NIH Collaboratory Rethinking Clinical Trials®

Health Care Systems Research Collaboratory

NIH Collaboratory Data Sharing Policy and Considerations

Adrian Hernandez, MD, MHS Duke University School of Medicine Duke Clinical Research Institute

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.

NIH Collaboratory Rethinking Clinical Trials®



Why?

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

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

Recently...

The NEW ENGLAND

JOURNAL of MEDICINE

Annals of Internal Medicine

IDEAS AND OPINIONS

Data Sharing and Embedded Research

Gregory E. Simon, MD, MPH; Gloria Coronado, PhD; Lynn L. DeBar, PhD, MPH; Laura M. Dember, MD; Beverly B. Green, MD, MPH; Susan S. Huang, MD, MPH; Jeffrey G. Jarvik, MD, MPH; Vincent Mor, PhD; Joakim Ramsberg, PhD; Edward J. Septimus, MD; Karen L. Staman, MS; Miguel A. Vazquez, MD; William M. Vollmer, PhD; Douglas Zatzick, MD; Adrian F. Hernandez, MD, MHS; and Richard Platt MD, MS

Data Sharing Statements for Clinical Trials — A Requirement of the International Committee of Medical Journal Editors

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Harlan Krumholz @hmkyale



The answer is clearly: Yes!!! [Whose Data Are They Anyway? Can Patient Perspective Advance the Data-Sharing Debate?] nejm.org/doi/pdf/10.105...

Whose Data Are They Anyway? Can a Patient Perspective Advance the Data-Sharing Debate? Charlotte J. Haug, M.D., Ph.D.

Most patients haven't thought disease — ways to use technology summit on aligning incentives in monitoring and treating one- for data sharing want their data according to Sara Riggare, but self. She is also a patient. Riggare shared quickly, especially to enthose who have 'find the current had her first symptoms of Parkin- sure that other patients knows.

Data Sharing in Clinical Trials



Jeffrey Drazen, MD – Editor-in-Chief of *The New* England Journal of Medicine –

Editorials

Data sharing in medical research

BMJ 2018 ; 360 doi: https://doi.org/10.1136/bmj.k510 (Published 14 February 2018) Cite this as: *BMJ* 2018;360:k510

JAMA Network

September 2017

Sharing Clinical Research Data—Finding the Right Balance

Bernard Lo, MD1; Steven N. Goodman, MD, PhD2



Annals of Internal Medicine

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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.

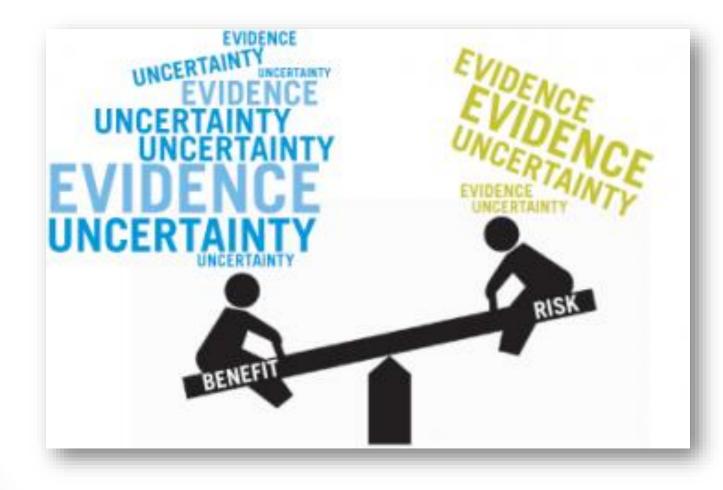


Principles

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



The Balance of Benefits & Risks



• NIH Collaboratory Rethinking Clinical Trials®

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 HIPAAspecified 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

