

Beginning with end in mind: how superb planning and good data collection hygiene will set you up for research success

5/08/2023

K-Club

Sponsors:



Department of Medicine



Department of Pediatrics



Children'sSM
Healthcare of Atlanta

Survey Drawing



Survey Drawing



**Winner:
Kait Proctor**



K-Club Special: American Society of Transplantation Career Transition Grant

- The Career Transition Research Grant seeks to:
 - 1. Foster the transition of early to mid-career scientists who are contributing to our understanding of transplant science/immunobiology and/or treatment of transplant recipients and need funding to start or strengthen work that is not yet funded by larger grants.
 - 2. Foster research that is of high merit.
 - 3. Encourage the continued commitment of high-quality applicants to careers in academic transplantation
- Career Transition Research Grants are awarded in the amount of \$125,000 for two years, with \$75,000 disbursed in Year One and \$50,000 disbursed in Year Two.

Deadline: June 15, 2023

https://www.myast.org/sites/default/files/research/2024_AST_Career_Transition_Research_Grant.pdf

K-Club Special: AACR-NOVOCURE CAREER DEVELOPMENT AWARD FOR CANCER RESEARCH

- Purpose: to promote and support early-career investigators who are conducting innovative research focused on Tumor Treating Fields (TTFields; intermediate frequency, low intensity, alternating electric fields that disrupt cell division in cancer cells) as well as to encourage early-career investigators to enter the TTFields research field
 - Projects focused on one or more of the areas outlined below are strongly encouraged:
 - Key cancer-related signaling and cellular pathways
 - Metabolic effects of TTFields
 - Studies that include Omics data (genomics, transcriptomic, proteomics)
 - TTFields immunological aspects and the potential combination with immunotherapy
 - Combinational studies with approved agents, preferably to include mechanistic aspects
- \$300,000 over three years for expenses related to the research project, which may include salary and benefits of the grant recipient and any collaborators

Deadline for LOI: May 30, 2023

<https://www.aacr.org/grants/aacr-novocure-career-development-award-for-cancer-research/>

Today's program

Discussion facilitated by Beth Stenger, MD

Panelists Include:



Jordan Gilleland Marchak, PhD, ABPP
Associate Professor of
Pediatrics, Emory University
School of Medicine
Aflac Cancer & Blood Disorders
Center at Children's
Healthcare of Atlanta



Jeremy Kupsco, PhD
Research Informationist,
Woodruff Health Sciences
Center Library, Emory
University



Jonathan Park
Applications Analyst Team
Lead, Children's Healthcare
of Atlanta



**Rebecca Williamson
Lewis, MPH**
Research Epidemiologist
Team Lead, Aflac Cancer &
Blood Disorders Center at
Children's Healthcare of
Atlanta

Monday, May 8, 2023

12:00 pm—1:00 pm

Data Management Tools in REDCap

How to utilize all of REDCaps tools to collect clean and accurate data



Useful Tools for Data Collection and Entry

- Data Validation Settings/Action Tags
- Data Resolution Workflow
- Data Quality Rules

Data Validation Settings

Add New Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type:

[Codebook](#)

Field Label

Use the Rich Text Editor [?](#)

Variable Name (utilized in logic, calcs, and exports)

 Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#) [Field Embedding](#)

Validation? (optional)
Minimum:
Maximum:

Tip for min/max limits: You may pipe a value from another field to set dynamic range limits - e.g., [visit_date] or [event_1_arm_1][age]. You may also use the word today or now (not wrapped in quotes) for date/time fields.

– OR –

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Save

Cancel



Data Validation Settings

- In combination with the Field Validation type, you can add Min/Max validation settings, as well as the @FORCE-MINMAX action tag

Double Data Entry

User Access:

Creating new role "First Entry"

You may set the rights for the user below by checking the boxes next to the application tools to which you wish to grant them access. You may also grant the collection instruments, if so desired. To save your selections, click the "Create role" button at the bottom of the page.

Creating new role "First Entry"

Basic Privileges

Highest level privileges:

- Project Design and Setup
- User Rights
- Data Access Groups

Other privileges:

- Alerts & Notifications
- Calendar
- Add/Edit/Organize
- Reports
Also allows user to view ALL reports (but not necessarily all data in the reports)
- Stats & Charts

- Double Data Entry
 - Reviewer
 - Person #1
 - Person #2

Privileges for Viewing and Exporting Data

Data Viewing Rights pertain to a user's ability to view or edit data on pages in the pro with 'No Access' Data Viewing Rights for a given instrument will not be able to view th able to view fields from that instrument on a report. Data Export Rights pertain to a whether through the Data Exports page, API, Mobile App, or in PDFs of instruments c Rights and Data Export Rights are completely separate and do not impact one another.

Data Viewing Rights

	No Access (Hidden)	Read Only	View & Edit
Form 1	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

* De-identified means that all free-form text fields will be removed, as well as any date/ti

External Modules: Configuration Permissions

Privileges may be defined regarding whether the user can set or modify the configur enabled on this project. Below are the currently enabled modules. NOTE: Only admi configuration permissions here.

- Auto Record Generation*
- Image Map*
- Inline Descriptive Pop-ups
- M...




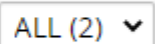
Double Data Entry

Entry Records:

Record Status Dashboard (all records)


Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard]  

Displaying record Page 1 of 1: "1--1" through "1--2"  of 2 records 

Enter new record name 

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

Record ID	Form 1
1--1	
1--2	

Double Data Entry: Reviewing Entries

Project Home and Design

- Project Home · Project Setup
- Designer · Dictionary · Codebook
- Project status: **Development**

Data Collection

- Record Status Dashboard
- View data collection status of all records
- Add / Edit Records
- Create new records or edit/view existing ones
- Show data collection instruments


Applications

- Project Dashboards
- Alerts & Notifications
- Multi-Language Management
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool**
- Logging and Email Logging
- File Repository
- User Rights and DAGs
- Customize & Manage Locking/E-signatures
- Data Quality and Resolve Issues
- API and API Playground

≠ Data Comparison Tool for Double Data Entry

This page may be used for comparing project records that have been entered by designated data entry persons. Select a record from the list below and hit the 'Compare' button. A comparison table will then be displayed showing the differences between the records. Only records that have been entered by both data entry persons will be displayed in the selection box below.

