Revising Consent Forms Approved Prior to 2019: Guidance For Banking Studies /Other Research that Stores and Shares Specimens or Data

When data or specimens have been previously collected under a banking protocol, OHRS will review the relevant Protocol(s) and Informed Consent Form(s) (ICFs) for the studies from which the collected data and/or specimens will be used or transferred. The Protocol(s) **and** signed ICFs must allow for the use of the data and/or specimens as proposed. Depending on the proposed use, the ICFs that the participants signed must include language that permits use or analysis of the whole genome, commercialization, and sharing of data and/or specimens for future research.

This document provides the required language for various future use of samples collected under banking studies. This language is also found in the DF/HCC Informed Consent Template.

Whole Genome Sequencing

With the Common Rule updates that went into effect January 18, 2019 was a requirement that consent forms contain a statement regarding whether the research will or might include whole genome sequencing or germline data. For research occurring after the effective date, the consent form must ***explicitly*** allow for the use of whole genome or exome sequencing to conduct this type of future research or to share the genomic data or samples with external collaborators for future genomic research. As part of this response, the DF/HCC consent form templates have been updated to include NIH-suggested language to allow for the sharing of data. This language should align with any sharing plans outlined in the study protocol.

Data and specimens collected prior to January 2019 may be shared under the provisions of the prior rule. However, modifications to the ICF will be required to align the consent process with the Revised Common Rule and allow or for future sharing of genomic data or specimens consistent with the current regulatory standards. *This language should be added to all studies' ICFs unless samples will not be used for genetic sequencing at any time in the future.*

We encourage study teams to think broadly on potential use of samples collected since the practicality of re-consenting for whole genome and/or exome sequencing may be challenging, particularly for samples collected for a broad biospecimen bank.

The consent forms must be updated to include the following language:

Genetic Research

*[Include the following if the genetic research on the samples may involve somatic genetic testing, but **will not** involve germline or whole genome sequencing]*

This research may involve somatic genetic testing. Somatic testing involves testing or sequencing of your tumor and looks for acquired mutations that may have developed due to your cancer. The results may be used to plan treatment, including the use of targeted therapy and immunotherapy, and to learn more about cancer biology.

[If the study includes whole genome or whole exome sequencing, include the following language.]

This research will involve germline testing or genomic sequencing of all or part of your DNA. Sequencing allows researchers to identify your genetic code.

*Two methods of genetic analysis, **whole exome sequencing and whole genome sequencing**, are increasingly used in healthcare and research to identify genetic variations; both methods rely on new technologies that allow rapid sequencing of large amounts of DNA.*

[Include this section if the research includes any type of genetic testing (including, but not limited to genomic, somatic, and/or germline testing)]

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health, and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health, and enable people to take part in research studies such as this without fear that their DNA information might be used against them by health insurers or their workplace. This protection does not extend to disability or life insurance. Additional information can be found at

http://www.genome.gov/10002328.

NIH Genomic Data Sharing Policy

To allow for depositing genomic data to dbGaP or other repositories, banking protocols must state the following:

As part of this study, your [anonymized/de-identified] specimens or genetic data may be placed into one or more publicly-accessible scientific databases, such as the National Institutes of Health's Database for Genotypes and Phenotypes (dbGaP). Through such databases, researchers from around the world will have access to [anonymized/de-identified] samples or data for future research.

Commercialization and General Future Use

Should data or samples be used for any potential commercialization, the consent form must include:

This study is collecting data and biospecimens from you. We would like to make your data and biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including for-profit entities, such as pharmaceutical companies and other biotechnology companies. Our goal is to make more research gains possible from your contribution. Your [(Select any that apply) anonymized/deidentified/coded] specimens or genetic data may also be placed into one or more scientific databases, some of which are publicly

accessible. Through such databases, researchers from around the world will have access to [(Select any that apply) anonymized/deidentified/coded] samples or data for future research.

Risk of Re-Identification

As the likelihood of genetic information, or other data being identifiable increases, consent forms should outline the given risks of re-identification in research studies. For sharing of genetic data, consent forms should state:

We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero. Future research studies may include genetic research. Your genes are unique to you. At this time, you cannot be identified through this research, if the samples and specimens are [anonymized/de-identified]. There is a risk that you might be reidentified in the future as genetic research progresses.