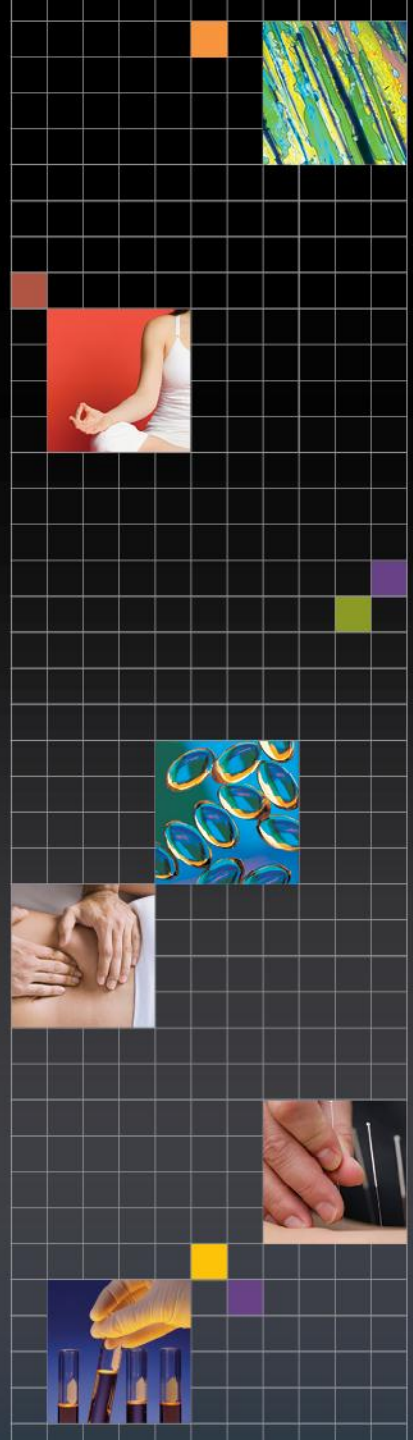



# Federal Funders Perspective


Sharing Clinical Research Data: An IOM Workshop  
October 5, 2012


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Director, NCCAM, NIH  
Acting Director, DCI, NCATS, NIH




# Step 1: NIH Data Sharing Policy

 U.S. Department of Health & Human Services



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National Institutes of Health

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## Grants Policy

- [Policy & Guidance](#)
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- [Research Integrity](#)

## Global OER Resources

- [Glossary & Acronyms](#)
- [Frequently Used Links](#)
- [Frequently Asked Questions](#)

## NIH Data Sharing Policy and Implementation Guidance

(Updated: March 5, 2003)

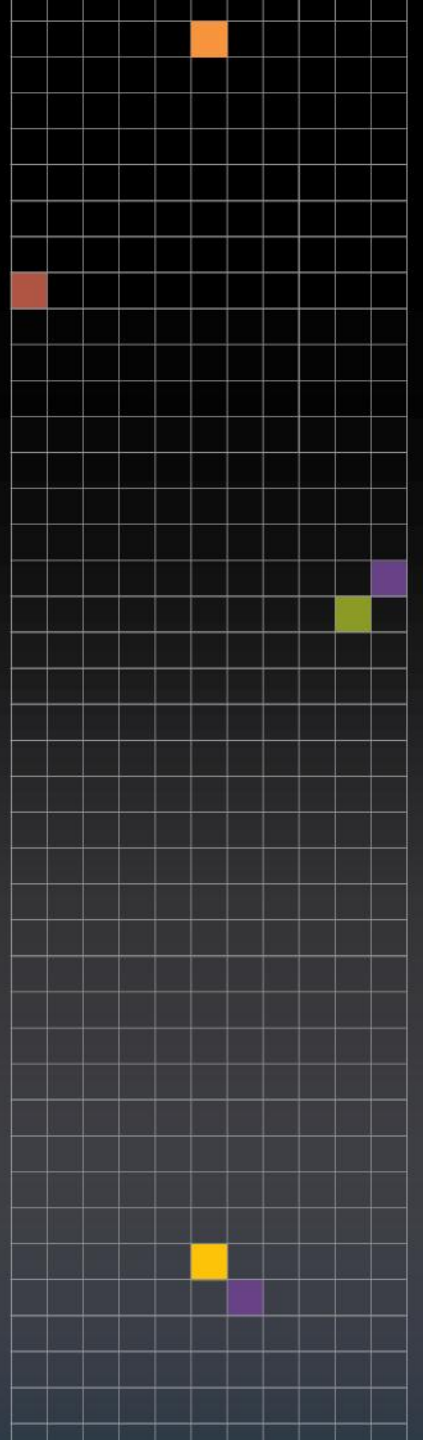
This guidance provides the National Institutes of Health (NIH) policy statement on data sharing and additional information on the implementation of this policy.

