**INSTRUCTIONS:**

***If you do not have direct access to participant files, (e.g., they are not stored locally and/or easily accessible virtually), you may skip completing the Participant File Self-Assessment. Alternatively, you may choose to have a member of a remote study team complete this section of the Self-Assessment for the participant files available at their site.***

***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 at qip@hsph.harvard.edu.*

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| 1. Participant Files
 |
| Protocol # |  |
| Total Number Enrolled to Date |  |
| **Number Reviewed for Self-Assessment** |  |
| Person(s) Completing Checklist |  |
| Date Completed |  |
|  |
| 1. Participant Selection
 |
| [ ]  Yes [ ]  No [ ]  N/A | Eligibility is assessed and documented for each participant (e.g., eligibility checklist) |
| [ ]  Yes [ ]  No [ ]  N/A | The eligibility 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/data included is no greater than the IRB-approved enrollment/sample size  |
| Comments (optional) | Additional information on any No or N/A response above:  |
|  |
| 1. Consent, Assent, and Parental Permission (For information on requirements of Informed Consent please reference the HLC IRB Review Worksheet [HRP-314 - Worksheet - Criteria for Approval and Additional Considerations](https://irb.harvard.edu/IRB/sd/Doc/0/VO40PA5EJ88UOJK4DPNAULIG00/HRP-314-WORKSHEET-Criteria%20for%20Approval.docx).)
 |
| [ ]  Yes [ ]  No | This protocol requires informed consent, assent, and/or parental permission *(If no, skip to section 3)* |
| [ ]  Yes [ ]  No [ ]  N/A | An IRB-approved study representative obtained consent/assent/parental permission for all participants according to the approved protocol |
| [ ]  Yes [ ]  No [ ]  N/A | The correct version of the form was used for each participant (i.e., the most recently approved version prior to the participant’s enrollment) |
| [ ]  Yes [ ]  No [ ]  N/A | Stamped/watermarked IRB-approved forms were used |
| [ ]  Yes [ ]  No [ ]  N/A | Forms are free of any handwritten changes or corrections  |
| [ ]  Yes [ ]  No [ ]  N/A | There is documentation of the participant's/participant representative’s receipt of a copy of the form (e.g., via Enrollment Log or study visit progress notes)  |
| [ ]  Yes [ ]  No | This protocol requires signed consent, assent, and/or parental permission forms *(If no, skip to section 3)* |
| [ ]  Yes [ ]  No [ ]  N/A | Original copies of all signed consent, assent, and/or parental permission formsare on file |
| [ ]  Yes [ ]  No [ ]  N/A | All pages of the forms are on file for each participant  |
| [ ]  Yes [ ]  No [ ]  N/A | All yes/no checkboxes or similar options on the forms are completed and/or initialed |
| [ ]  Yes [ ]  No [ ]  N/A | The participant/participant representative printed his/her own name on the consent form(s) |
| [ ]  Yes [ ]  No [ ]  N/A | The participant/participant representative or parent signed his/her own form(s) (i.e., signature, thumbprint or other IRB approved mark)  |
| [ ]  Yes [ ]  No [ ]  N/A | The participant/participant representative or parent dated his/her own form(s) |
| [ ]  Yes [ ]  No [ ]  N/A | The IRB-approved study representative who conducted the consent/assent process signed the form(s) |
| [ ]  Yes [ ]  No [ ]  N/A | The IRB-approved study representative who conducted the consent/assent process dated the form(s) |
| [ ]  Yes [ ]  No [ ]  N/A | The IRB-approved study representative entered the same date as the participant/participant representative or parent on the form(s) |
| [ ]  Yes [ ]  No [ ]  N/A | Forms are dated on or prior to the date study procedures were initiated for each participant |
| [ ]  Yes [ ]  No [ ]  N/A | If parental/guardian permission for the participation of minors is required for two parents/guardians, the consent form contains both signatures |
| [ ]  Yes [ ]  No [ ]  N/A | Enrolled minors that reach local age of majority during the study are consented as adults, if specified in the approved protocol  |
| [ ]  Yes [ ]  No [ ]  N/A | If Short Form Consent is implemented with participants, a witness signed and dated the full consent form  |
| Comments (optional) | Additional information on any No or N/A response above:  |
|  |
| 1. Data Collection
 |
| [ ]  Yes [ ]  No [ ]  N/A | Data collection is complete and appropriate for each participant (e.g. no blank fields/missing data or out of range responses) |
| [ ]  Yes [ ]  No [ ]  N/A | Original data collection instruments are available to support data entry (i.e., source documentation)  |
| [ ]  Yes [ ]  No [ ]  N/A | The original data collection instrument(s)/CRF(s) for each participant include the dated signature/initials of the person obtaining the information for each participant *(N/A if* *electronic data capture is used)* |
| [ ]  Yes [ ]  No [ ]  N/A | Changes/cross-outs, additional comments (if any) in participant files are 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) |
| Comments (optional) | Additional information on any No or N/A response above:  |
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| 1. General Study Conduct *(responses for the items below should reflect what is happening in the field)*
 |
| [ ]  Yes [ ]  No [ ]  N/A | A consent process is conducted with participants  |
| [ ]  Yes [ ]  No [ ]  N/A | Participants are asked to sign a consent form  |
| [ ]  Yes [ ]  No [ ]  N/A | Investigators seek consent only under circumstances that provide the prospective subject or their Legally Authorized Representative (LAR) sufficient opportunity to consider whether or not to participate, and under circumstances that minimize the possibility of coercion or undue influence |
| [ ]  Yes [ ]  No [ ]  N/A | The IRB approved information communicated to the subject or the LAR is in language understandable to the subject or the LAR (e.g., participant’s preferred language, appropriate reading level for the population). |
| [ ]  Yes [ ]  No [ ]  N/A | Investigators do not use any language through which the subject or the LAR is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. |
| [ ]  Yes [ ]  No [ ]  N/A | Participants or LAR have the opportunity to read the consent form and ask questions and have all of their questions answered prior to signing the consent form |
| [ ]  Yes [ ]  No [ ]  N/A | Investigators conduct a consent conversation/discussion during which they disclose to the participant/ LAR the information in the IRB approved consent document so they may make an informed decision about whether to participate and have an opportunity to discuss that information. |
| [ ]  Yes [ ]  No [ ]  N/A | A copy of the consent or study information document is given to the participant or the LAR (e.g., electronic or hard copy) |
| [ ]  Yes [ ]  No [ ]  N/A | All study procedures are being completed in accordance with IRB approved protocol (recruitment consent data collection) |
| [ ]  Yes [ ]  No [ ]  N/A | All study documents being used with participants have been approved by the IRB (recruitment consent data collection) |
| Comments (optional) | Additional information on any No or N/A response above:  |
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