# Tool Summary Sheet

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| **Tool:** | Suggestions for Consenting/Assenting Research Subjects/Participants |
| **Purpose:** | This tool serves to provide guidance on practices to consider when conducting and documenting the informed consent process with study participants. |
| **Audience/User:** | Principal Investigators, Research Nurses and Coordinators, other site staff, clinical monitors |
| **Details:** | This document can be used as a training tool for new site staff members who participate in the consent process. Additionally, it can serve as a reminder for existing staff of the tasks associated with adequate consent practices and documentation. |
| **Best Practice Recommendations:** | The tool can be customized to reflect additional institutional best practices and details. |
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Tool Revision History:

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| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| **1.0** | **22Mar2012** | **First approved version** |
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BEFORE CONSENT/ASSENT

* Ensure the subject/participant is signing the most recently IRB-approved consent/assent document version and that the consent document is complete.
* If multiple copies or screening packets are prepared in advance of screening visits, it is recommended that they are checked periodically to be sure that the current consent/assent is being used.

THE INFORMED CONSENT/ASSENT PROCESS

* Regulations require a subject to sign and date a consent document unless otherwise approved by the IRB.
* The informed consent process begins with the initial study discussion with the subject/participant and continues throughout his/her participation in the study.
* Check with the institution’s IRB for policies on who is authorized to consent a subject.
* Once the subject/participant is ready to sign the consent/assent form, follow institutional and IRB recommendations regarding the requirement for a witness to the consent discussion and signatures. Follow institutional guidelines to determine if the witness can be a member of the research team.
* In some limited cases and as approved by the IRB in advance, alternative methods of consent/assent (e.g., fax, mailed, or via telephone) may be available based on IRB consenting requirements. The possibility of using alternative methods is likely noted within the protocol and, if approved, most IRBs require written documentation that the investigator spoke with the subject about the study. The witness signature is usually waived; once the consent/assent is returned to the investigator. Follow IRB requirements to determine if the investigator signature is required on the form.
* Follow institution and IRB policies regarding any labeling of the consent document and requesting subject/participant initials and/or date on each page of the document.

AFTER ALL SIGNATURES ARE OBTAINED ON THE CONSENT/ASSENT DOCUMENT

* Once all parties have signed the consent document, the designated research team member should review the form to ensure that all sections of the document, check boxes (if appropriate), signatures, initials (if required), and dates have been completed appropriately. Recommendations include:
  + Confirm that all parties have signed their name in the correct area(s) on the form.
  + Confirm that the correct date, time (if collected), and date/time format have been recorded, if a specific date format is required by the form.
  + Confirm that all areas for subject/participant initials or check box options within the body of the document have been completed as needed. Note that subject/participant initials are preferable over check boxes to confirm the subject’s/participant’s responses.
  + Confirm that any errors are corrected by the party who made the error. Errors are corrected with a single line through the incorrect entry (do not obliterate), the initials of the person correcting the entry, and the date next to the correction.

AFTER CONSENTING/ASSENTING

* Give a copy of the signed consent/assent document to the subject and/or parent/legal guardian.
* Retain the original as determined by institutional and/or departmental requirements (e.g., in the Medical Records Department, subject/participant research chart, or consent document binder).
* Update the study enrollment or screening log.

DOCUMENTING THE CONSENT/ASSENT PROCESS

* The informed consent/assent process should be documented, to include key details of the process. The “Documenting the Consent Process” tool, available on the NIDCR-CROMS website, can be utilized for this purpose.
* The following should be included in documentation of the consent process:

| Essential | Date and time the consent/assent was obtained. |
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| Essential | The subject/participant read/understands the consent document. |
| Essential | All questions were answered and risks were reviewed. |
| Essential | The subject, or his/her legally authorized representative, personally signed and dated the document and received a copy. |
| Essential | No study-related procedures were initiated prior to obtaining a signed consent document. |
| Additional | Ample time was allowed for review and discussion. |
| Additional | The version of the consent/assent document that was signed. |
| Additional | The witness, if used, and person obtaining consent have signed and dated the document, if applicable. |
| As applicable | Special issues, such as non-English speaking subjects, were appropriately addressed. |

RE-CONSENTING

* Follow IRB guidelines regarding the need to re-consent subjects/participants in the event of an updated and IRB-approved consent/assent document, if no significant changes are made to the risk profile or procedures associated with the study.
* If changes are made to the protocol that may affect the subject’s willingness to continue participating in the study, subjects/participants must be re-consented.
* Minor subjects/participants who signed an assent document and subsequently reach 18 years of age during study participation must then sign a consent document.