INFORMED CONSENT

STUDY TITLE:	*[Insert Title of Project]*
PRIMARY INVESTIGATOR:	*[Insert name]*
SUB-INVESTIGATOR:	*[Insert name]*
ADDRESS:	*[Insert Address]*
VERSION DATE:	*[Insert Version Date]*

SUMMARY OF RESEARCH

Provide a concise and focused presentation of the key information that is most likely to assist a prospective subject on legally authorized representative in understanding the reasons why only one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

This is an important form. It is up to you to decide whether or not to take part in this study. Please read this entire consent form as it tells you what you need to know about this research study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is ***[give a general description of the project-what is being investigated, what is the hypothesis, what knowledge is being sought and why].***

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately ***[number]*** people will take part in this study. ***[Add a sentence if study will be done at other sites and how many total subjects are expected to be enrolled].***

WHAT ARE THE BENEFITS OF THIS STUDY?

You ***[may or may not/will or will not]*** benefit personally from being in this study. However, others may benefit in the future from information discovered during this study.

WHAT WILL HAPPEN DURING THE STUDY?

[Describe the procedures/process in chronological order, define and explain all technical terms.]

[Identify and explain any procedures that are experimental]

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last ***[insert total length of the study]***. You will need to ***[visit the (insert location)….and (insert number)]*** times. Each visit will take about ***[insert number of minutes/hours]*** minutes/hours.

IS THIS STUDY VOLUNTARY?

Your participation is voluntary. You may choose not to participate, or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with, or treatment at, this medical center.

If appropriate add:
You will be informed by the research investigator***[s]*** of this study of any significant new findings that develop during the study which may influence your willingness to continue to participate in the study.

If appropriate add:
If you decide to leave the study early, we ask that you ***[Describe the procedures the subject may need to follow, such as calling the study researcher, coming in for a close out visit. Describe any consequences of the subject's withdrawal].***

If appropriate add:
[Specify any circumstances of early withdrawal from the study without participant's approval, such a deteriorating health or other conditions that might make continued participation harmful].

WHAT ARE THE RISKS FOR TAKING PART IN THIS STUDY?

There may be some risk from being in this study ***[Describe the risks-psychological, emotional, physical, legal, privacy issues, etc. If there are no known risks, state that there are "no foreseeable risks" to participating].***

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

[Describe and explain the procedures that will be employed to provide alternative treatment for those who do not wish to participate.]

WHAT ARE THE COSTS FOR TAKING PART IN THIS RESEARCH STUDY?

You ***[will/will not]*** have any costs for being in this research study. ***[Describe any costs to the subject. And add a statement if the patient's insurance company has to pay for any standard care.]***

CONFIDENTIALITY

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis could include:

- *[sponsor]*
- *[government agencies such as Food and Drug Administration (FDA)]*
- *[Hospital or clinic]*
- *[study doctors, study staffs]*
- *[**Altru Health System IRB** + explain who they are]*

WILL I BE PAID FOR PARTICIPATING?

You ***[will/will not]*** be paid for being in this research study. ***[Describe the monetary compensation, if there is any. Also indicates if there is non-monetary compensation (e.g. coupon, gift certificate).***

In some studies, if the physician will get some compensation, that must be described.

WHAT WILL HAPPEN IF I AM INJURED?

It is important that you tell your healthcare provider ***[insert names and phone numbers]*** if you feel that you have been injured by taking part in this study.

You will get medical treatment if you are injured as a result of taking part in this study. ***[Explain if the study will pay or not].***

COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS (Include only if applicable) State either that (1) identifiers might be removed from your identifiable private information or identifiable biospecimens, and that after such removal the information or biospecimens could be used for future research studies without additional, informed consent from you or your legally authorized representative or (2) your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

If appropriate add
Your biospecimens (even if identifiers are removed) may be used for commercial profit and you (will/will not) share in this commercial profit.

If appropriate add
Research with your biospecimens (will/will not) include whole genome sequencing (ie sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

If appropriate add
Clinically relevant research results, including individual research results, (will/will not) be disclosed to you. (Describe under what conditions research results will be disclosed, if this will occur.

CONTACTS AND QUESTIONS

The researchers conducting this study are ***[insert name(s) of investigator(s)]***. If you have any questions about the research, please contact ***[insert name(s) of investigator(s)*** at ***[insert***

telephone number] during the day and at **[*insert after hour's telephone number, if appropriate]*** after hours.

If you have questions regarding your rights as a research subject, or if you have any concerns about the research, you may contact the Altru Health System Institutional Review Board (IRB) office at (701) 780-6161.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subjects Name: _____

Signature of Subject_____ Date _____