NHLBI Data Repository (BioLINCC) Data Submission Worksheet

General Instructions

Use the checklist below as a guide for compiling and preparing documentation and data for submission to the Data Repository (BioLINCC). Please complete the study details worksheet and informed consent questionnaire. Guidelines for preparing data for submission are provided on page 4. The worksheet can be submitted to your NHLBI PO or the NHLBI Data Repository representative (coadys@nhlbi.nih.gov). Questions or comments can be forwarded to biolincc@imsweb.com or coadys@nhlbi.nih.gov .

Submission Elements (All Studies)

- ☐ Study Details Worksheet
- ☐ Informed Consent Questionnaire
- ☐ Internal participant ID to new randomized ID link/crosswalk file
- ☐ De-identified data sets, all data elements with descriptive labels

Study Documentation Elements (All Studies)

- ☐ Study protocol
- ☐ Manual of Operations/Manual of Procedures (e.g. Venipuncture, Blood Pressure, Event Ascertainment, Quality Control, etc.)
- ☐ Annotated data collection forms
- ☐ Code book or data dictionary containing variables and the values to which they map
- ☐ For SAS based data sets with embedded formats, the SAS formats library, data set, or SAS program file that provides definitions of numeric category indicators, e.g. for marital status 1=Married, 2=Divorced/Separated, 3=Widowed, 4=Never Married (if applicable)
- ☐ Calculated variables documentation, e.g. algorithms, guidance for use, publication references, etc. of data which have undergone expert adjudication (diagnosis or outcome data), summary scores from procedures (Echocardiography, spirometry, CT scans, ECGs, etc.), and scored questionnaires.
- ☐ Summary of de-identification changes made to the data
- ☐ Summary of the study and submitted materials including the dataset names
- ☐ Any other guidance that would be helpful for someone unfamiliar with the study or data (if applicable)

Additional materials for Clinical Trials

- ☐ A summary of changes made to the protocol over time (PDF, Excel or Word)
- ☐ Primary publication (if published)
- ☐ Frozen datasets used for the primary publication, or variables indicating the study population used in the primary publication

Additional materials for Studies depositing biospecimens

- ☐ Private clinical datasets (will not be shared)

Study Details Worksheet

Title of Study: Long study name.

Study acronym: Acronym

ClinicalTrials.Gov Study ID: clinicaltrials.gov ID

Award Number: NIH grant, contract, or project number

Study Principal Investigator (PI): Study PI name

Study URL: Copy and paste the URL for the study website if available

Coordinating Center: Institution Name

Contact Name and email address: Name(s) and email address(es) of those that will interact with BioLINCC

NHLBI project officer: Name of NHLBI project officer or program official

Preferred Release Date: If an early release date is desired, indicate month and year of release; otherwise the information below will be used to determine the release date according to NHLBI guidelines.

☐ Clinical Trial (interventional)

If the study is a clinical trial:

Primary publication reference: Citation of primary outcome paper if available

Date of publication for primary outcome paper: Primary publication date if available

Approximate date of last clinic activity: Approximate date of last participant visit or end of data collection activities

Date of expected end of funding: Date funding is expected to end

☐ Observational Study

If the study is observational:

Date of last participant visit or follow-up close out date: Approximate date of the last visit of a participant to a clinic site or thru date for follow-up assessment

Approximate date of database lock for release to study investigators: Approximate date database was locked or frozen for within study analysis

Date of expected end of funding: Approximate date funding is expected to end

Informed Consent Questionnaire

Data and the Informed Consent

Widely shared data from human subjects must be prepared in a matter consistent with the Informed Consent (IC). Informed consents may be tiered with a number of restrictions, broad with a general or global restriction applicable to all study participants, or broad in which there are no implied or explicit restrictions**. Note that if a tiered consent is used then an informed consent dataset delineating the restrictions each participant selected may be needed**. Please complete the following:

☐ 1. An exception from informed consent was received for this study and the IRB approved protocol for this study does not restrict the sharing of de-identified data. If yes, check box, initial Initials, and stop here. If no, proceed to 2.

