**INSTRUCTIONS:**

***Please complete the Participant File Assessment page only if you have direct access to participant files, e.g., they are stored locally and/or easily accessible virtually/remotely.***

***It is not necessary to review every participant file for the purposes of this self-assessment. QIP recommends randomly sampling approximately 10 participants.***

*If you have questions while filling out the Investigator Self-Assessment, or would like the Quality Improvement Program (QIP) team to complete the assessment for you, please contact us (http://www.hsph.harvard.edu/orarc).*

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| --- | --- | --- | --- | --- | --- | --- |
| 1. Participant Files | | | | | | |
| Protocol # | |  | | | | |
| Total Number Enrolled to Date | |  | | | | |
| **Number Reviewed for Self-Assessment** | |  | | | | |
| Participant IDs | | 1) | 2) | 3) | 4) | 5) |
| 6) | 7) | 8) | 9) | 10) |
| Person(s) Completing Checklist | |  | | | | |
| Date Completed | |  | | | | |
|  | | | | | | |
| 1. Participant Selection | | | | | | |
| Yes  No  N/A | Eligibility is assessed and documented for each (e.g., eligibility checklist) | | | | | |
| Yes  No  N/A | The eligibility criteria checklist or documentation includes dated signature/initials of the person making the eligibility determination | | | | | |
| Yes  No  N/A | For participants who did not meet eligibility (e.g. screen-failures), identifiable information was destroyed or authorization was obtained to keep participant information | | | | | |
| Yes  No  N/A | The number of participants screened is no greater than the IRB-approved screening sample size | | | | | |
| Yes  No | The number of participants enrolled/samples included is no greater than the IRB-approved enrollment/ sample size | | | | | |
|  | | | | | | |
| 1. Consent | | | | | | |
| Yes  No | This protocol requires informed consent and/or assent *(If no, skip to section 3)* | | | | | |
| Yes  No  N/A | Investigators obtained consent from each participant prior to the start of any study procedures *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | An IRB-approved study representative obtained consent for all participants *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | Valid IRB-approved consent forms were used, i.e., the correct version *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | Stamped/watermarked IRB-approved consent forms were used *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | All pages of the consent forms are on file for each participant *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | All yes/no, checkboxes, or similar options on the consent forms are completed and/or initialed *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | Consent forms are free of any handwritten changes or corrections *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | Original copies (not photo copies) of all consent forms signed and dated by participants are on file *((N/A if the IRB granted a waiver of consent or documentation of consent)* | | | | | |
| Yes  No  N/A | The participant/participant representative signed his/her own consent forms (Exceptions: IRB-approved surrogate) *(N/A if the IRB granted a waiver of consent or documentation of consent)* | | | | | |
| Yes  No  N/A | An IRB-approved study representative signed/dated the consent *(N/A if the IRB granted a waiver of consent or documentation of consent)* | | | | | |
| Yes  No  N/A | An IRB-approved study representative entered the same date as the participant/participant representative on the consent form *(N/A if the IRB granted a waiver of consent or documentation of consent)* | | | | | |
| Yes  No  N/A | If Short Form Consent is implemented, a witness signed and dated the consent form *(N/A if the IRB granted a waiver of consent or documentation of consent)* | | | | | |
| Yes  No  N/A | There is documentation of the participant's/participant representative’s receipt of a copy of the consent form (e.g., Enrollment Log or progress notes) *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | For protocols that include minors: Parental/guardian permission for the participation for minors was obtained using the IRB approved parent/guardian permission/consent form *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | Parental/guardian permission for the participation for minors was obtained from the IRB approved number of parents/guardians *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | Minors were assented using the IRB approved assent form *(N/A if the IRB granted a waiver of consent)* | | | | | |
| Yes  No  N/A | Enrolled minors that reach local age of majority during the study are consented as adults *(N/A if the IRB granted a waiver of consent)* | | | | | |
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| 1. Data Collection | | | | | | |
| Yes  No  N/A | Data collection complete/accurate for each participant (e.g. no blank fields/missing data) | | | | | |
| Yes  No  N/A | Original data collection instruments are available to support data entry | | | | | |
| Yes  No  N/A | The original data collection instrument(s)/CRF(s) for each participant includes the dated signature/initials of the person obtaining the information for each participant | | | | | |
| Yes  No  N/A | Changes/cross-outs, additional comments (if any) in participant files routinely initialed and dated | | | | | |
| Yes  No  N/A | For any changes/cross-outs being made, the original entry is still legible (e.g. use of white-out or pencil erased entries is not acceptable) | | | | | |
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| 1. Prompt Reporting Requirements | | | | | | |
| Yes  No  N/A | All prompt reporting requirements have been fulfilled (*Reportable events include adverse events, unanticipated problems involving risk to participants or others and deviations from the IRB approved protocol. These must be reported to the IRB within 5 business days of the time the study team became aware of the information.)* | | | | | |
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