



# Toronto Academic Health Science Network

## TAHSN Board of Record Tip Sheets

### PURPOSE

The following Tip Sheet outlines the responsibilities and step by step instructions of the Site Principal Investigator "Site PI" in the TAHSN Board of Record process.

### DEFINITIONS

See glossary of terms.

### RESPONSIBILITIES

- The Site PI will submit any Site-specific application materials to the Lead REB in accordance with the Lead's REB policies, procedures and requirements.
- The Site PI is to conduct the study at the Site in accordance with the Study protocol, the Lead REB's policies, procedures and requirements.
- The Site PI must be qualified to conduct the study at all times and the Site and/or Site PI must immediately advise the Lead REB if they become aware of any information that would indicate that the qualifications of the Site PI may no longer be appropriate.
- The Site PI should comply with all the Lead's REB continuing ethics review requirements, including the submission of all protocol amendments/modifications, submission of an annual report of the approved study and must provide access to all site-related study documents in the event of an on-site assessment by the Lead REB.

### STEP #1: Initial Application

- Upon receiving the *Site Specific Information Form* from the Lead Applicant, the Site PI is to complete the form and send the completed form back to the Lead Applicant.
- The Site PI will be notified by the Lead Applicant of the Site Navigators' decision to proceed (or not to proceed) with using the TAHSN Board of Record model.

### STEP #2: Process for Accepted Studies

- The Navigator will inform the Site PI, once the site has received REB approval for the study from the Lead REB.
  - The Site PI is to ensure that all site-specific requirements set by their institution are complete prior to study initiation. For example, data transfer agreements, Institutional Authorization (University Health Network), etc.
- The Site PI is to review and sign the *TAHSN Board of Record Study Agreement* upon request by the Navigator or Lead Applicant and return the agreement to the Navigator.
- Once a site has received approval from the Lead REB and has a complete agreement, the Navigator will provide the Site PI with the following fully executed and approved documents:
  - Lead REB Approval Letter
  - *TAHSN Board of Record Study Agreement* for the Site(s)
  - Approved study documents (Final Protocol and Consent forms)