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:

EMORY UNIVERSITY SCHOOL OF MEDICINE
Department of Medicine

Georgia CTSA
Georgia Clinical & Translational Science Alliance

EMORY UNIVERSITY SCHOOL OF MEDICINE
Department of Pediatrics

PEDIATRIC & REPRODUCTIVE ENVIRONMENTAL HEALTH SCHOLARS
Southeastern Environmental Exposures and Disparities
A K12 Research Career Development Program

EMORY WINSHIP CANCER INSTITUTE
National Cancer Institute-Designated Comprehensive Cancer Center

CFAR

Children's 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

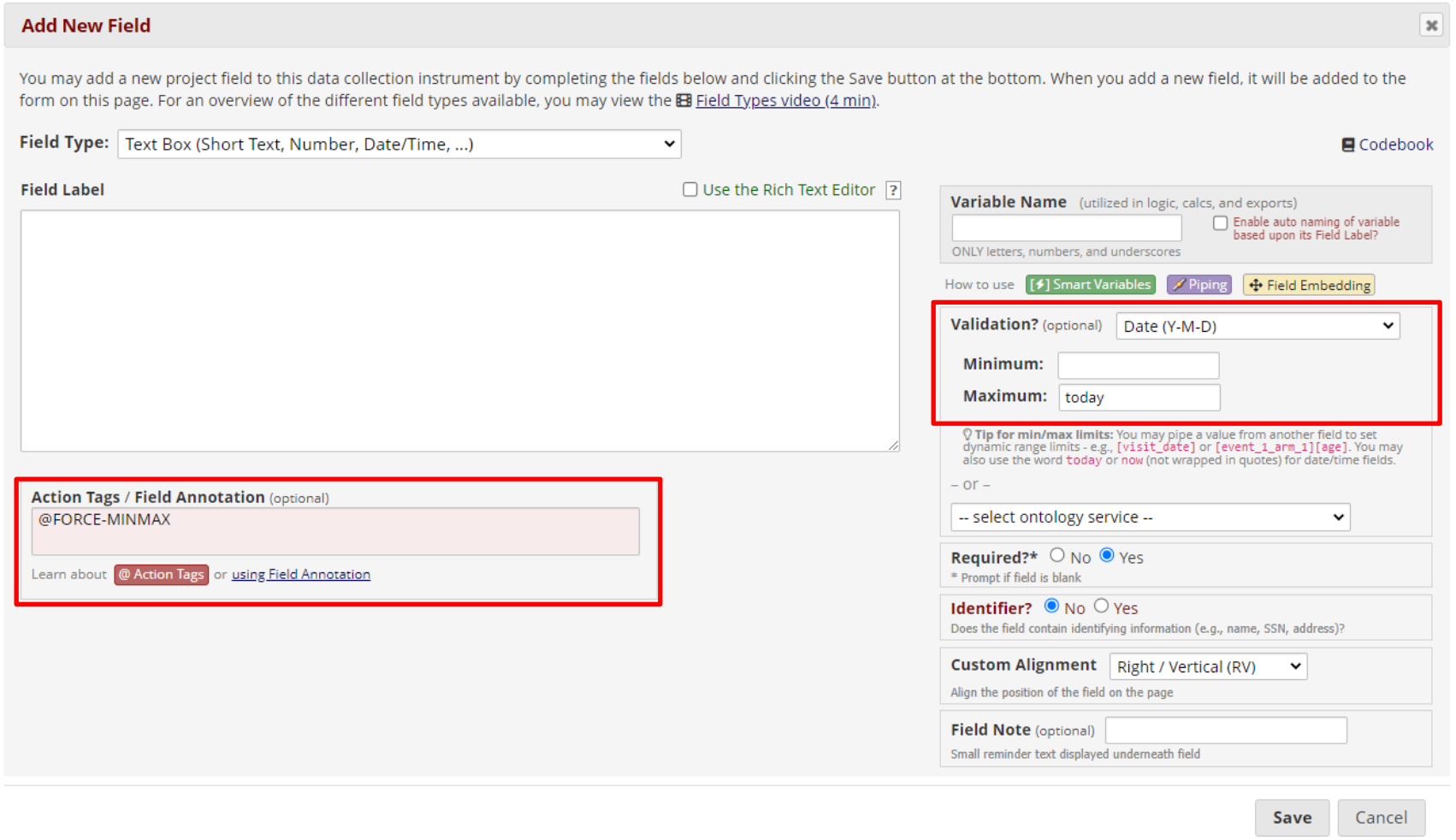
Data Management Tools in REDCap

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

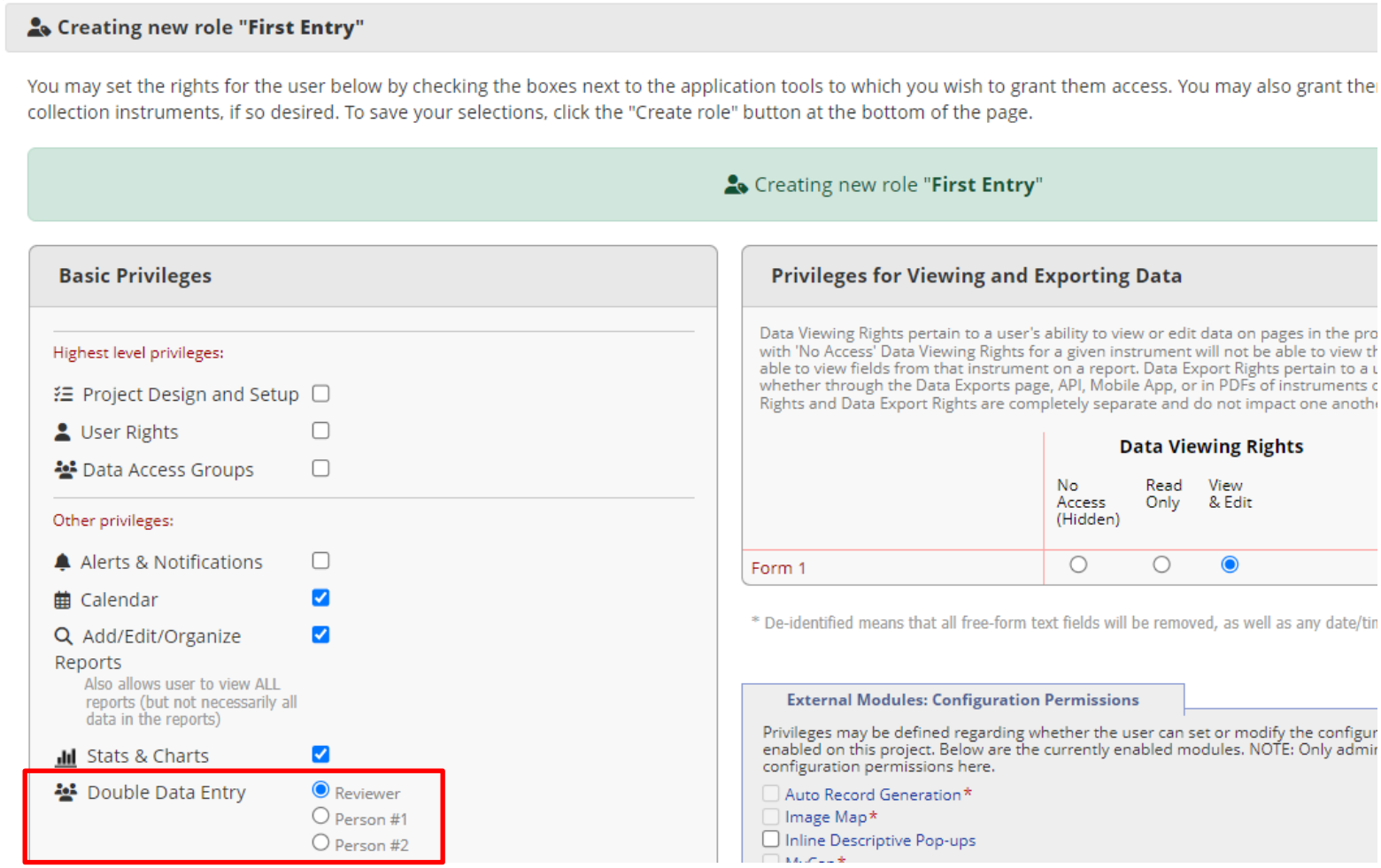


Data Validation Settings

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

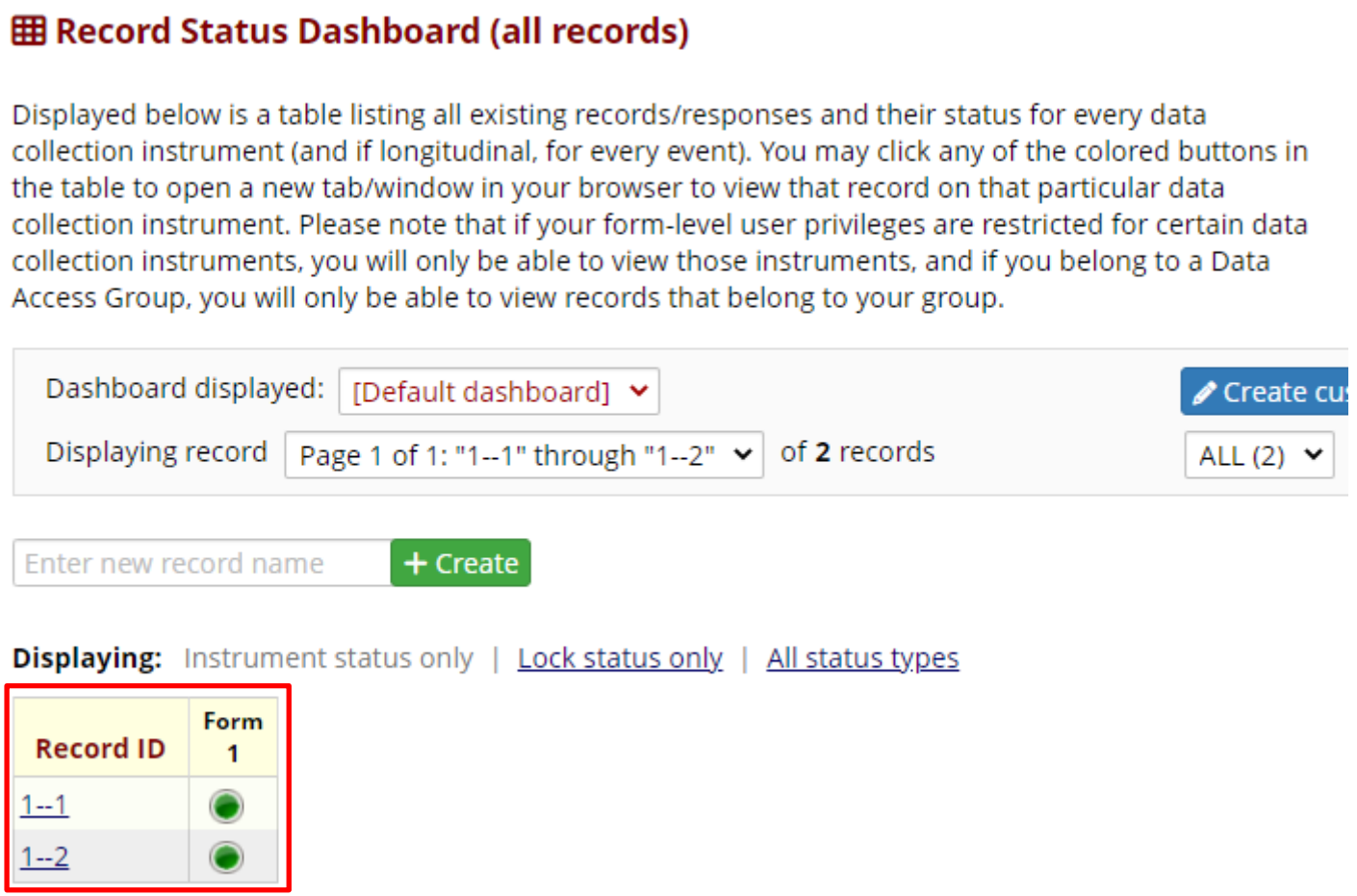
Double Data Entry

User Access:

