Templates for “Key Information” Section of Informed Consent Document

As stated in the updated Federal Policy for the Protection of Human Subjects (also known as, the “Revised Common Rule” or “Final Rule” or “2018 Requirements”), Informed Consent documents must now “begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research”.

The following elements must be included in the Key Information section:

- The fact that consent is being sought for research and that participation is voluntary.
- The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research.
- The reasonably foreseeable risks or discomforts to the prospective subject.
- The benefits to the prospective subject or others that may reasonably be expected from the research.
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

Please note that this information should already be included in the body of your current consent document, however, a brief synopsis (or abstract) which includes the elements above will need to be included at the beginning of your consent statement / form.

The North Texas Regional IRB has included templates below, in order to provide investigators with examples of how this “Key Information” section should be presented in the consent document. Please note that these are examples only – investigators should update and tailor the Key Information section for their respective informed consent documents, as appropriate.

- Template for Non-FDA regulated Federally Funded Studies, Clinical Trials, and Biomedical Studies using a standard consent form
- Template for Investigator-Initiated Social/Behavioral Studies and Consent Letters/Scripts
Template for Non-FDA regulated Federally Funded Studies, Clinical Trials, Biomedical Studies or More than Minimal Risk Social Behavioral Studies using a standard consent form:

“Key Information for a Research Study of the [INCLUDE EITHER FULL STUDY TITLE OR CAN INCLUDE AN ABBREVIATED TITLE]”

“We are inviting you to take part in a research study to [INCLUDE BRIEF PURPOSE OF STUDY]. Please note that your participation in this research study conducted by [INCLUDE INSTITUTION(S) AS APPROPRIATE] is completely voluntary, and you do not have to participate.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?
By doing this study, we are trying to … [INCLUDE BRIEF PURPOSE AND OVERVIEW OF STUDY PROCEDURES, ALONG WITH THE APPROXIMATE AMOUNT OF TIME SUBJECTS’ PARTICIPATION WILL LAST]

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
There [may be OR is no – INCLUDE LANGUAGE AS APPROPRIATE FOR STUDY] physical or medical risk to you if you participate in this study. [IF THERE IS SOME PHYSICAL OR MEDICAL RISK, PLEASE INCLUDE A BRIEF SYNOPSIS HERE.] [INCLUDE ANY OTHER SOCIAL/ECONOMIC, PSYCHOLOGICAL, AND/OR INFORMATIONAL RISKS THAT MAY OCCUR IN THE STUDY, INCLUDING LANGUAGE ABOUT HOW THE RISK(S) WILL BE MANAGED. HERE IS SOME EXAMPLE LANGUAGE (THIS SHOULD BE REVISED AS APPROPRIATE FOR YOUR STUDY): “Some of the questions we ask may feel personal or we may ask for information that some people feel uncomfortable answering. Please know that you do not have to answer any question in this survey that makes you feel uncomfortable. In addition, there is always a slight risk of loss of confidentiality, meaning that the information we collect about you could possibly be accessed by someone not authorized to see it. However, we will work hard to protect the information we collect about you and to keep it private, and your name will not ever be recorded on the study answer forms.”] For a complete description of risks, refer to the detailed consent that follows.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
Your participation in this study may not directly benefit you. However, your participation in the study will help us learn more about [INCLUDE BRIEF LANGUAGE ABOUT POSSIBLE OVERALL BENEFITS OF STUDY]. We will also learn more about [INCLUDE ANY OTHER POSSIBLE BENEFITS, IF APPLICABLE].

WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THIS STUDY?
You will receive the same medical care for your physical health problem whether you participate in this study or not. Hospitalized individuals can request the opportunity to speak to a mental health provider outside of this study if they are feeling depressed or having thoughts of suicide.
Template for Investigator-Initiated Minimal Risk Social/Behavioral Studies and Consent Letters/Scripts:

“Key Information for [INCLUDE EITHER FULL STUDY TITLE OR CAN INCLUDE AN ABBREVIATED TITLE, if applicable]”

You are being invited to participate in [INCLUDE BRIEF DESCRIPTION OF STUDY, IN ADDITION TO THE PURPOSE]. This research study conducted by [INCLUDE INSTITUTION(S) AS APPROPRIATE] is completely voluntary. If you consent, you will [INCLUDE A BRIEF DESCRIPTION OF THE STUDY PROCEDURES, INCLUDING ANY FOLLOW-UP PROCEDURES AND STUDY DURATION]. Although there is a chance you [INCLUDE ANY POSSIBLE SOCIAL/ECONOMIC, PSYCHOLOGICAL, AND/OR INFORMATIONAL RISKS], these risks are minimal. [INCLUDE LANGUAGE ABOUT HOW THE RISK(S) WILL BE MANAGED]. For a complete description of risks, refer to the detailed consent that follows. While there is no direct benefit for participating in this study, [INCLUDE BRIEF LANGUAGE ABOUT POSSIBLE OVERALL BENEFITS OF STUDY]. You do not have to participate in this study.