|  |
| --- |
| **INFORMED CONSENT SELF-ASSESSMENT TOOL**  **GENERAL INSTRUCTIONS** – delete this box before using.  **NOTE: This form is designed to be a starting point on consent documentation and process self-assessment. Update it as necessary to meet the needs of your specific study.**   * Decide which participants you will review to assess consent documentation and process adherence. It is best practice to review all participant consent forms. * Each Self-Assessment tool form provides space to review five consent forms. Use additional forms if reviewing more than five consent forms at one time. * List all versions of the consent forms (by approval date) in the “IRB approved consent form versions cross-check” table below. This will help you easily determine whether a certain consent signed on a certain date was the valid consent to use at the time. * All consent forms for each selected participant should be reviewed, including when reconsenting occurs, if there are sub-study consents, or other circumstances. Study teams should be aware of all possible consenting scenarios for their study including if consenting non-English speakers, etc. See Appendix Category B for instructions. * For each participant consent reviewed, note the participant ID # in column A and note the consent form type in column B. Assess for the self-assessment criteria for each of the columns moving right. * Use the Appendix for what to assess for each row in the “Consent Self-Assessment Review” table. Any “No” response signifies a deviation and further documentation. Review HRPP Policy 6.6.3.2 and 6.6.3.4 for reporting requirements to BU Medical Campus/BMC IRB. If an external IRB approved the study, those policies should be reviewed for reporting requirements. * Depending on if this form is used by printing out on paper/hard copy or used electronically, study teams can edit as needed for spacing. * Keep these completed Self-assessment forms as documentation of on-going oversight of your monitoring of the conduct of the study. |

|  |  |
| --- | --- |
| **Date of Consent Self-Assessment Review:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Name Performing Consent Self-Assessment Review:** \_\_\_\_\_\_\_\_­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |
| --- | --- | --- |
| **IRB approved consent form versions cross-check (list IRB-approval dates of all consent form versions that have been used in the study)** | | |
| 1. | 4. | 7. |
| 2. | 5. | 8. |
| 3. | 6. | 9. |

| **Consent Self-Assessment Review** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **A** | Participant ID |  |  |  |  |  |
| **B** | Consent form type |  |  |  |  |  |
| **C** | Date signed by participant |  |  |  |  |  |
| **D** | Signed on correct, current IRB-approved version | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
| **E** | Signed and dated by participant | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
| **F** | Signed and dated by delegated and IRB-approved researcher | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
| **G** | Consented signed prior to any study procedure | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
| **H** | Signed copy given to participant with documentation | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
| **I** | No handwritten edits on consent | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
| **J** | If applicable, re-consent completed | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A |
| **K** | If applicable, documentation of limited-reader with either witness or teach-back method used | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A |
| **L** | If applicable, documentation of non-English speaker with either short form with a witness or translation used | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A |
| **M** | If applicable, LIP involvement documented | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
| **N** | If applicable, all checkboxes completed | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A | Yes  No  N/A |
| **Issues Identified** –  *All answers above should be either “Yes” or “N/A”.*  *Any “No” requires further documentation below.* | | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |

|  |  |
| --- | --- |
| **Participant ID** | **Notes on identified issues above – Any “No” requires further documentation.**  *Review HRPP Policy* [*6.6.3.2*](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.3.2) *and* [*6.6.3.4*](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.3.4) *for Reporting Requirements. Review* [*Reporting Charts and Algorithm*](https://www.bumc.bu.edu/irb/maintaining-irb-approval/monitoring-and-reporting/) *for more info. Studies approved by an external IRB should review those policies for all requirements.* |
| ***No identified issues on any participant reviewed as listed above. Below sections in this table may remain blank.*** | |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| **Appendix: Definitions and instructions** |
| 1. Record the participant/subject ID number. Be sure to repeat if table runs into second page. |
| 1. Record the consent form type, such as Main, Screening, Sub-study, Re-Consent, Short-Form with witness, translation, etc. |
| 1. Date that the participant signed the consent. |
| 1. Check to ensure that the correct version of the consent form was used. To help do this, record all IRB approved versions and dates of approval in the “IRB approved consent form versions cross-check” table. This will help you easily do a cross-check. If the consent is signed using a version other than what should have been used then this is a deviation. If there are any changes between the consent used and what should have been used that have potential to impact subject safety or data quality then it is a major deviation. The consent form signed by participants must be IRB-approved and include the IRB approval date in the footer. If the consent was approved by an external IRB that stamps consents, the approval stamp must be available on the document regardless of where it appears. If a consent form that was not IRB-approved was used, this is a deviation. |
| 1. Check whether the consent form is signed and dated by the participant/LAR. The researcher conducting the consent discussion should NOT sign or date for the participant. If it is apparent that an investigator signed or dated for the participant, this is a deviation. |
| 1. Check if the consent form is signed and dated by a member of the research team that is approved by the IRB and if one is used by the study, is listed on the Delegation of Authority/Responsibility log as performing consent. |
| 1. The documentation on the consent process should show that consent was signed prior to any research procedures (unless there is a waiver of consent). If the consent is signed on a different day prior to research procedures, then the consent form can serve as this documentation. If research procedures begin the same day as signing the consent form, then there should be some documentation such as a progress note to make it clear that consent happened prior to research procedures. |
| 1. Regulations dictate that a copy of the consent form must be given to the subject. If there is no documentation about giving a copy of the consent form to the subject (such as a progress note) this is a deviation. |
| 1. If there are any handwritten modifications to the approved language in the consent form (even if the changes are initialed/dated by the participant) these modifications invalidate the consent form and are deviations. |
| 1. Check to see if re-consent was needed. Typically, the IRB approval letter for a new consent version will specify if reconsent is needed, along with any requirements for the process (such as all subjects re-consented within a specific timeframe). If re-consent was not done, this is a major deviation. |
| 1. Check if there is documentation/evidence that the participant is considered a limited-reader and if either a witness was present during the entire consent discussion or the teach-back method was used. THIS TABLE ROW CAN BE DELETED IF NON-READERS ARE ECXLUDED ENTIRELY PER THE IRB APPLICATION OR PROTOCOL. Do not delete in Appendix. |
| 1. Check if there is documentation that either a short-form or a translated consent was used. THIS TABLE ROW CAN BE DELETED IF NON-ENGLISH SPEAKERS ARE EXCLUDED ENTIRELY PER THE IRB APPLICATION OR PROTOCOL. Do not delete in Appendix. |
| 1. Per [HRPP Policy 8.1.3.7](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.1.3.7)., a Licensed Independent Provider (LIP) is required for any biomedical clinical trial. Documentation of the consent process for these studies should include either 1. that the LIP signed and dated the consent form or 2. there is a progress note on the process that describes that the LIP was involved in discussion of purpose, risks, benefits, alternatives. THIS TABLE ROW CAN BE DELETED IF LIPs ARE NOT RELEVANT TO THE STUDY. Do not delete in Appendix. |
| 1. Check to see that checkboxes were completed, if applicable to the IRB-approved consent form and process. Checkboxes should be completed by the research participant and typically will be initialed and dated by the research participant. THIS TABLE ROW CAN BE DELETED IF THERE ARE NO CHECKBOXES IN THE CONSENT. Do not delete in Appendix. |