

REDCap Database Design Best Practices

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Activity Code

Activity Code: **27438**

Instructions for claiming credits/contact hours can be found [here](#)

Introduction

- Data collection and management is a critical part of any research study
- Many tools exist for data collection and/or data management
 - OnCore
 - Advarra EDC
 - REDCap
 - Qualtrics
 - EPIC

REDCAP

- <https://projectredcap.org/>
- REDCap can be used to collect virtually any type of data in a HIPAA-compliant environment
 - **NOT** 21 CFR Part 11 compliant
- Timeline:
 - 2004: Created at Vanderbilt University
 - 2006: REDCap consortium officially launched
 - ~2017: UVA joined consortium
- At UVA:
 - <https://portal.ithriv.org/#/resource/171>
 - <https://redcap.healthsystem.virginia.edu/>

Why Use REDCap?

- User-friendly interface
- Allows easy build of electronic case report forms (CRFs)
- Implementation of repeated instruments and events
 - Build CRF once, use multiple times per subject to collect data
- Built in quality control tools
- Ability to control user access to select CRFs or subjects
- Automatic creation of pdf CRFs for use as backups
- Automatic creation of codebook, data dictionary, etc. for analyses and data sharing

Creating repeating CRFs

- Longitudinal studies have multiple subject visits over time
- Often collect the same data at multiple visits
 - Repeating events
- Or need to complete the CRF at multiple unknown times
 - E.g. Adverse Events
- Repeating instrument

Repeating Instruments

- CRFs that need to be completed as often as needed

The screenshot shows a user interface for enabling optional modules. At the top, a grey bar contains a gear icon and the text 'Enable optional modules and customizations'. Below this, a list of modules is shown. The first module, 'Repeating instruments', is highlighted with an orange arrow pointing to its 'Enable' button. The 'Repeating instruments' button is red with a minus sign, while the others are green with a plus sign. A second, larger window is open in the foreground, showing the same interface but with the 'Repeating instruments and events' button highlighted. This window also has an 'I'm done!' button and an 'Additional customizations' button. A link at the bottom right says 'Learn about Data Collection Strategies for Repeating Surveys'.

Enable optional modules and customizations

Optional **Enable** **Repeating instruments** ?

Enable optional modules and customizations

Optional **Modify** **Repeating instruments and events** ?

Disable **Auto-numbering for records** ?

Enable **Scheduling module (longitudinal only)** ?

Disable **Randomization module** ?

Enable **Designate an email field for communications (including survey invitations and alerts)** ?

I'm done!

Additional customizations

Learn about [Data Collection Strategies for Repeating Surveys](#)

Repeating instruments



An excellent way to collect repeating data in REDCap is to use repeating instruments and/or repeating events. This is sometimes called one-to-many data collection. Some examples may include but are not limited to the following: data from multiple visits or observations, concomitant medications, adverse events, or repetitive surveys (daily, weekly, etc.).

Below you can specify a data collection instrument to be infinitely repeatable, which means that an instrument can be repeated over and over again (a different number of times for each record) even without enabling REDCap's longitudinal module. Once an instrument is set to repeat, you will see options on the Record Home Page to add another instance of the instrument for the currently selected record. All instances of a repeating instrument will then be displayed as a table near the bottom of the Record Home Page, thus allowing viewing of the instances and easy navigation within them.

Repeat this instrument?	Instrument name	Custom label for repeating instruments (optional)  Example: [visit_date], [weight] kg
☐	Demographic Information	
☐	Promis Bank V10 Fatigue	
☐	PROMIS SF v1.0 - Fatigue 6a	
☐	PROMIS SF v1.0 - Pain Interference 4a	
☒	Adverse Event	

Save

Cancel

Repeating Instruments

Repeating Instruments

- Record Status Dashboard

Record ID	Demographic Information	Promis Bank V10 Fatigue	PROMIS SF v1.0 - Fatigue 6a	PROMIS SF v1.0 - Pain Interference 4a	Adverse Event
1					 
2					

Record ID 1

Data Collection Instrument	Status
Demographic Information	
Promis Bank V10 Fatigue (survey)	
PROMIS SF v1.0 - Fatigue 6a (survey)	
PROMIS SF v1.0 - Pain Interference 4a (survey)	
Adverse Event	 

Repeating Instruments

Adverse Event (1)

1



+ Add new

Repeating instruments

An excellent way to collect repeating data in REDCap is to use repeating instruments and/or repeating events. This is sometimes called one-to-many data collection. Some examples may include but are not limited to the following: data from multiple visits or observations, concomitant medication surveys (daily, weekly, etc.).

Below you can specify a data collection instrument to be infinitely repeatable. An instrument can be repeated over and over again (a different number of times) by enabling REDCap's longitudinal module. Once an instrument is set to repeat, the Record Home Page to add another instance of the instrument for the current record. A table of a repeating instrument will then be displayed as a table near the bottom of the record page, allowing viewing of the instances and easy navigation within them.

Repeat this instrument?	Instrument name	Custom label for repeating instrument Example: [visit]
☐	Demographic Information	
☐	Promis Bank V10 Fatigue	
☐	PROMIS SF v1.0 - Fatigue 6a	
☐	PROMIS SF v1.0 - Pain Interference 4a	
☒	Adverse Event	[aedate]

Repeating Instruments

Record ID 1

Data Collection Instrument	Status
Demographic Information	☒
Promis Bank V10 Fatigue (survey)	☐
PROMIS SF v1.0 - Fatigue 6a (survey)	☐
PROMIS SF v1.0 - Pain Interference 4a (survey)	☐
Adverse Event	☒ +

Repeating Instruments

Adverse Event (1)			
1	☒	01-30-2025	
			+ Add new

Creating repeating **Sets** of CRFs / Events

- Multiple CRFs to be completed together; or
- Single CRF to be completed at set times



Not started

Main project settings

☒ Use surveys in this project? [?](#) [VIDEO: How to create and manage a survey](#)

☒ Use longitudinal data collection with defined events? [?](#)

☒ Use the MyCan participant-facing mobile app? [Learn more about MyCan](#)



In progress

[I'm done!](#)

Define your events and designate instruments for them

Create events for re-using data collection instruments and/or set up scheduling.

Go to [Define My Events](#) or [Designate Instruments for My Events](#)

Define My Events

Arm 1: Arm 1

+Add New Arm

Arm name: Arm 1

[Rename Arm 1](#)

		Event # [event-number]	Event Label [event-label]	Custom Event Label ? (optional)	Unique event name ? (auto-generated) [event-name]	Event ID (auto-generated, unchangeable) [event-id]
	 	1	Event 1		event_1_arm_1	5397
	 	2	3 Months		3_months_arm_1	17872
	 	3	6 Months		6_months_arm_1	17873
	Add new event		Descriptive name for this event	Custom Event Label (optional) Example: [visit_date], [weight] kg		

Designate Instruments for My Events

Begin Editing

Save

Select All | Deselect All

Data Collection Instrument	Event 1 (1)	3 Months (2)	6 Months (3)
Demographic Information	☒	☐	☐
Promis Bank V10 Fatigue (survey)	☒	☒	☒
PROMIS SF v1.0 - Fatigue 6a (survey)	☒	☒	☒
PROMIS SF v1.0 - Pain Interference 4a (survey)	☒	☒	☒
Adverse Event	☐	☐	☐

Record Status Dashboard

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

Record ID	Event 1				3 Months			6 Months		
	Demographic Information	Promis Bank V10 Fatigue	PROMIS SF v1.0 - Fatigue 6a	PROMIS SF v1.0 - Pain Interference 4a	Promis Bank V10 Fatigue	PROMIS SF v1.0 - Fatigue 6a	PROMIS SF v1.0 - Pain Interference 4a	Promis Bank V10 Fatigue	PROMIS SF v1.0 - Fatigue 6a	PROMIS SF v1.0 - Pain Interference 4a
1										
2										

Problem: No adverse events form shown

Designate Instruments for My Events

Begin Editing

Save

Select All | Deselect All

Data Collection Instrument	Event 1 (1)	3 Months (2)	6 Months (3)
Demographic Information	☒	☐	☐
Promis Bank V10 Fatigue (survey)	☒	☒	☒
PROMIS SF v1.0 - Fatigue 6a (survey)	☒	☒	☒
PROMIS SF v1.0 - Pain Interference 4a (survey)	☒	☒	☒
Adverse Event	☐	☐	☐



Designate Instruments for My Events

Data Collection Instrument	Baseline (1)	3 Months (2)	6 Months (3)	Adverse Events (4)
Demographic Information	✓			
Promis Bank V10 Fatigue (survey)	✓	✓	✓	
PROMIS SF v1.0 - Fatigue 6a (survey)	✓	✓	✓	
PROMIS SF v1.0 - Pain Interference 4a (survey)	✓	✓	✓	
Adverse Event				✓



		4	Adverse Events		adverse_events_arm_1	17874
Add new event						
		Descriptive name for this event		Custom Event Label (optional) Example: [visit_date], [weight] kg		

Record Status Dashboard

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

Record ID	Baseline				3 Months			6 Months			Adverse Events
	Demographic Information	Promis Bank V10 Fatigue	PROMIS SF v1.0 - Fatigue 6a	PROMIS SF v1.0 - Pain Interference 4a	Promis Bank V10 Fatigue	PROMIS SF v1.0 - Fatigue 6a	PROMIS SF v1.0 - Pain Interference 4a	Promis Bank V10 Fatigue	PROMIS SF v1.0 - Fatigue 6a	PROMIS SF v1.0 - Pain Interference 4a	Adverse Event
<u>1</u>											
<u>2</u>											

Creating repeating **Sets** of CRFs / Events

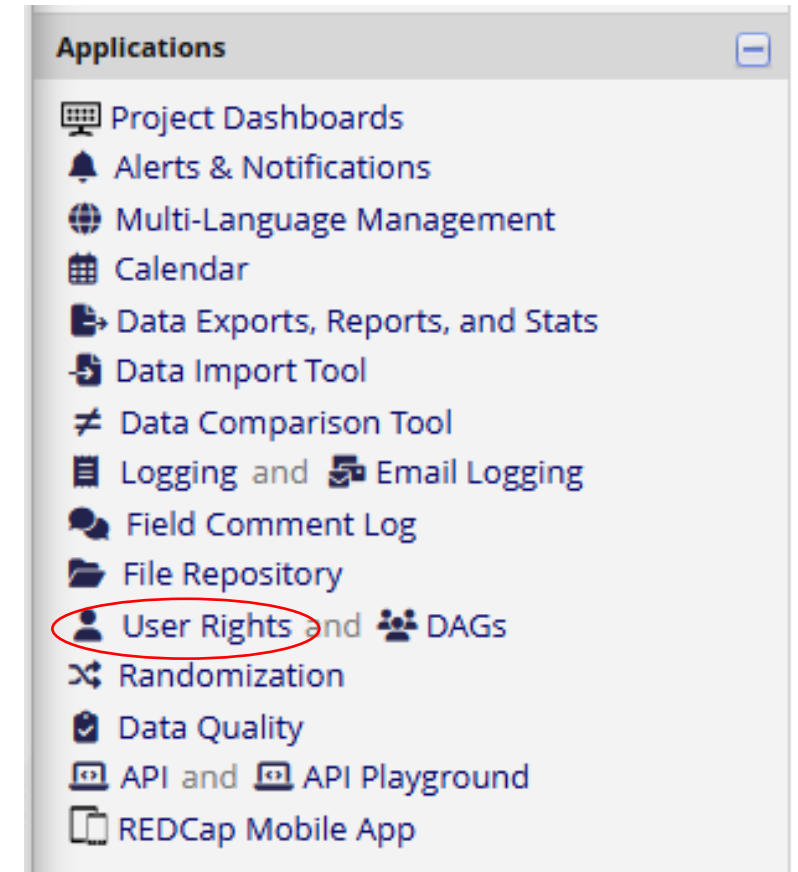
- Use branching logic to show / hide questions based on Event (visit)
- Use Form Display Logic to hide forms based
 - Visit
 - On answers to previous questions. E.g. only show a form if patient is randomized to intervention arm (considering blinding requirement).

Control User Access

- Studies often need to limit who has access to what information
- REDCap can limit access to CRFs, subjects, editing, exporting, and locking records
- “User roles” can be generated to define rights based on responsibilities

User Roles

- Role permissions are built under “User Rights”
- Can have multiple roles in a project
- Good practice to add users to roles to control permissions



User Roles

[🏠 Project Home](#)

Project Setup

 **User Rights**

Data Access Groups

This page may be used for granting users access to this project and for managing the user privileges of those users. You may also create roles to which you may assign users (optional). User roles are useful when you will have several users with the same privileges because they allow you to easily add many users to a role in a much faster manner than setting their user privileges individually. Roles are also a nice way to categorize users within a project. In the box below you may add/assign users or create new roles, and the table at the bottom allows you to make modifications to any existing user or role in the project, as well as view a glimpse of their user privileges.

Upload or download users, roles, and assignments

Upload users (CSV)

Download users (CSV)

Upload user roles (CSV)

Download user roles (CSV)

Upload user role assignments (CSV)

Download user role assignments (CSV)

Add new user

— OR —

Assign new user to role

+ Add with custom roles

Assign to role

Create new role

Enter new role name

(e.g., Project Manager, Data Entry Person)

Reuse roles in another project

Basic Privileges

Highest level privileges:

- Project Design and Setup

☐
- User Rights

☒ No Access

☐ Read Only

☐ Full Access
- Data Access Groups

☐

Other privileges:

- Survey Distribution Tools

☒
- Alerts & Notifications

☐
- Calendar

☒
- Add/Edit/Organize Reports

☒

Also allows user to view ALL reports (but not necessarily all data in the reports)
- Stats & Charts

☒
- Data Import Tool

☐
- Data Comparison Tool

☐
- Logging

☐
- Email Logging

☐
- File Repository

☒

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 (e.g., data entry forms, reports). Users with 'No Access' Data Viewing Rights for a given instrument will not be able to view that instrument for any record, nor will they be able to view fields from that instrument on a report. Data Export Rights pertain to a user's ability to export data from the project, whether through the Data Exports page, API, Mobile App, or in PDFs of instruments containing record data. Note: Data Viewing Rights and Data Export Rights are completely separate and do not impact one another.

	Data Viewing Rights				Data Export Rights			
	No Access (Hidden)	Read Only	View & Edit	Edit survey responses	No Access	De-Identified*	Remove All Identifier Fields	Full Data Set
Demographic Information	☐	☐	☒		☐	☐	☐	☒
Promis Bank V10 Fatigue (survey)	☐	☐	☒	☒	☐	☐	☐	☒
PROMIS SF v1.0 - Fatigue 6a (survey)	☐	☐	☒	☒	☐	☐	☐	☒
PROMIS SF v1.0 - Pain Interference 4a (survey)	☐	☐	☒	☒	☐	☐	☐	☒
Adverse Event	☐	☐	☒		☐	☐	☐	☒

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

 Randomization
[What is randomization?](#)

- ☐ Setup
- ☐ Dashboard
- ☒ Randomize

 Data Quality
[What is Data Quality?](#)

- ☐ Create & edit rules
- ☐ Execute rules

 API
[What is the REDCap API?](#)

- ☐ API Export
- ☐ API Import/Update

Settings pertaining to the REDCap Mobile App:

 REDCap Mobile App
[What is the REDCap Mobile App?](#)

- ☐ Allows user to collect data offline in the mobile app

Allow user to download data for all records to the app? ☐

Settings pertaining to project records: [Explain these settings](#)

 Create Records ☒

 Rename Records ☐

 Delete Records ☐

* Includes ability to delete all data on an instrument or on a repeating event.

Settings pertaining to record locking and E-signatures:

 Record Locking Customization ☐

 Lock/Unlock Records (instrument level) ☒ Disabled
Users with locking privileges also have access to the E-signature and Locking Mgmt page on the left-hand Applications menu.
 [Watch video about locking](#)
☐ Locking / Unlocking
☐ Locking / Unlocking with E-signature authority
[What is an E-signature?](#)

 Lock/Unlock *Entire* Records (record level) ☐

Randomization options only available if randomization set up in project

Suggested User Rights for Roles

User Right	PI	Project Administrator	Data Entry	Data Monitor	Biostat.
Project Design & Setup	✓	✓			Development
User Rights		✓			Development
Data Access Groups	Full access	Full access			
Data Viewing Rights*	View & Edit	View & Edit	View & Edit	Read only	Read only
Data Export Rights*	De-identified	De-identified	No Access	No Access	Full Data
Reports & Report Builder	✓	✓		✓	✓
Data Comparison Tool		✓	✓		
Logging	✓	✓		✓	
Locking/unlocking	✓	✓	Disabled	Disabled	Disabled

*** Individual CRFs can vary - Full access given on forms created after roles created**

Suggested User Rights for Roles

User Right	PI	Project Administrator	Data Entry	Data Monitor	Biostat.
Data Quality (create/edit rules)		✓		✓	
Data Quality (execute rules)	✓	✓		✓	✓
Create Records	Development	✓	✓		Development
Rename Records		✓			
Delete Records		✓			
API					API Export
Randomization (Setup)					✓
Randomization (Dashboard)		✓			✓
Randomization (Randomize)			✓		

User Roles

- CRC role specific to each study
- Different roles on different studies gives different access

Data Access Groups (DAGs)

- Assigns users to a set of subjects / records
 - Generally used in multi-site projects to only give users access to data at their site
- Can be assigned to multiple DAGs
 - Users switches between DAGs as needed
- Must maintain [No assignment] DAG to edit permissions
 - Once [No assignment] removed there's no going back even with DAGs permission in Roles

 Upload or download DAGs/User-DAG assignments ▾

+ Create new groups: Add new data access groups to which users may be assigned.

Enter new group name

+ Add Group

 **Assign user to a group:** Users may be assigned to any data access group. To assign users to multiple groups, use the DAG Switcher at the bottom.

Assign user

-- Select User -- ▾

to

[No Assignment] ▾

 **Assign**

Data Access Groups	Users in group	Number of records in group	Unique group name  (auto-generated)	Group ID number 	Delete group?
UVA		0	uva	1142	
[Not assigned to a group]	sjr7pc (Sarah Ratcliffe) * Can view ALL records				

DAG Switcher: Enable multiple Data Access Groups for users

Display options:

☒ Rows are DAGs

☐ Rows are Users

Users assigned to Data Access Groups (DAGs) can optionally be assigned to multiple *potential* DAGs, in which they may be given the privilege of switching in and out of specific DAGs on their own whenever they wish. To assign a user to multiple DAGs, check the checkboxes below for that user. At least two DAGs must be checked for a user in order for them to use the DAG Switcher. NOTE: This does not override a user's current DAG assignment, as set above or on the User Rights page.

Show 25 ▾ entries

Search

Data Access Groups	Users
	sjr7pc
[No Assignment]	☐
UVA	☐

Statistical Review

- Before going from *Development* to *Production* a project should be thoroughly tested and reviewed by the statistical team
 - Quality control options set
 - CRF setup for repeating forms/events
 - Variable set-up / coding
 - Permissions
- Permissions often changed for team members after review / testing as part of moving to *Production*

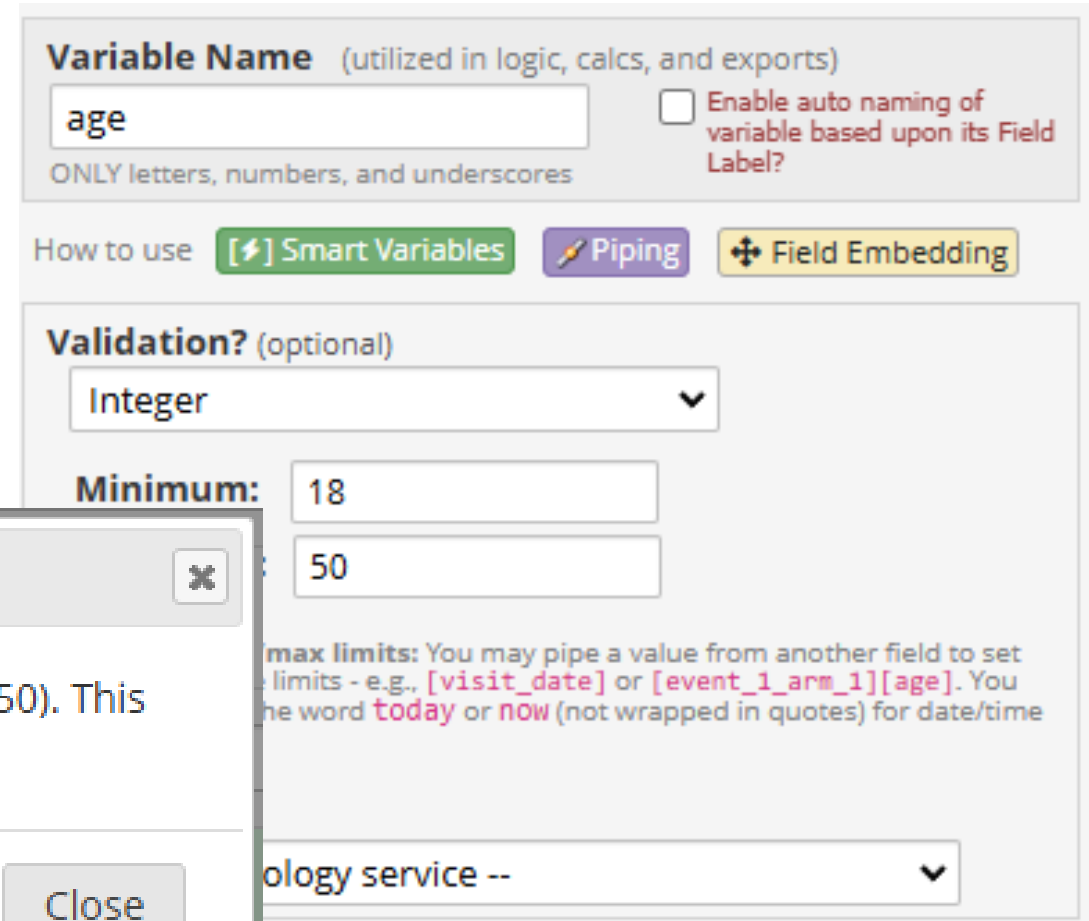
Statistical Review checks include:

- Variables with 2-levels should be coded as 0,1 (NOT 1,2)
- Missing data
 - Consistent missing data codes used. E.g. -99
 - Missing flags set up at project level
- Only one piece of information being collected in each spot. E.g.
 - Surgery [y/n]; Date of surgery [mm/dd/yyyy] ✓
 - If surgery, date of surgery [mm/dd/yyyy] ✗

<https://kb.wisc.edu/smph/informatics/page.php?id=108107>

Statistical Review Checks

- Variable Limits
 - Set data entry type (e.g. date, number, zip code)
 - Set **suggested** minimum and maximum values



The screenshot shows a data entry interface. At the top, there's a 'Variable Name' field with the value 'age' and a checkbox for 'Enable auto naming of variable based upon its Field Label?'. Below this is a section 'How to use' with buttons for 'Smart Variables', 'Piping', and 'Field Embedding'. The 'Validation?' section is set to 'Integer'. The 'Minimum' is set to 18 and the 'Maximum' is set to 50. An alert message is displayed: 'The value you provided is outside the suggested range (18 - 50). This value is admissible, but you may wish to double check it.' The alert has a 'Close' button.

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

age ☐ 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)

Integer

Minimum: 18

50

Alert

The value you provided is outside the suggested range (18 - 50). This value is admissible, but you may wish to double check it.

Close

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

ology service --

Statistical Review Checks

- Variable Limits
 - Set **enforced** minimum and maximum values:

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

age ☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use [\[⚡\] Smart Variables](#) [✍ Piping](#) [⛶ Field Embedding](#)

Action Tags / Field Annotation (optional)

@FORCE-MINMAX

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

Annotation? (optional)

age

min: 18

max: 50

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

ontology service --

Alert

The value you provided must be within the suggested range (18 - 50).

Close

Data Harmonized to National Standards

- Federal data sharing requirements critical to incorporate into database design
 - E.g. Repositories require certain variable names and coding to be used, as applicable. May supply REDCap coding to use in building database.
- NIH Common Data Element Standards
 - <https://cde.nlm.nih.gov/home>
 - Helps with data reuse and combining datasets
- A few hours to build at the start, 10x hours to fix at the end

REDCap Help

- REDCap Virtual Office Hours
 - Thursdays 9am-12pm: [REDCap Virtual Office Hours Registration](#)
 - Email redcap @ uvahealth.org
- PHS @ the Library - <https://guides.hsl.virginia.edu/phs>
 - Monday, Friday 2-4pm: Virtual
 - Tuesday, Wednesday, Thursday 2-4pm: In-person

Activity Code

Activity Code: **27438**

Instructions for claiming credits/contact hours can be found [here](#)

Questions

