SAMPLE CDS-IRB APPLICATION FORM

TITLE

LEAD INSTITUTION

The relying institution through which the lead principal investigator (PI) identified on this application will conduct research.

Institution:

Address:

City: State/Province: Zip Code: Country:

Federalwide Assurance (FWA) - Provide the FWA information of the lead institution identified above. You can obtain this from your institutional official or *here*.

FWA # FWA expiration date:

Institutional Signing Official (SO) – Identify an individual who has institutional legal and signatory authority who will be responsible for the oversight of the research and who should receive copies of all pertinent IRB actions, such as approvals, and other serious actions (i.e., termination, suspension, serious and continuing non-compliance, etc).

Name:

Department/Office: Title:

Phone: Email:

Type of Institution – Check all the categories below that are applicable to the relying institution identified above. Provide any additional information, if prompted.

- ☐ Not-for profit academic institution
- ☐ Not-for-profit healthcare institution
- ☐ Not-for-profit research institution
- ☐ US institution
- ☐ International institution – identify:
- ☐ Other_For-profit entity – identify:
- ☐ For-profit academic institution
- ☐ For-profit healthcare institution
- ☐ For-profit research institution
- ☐ US Government institution - identify:
- ☐ Foreign government - identify:
- ☐ Other_Not for-profit entity - identify institution:

RESEARCH PERSONNEL OF LEAD INSTITUTION

Identify **key study personnel** which include the Principal Investigator (PI), other internal investigators and research personnel who are directly involved in contributing to the scientific development and/or execution of a project in a substantive and measurable way. This usually includes any personnel involved in the day-to-day decision-making related to the study conduct and/or data analysis. Copies of human subjects protection training certificate(s) for key study personnel and a copy of the PI's curriculum vitae (CV) must be provided.

PI Name*: Degree:

Institutional Title/Position: Dept/Div:

Email: Phone:

**If the PI does not meet the DAC required qualifications listed here then a Co-PI at the same institution who does meet the qualifications must also be designated.*

Project Point of Contact (POC) – Provide the name of a project POC, *if different* than the PI listed above.

POC Name: Phone: Email:

Local Project Team - Identify any additional key study personnel at your institution who will be working on this project. Provide their name, email, and role and responsibilities to the project. Information on collaborators at other institutions will be requested in a different section.

Name: Degree:

Institutional Title/Position: Email:

Study Role/Responsibility:

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COLLABORATING INSTITUTIONS

Provide information for all collaborating sites who will be a part of this project and conducting any type of data analysis, and/or receiving or sharing any derivative data. For each institution, indicate whether that institution will also be requesting the services of the CDS-IRB to serve as the IRB of Record for that site.

Does this project include collaborative institutions? Yes / No *If **No**, skip this section and go to Funding Information.*

Institution:

Requesting IRB review from the CDS-IRB? Yes* / No *If **No,** skip the rest of this section and either enter information for another collaborating institution or go to Funding Information.*

Address:

State/Province: Zip Code: Country:

**Institution will need to obtain a reliance agreement with either NHLBI or the SMART IRB and must be in place prior to IRB approval. Any site delayed with getting an agreement can be approved separately through an amendment to prevent delays for other institutions to move forward.*

Federalwide Assurance (FWA) - Provide the FWA information of the collaborating institution. You can obtain this from your institutional official or *here*.

FWA # FWA expiration date:

Institutional Signing Official (SO) – Identify an individual who has institutional legal and signatory authority who will be responsible for the oversight of the research and who should receive copies of all pertinent IRB actions, such as approvals, and other serious actions (i.e., termination, suspension, serious and continuing non-compliance, etc).

Name:

Department/Office: Title:

Phone: Email:

Type of Institution – Check all the categories below that are applicable to the collaborating/relying institution identified above. Provide any additional information, if prompted.

