THE NIH HEALTH CARE SYSTEMS RESEARCH COLLABORATORY

Steering Committee Meeting

COLLABORATORY DATA SHARING

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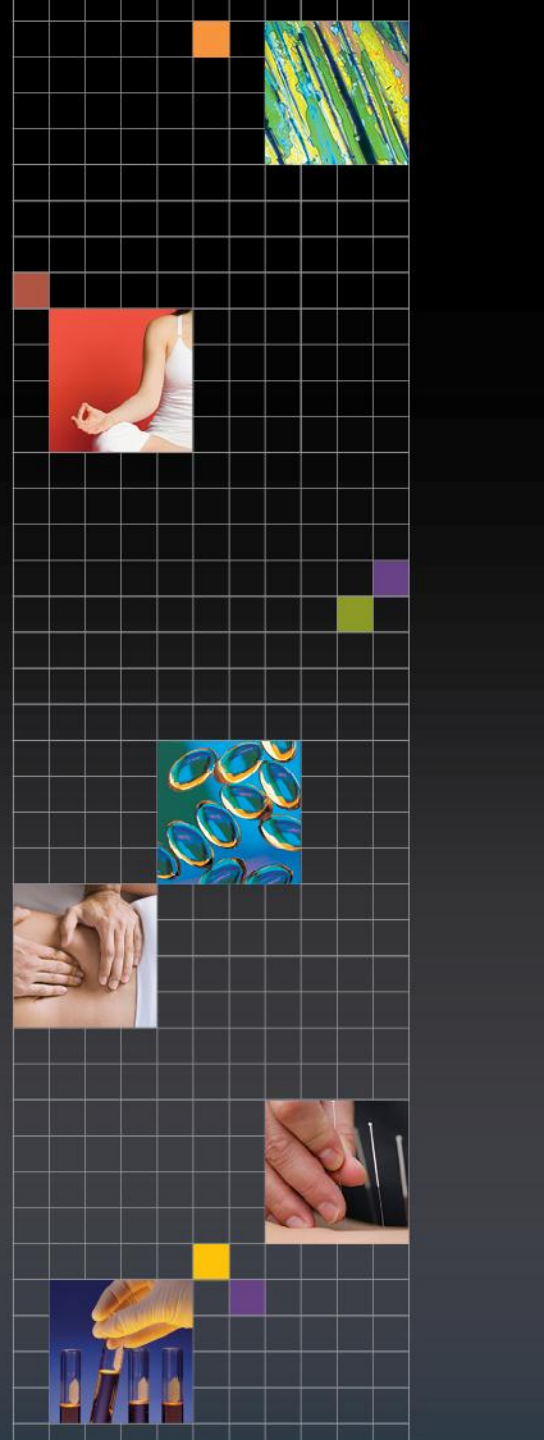
NIH/NCCAM
24 February 2014



