SOP#: RPS-24	**Establishing GDS Institutional Certification**
Version #: 1.0	**Next Review Date: 8/2019**
Approved Date: 8/2017	**Review Interval Period: Biennial**
NCI Clinical Director Signature:	William L. Dahut -S Digitally signed by William L. Dahut -S DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010106299, cn=William L. Dahut -S Date: 2017.09.01 10:41:28 -04'00'

POLICY

The Genomic Data Sharing (GDS) Policy applies to all NIH intramural research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data.

An Institutional Certification must accompany the submission of all large-scale human data to the NIH Database of Genotypes and Phenotypes (dbGaP). The memo certifies that data submission and sharing is consistent with the informed consent of the study participants; that consideration was given to risks to individual participants and their families associated with the shared data; that to the extent possible, consideration was given to risks to groups or populations associated with the shared data and that the principal investigator's plans of de-identifying data sets is consistent with the GDS policy.

Multi-Institutional studies require an institutional certification (IC) memo from each site that is accruing samples/subjects.

PURPOSE

The purpose of this standard operating procedure is to provide instructions on completion and approval of the Institutional Certification Memo.

RESOURCES

- NIH Genomic Data Sharing Policy
- NIH Genomic Data Sharing Website
- CCR Genomic Data Sharing Website

Genomic Program Administrators (GPA)

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PROCEDURES

STEP 1: Institutional Certification

- After a study has been approved by the either the IRB or OHSRP if exempt and the Genomic Data Sharing Plan has been accepted, complete an Institutional Certification (IC) Memo. The IC memo assures that data collection and sharing follow Federal Regulations protecting human research subjects.

STEP 2: Select the Applicable IC Memo Template

- For studies using data generated from cell lines created or clinical specimens collected **AFTER August 31,2015**
  - CCR Single Site Institutional Certification for samples collected after August 31, 2015
  - Multi-Institutional studies require an institutional certification memo from each site that are accruing samples/subjects.
- For studies using data generated from cell lines created or clinical specimens collected **BEFORE August 31,2015**
  - CCR Single Site Institutional Certification for samples collected with consent before August 31, 2015
  - CCR Single Site Institutional Certification for samples collected without consent before August 31, 2015

STEP 3: Complete the Memo Using the Template

Address Header

- Update the memo date

Subject

- Enter the study name
- Enter the project title for data to be submitted
  - The Project Title may be the same as the study name or different for studies that generate more than one set of data applicable to the GDS

Paragraph One

- Add collaborating sites in the left-hand box

Paragraph Two

- Enter study name
  - The remainder of the fields are auto-populated so verify that you agree or make any applicable changes

Data Use Limitations

Data Use Limitations are based on the terms of the informed consent of the study participants from whom the genomic data are being generated. Refer to Appendix A for further explanation of data use limitations.

- For each institution, enter the data use limitation and any data use limitation modifiers
  - Use one row for each consent group data use limitation

Signature Page

- Enter your name and title
- Sign electronically and update the date

STEP 4: Institutional Memo Approval

- Submit signed form to the Genomic Program Administrator
- The GPA will review and either return to you for revision or submit to the Scientific Director for final approval
- Scientific Director will return IC memo with e-signature to PI with a copy to the GPA
- Mail an electronic copy of the signed IC to the Protocol Support Office at nciprotocolsupportoffice@mail.nih.gov

For questions or concerns on any of aspect of creating an IC memo, please email your GPA/GPA admin for help.

Appendix A: Points to Consider in Developing Effective Data Use Limitation Statements

National Institutes of Health

Points to Consider in Developing Effective Data Use Limitation Statements

Introduction

The National Institutes of Health (NIH) promotes the broad and responsible sharing of genomic research data because it promotes the rapid advancement of science by enabling the widest utility of the data. However, NIH also recognizes that in some circumstances broad sharing may not be consistent with the informed consent of the research participants whose data are included in the dataset. A data use limitation (DUL) statement is a brief written description of limitations, if any, on the distribution and use of human data submitted to controlled-access NIH designated data repositories, such as the NIH database of Genotypes and Phenotypes (dbGaP). DULs are developed by the submitting institution and are based on the terms of the informed consent of the study participants from whom the genomic data are being generated, or otherwise stipulated by the submitting institution.