Record ID	<input type="button" value="Compare selected record"/>
<input type="text" value="1"/>	— OR —
	<input type="button" value="Compare all records"/>

 Print page

Differences were found between the two records named 1--1 and 1--2.

The table below compares the two records named 1--1 and 1--2. Only the fields that have differing values are listed below. If you need to correct or change the value of one of the records below, simply click on the data displayed in red, and it will take you to that form for that particular record.

MERGE THEM?

If you wish to merge selected values from the two records below into a NEW third record, you may [click here to merge them](#).


Label (<i>field name</i>)	Form Name	Record ID	
		1--1	1--2
Question 1 (<i>q1</i>)	Form 1	5 (5)	2 (2)

Double Data Entry: Reviewing Entries

≠ Data Comparison Tool for Double Data Entry

This page may be used for comparing project records that have been entered by designated data entry persons. Select a record from the list below and hit the 'Compare' button. A comparison table will then be displayed showing the differences between the records. Only records that have been entered by both data entry persons will be displayed in the selection box below.

Record ID	Compare selected record
1	— OR —
	Compare all records

 Print page


The two records named 1--1 and 1--2 are identical. No differences were found.

If you wish to merge these records into a new record named 1, then click the 'Create Record' button below.

Create Record 1

Data Resolution Workflow

Additional Customizations:



Optional

I'm done!

⚙️ Enable optional modules and customizations

- Modify Repeating instruments [?](#)
- Disable Auto-numbering for records [?](#)
- Enable Scheduling module (longitudinal only) [?](#)
- Enable Randomization module [?](#)
- Enable Designate an email field for communications (including survey invitations and alerts) [?](#)

Additional customizations


Settings displayed to Administrators only:

- Enable Clinical Data Pull from EPIC [?](#)
- Enable Twilio SMS and Voice Call services for surveys and alerts [?](#)
- Enable Mosio SMS services for surveys and alerts [?](#)
- Enable SendGrid Template email services for Alerts & Notifications [?](#)


Data Resolution Workflow

Enable Data Resolution Workflow:

Additional customizations

-  **Order the records by another field**
The default setup is that all records are ordered by their record name (e.g., Study ID) when displayed in the drop-down lists on your data collection instruments, but you may alternatively order the drop-down lists by the values of another field in the project (e.g., last name), if desired. If you wish to order the records by another field, select the field below. **NOTE: This feature does not work for longitudinal projects (such as this one).**

-- select field to order records by --

-  **Enable the Field Comment Log or Data Resolution Workflow (Data Queries)?**
For this project, you may enable either the Field Comment Log or Data Resolution Workflow (also known as the Data Queries module). The Field Comment Log (enabled by default) allows users to leave comments for any given field on a data entry form by clicking the balloon icon next to the field. All comments can also be viewed, searched, and downloaded on the Field Comment Log page. Alternatively, if the Data Resolution Workflow is enabled, users will be allowed to open a workflow for documenting the process of resolving issues with data in the project (i.e. opening, responding to, and closing data queries). [View more details](#)

Enable: Data Resolution Workflow

Allow comments (excludes Data Resolution Workflow comments)?

- None
- Field Comment Log
- Data Resolution Workflow

PDF C

Data Resolution Workflow

Data Resolution Access Settings:

Data Quality

[What is Data Quality?](#)

Create & edit rules

Execute rules

Data Resolution Workflow

[What is Data Resolution Workflow?](#)

No Access

View only

Open queries only

Respond only to opened queries

Open and respond to queries

Open, close, and respond to queries

Data Quality Rules

Project Home and Design

- Project Home · Project Setup
- Designer · Dictionary · Codebook
- Project status: **Development**

Data Collection

- Survey Distribution Tools
 - Get a public survey link or build a participant list for inviting respondents
- Record Status Dashboard
 - View data collection status of all records
- Add / Edit Records
 - Create new records or edit/view existing ones

Applications

- Project Dashboards
- Alerts & Notifications
- Multi-Language Management
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging and Email Logging
- File Repository
- User Rights and DAGs
- Customize & Manage Locking/E-signatures
- Randomization
- Data Quality and Resolve Issues**
- API and API Playground
- REDCap Mobile App

Clinical Data Interoperability Services

- Standalone Launch
- Mapping Helper
- Messages
- Valid access token
- auto-login
- break the glass disabled

Sign Up for REDCap Training

Reports Search Organize Edit

- 1) Repeating Report

Data Quality

Find Issues Resolve Issues Resolution Metrics

This module will allow you to execute data quality rules upon your project data to check for discrepancies in your data. Listed below are some pre-defined data rules that you may utilize and run. You may also create your own rules or edit, delete, or reorder the rules you have already created. To find discrepancies for a given rule, simply click the Execute button next to it, or click the Execute All Rules button to fire all the rules at once. It will provide you with a total number of discrepancies found for each rule and will allow you to view the details of those discrepancies by clicking the View link next to each. [Read more detailed instructions.](#)

Upload or download Data Quality Rules

Execute rules: All All except A&B Clear

Apply to: All Records

Rule #	Rule Name	Rule Logic (Show discrepancy only if...)	Real-time execution ?	Total Discrepancies	Children's Hospital of Test	Test Children's Hospital	Delete rule?
A	Blank values*	-		Execute			
B	Blank values* (required fields only)	-		Execute			
C	Field validation errors (incorrect data type)	-		Execute			
D	Field validation errors (out of range)	-		Execute			
E	Outliers for numerical fields (numbers, integers, sliders, calc fields)**	-		Execute			
F	Hidden fields that contain values***	-		Execute			
G	Multiple choice fields with invalid values	-		Execute			
H	Incorrect values for calculated fields	-		Execute			
I	Fields containing "missing data codes"	-		Execute			
Add	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>				

Enter descriptive name for new rule
(e.g., Participants below age 18)

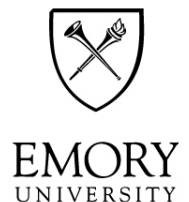
Enter logic for new rule
(e.g., [age] < 18)
[How do I use special functions?](#)

Execute in real time on data entry forms ?