- ☐ Not-for profit academic institution
- ☐ Not-for-profit healthcare institution
- ☐ Not-for-profit research institution
- ☐ US institution
- ☐ International institution – identify:
- ☐ Other_For-profit entity – identify:
- ☐ For-profit academic institution
- ☐ For-profit healthcare institution
- ☐ For-profit research institution
- ☐ US Government institution - identify:
- ☐ Foreign government - identify:
- ☐ Other_Not for-profit entity - identify institution:

RESEARCH PERSONNEL OF COLLABORATING INSTITUTION

Identify **key study personnel** which include the Principal Investigator (PI), other internal investigators and research personnel who are directly involved in contributing to the scientific development and/or execution of a project in a substantive and measurable way. This usually includes any personnel involved in the day-to-day decision-making related to the study conduct and/or data analysis. Copies of human subjects protection training certificate(s) for key study personnel and a copy of the PI's curriculum vitae (CV) must be provided.

PI Name*: Degree:

Institutional Title/Position: Dept/Div:

Email: Phone: Other:

**If the PI does not meet the DAC required qualifications listed here then a Co-PI at the same institution who does meet the qualifications must also be designatec*

Project Point of Contact (POC) – Provide the name of a project POC, *if different* than the PI listed above.

POC Name: Email: Phone:

Local Project Team - Identify any additional key study personnel at your institution who will be working on this project. Provide their name, email, and role and responsibilities to the project.

Name: Degree:

Institutional Title/Position: Email:

Role/Responsibility:

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FUNDING INFORMATION

Provide information on how this project is being funded. Check the appropriate categories below.

- ☐ Federal funding agency //List Agency:
- ☐ Non-federal sponsor //List Sponsor:
- ☐ Foreign government //List Source:
- ☐ Other funding source //List Source:
- ☐ This research is not funded by any agency/sponsor outside my institution

Additional Funding Information - Provide any additional information that may be appropriate. For example, describe if key study personnel are funded outside of the research funding mechanism(s), or the role of any support through a foreign government, etc.

Will any of the funders and/or sponsors listed above receive any results data derived data from any of the investigators or institutions? Yes / No

*If **Yes**, describe in detail how and what data will be provided.*

NIH/NHLBI DATASET INFORMATION

For each dataset provide the following information associated with the internal dataset from the NIH cloud-based data repository for which you will be seeking access, such as the NHLBI BD Catalyst. Include the original study title, study accession number, the selected consent group, and any data use limitations (DUL) associated with that consent group.

NIH Dataset(s)

Original Study Name	Study Accession #	Consent Group *(check only one)*	DUL *(check all that apply)*	*For definitions go here.*
		☐ General Research Use (GRU) ☐ Health/Medical/Biomedical (HMB) ☐ Disease: specify _____ ☐ Other: specify _____	☐ IRB approval required ☐ Publication required ☐ Collaboration required ☐ Not-for-profit use only	☐ Methods ☐ Genetic studies only ☐ Related disorder: specify _____

Data Use Limitations (DUL) – Review the dataset DULs identified in the Data Use Certification (DUC) Agreement which you have indicated above. Confirm that your proposed research is consonant with or not inconsistent with the DUL by checking the box. ☐

Data Restrictions - Are there additional data use restrictions associated with this dataset? Yes / No *If **Yes**, describe below.*

Data Description - Provide a description of the NIH/NHLBI dataset.

Types of Data - Do any of the datasets being accessed include any of the following types of data or populations. Check all that apply.

- ☐ Genomic data
- ☐ Imaging data
- ☐ Rare disease
- ☐ Pediatric population
- ☐ Tribal population
- ☐ Small and geographically-restricted community/population (e.g., Amish, Samoan)
- ☐ Illegal activity (e.g., illicit drug use)
- ☐ Unauthorized activity (e.g., undocumented immigrant)

EXTERNAL DATASET INFORMATION

Certain NIH cloud-based repositories and platforms, such as the NHLBI BioData Catalyst, permits researchers to upload external datasets into the platform to utilize the workspace and analysis tools. For each dataset, provide the following information related to each dataset that you will be uploading into the platform to be used as a part of this project.

Will you be uploading any external datasets into the cloud environment? Yes / No *If **No**, skip this section and go to Dataset Justification.*

Data Source - Provide information on the source or where the data was obtained.

