1. Purpose
	1. This Standard Operating Procedure (SOP) describes the initial application process to use the TAHSN Board of Record (BoR) to undergo ethical review of a research study involving human participants.
2. Scope
	1. The scope of this SOP is to outline the process for completing, submitting and approving the initial application to use the TAHSN BoR.
3. Responsibilities
	1. Each individual involved in the initial application for the TAHSN BoR is responsible for complying with the SOP and other applicable SOPs.
4. Definitions
	1. Refer to Glossary of Terms.
5. Procedure

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| Step | Task Lead | Action |
| 5.1 | Navigator | 1. The Navigator is to provide the *TAHSN Board of Record Request Form* and TAHSN Board of Record Site-specific Form to interested parties or new Lead Applicant upon request.
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| 5.2 | Lead Applicant | 1. The Lead Applicant is to complete the *TAHSN Board of Record Request Form.*
	1. Lead Applicant to provide each Site PI with the TAHSN Board of Record Site Specific Form*.*

**Note:** Lead Applicant is NOT required to complete the *TAHSN Board of Record* *Site Specific Information Form* for their site. |
| 5.3 | Site PI | 1. 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.
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| 5.4 | Lead Applicant | 1. Lead Applicant is to submit to the Navigator
	1. Completed *TAHSN Board of Record Request Form*
	2. *One Site Specific Information Form(s)* for each participating site
	3. All supporting study documents (final protocol, consent form template(s), data collection forms)
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| 5.5 | Navigator | 1. The Navigator is to screen the application for completeness and eligiblity.
	1. If the study is not eligible to use the TAHSN BoR, the Navigator is to send communications to the Lead Applicant and applicable Site Navigators to let them know.
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| 5.6 | Navigator | 1. The Navigator is to send the application and supporting documents to the Site Navigators from the TAHSN institutions potentially participating in the research study.
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| 5.7 | Site Navigator | 1. The Site Navigator is to review the proposed research study application and supporting documents to determine if it is acceptable to use the TAHSN Board of Record model.
	1. The Site Navigators are to inform the Navigator of their decision. If the Site Navigator does not accept the study, they are to directly inform the Lead Applicant with rationale.
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| 5.8 | Navigator | 1. If accepted, the Navigator is to inform the Lead Applicant and applicable Site Navigators of the decision to use the TAHSN Board of Record and next steps for obtaining ethical approval. If the study was not accepted, the Navigator will share the reasons why with the Lead Applicant unless already informed by the Site Navigator(s).
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| 5.9 | Lead Applicant | 1. The Lead Applicant is to inform the Site PI of the decision to proceed, or not, with using the TAHSN Board of Record.
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1. References
	1. Glossary of Terms; Version Date: 29-DEC-2014
	2. SOP002 - TAHSN Board of Record Process for Accepted Studies; 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  |
| 01 | 27-Mar-2015 | Initial |
| 02 | 08-Dec-2017 | Editing form names and adding more detailed instructions |
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