Sample Informed Consent Document (ICD) Format
5/15/07

Formatting Recommendations:

Margins	At least 3/4 inch on all sides.
Font Styles & Point Size	Use a font and point size that is easy to read, will not distract from the information being provided, and appropriate for the study participants (i.e., elderly or visually impaired subjects should be in a larger than normal font). Times New Roman – 12 point or Arial – 11 point are recommended.
ICD Version Date	Please include a version date on every ICD. This date should be changed each time the Consent Document is modified.
Title/PI/Sponsor	At the top of the front page of the document, include the full study title (and number if appropriate); the name of the PI; and, for studies that are funded, the sponsor's name.
Section Headings	Section headings improve the readability of the ICD. When used these should be in bold type and underlined.
	Adjust the formatting so that headers remain with the first paragraph of the related text rather than falling at the bottom of a page with the related text starting at the top of the next page.
Page Footer	Beginning on page 2 of the ICD, include the study identifier (i.e., study number, study acronym, or abbreviated title).
	Include the ICD version date and page numbers.
Page Numbers	These should be included on every ICD and paginated separately from the protocol.

Notes:

- Section headers are underlined;
- *Instructions are italicized in black*;
- Suggested language is in red,

Consent to be a Research Subject
modify appropriately

Title: *Title of Protocol*

Principal Investigator: *Include name of PI and other investigators as appropriate*

Sponsor's Name: *(if study is funded, include the sponsor's name)*

Introduction/Purpose: *(Required in all consent forms) May be one or more sections; modify headings as appropriate.*

Required Elements ***(The following elements of informed consent must be provided to each subject)***

Requirement 1a - A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, … [Federal Regulation 45 CFR 46.116(a)(1)]

This part must include:

- *A statement that potential subjects are being asked to volunteer for a research study*
- *An explanation of why the subject is being ask to volunteer*
- *A clear explanation of the purpose of the research*
- *The expected duration of the subject's participation*
- *The approximate number of subjects to be enrolled at study site and overall*

Procedures:*(Required in all consent forms)*

Requirement 1b - A statement that …identifies any procedures that are experimental. [Federal Regulation 45 CFR 46.116(a)(1)]

This section must include:

- *Detailed description of the procedures to be performed on the subject, in chronological order.*
- *Experimental procedures must be stressed, and clearly distinguished from the non-experimental procedures (routine care).*
- *A full explanation of all responsibilities and expectations of the subjects.*
  If blood is drawn, please indicate the amount in lay terms (e.g., teaspoons, tablespoon, ounces or pints).
- *If the study involves random assignment, the process must be specified*
  (e.g., "Like flipping a coin" or " you will have 1 in____ chances…).

Be sure to communicate the following to the subject:

- *All the people with whom the subject will interact*
- *Where and when the research will be done*
- *How much of the subject's time will be involved*

Risks*:* *(Required in all consents)*

Requirement 2 – A description of any reasonably foreseeable risks or discomforts to the subject [Federal Regulation 45 CFR 46.116(a)(2)]

Inform the subject of all foreseeable risks or discomforts associated with the research.
Include common risks such as venipuncture, skin tape reactions, radiation exposure, special tests and emotional stress.

The following is acceptable wording for the statement regarding unforeseeable risks:

This study is designed to test a new [treatment/procedure]*. There may be risks, discomforts or side effects that are not yet known.
**State as appropriate*

Benefits: *(required in all consent forms)*

Requirement 3 - A description of any benefits to the subject or to others, which may reasonably be expected from the research [Federal Regulation 45 CFR 46.116(a)(3)]

This section should include the following:

Any benefits to the subject or others should be presented in a way that is not coercive, enticing or self-serving. This section should include a statement that there may be no benefit to the subject.

The following is acceptable wording for this statement: (This can be modified to suit the needs of the particular study consent form)

Taking part in this research study may not benefit you personally, but we [doctors, researchers and scientists] may learn new things that will help others.

DO NOT REFER TO ANY COMPENSATION (e.g. free drugs, money, etc.) IN THIS SECTION.

