**** TAHSN SOP006: TAHSN Board of Record Process for Closing a Site

Toronto Academic Health Science Network

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| **SOP Title:**  TAHSN Board of Record Process for Closing a Site | | |
| **SOP Number:**  SOP006 | **Version Number:**  02-April 15 2016 | **Effective Date (DD-MMM-YYYY):** April 15 2016 |

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 closing an approved TAHSN BoR Site.
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 Site Closure Form*.    1. The Lead Applicant must consult with the applicable Site PI to collect all site-specific information required to complete the *TAHSN BoR Site Closure 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 Site Closure must sign a *TAHSN BoR Site Closure Form– Addendum A (Site PI Declaration and Signature)*, which is to be attached to the *TAHSN BoR Site Closure Form.* |
| 5.4 | Lead Applicant | 1. The Lead Applicant is to submit the *TAHSN BoR Site Closure Form*, including the Site PI’sDeclaration and Signature Page, to the Lead REB for review. |
| 5.5 | Lead REB | 1. The Lead REB reviews the *TAHSN BoR Site Closure Form*. The review will be conducted as per the Lead REB’s normal review process, including:    1. conduct the ethics review of the site-specific closure details    2. correspond with the Lead Applicant regarding any issues or recommendations    3. provide confirmation of site closure by providing 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 Approval Letter*. |
| 5.7 | Navigator | 1. The Navigator will promptly inform the Lead Applicant, the applicable Site PI and the applicable Site Navigators of the Lead REB’s decision and provide the *Lead REB Closure Letter*. |

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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