☐ 2. The informed consent has been reviewed and there are no implied or explicit restrictions on the wide sharing of clinical data and a tiered structure with respect to uses or other restrictions was not used. If yes, check box, initial Initials, and stop here. If no, proceed to 3.

If the informed consent contains explicit or implied restrictions, please consult with BioLINCC or the NHLBI data Repository representative on the need for a participant level dataset regarding informed consent restrictions.

☐ 3. The informed consent has been reviewed and a tiered structure was used such that study participants could opt-out of certain uses of their data, or the informed consent explicitly or implies a general or global restriction applicable to all study participants. If yes, check box and continue to 3a:

☐ 3a. Study participants could opt-out of sharing data beyond study investigators (if yes, check box and proceed to 3b, leave blank if no and proceed to 3b)

☐ 3b. Study participants could opt-out of use or sharing of data for specific research purposes, or the informed consent globally restricted use of data to a specific purpose. If yes, check box and respond to sub-statements 3b.1 or 3b.2. If no, skip sub-statements and proceed to 3c,

☐ 3b.1. (General or global restriction) For all study participants the informed consent restricted use of their data to Describe briefly the research use restriction applicable to all study participants

☐ 3b.2. (Tiered consent) Study participants could restrict use of their data to the following purposes Describe briefly the opt-in or opt-options for participants. For example, **participants could limit use of data to 1) lung disorders or 2) for any purpose**

☐ 3c. Study participants could opt-out of sharing data with commercial entities or for a commercial purpose (If yes, check box, leave blank if no)

Data de-identification guidelines

Overview. Investigators in NHLBI studies covered by the Policy for Data Sharing from Clinical Trials and Epidemiological Studies are required as part of the terms and conditions of their awards to prepare and deliver to the NHLBI data sets that satisfy NHLBI requirements. Included among these required components are the elimination of personal identifiers and the modification of other data elements so as to reduce the likelihood that any individual participant can be identified.

Informed Consent dataset (if applicable). Investigators must provide the Institute with a list of participant identification numbers, with data fields indicating participants who asked that their data not to be shared beyond the initial study investigators, participants who asked that their data not be used for commercial purposes (if applicable), and participants who asked that use of their data be restricted to specific types of research activities (if applicable).

Ancillary Studies. Investigators in ancillary studies based on ongoing (parent) studies that are required by this policy to produce data sets must submit ancillary study data to the NHLBI through the parent study coordinating center or data submission process established by the parent study.

Types of Data to be Included in NHLBI Repository Data Sets

In addition to summary information, data sets include for each participant those raw data elements (e.g., case report forms, food item data, individual electrocardiographic lead scores, echocardiography, etc.) that have not otherwise been processed into summary information.

- Clinical Trials - included are screening, baseline, interim visit, ancillary data, and outcome data, along with associated laboratory and procedure measurements not otherwise summarized.
- Observational Epidemiology Studies - included are all of the examination data obtained in each examination cycle, ancillary data, and/or all of the follow-up information available up to the last follow-up cycle cutoff date.

Guidelines for Redaction/Summarization of NHLBI Data Sets

The NHLBI requires that the data be provided in a manner that protects the privacy of study participants. The Institute requires appropriate documentation of the steps taken to protect their privacy in preparing a data set. A summary of all proposed modifications and deletions to be made to a data set should be submitted to and approved by the NHLBI Data Repository representative prior to their implementation.

The following guidelines provide a framework for decision-making regarding preparation of data sets:

1) Participant identifiers:
   a) Obvious identifiers (e.g., name, addresses, social security numbers, place of birth, city of birth, contact data) must be deleted.
   b) New identification numbers must replace original identification numbers. Codes linking the new and original data should be sent to the NHLBI in a separate file along with data fields indicating relevant consent restrictions (i.e. commercial use restriction Yes/No), so that linkage may be made if necessary for future research.
2) Dates: All dates should be coded relative to a specific reference point (e.g., date of randomization or study entry). This provides privacy protection for individuals known to be in a study who are known to have had some significant event (e.g., a myocardial infarction) on a particular date.

