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 the continuing ethical review 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 |
| 5.0 | Navigator | 1. The Navigator is to send the Lead Applicant and primary TAHSN BoR contact a reminder of expiry email 2 months prior to a study’s expiry date, so they are aware of the necessary steps and deadlines to submit the TAHSN BoR Continuing Review Form.
 |
| 5.1 | Lead Applicant | 1. The Lead Applicant is to complete the *TAHSN BoR Continuing Review Form before the deadline outlined in the reminder of expiry email sent by the TAHSN BoR Navigator*.
	1. The Lead Applicant must consult with the Site PIs to collect any necessary site-specific information required to complete the *TAHSN BoR Continuing Review Form*.
 |
| 5.2 | Site PI | 1. Upon request by the Lead Applicant, the Site PI is to provide required information to the Lead Applicant in a timely manner.
 |
| 5.3 | Site PI | 1. Each applicable Site PI signs a *TAHSN BoR Continuing Review Form - Addendum A (Site PI Declaration and Signature)*, and returns a signed copy to the Lead Applicant.
 |
| 5.4 | Lead Applicant | 1. The Lead Applicant is to submit the *TAHSN BoR Continuing Review Form*, including each Site PI’s *signed Addendum A – (Site PI Declaration and Signature)*, to the Lead REB for review before the deadline.
 |
| 5.5 | Lead REB | 1. The Lead REB is to review the *TAHSN BoR Continuing Review 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 Continuing Review Approval Letter* to the Site Navigator
 |
| 5.6 | Site Navigator | 1. The Site Navigator will provide the Navigator with the *Lead REB Continuing Review Approval Letter*.
 |
| 5.7 | Navigator | 1. The Navigator will promptly inform the Lead Applicant, applicable Site PI(s) and applicable Site Navigators of the Lead REB’s decision and provide the Lead REB Continuing Review Approval Letter 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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