

Charter of the Clinical Data Science Institutional Review Board

I. Authority

This Charter empowers the Clinical Data Science Institutional Review Board (CDS-IRB) established under the Institutional Review Board for the Extramural Research Program (IRB for the ERP) of the National Heart, Lung, and Blood Institute (NHLBI).

The NHLBI IRB for the ERP has one IRB registered with the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP): IRB00011784 and FWA00027544.

II. Principles

1. The CDS-IRB is guided by principles delineated in the [Belmont Report](#), provisions of the Code of Federal Regulations (CFR) [Title 45 Part 46](#) (Protection of Human Subjects), [NIH scientific data sharing policies](#), and the CDS-IRB standard operating procedures (SOPs). This document summarizes the roles and responsibility of the CDS-IRB in the confidentiality of research participant data, including maintaining their privacy, and ensuring that their stipulations regarding the future use of their data are upheld.
2. Fundamental ethical principles that underlie ethics review of secondary research include those elucidated in the Belmont Report - respect for persons, beneficence, and justice - as well as nonmaleficence and considerations beyond the individual for the community and society. The key principles include:
 - *Principle: Beneficence and Respect for Persons*
Respect must be given to matters of identity, privacy, dignity, and confidentiality as they pertain to the individuals and communities from and/or about whom the data are collected.
 - *Principle: Respect for Persons*
Indirect respect to persons by ensuring secondary use of data is consistent with the Data Use Limitations (DUL).
 - *Principle: Beneficence/Nonmaleficence*
An obligation to do no harm and to maximize possible benefits and minimize possible harms (e.g., minimize risks to harm).
3. The [NIH Genomic Data Sharing policy](#) delineates practices for the responsible sharing of genomic research data. This includes mechanisms such as:
 - Controlled-access to sensitive individual-level research data and the use of data access committees
 - Institutional Certification of genomic data sharing plans outlining any data use limitations associated with the data at the time of original data collection.
 - Data de-identification in accordance with HHS regulations and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.
 - Certain NIH genomic databases maintain Certificates of Confidentiality as a precautionary measure to protect the privacy of research participants in the case of re-identification. These certificates prevent any forced disclosure of identifiable,

sensitive research information of participants to those outside the research in civil, criminal, administrative, legislative, or other proceedings.

- Expectations related to data security measures.

III. Purpose of the CDS-IRB

The CDS-IRB provides regulatory and ethical guidance on human subjects research and other types of research requiring IRB oversight. The CDS-IRB is responsible for:

1. Advising the Institutional Official (IO) of the NHLBI IRB for the ERP on issues related to the protection of research participants.
2. Ensuring a consistent and comprehensive review that comports with IRB policy, federal regulations, and ethical principles especially as they relate to secondary analysis of existing data.
3. Facilitating communications and exchange of information about human research protection among the NHLBI IRB for the ERP research community.
4. Advising the IO of the NHLBI IRB for the ERP regarding the suspension of human research privileges and reporting to federal authorities in matters involving noncompliance, unanticipated problems, and suspension and termination of research.
5. Providing IRB oversight for extramural institutions who cede the IRB review requirement to the CDS-IRB under an authorized agreement.

IV. Scope of the CDS-IRB

1. The CDS-IRB advises and makes recommendations to the IO of the NHLBI IRB for the ERP on human subjects research (HSR) and research that may qualify as non-human subjects research but nevertheless requires IRB oversight based on the data use limitations set forth by the original institution that submitted the data to the NIH repository. This includes secondary analyses of existing data, images, and samples maintained in the NHLBI BioData Catalyst.
2. In accordance with this Charter, ethical guidance, CDS-IRB SOPs, institutional policies, applicable federal regulations, state and local laws, and when the CDS-IRB is serving as the IRB of record under an IAA, the CDS-IRB has the authority to:
 - Approve, disapprove, or modify, research based upon consideration of any issue it deems relevant to human subject protection.
 - Suspend or terminate approval of research not being conducted in accordance with the CDS-IRB's requirements or that has been associated with unexpected serious harm.
 - Require progress reports from the investigators and oversee (or observe) the conduct of the research.
 - Access and make copies of records related to any research approved by the CDS-IRB for any reason, regardless of the location of those records.
 - Evaluate financial interests of investigators and research staff that have submitted conflict of interest statements and any management plans in the decision to grant final approval.

- Research that has been approved by the CDS-IRB may be subject to further review and approval or disapproval by institutional officials. However, no institutional official can approve research to move forward if it has not been approved by the CDS-IRB.

V. Appointment to the CDS-IRB

1. NHLBI IRB for the ERP solicits names for appointments from a variety of sources (e.g., advocacy groups, federal agencies, and professional organizations). The names of persons in ethics, healthcare, or advocacy who have demonstrated expertise, experience, and interest regarding the protection of the rights and welfare of study participants are considered for appointment.
2. When selecting members, consideration is given to assuring appropriate diversity by profession, ethnic background, and gender, and to include both non-scientific and scientific members. Consideration is also given to the representation of sensitive populations.

