FSU Guidelines when Genomic Data is Generated or Accessed

A. Proposal Preparation

Prior to proposal preparation, the PI is responsible for:

1. Reviewing the NIH Genomic Data Sharing Policy (GDS) and NIH's Genomic Data Sharing website for further clarification and understanding.
2. Contacting the relevant NIH Program Official or Project Officer or the IC's Genomic Program Administrator (GPA) as early as possible to discuss data sharing expectations and timelines that would apply to their proposed studies.

The PI is responsible for including in the Resource Sharing Plan section of the proposal a Genomic Data Sharing Plan that follows the GDS Policy. The proposal should also include resources needed to support a proposed genomic data sharing plan in the project budget. See Guidance for Institutions Submitting Grant Applications and Contract Proposals under the NIH Genomic Data Sharing Policy for Human and Non-Human Data for more information.

B. NIH Just-In-Time Request

NIH will send a Just-In-Time (JIT) request following their proposal review when the application is under consideration for funding. FSU SRA will respond if instructed by the PI that he/she wishes to move forward (generally based upon the proposal's score and NIH Institute/Center payline). The JIT response varies depending on whether human or non-human genomic data will be generated.

1. Non-Human Genomic Data
   For proposals generating non-human genomic data, FSU's response to the JIT request will include a more detailed genomic data sharing plan consistent with the GDS Policy and NIH's expectations for data sharing and timing of data release, as described in the Supplemental Information referenced in A. above. Data is made available through any widely used data repository, whether NIH-funded or not, such as the Gene Expression Omnibus (GEO), Sequence Read Archive (SRA), Trace Archive, Array Express, Mouse Genome Informatics (MGI), WormBase, the Zebrafish Model Organism Database (ZFIN), GenBank, European Nucleotide Archive (ENA), or DNA Data Bank of Japan (DDBJ).
2. Human Genomic Data
   For proposals generating human genomic data, FSU's response to the JIT request will include:
   a. A more detailed genomic data sharing plan that:
      i. Is consistent with the GDS Policy and NIH's expectations for data sharing and timing of data release, as described in the Supplemental Information referenced in A. above.
      ii. Includes submission of any information necessary to interpret the submitted human genomic data, such as study protocols, data instruments, and survey tools.
      iii. Ensures data submitted to NIH-designated data repositories have been stripped of any data identifiers that, alone or in combination, allow for the re-identification of an individual.

iv. Ensures data submitted to NIH-designated data repositories do not consist of individually identifiable health information according to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. See 45 CFR 164.514(b).

v. Ensures the de-identified data are assigned random, unique codes by the PI, and the key to other study identifiers held by FSU.

vi. Ensures data are *registered* in dbGaP (see Database of Genotypes and Phenotypes at https://www.ncbi.nlm.nih.gov/gap by the time that data cleaning and quality control measures begin.

vii. Ensures data are *submitted* to the relevant NIH-designated data repository (e.g., dbGaP, GEO, SRA, the Cancer Genomics Hub), regardless of whether the data will also be submitted to a non-NIH-designated data repository.

b. An Institutional Certification signed by a FSU's Vice President for Research (see C. below) that:

i. Assures that submission of data from the study in question to an NIH-designated data repository meets the expectations of the GDS Policy.

ii. Certifies on behalf of all collaborating sites in a multi-center study, when applicable. (As an alternative, each collaborating site may provide its own Institutional Certification.)

iii. States whether the data will be submitted to an unrestricted- or controlled-access database.

iv. Assures the data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies;

v. Delineates any limitations on the research use of the data, as expressed in the informed consent documents, including whether any aggregate-level data are appropriate for general research use;

vi. Assures identities of research participants will not be disclosed to NIH-designated data repositories; and

vii. Assures a FSU IRB has reviewed the PI's proposal for data submission and that:

1. The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;

2. Data submission and sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;

3. Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;

4. 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; and

5. The investigator's plan for de-identifying datasets is consistent with the standards outlined in the GDS Policy.

viii. To the extent the study will use genomic data from cell lines or clinical specimens created or collected after the effective date of the GDS Policy and they lack consent for research use and data sharing, the Institutional Certification need only provide a justification for the use of such data. The NIH funding Institute/Center will review the justification and decide whether to grant an exception to the GDS policy.