Alternatives: *(Required only if the study involves treatment)*

Requirement 4 - A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject [Federal Regulation 45 CFR 46.116(a)(4)]

The following is acceptable wording for this section if there are no other alternative treatments or procedures:

There are no alternative treatments [and/or procedures] to those offered in this research study.

Confidentiality:*(Required in all consent forms)*

Requirement 5 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained [Federal Regulation 45 CFR 46.116(a)(5)]

This section should include the following:

- *How the study records will be protected while the research is active,*
- *How and when the records will be destroyed when the research ends*
- *Who will be allowed to view the records and why*

Compensation:*(required when research involves more than minimal risk)*

Requirement 6 - For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained [Federal Regulation 45 CFR 46.116(a)(6)]

This section should include the following:

- *If subjects are to be paid, the anticipated (prorated) amount of payment should be stated in the consent.*
- *For study-related injuries a statement should be include that immediate medical care will be provided.*
- *Make clear whether the sponsor/investigator will pay for the care.*
- *Name and phone number of someone to contact if injury occurs.*

Contact Persons:*(Required in all consent forms)*

Requirement 7 - An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject [45 CFR 46.116(a)(7)]

(If the study is to be performed at more than one site, please provide contact information for all sites.)

The following wording is acceptable for this section (modify as appropriate):

If you have any questions about this study call [name of contact, can be the PI or study coordinator]. Call [name of contact] if you have been harmed from being in this study. If you have any questions about your rights as a participant in this research study, you may call the following:
[Name of contact]: [phone number], or
DSHS IRB #1 Office at 1-888-777-5037 *(the DSHS IRB contact number is required)*

Voluntary Participation and Withdrawal: *(Required in all consent forms)*

Requirement 8 - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled [Federal Regulation 45 CFR 46.116(a)(8)]

This section should include:

- *That the subject's participation is voluntary*
- *That refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled*
- *That the subject may withdraw from the research at any time without penalty or loss of benefits to which the subject is otherwise entitled*

The following is acceptable wording for this statement:

Your participation is completely voluntary and you have the right to refuse to be in this study. You can stop at anytime after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled.

The study doctor/investigator and/or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest, or if you do not follow study instructions.

Additional statements - When appropriate, one or more of the following elements of information must also be provided to each subject

Unforeseeable Risks

Additional Statement 1 - A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable [Federal Regulation 45 CFR 46.116(b)(1)]

Ending Subject Participation

Additional Statement 2 - Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent [Federal Regulation 45 CFR 46.116(b)(2)]

Such a statement is appropriate in any consent form, but is required in studies if there is a realistic possibility that subjects might raise serious objections to being terminated from participating in the study. An example of this situation would be if the research study involves treatment that subjects might consider beneficial, or if the study pays subjects for participation and payment would be lost if the subject is dropped.

The following is an example of how such a statement might be worded. It should be modified as appropriate.

The study researchers/sponsor/doctors have the right to end your participation in this study for any of the following reasons. It would be dangerous for you to continue. You do not follow study procedures as directed. The sponsor decides to end the study.

Costs

Additional Statement 3 - Any additional costs to the subject that may result from participation in the research [45 CFR 46.116(b)(3)]

Consequences of Participant Withdrawal

Additional Statement 4 - The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject [Federal Regulation 45 CFR 46.116(b)(4)]

Such a statement would be appropriate in studies where discontinuation of study treatment could have a deleterious effect, and where substitute treatment may be necessary. Examples would include treatment for hypertension; diabetes; psychosis; other chronic diseases; studies of contraception; implanted devices, etc.

New Findings: *(required when appropriate)*

Additional Statement 5 - A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject [Federal Regulation 45 CFR 46.116(b)(5)]

This section should be included whenever the possibility exists that new risks or dangers could emerge that the subject could avoid by dropping out of the study.

The following is acceptable wording for this statement:

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

Documentation of Informed Consent

Additional Statement 6 - Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form [Federal Regulation 45 CFR 46.117(a)]

The following is acceptable wording for this statement:

We will give you a copy of this consent form to keep.

If you're willing to volunteer for this research, please sign below.

_____ _____ _____
Subject's name **Date** **Time**

_____ _____ _____
Subject's legally authorized representative - Date Time
(if required)

_____ _____ _____
Person Obtaining Consent **Date** **Time**