

NHLBI Data Repository (BioLINCC)

Sean Coady

National Heart, Lung, and Blood Institute

NIH Health Care Systems Research Collaboratory
Steering Committee Meeting

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Outline

Studies currently in the data repository
Policies – Timing for release of data
Policies – Typical data modifications
De-identification notes
Submitting datasets
Requesting data from the repository
'Issues' associated with data requests
Oversight
Data repository activities

Data Repository Studies

- Data from more than 600,000 participants in over 100 observational and clinical trial studies.

- 32 Observational studies:

General population studies (Framingham, ARIC, CHS, CARDIA, MESA) *Post-menopausal women* (WHI-OS); *African-Americans* (Jackson), *Puerto Ricans* (PRHHP); *Asian Americans* (HHP); Patient populations *Sarcoidosis* (ACCESS); *Sickle Cell* (CSSCD); *Iron Overload* (HEIRS); *Primary Pulmonary Hypertension* (PPH); *Human retrovirus infected blood donors* (REDS-HTLV, REDS2-MS); *Alpha₁ Antitrypsin deficiency patients* (Alpha₁ registry); *Women with suspected myocardial Ischemia* (WISE, 1024); *hemophilia* (MHCS); Adolescents (Bogalusa, NGHS)

Data Repository Studies

- 77 Clinical Trials:

Asthma Clinical Research Network Trials (BAGS, CIMA, SOCS/SLIC, MICE, DICE, BARGE, IMPACT, PRICE, MIA, LARGE, BASALT/TALC); Acute Respiratory Distress Network (ARMA/LARMA, ALVEOLI, FACTT, LaSRS); Community Interventions (REACT, PAD); Hypertension Treatment (TOHP I&II, DASH, DASH-Sodium, PREMIER, PATHS); Primary Prevention (MRFIT, ACT, LRC-CPPT); Secondary Prevention (BEST, BHAT, AMIS, CASS, MAGIC, WAVE, CAST, SOLVD, TIMI II & III, PEACE, ESCAPE, AFFIRM, OAT, ENRICHED, BARI 2D); Lung function/Respiratory (LHS, NETT, IPPB), Diagnostic (PIOPED); Other Treatment (MSH, WLM, RTS, VATS); Primary/Secondary Prevention (ALLHAT, HDFP, SHEP, WHI-CT, ACCORD); Emergency Medicine (ROC-HS, ROC-PRIMED, ROC-CPR); Adolescents (CAMP and CAMPCS, DISC, HIFI, TAAG)

Timing for release of data

- **Clinical Trials:**
 - ✓ **3 years after the final visit of the participants to their clinical trial sites,**
or
 - ✓ **2 years after publication of primary outcome paper**

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- **Clinical Trials:**
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- **Observational Epidemiology Studies:**
 - ✓ 3 years after the completion of each examination or follow-up cycle, or
 - ✓ 2 years after the baseline, follow-up, genetic, ancillary study, or other data set is finalized within the study for analysis

Data De-identification

- 1. Be prepared in a manner consistent with the informed consent (eg. Commercial use restrictions, sharing restrictions, research use restrictions)**
- 2. Obvious identifiers removed (i.e. HIPAA identifiers).**
- 3. Geography is generally removed.**
- 4. Dates are recoded as a time interval.**
- 5. Sensitive data removed when not integral to the study**
- 6. Other data may be recoded to minimize the possibility of re-identification of a participant.**
 - a. Top/bottom coding for height/weight**
 - b. Grouping of race/ethnicity**
 - c. Grouping of marital status, education, income, etc.**

Submitting Data

- **Data:**
 - ✓ Individual level data, preference is for SAS v9 format, or text files with appropriate coding manuals.
- **Documentation**
 - ✓ Case reporting forms, protocols, manual of operations, data dictionaries or coding manuals in MS Word format for 508 compliance (select documentation will be posted on the website)
 - ✓ Basic readme file with a description of the data, de-identification notes, or data ‘tips’
- **Data and documentation uploaded to a secure FTP site**
- **Data and documentation reviewed for compatibility with guidelines and usability**

Requesting data from the Repository

1. Register on website and complete data request form

Collections

- Register a Biospecimen Collection
- Preparing and Submitting Data Repository Datasets

About BioLINCC

- BioLINCC Handbook
- Forms and Templates
- FAQs
- Glossary

Proprietary Studies

Questions/Comments

My BioLINCC

Support information

***Institution type:** Non-Profit Organization Commercial Organization

***Support type:**

Other:

Request Details

***Describe this request:**

A brief overview of your research needs.

***Study:**

Hold down "Control", or "Command" on a Mac, to select more than one.

***Design and analysis plan:**

Include the participant inclusion/exclusion criteria, expected study visit periods, key analytic variables, primary and secondary outcome measure, follow-up period (if applicable), and intended statistical methods. Inadequately described requests may be deferred until a complete description is included.

***Information Security: Please check the information security practices to be used:**

- Institute supported, controlled access server
- Institute supported, password protected desktop computer
- Encrypted, password protected laptop computer
- Encrypted portable media (encrypted external hard drive, encrypted thumb drive)
- Unencrypted portable media backup (CD, DVD, thumb drive) stored in locked file cabinet

Study data must be maintained in a secure and controlled environment

***Will the results be used for a commercial purpose?** Yes No - the results will not be used for a commercial purpose.

A "Yes" response defines this as a "Commercial Purpose" request.

Comments:

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3. Sign a Research Materials Distribution Agreement that:
 - ✓ Prohibits the transfer of data
 - ✓ Limits use of the data to three years
 - ✓ Specifies a required acknowledgment in manuscripts/abstracts
 - ✓ Requires notification of any new projects
4. Obtain institutional sign-off on the research materials distribution agreement.

Data Requests - Issues

- There is no scientific merit review of requests for data or screening of manuscripts prior to Journal submission
 - “Head scratching” data requests
 - Pre-hypertension & risk for CVD (sickle-cell, DISC, Alpha1)
 - Possibility of poor or incorrect analyses getting published
 - “Embarrassing presentation”
 - “very sloppy work”
- Ask for a progress report once a year, but response rate is low.
- Manually search for manuscripts based on investigator name and institution

Oversight

Data repository operates under NHLBI IRB approved protocol

- Policy and procedures are somewhat insulated from arbitrary changes that may be encouraged by NHLBI staff or leadership
- Protocol is not strictly rigid. There is some flexibility in the protocol (there are both 'rules' and 'guidelines')
- Management of the data repository is also insulated from arbitrary demands by those requesting access.

Data Repository Activities

- Approximately 640 investigators from the US and 20 other countries have received data
- Nearly 35% of requested datasets include data from clinical trials
- More than 450 publications in 179 different Journals
- Several data repository investigators elected to collaborate with study investigators

Participant Privacy