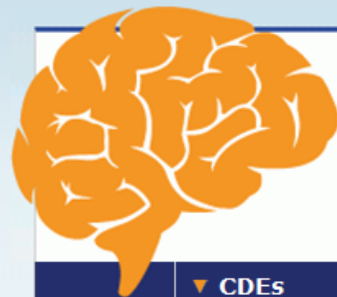
- [Goals of Data Sharing](#)
- [Applicability](#)
- [Implementation](#)
  - [Timeliness of Data Sharing](#)
  - [Human Subjects and Privacy Issues](#)
  - [Proprietary Data](#)
  - [Methods for Data Sharing](#)
  - [Data Documentation](#)
  - [Funds for Data Sharing](#)
  - [Review Considerations](#)
- [What to Include in an NIH Application](#)
- [Examples of Data Sharing Plans](#)
- [Definitions](#)
  - [Covered Entity](#)
  - [Data](#)
  - [Data Archive](#)
  - [Data Enclave](#)
  - [Final Research Data](#)
  - [Restricted Data](#)
  - [Timeliness](#)
  - [Unique Data](#)

# Subsequent Steps:

- 1. Investments in in data standards
- 2. Support for resources to make data sets findable, accessible and usable
- 3. Encouragement and support for analytic work using available data sets

# Data Standards





# NINDS Common Data Elements

Harmonizing Information. Streamlining Research.

[▼ CDEs](#)[▼ Tools](#)[▼ Learn](#)

## Streamline Your Neuroscience Clinical Research

using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). [Learn more about the CDE Project.](#)



### Launch Your Own Studies Faster

- ▶ Case report form modules
- ▶ Standardized data element definitions
- ▶ Instrument recommendations



### Incorporate CDEs Into Systems

- ▶ Search for current CDEs
- ▶ Download CDE metadata
- ▶ Download Case Report Forms



### Learn About the CDE Project

- ▶ Project overview and background
- ▶ Meetings and Presentations
- ▶ Collaboration with developers around the world

**CDEs Now Available****CDEs Under Review****CDEs in Development**[Multiple Sclerosis \*New!\*](#)[Huntington's Disease \*New!\*](#)[Headache \*New!\*](#)[Traumatic Brain Injury \(Version 2.0\) \*New!\*](#)[General \(CDEs that cross diseases\)](#)[Amyotrophic Lateral Sclerosis](#)[Congenital Muscular Dystrophy](#)[Epilepsy](#)[Friedreich's Ataxia](#)

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# Data sharing resources



## National Addiction & HIV Data Archive Program



### SEARCH

- ☒ NAHDAP Data
- ☐ Related Literature


[View all studies](#)
[Browse recent updates & additions \(last 90 days\)](#)

### About NAHDAP

NAHDAP acquires, preserves and disseminates data relevant to drug addiction and HIV research. By preserving and making available an easily accessible library of electronic data on drug addiction and HIV infection in the United States, NAHDAP offers scholars the opportunity to conduct secondary analysis on major issues of social and behavioral sciences and public policy.

[Read More](#)

### Quick Links

- [Preparing Data for Deposit to NAHDAP \(PDF 966K\)](#)
- [Ways to Release Data from NAHDAP \(PDF 1MB\)](#)
- [Why Share Data With NAHDAP? \(PDF 1.1MB\)](#)
- [Five Criteria for an Effective Data Sharing Plan \(PDF 37K\)](#)
- [Restricted Data Use Agreement \(PDF 51K\)](#)

### Announcements

**2012-08-23**

NAHDAP releases Pathways to Desistance baseline data

**2012-08-13**

NAHDAP releases four datasets from subcontract competition

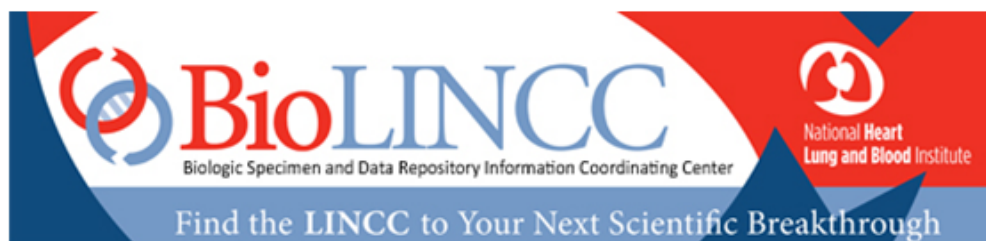
**2012-05-07**

Research paper competition winners

### Quick Searches

- crime
- "substance abuse treatment"
- "risk factors"
- "mental health"
- "program evaluation"
- "sexual behavior"
- youth



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## Welcome to the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) website!

