

Medical Information Commons Data Collection Instrument

Overview

Question 1. Name of initiative:

(Enter full name, not the acronym)

Question 2. Year founded:

Question 3. Funding source:

- Academic Institution
- Non-profit Organization
- Federal Government
- Clinical Laboratory
- Technology Companies
- Pharmaceutical
- Private Foundation
- Commercial Genetic Testing Company
- Managed Care/Insurance Company
- Other

If other, please specify:

Question 3a. Name of funding source(s):

Question 3b. Please list all sponsoring/collaborating organizations/companies (excluding funding source).

Question 3c. Overall review of funding source type:

- Government funding only
- Non-profit only
- For-profit only
- Government and non-profit
- Government and for-profit
- non-profit and for-profit
- Government, non-profit, and for-profit
- Not mentioned online

Question 4. Data initiative/biobank promotes disease-specific research?

- Yes
- No

Question 4a. Please enter the specific disease(s):

Question 5. Data is collected from:

- Affected individuals
- Well individuals related to the affected individual
- General population/individuals who elect to donate their data (Think 23andme).
- Deceased individuals
- Published studies
- Databases(s)
- Clinical lab(s)
- Other

Please specify other:

Question 6. Type of Information Banked and Shared:

Yes

No

Not mentioned online

Genetic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Proteins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Phenotypic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Histopathology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Images (MRI, CT Scan)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Contact Information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Results From Validated Scales	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Research Questionnaires	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Data From Medical Record	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Biometric Data From Wearable Device	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Geospatial and Environmental Data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Family History	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ancestry Data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Demographic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nutrition/Diet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fitness/Physical Activity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mental Health Status/History	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Drug/Alcohol Dependence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medical History	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Question 6a. Please enter type of genetic information shared as it reads on the website.

Question 6b. Type of environmental data shared:

-
- Air quality
 - Environmental pollutant exposures (e.g. lead, cigarette smoke, mold)
 - Access to fresh fruits and vegetables (Food deserts)
 - Access to sidewalks (Walkability)
 - Population density
 - GPS location
 - Other

Please specify other:

Question 6c. What demographic information is shared?

- Race
- Ethnicity
- Gender
- Age
- Education
- Socio-economic status
- Handedness
- Country of residence
- Country of origin
- State of residence
- Zip code
- Other

Please specify other type of demographic information:

Question 7. Overall environmental (including SoD), data collected:

- Economic Stability (Employment; Food Insecurity; Housing Instability; Poverty)
- Education (Early Childhood Education and Development; Enrollment in Higher Education; High School Graduation; Language and Literacy)
- Social and Community Context (Civic Participation; Discrimination; Incarceration; Social Cohesion)
- Health and Health Care (Access to Health Care; Access to Primary Care; Health Literacy)
- Neighborhood and Built Environment (Zip code; Access to Foods that Support Healthy Eating Patterns; Crime and Violence; Environmental Conditions; Quality of Housing)
- None
- Not mentioned online

Question 8. Information banked is collected from:

- Adults (>18 years old)
- Minors (< 18 years old)
- Not mentioned online

Question 9. Are research participants paid to give their biospecimen/data?

- No
- Yes, for biospecimens only
- Yes, for biospecimen plus other type of data (clinical, demographic, contact info)
- Not mentioned online

Comments:

Question 9a. Please select the accurate statement:

- Individuals/participants send their data directly to the initiative
- Data from individuals/participants are obtained by researchers (or institutions) who then submits the data to the database
- Not mentioned online
- Other

Please specify other:

Question 9b. Can individuals control how their data are used?

- No
- Yes
- Unclear
- Not mentioned online

Comments:

Question 9c. Can individuals control who uses their data?

- No
 Yes
 Unclear
 Not mentioned online
-

Comments:

Question 9d. Are revenues generated from discovery/scientific advancement shared with research participants?

- Yes
 No
 Not mentioned online
-

Comments:

Question 9e. Can people who give their health data edit/update it?

- Yes
 No
 Not mentioned online
-

Comments:

Question 10. Are the tools that were used to interpret/analyze the data detailed?

- Yes
 No
-

Please upload a PDF copy of the webpage detailing tools used:

Question 11. Does [name] share data internationally?

