

**SOP#: RPS-22**

**Requesting a Genomic Data Sharing Exception**

**Version #: 2.1**

**Next Review Date: 03/2022**

**Approved Date: 03/2020**

**Review Interval Period: Biennial**

**NCI Clinical Director Signature:**



William L. Dahut

## **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.

The Center for Cancer Research (CCR) recognizes that in rare circumstances open or controlled access genomic data sharing may not be appropriate. Should you feel your project should be excepted from GDS, CCR will abide by the NCI central review for exceptions. A written exception request approved by the Branch Chief should be submitted to the Genomic Program Administrator (GPA) which will then be submitted to the NCI leadership for consideration. Any request for an exception must be accompanied by an Alternative Data Sharing Plan that specifies how the investigator will provide access to the data.

NCI will use the following criteria to assess the circumstances involved in the exception request:

- Impact of data sharing compliance on scientific merit
- Unique resource
- High value resource
- Regulatory considerations including consent
- Ethical considerations
- NIH data sharing exception precedents
- Is there an acceptable alternative data-sharing plan (ADSP)?
  - Impact of ADSP on data re-use
  - Impact of ADSP on data discoverability
  - Burden
  - Feasibility

## **PURPOSE**

The purpose of this standard operating procedure is to provide instructions for requesting a Genomic Data Sharing Exception.

## RESOURCES

- CCR Genomic Data Sharing [Website](#)
- [NIH Genomic Data Sharing Policy](#)
- NIH Genomic Data Sharing [Website](#)

### Genomic Program Administrators (GPA)

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### GPA Assistant

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## PROCEDURES

### Step 1: Document Preparation

- Complete the CCR Genomic Data Sharing Exception Request [Form](#)
- Included in the Exception Request form is the Alternative Data Sharing Plan (ADSP). If you require additional space, attach the ADSP as a separate document.
  - Please include the impact of the ADSP on data re-use and discoverability, burden, and feasibility.
- Provide written justification for the exception
  - Please address: scientific importance of this study; whether specimens/data are unique and/or a high valued resource; whether this research could be conducted using other methods/specimens/data; whether there are unique regulatory considerations; if the study population has specific restrictions on the use of the specimens/data; whether there are other ethical considerations; and whether there have been any other similar exceptions within NCI that establish a precedence.

### Step 2: Obtain Branch Approval

- Submit the request form to Branch Chief for approval
- Branch Chief will indicate approval via signature on the form

### Step 3: Submit to GPA

Submit the following to the GPA:

- Completed Exception Request form which includes your Alternative Data Sharing Plan
- Justification for the Exception
- Copy of the entire consent form, if applicable

#### Step 4: Review Process

GPA to review the Exception Justification Package

- If Exception Justification Package is complete and sufficiently justified:
  - GPA will forward the Exception Package with a cover memo to the CCR Scientific Director for Basic Research OR the CCR Scientific Director for Clinical Research as applicable.
  - CCR Scientific Director will make their determination and return the signed form to the GPA.
  - GPA will forward the Exception Package with a cover memo to the CCR Director.
  - CCR Director will make their determination and return the signed form to the GPA.
  - GPA will submit to the exception package with a cover memo to the National Cancer Institute (NCI) Director.
  - NCI Director will make their determination and return the exception package and the signed form to the GPA.
  - If approved by the NCI Director, GPA will submit the exception package with a cover memo to the Deputy Director of Intramural Research.
  - Deputy Director of Intramural Research will make their determination and return the signed form to the GPA.
- If the Exception Justification Package is incomplete or the exception justification is not adequate, the GPA will return the package to the PI for revision with guidance as to what things need to be addressed.
- If Exception Justification is **NOT APPROVED**, the GPA will:
  - Return the Exception Request Package to the PI for revision to ensure compliance with the GDS Policy.

#### Step 5: Exception Study Registration

- All projects/protocols that have an approved exception must still be registered in dbGaP, documenting the reason for the exception and provide the Alternative Data Sharing Plan.
  - Refer to CCR SOP RPS-23: *Registering a Clinical Trial in dbGaP* for guidance on registering the study.