1. Purpose
	1. This Standard Operating Procedure (SOP) describes the process for studies accepted 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 applying to and receiving ethics approval from the Lead REB. as well as executing the *TAHSN Board of Record Study Agreement(s).*
	2. The processes in this SOP as well as SOP003, *TAHSN Board of Record Study Agreement(s)* should be completed in parallel.
3. Responsibilities
	1. The Lead Applicant and all site Principal Investigators identified in the initial 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 | Navigator | 1. Once the Navigator informs the Lead Applicant and applicable Site Navigators of the decision to use the TAHSN BoR model (see SOP001). The Navigator is to instruct the Lead Applicant to apply to the Lead REB as per the Lead REB’s process.
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| 5.2 | Navigator | 1. The Navigator is to also begin the process for executing the *TAHSN Board of Record Study Agreement(s)* (see SOP003).
 |
| 5.3 | Lead Applicant | 1. The Lead Applicant is to apply to the Lead REB (on behalf of all participating sites) as per the Lead REB’s process.
 |
| 5.4 | Site Navigator(s) | 1. The Site Navigator from each participating site may inform the Lead Applicant and Site PI(s) to begin completing all site-specific requirements set by their institution (ie. data transfer agreements, Institutional Authorization, etc). Such site-specific requirements must be complete prior to study initiation at the site.
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| 5.5 | Lead Applicant | 1. The Lead Applicant is to begin site-specific processes to ensure that all site-specific requirements set by their institution are complete prior to study initiation.
 |
| 5.6 | Site PI | 1. The Site PI is to begin site-specific processes to ensure that all site-specific requirements set by their institution are complete prior to study initiation.
 |
| 5.7 | Lead REB | 1. The Lead REB will accept and review the Lead Applicant’s submission of the study at the designated sites. The review will be conducted as per the Lead REB’s normal review process.
	1. The Lead REB is to:
		1. conduct the initial ethics review of the study
		2. correspond with the Lead Applicant regarding any issues or recommended changes to the submitted study-related materials, and
		3. make a decision regarding the study.
 |
| 5.8 | Lead REB | 1. The Lead REB will provide the Navigator with the decision letter as well as any approved protocol or consent form(s).
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| 5.9 | Navigator | 1. Upon completion of the *TAHSN Board of Record Study Agreement* (see SOP003) AND once the Navigator has received the REB decision letter, the Navigator will inform the Lead Applicant, the Site PI and the Site Navigators of the Lead REB’s decision and disseminate the following fully executed and approved documents from the Navigator:
* Lead REB Approval Letter
* *TAHSN Board of Record Study Agreement* for the Site(s)
* Approved study documents (Final Protocol and Consent forms
 |
| 5.10 | Lead REB | 1. The Lead REB will conduct ongoing and continuing reviews of an approved study and review all relevant unanticipated problems (including local serious adverse events) and review of and decision regarding approval of any protocol amendments or modifications to the study submitted by the Lead Applicant or Site PI.
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1. References
	1. Glossary of Terms; Version Date:
	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)*
	4. Lead Applicant Tip Sheet; Version Date:
	5. Lead REB Tip Sheet; Version Date:
	6. Navigator Tip Sheet; Version Date:
	7. Site Navigator Tip Sheet; Version Date:
	8. Site PI Tip Sheet; Version Date:
2. Appendix I: Revision History

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| --- | --- | --- |
| Version Number | Effective Date *(yyyy-mm-dd)* | History of change  |
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