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:
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

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: Text Box (Short Text, Number, Date/Time, ...)

Field Label

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

How to use

Validation? (optional) Date (Y-M-D)

Minimum:

Maximum: today

Action Tags / Field Annotation (optional)

@FORCE-MINMAX

Learn about Action Tags or using Field Annotation

Required?*  Yes

* Prompt if field is blank

Identifier?  Yes

Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment  Right / Vertical (RV)

Align the position of the field on the page

Field Note (optional)

Small reminder text displayed underneath field

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

Privileges for Viewing and Exporting Data

Data Viewing Rights pertain to a user's ability to view or edit data on pages in the project with "No Access". Data Viewing Rights for a given instrument will not be able to view fields that are marked as "Read Only". Data Export Rights pertain to a user's ability to view fields from that instrument on a report. Data Export Rights and Data View Rights are completely separate and do not impact one another.

Data Viewing Rights

<table>
<thead>
<tr>
<th>Form 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Access (Hidden)</td>
</tr>
<tr>
<td>o</td>
</tr>
</tbody>
</table>

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

External Modules: Configuration Permissions

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

- Auto Record Generation
- Image Map
- Inline Descriptive Pop-ups
- More...
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 + Create

Displaying: Instrument status only ▼ Lock status only ▼ All status types

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Form 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1--1</td>
<td></td>
</tr>
<tr>
<td>1--2</td>
<td></td>
</tr>
</tbody>
</table>
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.

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.
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.

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Compare selected record</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>— OR —</td>
</tr>
<tr>
<td></td>
<td>Compare all records</td>
</tr>
</tbody>
</table>

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:

- 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:
- 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
Children's Healthcare of Atlanta

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]
Data Resolution Workflow

Data Resolution Access Settings:

- Data Quality
  - What is Data Quality?

- Data Resolution Workflow
  - What is Data Resolution Workflow?

- Create & edit rules
- Execute rules
- 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

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 predefined 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.

Data Quality Rules

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Rule Name</th>
<th>Rule Logic (Show discrepancy only if...)</th>
<th>Real-time execution?</th>
<th>Total Discrepancies</th>
<th>Delete rule?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Blank values*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Blank values* (required fields only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Field validation errors (incorrect data type)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Field validation errors (out of range)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Outliers for numerical fields (numbers, integers, sliders, calc fields)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>Hidden fields that contain values***</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>Multiple choice fields with invalid values</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>Incorrect values for calculated fields</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Fields containing &quot;missing data codes&quot;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add

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

Enter logic for new rule (e.g., [age] < 18)

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**

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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

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<table>
<thead>
<tr>
<th>Record ID</th>
<th>Patient Information &amp; Tracking</th>
<th>Survey 1</th>
<th>Survey 2</th>
<th>Medical Record Abstraction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient Information</td>
<td>Contact Tracking</td>
<td>Consent</td>
<td>YA Survey</td>
</tr>
<tr>
<td>258</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>259</td>
<td>●</td>
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<td>265</td>
<td>●</td>
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<td>●</td>
</tr>
<tr>
<td>266</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

*Had a waiver 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

### Epic Contact Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
<td></td>
</tr>
<tr>
<td>DOB:</td>
<td></td>
</tr>
<tr>
<td>CID:</td>
<td></td>
</tr>
<tr>
<td>Parent 1 Last Name:</td>
<td></td>
</tr>
<tr>
<td>Parent 1 First Name:</td>
<td></td>
</tr>
<tr>
<td>Parent 2 Last Name:</td>
<td></td>
</tr>
<tr>
<td>Parent 2 First Name:</td>
<td></td>
</tr>
<tr>
<td>Epic Address:</td>
<td></td>
</tr>
<tr>
<td>Street:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
</tr>
<tr>
<td>State:</td>
<td></td>
</tr>
<tr>
<td>Zip:</td>
<td></td>
</tr>
</tbody>
</table>

### Survey 1 Tracking

<table>
<thead>
<tr>
<th>Attempt</th>
<th>Date</th>
<th>Number Used</th>
<th>Outcome</th>
<th>Next/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td></td>
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<tr>
<td>4</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Contact Information from Survey 1

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent Information given?</td>
<td></td>
</tr>
<tr>
<td>Parent Name:</td>
<td></td>
</tr>
<tr>
<td>Parent Email:</td>
<td></td>
</tr>
<tr>
<td>Parent Cell:</td>
<td></td>
</tr>
<tr>
<td>YA Information given?</td>
<td></td>
</tr>
<tr>
<td>Survivor Email:</td>
<td></td>
</tr>
<tr>
<td>Survivor Cell:</td>
<td></td>
</tr>
</tbody>
</table>

### Important Notes:

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*Email Sent Outside of REDCap:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Sent:</td>
<td></td>
</tr>
<tr>
<td>Email Address Sent to:</td>
<td></td>
</tr>
</tbody>
</table>

*Emails to be sent by coordinators using Emory/CMH email to determine if bounce back. CC Study PI, Karen Finger & Jordan Dillard Mende

### Email Reminder 3

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date survey reminder 2 sent:</td>
<td></td>
</tr>
<tr>
<td>Email Used for Survey Reminder 3:</td>
<td></td>
</tr>
</tbody>
</table>

### Survey 1 Outcome

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree to Participate:</td>
<td></td>
</tr>
<tr>
<td>Respondent Type:</td>
<td></td>
</tr>
<tr>
<td>Survey Completion YA Survey:</td>
<td></td>
</tr>
<tr>
<td>Parent Survey:</td>
<td></td>
</tr>
</tbody>
</table>

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*Survey 1 Outcome:

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**Children's Healthcare of Atlanta**
Recruitment: Management

