Guideline for Human Genomic Data Sharing and Institutional Certification

The purpose of this guideline is to outline the responsibilities of the Investigator, ORPA, and the RSRB regarding human genomic data sharing and institutional certification. This guideline applies to NIH funded as well as non-NIH funded research. The NIH Genomic Data Sharing (GDS) Policy outlines NIH's requirements for broad and responsible sharing of genomic data. The policy applies to all NIH-funded research that generates large-scale human genomic data, as well as the use of that data for subsequent research. Additional details regarding the NIH policy, including exceptions to the GDS policy, supplemental information regarding data sharing plans and considerations for informed consent, as well as Investigator responsibilities, may be found on the NIH Genomic Data Sharing website.

Note: For multi-site studies, certification must be provided for all sites contributing samples to dbGaP or another NIH genomic data repository. When the UR is the lead site, one institutional certification may be submitted on behalf of all collaborating sites. Alternatively, each site providing data may provide its own institutional certification.

The process for obtaining institutional certification and completing NIH study registration depends on whether the study involves human subjects. The following sections address the steps and information needed to obtain the required institutional certification and IRB review, as applicable.

1. Not Human Subject Research

A. Investigator must ensure that the grant application adequately describes the data sharing plan and includes any relevant budget information pertaining to funds needed for data sharing activities. The data sharing plan should describe how the expectations of the GDS Policy will be met and denote the type(s) of data to be submitted, which data repository(s) data will be submitted to, the appropriate uses of the data (i.e. data use limitations), and the data sharing timeline.

B. Investigator completes the Extramural Institutional Certification form.

C. Investigator submits the signed Institutional Certification form to the Office for Research and Project Administration (ORPA) for signature as the Authorized Institutional Official. ORPA will upload the document along with other required materials as part of the (Just-In-Time) grant registration process.

2. Human Subject Research – NEW RSRB Applications

A. Investigator must ensure that the grant application adequately describes the data sharing plan and includes any relevant budget information pertaining to funds needed for data sharing activities. The data sharing plan should describe how the expectations of the GDS Policy will

be met and denote the type(s) of data to be submitted, which data repository(s) data will be submitted to, the appropriate uses of the data (i.e. data use limitations), and the data sharing timeline.

B. Investigator completes the Extramural Institutional Certification form. The Provisional Institutional Certification may be used if the RSRB has not yet completed its review of the protocol.

C. Investigator completes a new research application in the RSRB online review system. *NOTE: Include a copy of the institutional certification form in the application Local Site Documents, Question 3 Other Attachments.*

   i. **Protocol:** The protocol should include a data sharing plan which, at minimum, addresses the following:
      - Indication that data will be sent to NIH for genomic data sharing and whether purpose will be for broad use (i.e., unrestricted or open access) or limited to specific disease or conditions (i.e., controlled access);
      - Specific sources of the data to be submitted (e.g., all subjects in the study, a specific subset of individuals, subjects from all sites, etc.)
      - Type of data that will be shared (i.e., type of genomic data, relevant associated data, and information necessary to interpret the data);
      - Timeline for the data to be shared
      - Any limitations on the secondary research uses of the data;
      - Description of risks associated with broad data sharing (i.e., risks to individuals, families, groups) and how those risks will be minimized (i.e., plan for removing identifiers from the data to be provided)
        Note: The identities of research subjects cannot be disclosed to NIH data repositories; only coded data with all 18 HIPAA identifiers removed will be accepted. The IRB must review researchers' plans for data coding to determine the plan's appropriateness for the specific dataset and to provide the assurances required by the institutional certification.
      - For multisite studies, a statement of whether University of Rochester will be providing certification on behalf of all participating institutions, and if so, confirmation that the other institutions have agreed.

   ii. **Consent:** The consent form should include all applicable elements regarding genomic data sharing. Refer to the RSRB Genomic Data Sharing Open Access or RSRB Genomic Data Sharing Controlled Access consent form template language, as applicable.

D. The RSRB will review the protocol materials and certification form to assure the following:
   i. The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;

ii. Data submission and subsequent data sharing for research purposes are consistent with the informed consent of subjects from whom the data were obtained;
iii. Consideration was given to risks to individual subjects and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
iv. To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing;
v. The investigator's plan for de-identifying datasets is consistent with the standards outlined in the NIH GDS Policy.

E. Investigator provides a copy of the RSRB Initial Approval Letter and completed signed Institutional Certification form to the Office for Research and Project Administration (ORPA) for signature as the Authorized Institutional Official. ORPA will upload the document along with other required materials as part of the (Just-In-Time) grant registration process.

3. Human Subject Research – Existing, Open RSRB Approved Studies

A. Investigator will need to submit the completed Institutional Certification form and protocol revisions as an amendment to the RSRB for review. Note that the protocol and consent should be revised accordingly to include information listed in C(i) and C(ii) above.

B. Investigator provides a copy of the RSRB Amendment Approval Letter and completed signed Institutional Certification form to the Office for Research and Project Administration (ORPA) for signature as the Authorized Institutional Official. ORPA will submit the certification to NIH.

4. Human Subject Research – Closed Studies

A. Investigator will need to submit the completed Extramural Institutional Certification form along with the request for data sharing to the closed study within the online review system (upload as a Comment to the STUDY workspace). The request should include information listed in C(i) and C(ii) above, as applicable.

B. The RSRB will determine whether the proposal to submit data is consistent with the related protocol and consent form(s).

C. Investigator provides a copy of RSRB documentation approving the data sharing and the completed signed Institutional Certification form to ORPA for signature as the Authorized Institutional Official. ORPA will then proceed to facilitate the appropriate data and/or materials transfer agreements.