HCS Research Collaboratory DATA SHARING

NIH Data Sharing Policy

Additional Considerations

Collaboratory Goals

BioLINCC – an NIH-supported Repository

NIH Common Fund Programs

Criteria for Common Fund Programs

Transformative

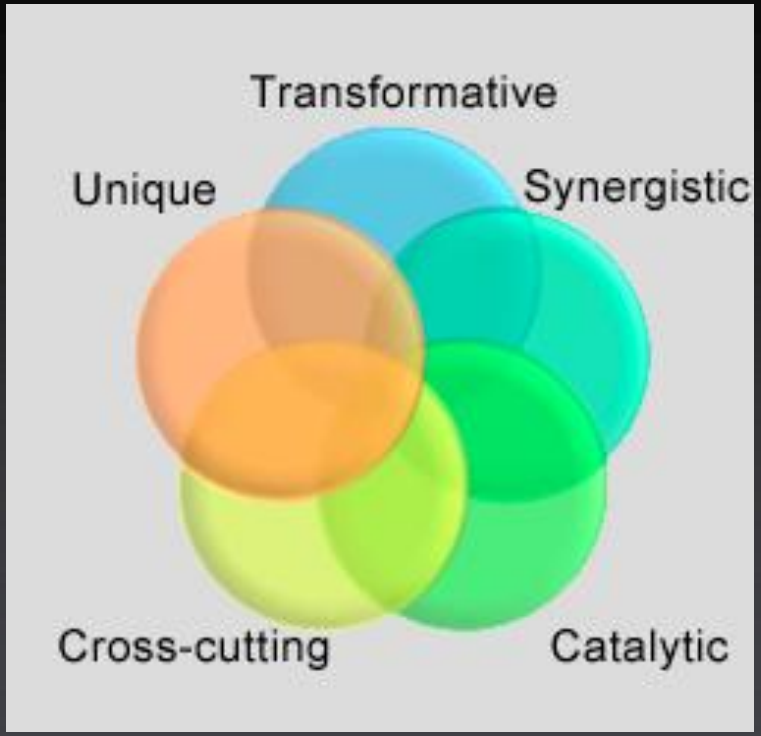
Catalytic

Synergistic

Cross-cutting

Unique

Serve as a test bed for high-risk, enabling, or emerging scientific opportunities



NIH DATA SHARING POLICY

"Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data." (Final NIH Statement on Sharing Research Data February 26, 2003)

http://grants.nih.gov/grants/policy/data_sharing/

The NIH Policy on Data Sharing Applies:

- To the sharing of **final research data** for research purposes.
- To basic research, **clinical studies**, surveys, and other types of research supported by NIH. It applies to research that involves human subjects and laboratory research that does not involve human subjects. It is especially important to share unique data that cannot be readily replicated.
- To applicants seeking $500,000 or more in direct costs in any year of the proposed project period through grants, cooperative agreements, or contracts.
- To research applications submitted beginning October 1, 2003.

Final Research Data

For most studies, final research data will be a computerized dataset. For example, the final research data for a clinical study would include the computerized dataset upon which the accepted publication was based, not the underlying pathology reports and other clinical source documents.

For some but not all scientific areas, the final dataset might include both raw data and derived variables, which would be described in the documentation associated with the dataset.

Final Research Data

Given the **breadth and variety** of science that NIH supports, neither the precise content for the data documentation, nor the formatting, presentation, or transport mode for data is stipulated.

What is **sensible** in one field or one study may not work at all for others.

Methods for Data Sharing

There are many ways to share data

- Publications
- Researcher's Efforts
- Data archive – readable data sets are acquired and distributed
- Data enclave – secure environment where eligible researchers perform analyses
- Mixed mode sharing – more than one version/type of data set, each with different access

Timeliness of Data Sharing

- Recognizing that the value of data often depends on their timeliness, data sharing should occur in a timely fashion.
- NIH expects the timely release and sharing of data to be no later than the acceptance for publication of the main findings from the final dataset.
- The specific time will be influenced by the nature of the data collected.

Discussion Framework for Clinical Trial Data Sharing*

Guiding Principles for Responsible Sharing of Clinical Trial Data

- **Respect** the individual participants whose data is shared
- **Maximize benefits** to participant in clinical trials and to society, while minimizing harms
- Increase **public trust** in clinical trials
- Carry out sharing of clinical trial data in a manner that enhances **fairness**

* Institute of Medicine. 2014. Washington, DC; The National Academies Press.

NIH HCS Research Collaboratory

Pragmatic Clinical Trials Demonstration Projects

RFA-RM-12-002

The HCS Research Collaboratory Program

- **Encourages** sharing of resources with broad availability – of policies, practices, materials and tools to facilitate collaboration, reuse, and replication;
- **Encourages** sharing of study data from Demonstration Projects in a timely manner with appropriate privacy and confidentiality protections to facilitate further research;
- **Expects** grantees to implement a Resources and Data Sharing Plan consistent with achieving these goals.

Data Sharing Plans
Key Elements

- **What** data will be shared?
- **Who** will have access to the data?
- **Where** will the data to be shared be located?
- **When** will the data be shared?
- **How** will users locate and access the data?

Collaboratory Data Sharing Session

- How can the Collaboratory **maximize** data sharing?
- Data Sharing Working Group – **Draft Policy and Principles**
- UH3 **Project-Specific** Data Sharing Plans

Collaboratory Data Sharing

- How has NIH supported Data Sharing for Clinical Trials Research?
- How can this inform efforts for Collaboratory Data Sharing?
  - BioLINCC – an NIH-supported Repository (Dr. Sean Coady, NHLBI)

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