**Research Subject
Key Information Form Instructions**

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 **\*\*\* Directions for Use for this Template \*\*\***

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| --- |
| ***THIS DOCUMENT****: is Key Information required* under the new common rule at 45 CFR 46.116(a)(5)(i). We are expected to make sure that the beginning of an informed consent includes a concise explanation of the following:  the fact that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research; (3) the reasonably foreseeable risks or discomforts to the prospective subject; (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. This template provides a brief description of these five factors. Please make sure to add your studies key information that is most likely to assist a reasonable person in understanding the reasons why one may or may not want to participate in research. Do not cut and paste from the protocol or the full informed consent.Remove this page “Directions for Use for this Template” before IRB submission. |

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***BLUE TEXT****: represents guidance language on the use of the standardized language text provided by this document.*

**BLACK TEXT***: represents example standardized language text. The standardized language text is presented under the applicable numbered consent section to make it easier to cut and past from this document into the Consent Form Template*

**Research Subject**

**Key Study Information Form**

|  |  |
| --- | --- |
| **Title of Study:** | Insert Brief Title of Research StudyInset Study Number |
| **Principal Investigator:** | Name of the Principal InvestigatorDepartment of Principal InvestigatorPhone Numbers |

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

**Purpose of the Research Study**

The purpose of this research study is to *[Briefly describe the* ***purpose******or research*** *in non-medical terms and at an 8th grade reading level].*

*Choose one and briefly describe what is being studied.*

We are asking you to take part in this research study because you have a medical condition being studied and/or are scheduled to have test/procedure.

*OR* This research study is being done to collect your thoughts/reactions/opinions. We will do this through a Survey/Questionnaire/Focus Group/etc.

**Other Key Information**

This study will last about *[# of days, months, years]* and will involve about *[# of visits].* While in this study you will be asked *[briefly describe what the participant will be asked to do during this study].*

**Foreseeable Risk and Benefits**

A comprehensive list of all possible risk and discomforts related to this research is included in the full consent, the most common risk experienced include *[insert the most foreseeable risk and discomforts reported or encountered as a result of participation].*

You *[may/ may not/will not]* benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because *[describe why others might benefit in the future in terms of the knowledge that will be gained].*

**Alternatives to Participation**

Should you choose not to participate, the following alternative options are available to you: *[Insert and explanation of the alternatives to participation].*

For in-depth details regarding this study, please refer to the full informed consent document attached.

For questions and concerns regarding any of this information, contact *[insert study contact name, phone number and/or email address].*