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:

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Summary of Revisions Made:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.0</td>
<td>24Apr2013</td>
<td>Approved version</td>
</tr>
</tbody>
</table>
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