3) Variables that are administrative, sensitive in nature, or related to centers in multicenter studies:
   a) Clinical center identifier -- In trials or studies that have only a few centers and/or relatively few participants per center, the data set should not contain center identifiers. In trials that have either many centers or a large number of participants per center, the data may offer little possibility of identifying individuals. For them, the investigators and the NHLBI will determine whether to include them on a case-by-case basis.
   b) Interviewer or technician identification numbers, batch numbers, or other administrative data should be deleted.
   c) Sensitive data, including incarcerations, illicit drug use, risky behaviors (e.g., carrying a gun or exhibiting violent behavior), sexual behaviors, and selected medical conditions (e.g., alcoholism, HIV/AIDS) must be deleted when not directly relevant to the original aims of the study.
   d) Regional variables with little or no variation within a center because they could be used to identify that center should be deleted.
4) Unedited, verbatim responses that are stored as text data (e.g., specified in "other" category) should be deleted or edited to remove any embedded dates, names, or geographic identifiers (hospital names, city name, etc.).
5) Variables with low frequencies for some values that might be used to identify participants (traits with visual or casual knowledge component), may be recoded. These might include:
   a) Socioeconomic and demographic data (e.g., marital status, occupation, income, education, language, number of years married).
   b) Household and family composition (e.g., number in household, number of siblings or children, ages of children or step-children, number of brothers and sisters, relationships, spouse in study).
   c) Number of pregnancies, births, or multiple children within a birth.
   d) Anthropometric measures (e.g., height, weight, waist girth, hip girth, body mass index).
   e) Physical characteristics (e.g., missing limbs).
   f) Detailed medication, hospitalization, and cause of death codes, especially those related to sensitive medical conditions as listed above, such as HIV/AIDS or psychiatric disorders.
   g) Prior medical conditions with low frequency (e.g., group specific cancers into broader categories) and related questions such as age at diagnosis and current status
   h) Parent and sibling medical history (e.g., parents' ages at death).
   i) Race/ethnicity information when very few participants are in certain groups or cells.
6) Data elements with no visual or casual knowledge component or that cannot be linked to existing databases should be not modified. For those data elements that do require modification suggested approaches include:
   a) Polychotomous variables: values or groups should be collapsed so as to ensure a minimum number of participants (e.g., at least 15-20 or approximately 5%, whichever is less) for each value within a categorical cell.
   b) Dichotomous variables: data may either be grouped with other related variables so as to ensure a minimum number of participants (e.g., at least 15-20 or approximately 5%) in a specific cell or deleted.
7) The investigators may realize that other variables may make it easy to identify individuals. All such variables should be recoded or removed. The NHLBI Data Repository representative should be consulted concerning such variables.

To post a study on the BioLINCC website, please enter details for the following fields:

Study Title (Name of Study):

Study Acronym:

ClinicalTrials.gov URL:

Study Website URL (*Optional*):

Study Type:

Study Period (month/year – month/year):

HIV Study Classification:

COVID Study Classification:

Cohort Type:

Primary Outcome Paper URL (*PubMed*):

Related BioLINCC studies (*Optional*):

NHLBI Division:

Each of the following fields is typically answered with a 1-2 paragraph description.

Objective (*the study objective(s)***):**

Background (*The scientific rationale for conducting the study and background information regarding the condition(s) being studied, including morbidity, mortality, shortcomings in existing treatment options, etc.***):**

Participants (*Information about the study participants, inclusion/exclusion criteria, include the final number of subjects enrolled within each treatment arm, if applicable***):**

Design (*Design of the study, ex: randomization strategy, frequency of visits, types of assessments, administration of study drug, follow-up, etc., include the primary outcome measurement, where applicable***):**

Conclusions (*Conclusions of the study as determined by the primary outcome measurement, if available, or primary findings***)**:

Publications (*List of URLs linking to related study publications. Optional***):**

EXAMPLE Study Collection Details

To post a study on the BioLINCC website, please enter details for the following fields:

Study Title (Name of Study): Cardiothoracic Surgical Trials Network (CTSN) Surgical Ablation Versus No Surgical Ablation for Patients With Atrial Fibrillation Undergoing Mitral Valve Surgery (AFB)
Study Acronym: CTSN-AFB
ClinicalTrials.gov URL: https://clinicaltrials.gov/study/NCT00903370
Study Website URL (*Optional*): https://www.ctsurgerynet.org/
Study Type (*Clinical Trial or Epidemiology Study?):* clinical trial
Study Period (month/year – month/year): January 2010 – September 2015
HIV Study Classification (*non-HIV, HIV-related, or HIV):* non-HIV
COVID Study Classification (*non-COVID, COVID, or COVID-related):* non-COVID
Cohort Type (*pediatric, adult, or both):* adult
Primary Outcome Paper URL (*PubMed*)**:** https://pubmed.ncbi.nlm.nih.gov/25853744/
Related BioLINCC studies (*Optional*): n/a
NHLBI Division (*DBDR, DCVS, DLD, CTRIS*): DCVS

Each of the following fields is typically answered with a 1-2 paragraph description.

Objective:

To assess the effect of surgical ablation, as well as the effects of two different ablation procedures, on the recurrence of atrial fibrillation in participants with persistent or long-standing persistent atrial fibrillation who were undergoing mitral-valve surgery.

Background:

Atrial fibrillation (AF), which is associated with reduced survival and increased risk of stroke, is present in 30 to 50% of patients presenting for mitral-valve surgery. The development of open surgical procedures for the ablation of AF has led to their widespread application during cardiac operations, but their effectiveness and safety have not been rigorously established. Moreover, although the pulmonary-vein isolation procedure is used more frequently than the biatrial maze procedure, data on the comparative effectiveness of the two ablation procedures are also limited.

The CTSN-AFB trial sought to determine the effect of surgical ablation on the recurrence of AF in the first year after surgery and to explore the effects of two different ablation procedures (pulmonary-vein isolation or biatrial maze procedure) on freedom from AF during the same period in patients with persistent or long-standing persistent AF who were undergoing mitral-valve surgery.

Participants:

Eligible participants were adults with persistent or long-standing persistent AF who also had mitral-valve disease requiring surgical intervention. Persistent AF was defined as non–self-terminating AF lasting more than 7 days, or less than 7 days if cardioversion was required. Long-standing persistent AF was defined as continuous AF for more than 12 months. This definition applied only to AF episodes that were of at least 30 seconds' duration and did not have a reversible cause such as acute pulmonary disease or hyperthyroidism.

A total of 260 participants underwent randomization, with 133 randomly assigned to mitral-valve surgery with ablation and 127 randomly assigned to mitral-valve surgery alone. In the ablation group, 67 participants were randomly assigned to pulmonary-vein isolation and 66 to the biatrial maze procedure.

Design:

The CTSN-AFB study was performed at 20 centers in the Cardiothoracic Surgical Trials Network. Eligible participants were randomly assigned in a 1:1 ratio to undergo either surgical ablation or no ablation (control group) during the mitral-valve operation. Participants in the ablation group underwent further randomization to one of two lesion sets: pulmonary-vein isolation or biatrial maze. All participants also underwent closure of the left atrial appendage to reduce the risk of formation of a left atrial thrombus. Unless contraindicated, all participants received Class I or III anti-arrhythmic drugs within 24 hours of surgery, which were discontinued at three months.

Follow-up assessments were conducted by telephone interview at 3, 6, and 9 months and in person at 12 months. The primary end point was freedom from AF at both 6 months and 12 months after surgery, as assessed by means of 3-day continuous Holter monitoring. Secondary end points included major cardiac or cerebrovascular adverse events (death, stroke, hospitalization for heart failure, worsening heart failure [as defined by an increase of one or more classes in the New York Heart Association classification], or mitral-valve reintervention), mortality, the need for rhythm-related interventions, quality of life, and rehospitalization.

Conclusions:

In participants with persistent or long-standing persistent atrial fibrillation, the addition of surgical ablation at the time of mitral-valve surgery significantly increased the rate of freedom from atrial fibrillation at one year.

Gillinov AM, Gelijns AC, Parides MK, et al. Surgical ablation of atrial fibrillation during mitral-valve surgery. *N Engl J Med*. 2015;372(15):1399-1409. doi:10.1056/NEJMoa1500528