INFORMED CONSENT

Key Information

Effective January 21, 2019

DOES NOT APPLY TO FDA-REGULATED STUDIES

Per the revised Common Rule, section 45 CFR 46.116(a)(5)(i), requires informed consent to 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."

*Use the template below to comply with presentation/organization of "key information" to be included at the beginning of your informed consent document. This information is **NOT** required for (i) exempt studies or (ii) consent documents that are brief in nature.*

Here you will find a brief summary of key points to inform you about the research study you are being invited to participate in. You can find more detailed information throughout this document.

You are being asked to participate in a voluntary research study. Even if you decide to join the study, you are free to leave at any time if you change your mind. The purpose of this study is to [. Participating in this study will involve] and your participation will last [ ].

Risks related to this research include [ ]; and benefits related to this research include [. The alternative to participating in this study is to [ ]

NOTE: If your research includes an optional sub-study, briefly summarize here.