

# Tool Summary Sheet

|  |  |
| --- | --- |
| Tool: | Documenting the Consent Process |
| Purpose: | To assist the user in documenting the consent process |
| Audience/User: | Principal Investigators (PIs), Sub/Associate Investigators, Site Study Coordinators |
| Details: | This template provides an initial framework for documenting the consent discussion and process with the potential study subject. Please feel free to customize this tool to meet your study-specific needs/requirements. |
| Best Practice Recommendations: | * If used, this sheet should be printed and available for completion as a source document at the time of consent.
* This tool can be used at the beginning of the study and throughout the clinical research study when updates and revisions to the consent form(s) are required.
* Suggestions for inclusion in the section entitled “Additional Notes” include the following: a statement that the risks associated with the study, if any, are known and were reviewed with the participant; if a witness was required and present for the consent discussion; and if any special circumstances were addressed (e.g., literacy of the participant or if translation of the discussion was required).
* Remove the Tool Summary Sheet prior to use.
 |

## **Tool Revision History:**

|  |  |
| --- | --- |
| ****Version**** |   |
| Number | Date | Summary of Revisions Made: |
| 1.0 | 24Apr2013 | Approved version |
| 2.0 | 30Apr2020 | Verbiage added regarding subjects’ primary language, availability of an interpreter, and training and/or delegation of staff conducting consent process. |

Protocol Number and Title:

PI/Site Name:

Participant/Subject Name:

# Documenting the Consent Process

Date:

Consent Forms (CFs) reviewed:

 Main Study CF, Version/Date:

 Other CF, Specify: Version/Date:

 Other CF, Specify: Version/Date:

What is the subject’s primary language? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Language of CF(s) reviewed:

 English  Spanish  Other, specify:

If a consent form written in a language other than English is used, was an interpreter
available?  Yes  No

Study staff member(s) conducting CF discussion:

Is the staff conducting the CF discussion qualified and/or trained to do so?  Yes  No

If a delegation log is used for this study, is the person conducting the CF discussion delegated to this task?  Yes  No

Was time allowed to ask/answer questions?   Yes  No

If not, please explain:

Was/were a copy of the signed CF(s) provided to the study subject?  Yes  No

If not, please explain:

Was/were the CF(s) signed prior to initiation of study procedures?  Yes  No

If not, please explain:

Additional Notes:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent Date