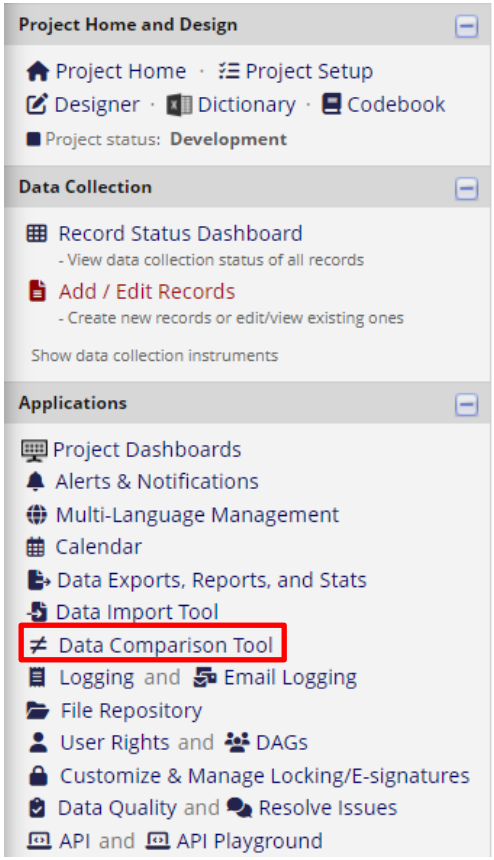


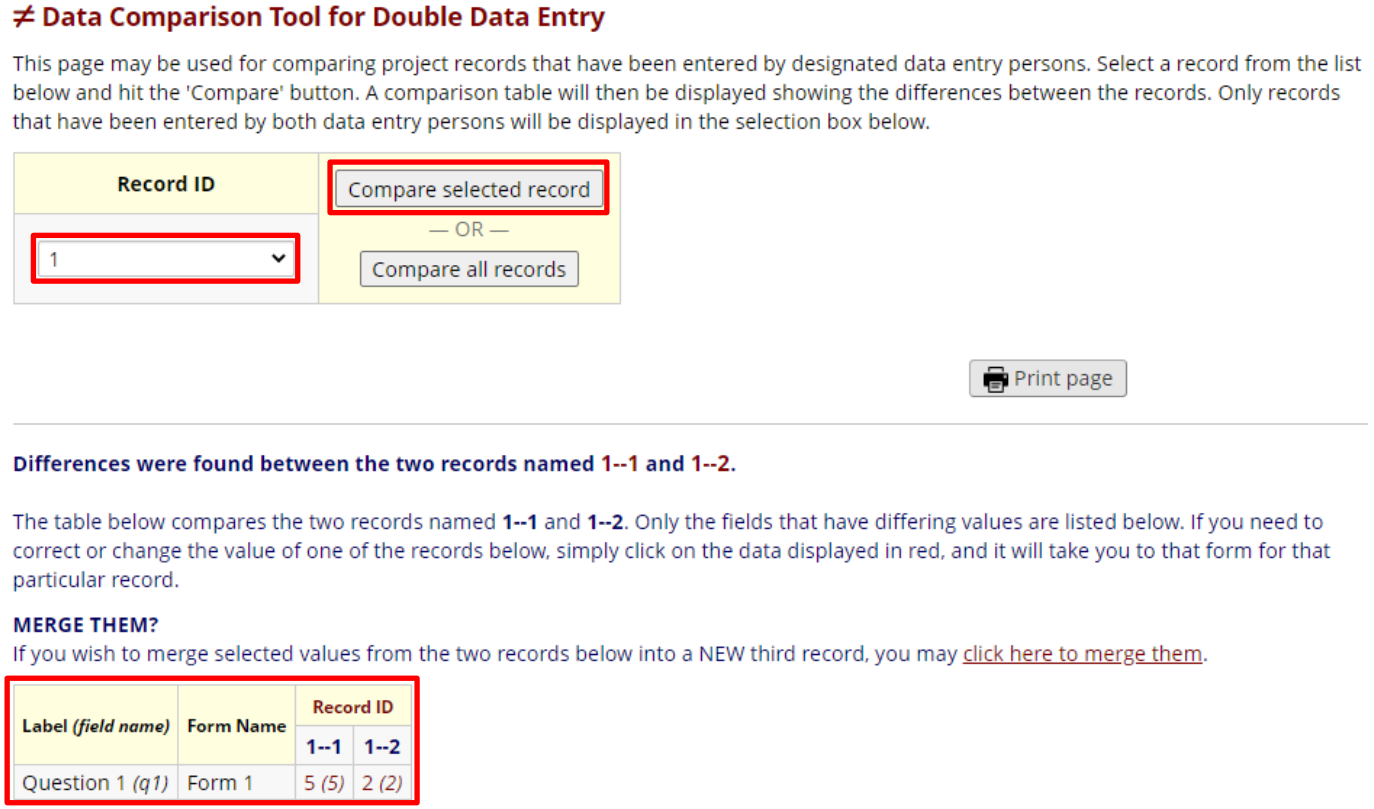
Double Data Entry

Entry Records:



Double Data Entry: Reviewing Entries





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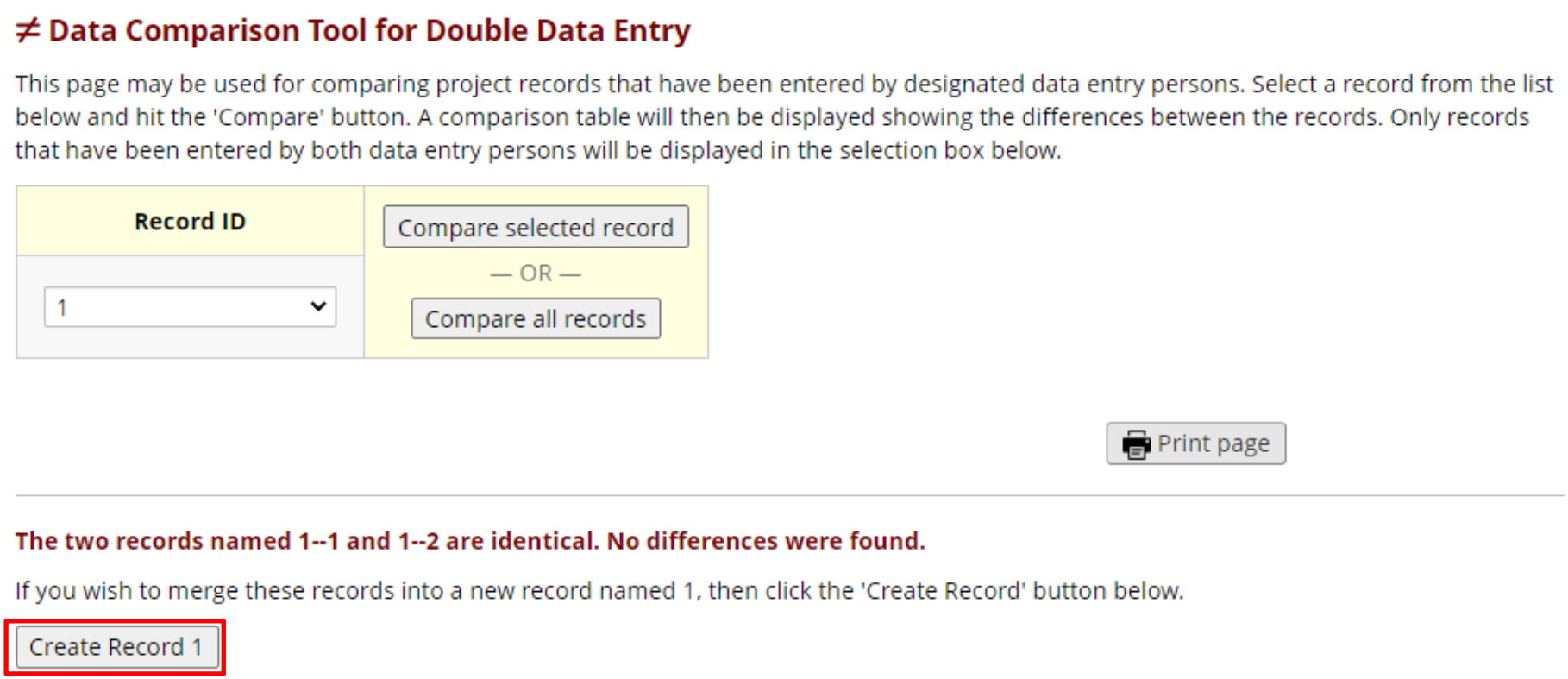
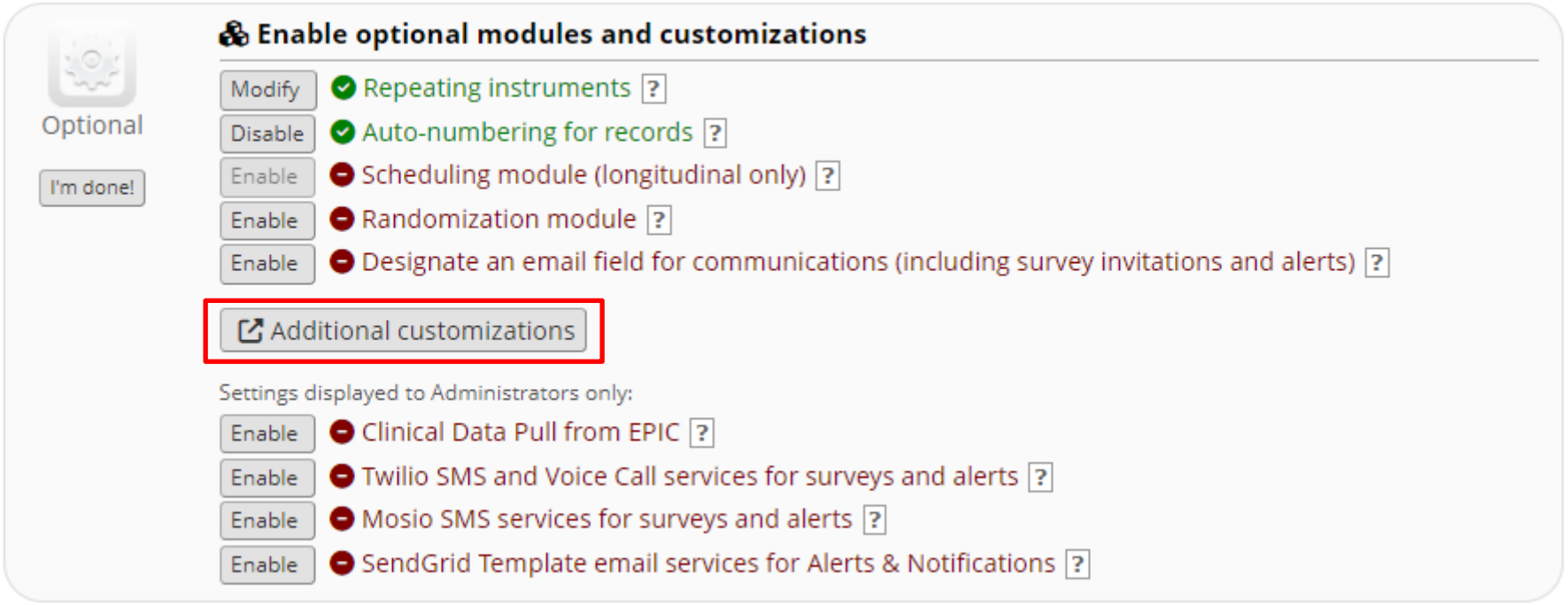


