National Center for Complementary and Integrative Health

Tool Summary Sheet

Tool: Documenting the Consent Process

Purpose: To assist the user in documenting the consent process

Audience/User: Principal Investigators, 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 utilized, this sheet should be printed and available for completion as a source document at the time of consent.
- This tool can be utilized 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

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:_____

Language of CF(s) reviewed:

☐ English ☐ Spanish ☐ Other, Specify:_____

Study Staff Member(s) Conducting CF discussion:_____

Was time allowed to ask/answer questions? ☐ Yes ☐ No

If not, please explain:_____

Was 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:_____

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

If not, please explain:_____

Additional Notes:

_____ _____

Signature of person obtaining consent Date