C. FSU Process for Obtaining a Signed Institutional Certification Associated with a Proposal Involving Human Genomic Data

1. The investigator should contact the Office of Human Subjects Protection (OHSP) for guidance on requirements for submission for specific projects as per established SOPs.
2. FSU IRB reviews and approves the information provided in C.1. above, and forwards the Institutional Certification to the Vice President for Research for final approval. Once final approval is obtained, the VPR will return the approved documents to the OHSP for distribution to the assigned SRA Grants Officer.
3. The assigned SRA Grants Officer forwards both the Institutional Certification and detailed data sharing plan to NIH as part of the JIT response. The SRA Grants Officer will email a copy of the final Institutional Certification to the PI.

D. FSU Process for Submitting Human Genomic Data to dbGaP

1. If the PI has a Human Subjects Protocol, an Institutional Certification, and a data sharing plan (for the particular dataset to be uploaded) that has been approved, then the PI may proceed with submission in accordance with the dbGaP Submission Process flowchart.
2. If the PI has an approved Human Subjects Protocol and needs an Institutional Certification for the particular dataset to be uploaded, then the PI submits the following to the OHSP as per IRB established procedures:
    a. Detailed data sharing plan, and
    b. Institutional Certification (signed by PI). The PI should select the appropriate form from the Extramural Investigators section at https://osp.od.nih.gov/scientific-sharing/researchers-institutional-certifications/.
3. FSU IRB reviews the information provided in D.2. above. If acceptable, the Institutional Certification and detailed data sharing plan are sent to the Vice President for Research for final approval. Once final approval is obtained, the VPR will return the approved documents to the OHSP for distribution to the PI, with copies to the assigned SRA Grants Officer.
4. The SRA Grants Officer files the approved documents in the project file.
5. The PI submits the Institutional Certification to the funding NIH Institute, then proceeds with submission in accordance with the dbGaP Submission Process flowchart.

E. FSU Process for Requesting Access to Human Genomic Data

1. PI submits a Project Request through the NIH Commons. When SRA is notified by NIH, the Grants Officer will print the Project Request that was submitted through NIH Commons and send it to the OHSP.

2. PI contacts FSU's Office of Commercialization to discuss the data request and NIH's Data Sharing Policy's intellectual property limitations.
3. The PI completes and signs an FSU dbGaP PI Data Access Certification Form.
4. The investigator should contact the OHSP for guidance on requirements for submission for specific projects as per established SOPs.
5. FSU IRB reviews the information provided above in E.4. If approved, dbGaP PI Data Access Certification Form and the copy of the NIH Commons Project Request are sent to the Vice President for Research for final approval. Once final approval is obtained, the VPR will return the approved documents to the OHSP for distribution to the assigned SRA Grants Officer and PI.
6. The SRA Grants Officer approves the request through NIH Commons on behalf of FSU's Authorized Signing Official (VPR), and files the approved documents in the project file.

G. Project Renewals and Project Closeouts

For Project Renewals and Project Closeouts, investigators will receive automatic messages from the dbGaP system prompting them to login and complete the necessary renewal or closeout procedure. Submit the renewal or closeout to the SO. How-To Tutorials/Videos can be accessed here.

For renewals, the PI completes and signs an FSU dbGaP PI Data Access Certification Form, and submits it to the SRA Grants Officer.

When SRA is notified by NIH Commons, the Grants Officer will print the renewal or closeout application that was submitted through NIH Commons and send it to the OHSP with the PI Certification if applicable. The OHSP will review the information in conjunction with the approved IRB protocol. OHSP will submit required approvals to SRA.

SRA will send a copy of the renewal or closeout application and PI Certification to the VPR for final approval. Once final approval is obtained on the PI Certification, the VPR will return the approved documents to the assigned SRA Grants Officer. The SRA Grants Officer approves the request through NIH Commons on behalf of FSU's Authorized Signing Official (VPR), and files the approved documents in the project file.

H. Additional FSU Resources

1. FSU Libraries offer support in drafting the required data sharing plan and has experience working with NIH researchers on data sharing agreements. Here's the link where researchers may request a consultation: http://guides.lib.fsu.edu/datamanagement.
2. The DMPTool (data management planning tool) has a NIH Genomic Data Sharing (NIH-GDS) template that researchers can use.
3. ITS Information Security and Privacy Office provides online IT security and privacy training to assist in meeting that component of the NIH requirements. Upon completion of the training, the researcher can print a certificate to make this process auditable. Here is the link: http://its.fsu.edu/IT-Security/IT-Security-Awareness-Education/Security-Training-Videos