

NIH Collaboratory Data Sharing Policy and Considerations

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Data Sharing Mandate (from 2017 RFA):

“The HCS Research Collaboratory program encourages sharing of resources with broad availability of **policies, practices, materials, and tools** to facilitate **collaboration, reuse, and replication**. In addition, the HCS Research Collaboratory program **requires sharing of study data** from Demonstration Projects in a timely manner with appropriate privacy and confidentiality protections, in accordance with the Data Sharing Policy developed by the HCS Research Collaboratory.”

Data Sharing Policy and Considerations are included in the meeting materials.

Why?

- Public health
- Maximizing investment
- Accelerate learning
- Foster collaboration (pay it forward)

Ultimately... transparency, reproducibility, secondary use of medical research, are good for society

Data Sharing and Embedded Research

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- The ethical responsibility to share data generated by publicly funded research must be balanced against the need to protect *patient privacy* and scientific *integrity*
- Data sharing policies must not dissuade health system participation

NIH Data Sharing Policy and Implementation Guidance

- The privacy of participants should be safeguarded.
- Data should be made as widely and freely available as possible.
- Data should be shared no later than the acceptance for publication of the main study findings.
- Initial investigators may benefit from first and continuing use of data, but not from prolonged exclusive use.

Principles

- Patient privacy: Essential obligation
- Health system privacy: Sometimes necessary

The Balance of Benefits & Risks



Our Policy Summarized

- Share the final research data set
- Protect specific interests of health care systems partners
- Choose the least restrictive method for sharing
- Balance protection of participant privacy, health system privacy, and scientific integrity.
- Collaborate with NIH to implement this data sharing policy

Expectations for Collaboratory Trials

- Datasets will be structured to maximize future scientific value while protecting patient and health system privacy
- Data should not include any of the 18 HIPAA-specified direct identifiers
- Investigators may make more detailed data available through a more “restrictive” data sharing option

See full policy in meeting materials

Three levels of data

- What we can touch: original health system data
- What we can use: limited by consent or waiver
- What we can share: further limited by regulation (and possibly health system policy)

Structures and Tools (from least to most restrictive)

- **Public archive** – send data to any user
- **Private archive** – send data to approved users
 - For any purpose
 - For approved purposes only (e.g. governed by DUA)
- **Public enclave** – any user may send questions to data
- **Private enclave** – some users may send questions to data
 - Automatically executed
 - Moderated (either queries or results)

It's not all about the data

- Share policies, practices, materials, and tools
- The Collaboratory EHR Core Resource and Sharing Checklist
 - Key study documents
 - Publications
 - Study tools
 - Datasets and documentation

The Core will share the checklist during a breakout session

Summary

- Data sharing is a societal good
- Like healthcare, health systems are....
complex
- Collaboratory is leading the way



Thank You