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| The purpose of this worksheet is to provide support for analysts reviewing use of Electronic Consent (or e-IC) platforms by study teams and to provide support to Designated Reviewers reviewing such uses. Complete the worksheet in its entirety. If an item is marked “no”, request the documentation/clarification/corrections from the study team/PI. Once completed, include as reference for the Designated Reviewer; it does need to be retained. | | | |
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| 1. Review of e-IC Platform | | | |
| Will the study team be utilizing REDCap or a Sponsored e-IC platform? SH Approved REDCap  Sponsor/Lead Site-Provided Platform   * If REDCap – skip below steps and only complete sections 2 - 5 (REDCap has been vetted/approved for use by IS) * If sponsored/lead-site e-IC platform is being used, complete all remaining steps | | | |
| Yes  No | | IS Risk Review has been initiated/completed by OSP \*\* *If no, send email to OSP and study team to initiate IS Risk Review.* | |
| Yes  No | | Is the study FDA Regulated? If so, has documentation of compliance with 21CRF11 been provided?  If not FDA Regulated – skip this question | |
| 1. Review for Single IRB studies (skip this section if not Single IRB Review) | | | |
| Yes  No | | IS Risk Review has been initiated/completed by OSP \*\* *If no, send email to OSP and study team to initiate IS Risk Review.* | |
| Yes  No | | Approval of e-IC platform received from relying IRB | |
| Yes  No | | Confirmation that there are no changes to HIPAA documents or HIPAA process | |
| 1. Document Review – were the following documents submitted and reviewed for completeness and appropriateness? | | | |
| Yes  No | | Copies of all forms (electronic and paper) and informational materials, including any videos and Web-based presentations, which the subject/LAR will receive and view during the e-IC process | |
| Yes  No | | Consent documents that will be used in the e-IC platform on the SH IRB consent template(s) and if applicable:   * Separate HIPAA Authorization * HIPAA Authorization for Reimbursement * Assent Form(s) | |
| Yes  No | | Information and documents related to any optional questions or methods used to gauge subject comprehension of key study elements | |
| Yes  No | | For local site protocols: Updated protocol with changes to the consent plan to include e-IC  For multi-site protocols: Updated protocol OR appropriate documentation from main site regarding use of e-IC | |
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| 1. Confirmation of Consent Process | | | |
| Yes  No | There is sufficient detail as to when and where the e-IC and other consent related discussions will occur | | |
| Yes  No | There is a description of who will perform each portion of the consent discussion | | |
| Yes  No | There is a description of the mechanisms that will be used to conduct the discussions outside of the e-IC portal (approved mechanisms include Microsoft Teams, phone calls utilizing the secure call feature within PerfectServe, Cisco IP Communicator or Voalte phones, etc.) | | |
| Yes  No | There is a description of an alternate plan if a prospective subject or LAR prefers a paper form or if the e-IC system is unavailable | | |
| Yes  No | There is a description of how participant/LAR privacy will be maintained during the e-IC process | | |
| Yes  No | There is a description of how the participant/LAR will be provided with a signed copy of the ICF | | |
| 1. Vulnerable Populations (when applicable) | | | |
| The e-IC plan includes:  Description of how assent will be obtained from this population  Request for a waiver of assent (*If a waiver of assent is requested, do not complete the remaining questions)* | | | |
| Yes  No | | The use of e-IC is appropriate to the age and ability of the population requiring assent | |
| Yes  No | | The e-IC plan includes how the assent will be recorded (i.e. e-signature obtained or verbal) | |
| 1. Waiver of Documentation of Consent Process (when applicable)   If the PI is requesting a waiver of documentation of consent was the following submitted:  Information sheet that contains the required elements of consent  Documentation of why the waiver can be met using protocol-specific justification  Description of how the consent process discussion will be completed and consent obtained | | | |
| Analyst Signature: | | | **Date:** |