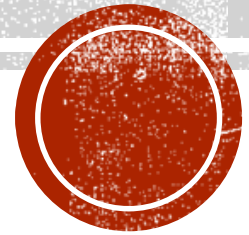


REDCAP FOR LONGITUDINAL MOM NEST STUDY

Hira Shrestha



INTRODUCTION



- **Maternal Opioid Medication: Naltrexone Efficacy Study (MOM NEST)**
 - A longitudinal observational study to examine safety and efficacy of Naltrexone (opioid-antagonist) in comparison to Suboxone (opioid-agonist) medication during pregnancy
 - Both are opioid maintenance medications to manage particular Substance Use Disorders (SUD)
- **Involves collection of:**
 - Biological samples such as blood, urine, placenta, saliva, hair AND sampling dates
 - Data on medical and psychosocial factors affecting pregnancy and sobriety
 - Short- and Long-term infant medical and neurobehavioral outcomes of prenatal opioid exposure
- **Some data points collected at various time points during pregnancy up to one year after birth**



REDCAP SET UP FOR THE STUDY

- **Longitudinal Data Collection Method**

- To address data collection at more than one time point
- E.g. Baseline, 36-Weeks of gestation, Delivery, etc.

- **Repeated Measures**

- To collect same data points that needed to be collected multiple times
- E.g. Ultrasound Results, Urine Toxicology Screen, PK Blood Draws, etc.

- **Survey Features**

- To be able to collect self-reported patient data
- E.g. Subjective Opioid Withdrawal, Addiction Severity Index, Side Effect Questions, etc.

- **Branching Logics**

- To filter out variables based on various criteria
- E.g. Study group, sample type, items within a questionnaire, etc.

- **Calculated Fields**

- To auto calculate duration between many dates
- E.g. Minutes between PK blood collection and processing,



DATABASE DESIGN PROCESSES

■ Categorizing Variables for Each Instrument

- **Patient-entered Data:** Survey feature
 - Visit-specific Questionnaires
 - Online or on a study tablet using REDCap App
- **RA Entered Data:** Direct data entry
 - Chart abstraction data
 - Interview Data
 - Crisis Management Report
 - Sample collection and processing dates

Determining Frequency of each Instrument

- **Fixed repetition:** Instruments with fixed timelines
- **As needed:** Instruments that can be repeated as needed

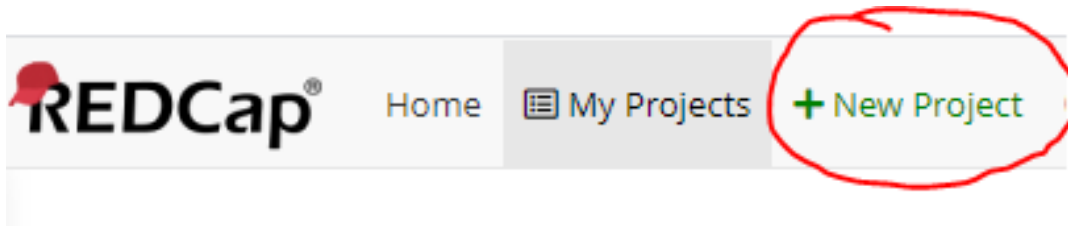
Determining Visit Time Points

- Define Events
- Designate Instruments



REDCAP PROJECT SET-UP

- Created a new project database following REDCap website instructions:



Modify Project Settings

Project title: MOM NEST - LOCAL
Title to be displayed on project webpage

Purpose of this project: Research
How will it be used?

Name of P.I. (if applicable): Elisha M Wachman
First name MI Last name

Email of P.I. (if applicable): Elisha.Wachman@bmc.org

Name of P.I. as cited in publications (if applicable):
(e.g., Harris PA)

IRB number (if applicable): H-37773

Please specify:

- Basic or bench research
- Clinical research study or trial
- Translational research 1 (applying discoveries to the development of trials and studies in humans)
- Translational research 2 (enhancing adoption of research findings and best practices into the community)
- Behavioral or psychosocial research study
- Epidemiology
- Repository (developing a data or specimen repository for future use by investigators)
- Other

Project notes (optional):
Comments describing the project's use or purpose that are displayed on the My Projects page.

