

# International HundredK+ Cohorts Consortium

## Membership Agreement

This Membership Agreement outlines requirements and expectations by which members of the International HundredK+ Cohorts Consortium (IHCC) agree to collaborate.

### 1. Vision

The IHCC is a global network of large cohorts with multi-dimensional data from diverse populations. IHCC aims to facilitate translational research that will be maximally utilized to enhance scientific understanding of the biological, environmental and genetic basis of disease and research to improve population health.

The IHCC values inclusivity of scientific expertise and diversity in cohort populations and data. The consortium supports open and timely access to research outputs generated through any IHCC activity. The IHCC promotes transparency in process, practice, and outcomes in all projects and policies.

### 2. Governance

The **IHCC Executive Committee (EC)** has 7 members:

- **IHCC Co-Chair(s):** Co-Chair(s) are accountable to the funders and to the membership of IHCC for delivering the objectives of IHCC. Chair(s) are appointed for a 5-year renewable term. From May 2023, Chair(s) are appointed through a simple majority vote of the Scientific Steering Committee.
- **Executive Members:** Executive Members are appointed through nomination from any IHCC Cohort Member and are voted in by the Scientific Steering Committee through a simple majority vote. Executive Membership terms are for 3 years and are staggered (a change in membership of one Executive Member each year).

The functions of the EC comprise:

- Responsible to the members and funders of IHCC to deliver the strategic objectives of IHCC.
- Direct the administrative activities of IHCC including financial management of the IHCC budget.
- Lead funding procurement to meet the needs of the organization.
- Provide fiduciary responsibility to ensure the consortium can operate and execute on its projects and infrastructure.
- Provide assignments to Workgroups.
- In the unusual circumstance that individual IHCC members cannot resolve conflicts independently, resolve any disputes that arise within IHCC by reconciling differences of opinion or approach.

The **IHCC Scientific Steering Committee (SSC)**. The SSC has 15 voting members. These comprise:

- **Cohort representatives:** Cohort Members elected by the IHCC membership to represent the diversity of the membership of IHCC.

- Workgroup co-Chairs: elected by the SSC.

Executive Committee Members can attend the SSC as observers but do not vote as the SSC provides strategic advice to the EC. Membership of the SSC is for 3 years, with staggered membership terms.

The functions of the Scientific Steering Committee comprise:

- Vote on Executive Membership of the EC
- Provide guidance to the EC on the long-term strategic direction of IHCC
- Approve program goals set out by the EC
- Commission and approve papers explaining IHCC policy and views
- Review and provide formal acceptance of IHCC-wide policies, protocols, and procedures including this IHCC Membership Agreement
- Approve new IHCC members (Cohort Members, Affiliate Members and Industry Members) by majority vote.
- Vote on Workgroup chairs (current workgroup chairs excused from voting)

The SSC has a sub-committee, chaired by a member of the SSC:

- Scientific Projects Sub-Committee: This committee reviews and approves IHCC scientific projects, including those involving partnerships with external organizations or Industry Members, and provide feedback regarding process, goals, and timelines.

The SSC may create **IHCC Workgroups** to carry out governance functions integral to IHCC activities, recruiting individuals with relevant expertise from among the IHCC membership to serve on these workgroups. Workgroups are responsible for leading specific areas of IHCC strategy, policy, and delivery. Workgroup Chairs provide regular updates on their work to the SSC. Current (2020) IHCC Workgroups comprise:

- Data Standards and Interoperability Workgroup
- Scientific Strategy and Cohort Enhancements Workgroup
- Policy and Bio-Data Sharing Workgroup

