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| **Worksheet: Informed Consent Process**  |  |  |
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| The purpose of this worksheet is to provide support for study team members performing and documenting the informed consent process. ICF = Informed consent forms is used general abbreviation for permission/assent and consent forms. LAR = Legally authorized representative   |
| **Yes**  | **N/A**  | **Consent Prerequisites** (Check if **“Yes”** or **“N/A”**. All must be checked) |
| ☐ | ☐ | The study has been approved by IRB and all other requirements of sponsor or other entity have been fulfilled  |
| ☐ | ☐ | If recording identifiable information about subject prior to signing the ICF, a partial waiver of informed consent/HIPAA has been approved by the IRB.  |
| ☐ | ☐ | ICF is approved by the IRB as demonstrated by stamp (with IRB #, approved and expiration dates). Unstamped ICFs SHALL NOT be used to consent subjects.  |
| ☐ | ☐ | The ICF is not expired and is the most recent IRB-approved version. 1. Check the IRB stamp dates. Expired consents should NEVER be used.
2. Check that the ICF is the most recently approved version (even though it may not be expired).
	* One central supply of current forms is printed and available for study team members to access. When a new form is approved, all outdated copies are removed from this central location.
	* Study team members are not allowed to stockpile forms as these often do not get replaced when the form changes.
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| ☐ | ☐ | The correct ICF is used when multiple types are approved. 1. If enrolling a child, use the permission/assent.
2. If enrolling an adult, use adult consent.
3. If the study has multiple arms, use the document specific to the arm in which the subject is being enrolled
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| ☐ | ☐ | No procedures have been performed prior to signing the consent form (including asking a subject to fast, withdrawal from current medication (washout), obtaining clinical specimens for the study, conducting diagnostic exams for research purposes when not routinely required, collecting data.).  |
| ☐ | ☐ | Staff conducting consenting process are listed on the IRB-approved protocol  |
| ☐ | ☐ | Study team member understands the requirements for the consent process for this particular study: 1. Is assent of minors required by the IRB?
2. Are signatures of both parents required? (All risk category 3 studies require the signatures of both parents, or as otherwise deemed necessary by IRB).
3. Is a witness required? If utilizing phone consent, a fully translated consent, using Short Form consent, a witness is required. In all other circumstances, unless specifically required by the IRB, witnessing of consent is optional.
4. Is the patient or parent non-English speaking? If yes, confirm you have IRB approval for enrolling non-English speaking persons and secure an interpreter.
5. Is the study team member knowledgeable about study procedures to answer potential subject’s questions?
 |
| **Yes**  | **N/A**  | **Appropriate individual approached**  |
| ☐ | ☐ | Confirm the IRB has approved the inclusion of the subject you wish to enroll.  |
| ☐ | ☐ | If enrolling children, confirm you are speaking with the parent or legal guardian. For legal guardian, verify court issued guardianship documents are in medical record. The following cannot grant permission for research unless they are also legal guardians: * Stepparents • Individuals with Power of Attorney
* Grandparents, aunts, uncles, etc. • Foster parents for Wards

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| **Elements of Consent Disclosure** (The following issues will be discussed with the subject)  |
| **Required Disclosures:** *(\*Starred elements can be omitted if there are none*.) ☐ Who is sponsoring the study.\* ☐ Conflicts of interest, if any.*\** ☐ Purpose of the study and make sure the subject understands this is research. ☐ Procedures to be followed in simple language. ☐ Probability for random assignment to each treatment.\* ☐ Procedures, which are experimental.*\** ☐ Expected duration of the subject’s participation. ☐ Any reasonably foreseeable risks or discomforts to the subject ☐ Any potential benefits, making it clear if there is no direct benefit to the subject.  | ☐ 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)  |
| ☐ | ☐ | Copy of ICF provided to subject and/or LAR before beginning discussion.  |
| ☐ | ☐ | All questions by subject and/or LAR were answered to their satisfaction.  |
| ☐ | ☐ | Provide sufficient time for subject to review and consider whether to participate.  |
| ☐ | ☐ | To the degree possible, ensure the potential subject and/or LAR comprehend the information provided about the research.  |
| ☐ | ☐ | Capacity of minor to assent has been determined. If capable, assent is obtained (unless requirement waived by IRB).  |
| **Yes**  | **N/A**  | **Signing Consent Form** (Check if “Yes” or “N/A”. All must be checked)  |
| ☐ | ☐ | The subject or LAR will sign and date the consent document.  |
| ☐ | ☐ | Minor will sign and date the assent portion, if applicable.  |
| ☐ | ☐ | The person obtaining consent will sign and date the consent document.  |
| ☐ | ☐ | The witness will sign the consent document, when required.  |
| ☐ | ☐ | Review form for completion prior to ending visit with family. * All blanks completed • Dates are entered correctly.
* Check for all signatures. • Future use options are answered.
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| ☐ | ☐ | Corrections/notations are to be initialed and dated. Entries made by subject are corrected only by subject or LAR. 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.  |
| ☐ | ☐ | Distribute a copy of the signed and dated consent form to: Subject, LAR and original to research record  |
| **Yes**  | **N/A**  | **Document Consent Process in Research Record** (Check if “Yes” or “N/A”. All must be checked)  |
| ☐ | ☐ | Required elements to document in research record: * Date and time of discussion • Notations of special circumstances (examples)
* Study identification (protocol # or abbreviated title) o Why child is not capable of assent if assent not obtained.
* Individuals involved in discussion o Explanation of any corrections
* Individuals to whom study was explained o Notation if phone consent was used and description of process (can only
* Notation that concerns and/or questions were addressed be used if IRB approved)
* Notation of who copies were given to o Notation of use of interpreter
* Notation that consent obtained prior to performing procedures
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