What is “informed consent”

Voluntary informed consent is a requirement for a person to participate in research. Above all, informed consent and the consenting process is about the protection and respect for study participants.

Informed Consent is a voluntary agreement to participate in research. It is not merely a form that is signed but it is a process, in which the person has an understanding of the research and its risks before agreeing to participate in the study. Informed consent is essential before enrolling a person on a study and continues once enrolled.

Because participation in research is voluntary the person has the right to change their mind at any time before, during or after the start of the clinical trial. When a person changes their mind about participation in a study they will withdraw consent and end their clinical trial participation. The physician will make sure the patient stops any treatment safely and will have other treatment options available prior to stopping any needed treatments.

Oftentimes a withdrawal of consent document will be completed that provides explanation of choices for follow-up options and if provided by the patient, documents the reason for withdrawal.

Options for follow-up include:

Option 1 - provide continued follow-up with further data collection limited to what is collected in my medical chart during normal clinic visits

Option 2 - provide only data related to the my health status

Option 3 - provide no additional information to the study at all.