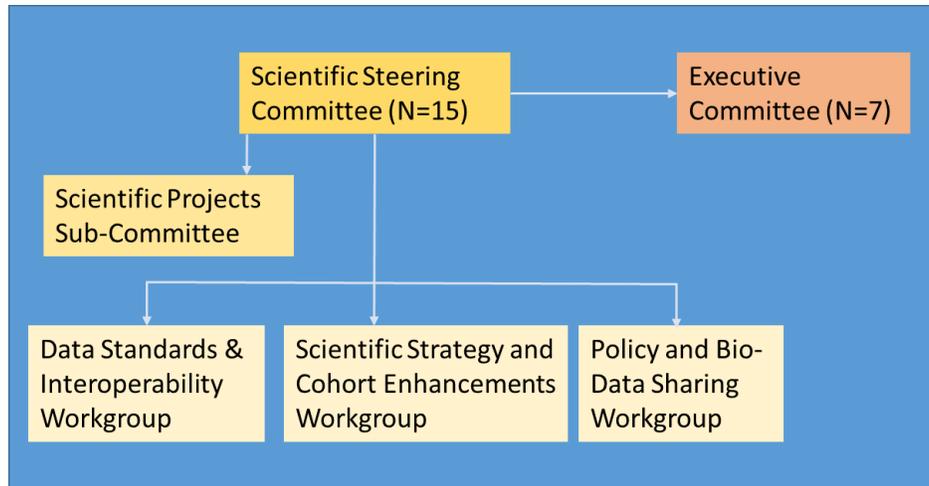


Figure 1: Organogram of IHCC Committees and Workgroups

### 3. Membership

The IHCC recognizes three types of members: Cohort Members, Industry Members, and Affiliate Members. All IHCC members are expected to adhere to any applicable local and international laws governing the use and sharing of human subject data. All Members are required to abide by IHCC policies and principles including those written in this Membership Agreement. IHCC members also agree to abide by future policies agreed by the SSC.

#### 3a. IHCC Cohort Member

The following criteria define eligibility for Cohorts to be members of IHCC:

- Cohorts from any country with 100,000+ participants enrolled.  
AND
- Cohorts with longitudinal follow-up for health outcomes.  
AND
- Cohorts without selection based on a specific disease process or a particular existing condition.  
AND
- Cohorts with participants who have contributed biological samples. Cohorts with the ambition to collect samples but who have not yet done so can be Affiliate Members.  
AND
- Cohorts willing and able (through having the appropriate consents and/or human subject ethics committee approval) to share data or metadata with IHCC members.

Cohorts with less than 100,000 participants can apply to be a Cohort Member if they include low- and middle-income country/countries, and/or cohorts of disadvantaged populations in high income countries, and/or collect data from exceptional, unique, or hard to accrue groups.

If a cohort has collected biological samples from less than 100,000 participants, the approved cohort protocol must allow for biological sample collection with demonstrated ability to collect biological samples in a subset of the cohort.

Cohorts who align with the aspirations of IHCC but who have not yet met full criteria for membership will be assessed on a case by case basis by the SSC.

**Cohort Membership** shall be granted to a cohort by a majority vote of the SSC based on the cohort completing and submitting this Membership Agreement, attesting that the cohort meets the eligibility criteria. Membership refers to the cohort entity rather than individuals. Upon joining IHCC, the cohort must designate a delegate who will represent the cohort on voting matters and serves as the primary contact for the cohort. Each Cohort Member is entitled to one vote in IHCC ballots (e.g. nomination and election of Scientific Steering Committee members). Consortiums made up of smaller cohorts can join IHCC as a single Cohort Member, with each consortium entitled to one vote. Cohort members can withdraw their membership of IHCC (including their data) at any time by informing the Executive Committee.

### **3b. IHCC Affiliate Members**

The IHCC welcomes Affiliate Members who do not fulfill the criteria for full Cohort Membership. Affiliate Members may bring specific expertise to IHCC, for example expertise in biobanking, genomics, data standards, IT infrastructure, or data analytics, but do not bring a cohort into IHCC. Cohorts who plan to enroll 100,000+ participants but are still in the process of recruitment, are also eligible to be Affiliate Members. Cohorts with 100,000+ participants who have not yet and do not intend to collect biological samples can be Affiliate Members and contribute to cross-cohort analyses which do not require the analysis of biological samples (for example on social, environmental, anthropometric, health behaviors and other risk factors). Affiliate membership is decided by the SSC. IHCC Affiliate Members are required to sign and abide by this Membership Agreement. Affiliate members do not have voting rights but can lead or be members of Project Teams and have access to IHCC data under the same terms as Cohort Members.

### **3c. IHCC Industry Members**

The IHCC aims to strengthen links between academic and industry/commercial sector researchers, where collaboration is consistent with our vision of enhancing the understanding of the biological, genetic, social and environmental basis of disease, and to improve population health. Where they contribute a cohort which meets the membership criteria, Industry Members are eligible for Cohort Membership. Industry Members agree to abide by the IHCC Guidance for Collaboration with Industry. Industry membership is decided by the SCC. IHCC Industry Members are required to sign and abide by this Membership Agreement. Industry Members do not have voting rights unless they are also Cohort Members but can lead or be members of Project Teams and have access to IHCC data.

## **4. IHCC Projects**

Any IHCC member may propose a project for approval by the Scientific Projects Sub-Committee, a sub-committee of the Scientific Steering Committee. The IHCC is committed to sharing data with the scientific community. Access to and use of IHCC-managed data is limited to projects that have obtained Scientific Projects Sub-Committee approval.

