Patient and Family Perspectives on Computable Consent and CCDI Participant Index

2023 Childhood Cancer Data Initiative Annual Symposium
Breakout Session #2

NIH NATIONAL CANCER INSTITUTE

3/28/2023

Computable Consent and Participant Index

Goal: In this breakout session, participants will discuss the patients and families perspectives in implementing “Computable Consents” and “Participant Index”

Facilitators:

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Computable Consent: Benefits

Access to consent parameters for investigators: being able to maintain consent parameters in an online database would make it much easier for investigators to know what permissions have been granted by a participant. Currently, an inordinate amount of time is spent tracking down paper consents before research can be conducted.

Tracking multiple consents: if a participant consents to multiple protocols, there should be a way to tie those multiple consents back to the same individual. E.g., a computable chain of linked computable consents that the participant had signed.

Tracking use of a participant's data/materials: Parents and families are interested in knowing the downstream use of data shared. So, having an online system would allow investigators/projects to update a participant's consent record to indicate data use. Much like publications acknowledging funding sources.

Computable consent proof of concept: components

- Consent should be simple, engageable, and accessible
  - Context should be patient focused
- Focus on the permissions granted for storage and sharing of data and biospecimens for future use
  - Provide information on NIH's data distribution process
- Pilot with interventional studies (clinical trials)
- Should CCDI (NCI/NIH) or non-profit organization be the custodian for holding the consent?
  - Assurance of privacy, protection, longevity, and security

Computable Consents: Jump-start Discussion Points

- What is your assessment of the adequacy of patient protection by the use of computable consent?
- Do you see opportunities for a single consent process for multiple planned and even future, yet to be planned, research efforts.
- What plans should be developed to assure consent by patients at the age of majority and to allow patients to withdraw consent should they choose and how previously collected/submitted data will be handled when consent is withdrawn?

CCDI Participant Index

To facilitate integrated data analysis its important to connect data from multiple sources to address multifaceted research questions, understand the disease, develop new therapies, and advance existing treatments.

CCDI is exploring ways to connect different data types such as genomic, proteomic, image, transcriptomics, EHR that is collected over time, from different sources at the patient level while preserving the privacy of the patient.

CCDI Participant Index (CPI) will be a digital ID mapping and matching reference service to the CCDI Data Ecosystem. It only holds IDs and not the underlying data. The service returns IDs and primary resource still controls data access.

CPI leverages direct and transitive associations between known identifiers that represent the same person. Patients and families are fully supportive of this system. Parents are interested in knowing how data sharing impacted research.

Participant Index: Jump-start Discussion Points

- How do patients and families perceive the CCDI Participant Index (CPI)?
- What is necessary to prevent/mitigate concerns related to confidentiality and intended pirating data from studies in progress?
- Do current plans adequately address the needs to link a single patient whose data may exist in multiple, disparate datasets?
- What current challenges need to be addressed in linking data to other existing data to accomplish planned and ongoing research efforts?

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