Data Restrictions - Are there any data use restrictions associated with this dataset? Yes / No *If **Yes**, describe below.*

Data Description - Provide a detailed description of the data. Indicate the variables of interest, any type of identifiers, population information, limitations, etc.

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Types of Data - Do any of the datasets being accessed include any of the following types of data or populations. Check all that apply.

☐ Genomic data	☐ Pediatric population	☐ Illegal activity (e.g., illicit drug use)
☐ Imaging data	☐ Tribal population	☐ Unauthorized activity (e.g., undocumented immigrant)
☐ Rare disease	☐ Small and geographically-restricted community/population (e.g., Amish, Samoan)	

DATASET JUSTIFICATION

Provide justification for why the listed dataset(s), and if applicable, the combining or linking of those datasets are appropriate in addressing your hypothesis and/or scientific question(s). *Your justification should refer to both NIH cloud-based data and any external data.*

Population – Provide justification for any limits that will be applied to populations (e.g., European ancestry only).

EXTERNAL APPLICATIONS AND TOOLS

Certain NIH cloud-based repositories and platforms, such as the NHLBI BioData Catalyst, permits researchers to upload external applications and analysis tools into the platform to utilize with the data. For each application and/or analytic tool, provide the following information.

Will you be uploading and utilizing any applications or analytical tools into the NIH cloud-based platform for computing and analysis? Yes / No *If **No**, skip this section and go to Analysis Results Data.*

External Applications and Tools- List and describe any external applications and/or tools that will be uploaded to the NIH cloud-based platform and utilized for data computing and analysis.

ANALYSIS RESULTS DATA

The NIH cloud-based computing platforms do not permit the downloading of individual level data. However, the downloading of meta-data, analysis results, or genomic summary results (GSR) data are permitted in accordance with NIH GSR policy and security best practices. Briefly describe the *expected* type of GSR or analysis results data that will be downloaded from the platform (e.g., allele frequency information, association analysis statistics, etc.) and indicate who will have access. Specific analysis will be requested in a later section.

PROJECT INFORMATION

In a separate document, compose a detailed research plan that includes, at a minimum, the categories listed below.

Note: For each section, ensure the information is readily accessible to a non-expert audience, otherwise the application may be returned to you for further information which will delay the IRB review.

Summary - Provide a non-technical summary, to include the research background and rationale for this research project.

Purpose – State the hypothesis or research questions. Include the purpose and primary and secondary objectives of the proposed research.

Methods - Describe the research methods, procedures, techniques, and covariates. If applicable, describe the process of how datasets will be combined or linked and who will have access to any codes. If any methods are to be performed collaboratively, please specify who will be performing which procedures.

Data Analysis - Describe the data analysis plan, including (anticipated) primary and secondary outcomes. Include any phenotypic characteristics that will be evaluated in association with genetic variants.

Research Benefit – Describe the anticipated benefits from this study and include in what way(s) it will contribute to generalizable knowledge.

Research Risks – Describe any potential and reasonably foreseeable risks of harm, discomforts, or inconveniences to the original participants, the group, community, and/or society to which they may belong. Risk remediation will be asked in the next section.

RISK MANAGEMENT

The IRB is responsible for evaluating potential risks and weighing the probability of the risk occurring and the magnitude of harm that may result. Please be diligent in your consideration of potential risks that may apply if a data breach and/or the re-identification of an individual or small group

should happen. Applications that incompletely describe the potential risks and the management of those risks frequently result in requests for more information.

Note: *Write NA, if not applicable or if you have previously addressed an item in this section, provide a reference (e.g., See section X in research plan document, etc.) in the text field.*

Risk Mitigation - Previously, you were asked to describe any potential or foreseeable risks. Outline the measures to be taken to reduce or manage those risks, OR if you indicated there were **no** potential or foreseeable risks, provide a rationale on why you think that is the case.