- [Learn](#) about Open Collections and request processes
- [Request](#) data and/or biospecimens from Open Collections
- [Register](#) study information to submit a new biospecimen collection
- [Learn](#) about requesting biospecimens in the Proprietary Period

## Search for Study Datasets and/or Biospecimens

From here you can search study description pages for studies that meet your criteria and request more information on available data and/or biospecimens. Enter keyword(s) into the "Search For" field below and check the boxes to indicate if you are interested in studies with available datasets, biospecimens, or with both. Leaving the checkboxes blank will return studies with either material type:

Search For: [Search Studies](#)[Common Properties](#)[Material Types](#)[Conditions](#)[Study Type](#)[Period](#)☐ **Select All**☐ **Has Study Datasets**☐ **Has Specimens**☐ **Do Not Include Studies with Commercial Use Restrictions**

### Recent News

[RFI: Building an MDS  
National Resource](#)

2012-09-12

[NHLBI and NCI are seeking  
input on building a...](#)[MHCS-I and MHCS-II Data  
Available](#)

2012-09-04

[Data from the Multicenter  
Hemophilia Cohort S...](#)[DISC Biospecimens  
Available](#)

2012-08-31

[Biospecimens from the  
Dietary Intervention St...](#)[New Other Open Resource:  
GenTAC](#)

2012-08-24

[Resource and study contact  
information for th...](#)[New Resource Section  
Launched: Other Open  
Resources](#)

2012-08-24

[Resource information  
available on BioLINCC is...](#)[more news...](#)



# Activities of the Trans-NIH BioMedical Informatics Coordinating (BMIC) Committee

## NIH Data Sharing Policy

- Working group to improving implementation of existing policy
- Best practices document for program staff  
[https://bmic.nih.gov/documents/patents\\_best\\_practices.pdf](https://bmic.nih.gov/documents/patents_best_practices.pdf)
- Guidance document for awardees – “Key Elements to Include in Data Sharing Plans”
  - [http://grants.nih.gov/grants/sharing\\_key\\_elements\\_data\\_sharing\\_plan.pdf](http://grants.nih.gov/grants/sharing_key_elements_data_sharing_plan.pdf)
  - Specifies description of commonly accepted data standards and vocabularies used to collect or characterize data

# Activities of the Trans-NIH BioMedical Informatics Coordinating (BMIC) Committee

Common Data Elements for use in research and registries

- Working Group to coordinate development and encourage greater use of and common data elements in NIH and HHS supported research projects and patient registries
- Web portal (under development) to provide access to information about NIH and HHS supported common data element
- E.g., PhenX (for GWAS studies), PROMIS (patient-reported outcomes), NINDS CDEs (for neurological disease and stroke)

Encourage alignment between standard used in clinical care and clinical research

- Standards required for Meaningful Use of EHRs
- e.g., SNOMED-CT (clinical terminology), RxNORM (drug names), LOINC (lab tests and observations)

# Examples of funding solicitations for secondary analyses



Participating Organization(s)	National Institutes of Health ( <a href="#">NIH</a> )
Components of Participating Organizations	National Institute of Diabetes and Digestive and Kidney Diseases ( <a href="#">NIDDK</a> ) National Institute on Alcohol Abuse and Alcoholism ( <a href="#">NIAAA</a> ) Office of Dietary Supplements ( <a href="#">ODS</a> )
Funding Opportunity Title	<b>Secondary Analyses in Obesity, Diabetes and Digestive and Kidney Diseases (R21)</b>
Activity Code	<a href="#">R21</a> Exploratory/Developmental Research Grant Award
Announcement Type	Reissue of <a href="#">PA-09-131</a>
Related Notices	None
Funding Opportunity Announcement (FOA) Number	<b>PA-12-125</b>

Participating Organization(s)	National Institutes of Health ( <a href="#">NIH</a> )
Components of Participating Organizations	National Institute on Alcohol Abuse and Alcoholism ( <a href="#">NIAAA</a> )
Funding Opportunity Title	<b>Secondary Analysis of Existing Alcohol Epidemiology Data (R01)</b>
Activity Code	<a href="#">R01</a> Research Project Grant
Announcement Type	Reissue of <a href="#">PA-08-167</a>
Related Notices	None
Funding Opportunity Announcement (FOA) Number	<b>PA-11-308</b>

Title: **Secondary Analyses of Existing Data Sets and Stored Biospecimens to Address Clinical Aging Research Questions (R01)**

Announcement Type

New

**Update:** The following updates relating to this announcement have been issued:

- [September 29, 2010](#) (NOT-OD-11-007) - NIH to Require Use of Updated Electronic Application Forms in 2011. Adobe B1 forms are required for due dates on or after May 8, 2011.
- [August 16, 2010](#) - IMPORTANT NOTE! NIH has eliminated the error correction window for due dates of January 25, 2011 and beyond. As of January 25, all corrections must be complete by the due date for an application to be considered on-time. [See NOT-OD-10-123](#).
- [January 6, 2010](#) - This FOA has been updated to reflect the new requirements from NIH's Enhancing Peer Review Initiative. The new requirements are effective for submissions intended for due dates January 25, 2010 and beyond. If submitting an application intended for a due date of January 25, 2010 and beyond, follow the guidance below and be sure to use the Adobe-Forms-B version of the application forms and instructions. If applying for a due date before January 25, 2010, follow the guidance in the [archived version of this FOA](#) and be sure to use the Adobe-Forms-A version of the application forms and instructions.
- [October 22, 2009](#) - Notice from NIA with Corrections on PA-09-265. See NOT-AG-10-001.

Program Announcement (PA) Number: **PA-09-265**

# Big data and small science

