CLINICAL TRIALS TRANSFORMATION INITIATIVE

CTTI RECOMMENDATIONS: INFORMED CONSENT

Long and complex informed consent documents and ineffective informed consent processes obscure the information most relevant to the potential research participant and appear to be designed primarily to serve the role of protecting institutions and meet regulatory needs rather than to inform participants. Therefore, we recommend:

Conducting the Informed Consent Process

- The informed consent process should involve an ongoing, interactive conversation between the research participant and the research staff, beginning with initial consideration of study participation and continuing through study completion.
- The informed consent process should be customized to meet the particular needs of individual study participants.
- The person or persons obtaining consent should be skilled in communicating trial-specific information and be responsive to the needs and concerns of individual research participants.
- A discussion tool, not intended as a required regulatory compliance document (Appendix I), could be used as part of the consent process to ensure the following:
    1. The specific needs of each study participant are considered,
    2. Key elements of the trial are reviewed and addressed, and
    3. Interactive techniques are used to facilitate participant understanding of the information imparted.
        - This tool could be used for documenting the informed consent process.
- Study participants should be provided with available resources to enhance their understanding of clinical trials, including sample questions to ask the investigator so he/she can better engage in a dialogue about the benefits and risks of participation. [1,2]
- The informed consent document should be viewed as supportive to the consenting process, rather than the primary focus.

Training of Research Staff

- Research staff obtaining consent should be trained to do so.
- Training programs should be determined by individual research sites and tailored to local and organizational needs. A uniform training program is not required and programs should not be nationally driven or sponsor-specific.
- For research staff designated to obtain consent, an informed consent training program should aim to improve their knowledge and communication skills, including best practices to impart trial-specific information while remaining sensitive to participants' needs.
- An ideal training program should include the following:
    1. Didactic information, which may be part of other general clinical research training
    2. Interactive opportunities to practice or get feedback on communication techniques, and

[1] https://www.ciscrp.org/education-center/questions-to-ask/
[2] http://www.nih.gov/health/clinicaltrials/index.htm

3. Continuing education as needed.

- Professional organizations and/or NIH should develop comprehensive training programs research sites can choose to use as, or as a part of, their organizational informed consent training program.
- Patients should be included in the development and/or implementation of the training program. Resources for meaningful patient engagement should be utilized.[3,4]
- Appendix II provides potential criteria by which to evaluate training programs.
- The benefits and effectiveness of training should be assessed.

Informed Consent Document Template

- A tiered approach should be used in the informed consent document.
    - The first tier of the informed consent document should contain only the elements of informed consent required by federal regulation (See example, Appendix III).
    - The second tier should contain additional information, in chapter format, on a range of study-related issues for each study participant to review as deemed necessary. This detailed reference section would provide an elaboration of the information in the informed consent document and be made available to study participants who wish to review it.
    - A third tier consisting of a 1-2 page introduction or a summary of the study may be valuable for more complex studies.
- Draft informed consent documents should be evaluated with the following methods:
    - Standardized health literacy/plain language assessments
    - Reading level assessments [5,6]
    - Usability testing with patients similar to those who would be eligible for the study
- A standard language library should be developed for text that is not specific to the study, and is universally accessible to study sponsors.

E-Consent

- E-consent facilitates the use of the recommended tiered informed consent document.
- Research sponsors and investigative sites should continue to explore the use of e-consent and share best practices and lessons learned. Interventional trials of e-consent documents should be conducted to evaluate the effects on study feasibility and participant comprehension, decision-making, and satisfaction.

- *These recommendations are based on results of the Informed Consent Project.*
- *CTTI's Executive Committee approved the recommendations.*
- *Released in November 2015*

[3] PCORI. http://www.ctti-clinicaltrials.org/what-we-do/investigational-plan/patient-groups.
[4] CTTI Patient Groups in Clinical Trials Project. http://www.ctti-clinicaltrials.org/what-we-do/investigational-plan/patient-groups.
[5] PRISM Readbility Toolkit. https://www.grouphealthresearch.org/about-us/capabilities/research-communications/prism/
[6] Suitability Assessment of Materials (SAM). http://aspiruslibrary.org/literacy/sam.pdf

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

Appendix II
Informed Consent Training Resources

Organization	Didactic	Interactive	Testing	Review of Required Elements	CME Credit	Documentation of the IC Process	Patient Communication	In-person	On-line or Webcast	Ideal for Continued Education Purposes
Training program A										
Training program B										
Training program C										

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.]