National Center for Complementary and Alternative Medicine

NIH Health Care Systems Research Collaboratory: *Steering Committee Meeting*

COLLABORATORY DATA SHARING

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HCS Research Collaboratory Data Sharing

- NIH Data Sharing Policy
- Collaboratory Goals
- Additional Considerations
- Collaboratory Data Sharing Policy

NIH Common Fund Programs

Criteria for Common Fund Programs

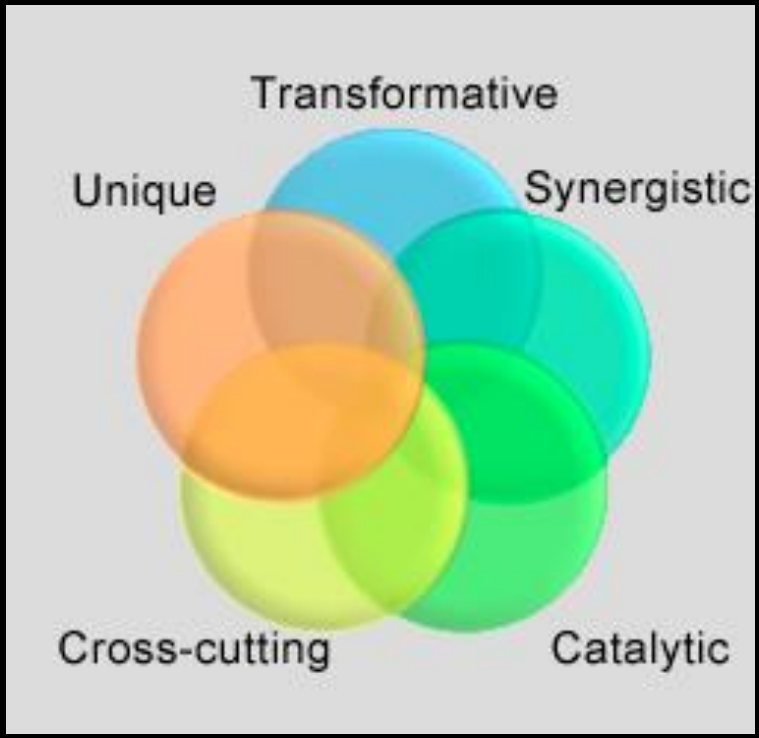
Transformative

Catalytic

Synergistic

Cross-cutting

Unique



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

Existing Regulatory Requirements

- All NIH Collaboratory Pragmatic Trials are expected to adhere to existing NIH Data Sharing Policy and Implementation Guidance (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)

- Key points in that policy and guidance include:

  - The privacy of participants should be safeguarded.

  - Data should 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.

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.

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

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 & RFA-RM-13-012

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.

Considerations For Use of HCS Data

– NIH Collaboratory trials rely on data extracted from health systems' EHR;

– Collaboratory trials are allowed to use specific health information through either an explicit informed consent process and/or a waiver of consent granted by one or more supervising IRBs;

Considerations For Use of HCS Data

- **Collaboratory trials may have access to a wide range of original health system data, trials are only allowed to use and store data elements specifically authorized for research use - either by participant consent or by formal waiver of consent by the responsible IRBs;**

- **Investigators are not expected to share or give access to original health system data in EHR or other administrative data systems. Rather, they are expected to give access only to the research data on which their analyses are based and conclusions drawn.**

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 Policy - 2014

- Collaboratory investigators will each share, at a minimum, a final research data set upon which the accepted primary pragmatic trial publication is based.

- The Collaboratory recognizes that sharing data derived from studies performed in partnership with HCS may, under some situations, require precautions in addition to those regarding patient confidentiality, to protect specific interests of collaborating HCS, facilities or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs in implementing this data sharing policy.

Collaboratory Data Sharing Policy - 2014

- **Consistent with NIH policy and guidance, Collaboratory investigators will choose the least restrictive method for sharing of research data that provides appropriate protection for participant privacy, health system privacy, and scientific integrity.**

- **Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infra-structure are in place to support timely data sharing for the Collaboratory.**

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