VI. Membership of the CDS-IRB

1. The CDS-IRB is composed of at least five voting members, including the Chair.
2. The CDS-IRB does not designate alternate members; however, it may consult unaffiliated subject matter experts for a specific review if requested by the CDS-IRB Chair.
3. The CDS-IRB is composed of qualified members with varying backgrounds and expertise in special areas to facilitate appropriate and comprehensive review of the research. Areas of expertise may include, but are not limited to medicine, clinical research, law, privacy, ethics, genetics and genomics, data science, population research, epidemiology, and public health.
4. The CDS-IRB has at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
5. None of the CDS-IRB members are employees of the NHLBI.
6. CDS-IRB members who indicate a perceived or actual conflicting interest with any research under review will be recused from that discussion and from voting on that application. If requested, they may provide information about the proposed project to inform the IRB review.
7. When the CDS-IRB reviews research involving vulnerable or sensitive populations, consideration is given to seeking the input of one or more individuals who are knowledgeable about and experienced in working with that population.

VII. Management of the CDS-IRB

1. The CDS-IRB is administratively responsible for reporting to the IO of the NHLBI IRB for the ERP.
2. The CDS-IRB Chair presides over all review sessions and convened IRB meetings and has the authority to sign all actionable IRB items.
3. Members are generally asked to serve a two-year term. Terms may be renewed based on member interest, availability, and performance. Members may resign by notification

to the IO of the NHLBI IRB for the ERP. Members may also be terminated by notification from the IO of the NHLBI IRB for the ERP.

4. All CDS-IRB members are required to attend an orientation session that covers the structure and mandate of the CDS-IRB, the Belmont Report, applicable federal regulations, and NIH data sharing policies.
5. All CDS-IRB members must have completed training in the protection of human subjects that meets the requirements of the CDS-IRB policy. Members must provide documentation of completion to the CDS-IRB Office. Continuing education and/or training must be completed at least once every three years.

VIII. Operations of the CDS-IRB

1. Meetings are held as needed and may consist of expedited review sessions/designated ethics review, review of research requiring a convened board, or both. Agenda, research material to be reviewed, and reviewer assignments are distributed at least seven days prior to the meeting.
2. With the exception of expedited review/designated ethics review, research applications and required lifecycle actions (i.e., amendments, continuing review, reportable events, etc.) will be reviewed at convened meetings where at least a simple majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas. For an initial review or lifecycle action to be approved by the CDS-IRB, a simple majority of those members present at the meeting must have voted in favor of the action.

IX. Responsibilities of CDS-IRB Members

1. IRB members should be familiar with the ethical principles underpinning the IRB's reviews, research ethics, applicable federal regulations, and the CDS-IRB policies germane to human subjects protection.
2. CDS-IRB members are expected to fully understand the responsibilities and commitment of membership as described during their orientation.
3. Members shall be responsible for initial and continuing ethical review of research that requires IRB oversight and that the CDS-IRB has been designated as the IRB of record for a relying institution. Additionally, members shall be responsible for the review of proposed changes in approved research, review of unanticipated problems, and review of reports of serious or continuing noncompliance.
4. CDS-IRB members must disclose conflicts of interest and recuse themselves from participating in the discussion and voting on any research with which they have a conflict of interest.

X. Responsibilities of the CDS-IRB Office

1. The CDS-IRB is managed through the CDS-IRB Office which provides administrative coordination of the IRB with the NHLBI program, the institutional officials, researchers, relying institutions, and the research community.
2. The CDS-IRB Office manages and maintains the Federalwide Assurance (FWA) and reports to OHRP on renewals and any changes within set timelines.

3. The CDS-IRB Office prepares and maintains adequate documentation of IRB activities, and retains this documentation for at least three years, or three years after completion of the research. Documentation includes:
 - All research submission documentation for all lifecycle actions;
 - All correspondence between the IRB, investigators, relying institutions, and any other correspondence related to the research;
 - Correspondence or documents generated by the CDS-IRB;
 - IRB rosters.
4. The CDS-IRB Office receives, prepares, and distributes the necessary documentation and meeting materials to CDS-IRB members for their review. Additionally, office staff provide and manage the setting for holding the IRB meetings.
5. The CDS-IRB Office in collaboration with the CDS-IRB Chair prepares and provides educational materials to the CDS-IRB members and the NHLBI IRB for ERP community.

XI. Responsibilities of the NHLBI (NHLBI IRB for ERP)

1. The NHLBI is responsible for upholding the institutional commitment and its role in ensuring the rights, safety, and welfare of all human subjects in accordance with their Federalwide Assurance (FWA).
2. The NHLBI assumes responsibility for communicating and explaining the institutional commitment and ethical principles under the FWA in the protection of human subjects to personnel, and for providing procedural guidelines to affect their observance.