**Instructions**

* Decide how many participant records and associated consent forms you will review. We recommend assessing ALL consent forms, even if you are choosing to review only a certain percentage of participant records to evaluate inclusion/exclusion criteria and protocol adherence. If you are doing these self-assessments on an on-going basis, it is a good idea to define a process where you decide how frequently you will perform your assessments. Assess consents from all participants enrolled since the last assessment. Any deviation from the protocol should be reported to the IRB as appropriate.
* Complete the heading information on the form.
* List all versions of the consent forms (by approval date) in the space provided. This will help you know whether a certain consent signed on a certain date was the valid consent to use at the time.
* For each participant file reviewed, note the participant ID # at the left of the appropriate row. Assess for the criteria in the columns moving right.
* Each participant should sign AND date his/her own consent form in his/her own handwriting. If it is apparent that an investigator signed or dated for the participant, this would be a deviation.
* The investigator or designated staff member listed on the protocol who obtained consent should sign AND date the form. If the participant and investigator dates do not match, see if there is an approved protocol process, a progress note, or note-to-file that explains the discrepancy. If there is no such documentation, then this would be a deviation.
* Ensure that the appropriate version of the consent form was used by noting the approval date for the consent versions used by checking the signed version against your version list and the date the consent was signed to ensure the correct version was used. If not, this would be a deviation.
* The consent form signed by participants must be IRB-approved and include the IRB watermark in the footer. If a consent form that was not IRB-approved was used, this would be a deviation.
* If there are any handwritten modifications to the approved language in the consent form (even if they are signed and dated by the participant) these essentially invalidate the consent form and thus would be a deviation.
* It is important to keep these completed forms as documentation of on-going oversight of the study.

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| **Study Title:** |  |
| **IRB Protocol #:** |  |
| **Staff Member Completing Self-Assessment:** |  |
| **Self-Assessment Date:** |  |

**IRB Approved Consent Form Versions (applicable to the study) :**

1. *[Enter ICF version date from footer]*
2. *[Enter ICF version date from footer]*
3. *[Enter ICF version date from footer]*

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| **Participant ID** | **Date Signed** | **ICF Signed & Dated by Participant? (Y/N)** | **ICF Signed & Dated by Investigator/Designee?**  **(Y/N)** | **Signed Prior to Study Procedures**  **(Y/N)** | **Correct ICF Version Signed?** | **Handwritten Notes? (Y/N)** | **Re-consent Needed/Performed? (Y/N)** | **Comments** |
| *001* | *04/21/2018* | *Y* | *Y* | *Y* | *04/18/2018* | *N* | *N/N* | *N/A* |
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