Beginning with the end in mind: how superb planning & good data collection hygiene will set you up for research success

Rebecca Williamson Lewis, MPH

Jordan Gilleland Marchak, PhD, ABPP



IS SET Project

“Improving Support for Survivors Engaged in Transition (IS SET)”

Gilleland Marchak & Effinger (MPI)

3P30CA138292-13S2- Administrative Supplement

THE HEALTH PROBLEM



Local & national **gaps in care** to support **healthcare transition** place adult-aged survivors of pediatric cancer at increased **risk for disparities** in outcomes

OUR STUDY

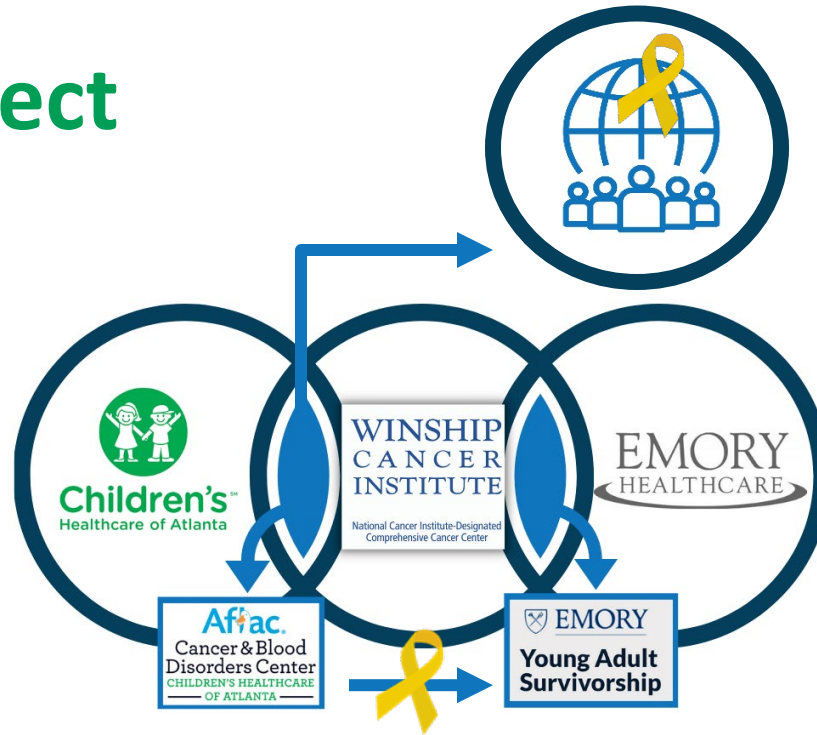


GOAL: Reduce inequities in care for adult survivors of pediatric cancer through **understanding** and **improving** formal **healthcare transition practices**

AIM 1: Evaluate **organizational programming** needed to promote **continuation of risk-based care** among young adult aged survivors of pediatric cancer

AIM 2: Identify **organizational barriers & facilitators** to **implementing** the **Six Core Elements of Transition** in the context of survivor care

IS SET Project



OUR STUDY



IMPACT: Inform **organizational changes** to **improve healthcare transition supports** for survivors at the Winship Cancer Institute & across the US

AIM 1: Evaluate **organizational programming** needed to promote **continuation of risk-based care** among young adult aged survivors of pediatric cancer

AIM 2: Identify **organizational barriers & facilitators** to implementing the **Six Core Elements of Transition** in the context of survivor care

IS SET Project

AIM 1: Evaluate **organizational programming** needed to promote **continuation of risk-based care** among young adult survivors of pediatric cancer



DATA NEEDS

Identify patients who had **aged out** of our center between 2016-2020

Re-contact young adult survivors to determine patterns of **successful healthcare transition (HCT)**

Solicit feedback from young adults & caregivers using the **GotTransition™ HCT Feedback Survey**



DATA CHALLENGES

Identify patients who had **aged out** of our center between 2016-2020

Re-contact young adult survivors to determine patterns of **successful healthcare transition (HCT)**

Solicit feedback from young adults & caregivers using the **GotTransition™ HCT Feedback Survey**

IS SET Project

AIM 1: Evaluate **organizational programming** needed to promote **continuation of risk-based care** among young adult survivors of pediatric cancer



DATA NEEDS

Identify patients who had **aged out** of our center between 2016-2020

Re-contact young adult survivors to determine patterns of **successful healthcare transition (HCT)**

Solicit **feedback** from young adults & caregivers using the **GotTransition™ HCT Feedback Survey**



DATA CHALLENGES

Remote recruitment of patients no longer in engaged in our care

- Outdated contact information
- Missing contact information

Seeking **dyadic data** from young adults & caregivers

- Parallel recruitment
- Respect for YA preferences
- Guardianship issues
- Gather contact information

Tracking to accurately identify **responders v. non-responders**

Overall Project Management

PI Study Management

Identify
Eligible
Participants



Participant
Recruitment



Survey
Collection



Medical
Record
Abstraction



Coordinator Data Collection

Statistical Analysis



REDCap Structure

- Good data hygiene starts with the structure of your data collection tools
- REDCap has lots of settings and features that impact data collection interface and underlying data structure
- ~~One row per patient/Default 'classic' data collection~~
 - Wanted same variable names regardless of which version was completed first
- ~~Repeating Forms~~
 - Wanted to quickly see survey version completed on dashboard
 - Knew we only needed 2 surveys per patient
- Longitudinal Data Collection with Defined Events ✓
 - Ok with a data structure having one row per event (≥ 1 row per record/patient)

REDCap Structure

Forms

- Patient Information
- Contact Tracking
- Consent*
- YA Survey
- Caregiver Survey
- Incentive Tracking
- Medical Record Abstraction

Events

- Patient Information & Tracking
- Survey 1
- Survey 2

Record ID	Patient Information & Tracking		Survey 1				Survey 2				Medical Record Abstraction
	Patient Information	Contact Tracking	Consent	YA Survey	Caregiver Survey	Incentive Tracking	Consent	YA Survey	Caregiver Survey	Incentive Tracking	Medical Record Abstraction
258	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
259	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
260	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
261	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
262	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
263	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
264	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
265	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
266	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

*Had a wavier of documentation of consent (i.e., signature) so did not use REDCap e-consenting.



