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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**This form is designed to be a starting point on Informed Consent Documentation. Update it as necessary for your specific study.** **This tool SHOULD NOT BE USED without reviewing and editing to align with study-specific, IRB-approved procedures.** * This templated tool contains additional tables at the end of special procedures. Study teams should carefully review and update or delete for their very specific IRB-approved procedures.
* For studies requiring a Licensed Independent Practitioner, see [HRPP Policy 8.1.3.7](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.1.3.7) for more information.
* For studies enrolling limited or non-readers, see [HRPP Policy 8.4.6](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.4.6) for more information.
* For studies enrolling those with Limited English Proficiencies, see [HRPP Policy 8.4.5](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.4.5) and [IRB Guidance](https://www.bumc.bu.edu/irb/submission-requirements/special-submission-requirements/non-english-speaking-subjects/) for more information. Information on witnesses and translators can be found in [HRPP Policy 8.4.5.3](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.4.5.3). Specific short form guidance can be found [here](https://www.bumc.bu.edu/irb/submission-requirements/special-submission-requirements/non-english-speaking-subjects/short-consent-form-process/).
* For studies using a Legally Authorized Representative (LAR), see [HRPP Policy 9.5](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#9.5) for more information.
* For studies following ICH Good Clinical Practice guidelines, see [Section 4.8](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf) for more information.
* The note section should include information about the consent process. For example, but not limited to, what questions did the participant have including answers, if family members or friends were present, and whether a teach-back process was used. Generally speaking, any *no* answer below should be followed up with an explanation in a notes section.
* Additional resources for Consent are available within the [Standard Operating Procedure guidance document](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/).
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| Informed Consent Process |
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| Informed Consent Obtained By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| IRB-Approval Stamp Date on Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Consent Discussion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| The study was explained and the consent form was reviewed with the participant. All the consent elements were reviewed. | [ ]  Yes[ ]  No *(If no, participant should not be enrolled)* |
| The participant had the opportunity to ask questions and all questions were answered to the participant's satisfaction before signing consent. | [ ]  Yes [ ]  No questions |
| The participant has voluntarily agreed to participate in the study. | [ ]  Yes[ ]  No *(If no, participant should not be enrolled)* |
| Participant signed and dated the most-recent IRB-approved and stamped informed consent form.  | [ ]  Yes[ ]  No *(If no, participant should not be enrolled)* |
| Delegated study staff has signed and dated the most-recent IRB-approved and stamped informed consent form.  | [ ]  Yes[ ]  No *(If no, participant should not be enrolled)* |
| Consent was obtained with all required signatures prior to the start of any research procedure.  | [ ]  Yes[ ]  No  |
| A copy of the signed and dated consent form was given to the participant. | [ ]  Yes[ ]  No |
| The original signed and dated consent form was placed in the study binders. | [ ]  Yes[ ]  No |

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| **Studies Approved for the Use of a Legally Authorized Representative** |
| Consent to participate was provided by and document signed by an LAR | [ ]  No, individual able to consent for themselves [ ]  Yes, LAR provided consent for individual unable to consent for themselves |

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| **Studies Required to have a Licensed Independent Practitioner. Present and Involved in Consent Discussion** |
| An LIP was present and involved in the consent discussion. | [ ]  Yes – Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No *(If no, explain why not in note section)* |

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| **Studies Approved to Enroll Limited or Non Readers AND is Greater Than Minimal Risk** |
| Individual is considered a limited or non-reader | [ ]  No, individual did not request to have the consent read to them nor was there any indicated that there may be difficulty with reading[ ]  Yes – Impartial Witness present for discussion and signed consent as Witness[ ]  Yes – Teach-Back Method used for discussion |

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| **Studies Approved to Enroll Individuals with Limited English Proficiencies** |
| What version of the consent was used?  | [ ]  English Version[ ]  Non-English, Fully-Translated Version (Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)[ ]  Short-Form Version (Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |

| **Short Form Consent Process** |
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| The English narrative has been verbally translated to the participant. *The English consent form can serve as the English narrative, this process must be IRB-approved.* | [ ]  Yes[ ]  No *(If no, explain why not in note section)* |
| An impartial witness was present for the entire consent discussion.  | ☐ Yes☐ No (If no, explain why not in note section) |
| The short form was signed and dated by the study staff conducting the consent discussion.  | [ ]  Yes[ ]  No *(If no, explain why not in note section)* |
| The short form was signed and dated by the participant.  | [ ]  Yes[ ]  No *(If no, explain why not in note section)* |
| The short form was signed and dated by the witness. *Interpreter ID# only allowed if remote process being used for interpretation and when interpreter is acting as witness.*  | [ ]  Yes[ ]  No *(If no, explain why not in note section)*[ ]  Interpreter Identification Number recorded by study team on short form as witness signature |
| The Signature Page for Short Form Use contains all of the following: * Printed name of the subject
* Language of consent
* Printed name of the witness
* Witness signature and date OR Interpreter ID#
* Signature and date of the person conducting the consent discussion
 | [ ]  Yes[ ]  No *(If no, explain what is missing in notes section)* |
| The Signature Page for Short Form Use contains the following statement on the participant signature line: *“See attached signature page”* | [ ]  Yes[ ]  No *(If no, explain why not in note section)* |
| A copy of the signed and dated short form and English narrative was provided to the participant. | [ ]  Yes[ ]  No *(If no, explain why not in note section)* |
| The original signed and dated Short Form, Signature Page for Short Form Use and English narrative were stapled together or otherwise permanently attached to each other and placed in the study binders. | [ ]  Yes[ ]  No *(If no, explain why not in note section)* |

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| **Notes** |
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| **STAFF COMPLETING FORM** |
| Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_ |
| *Individuals signing consent are per HRPP policy. The person signing this form is confirming the consent procedures documented above were completed.*  |