- Yes
 No
 Not mentioned online
-

Question 12. Mission Statement (copy and paste):

(Copy and Paste)

Question 13. Website URL:

Question 14. Is [name] of U.S. origin?

- Yes
 No
-

Question 15. Does [name] contribute data to any of the following databases/consortia?

- dbGAP
 dbSNP
 ClinVar
 ClinGen
 eMERGE
 GAAIN
 Other
 No
 Not mentioned online
-

If other, please specified:

Question 16. Initiative has IRB approval?

- Yes
 - No
- ('No' here means NMO)

Question 16a. Type of IRB:

- Academic
- Non-academic
- IRB mentioned but unspecified

Question 17. Does initiative say they are open access?

- Yes
- No

Comments:

Decision/Policy Making -- [name]
1. Which of the following are involved in decision/policy-making processes?

	Yes	No	Unclear
Representatives from member organizations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Academic physicians	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Academic scientists	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Academic ethics and regulatory	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Industry physicians	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Industry scientistis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Independent External Advisors (scientific)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Independent Ethics Advisors (ethics and regulatory)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Site miners	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Representatives from patient advocacy groups	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Individual patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Community leaders	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Parents/Family members of patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
None mentioned online	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Question 2. Are research participants actively engaged in decision/policy-making processes (e.g. Steering Committees, voting sessions)?

- Yes
 No
 Not mentioned online

Question 2a. How are research participants engaged in decision/policy-making processes?

Comments:

Data Use and Sharing -- [name]

Question 1. Which of the following data sharing policies/principles are referenced by the initiative?

- NIH Genomic Data Sharing (GDS) Policy
 Bermuda Principles
 Fort Lauderdale Principles
 Internal, institution-specific principles
 Other
 None

Please specify other:

Please detail internal, institution-specific principles:

Question 2. What levels of data access are offered for each type of data?

	Identifiable individual-level	De-identified individual-level	Aggregate
Open/public access	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Controlled access	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Registered access (https://genomicsandhealth.org/working-groups/our-work/register-access)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not mentioned online	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Question 2a. Overall type of data-sharing initiative:

- All controlled access
 Some open data, some controlled access
 All open data

Question 3. What are the requirements to access data?

	Identifiable individual-level	De-identified individual-level	Aggregate
Submit an online application	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Create a user account	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Email a request	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sign Data Use/Transfer Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Through dbGap or other external database	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Submit IRB approval documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
None	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not mentioned online	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Question 3a. Overall (all data types) requirements to access data:

- Submit an online application
- Create a user account/sign terms of use
- Email a request
- Sign Data Use/Transfer Agreement
- Through dbGap or other external database
- Submit IRB approval documentation
- Other
- None
- Not mentioned online

Question 4. Who can request data access?

	Identifiable individual-level	De-identified individual-level	Aggregate
Academic researchers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
General public	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Private industry researchers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
People with disease of interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unclear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not mentioned online	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please specify other:

Question 4a. Who is invited to access data (for all data types)?

- Researchers (general, unspecified)
- Academic researchers
- Industry researchers
- Clinicians/Healthcare providers
- General public
- Individuals who the data describe
- People with disease of interest
- Not mentioned online

Question 5. Are data requests reviewed for intended use of the data before granting access?

- Yes
- No
- Not mentioned online
- Not applicable

Comments:

Question 6. Is follow up conducted to ensure data is only used as indicated in the application?

- Yes
- No
- Not mentioned online
- Not applicable

Comments:

Question 7. Are audits conducted to monitor data security?

- Yes
- No
- Not mentioned online
- Not applicable

Comments:

Question 8. Are strategies to prevent data misuse detailed on the initiative's website?

- Yes
 No
-

Comments:

Question 9. Are there monetary costs associated with accessing data?

- Yes
 No, no costs
 Not mentioned online
-

Comments:

Question 10. Is there any discussion of how data sharing benefits data research participants?

- Yes
 No
 Yes, but participants told there are no benefits
-

Comments:

Question 11. Is there any discussion of how data sharing benefits data contributors?

- Yes
 No
 Not Applicable
(E.g. requirement that data contributor be credited in any publications that result)
-

Comments:

Question 12. Are legal structures related to intellectual property, licensing, etc. discussed on the initiative's website?

- Yes
 No
-

Comments:

Question 13. Are state-specific property laws protecting individual's ownership of their genetic information discussed on the initiative's website?