Investigators should consult with their IRB and institutions to determine whether the data can be shared and what DULs, if any, are needed for a dataset. Drafting clear, understandable DULs is critical to ensure that data are made available for the full range of appropriate uses and not for unauthorized uses. Factors to consider in developing DULs may include whether the informed consent stated that the data would be shared with other investigators, was silent on the matter of data sharing or future uses of data, or stated that the data could only be used for a specific purpose. Investigators and institutions may additionally wish to consider the original purpose of the research, the feasibility of re-consenting if appropriate, and the study participants' understanding of the secondary use of the data.

This guidance document provides points to consider when drafting DULs for data submitted to controlled-access NIH-designated data repositories under the NIH Genomic Data Sharing (GDS) Policy.

Standard Data Use Limitations

NIH provides standard categories and DULs for appropriate secondary research use. If DULs are needed, they should be specified in the genomic data sharing plan submitted as part of the funding request, and delineated in the Institutional Certification. The four main categories of consent groups are: General Research Use, Health/Medical/Biomedical, Disease-Specific, and Other. Additional modifiers to these four main categories, e.g., use by nonprofit organizations only, are described further below. Upon submission of the Institutional Certification, standard text for the DULs is automatically generated in the dbGaP registration system and can be edited as needed. Any other DULs that do not conform to the standard consent groups can be listed as "other" and explained by customized text provided by the submitting investigator.

Interpretations of the Standard Data Use Limitations

A. *General Research Use:* Data can be used for any research purpose but would not be made available for non-research purposes. These data would generally be made available to any qualified investigator, irrespective of the specific research purpose for which the data are requested. Examples of research using data for General Research Use may include, but are not limited to:

- Research on any disease or condition, even if the research is on a disease very different from the disease being studied in the original project;
- Statistical methods research and development (e.g., development of software or algorithms) that may have applications to many different diseases or conditions;
- Research on non-disease traits (e.g., intelligence, personality traits); and

- Research relating to population structure including research that involves the determination of allele frequencies in different populations or ancestries (note that applications of these types may be objectionable to members of groups that have historically been the targets of discrimination).

B. *Health/Medical/Biomedical:* Use of these data is limited to a focus on health/medical/biomedical research objectives, excluding the study of population origins or ancestry. These data would generally be made available to any qualified investigator, for:

- Research on any disease or health condition; and
- These data would not be made available for research on non-disease traits (e.g., intelligence, personality traits), or population structure or ancestral origin, with no clear relationship to disease.

C. *Genetic Studies Only:* Data can be used only for genetic studies. Examples of research using data for Genetic Studies Only may include, but are not limited to:

- Research on the role of genetics in any disease, condition or non-disease trait;
- Statistical methods development research that may have general applications to studying the genetics of different diseases); and
- Research relating to population structure, including research that may have applications or implications for the understanding of ancestral history because of the information it may provide about allele frequencies in different populations.

D. *Disease-specific:* Data can be used only for research on a specific disease or related condition. When the informed consent documents that allowed the data to be used for future studies related only to a particular disease (e.g., diabetes and related conditions), a disease-specific DUL would be appropriate.

E. *Methods:* Data can be used for statistical methods research and development (e.g., development of statistical software or algorithms).

F. *Not-for-profit Use Only:* Data can be used only by not-for-profit organizations. If the data should not be made available to commercial entities, this restriction should be stated specifically in the DUL.

G. *Publication Required:* The informed consent of the study participants requires that the investigator requesting the data and his/her institution disseminate the findings of studies using the data to the larger scientific community.

H. *IRB Approval Required:* If required by the submitting institution's IRB, approval of secondary research by the requesting institution's local IRB can be stipulated as part of the DUL. Documentation of local IRB approval, including a description of the type of review, e.g., full or expedited, would be submitted as part of the data access request which is reviewed by the DAC.