Guidance on the Sharing and Transfer of Data or Specimens

Summary:

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4. **NIH Data Sharing Policy**

(1) Data Sharing with External Collaborators and Sponsors

IRB approval or exemption of research, or a determination that the use does not meet the definition of human subjects research is needed for the use, sharing, and transfer of data and specimens.

When data or specimens have been previously collected under an existing protocol (e.g., banking studies or clinical trials), 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 of the research, the ICFs that the participants signed must include language that permits future research, commercialization, and sharing of data and/or specimens.

Data generated as a result of secondary research on banked samples or previously collected research data are subject to any existing restrictions in place (contractual or otherwise) for the primary research under which the samples/data were collected.

Data originating from industry-supported research cannot be shared unless or until the DF/HCC Sponsor-Investigator consults with and receives written permission (via an email or contract amendment) from all industry parties supporting the research or the DF/HCC Sponsor-Investigator confirms the provisions of the existing Clinical Trial Agreements contain no restrictions and allow such sharing. The DF/HCC Sponsor-investigator should first consult with his/her home institution's Clinical Trials Contracts Office to review the terms of the Agreement. When sharing or posting research documents to Clinicaltrials.gov (e.g., protocol, statistical analysis plan, informed consent document), the industry parties supporting the research must be given ample opportunity to redact confidential information from the documents prior to posting.

If your institution's technology office (e.g., BODFI, Innovations) requires verification of appropriate IRB approval and consent language to create a material transfer agreement (MTA) or data use agreement (DUA), please contact OHRS_Verification@dfci.harvard.edu. OHRS will determine whether the IRB approval and consent documents allow for the transfer of the data and specimens. Further information on creating such agreements can be found in the OHRS guidance document **Guidance on Requesting OHRS Verification for the Transfer of Data or Specimens.**

(2) Sharing Whole Genome or Exome 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. 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.

Participants must be informed if the research will, will not, or might include whole genome sequencing. Whole genome sequencing is increasingly being used in research to identify genetic variations and is expected to continue to expand. Whole genome sequencing provides information that could predict participants' future medical conditions and has the potential to impact an individual's family members. Ethical and practical concerns related to whole genome sequencing include storage, analysis, and return of results. Because every person's DNA is unique, the realization that fully guaranteeing privacy may be impossible is becoming increasingly evident.

When future research will entail whole genome sequencing, or when sharing whole genome sequencing with internal and external collaborators, the following will be considered. OHRS will work with research teams and partnering technology offices to always verify the specifics of the consent form and whether sharing and commercial use of information is allowable. In general, the use of such data and samples are circumstance dependent but generally may be done if no PHI is shared or a limited data set is shared with a data use agreement attesting to no attempt to re-identify.

- Data and specimens collected on studies approved under the previous common rule (e.g., approved prior to January 2019) will be allowed to be shared for future use under the regulations at the time, including whole genome and germline sequencing. However, the consent forms should be amended to include specifically allow even if the signed consent forms do not whole genome sequencing per the current Common Rule requirements.
- For studies approved after January 2019, any whole genome sequences, or samples shared with the intent to generate the whole genome must be consented to. Participants can either provide consent for the study prospectively or have provided consent via an existing banking study. OHRS will review the proposed intent of the research and the consent forms signed by the participants to confirm that consent has been properly granted, regardless of whether the samples and/or sequences are being shared with any additional PHI.
- Samples collected for clinical purposes only, for which there is no consent, may not be used or shared for the purpose of generating genomic data.

As noted above, OHRS will review the consent forms under which the samples were collected to ensure the participants were informed if the research will, will not, or might include whole genome sequencing.

- This research may involve somatic genetic tests or whole genomic sequencing including all or part of your DNA. Sequencing allows researchers to identify your genetic code.
- If you consent to this study, tissue samples that have already been collected through a biopsy or procedure or will be collected in the future as part of your clinical care may be retrieved for DNA testing. Genetic material will be obtained from this sample, sequenced to identify changes present in the tissue or cancer that are specific to your cancer.

(3) NIH Genome Data-Sharing Policy

The NIH Genome Data-Sharing Policy (GDS) applies to all National Institute of Health (NIH)-funded research that generates large-scale human or non-human genomic data as well as the use of the data for subsequent research initiated after the effective date of January 25, 2015. Under this policy, an Institutional Certification, outlining

the data sharing provisions in the study, must be provided by the Institutional Signing Official of the submitting institution, prior to the award of funding or prior to data deposition.

NIH has strict standards for IRB review and informed consent for the human genomic data they will accept for inclusion in public data repositories whether or not your project has NIH funding. Even if you do not currently anticipate depositing genomic data or human tissue into NIH repositories, research overseen by the DFCI IRB is expected to meet the consent requirements for sharing data. Your plans for depositing may change in the future and we strongly suggest maximizing the downstream use of tissue and/or data by including all of the required consent language.

For existing research using or generating genomic data, the IRB is required to review investigators' submissions to NIH data repositories. The primary focus of the review is on whether informed consent is obtained from subjects in a manner that is consistent with NIH requirements for sharing genomic data and the data sharing plan is consistent with GDS policy. An Institutional Certification is needed to deposit data or tissue into NIH repositories. If genomic data is being generated, the NIH GDS policy requires an Institutional Certification as part of the Just in Time submission, as well as a Certification at the time of data submission to a data repository. The policy also applies to subsequent research studies that use this type of data (secondary use studies).

In addition to NIH policy, many journals require broad sharing of genomic data with NIH or other central repositories. NIH may expect submission of data from smaller scale research projects based on the state of the science, the programmatic priorities of the Institute funding the research, or the utility of the data for the research community. The GDS Policy does not apply:

- When the genomic data is generated without NIH funds and will never be deposited into a central database.
- When NIH-funded projects involve instrument calibration exercises, statistical or technical methods development, or the use of genomic data for control purposes, such as for assay development.

Smaller studies (e.g., sequencing the genomes of fewer than 100 human research participants) are generally not subject to the GDS policy.
For more information on types of Institutional Certificates and the process for requesting a signed Institutional Certificate, see the OHRS guidance document, **Institutional Certification Process for Genomic Data Sharing.**

(4) NIH Data Sharing Policy

As of January 25, 2023, NIH has issued the Policy for Data Management and Sharing (DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research. The policy applies to all research funded by NIH intended to generate scientific data, and establishes the requirements to submit Data Management and Sharing Plans to the NIH as part of the grant submission. Investigators are responsible for adherence to their plans. The intention is to establish the expectation that data sharing is a fundamental component of the research process and maximizes the public's access to research results that arise from NIH-funded research.

As part of the criteria for IRB approval outlined in the federal regulations, the IRB must confirm that informed consent has been sought from participants and that there are adequate provisions to maintain confidentiality of data. Hence, this policy has impact on confidentiality plans and informed consents submitted to the IRB. 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.

OHRS will adhere to NIH's stance that "access to scientific data derived from humans should be controlled, even if de-identified and lacking explicit limitations on subsequent use." As such, data should be shared to controlled access repositories (e.g., dbGaP), especially if the data are considered "sensitive, such as including information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes." As such, when depositing data to dbGaP, OHRS suggests using the "health/biomedical" data use limitation in the Institutional Certificate. Should there be any questions about whether a repository is considered controlled access, please contact OHRS_Verification@dfci.harvard.edu.