

CCR Genomic Data Sharing Exception Request

Demographics

Investigator: _____

Email: _____ Phone: _____

Date: _____
Month/Day/Year

Project Information

Project Name: _____

Planned enrollment/Sample Size: _____

Collection Type

- Prospective
- Retrospective

Data

Source [check all that apply]

- Human
- Non-Human

Sample Types [check all that apply]

- Germ line
- Somatic
- DNA
- RNA
- Microbiome
- Mitochondria
- Other, please specify : _____

Type [check all that apply]

Array Data

- Single Nucleotide Polymorphisms (SNP)
- Expression Array
- Methylation Array

Genotypes

- Array Derived Genotypes
- CNV Calls from Microarray
- CNV Calls Derived from Sequencing
- Somatic SNV(.MAF)
- Array CGH CNVs

Sequencing

- Whole Genome
- Whole Exome
- Targeted Genome
- Targeted Exome
- Whole Transcriptome
- Targeted Transcriptome
- Epigenomic Marks
- Sanger
- 16S rRNA

Analysis

- Association/Linkage
- Array Derived Expression
- RNA Seq Derived Expression
- Array Derived Methylation

Other

- Other, please specify : _____

Data Form [check all that apply]

- Individual Aggregate Not applicable

Exception Justification

- Legal restrictions prohibit broad data sharing

Please describe : _____

- Informed consent inadequate to support data sharing (please complete the specific informed consent limitation(s) section below).

- Other, please specify: _____

Informed Consent Limitations(s) [complete only if applicable]

- The consent forms are unavailable or non-existent
- The consent did not explicitly address future use or broad data sharing
- The consent did not adequately address risks related to future use or broad data sharing
- The consent precludes future use or broad data sharing
- Other, please specify : _____

Please attach

- A copy of the consent(s)

GPA Consent Review [completely by the GPA]

The CCR GPA has reviewed the consent(s) provided and:

- Agrees** that the consent does not permit Genomic Data Sharing.
- Disagrees**, the consent does permit Genomic Data Sharing. Please comply with Genomic Data Sharing Policy.
- Unclear**, submitted by the GPA to the IRB for review regarding whether the consent permits Genomic Data Sharing.

IRB Consent Review [completed by the IRB at the request of the GPA]

The IRB has reviewed the consent(s) provided and:

- Agrees** that the consent does not permit Genomic Data Sharing.
- Disagrees**, the consent does permit Genomic Data Sharing. Please comply with Genomic Data Sharing Policy.

Alternative Data Sharing Plan

Please describe how access to the data will be provided. Please refer to the NIH Guidance for Investigators in Developing Genomic Data Sharing Plans https://gds.nih.gov/pdf/NIH_guidance_developing_GDS_plans.pdf Example 3 on page 4 for an example of an Alternative Data Sharing Plan.

Approvals

	DATE	APPROVAL	NAME (Typed or Printed)	SIGNATURE
Branch Chief		<input type="checkbox"/> Yes <input type="checkbox"/> No		
NCI IRB <input type="checkbox"/> Not Applicable		<input type="checkbox"/> Yes <input type="checkbox"/> No		
CCR GPA		<input type="checkbox"/> Yes <input type="checkbox"/> No		
CCR Director		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Trans-NCI Data Sharing Working Group		<input type="checkbox"/> Yes <input type="checkbox"/> No		
NCI Scientific Program Leaders Designee		<input type="checkbox"/> Yes <input type="checkbox"/> No		
NCI Director		<input type="checkbox"/> Yes <input type="checkbox"/> No		
NIH Deputy Director for Intramural Research		<input type="checkbox"/> Yes <input type="checkbox"/> No		