### **Project approval process**

IHCC members wishing to initiate a project must establish a Project Team and complete a Project Proposal Form. Projects should be initiated by submitting a Project Proposal Form to the Scientific Projects Committee. Project Proposals should include the following:

- a. Title
- b. Project lead and team members
- c. Background to the proposed project, including analysis plan and provisional budget
- d. Aims/approach
- e. List of participating IHCC partners (Cohort Members, Affiliate Members and Industry Members)
- f. List of non-IHCC collaborators
- g. Confirmation that participating cohorts have consent to share data consistent with the project aims and IHCC values
- h. Proposed data required to participate
- i. Preliminary timeline
- j. A publication and authorship plan
- k. Data management plan
- l. Description of where funds have been/are being sought for the project

All proposals will be distributed to all Scientific Projects Sub-Committee members. Each proposal will be discussed during Scientific Projects Sub-Committee meetings and approved by consensus. All approved Project Proposals will be made available to the full IHCC membership so that members can see which projects have been approved and members can request to join Project Teams/contribute data if appropriate. Team Leaders are responsible for obtaining the relevant and required ethics approvals before commencing work IHCC approved projects.

Project Team Leaders are required to

- a. Establish a Project Team that ensures the successful completion of the project;
- b. Report progress to the Scientific Projects Sub-Committee on a regular basis as defined by that Committee;
- c. Ensure that all communication of research results (abstracts, manuscripts, etc.) abide by the [IHCC Publication Policy](#) including ensuring that all publications arising from these projects are published in open access format.

## **5. Data Management Requirements**

In most cases, data generated by IHCC Projects (e.g. genotype, phenotype, demographics, health information, etc.) will be securely stored and managed by participating cohorts using a federated model of data storage and access. No identifying information (e.g. names, medical record numbers) should be shared or made publicly available without complying with local data protection legislation, ethics approval and adequate safeguards to protect against individual identity disclosure.

It is possible that for specific projects some data types (e.g. sequencing data) may be stored on another data platform at the request of the Scientific Projects Sub-Committee, and as agreed upon by participating Cohort Members. In such circumstances, equivalent Data Management Requirements will be respected and will be made transparent to IHCC members via project description and pending Scientific Projects Sub-Committee approval. As per data protection laws, Cohort Members retain the right to withdraw data from individual participants from IHCC Projects, should those participants request it.

## **6. Data Sharing and Access**

The IHCC Core Data Sharing Principles aim to promote open collaboration and wide and timely dissemination of data within Consortium members and the broader scientific community. All IHCC members are expected to honor this through their participation in IHCC activities.

## **7. Publication**

Disseminating results in a broad and timely manner is important to optimize scientific progress. All IHCC members are required to abide by the [IHCC Publication Policy](#).

## **8. Intellectual Property**

The IHCC aims to make all derived products, services, and research output publicly available in a timely and responsible manner to promote freedom to operate and the potential for maximum public benefit to be realized. The IHCC may pursue protection/filings of intellectual property through IHCC collaborations to maintain freedom to operate for IHCC members and IHCC projects.

Where it does not impinge upon other members' freedom to operate, IHCC members are free to pursue intellectual property protection of their own data at any time, but such IP-related activities cannot prevent or delay the public release or publication of IHCC results and findings. Other than members' own data, use of IHCC-generated and managed data or results for intellectual property purposes is allowed only after public release.

## **9. Use of the IHCC name**

The IHCC name shall not be used for commercial purposes (e.g. promotional material or other public announcement or disclosure) without the prior written consent of the Executive Committee.

## **10. Conflict Resolution**

If any unresolved conflicts arise, the Executive Committee must be informed. Executive Committee decisions will be final.

## **11. Electronic Execution**

Each Member intends that an electronic copy of their signature stored in a PDF software application format shall be regarded as an original signature and agrees that this Membership Agreement may be executed in any number of counterparts, each of which shall be effective upon delivery and thereafter shall be deemed an original, and all of which shall be taken to be the one and the same instrument.

## **12. Amendments**

Revisions to this Membership Agreement and any policies or guidelines governing IHCC activities may be initiated and approved by the SSC. Significant changes to membership criteria or policies and guidelines governing IHCC activities will require approval of a simple majority of Cohort Members.

## Acknowledgement of Membership Agreement

I understand and accept all the requirements and responsibilities outlined above including the IHCC Core Data Sharing Principles, the IHCC Publication Policy, and the IHCC Collaboration with Industry Guidelines. I understand that failure to comply with this Membership Agreement or any IHCC-approved policies or guidelines may result in loss of access to IHCC-managed data and/or loss of membership of IHCC, as well as a notification to my organizational representative.

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**To be completed by the Cohort Principal Investigator/individual nominated to represent Cohort on voting matters:**

**Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

.....

**To be completed by the Signing Official from the Organization of the Cohort representative:**

**Name:** \_\_\_\_\_

**Title:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Organization:** \_\_\_\_\_

**Address:** \_\_\_\_\_

\_\_\_\_\_

**Email:** \_\_\_\_\_