



May 25, 2021

Policy & Bio-Data Sharing Working Group

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International 100K Cohort Consortium



Disclaimer

All statements, opinions, or discussions are solely representative of my personal views and are not reflective of any positions of the Patient-Centered Outcomes Research Institute (PCORI)



Topics to Discuss

- Review of Foundational IHCC Policies
- Working Group Updates



Review of Provisionally Approved IHCC Policies



IHCC Policy Overview

- Updates to drafts made based upon:
 - Discussion at May Summit
 - Additional comments received from:
 - 23andMe, Inc.
 - *All of Us* Research Program
 - National Cancer Institute
 - Regeneron
 - Verily
- Provisionally Approved Winter 2021

What it Proposes

- Defines & details expectations for:
 - Types of IHCC-related publications & acknowledgements
 - Publishing in a timely way and in open access formats
 - Writing Groups, Authorship contributions, Acknowledgement Statements
 - Publication & Authorship Plan to be submitted with any IHCC Project Proposal
- Provides template for Publication & Authorship Plans





Changes Made

- Clarified language re: options for designating IHCC Consortium Papers and Non-consortium papers
- Added explicit language to encourage inclusion of and authorship recognition for junior investigators
- Added expectation for research participants to be acknowledged in IHCC cohort citation statements for use in publications
- Added explicit allowance for organizational review of publications and communications planning in timelines



What it Proposes

- Defines & details:
 - Types of IHCC collaborations (Members & industry partners, between Cohort Members, resource provision)
 - Principles upon which collaborations should be built
 - Points to Consider in drafting collaboration agreements
 - Considerations for maintaining IHCC principles for industry partnerships
- Provides checklist resource for Members' use





Changes Made

- More explicit reference made to reciprocal interests of forming partnerships and the respective issues to be addressed
- Clarified that Guidance applies to IHCC-approved Projects involving industry partners
- Modified language in “First Principles” to be inclusive of broader set of examples to realize value for partners or study stakeholders
- Clarified that public posting of collaboration agreements was limited to a general summary



Core Data Sharing Principles

What it Proposes

- Reliance upon GA4GH Framework for ethical foundation
- Defines & details:
 - Expectation is that principles work together and that local concerns and legal requirements are prevailing factors
 - “Foundational” Principles – basic expectations to promote IHCC strategic goals and values while respecting cohort policies
 - “Aspirational” Principles – build on Foundational Principles to move toward long-term data sharing goals (e.g., streamlined data access)



Core Data Sharing Principles



Changes Made

- Clarified upfront that the Principles will be used to develop IHCC Project-specific data sharing plans based on the data sharing capacities and policies of participating cohorts
- Added more explicit statement that the Principles will serve as a living document to be updated based on experience in IHCC Projects
- Re-ordered the Principles to improve clarity and flow





Working Group Updates



Policy & Bio-Data Sharing Working Group

Kate Blizinsky

All of Us Research Program,
USA

Lynsey Chediak

World Economic Forum,
USA

John Gallacher

Dementias Platform, UK

Heather Eliassen

Nurses' Health Study, USA

Sarah Elson

23andMe, Inc., USA

Arash Etemadi

Persian Cohort Study &
Golestan Cohort Study, Iran

Farin Kamangar

Golestan Cohort Study,
Iran

Reza Malekzadeh

Golestan Cohort Study &
Persian Cohort Study, Iran

Usha Menon

UK Collaborative Trial of
Ovarian Cancer Screening
& Longitudinal Women's
Cohort

Paul Pinsky

Prostate, Lung, Colorectal
and Ovarian Cancer
Screening Trial, USA

Elissa Prichep

World Economic Forum,
USA

Laura Lyman Rodriguez

Patient-Centered Outcomes
Research Institute, USA

Nicki Tiffin

H3Africa Consortium,
South Africa

Camilla Stoltenberg

Cohort of Norway &
Norwegian Mother and
Child Cohort Study

Ma'n Zawati

International Law & Data
Sharing, Canada



Considerations for Prioritizing Our Work

- What challenges are being identified through IHCC Projects? What needs do IHCC Members have to advance their cohort's work?
- What are the specific issues fundamental for IHCC that the Working Group should take up immediately? Are there opportunities to collaborate with other international consortia to advance IHCC priorities?
- Are there resources that others have developed or are working on that we should look to, or that could be helpful to collate for Members and the broader research community?



Thank You & Questions



*Additional comments or questions to
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