|  |  |  |
| --- | --- | --- |
|  | Diagram  Description automatically generated | **FORM: Genomic Data Sharing Supplement** |

|  |  |
| --- | --- |
| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

This supplement should be completed for studies involving the proposed submission of genotype and phenotype or other genetic data (referred to here as “genomic data” or “dataset”) into genomic repositories created to share genetic information within the wider research community for research purposes.

The responses to these questions will guide the IRB in its deliberations as to whether the proposed submission will be permitted and whether any conditions or restrictions will be imposed on the use of the data. In some instances, the IRB determinations will be forwarded to the Office of Sponsored Research to guide decisions with respect to any institutional official certifications that may be required under the NIH Genomic Data Sharing Policy or related policies and procedures.

IMPORTANT NOTE: This form should only be completed when Fred Hutch will be uploading the final genomic data to the central repository (e.g., dbGaP). If another institution will be doing the final upload, it is that institution’s responsibility to complete the Genomic Data Sharing analysis using its own local standards. Further, Fred Hutch cannot issue an “Institutional Certification” unless Fred Hutch is uploading the final genomic data. For instance, if a Fred Hutch repository provides samples to an NIH intramural researcher for further genomic analysis, it is the NIH intramural researcher’s responsibility to complete the certifications.

Please complete the following checklist, respond to the following questions and submit the documents requested:

# I. General Background Information

1. [ ]  Identify the central repository to which genomic data will be submitted (e.g., dbGaP, ATLAS, Etc.):

|  |
| --- |
|       |

1. Is this a: (check all that apply).

[ ]  PROSPECTIVE Study (Dataset is not yet in existence).

[ ]  RETROSPECTIVE Study (Dataset is in existence).

1. If the NIH Genomic Data Sharing policy is applicable, summarize here your plan to de-identify the dataset to be submitted and describe how your plan is consistent with the NIH Genomic Data Sharing Policy.

|  |
| --- |
|       |

1. If NIH Genomic Data Sharing Policy **is not applicable,** please summarize your plan to de-identify the dataset.

|  |
| --- |
|       |

1. Summarize any general background information about the informed consent form(s) (including discussion of historical consents) that will be relied upon in requesting IRB review of the proposed submission.

|  |
| --- |
|       |

1. Which individuals at Fred Hutch will be involved with the posting of genomic data to the database?

|  |
| --- |
|       |

# II. Please submit the following documents:

[ ]  List Relevant Foundational Consent Form(s) used to collect specimens originally:

|  |
| --- |
|       |

[ ]  Data Sharing Plan for the dataset to be submitted (for guidance see: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>).

[ ]  Description of study population whose genomic data will be provided under the Data Sharing Plan and the data elements (variables or data fields) that will be submitted.

**COMPLETE SECTION III.1. THROUGH III.8. FOR EACH VERSION OF THE FOUNDATIONAL CONSENT FORMS USED TO COLLECT SAMPLES.**

# III. Verification the foundational consent is consistent with sharing

Please separately complete Sections 1-8 for each version of the Consent Forms noted on the cover page. This section should be completed for all relevant consent forms, including those used for donation of human specimens if those specimens were the source for the dataset proposed for submission in this application.

## Scope of Foundational Informed Consent:

1.1. Does the consent form describe genetic research and data sharing? *Respond to the following:*

|  | **Allow****(Identify where in the consent)** | **\*Preclude****(Identify where in the consent)** | **\*Silent, or does not expressly Preclude** |
| --- | --- | --- | --- |
| Genetic research or analysis. | [ ]  Page:       | [ ]  Page:       | [ ]  |
| Future use and broad sharing of the participant’s coded phenotypic and genotypic data for research. | [ ]  Page:       | [ ]  Page:       | [ ]  |
| Submission of the participant’s coded phenotypic and genotypic data to a government health research database for broad sharing to qualified investigators. | [ ]  Page:       | [ ]  Page:       | [ ]  |

\*Note: Informed Consent required on or after January 25, 2015, per [*IRB Policy 2.27 IRB Review of Genomic Data Sharing Studies*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_27/file.res/Review-Genomic-Data-Sharing.pdf) (0317).

1.1.a. Provide additional information and/or comments as to how (if at all) the informed consent form includes reference to the proposed submission of the dataset:

|  |
| --- |
|       |

1.1.b. If the consent form is either silent or does not expressly preclude any of the areas listed above, do you plan to seek re-consent?

