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|  | |  |  |  |  | | --- | --- | --- | --- | | **Worksheet: Consenting Non-English Persons** | |  |  | | POLICY | DATE | VERSION | PAGE | | 1200.04 | 2/10/2019 | 3 | 1 of 2 | |

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| The purpose of this worksheet is to support performing and documenting the informed consent process when consenting persons with limited English proficiency. | | | |
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| **Yes** | **N/A** | **Consent Prerequisites** (Check if **“Yes”** or **“N/A”**. All must be checked) | |
| ☐ | ☐ | All prerequisites are met for the written informed consent process in general. | |
| ☐ | ☐ | Are you approved by the IRB to enroll Non-English-speaking persons? If no, then you cannot enroll the subject and must submit an amendment to the IRB. | |
| **Yes** | **N/A** | **Secure an Interpreter and witness** (Check if **“Yes”** or **“N/A”**. All must be checked) | |
| ☐ | ☐ | An Interpreter will provide interpretation. | |
| ☐ | ☐ | A witness is required for the short form method only. The witness is fluent in both English and the language of the subject/LAR. Family members of subjects cannot be a witness. | |
| **Elements of Consent Disclosure** (The following issues will be discussed with the subject) | | | |
| **Required:** *(\*Starred elements can be omitted if there are none*.). Explain the following:  ☐ Who is sponsoring the study.  ☐ Any conflicts of interest, if any.*\**  ☐ Purpose of the study and that this is research.  ☐ Procedures to be followed in simple language.  ☐ Probability for random assignment to each treatment. ☐ Any procedures, which are experimental*\**  ☐ Expected duration of the subject’s participation.  ☐ Any reasonably foreseeable risks or discomforts to the subject  ☐ Potential benefits, making it clear if there is no intended benefit. | | | ☐ Any appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*\**  ☐ Participation is voluntary and he/she may withdraw at any time.  ☐ Methods to ensure confidentiality of information are maintained.  ☐ The subject's responsibilities.  ☐ Any additional costs to the subject that may result from participation in the research.  ☐ Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.  ☐ How to contact the research team for questions, concerns, or complaints about the research. |
| **Yes** | **N/A** | **Consent Process** (Check if “Yes” or “N/A”. All must be checked). See also Worksheet Written Informed Consent Process. | |
| ☐ | ☐ | Copy of ICF (and short form if used) is provided to subject and/or LAR before beginning discussion. | |
| ☐ | ☐ | All questions by participant and/or LAR were answered to their satisfaction. It is the investigator’s responsibility to judge comprehension of consent information. A subject’s autonomy should not be jeopardized due to a language barrier. | |
| ☐ | ☐ | Provide sufficient time for subject to review and consider whether to participate. | |
| ☐ | ☐ | To the degree possible, ensure the potential participate and/or LAR comprehends the information provided about the research. | |
| **Yes** | **N/A** | **Short Form of Consent Documentation (Check if “Yes”. All must be checked)** | |
| ☐ | ☐ | Elements of consent have been presented orally to the subject or the subject’s legally authorized representative. | |
| ☐ | ☐ | A bilingual witness will be present during the consent discussion. Witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that consent was freely given. | |
| ☐ | ☐ | The following signs the short form:   * Subject, if applicable • Witness * Subject’s LAR • Interpreter | |
| ☐ | ☐ | The following will sign the English consent form.  • Witness • Study staff obtaining consent | |
| ☐ | ☐ | A copy of the signed and dated English consent form and short form will be given to the person signing the document. | |

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| **Yes** | **N/A** | **Consent Documentation with fully translated consent document (Check if “Yes”. All must be checked)** |
| ☐ | ☐ | The translated consent form is provided to participant/LAR. Elements of consent have been presented orally to the participant and/or LAR. |
| ☐ | ☐ | The participant and/or LAR will sign and date the translated consent form. |
| ☐ | ☐ | The interpreter will sign and date the translated consent form. |
| ☐ | ☐ | The person obtaining consent does not speak the subject’s language, the person obtaining consent will sign the English version of the consent form. The English and translated forms for the subject will be stabled together. |
| **Yes** | **N/A** | **Verification of proper documentation.** |
| ☐ | ☐ | Review form for completion prior to ending visit with family. |
| * All blanks completed; check for all • Dates are entered correctly signatures • Participant’s name recorded on at least first page and each signature page * Future use options are answered |
| ☐ | ☐ | Corrections/notations are to be initialed and dated. Entries made by participant or parent are corrected only by participant or parent. Staff may add notes of clarification to the side if family is no longer present. Entries by staff should be clarified by staff who obtained consent. |
| **Yes** | **N/A** | **Document Consent Process** (Check if “Yes” or “N/A”. All must be checked) |
| ☐ | ☐ | Required elements to document in medical/research record   * Date and time of discussion • Notation of name of interpreter * Study identification (protocol # or abbreviated title) • Notation of name of witness, if different * Individuals involved in discussion • Notations of special circumstances * Individuals to whom study was explained o Notation if subject or subject LAR declined interpretation services * Notation that concerns and/or questions were addressed o Explanation of any corrections * Notation of who copies were given to o Notation if phone consent was used (can only be used if IRB approved) * Notation that consent obtained prior to performing study related procedures |

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