Linked Data - If the NIH data will be **combined or linked** with other NIH or external data could the linkage introduce any new risks, such as re-identification or unintended consequences? *If **Yes**, explain.*

External Analytical Tools - Could any of the you will be uploading into the cloud-based platform introduce any new risks, such as re-identification or unintended consequences? *If **Yes**, explain.*

Re-evaluate your proposed data use, triangulation of data or data linking/combining *(if applicable)* and your methods of analysis. Are any of the following possible? *Explain, if prompted*.

- ☐ Identifiability of an individual participant (e.g., they have distinctive characteristics, a rare or ultra-rare disease, or the use of genomic or imaging data)
- ☐ Identifiability of a subgroup of participants (e.g., due to a proposed method of analysis that combines variables in ways that identify small groups within a larger population)
- ☐ *No/Not applicable.*

Now, consider the following situations, even if unlikely:

- a breach of confidentiality occurred, or
- an original participant/individual was re-identified, or
- your results include information about a sensitive population

Check any of the possible consequences below that could apply either to an individual or to a population. If applicable, ensure this information is captured in your Research Plan.

- ☐ emotional distress, embarrassment
- ☐ loss of reputation/standing within the community
- ☐ loss of income
- ☐ loss of professional standing/reputation
- ☐ disclosure of illegal activity (e.g., illicit drug use)
- ☐ disclosure of negligence
- ☐ loss of employment, insurability, or loss of insurance due to profiling
- ☐ harms to a larger group/community beyond the subjects of the study (e.g., stigmatization)
- ☐ disclosure of unauthorized activity (e.g. undocumented immigrant)
- ☐ *None of these consequences are known to apply to this project.*

Explain the **procedures** that will be taken if through your analysis or other accidental means you **do re-identify or have the potential to re-identify individuals**.

LOCAL AND STATE LAWS

Culturally appropriate procedures and an understanding of local context are an important part of protecting research participants and their communities.

Note: *It is the responsibility of the relying institution(s) and submitting researcher(s) to provide information of all applicable local, state, or tribal laws and regulations, and to maintain compliance with those laws and regulations.*

Are there any local, state, or tribal laws and regulations that may affect the research, how it is conducted, and/or how the results may impact the original participants or the communities to which they belong? Yes / No

*If **Yes**, describe these **local, state, or tribal laws and regulations** below. Provide law code references (if applicable).*

Reporting - Describe the **process for reporting** and ensuring compliance with local requirements.

REPORTING REQUIREMENTS

CDS-IRB policy requires the PI and associated institution to report any of the following events directly to the IRB within 24 hours of learning of the event. A reportable event consists of any event that is unanticipated and serious or suggests that the research places subjects or others at greater risk than was previously recognized. When reporting an event include a detailed description of the event, any actions taken or planned to be taken, and a plan to prevent this event in the future. Some reportable events include:

- Re-identification of individuals
- Data breach

Reporting - Provide the following information for the **process of communicating reportable events to the CDS-IRB**. Identify the responsible party who will report the events to the CDS-IRB, their email address, and their role at your institution. *This could be the institutional official, other institutional officer, researcher, study team member, or study monitor.*

Reporting Process - Describe the process for how reportable events are reported at your institution.

DATA SECURITY

Provide information related to the security measures that will be taken at the research site.

Security Measures - Describe the data security measures that will be taken for any GSR or results data downloaded from the cloud platform (e.g., training, authorization of access, password protection, encryption, physical controls, etc.).

Data Management - Describe how any GSR or results data will be managed at the local level. Include how data will be stored, who will have access, and if applicable whether any of the downloaded results data will be shared and/or transferred, describe with whom, how, and what.

Additional Security Information - Provide any other relevant information concerning data security.

ADDITIONAL COMMENTS

Provide any additional comments that may be pertinent for the CDS-IRB to take into consideration during their review.

RESEARCHER ASSURANCE SIGNATURE

By signing below, you are attesting that you and your research team have read and are knowledgeable of the PI responsibilities and requirements of conducting the research as described within this document.

Lead PI Signature. The signature of the Lead PI is required before this application may be processed *(electronic signatures are acceptable).*

_____ _____

Lead Principal Investigator *Date*