Identify Eligible Participants: Generate Cohort



Know **key sources** of data for your disease group

- Oncology registry, SCD Clinical database
- Epic Reporting Work Bench



Data **request** to the **Health Informatics Core**

- CareForce → IS&T Solution Center → Data & Reporting
 - Research requests will be re-directed to REDCap Link
- Ensure you have your documentation ahead of time (e.g., IRB, DUA)
- *Some things will still need manual abstraction and/or human interpretation*



Data **import** into REDCap

- Ensure matches REDCap variable names, coding, and text validation formats



Recruitment: Contact Tracking

Event: Patient Information & Tracking

Record ID: 462

Patient Name: _____
DOB: _____ CID: _____

EPIC Contact Information

Parent 1 Last Name: _____ Parent 1 First Name: _____
Parent 2 Last Name: _____ Parent 2 First Name: _____

Epic Address: Street: _____
City: _____ State: _____ Zip: _____

Email 1: _____ Email 2: _____ Email 3: _____
Phone 1: _____ Phone 2: _____ Phone 3: _____

Additionally Collected Contact Info:

Additional Phone 1: _____ Notes on Phone 1: _____
Additional Phone 2: _____ Notes on Phone 2: _____

Additional Email 1: _____ Notes on Email 1: _____
Additional Email 2: _____ Notes on Email 2: _____

Contact Information from Survey 1

Parent information given? _____
Parent Name: _____ Parent Email: _____ Parent Cell: _____

YA information given? _____
Survivor Email: _____ Survivor Cell: _____

Important Notes: _____

Survey 1 Tracking

Date Initial Survey Sent: _____ M-D-Y

Email Used: _____

Survey 1 Phone Follow-up:

Attempt	Date	Number Used	Outcome	Notes*
1	_____ M-D-Y	_____	_____	_____
2	_____ M-D-Y	_____	_____	_____
3	_____ M-D-Y	_____	_____	_____
4	_____ M-D-Y	_____	_____	_____
5	_____ M-D-Y	_____	_____	_____

*If sent survey link ensure to note which email you sent it to. If you collected additional contact information please add to additional contact information above.

Email Sent Outside of REDCap*

Date Sent: _____ M-D-Y Email Address Sent to: _____
Sent By: _____ Did the email bounce back? _____

*Email to be sent by coordinator using Emory/CHOA email to determine if it bounces back. CC Study PI: Karen Effinger & Jordan Gilleland Marchak

Email Reminder 3

Date survey reminder 3 sent: _____ M-D-Y

Email Used for Survey Reminder 3: _____

Post Card:

Date Sent: _____ M-D-Y Name of person sending postcard: _____

Survey 1 Outcome

Agree to Participate: _____ Date: _____
Respondent Type: _____
Survey Completion: YA Survey: _____
Parent Survey: _____

Survey 1 Outcome: _____



Recruitment: Management

Multi-method remote recruitment

Recruitment schedule.	
Week 1	Email 1: RedCap survey invitation
Week 2	Phone call 1
Week 3	Email 2: Emory Outlook
Week 4	Phone call 2
Week 5	Email 3: RedCap survey invitation
Week 6	Phone call 3
Week 9	Letter sent with QR code

Recruitment: Management

Multi-method remote recruitment

Recruitment schedule.	
Week 1	Email 1: RedCap survey invitation
Week 2	Phone call 1
Week 3	Email 2: Emory Outlook
Week 4	Phone call 2
Week 5	Email 3: RedCap survey invitation
Week 6	Phone call 3
Week 9	Letter sent with QR code

Reports for recruitment management

- Batches for coordinators
- Overview for PI

CONSORT diagram

<input type="checkbox"/> Shereen - Batch 2
1) Shereen - Batch 2 - Survey 1 Contact Tracking
2) Shereen - Batch 2 - Survey 1 Incentives
3) Shereen - Batch 2 - Survey 2 Contact Tracking
4) Shereen - Batch 2 - Survey 2 Incentives
<input type="checkbox"/> Study Management
1) Overall Survey 1 Incentives
2) Overall Survey 2 Incentives
3) Survey 1 Consented Participants
4) Caregiver Declines YA Participation
5) YA Declines Parent Participation
6) Ineligible consented participants

Dyadic Survey Collection

Survey version

- REDCap Survey Queue to automatically start the YA or Caregiver version based on response on consent

Survey Language

- REDCap Multi-language feature
 - It is AWESOME!but it is saved for all events
 - Wanted Caregiver and YA to choose language of survey

(Try to) Prevent Missing Responses

- Have all questions be required but build in response option 'Decline to answer'

REDCap – Variable Naming & Coding

VERY user-friendly interface but that doesn't mean it is simple!

A Few General Rules:

1. Stick to **accepted conventions**

- Short informative variable names
- Coding:
 - 0 = No; 1 = Yes
 - 0 is typically the reference group

2. Try to **limit free text**

- Use validation on text fields (e.g., date formats, numeric limits, email address, zip)
- Include the most common options with 'Other' textbox
- *Cavet:* On Contact Tracking Form use BIG paragraph text box!

REDCap – Variable Naming & Coding

3. Ensure **consistency** (same variable different timepoints, reporters, language)
 - Variable Name: Use simple suffixes
 - Coding: ensure the numbers mean the same thing!

4. **Validated measures**
 - Variable names: Use measure names/convention
 - Coding: Match coding OR Use scoring manual recoding (_r)
 - Ensure to check coding from any shared/library versions

Validated Measures – ASHS Example

Paper Version

Adolescent Sleep Hygiene Scale

Directions: Using the choices below, circle *how often* the following things have happened *during the past month*.

