**** TAHSN SOP005: TAHSN Board of Record Process for Amendments to Ongoing Research Studies

Toronto Academic Health Science Network

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| **SOP Title:**  TAHSN Board of Record Process for Amendments to Ongoing Research Studies | | |
| **SOP Number:**  SOP005 | **Version Number:**  01-September 29 2015 | **Effective Date (DD-MMM-YYYY):** September 29 2015 |

1. Purpose
   1. This Standard Operating Procedure (SOP) describes the process for studies using the TAHSN Board of Record (BoR) to undergo ongoing ethical review of a research study involving human participants.
2. Scope
   1. The scope of this SOP is to outline the process for Amendments of ongoing research studies involving human participants.
3. Responsibilities
   1. The Lead Applicant and all Site Principal Investigators (Site PI) identified in the initial or amended application for the TAHSN BoR submission must comply with this SOP and any other relevant SOP(s).
4. Definitions
   1. Refer to Glossary of Terms.
5. Procedure

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| Step | Task Lead | Action |
| 5.1 | Lead Applicant | 1. The Lead Applicant is to complete the *TAHSN BoR Amendment form*.    1. The Lead Applicant must consult with any applicable Site PIs to collect all site-specific information required to complete the *TAHSN BoR Amendment form*. |
| 5.2 | Site PI | 1. Upon request, the Site PI is to provide required information to the Lead Applicant. |
| 5.3 | Site PI | 1. Each Site PI impacted by the changes outlined in the Amendment must sign a *TAHSN BoR Amendment form–(Addendum A -Site PI Declaration and Signature)*, which is to be attached to the *TAHSN BoR Amendment form.* |
| 5.4 | Lead Applicant | 1. The Lead Applicant is to submit the *TAHSN BoR Amendment Form*, including each Site PI’sDeclaration and Signature Page, to the Lead REB for review. |
| 5.5 | Lead REB | 1. The Lead REB reviews the *TAHSN BoR Amendment Form*. The review will be conducted as per the Lead REB’s normal review process, including:    1. conduct the ongoing ethics review of the study    2. correspond with the Lead Applicant regarding any issues or recommendations    3. make a decision regarding the study and send the *Lead REB Approval Letter* to the Site Navigator |
| 5.6 | Site Navigator | 1. The Site Navigator will provide the Navigator with the *Lead REB Decision Letter*. |
| 5.7 | Navigator | 1. The Navigator will promptly inform the Lead Applicant, the applicable Site PI(s) and the applicable Site Navigators of the Lead REB’s decision and provide the Lead REB Approval Letter as well as any newly approved documents to all parties. |

1. References
   1. Glossary of Terms; Version Date: 29-DEC-2014
   2. SOP001 - TAHSN Board of Record Initial Application; Version Date:
   3. SOP003 - TAHSN Board of Record Process for executing the *TAHSN Board of Record Study Agreement(s) ;* Version Date:
   4. Lead Applicant Tip Sheet; Version Date: 22-DEC-2014
   5. Lead REB Tip Sheet; Version Date: 8-DEC-2014
   6. Navigator Tip Sheet; Version Date: 22-DEC-2014
   7. Site Navigator Tip Sheet; Version Date: 8-DEC-2014
   8. Site PI Tip Sheet; Version Date: 8-DEC-2014
2. Appendix I: Revision History

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| Version Number | Effective Date  *(DD-MMM-YYYY)* | History of change |
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