CLINICAL TRIALS TRANSFORMATION INITIATIVE

Appendix I
Informed Consent Discussion Tool

This tool is not intended to serve as a required regulatory compliance document, but may be useful for documenting the informed consent process. The tool can be modified to include checkboxes or room for notes if the user chooses to use it as a documentation tool.

I have considered:
A private, nonthreatening place to hold the informed consent discussion
Inclusion of family/friends in the informed consent discussion, as desired by the research participant
The research participant's individual needs and geared my discussion to match his/her • Learning style • Language facility • Education level • Health literacy • Interest in learning as much as possible • Comfort with numbers/probabilities • Disabilities that may hinder the ICP
Providing the research participant with ample time to review the informed consent document and ask questions as needed
I have described, when appropriate, the following items to the research participant using plain language:
• Purpose of the research • Research procedures, including those that are experimental, relative to visits required for standard care • Duration of participation, compared to standard of care • Reasonably foreseeable risks/discomforts, compared to standard of care • Benefits to participants and others

- Compensation for research-related injury
- Additional costs to the research participant for participation, compared to standard of care
- Voluntary nature of participation
- Confidentiality of records
- Available alternative treatments
- Whom to contact with questions/concerns
- Whom to contact in the event of a research-related injury
- Availability of trial information on clinicaltrials.gov
- Number of trial participants (if required)
- Reasons for terminating participation by research team
- Options for and consequences of research participant withdrawal
- Statement that participants will be updated throughout the process and informed of significant new findings

I have:
Answered all of the research participant's questions before the document was signed, and proactively asked participants about their questions.
Evaluated the research participant's understanding of the information discussed
Provided the research participant with a signed copy of the current version of informed consent document, and a copy of the detailed reference section