**Submission of Multi-Site Clinical Trials**

**Guidance Notes for Researchers re: the Submission of a Clinical Trial**

* **Initial submission of a new clinical trial**
  + In order to access the clinical trial application for HREB review in ROMEO, the appropriate research team members will require an account in ROMEO.
  + Typically there are one or two individuals who complete the required documentation for submission to the HREB for the review of a clinical trial:
    - The Sponsor/Sponsor Designate (assigned as the co-Principal Investigator (co-PI) with the site Principal Investigator (PI)) can complete the required information for Part A of the application and the local site (assigned as the PI) completes the required information for Part B, OR
    - The completion of Part A can be delegated to the local site (assigned as the PI), who then completes the entire application for submission.
* If a research nurse/coordinator is delegated the responsibility of starting a submission in the Researcher Portal on behalf of a site PI, the research nurse/coordinator will need to login as the PI for this application using their own username and password. It is important that individuals do not share their username and passwords with other users. Once the application is ready for review and submission by the site PI, the role of PI can be changed at any time in the Researcher Portal prior to submission. Therefore, the research nurse/coordinator who started the application for the site PI will select the ‘Change PI’ button on the Project Team Info tab in the Researcher Portal to remove them from the PI role and select the proper PI. The steps for changing the role of the PI can be found in the FAQ section here: <https://rpresources.mun.ca/human-ethics/hrea/faq/> or in section 8 of the ‘PI and Project Team Member User Manual – Creating a New Application’.
  + If the Sponsor/Sponsor Designate completes Part A of the application, it is important to note that once the application is approved by the HREB, the Sponsor/Sponsor Designate will be locked out of accessing the application for the remainder of the research process.  An Ethics Office administrator will remove the Sponsor/Sponsor Designate from the project team (making them an ‘inactive project team member’) and make a note in the ‘Investigator Comments’ box referencing the Sponsor/Sponsor Designate. These comments will be visible to the PI. The administrator will only remove the Sponsor/Sponsor Designate from the file once the application has been approved by the HREB.
  + It is important that the designated ‘key contact person’ for the clinical trial be affiliated with the local site, as they will be the only members of the research team who will have ongoing access to the application in ROMEO.  This contact will be responsible for coordinating and disseminating all pertinent information about the submission to the Sponsor/Sponsor Designate, the local site(s) and the HREB.  In addition, this contact will receive all correspondence (queries, approvals, acknowledgements, etc.) regarding the submission from the HREB.  Similarly, it will be this contact’s responsibility to coordinate and disseminate this information to the Sponsor/Sponsor Designate and the local site(s).
  + The Sponsor/Sponsor Designate is required to complete an attestation form – ‘Sponsor Submission Form’ – to accompany the submission of a clinical trial to the HREB.
  + The local site Principal Investigator (PI) is required to complete the ‘Declaration’ tab in the application form in ROMEO.  The completion of the declaration in ROMEO is in lieu of acquiring the PI’s signature.
* **Submission of a subsequent site to an already approved clinical trial**
  + In order to access the clinical trial application for HREB review in ROMEO, the appropriate research team members will require an account in ROMEO (as above).
  + The local site contact must coordinate with the key contact from the original submission to acquire any relevant documents for their submission (or request this information from the Sponsor).
  + The Sponsor/Sponsor Designate will not be involved in the submission of any documents for a subsequent local site.
  + If the Sponsor/Sponsor Designate is responsible for payment of the HREB review fee, then the local site must acquire accurate and relevant information for invoicing to be included in the application form for review by the HREB.
* **Submission of continuing review documents post-HREB approval**
  + The key contact for Part A and local site contacts for Part B applications are responsible for ensuring that post-approval documentation (amendments, revised consent forms, safety reports, updated Investigator Brochures/Product Monographs, etc.) are submitted to the HREB for review and approval.
  + It is the responsibility of the site PIs to ensure that all submitted documents are complete and accurate.
  + If the HREB requires further information on any submitted items they will contact the key contact or local site contact (whichever is relevant).  It will be the responsibility of the key contact or local site contact (whichever is relevant) to communicate any necessary queries to the Sponsor/Sponsor Designate and/or PI.