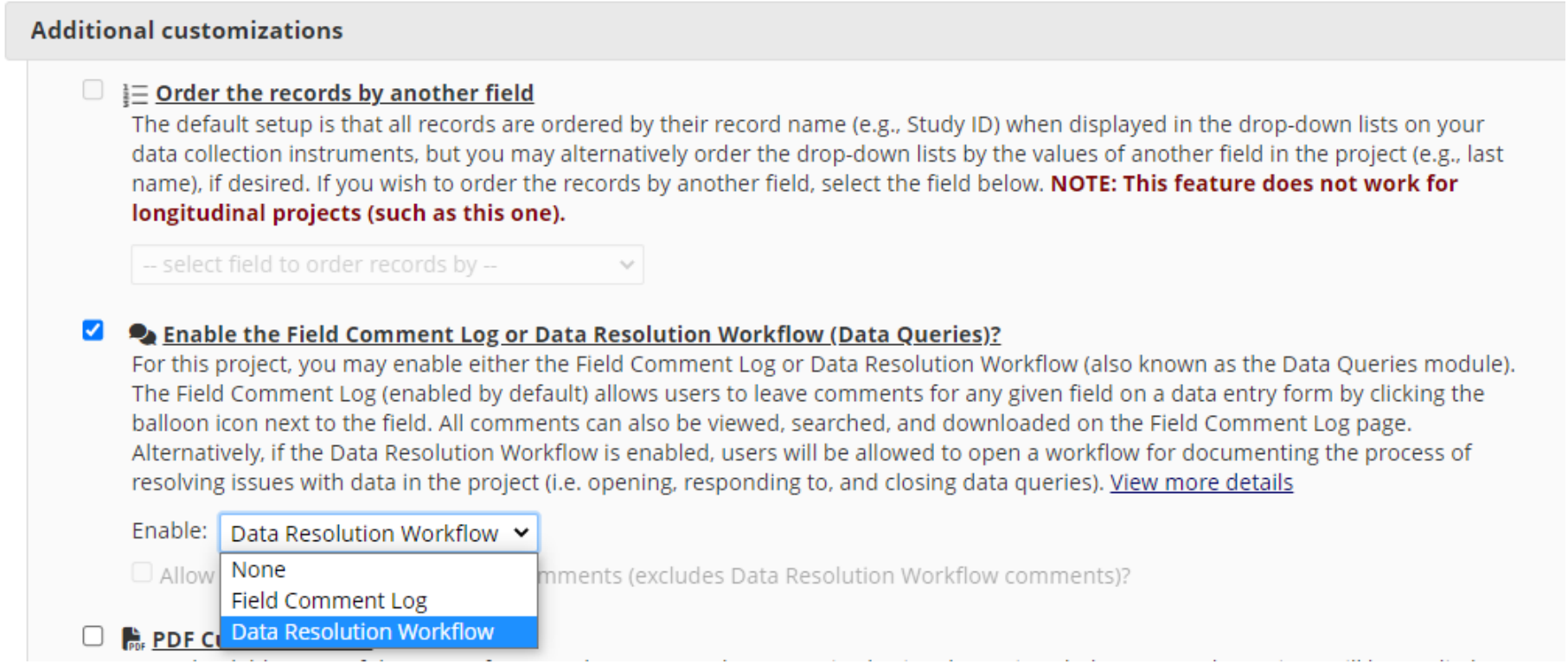
Data Resolution Workflow

Additional Customizations:



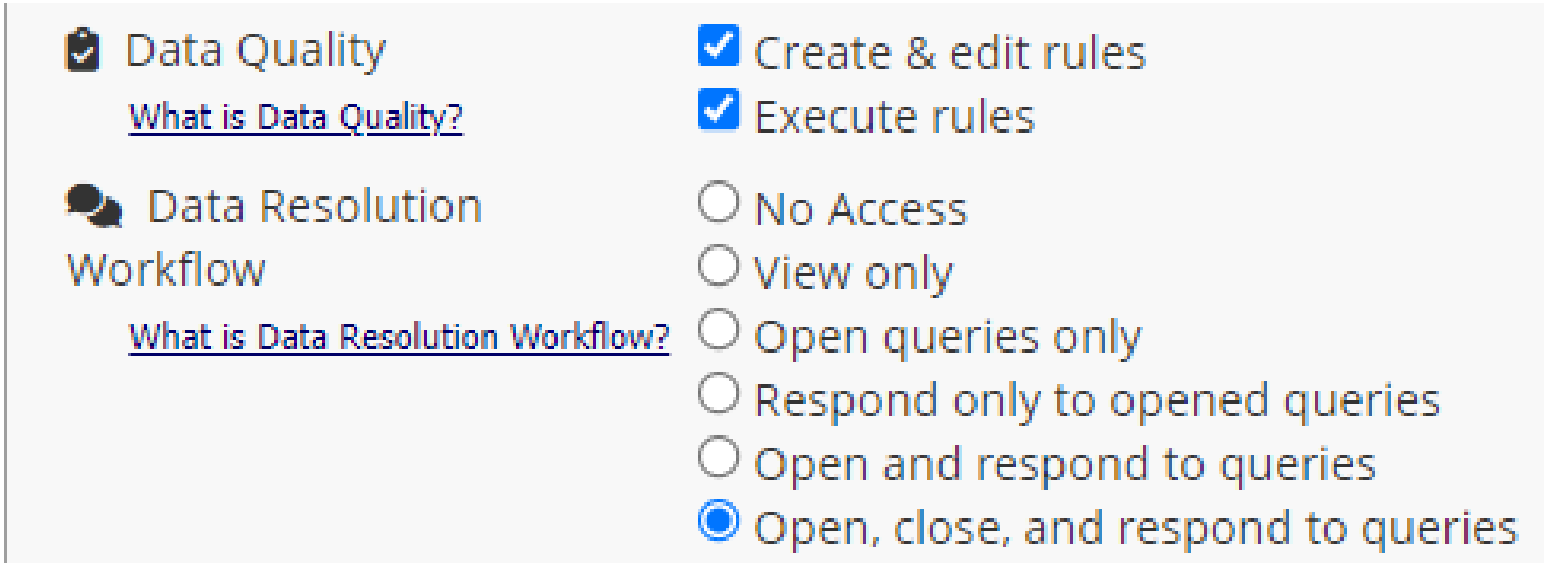
Data Resolution Workflow

Enable Data Resolution Workflow:

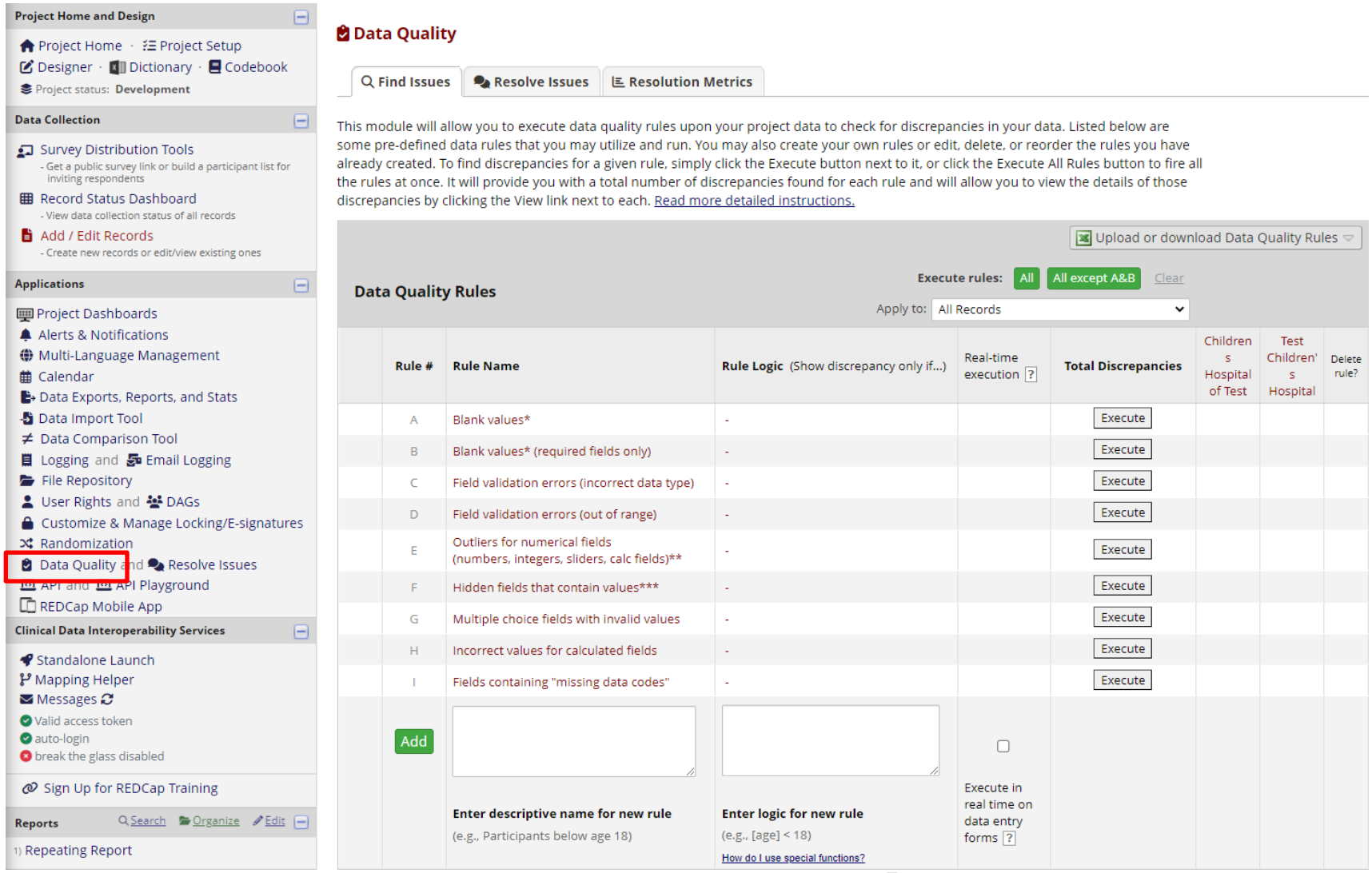


Data Resolution Workflow

Data Resolution Access Settings:



Data Quality Rules



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

Aflac Cancer & Blood Disorders Center
CHILDREN'S HEALTHCARE OF ATLANTA

EMORY UNIVERSITY

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

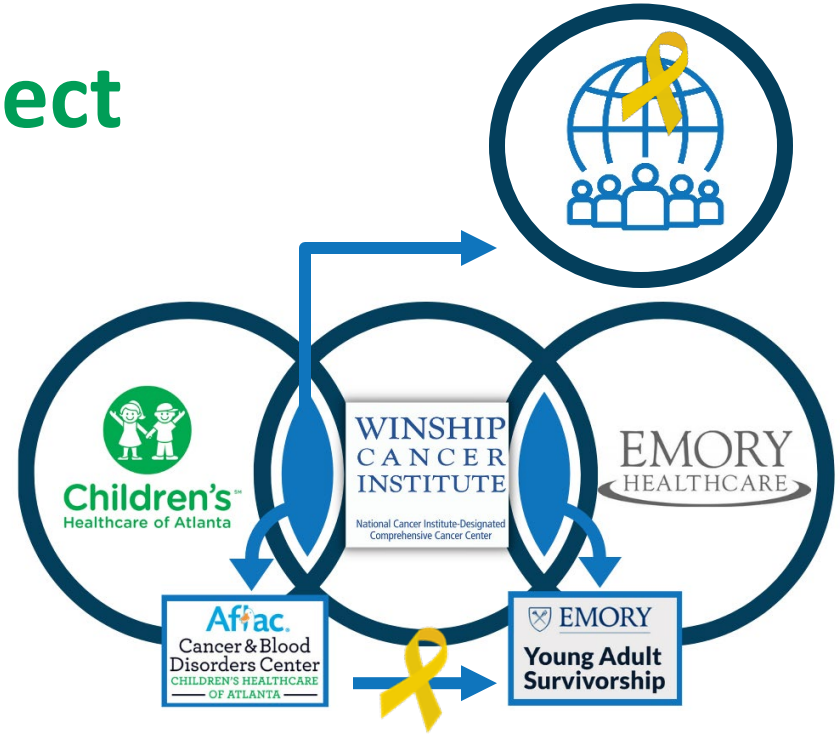
OUR STUDY

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

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DATA CHALLENGES

Remote recruitment of patients no longer in engaged in our care

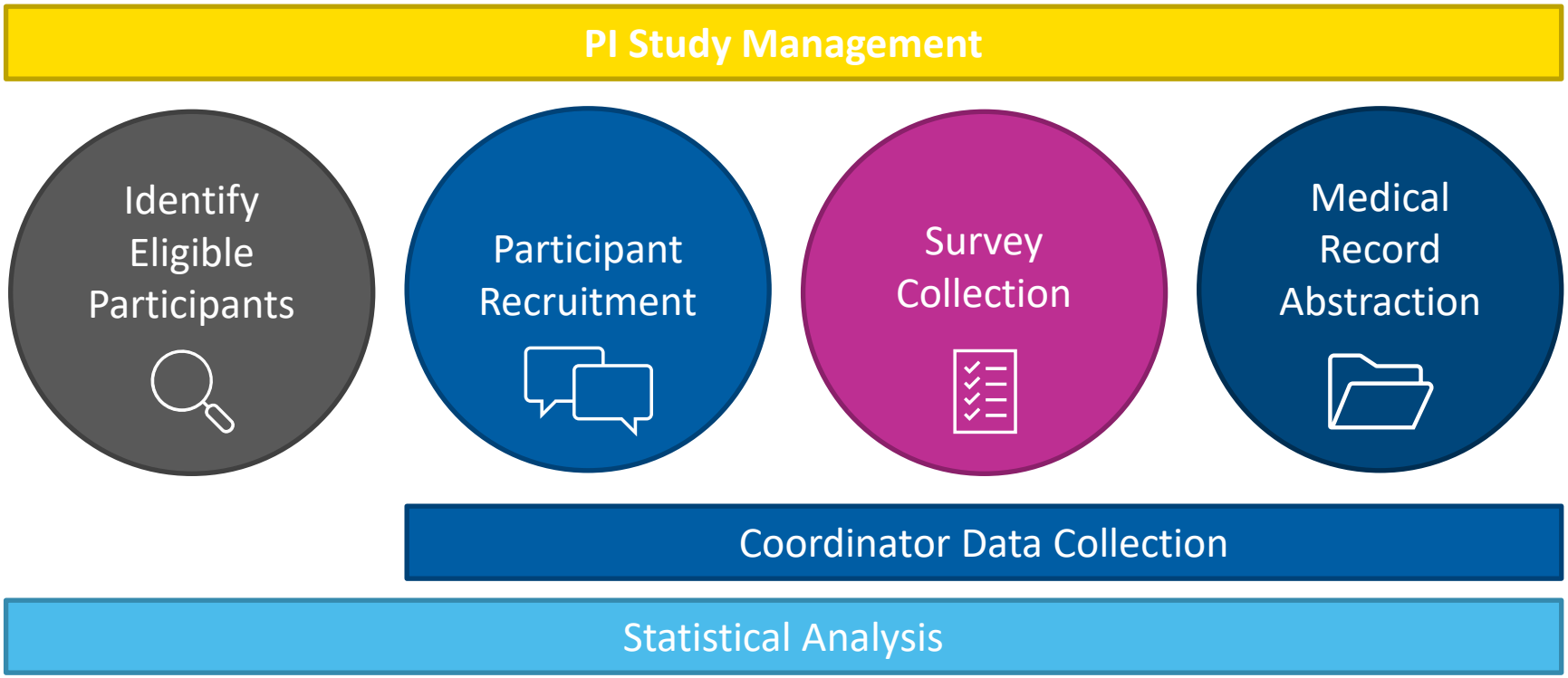
- Outdated contact information
- Missing contact information

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



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)

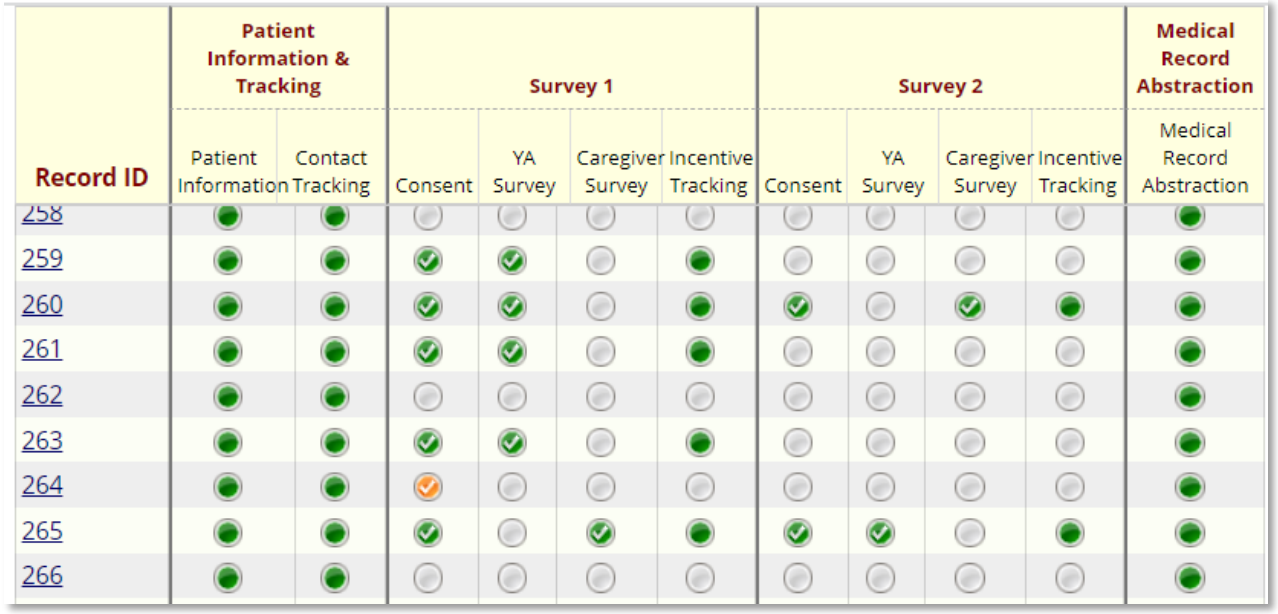
REDCap Structure

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	●	●	○	○	○	○	○	○	○	○	●
259	●	●	✓	✓	○	●	○	○	○	○	●
260	●	●	✓	✓	○	●	✓	○	✓	●	●
261	●	●	✓	✓	○	●	○	○	○	○	●
262	●	●	○	○	○	○	○	○	○	○	●
263	●	●	✓	✓	○	●	○	○	○	○	●
264	●	●	✓	○	○	○	○	○	○	○	●
265	●	●	✓	○	✓	●	✓	✓	○	●	●
266	●	●	○	○	○	○	○	○	○	○	●

*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

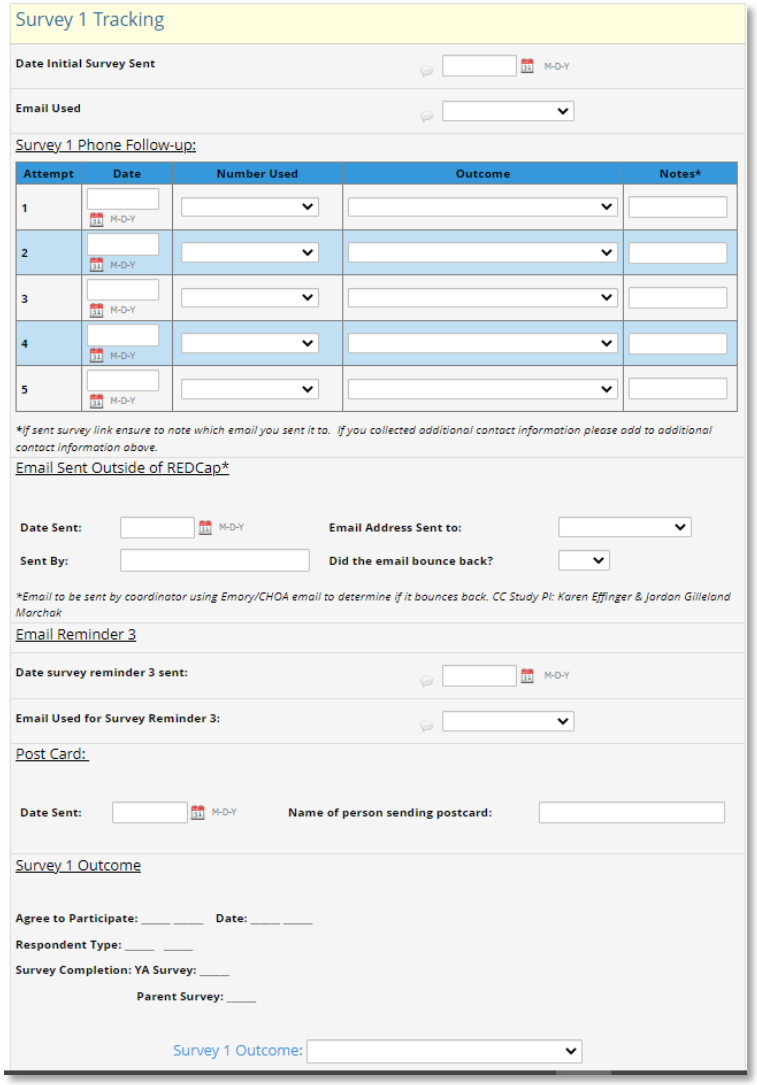
Data **request** to the **Health Informatics Core**