[ ]  Yes → A copy of the consent for this purpose is attached 

[ ]  No → Provide justification for the committee on why re-consent will not be sought. Address the following points (e.g., Waiver of Consent):

* Why the posting of data from your research to the database involves no more than minimal risk to the subjects from whom the samples were originally obtained.
* Why the posting of data will not adversely affect the rights and welfare of the subjects from whom the samples were originally obtained.
* Under what circumstances will subjects be presented with relevant information should it become available.
* Why re-consenting the subjects is impractical.

|  |
| --- |
|       |

1.2. Does the consent form have any of the following specific restrictions relating to the sharing of data?

|  | **Yes** | **No**  |
| --- | --- | --- |
| Types of subsequent research using the participant’s phenotype and genotype data | [ ]  | [ ]  |
| Location of such research | [ ]  | [ ]  |
| Types of medical conditions or diseases studied | [ ]  | [ ]  |
| Duration of storage and use of human specimens and/or phenotype and genotype data derived from such specimens. | [ ]  | [ ]  |
| Limitations on who can use the participant’s specimens and/or phenotype and genotype data (e.g., some consents may state that only non-commercial researchers can use the data) | [ ]  | [ ]  |

1.2.a. If you checked “yes” to any of the above, provide further information and/or comments relating to any of the limitations identified in the table above:

|  |
| --- |
|       |

1.2.b. Describe any additional limitations or restrictions on use contained in the informed consent form and not identified above:

|  |
| --- |
|       |

## Potential Benefits

2.1 Does the consent form discuss the possibility that benefits may accrue broadly to the public through the advancement of science and understanding of health and disease, rather than resulting in direct benefits to individuals?

[ ]  Yes

[ ]  No

2.2 Describe any additional benefits described in the consent form relevant to the proposed submission.

|  |
| --- |
|       |

## Risks

3.1. Does the consent form discuss risks associated with genetic or genomic research, such as the following?

|  | **Yes** | **No** |
| --- | --- | --- |
| Does the consent form discuss risks of broad sharing of phenotype and genotype data? | [ ]  | [ ]  |
| Does the consent form discuss privacy risk of data sharing (e.g., the possibility that the coded data may be released to members of the public, insurers, employers, and law enforcement agencies) | [ ]  | [ ]  |
| Does the consent form discuss the risks of computer security breaches relevant to maintaining data in an electronic format? | [ ]  | [ ]  |
| Does the consent form discuss relevant risks to relatives or identifiable populations or groups? | [ ]  | [ ]  |

3.2. Are there any other potential risks associated with proposed submission of the dataset which are not described in the consent form.

[ ]  Yes → Describe:

|  |
| --- |
|       |

[ ]  No

## Return of Research Results

4.1. Does the consent form include a discussion of whether or not human specimens or research results will be returned to subjects?

[ ]  Yes → Explain under what conditions:

|  |
| --- |
|       |

[ ]  No

4.2. If human specimens or research results will be returned, describe the conditions and procedures to be used for this purpose.

|  |
| --- |
|       |

## Privacy and Confidentiality Protections

5.1. Does the consent form address how the confidentiality of individually identifiable information about the participants will be protected?

[ ]  Yes → Provide a description:

|  |
| --- |
|       |

[ ]  No

5.2 Describe the information security provisions of the GWAS database: For the NIH dbGaP database you may reference the dbGaP website; for all other databases, provide a description or submit documentation of the information security and oversight mechanisms:

|  |
| --- |
|       |

5.3. Is the description of confidentiality measures described in the consent consistent with the gate keeping and information security measures of the GWAS database into which the dataset will be deposited?

[ ]  Yes

[ ]  No → Describe:

|  |
| --- |
|       |

## Withdrawal of Consent

6.1. Does the consent form address whether a subject can withdraw his/her phenotype and genotype data from research use?

[ ]  Yes → Provide a description of the procedures to be used for this purpose:

|  |
| --- |
|       |

[ ]  No

## Commercial Use

7.1. Does the consent form allow for the commercial use of the subject’s phenotypic and genotypic data?

[ ]  Yes → Provide a description of any restrictions:

|  |
| --- |
|       |

[ ]  No

7.2. Does the consent form preclude or restrict the commercial use of the subject’s phenotypic and genotypic data?

[ ]  Yes → Provide a description of any restrictions:

|  |
| --- |
|       |

Note: If restrictions are specified, they will be included within the institutional certification to the NIH.

[ ]  No

## Scope of Informed Consent

8.1. Scope of Informed Consent obtained on or after January 25, 2015, must describe the following:

* Prospective consent is required.
* Please append a copy.

## Other

9.1. Is there any other information in the consent form that is inconsistent with the information provided about the NIH GWAS data repository and the GWAS policies and procedures?

[ ]  Yes → Provide a description:

|  |
| --- |
|       |

[ ]  No