

DRAFT IHCC Core Data Sharing Principles

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Overview –

The purpose of the Draft IHCC Core Data Sharing Principles is to provide an outline of fundamental data sharing expectations for IHCC research activities. Once approved, 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.

Highlights within the Draft Data Sharing Principles –

- 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.
- 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.

Substantive 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.

Draft IHCC Core Data Sharing Principles

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.

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

27 principles in specific IHCC Projects will be informed by and interpreted through participating
28 IHCC Member cohorts' data sharing capacities and any existing cohort-specific or relevant local
29 and national policies.¹

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31 The Core Data Sharing Principles will remain a living document and be updated as experience
32 working with IHCC Members to develop IHCC Project-specific data sharing plans is accrued.

33 The Policy and Biodata Sharing Workgroup will present proposed updates to the Core Data
34 Sharing Principles to IHCC Members for comment and feedback prior to submission to the
35 Scientific Steering Committee for review.

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37 **Core Data Sharing Principles:**

38 *Foundational Principles*

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

- 44 1. Any access to IHCC-generated or underlying IHCC Member cohort data will occur
45 through robust data management practices to promote consistency with research
46 participant/data donor consent.
- 47 2. All relevant institutional, local, and national privacy, data security, and research ethics
48 policies, regulations, or laws pertinent to participating IHCC Members will be followed in
49 any IHCC Project and any IHCC data sharing activities.
- 50 3. No individually identifying information, or information anticipated to pose substantial risk
51 to research participant confidentiality, should be shared within IHCC activities or through
52 any future IHCC-directed data access models without appropriate local approval(s) and
53 adequate safeguards to protect against individual identity disclosure.
- 54 4. IHCC Members participating in an IHCC Project will provide maximally appropriate
55 access to cohort data, including pre-publication sharing of findings of summary results,
56 for Project collaborators based on research participant consent, the scientific aims and
57 study design of the IHCC Project, and any legal limitations.
- 58 5. IHCC-generated findings and relevant underlying data or metadata from an IHCC
59 Project should be made accessible to the scientific community through maximally
60 appropriate mechanisms no later than 12 months after completion of initial quality control
61 or at the time of first publication, whichever occurs first.

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63 *Aspirational Principles*

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

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

- 69 6. IHCC Members will work to develop streamlined data access procedures consistent with
70 relevant ethics oversight practices for IHCC Project collaborators and other IHCC
71 Members, including prior to publication of IHCC Project Papers when appropriate.
- 72 7. IHCC Members will support maximally appropriate secondary research access by the
73 broad scientific community to relevant cohort data or summary results used in IHCC
74 Projects according to any governing cohort policies and local or national laws.
- 75 8. IHCC Members will optimize access mechanisms for secondary research access by the
76 broad scientific community to cohort data types (e.g., summary results, meta-data, or
77 individual-level data) consistent with their cohort participants' consent and local or
78 national laws within two years of signing the IHCC Membership Agreement.

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