- 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



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

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Recruitment schedule.	
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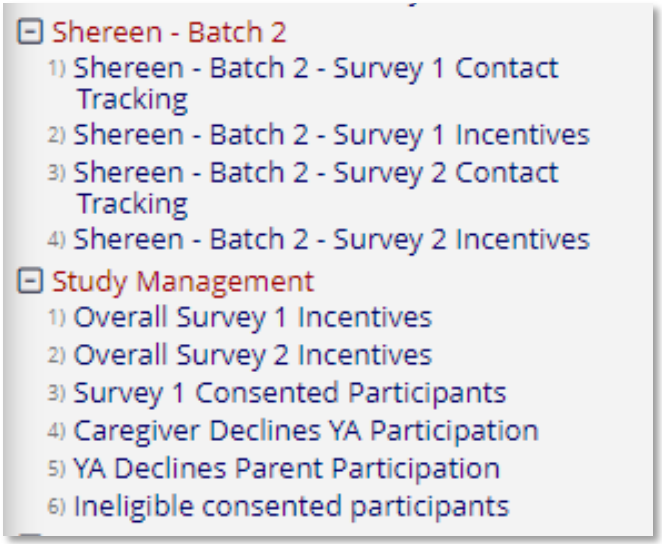
Reports for recruitment management

- 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’

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

		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 ***more than*** 1 hour.	N	O	S	Q	F	A
2.	…I play or exercise for ***more than*** 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

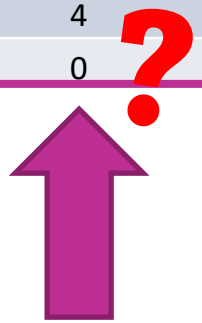
Behavioral Arousal Factor (mean of 3 items)

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)

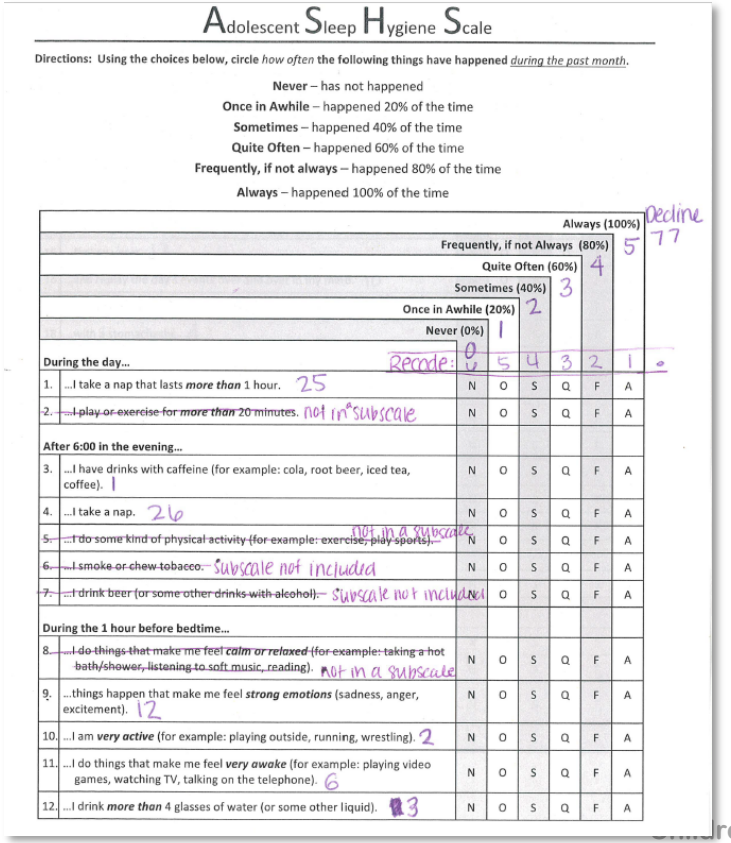
6 = Never
5 = Once in a while
4 = Sometimes
3 = Quite often
2 = Frequently, if not Always
1 = Always

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)	radio (Matrix), Required 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)	radio (Matrix), Required 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]	During the hour before bedtime, I drink >4 glasses of water (or some other liquid) **ASHS Question 12**	radio (Matrix), Required 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



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Always – happened 100% of the time

Always (100%) 5
Frequently, if not Always (80%) 4
Quite Often (60%) 3
Sometimes (40%) 2
Once in Awhile (20%) 1
Never (0%) 0

Decline 77

Recode: 0 1 2 3 4 5

During the day...							
1.	...I take a nap that lasts ***more than*** 1 hour. 25	N	O	S	Q	F	A
2.	~~...I play or exercise for ***more than*** 20 minutes.~~ not in subscale	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). 1	N	O	S	Q	F	A
4.	...I take a nap. 26	N	O	S	Q	F	A
5.	~~...I do some kind of physical activity (for example: exercise, play sports).~~ not in a subscale	N	O	S	Q	F	A
6.	~~...I smoke or chew tobacco.~~ subscale not included	N	O	S	Q	F	A
7.	~~...I drink beer (or some other drinks with alcohol).~~ subscale not included	N	O	S	Q	F	A
During the 1 hour before bedtime...							
8.	~~...I do things that make me feel ***calm or relaxed*** (for example: taking a hot bath/shower, listening to soft music, reading).~~ not in a subscale	N	O	S	Q	F	A
9.	...things happen that make me feel ***strong emotions*** (sadness, anger, excitement). 12	N	O	S	Q	F	A
10.	...I am ***very active*** (for example: playing outside, running, wrestling). 2	N	O	S	Q	F	A
11.	...I do things that make me feel ***very awake*** (for example: playing video games, watching TV, talking on the telephone). 6	N	O	S	Q	F	A
12.	...I drink ***more than*** 4 glasses of water (or some other liquid). 3	N	O	S	Q	F	A

