1. Purpose
   1. This Standard Operating Procedure (SOP) describes the process for studies accepted to use the TAHSN Board of Record (BoR) to receive fully executed TAHSN BoR Agreement(s).
2. Scope
   1. The scope of this SOP is to outline the process for executing the *TAHSN Board of Record Study Agreement(s).*
   2. The processes in this SOP as well as SOP002 TAHSN Board of Record Process for Obtaining an REB Decision Letter 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 (see SOP001), the Navigator is to:    1. Complete and send to the Lead PI and Site PIs the *TAHSN Board of Record Study Agreement* (complete the “Agreement Among” and “Study Title” sections as well as the signature sections for the Site and Lead Institutions, as well as the signature sections for the Lead Applicant and Site PI.    2. Begin the process for obtaining an REB decision letter(see SOP002). |
| 5.2 | Lead Applicant | 1. Upon request from the Navigator, the Lead Applicant must share the *TAHSN Board of Record Study Agreement* with the Site PI to confirm all contact information is accurate. |
| 5.3 | Site PI | 1. The Site PI is to review and sign the *TAHSN Board of Record Study Agreement* and return the agreement to the Lead Applicant. |
| 5.4 | Lead Applicant | 1. The Lead Applicant is to review and sign the *TAHSN Board of Record Study Agreement* and return the agreement to the Navigator. |
| 5.5 | Navigator | 1. The Navigator is to send the *TAHSN Board of Record Study Agreement* to the participating Site Navigators for signatures from their institution’s Authorized Signatory/ies. |
| 5.6 | Site Navigator | 1. The Site Navigator is to collect signatures for the *TAHSN Board of Record Study Agreement* from their site’s Authorized Signatory upon request from the Navigator and return a signed copy to the Navigator. |
| 5.7 | Navigator | 1. Upon completion of the *TAHSN Board of Record Study Agreement* AND once the Navigator has received the REB decision letter (see SOP002), the Lead Applicant, the Site PI and the Site Navigators will receive the following fully executed and approved documents from the Navigator:  * TAHSN BoR Decision Letter * *TAHSN Board of Record Study Agreement* for the site |
| 5.8 | 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. |

1. References
   1. Glossary of Terms; Version Date: 29-DEC-2014
   2. SOP001 - TAHSN Board of Record Initial Application; Version Date:
   3. SOP002 - TAHSN Board of Record Process for Obtaining an REB Decision Letter; 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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