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| **Date:** |  |
| **To:** |  |
| **From:** | Principal Investigator |
| **Protocol Title:** |  |

1. This document serves as an attestation that the data collected under the protocol(s) that comprise this data set were collected under the provisions of broad consent at 45 CFR 46.116 (a)(1)-(4); a(6); and d.
2. Specifically, with regards to the broad consent process:

Before involving a human subject in research related to this data set, investigator(s) obtained the legally effective informed consent of the subject or the subject's legally authorized representative

Investigator(s) sought informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether to participate and that minimize the possibility of coercion or undue influence.

The information given to the subject or the legally authorized representative was in language understandable to the subject or the legally authorized representative.

The prospective subject or the legally authorized representative were provided with the information that a reasonable person would want to have to make an informed decision about whether to participate, and an opportunity to discuss that information.

The informed consent did not include any exculpatory language through which the subject or the legally authorized representative was made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

If there have been any changes made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For any subjects potentially vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards were included in the study to protect the rights and welfare of these subjects.

1. The broad consent document(s) regarding this data set are attached. Specifically, with regards to the broad consent document(s), the broad consent contains:

A description of any reasonably foreseeable risks or discomforts to the subject;

A description of any benefits to the subject or to others that may reasonably be expected from the research;

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

A statement that participation is voluntary and that refusal to participate or a decision to terminate their participation will involve no penalty or loss of benefits to which the participant is otherwise entitled?

A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

1. I further attest that If the protocols under which these data/biospecimens were collected involved genetic/genomic testing that the broad consent contained the following as applicable:

A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit

For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Signature

     

Printed Name and Title Date