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

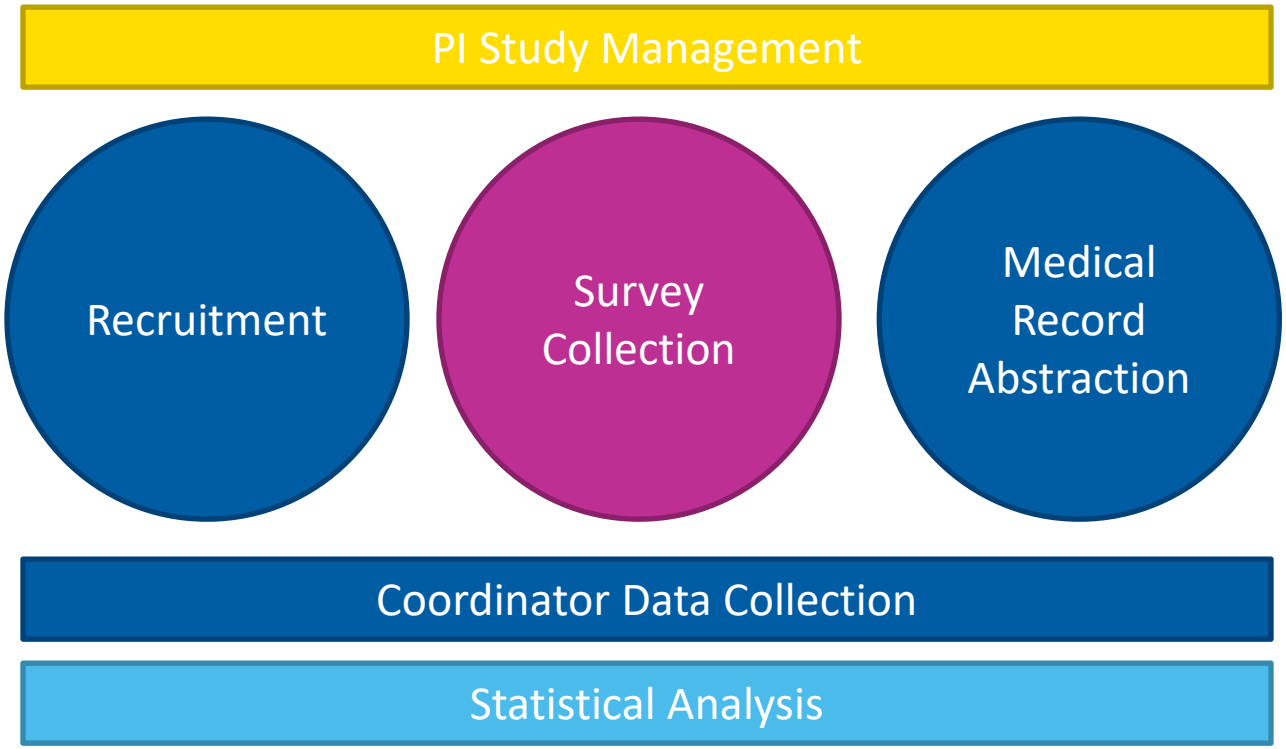
Support

Dana Ray & Winship Cancer Institute

Funding

National Cancer Institute

Overall Project Management



EMORY
LIBRARIES

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 <u>not</u> 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 <u>not</u> 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.

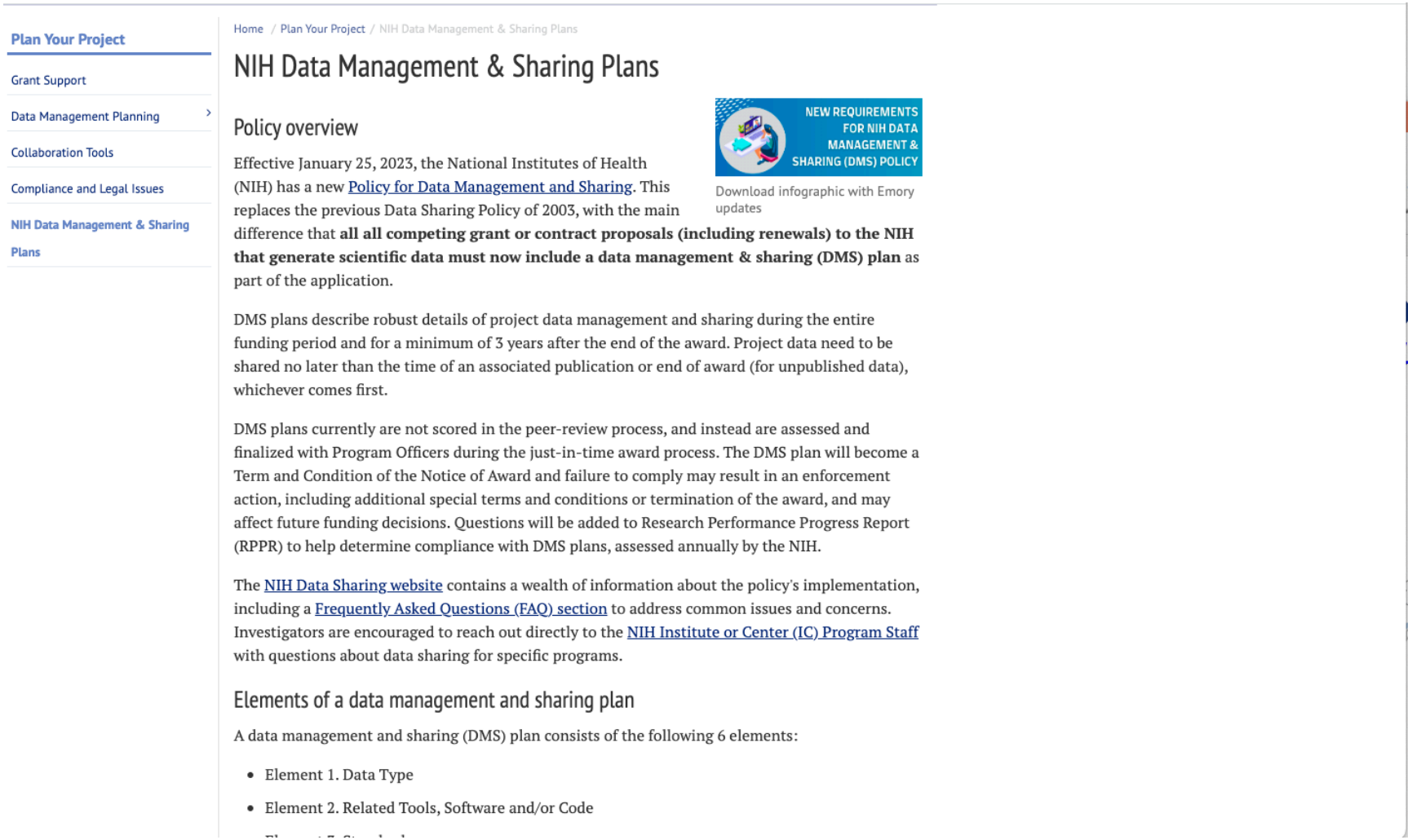
Allowable Costs

- **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



Plan Your Project

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

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

NIH Data Management & Sharing Plans

Policy overview

Download infographic with Emory updates

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.

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

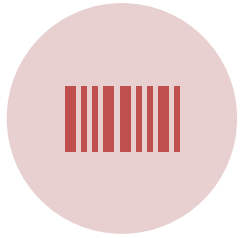
NIH OR DOMAIN-SPECIFIC DATA REPOSITORY

GENERALIST DATA REPOSITORY

LARGE DATA

SENSITIVE DATA

DATA USE AGREEMENTS



CODE/SOFTWARE

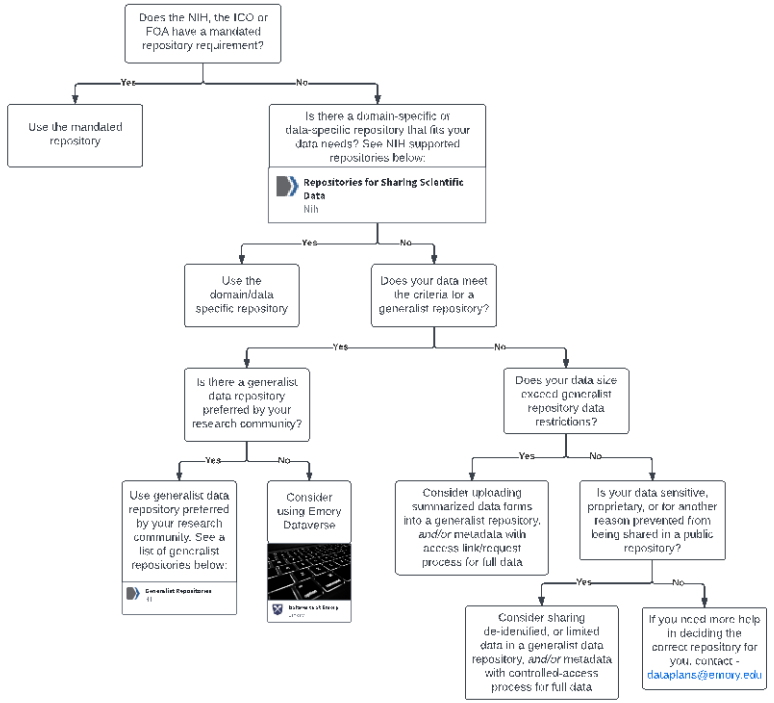
COMMERCIAL IMPLICATIONS

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 acccess / 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>