MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY ENGLISH – REVISED COMMON RULE FOR STUDIES INITIALLY APPROVED AFTER 1/21/2019

INSTITUTE/CENTER:

PRINCIPAL INVESTIGATOR:

STUDY NUMBER:

STUDY TITLE:

You are being asked to participate in a research study. Before you agree, you must first be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

After presenting the summary, the study team will provide you with additional details about the study which must include:

1) the purposes, procedures, and duration of the research;
2) any procedures which are experimental;
3) any reasonably foreseeable risks, discomforts, and benefits of the research;
4) any potentially beneficial alternative procedures or treatments; and
5) how confidentiality will be maintained.

Where applicable, the study team must also tell you about:

1) any available compensation or medical treatment if injury occurs;
2) the possibility of unforeseeable risks;
3) circumstances when the investigator may halt your participation;
4) any added costs to you;
5) what happens if you decide to stop participating;
6) when you will be told about new findings which may affect your willingness to participate;
7) how many people will be in the study;
8) use of your biologic specimens for commercial profit;
9) whether you will be told about your research results;
10) whether the research might include whole genome sequencing; and
11) any future research use of your information or biologic specimens.
12) For clinical trials: A description of this clinical trial will be available on https://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

    Further, a description of this clinical trial may be available on https://www.clinicaltrials.gov consistent with NIH policy.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact *(name)*_____ at *(phone number)* _____ any time you have questions about the research.

You may contact *(name)*_____ at *(phone number)* _____ if you have questions about your rights as a research subject or what to do if you are injured.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

Signature of Research Participant	Print Name of Research Participant	Date
Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is:_____.