CLINICAL TRIALS TRANSFORMATION INITIATIVE

Appendix III
Sample Tiered Informed Consent Model

The following text is intended as an example of the Tiered Informed Consent Model basic structure. It is not intended to be an informed consent document template. We encourage flexibility in individual informed consent document language, dependent upon the nature of the study. The third tier as described above is not described in this example.

[title of study]

The basics

- The consent form explains the study and what happens if you decide to join.
- Take as much time as you need to make a decision about joining the study.
- Feel free to ask any questions at any time.
- Your condition may or may not improve if you join the study. But, the information that we get from this study might help other patients with the same condition in the future.
- If you join the study, you can leave at any time. Leaving will not affect your care.
- If you choose to leave the study, please let us know as soon as possible.
- If you don't join the study, you will continue to receive care for your [condition]. [briefly describe]

Why do we want to talk to you about joining the study?

- You have [condition].
- We are doing this study to learn more about [experimental drug/device/procedure].
- Some parts of this study are experimental which means [define,"they have not been tested yet, fully tested", etc].
- The untested parts of the study are [description of which parts of research are experimental].
- About [number] [people/women/men] will take part in this study.

What will happen if you join the study?

- You will be in the study for [length of time].
- [if RCT] You will be randomly assigned a study treatment.
- "Randomly assigned" means that whatever treatment you get will be by chance, like flipping a coin or drawing names out of a hat.
- You will have to [describe number and type of procedures, such as "you will have 10 visits that will last between 1 and 3 hours"]
- To read more about this, turn to [refer to additional procedures information provided in the Detailed Reference Section]

What are the risks of joining the study?

- [Medications/procedures/other] that are part of this study may have side effects.
- The most common or serious side effects of this [treatment/medicine] are:
- It is possible that some patients could have side effects that we do not know about yet.

- If you have severe side effects from the [treatment/medicine], the study doctor may ask you not to continue in the study.
- To read more about the other risks turn to [refer to additional risk information provided in the Detailed Reference Section]
- [insert brief statement about reproductive risks, if applicable]

Could something change while you are in the study?

- Things may happen in the study that could make you change your mind about continuing to take part.
- If something changes, we will tell you as soon as possible.
- You can choose to leave the study at any time.
- The study doctor can also choose to take you out if they believe that it is best for you.

What will happen to your information if you join the study?

- We will protect your privacy and work to ensure that your information is kept confidential.
- Other people who look at study data and study quality may see your study information (like the study sponsor, US FDA or Institutional Review Board).
- We may share your study information with other researchers in the future.
- To read more about how your study information will be used turn to [refer to additional confidentiality and data sharing information in the Detailed Reference Section].

Will you get paid for joining the study?

- No/Yes, you [will/will not] be paid to be in this research study.
- [If yes, provide amount]

What do you have to pay if you join the study?

- [as applicable] Some of the tests that will be done in this study will be billed to your insurance.
    - If you have health insurance, you will be responsible for any copays or deductibles.
- Treatments/drugs you receive only as part of the study will not be billed to your insurance.

What happens if you are harmed or injured during the study?

- If it is an emergency, call 911 right away or go to the emergency room.
- Contact your study doctor as soon as you can.
- For other medical problems, contact your study doctor right away. They will treat you or contact another doctor.
- The costs for care you need because of an injury or illness during the study will be billed to you or your insurance.

Who can answer any questions you have?

Remember, there are no stupid questions! Feel free to ask at ANY TIME! It is your right to be fully informed before deciding to take part in this study.

Investigator	Study Coordinator
Address:	Address:
Phone:	Phone:
E-mail address:	E-mail address:

A description of this study will be available on *http://www.ClinicalTrials.gov,* as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time, using the following study number: [xxxx].

Detailed Reference Section

Chapter 1 Detailed Study Treatment Schedules

[INSERT TABLE(S)]

Chapter 2 Complete List of Risks and Side Effects

[INSERT TABLE(S)]

Chapter 3 HIPAA/Protected Health Information

Chapter 4 Additional Financial Information

Chapter 5 [additional information as necessary]

Chapter 6 [additional information as necessary]

[Note that the signature block may be appropriately placed prior to or following the detailed reference section, and its placement may vary based on the contents of the informed consent document (i.e., inclusion and placement of all elements required by federal regulation) and study complexity. Additional consideration of the signature block placement, and factors affecting it, should be undertaken.]