Multi-method remote recruitment

<table>
<thead>
<tr>
<th>Recruitment schedule.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week 1</strong></td>
</tr>
<tr>
<td>Email 1: RedCap survey invitation</td>
</tr>
<tr>
<td><strong>Week 2</strong></td>
</tr>
<tr>
<td>Phone call 1</td>
</tr>
<tr>
<td><strong>Week 3</strong></td>
</tr>
<tr>
<td>Email 2: Emory Outlook</td>
</tr>
<tr>
<td><strong>Week 4</strong></td>
</tr>
<tr>
<td>Phone call 2</td>
</tr>
<tr>
<td><strong>Week 5</strong></td>
</tr>
<tr>
<td>Email 3: RedCap survey invitation</td>
</tr>
<tr>
<td><strong>Week 6</strong></td>
</tr>
<tr>
<td>Phone call 3</td>
</tr>
<tr>
<td><strong>Week 9</strong></td>
</tr>
<tr>
<td>Letter sent with QR code</td>
</tr>
</tbody>
</table>
Recruitment: Management

Multi-method remote recruitment

<table>
<thead>
<tr>
<th>Recruitment schedule.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week 1</strong></td>
</tr>
<tr>
<td><strong>Week 2</strong></td>
</tr>
<tr>
<td><strong>Week 3</strong></td>
</tr>
<tr>
<td><strong>Week 4</strong></td>
</tr>
<tr>
<td><strong>Week 5</strong></td>
</tr>
<tr>
<td><strong>Week 6</strong></td>
</tr>
<tr>
<td><strong>Week 9</strong></td>
</tr>
</tbody>
</table>

Reports for recruitment management
- Batches for coordinators
- Overview for PI

CONSORT diagram
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’
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!
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 a while – 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

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

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 points)
  - Once in a while (5 points)
  - Sometimes (4 points)
  - Quite often (3 points)
  - Frequently, if not always (2 points)
  - Always (1 point)
- 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).

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

<table>
<thead>
<tr>
<th>adol_sleep_hyg_1_surv</th>
<th>adol_sleep_hyg_2_surv</th>
<th>adol_sleep_hyg_3_surv</th>
<th>adol_sleep_hyg_4_surv</th>
<th>adol_sleep_hyg_5_surv</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>0</td>
<td>5</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>[adol_sleep_hyg_1_surv]</td>
<td>After 6 p.m., I have drinks with caffeine (e.g., cola, pop, iced tea, coffee, energy drinks)</td>
<td>0: Never has not happened&lt;br&gt;1: Once in a while happened about 20% of the time&lt;br&gt;2: Sometimes happened about 40% of the time&lt;br&gt;3: Quite often happened about 60% of the time&lt;br&gt;4: Frequently if not always happened 80% of the time&lt;br&gt;5: Always happened 100% of the time&lt;br&gt;77: Decline to answer</td>
</tr>
<tr>
<td>[adol_sleep_hyg_2_surv]</td>
<td>During the hour before bedtime, I am very active (e.g., playing outside, running, wrestling)</td>
<td>0: Never has not happened&lt;br&gt;1: Once in a while happened about 20% of the time&lt;br&gt;2: Sometimes happened about 40% of the time&lt;br&gt;3: Quite often happened about 60% of the time&lt;br&gt;4: Frequently if not always happened 80% of the time&lt;br&gt;5: Always happened 100% of the time&lt;br&gt;77: Decline to answer</td>
</tr>
<tr>
<td>[adol_sleep_hyg_3_surv]</td>
<td>During the hour before bedtime, I drink &gt;4 glasses of water (or some other liquid)</td>
<td>0: Never has not happened&lt;br&gt;1: Once in a while happened about 20% of the time&lt;br&gt;2: Sometimes happened about 40% of the time&lt;br&gt;3: Quite often happened about 60% of the time&lt;br&gt;4: Frequently if not always happened 80% of the time&lt;br&gt;5: Always happened 100% of the time&lt;br&gt;77: Decline to answer</td>
</tr>
</tbody>
</table>

### ASHS Question 12
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 a while** – happened 10% of the time
- **Sometimes** – happened 30% 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

<table>
<thead>
<tr>
<th>Item</th>
<th>Never</th>
<th>Once in a while</th>
<th>Sometimes</th>
<th>Quite Often</th>
<th>Frequently, if not always</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I take a nap that lasts more than 1 hour</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I have drinks with caffeine (e.g., cola, root beer, iced tea, coffee)</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>After 6:00 in the evening...</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I do some kind of physical activity (e.g., exercise, sports games)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I smoke or chew tobacco (not included)</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I drink beer (or some other drinks with alcohol)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During the 1 hour before bedtime...</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I do things that make me feel calm or relaxed (e.g., sleeping, listening to soft music, reading)</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Things that make me feel angry or anxious (e.g., sadness, anger, sometimes)</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I am very active (e.g., playing outside, running, wrestling)</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I do things that make me feel more awake (e.g., playing video games, watching TV, talking on the telephone)</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I drink more than 4 glasses of water (or some other liquid)</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
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
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

- PI Study Management
  - Recruitment
  - Survey Collection
  - Medical Record Abstraction
- Coordinator Data Collection
- Statistical Analysis
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

Adapted from: NIH Webinar I: Understanding the New NIH Data Management and Sharing Policy
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)

Adapted from: NIH Webinar I: Understanding the New NIH Data Management and Sharing Policy
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)

Adapted from: NIH Webinar I: Understanding the New NIH Data Management and Sharing Policy
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

Adapted from: NIH Webinar I: Understanding the New NIH Data Management and Sharing Policy
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)
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 2013, with the main difference that 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.

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
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>