Contains visit dates and should be managed locally by participating sites

Save Cancel



PROJECT SETUP: MAIN PROJECT SETTING

- Under **Project Setup** > **Main Project settings**, “*Enable*” survey and longitudinal data collection features

Project navigation tabs: [Project Home](#), [Project Setup](#), [Other Functionality](#), [Project Revision History](#)

Project status: Development Completed steps 0 of 8

Main project settings

Not started [VIDEO: How to create and manage a survey](#)

Use surveys in this project? [?](#)

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



PROJECT SETUP: DESIGNING DATA COLLECTION INSTRUMENTS

- **Online Designer vs. Data Dictionary**

Design your data collection instruments & enable your surveys

Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). You may then enable your instruments to be used as surveys in the Online Designer. Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#)

Go to  [Online Designer](#) or  [Data Dictionary](#)

Explore the  [REDCap Shared Library](#)

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use [\[+\] Smart Variables](#) [🖋 Piping](#) [@ Action Tags](#) [↓ Field embedding](#)



PROJECT SETUP: DATA COLLECTION INSTRUMENTS

Data Collection Instruments

Add new instrument:

- Create** a new instrument from scratch
- Import** a new instrument from the official [REDCap Shared Library](#) ?
- Upload** instrument ZIP file from another project/user or [external libraries](#) ?

Survey options:

- Survey Queue
- Survey Login
- Survey Notifications

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions
Basic Identifying Information	5		Enable	Choose action ▾

- Created instruments from scratch and enabled survey features for patient-entered data
- Modified survey settings to match the need of the study


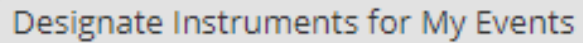


PROJECT SETUP: DEFINE EVENTS OR TIME POINTS

Selected “Define My Events”

 Define your events and designate instruments for them

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















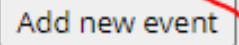
Go to  or 

Arm 1: MOM NEST

[+Add New Arm](#)

Arm name: **MOM NEST**

[Rename Arm 1](#)


	Event #	Event Name	Custom Event Label  (optional)	Unique event name  (auto-generated)
 	1	CONSENT & BASIC IDENTIFIER		consent__basic_ide_arm_1
 	2	PRENATAL DATA		prenatal_data_arm_1
 	3	DELIVERY ADMISSION DATA		delivery_admission_arm_1
 	4	FOUR WEEK DATA		four_week_data_arm_1
 	5	TWELVE MONTH DATA		twelve_month_data_arm_1
 	6	GENERAL FORMS		general_forms_arm_1
		<input type="text"/> Descriptive name for this event	<input type="text"/> Custom Event Label (optional) Example: [visit_date], [weight] kg	

Added Study Events using
Add new events field



PROJECT SETUP: DESIGNATE INSTRUMENTS FOR EVENTS

Selected “Designate Instruments for My Events”

 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](#)

[Begin Editing](#)

[Save](#)

[Select All](#) | [Deselect All](#)

Data Collection Instrument	CONSENT & BASIC IDENTIFIER (1)	PRENATAL DATA (2)	DELIVERY ADMISSION DATA (3)	FOUR WEEK DATA (4)	TWELVE MONTH DATA (5)	GENERAL FORMS (6)
Basic Identifying Information	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Important Visit Dates	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Baseline Questionnaire	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Baseline Crisis Management Report (CMR-BL)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
REPEATED: Prenatal Pk Sample Dates	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
REPEATED: ASI Partial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Delivery PK Sample Dates	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Four Week Visit Questionnaires	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Four Week Crisis Management Report (CMR-4W)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Four Week Pk Sample Dates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Twelve Month Visit Questionnaires	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Twelve Month Crisis Management Report (CMR-12M)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Genetic Samples Collection Dates All	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
REPEATED: Side Effect Questionnaire (SE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
REPEATED: Crisis Management Report (CMR-SE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
REPEATED: Adverse Event Entry Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
REPEATED: Protocol Deviation Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
REPEATED: Followup Call Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Hit “**Begin Editing**”, select instruments under each event, and hit “**Save**”



PROJECT SETUP: DESIGNATE INSTRUMENTS FOR EVENTS

Begin Editing

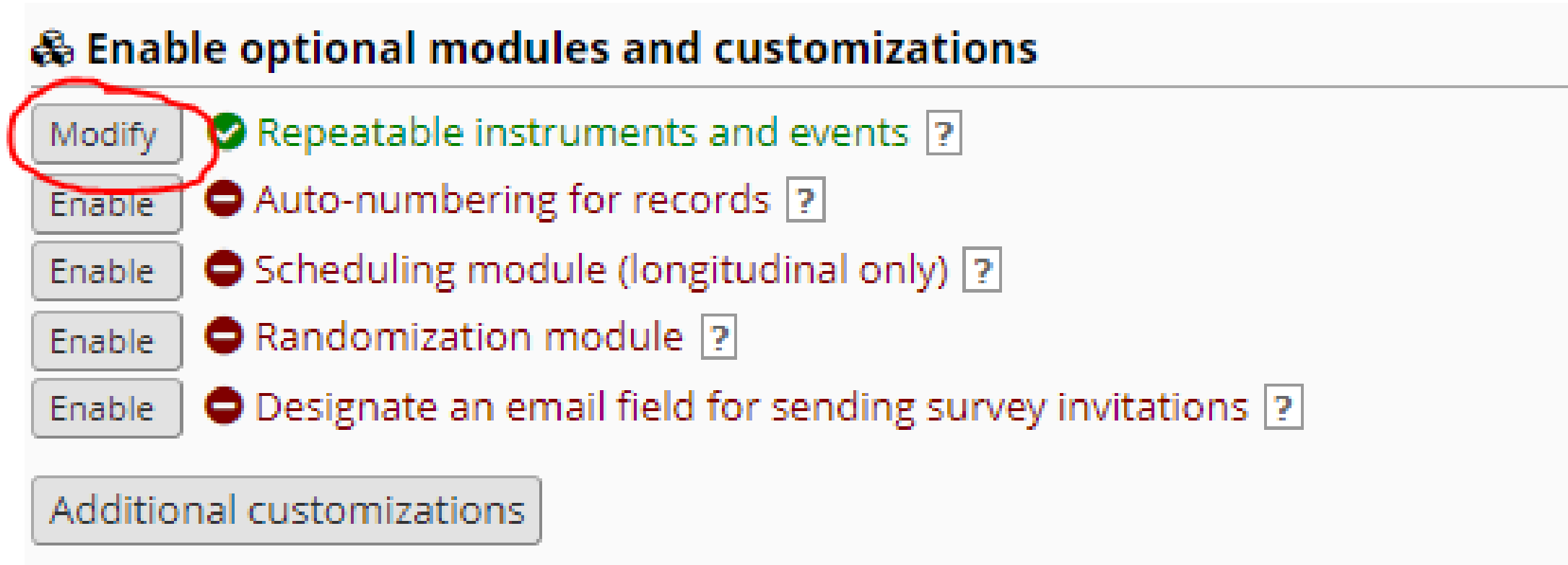
Save

Data Collection Instrument	CONSENT & BASIC IDENTIFIER (1)	PRENATAL DATA (2)	DELIVERY ADMISSION DATA (3)	FOUR WEEK DATA (4)	TWELVE MONTH DATA (5)	GENERAL FORMS (6)
Basic Identifying Information	✓					
Important Visit Dates	✓					
Baseline Questionnaire		✓				
Baseline Crisis Management Report (CMR-BL)		✓				
REPEATED: Prenatal Pk Sample Dates		✓				
REPEATED: ASI Partial						✓
Delivery PK Sample Dates			✓			
Four Week Visit Questionnaires				✓		
Four Week Crisis Management Report (CMR-4W)				✓		
Four Week Pk Sample Dates				✓		
Twelve Month Visit Questionnaires					✓	
Twelve Month Crisis Management Report (CMR-12M)					✓	
Genetic Samples Collection Dates All						✓
REPEATED: Side Effect Questionnaire (SE)						✓
REPEATED: Crisis Management Report (CMR-SE)						✓
REPEATED: Adverse Event Entry Form						✓
REPEATED: Protocol Deviation Form						✓
REPEATED: Followup Call Form						✓



PROJECT SETUP: OPTIONAL MODULES – REPEATABLE INSTRUMENTS

- Under **Enable optional modules and customizations** section, “*Enable*” **Repeatable Instruments and Events** > “*Modify*”



Enable optional modules and customizations

Modify	<input checked="" type="checkbox"/> Repeatable instruments and events ?
Enable	<input type="checkbox"/> Auto-numbering for records ?
Enable	<input type="checkbox"/> Scheduling module (longitudinal only) ?
Enable	<input type="checkbox"/> Randomization module ?
Enable	<input type="checkbox"/> Designate an email field for sending survey invitations ?

[Additional customizations](#)



PROJECT SETUP: OPTIONAL MODULES – REPEATABLE INSTRUMENTS

Event Name	Repeat entire event or selected instruments?	Instrument name (select instruments to repeat)	Custom label for repeating instruments (optional) ⓘ Example: [visit_date], [weight] kg
CONSENT & BASIC IDENTIFIER	-- not repeating --	<input type="checkbox"/> Basic Identifying Information <input type="checkbox"/> Important Visit Dates	<input type="text"/> <input type="text"/>
PRENATAL DATA	Repeat Instruments (repeat)	<input type="checkbox"/> Baseline Questionnaire <input type="checkbox"/> Baseline Crisis Management ... <input checked="" type="checkbox"/> REPEATED: Prenatal Pk Sampl...	<input type="text"/> <input type="text"/> <input type="text"/>
DELIVERY ADMISSION DATA	-- not repeating --	<input type="checkbox"/> Delivery PK Sample Dates	<input type="text"/>
FOUR WEEK DATA	-- not repeating --	<input type="checkbox"/> Four Week Visit Questionnaires <input type="checkbox"/> Four Week Crisis Managemen... <input type="checkbox"/> Four Week Pk Sample Dates	<input type="text"/> <input type="text"/> <input type="text"/>
TWELVE MONTH DATA	-- not repeating --	<input type="checkbox"/> Twelve Month Visit Questionn... <input type="checkbox"/> Twelve Month Crisis Manage...	<input type="text"/> <input type="text"/>
GENERAL FORMS	Repeat Instruments (repeat)	<input checked="" type="checkbox"/> REPEATED: ASI Partial <input type="checkbox"/> Genetic Samples Collection D... <input checked="" type="checkbox"/> REPEATED: Side Effect Questi... <input checked="" type="checkbox"/> REPEATED: Crisis Managemen... <input checked="" type="checkbox"/> REPEATED: Adverse Event Ent... <input checked="" type="checkbox"/> REPEATED: Protocol Deviation... <input checked="" type="checkbox"/> REPEATED: Followup Call Form	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Available options:

- Repeat Entire Event
- Repeat Instruments



DATA ENTRY INTERFACE

Choose action for record

Many statuses (mixed) Many statuses (all same)

Study ID 001

Data Collection Instrument	CONSENT & BASIC IDENTIFIER	PRENATAL DATA	DELIVERY ADMISSION DATA	FOUR WEEK DATA	TWELVE MONTH DATA	GENERAL FORMS
Basic Identifying Information	<input checked="" type="radio"/>					
Important Visit Dates	<input type="radio"/>					
Baseline Questionnaire		<input checked="" type="radio"/>				
Baseline Crisis Management Report (CMR-BL)		<input checked="" type="radio"/>				
REPEATED: Prenatal Pk Sample Dates		<input checked="" type="radio"/> +				
REPEATED: ASI Partial						<input type="radio"/>
Delivery PK Sample Dates			<input checked="" type="radio"/>			
Four Week Visit Questionnaires				<input checked="" type="radio"/>		
Four Week Crisis Management Report (CMR-4W)				<input checked="" type="radio"/>		
Four Week Pk Sample Dates				<input checked="" type="radio"/>		
Twelve Month Visit Questionnaires					<input type="radio"/>	
Twelve Month Crisis Management Report (CMR-12M)					<input checked="" type="radio"/>	
Genetic Samples Collection Dates All						<input checked="" type="radio"/>
REPEATED: Side Effect Questionnaire (SE)						<input type="radio"/>
REPEATED: Crisis Management Report (CMR-SE)						<input type="radio"/>
REPEATED: Adverse Event Entry Form						<input type="radio"/>
REPEATED: Protocol Deviation Form						<input type="radio"/>
REPEATED: Followup Call Form						<input type="radio"/>

Repeating Instruments

REPEATED:
Prenatal Pk Sample Dates
 PRENATAL DATA
 (1)

1	<input checked="" type="radio"/>
+ Add new	



LESSONS LEARNED

- Take enough time to design and think through all steps of data collection during database set up phase
- Once in production mode and data entered, changes to database needs to be admin approved. So test database multiple times
- Ensure all standardized questionnaires are approved for electronic reproduction on REDCap, licensing issue may present later.
- Spend time to initially learn about as many useful REDCap features as possible
- Know your data!



QUESTIONS?