- Never** – has not happened
- Once in Awhile** – happened 20% of the time
- Sometimes** – happened 40% of the time
- Quite Often** – happened 60% of the time
- Frequently, if not always** – happened 80% of the time
- Always** – happened 100% of the time

		Always (100%)					
		Frequently, if not Always (80%)					
		Quite Often (60%)					
		Sometimes (40%)					
		Once in Awhile (20%)					
		Never (0%)					
During the day...							
1.	...I take a nap that lasts <i>more than</i> 1 hour.	N	O	S	Q	F	A
2.	...I play or exercise for <i>more than</i> 20 minutes.	N	O	S	Q	F	A
After 6:00 in the evening...							
3.	...I have drinks with caffeine (for example: cola, root beer, iced tea, coffee).	N	O	S	Q	F	A
4.	...I take a nap.	N	O	S	Q	F	A
5.	...I do some kind of physical activity (for example: exercise, play sports).	N	O	S	Q	F	A
6.	...I smoke or chew tobacco.	N	O	S	Q	F	A
7.	...I drink beer (or some other drinks with alcohol).	N	O	S	Q	F	A

Scoring Manual

Scoring of the Adolescent Sleep Hygiene Scale (ASHS)

- The ASHS provides 8 subscale scores and an overall sleep hygiene score.
- Higher scores indicate better success on each of these dimensions of sleep hygiene.
- Response options are scored as follows:

- Never (6 point)
- Once in Awhile (5 points)
- Sometimes (4 points)
- Quite Often (3 points)
- Frequently, if not Always (2 points)
- Always (1 points)

- Reverse-code item 27

Physiological Factor (mean of 5 items)

- 3 After 6:00 in the evening, I have drinks with caffeine (e.g., cola, root beer, iced tea, coffee)
- 10 During the 1 hour before bedtime, I am very active (e.g., playing outside, running, wrestling)
- 12 During the 1 hour before bedtime, I drink more than 4 glasses of water (or some other liquid)
- 18 I go to bed with a stomachache
- 19 I go to bed feeling hungry

Behavioral Arousal Factor (mean of 3 items)

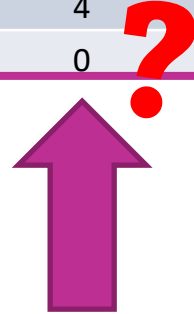
- 11 During the 1 hour before bedtime, I do things that make me feel very awake (e.g., playing video games, watching TV, talking on the telephone)
- 13 I go to bed and do things in my bed that keep me awake (e.g., watching TV, reading)
- 28 I use my bed for things other than sleep (e.g., talking on the telephone, watching TV, playing video games, doing homework)



Validated Measures – ASHS Example

- Glimpse of data received

adol_sleep_hyg_1_surv	adol_sleep_hyg_2_surv	adol_sleep_hyg_3_surv	adol_sleep_hyg_4_surv	adol_sleep_hyg_5_surv
2	1	1	0	3
4	5	2	2	2
1	3	4	0	0
0	5	0	2	0



Assumption:

3 After 6:00 in the evening, I have drinks with caffeine (e.g., cola, root beer, iced tea, coffee)

6 = Never

5 = Once in a while

4 = Sometimes

3 = Quite often

2 = Frequently, if not Always

1 = Always

Validated Measures – ASHS Example

[adol_sleep_hyg_1_surv]	After 6 p.m., I have drinks with caffeine (e.g. cola, pop, iced tea, coffee, energy drinks)	<p>radio (Matrix), Required</p> <table border="1"> <tr><td>0</td><td>Never-has not happened</td></tr> <tr><td>1</td><td>Once in a while-happened about 20% of the time</td></tr> <tr><td>2</td><td>Sometimes-happened about 40% of the time</td></tr> <tr><td>3</td><td>Quite Often-happened about 60% of the time</td></tr> <tr><td>4</td><td>Frequently if not always-happened 80% of the time</td></tr> <tr><td>5</td><td>Always-happened 100% of the time</td></tr> <tr><td>77</td><td>Decline to answer</td></tr> </table>	0	Never-has not happened	1	Once in a while-happened about 20% of the time	2	Sometimes-happened about 40% of the time	3	Quite Often-happened about 60% of the time	4	Frequently if not always-happened 80% of the time	5	Always-happened 100% of the time	77	Decline to answer
0	Never-has not happened															
1	Once in a while-happened about 20% of the time															
2	Sometimes-happened about 40% of the time															
3	Quite Often-happened about 60% of the time															
4	Frequently if not always-happened 80% of the time															
5	Always-happened 100% of the time															
77	Decline to answer															
[adol_sleep_hyg_2_surv]	During the hour before bedtime, I am very active (e.g. playing outside, running, wrestling)	<p>radio (Matrix), Required</p> <table border="1"> <tr><td>0</td><td>Never-has not happened</td></tr> <tr><td>1</td><td>Once in a while-happened about 20% of the time</td></tr> <tr><td>2</td><td>Sometimes-happened about 40% of the time</td></tr> <tr><td>3</td><td>Quite Often-happened about 60% of the time</td></tr> <tr><td>4</td><td>Frequently if not always-happened 80% of the time</td></tr> <tr><td>5</td><td>Always-happened 100% of the time</td></tr> <tr><td>77</td><td>Decline to answer</td></tr> </table>	0	Never-has not happened	1	Once in a while-happened about 20% of the time	2	Sometimes-happened about 40% of the time	3	Quite Often-happened about 60% of the time	4	Frequently if not always-happened 80% of the time	5	Always-happened 100% of the time	77	Decline to answer
0	Never-has not happened															
1	Once in a while-happened about 20% of the time															
2	Sometimes-happened about 40% of the time															
3	Quite Often-happened about 60% of the time															
4	Frequently if not always-happened 80% of the time															
5	Always-happened 100% of the time															
77	Decline to answer															
[adol_sleep_hyg_3_surv]	<p>During the hour before bedtime, I drink >4 glasses of water (or some other liquid)</p> <p style="text-align: center;">ASHS Question 12</p>	<p>radio (Matrix), Required</p> <table border="1"> <tr><td>0</td><td>Never-has not happened</td></tr> <tr><td>1</td><td>Once in a while-happened about 20% of the time</td></tr> <tr><td>2</td><td>Sometimes-happened about 40% of the time</td></tr> <tr><td>3</td><td>Quite Often-happened about 60% of the time</td></tr> <tr><td>4</td><td>Frequently if not always-happened 80% of the time</td></tr> <tr><td>5</td><td>Always-happened 100% of the time</td></tr> <tr><td>77</td><td>Decline to answer</td></tr> </table>	0	Never-has not happened	1	Once in a while-happened about 20% of the time	2	Sometimes-happened about 40% of the time	3	Quite Often-happened about 60% of the time	4	Frequently if not always-happened 80% of the time	5	Always-happened 100% of the time	77	Decline to answer
0	Never-has not happened															
1	Once in a while-happened about 20% of the time															
2	Sometimes-happened about 40% of the time															
3	Quite Often-happened about 60% of the time															
4	Frequently if not always-happened 80% of the time															
5	Always-happened 100% of the time															
77	Decline to answer															



Validated Measures – ASHS Example

- BEFORE able to score measure:
 1. Recode every single variable to match scoring manual
 2. Clearly map questions to their variable name

Adolescent Sleep Hygiene Scale

Directions: Using the choices below, circle *how often* the following things have happened *during the past month*.

Never – has not happened
 Once in Awhile – happened 20% of the time
 Sometimes – happened 40% of the time
 Quite Often – happened 60% of the time
 Frequently, if not always – happened 80% of the time
 Always – happened 100% of the time

	Never (0%)	Once in Awhile (20%)	Sometimes (40%)	Quite Often (60%)	Frequently, if not Always (80%)	Always (100%)
During the day...						
1. ...I take a nap that lasts <i>more than 1 hour</i> . <i>25</i>	N	O	S	Q	F	A
2. ...I play or exercise for <i>more than 20 minutes</i> . <i>not in subscale</i>	N	O	S	Q	F	A
After 6:00 in the evening...						
3. ...I have drinks with caffeine (for example: cola, root beer, iced tea, coffee). <i>1</i>	N	O	S	Q	F	A
4. ...I take a nap. <i>26</i>	N	O	S	Q	F	A
5. ...I do some kind of physical activity (for example: exercise, play sports). <i>not in a subscale</i>	N	O	S	Q	F	A
6. ...I smoke or chew tobacco. <i>subscale not included</i>	N	O	S	Q	F	A
7. ...I drink beer (or some other drinks with alcohol). <i>subscale not included</i>	N	O	S	Q	F	A
During the 1 hour before bedtime...						
8. ...I do things that make me feel <i>calm or relaxed</i> (for example: taking a hot bath/shower, listening to soft music, reading). <i>not in a subscale</i>	N	O	S	Q	F	A
9. ...things happen that make me feel <i>strong emotions</i> (sadness, anger, excitement). <i>12</i>	N	O	S	Q	F	A
10. ...I am <i>very active</i> (for example: playing outside, running, wrestling). <i>2</i>	N	O	S	Q	F	A
11. ...I do things that make me feel <i>very awake</i> (for example: playing video games, watching TV, talking on the telephone). <i>6</i>	N	O	S	Q	F	A
12. ...I drink <i>more than 4</i> glasses of water (or some other liquid). <i>3</i>	N	O	S	Q	F	A

Handwritten notes: "Recode: 0 5 4 3 2 1", "Decline 5 77", "Always (100%)", "Frequently, if not Always (80%)", "Quite Often (60%)", "Sometimes (40%)", "Once in Awhile (20%)", "Never (0%)".

REDCap – Variable Naming & Coding

Note on REDCap's Missing Data Codes

- You must select to display in any report
- For multi-select variables, the missing code will be a new variable
- Can be problematic in statistical software
 - Ex: date field with text “NI” missing code
- *Future Rebecca:*
 - Hardcode missing option when appropriate
 - Abstraction manual
 - Eg Enter 9/9/2099 as missing date or -999 as missing dose

Take Home Points



Good data hygiene starts with how you build your data collection tools.

REDCap has lots of features – be thoughtful on what you implement in your project.

Involve your statistician/epidemiologist from the outset

A good analyst can restructure the data but really HATES recoding everything!

No one best way. But there is a best way for your project.

THANK YOU!

Study Team

Karen Effinger, MD (Co-PI)

Ana Balthazar

Sarah Lau

Shereen Farooq

Alex Cummiskey

Support

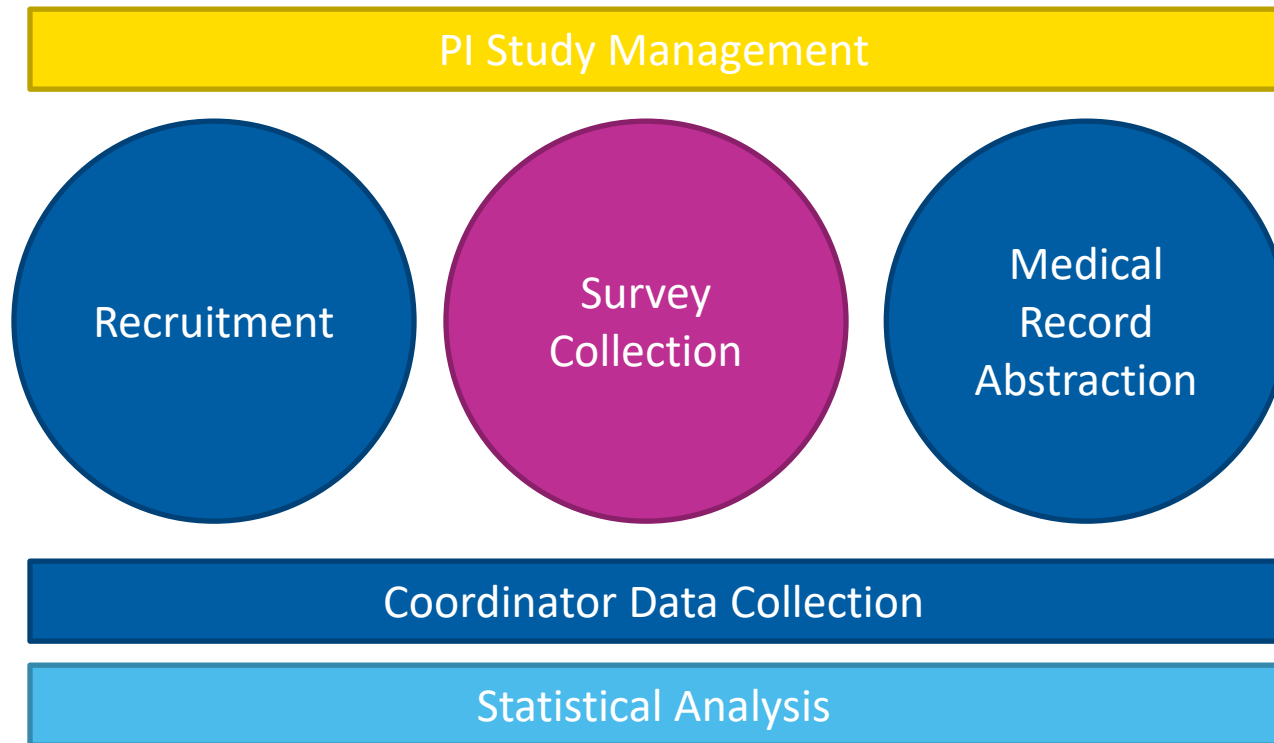
Dana Ray & Winship Cancer Institute

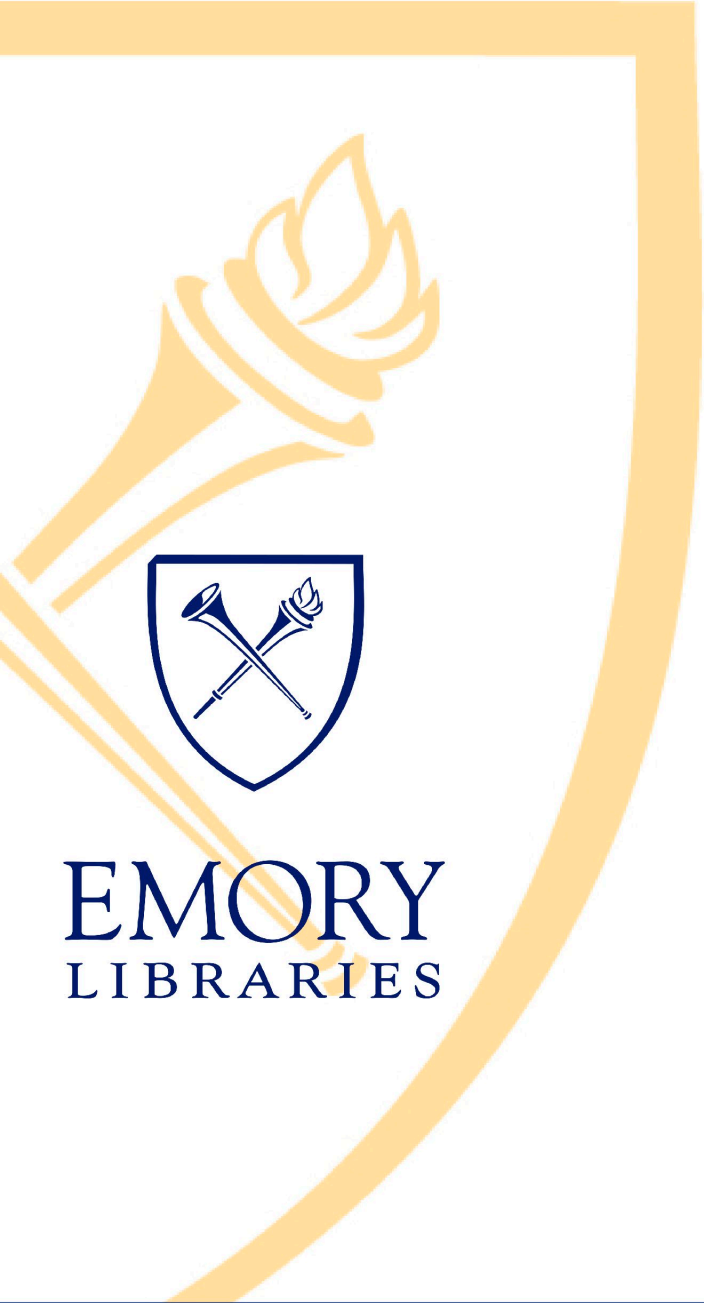
Funding

National Cancer Institute



Overall Project Management





An Introduction to the NIH Policy on Data Management and Sharing

Jeremy Kupsco, PhD, Research Informationist,
Emory Libraries

DMS Policy Overview

Applicability

All research, funded or conducted in whole or in part by NIH, that results in the generation of "**scientific data**". Effective Jan 25, 2023

See [Research Covered Under the Data Management & Sharing Policy](#)

Requirements

- ✓ **Submission of DMS Plan** with all applications for funding
- ✓ **Compliance with the DMS Plan** approved by the funding NIH Institute, Center, or Office

DMS Policy: Scope



Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of "scientific data".

"Scientific data" is defined as:

"the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."

Potential Examples of Scientific Data

Scientific data will vary depending on the project and the context.

Scientific data might include:

Single-cell RNA sequencing (scRNA-seq) of T lymphocytes or other immune cells in a study of HIV/AIDS

Electrophysiological recordings and fMRI images in a study of a rodent model of PTSD

Step activity from a wearable device in a study of cardiovascular health

Exclusions from the DMS Policy

**Scientific data do
not include:**

- Data **not** necessary for or of sufficient quality to validate and replicate research findings,
- Laboratory notebooks,
- Preliminary analyses,
- Completed case report forms,
- Drafts of scientific papers,
- Plans for future research,
- Peer reviews,
- Communications with colleagues, or
- Physical objects, (e.g., laboratory specimens)

Activities Subject to the DMS Policy

APPLIES TO...

All research generating scientific data, including but not limited to:

- Research Projects
- Certain Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers

DOES NOT APPLY TO...

research projects not generating scientific data or non-research projects, including but not limited to:

- Training (Ts)
- Fellowships (Fs)
- Construction (C06)
- Conference Grants (R13)
- Resources (Gs)
- Research-Related Infrastructure Programs (e.g., S06)

Requirements

- Submission of a Data Management and Sharing Plan in Budget Justification Section outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.
- Share and manage data according to plan. Data should be shared **No later than publication or end of award** (if unpublished); other relevant requirements and expectations (e.g., repository policies, retention requirements, journal policies) for minimum time frames data should be shared.
- All Scientific Data should be **managed**; not all scientific data must be **shared** due to legal, ethical or technical factors.

Limitations on Sharing

DMS Plans should maximize appropriate sharing

Justifiable ethical, legal, and technical factors for limiting sharing include:

- Informed consent will not permit or limits scope of sharing or use
- Privacy or safety of research participants would be compromised and available protections insufficient
- Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
- Restrictions imposed by existing or anticipated agreements with other parties

Limitations on Sharing: Other Considerations

Reasons **NOT** generally justifiable to limit sharing:

- Data are considered too small
- Researchers anticipate data will not be widely used
- Data are not thought to have a suitable repository

Compliance/Enforcement

- Extramural Awards: The Plan will become a Term and Condition of the Notice of Award. Failure to comply with the Terms and Conditions may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions.
- Compliance assessed annually. Questions will be added to Research Performance Progress Report (RPPR) to help determine compliance with Plan



When should I share my data?

As soon as possible!

- No later than the time of a **publication of findings** in a peer-reviewed journal OR at the **end of the award**, whichever comes first
- NIH considers **Publication Date, the first date the article is published**. I.E. If article had Epub date before physical publication the Epub date is the date of record.

Allowable Costs

- **Reasonable costs allowed in budget requests**
 - Curating data/developing supporting documentation
 - Preserving/sharing data through repositories
 - Local data management considerations
- **NOT considered data sharing costs**
 - Infrastructure costs typically included in indirect costs
 - Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

Emory Resources: Research Data Website

<https://researchdata.emory.edu/plan/nih-dmsp.html>

Home / Plan Your Project / NIH Data Management & Sharing Plans


NIH Data Management & Sharing Plans

Plan Your Project

- Grant Support
- Data Management Planning >
- Collaboration Tools
- Compliance and Legal Issues
- NIH Data Management & Sharing Plans**

Policy overview

Effective January 25, 2023, the National Institutes of Health (NIH) has a new [Policy for Data Management and Sharing](#). This replaces the previous Data Sharing Policy of 2003, with the main difference that **all all competing grant or contract proposals (including renewals) to the NIH that generate scientific data must now include a data management & sharing (DMS) plan** as part of the application.



Download infographic with Emory updates

DMS plans describe robust details of project data management and sharing during the entire funding period and for a minimum of 3 years after the end of the award. Project data need to be shared no later than the time of an associated publication or end of award (for unpublished data), whichever comes first.

DMS plans currently are not scored in the peer-review process, and instead are assessed and finalized with Program Officers during the just-in-time award process. The DMS plan will become a Term and Condition of the Notice of Award and failure to comply may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions. Questions will be added to Research Performance Progress Report (RPPR) to help determine compliance with DMS plans, assessed annually by the NIH.

The [NIH Data Sharing website](#) contains a wealth of information about the policy's implementation, including a [Frequently Asked Questions \(FAQ\) section](#) to address common issues and concerns. Investigators are encouraged to reach out directly to the [NIH Institute or Center \(IC\) Program Staff](#) with questions about data sharing for specific programs.

Elements of a data management and sharing plan

A data management and sharing (DMS) plan consists of the following 6 elements:

- Element 1. Data Type
- Element 2. Related Tools, Software and/or Code



Data Management and Sharing Plans: Scenarios



NIH OR DOMAIN-SPECIFIC DATA REPOSITORY



GENERALIST DATA REPOSITORY



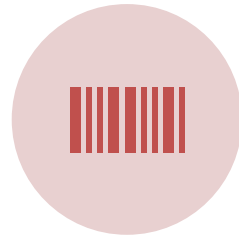
LARGE DATA



SENSITIVE DATA



DATA USE AGREEMENTS



CODE/SOFTWARE



COMMERCIAL IMPLICATIONS



Repository Decision Tree

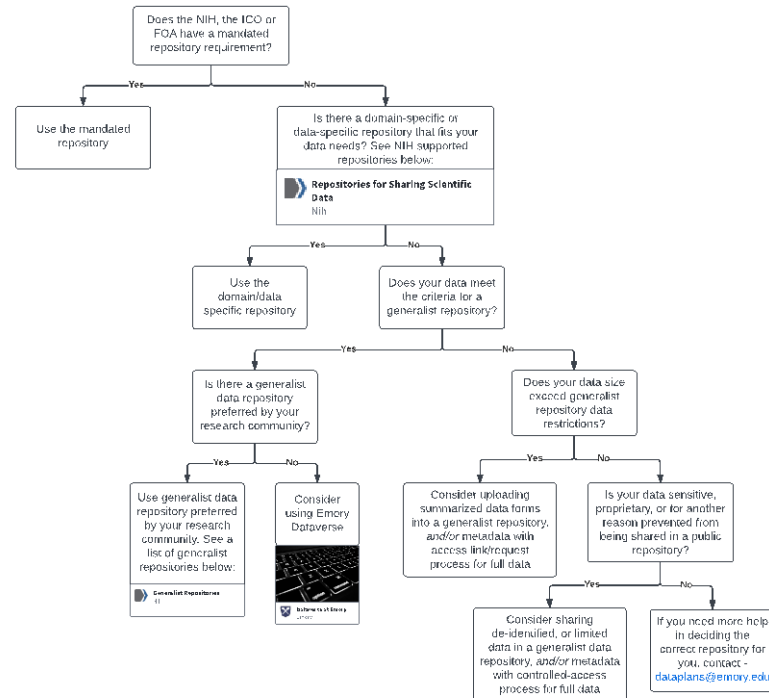
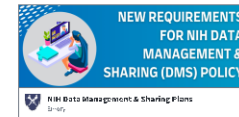
https://researchdata.emory.edu/documents/NIH_DMS_RepositorySelectionDecisionTree.pdf

Guide for selecting your research data repository

Please use this decision tree to select the right data repository for sharing the scientific data from your project and meet the 2023 NIH Data Management and Sharing policy.

Along with sharing as much of your scientific data as possible, include all relevant metadata and associated files, instructions/methods, web links or other access / request information that would allow someone else to reuse your data and reproduce the results of your research. In particular, consider providing access to associated software/analysis code through a code repository like GitHub.

For more information refer to NIH Data Management & Sharing Plans page below



Questions?

- Offline Contact:
 - Jenn Doty, Research Data Librarian, Woodruff Library,
jennifer.doty@emory.edu
 - Jeremy Kupsco, Research Informationist, WHSC Library,
jkupsco@emory.edu
 - Data Management Planning <DATAPLAN@LISTSERV.CC.EMORY.EDU>