- Yes
 No
-

Comments:

Question 14. Is there a data embargo period?

- Yes
 No
 Not mentioned online
-

Question 14a. How long (in days) is the data embargo period?

(Days only)

Question 14b. What are the conditions of the embargo?

Question 15. Does the initiative's website post information about who has accessed data - either publication list or data on sectors that accessed data?

- Yes
- No

Comments:

Privacy Rules and Norms -- [name]

Question 1. Are privacy policies and practices detailed online?

- Yes
- No

Please continue even if answer to the above question is 'No'. Answer as many questions as possible and note at the end the source of information.

Question 2. Which of the following laws are mentioned?

- Health Insurance Portability and Accountability Act (HIPAA)
- Genetic Information Nondiscrimination Act (GINA)
- State-specific privacy law
- Other applicable law
- None

Please specify other law(s):

Question 3. Is a Certificate of Confidentiality utilized?

- Yes
- No
- Not mentioned online

Comments:

Question 4. Are differences across state protections of genetic information mentioned?

- Yes
- No

Comments:

Question 5. Is a response plan in case of a privacy breach mentioned?

- Yes
- No

Comments:

Question 6. Are research participants notified when there is a privacy breach?

- Yes
- No
- Not mentioned online

Comments:

Comments:

Consent Process -- [name]

Question 1. Are consent requirements available?

- Yes, consent form is available online
- Yes, consent form shared for this review
- No, but consent is mentioned online
- No mention of consent on the initiative's website

Question 2. Is the possibility of a data breach addressed?

- Yes
- No

Comments:

Question 3. Are laws protecting from data misused mentioned?

- Yes
- No

Comments:

Question 4. Are protection limits in existing laws addressed?

- Yes
- No

Comments:

Question 5. Does the consent form reference the right to withdraw?

- Yes
- No

Comments:

Question 6. Can participants indicate choice in the type of future research they want their data to be used in?

- Yes
- No

Question 7. How often is consent obtained?

- One-time consent
- Re-consent after certain time

Question 8. Type of consent:

- Broad
- Dynamic
- Other

If other, please specify:

Question 9. Are research results disclosed?

- Not mentioned
- No. Findings are not disclosed.
- Yes. An individual's results are disclosed if findings are clinically actionable.
- Yes. An individual's results are disclosed, whether clinically actionable or not.
- Yes. Individual results and study findings are disclosed.
- Yes. Only aggregate study findings are disclosed.

Comments:

Question 10. Can the participant chose whether or not to receive results?

-
- Yes
 - No
 - Not mentioned on the ICF

Question 11. Is the concept of "data ownership" discussed?

- Yes
- No

Comments:

Question 12. Is compensation for discovery/scientific advancement addressed?

-
- No
 - Yes. Revenues gained from discovery/scientific advancement ARE NOT shared with research participants
 - Yes. Revenues gained from discoveries/scientific advancement ARE shared with research participants

Comments:

Public Outreach -- [name]

Please think of the 'public' in the context of this project: public = lay person.

Question 1. Are there modes of communicating with those whose data populate the database?

- Yes
 No

Question 2. Which of the following outreach methods are employed?

- Social media
 E-newsletters
 Online videos/YouTube links
 Webinars
 E-brochures
 Town Hall/In-person meetings
 Other
 Initiative's website

Please specify other:

Question 3. Which populations do outreach materials target?

- Adult men in general
 Adult women in general
 Adult men of a certain age
 Adult women of a certain age
 Adult men who have a certain condition
 Adult women who have a certain condition
 Veterans
 Parents of minors in general
 Parents of minors who have a certain condition

Age:

Condition(s):

Question 4. Which ethnic/racial groups do outreach materials target?

- None
 Hispanic/Latino
 White
 Black/African American
 American Indian/Alaska Native
 Asian/Indian
 Pacific Islander
 Other

Please specify other:

Question 5. Does the data initiative reach out to community leaders representing the target population(s)?

- Yes
 No
 Not mentioned online

Comments:

Question 6. Do outreach materials address privacy protections?

- Yes
 No

Comments:

Question 7. Do outreach materials address participant access to data/return of results?

- Yes
- No

Comments:

Question 8. Do outreach materials mention sharing of data with a third party?

- Yes
- No

Comments:

Comments:
