

# Protecting Sensitive Participant Information (PHI) in REDCap

# IRB comes first!

- Protecting PHI in REDCap is part of the larger picture of protecting sensitive participant information
- The IRB's job is to protect patients and their information
- Adhering to your IRB protocol is first and foremost for protecting your patient's data
- All, some, or none of the material here maybe relevant to your particular project
- When in doubt, please always refer your IRB and IRB protocol to ensure you are properly protecting sensitive patient information

# Traditional Research Protections for PHI

- PHI Protection: Collect only PHI that is necessary and separate PHI from study data and responses (de-identify)
- Traditionally this could be accomplished in a number of ways
  - Physical file location for sensitive PHI separate from digital files of study data.
    - Locked cabinet in locked office with limited researcher access
  - Password protected separate excel document of PHI information on locked server, with limited user access
- While necessary, this could have been cumbersome to maintain patient information in more than one location.

**REDCap has created tools to allow you to digitally separate PHI from patient responses with in a project. There are **steps** necessary to protect patient data in this way.**

# 2 Ways PHI needs to be protected in REDCap

- Protection from access outside REDCap (Exporting)
  - Limiting who can export what identifying information
- Protection from access inside REDCap
  - Seeing PHI linked to responses and health information

# Protecting PHI From Being Exported

- PHI must be marked as an identifier
- This must be done for each variable that would be considered PHI.
- Remember dates are PHI
  - However we usually need dates for analysis (more later)
  - Validate dates as dates

**Edit 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:** First Name [How to use Piping](#)

**Action Tags / Field Annotation (optional)**

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

**Variable Name (utilized during data export)**

first\_name  Enable auto naming of variable based upon its Field Label?

**Validation? (optional)** ---- None ----

OR

**Enable searching within a biomedical ontology?** [?](#)

-- choose ontology to search --

**Required?\* (optional)**  No  Yes

\* Prompt if field is blank

**Identifier? (optional)**  No  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

# Separate PHI variables into their own form(s)

- Separate PHI into its own form so it can be given special access
- Other demographics that are not PHI will likely need to be put in their own form

Print page

Data Dictionary Codebook

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: <b>Phi</b> (phi)			
 1	record_id	Study ID	text
 	first_name	Section Header: <i>Contact Information</i> First Name	text, Identifier
 	telephone	Phone number <i>Include Area Code</i>	text (phone), Identifier
 	last_name	Last Name	text, Identifier
 	email	E-mail	text (email), Identifier
 	dob	Date of birth	text (date_ymd), Identifier
	phi_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: <b>Basic Demography Form</b> (demographics)			
 	sex	Gender	radio 0 Female 1 Male
 	height	Height (cm)	text (number, Min: 130, Max: 215)
 	weight	Weight (kilograms)	text (integer, Min: 35, Max: 200)
	demographics_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: <b>Sensitive Info</b> (sensitive_info)			
 	sex_act	What is your history of sexual activity?	radio 0 None

# Decide upon and Assign User rights

- Decide who on your team can have access to PHI (according to IRB protocol)
- One person will need to have full access to PHI
  - This role is often the PI
- Restrict user access to PHI in the User Rights Application
  - Can be done individually for each user or with Roles

# Full Access

PI usually or clinical coordinator

**Creating new role "PHI Identified access"**

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 them or deny them access to individual data collection instruments, if so desired. To save your selections, click the "Create role" button at the bottom of the page.

**Basic Rights**

Highest level privileges:

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

Privileges for data exports (including PDES and API exports), reports, and stats:

- Data Exports
  - No Access
  - De-Identified\*
  - Remove all tagged identifier fields
  - Full Data Set
- Add / Edit Reports
  - Also allows user to view All reports (but not necessarily all data in the reports)
- Stats & Charts

Other privileges:

- Manage Survey Participants
- Calendar
- Data Import Tool
- Data Comparison Tool
- Logging

**Data Entry Rights**

*NOTE: The data entry rights \*only\* pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.*

	No Access	Read Only	View & Edit
Phi	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Basic Demography Form	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Sensitive Info	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>



# PHI Restricted Access

- No access to the PHI form
- Remove access to:
  - Project Design and Setup
  - User Rights
  - Data Access Groups
  - Add edit Reports
  - Stats and Charts
- Works best after development is completely finished

The screenshot shows the 'Creating new role' interface in REDCap. The role is named 'PHI De-Identified Access'. The interface is divided into several sections:

- Basic Rights:** Contains a list of privileges. Three items are highlighted with red boxes: 'Project Design and Setup', 'User Rights', and 'Data Access Groups'. Below this, 'Data Exports' is set to 'De-Identified\*'. 'Add / Edit Reports' is also highlighted with a red box. 'Stats & Charts' is unchecked.
- Data Entry Rights:** A table with columns 'No Access', 'Read Only', and 'View & Edit'. A note states: 'NOTE: The data entry rights \*only\* pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.' The table has three rows: 'Phi', 'Basic Demography Form', and 'Sensitive Info'. The 'Phi' row has 'No Access' selected. The 'Basic Demography Form' row has 'View & Edit' selected. The 'Sensitive Info' row has 'View & Edit' selected.
- Other privileges:** A list of tools with checkboxes: 'Manage Survey Participants' (checked), 'Calendar' (checked), 'Data Import Tool' (unchecked), 'Data Comparison Tool' (unchecked), 'Logging' (unchecked), and 'File Repository' (checked).

At the bottom right, there are 'Create role' and 'Cancel' buttons.

# PHI Restricted Access

- Data exports two options of de-identified data
  - De-Identified removes:
    - All tagged ID fields
    - **All free-form text fields**
    - All dates
      - Unless date shifted (more later)
  - Remove all tagged ID fields
    - Removes only tagged ID fields
    - Leave free-form text fields
    - Option to export as date shifted but not forced to

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Creating new role "PHI De-Identified Access"

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**Privileges for data exports (including PDFs and API exports), reports, and stats:**

- Data Exports
  - No Access
  - De-Identified\*
  - Remove all tagged Identifier fields
  - Full Data Set
- Add / Edit Reports

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

Stats & Charts

**Other privileges:**

- Manage Survey Participants
- Calendar
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository

**Data Entry Rights**

*NOTE: The data entry rights \*only\* pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.*

	No Access	Read Only	View & Edit
Phi	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Basic Demography Form	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Sensitive Info	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

**Create role** **Cancel**

## Full Access

### All data (all records and fields)

Study ID (record_id)	First Name (first_name)	Phone number (telephone)	Last Name (last_name)	E-mail (email)	Date of birth (dob)	Complete? (phi_complete)	Gender (sex)	Height (cm) (height)	Weight (kilograms) (weight)	Complete? (demographics_complete)	What is your history of sexual activity? (sex_act)	What is your history of drug use? (drug_use)	Complete? (sensitive_info_complete)
<a href="#">001</a>	Alison	(203) 206-6573	Chambers	alic@gmail.com	2017-11-16	Complete (2)	Female (0)	149	72	Complete (2)	Some (1)	None (0)	Complete (2)
<a href="#">002</a>	Ali		Biercevicz	alib@gmail.com	2017-11-15	Complete (2)	Female (0)	200	80	Complete (2)	Some (1)	A lot (2)	Complete (2)

## Restricted Access







### All data (all records and fields)

Study ID (record_id)	First Name (first_name)	Phone number (telephone)	Last Name (last_name)	E-mail (email)	Date of birth (dob)	Complete? (phi_complete)	Gender (sex)	Height (cm) (height)	Weight (kilograms) (weight)	Complete? (demographics_complete)	What is your history of sexual activity? (sex_act)	What is your history of drug use? (drug_use)	Complete? (sensitive_info_complete)
<a href="#">001</a>	-	-	-	-	-	-	Female (0)	149	72	Complete (2)	Some (1)	None (0)	Complete (2)
<a href="#">002</a>	-	-	-	-	-	-	Female (0)	200	80	Complete (2)	Some (1)	A lot (2)	Complete (2)

## Full Access





Displaying record Page 1 of 1: "001" through

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

Study ID	Phi	Basic Demography Form	Sensitive Info
<a href="#">001</a>			
<a href="#">002</a>			

## Restricted Access

Displaying: Instrument status only | [Lc](#)

Study ID	Basic Demography Form	Sensitive Info
<a href="#">001</a>		
<a href="#">002</a>		








# What is Date Shifting?

- Because dates are PHI and we often need dates for analysis, date shifting de-identifies your dates.
- Date shifting will not affect the actual saved dates in the project.
- Shifts the dates in their resulting format when performing a data export in REDCap
- Shifted amount (offset) will always be the same for each record when performing a data export.
- The dates are shifted back in time up to 364 days

### Exporting "All data (all records and fields)"

Select your export settings, which includes the export format (Excel/CSV, SAS, SPSS, R, Stata) and if you wish to perform de-identification on the data set.

#### Choose export format

-  CSV / Microsoft Excel (raw data)
-  CSV / Microsoft Excel (labels)
-  SPSS Statistical Software
-  SAS Statistical Software
-  R Statistical Software
-  Stata Statistical Software
-  CDISC ODM (XML)

#### De-identification options (optional)

The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that apply.

**Known Identifiers:**

- Remove all tagged Identifier fields (tagged in Data Dictionary)
- Hash the Record ID field (converts record name to an unrecognizable value)

**Free-form text:**

- Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)
- Remove Notes/Essay box fields

**Date and datetime fields:**

- Remove all date and datetime fields
- OR —
- Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each record) [What is date shifting?](#)

[Deselect all options](#)

**Additional export options**

- Export survey identifier field and survey timestamp field(s)?








# Export Options

- Full Access options
  - Can remove dates
  - Can shift them
  - Can choose neither
  - Can remove tagged ID fields or no or not
  - Can has the record ID or not

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[Deselect all options](#)

**Additional export options**

- Export survey identifier field and survey timestamp field(s)?

**Export Data** **Cancel**








# Export Options

- De-identified options
  - Must remove dates or Shift dates
  - Must remove unvalidated text fields
  - Must remove Notes/Essay box fields
  - Must remove all tagged identifier fields

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Select your export settings, which includes the export format (Excel/CSV, SAS, SPSS, R, Stata) and if you wish to perform de-identification on the data set.

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-  CSV / Microsoft Excel (labels)
-  SPSS Statistical Software
-  SAS Statistical Software
-  R Statistical Software
-  Stata Statistical Software
-  CDISC ODM (XML)

#### De-identification options (optional)

The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that apply. **Given that you have limited export rights, you may NOT modify the options below, except the Date fields option.**

**Known Identifiers:**

- Remove all tagged Identifier fields (tagged in Data Dictionary)
- Hash the Record ID field (converts record name to an unrecognizable value)

**Free-form text:**

- Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)
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**Date and datetime fields:**

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**Additional export options**

- Export survey identifier field and survey timestamp field(s)?

**Export Data** **Cancel**