IHCC Governance & Policies Documents
Title: IHCC Core Data Sharing Principles
Version: 1.0
Date Approved: 18-Nov-2020
Document Owner: Team Policy & Bio-Data Sharing

International 100K Cohort Consortium

IHCC Core Data Sharing Principles

Overview –

The purpose of the IHCC Core Data Sharing Principles is to provide an outline of fundamental data sharing expectations for IHCC research activities. These principles will be used as a basis for drafting data sharing policies or guidance for use in specific IHCC Projects, and eventually across all IHCC initiatives.

Background:

The vision of the International HundredK+ Cohorts Consortium (IHCC) is to facilitate translational research that will be maximally utilized to enhance scientific understanding of the biological, environmental, and genetic basis of disease and to improve population health. In conducting its activities, the IHCC supports open and timely access to IHCC-generated research findings (i.e., those resulting from an IHCC Project approved by the Scientific Projects Sub-Committee). The Core Data Sharing Principles defined below will underpin IHCC data sharing guidelines and practices developed for implementation in specific IHCC Projects and, with time, provide a broad framework for all IHCC initiatives.

The Core Data Sharing Principles draw upon an ethical foundation described in the *Framework for Responsible Sharing of Genomic and Health-Related Data* developed by the Global Alliance for Genomics and Health (GA4GH). As shown below, the framework articulates four foundational principles to guide the application of ten core elements through which to govern data sharing policies and practices in a manner that respects individuals' rights to participate in and enjoy the benefits of scientific research and to have their privacy, dignity, and other material interests protected. The Framework assumes that data donors (or their legal representatives) have provided consent for data use and that ethics oversight consistent with local, national, and relevant international laws as well as culturally appropriate ethics standards and best practices for governing future data use have been applied.

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GA4GH's Framework for Responsible Sharing of Genomic and Health-Related Data

Foundational principles for responsible sharing of genomic and health-related data:

- Respect Individuals, Families and Communities
- Advance Research and Scientific Knowledge
- Promote Health, Wellbeing and the Fair Distribution of Benefits
- Foster Trust, Integrity and Reciprocity

Core Elements of responsible data sharing:

- Transparency
- Accountability
- Engagement
- Data quality and security
- Privacy, data protection and confidentiality
- Risk-benefit analysis
- Recognition and attribution
- Sustainability
- Education and Training
- Accessibility and dissemination

Purpose:

The IHCC Core Data Sharing Principles will inform the development of data sharing practices or any broad guidances developed for conducting IHCC Projects. Implementation of these principles in specific IHCC Projects will be informed by and interpreted through participating IHCC Member cohorts' data sharing capacities and any existing cohort-specific or relevant local and national policies.[1]

The Core Data Sharing Principles will remain a living document and be updated as experience working with IHCC Members to develop IHCC Project-specific data sharing plans is accrued. The Policy and Biodata Sharing Workgroup will present proposed updates to the Core Data Sharing Principles to IHCC Members for comment and feedback prior to submission to the Scientific Steering Committee for review.

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[1] IHCC Members should provide information on cohort-specific data sharing and access parameters by completing the IHCC Policy Questionnaire.

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Core Data Sharing Principles:

Foundational Principles

The Foundational Principles provide a basic rubric that expresses IHCC values in support of achieving the IHCC vision. They should be considered and applied *en masse*. Each principle contributes to the collective intent to promote public trust and timely access to research by ensuring responsible and appropriate data sharing in all IHCC-related activities. Therefore, the expectation is that these principles will be understood as a whole and applied in good faith.

1. Any access to IHCC-generated or underlying IHCC Member cohort data will occur through robust data management practices to promote consistency with research participant/data donor consent.

2. All relevant institutional, local, and national privacy, data security, and research ethics policies, regulations, or laws pertinent to participating IHCC Members will be followed in any IHCC Project and any IHCC data sharing activities.

3. No individually identifying information, or information anticipated to pose substantial risk to research participant confidentiality, should be shared within IHCC activities or through any future IHCC-directed data access models without appropriate local approval(s) and adequate safeguards to protect against individual identity disclosure.

4. IHCC Members participating in an IHCC Project will provide maximally appropriate access to cohort data, including pre-publication sharing of findings of summary results, for Project collaborators based on research participant consent, the scientific aims and study design of the IHCC Project, and any legal limitations.

5. IHCC-generated findings and relevant underlying data or metadata from an IHCC Project should be made accessible to the scientific community through maximally appropriate mechanisms no later than12 months after completion of initial quality control or at the time of first publication, whichever occurs first.

Aspirational Principles

The Aspirational Principles are intended to encourage IHCC Members to optimize cohorts' data access procedures for both IHCC Members and the broader scientific community to promote disease understanding and improve health in accord with IHCC strategic goals. The application of these principles should be interpreted as complementary and in addition to the Foundational Principles.

6. IHCC Members will work to develop streamlined data access procedures consistent with relevant ethics oversight practices for IHCC Project collaborators and other IHCC Members, including prior to publication of IHCC Project Papers when appropriate.

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7. IHCC Members will support maximally appropriate secondary research access by the broad scientific community to relevant cohort data or summary results used in IHCC Projects according to any governing cohort policies and local or national laws.

8. IHCC Members will optimize access mechanisms for secondary research access by the broad scientific community to cohort data types (e.g., summary results, meta-data, or individual-level data) consistent with their cohort participants' consent and local or national laws within two years of signing the IHCC Membership Agreement.

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Revision History

Version Number	Section(s)	Summary of changes	Updated by	Approved by	Date
0.0	All	Drafts updates: -The Purpose portion of the document was edited to clarify that the principles will be used to inform development of IHCC Project-specific data sharing plans and implemented according to the data sharing capacities and policies of participating cohorts in each Project. -A more explicit statement was added to note that the Core Data Sharing Principles are intended to serve as a living document to be updated based on experience conducting IHCC Projects across the various cohorts. -The Principles themselves were re-ordered and edited to improve clarity and flow. No principles were moved between the Foundational and the Aspirational categories.	Laura Rodriguez		
1.0	All	Initial approved version	Laura Rodriguez	Steering Committee	18-Nov-2020

Highlights within the Draft Data Sharing Principles leading to V1 –

- Proposes that IHCC data sharing principles (and thus any future policy or guidance) rely upon the GA4GH Framework for Responsible Sharing of Genomic and Health-Related Data as an ethical foundation for data sharing activities.

- Identifies a set of Foundational Principles designed to promote IHCC strategic goals (e.g., broad and timely dissemination of research data), while recognizing cohort-specific data access requirements/processes and nation-specific laws.

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- Proposes a set of Aspirational Principles to move IHCC Members toward implementation of long-term IHCC data sharing goals to support the IHCC vision (e.g., creating streamlined data access procedures) while recognizing that it may not be possible for cohorts to accommodate these long-term goals at this time.

- Indicates that any future development of a trans-IHCC data sharing policy will be shared with the IHCC membership for feedback prior to submission to the Scientific Steering Committee for review and approval.