Form** | This application should only be used by researchers conducting external research studies (research being conducted at a non-Trillium Health Partners site by an external researcher) who wish to seek authorization to recruit participants (THP staff and/or patient population) at THP for their study using ONLY advertising materials (i.e. flyers, posters, brochures, study information letters, advertisements or other recruitment tools). |
| 1. **Case Report and Case Study Form** | Studies involving descriptive information and anecdotal accounts about a particular patient/person or small group (three or fewer patients). |
| 1. **Additional REB Forms** |  |
| 1. Amendment Submission Form | Any changes/updates made to a currently approved research project. The REB must review and approve all changes prior to implementation. |
| 1. Annual Renewal Application | A request for Annual renewal from the REB which includes a status report on the research conducted over the past year. Should be submitted in advance of the official study expiry date. |
| 1. Study Closure/Termination REB Form | When a study ends, is closed, canceled for any reason, or is prematurely completed, therefore all research activities are complete including interaction with participants, collection of data or specimens, analysis or use of identified or linked data for research purposes. |
| 1. Change in Investigator/Study Personnel Form | Any changes to previously listed and approved study personnel. |
| 1. Protocol Deviation/Violation REB Reporting Form | Any change, divergence, or departure from the approved study design or procedures of a research protocol that is under the investigator’s control and that has not been approved by the REB that may or may not affect the participant’s rights, safety, or welfare, and/or the completeness, accuracy and integrity of the study data. |
| 1. Human Participants Research Determination Request Form | To obtain written confirmation of the determination by the REB concerning whether the project constitutes research involving human participants. |
| 1. Supplemental Safe Research Practices Form | This form is designed to delineate any risks and benefits of proposed research activities in light of the recent pandemic, and the safety measures required to safely engage in research going forward. |
| 1. Serious Adverse Event Report | Used to report unanticipated problems that are serious in nature that occur in a study |
| 1. **Supporting Documents - The following documents should be submitted with the main application form and applicable appendices:** |  |
| 1. Full study protocol | **Required document submissions for all studies** |
| 1. All questionnaires/study instruments to be used in the study (i.e. data collection form(s)) |  |
| 1. Principal/Local Investigator CV(s) |  |
| 1. Consent/Assent form(s) | If applicable |
| 1. Health Canada CTA number and NOL | Only Regulated Clinical Trials |
| 1. Sponsoring company investigator brochure/product monograph | Only required for drug/device studies |
| 1. Advertisements and/or other recruitment tools (i.e. flyers, posters, brochures) | If applicable |
| 1. Any other documents that will be given to participants | If applicable |