

BU Clinical & Translational Science Institute

# CRRO RESEARCH SEMINAR OCTOBER 19<sup>TH</sup>, 2022

REDCap Case Studies – A deeper dive

#### HOUSEKEEPING AND REMINDERS

- Today's session is being recorded. All recordings and slides of previous seminars are available on CRRO website.
- We've turned on auto-captioning for accessibility and better understanding.
   You can turn this off on your own screen if it's distracting.



- Evaluation survey will be available at the end this is valuable to how these are presented and what topics we cover.
- It's great to see faces and make connections please turn your camera on if possible!
- Turning your camera on and off is a great way to fix connection issues but remember to turn back on.

#### Research Professionals Network → Join!

- Monthly workshops must be a member to attend
- Provides professional development opportunities

#### CRRO Clinical Research Resources Office

#### CRRO Mailing List → Join!

- Receives email communications on training

#### CRRO EDUCATION CALENDAR







All information including topics and dates available on CRRO Education Calendar

All active through June 2023



#### TODAY'S AGENDA

- Speakers will present on how they are using REDCap for their studies, exploring the different functionality of REDCap and more traditional data collection methods. This seminar will focus on real-world implementation and recommendations for learning and best practices.
  - Sarah Brédy, BA Research Assistant in General Internal Medicine
    - Worked on different BMC projects that included translations and recruitment from the clinic. Currently working on a multitude of projects such as writing
      a paper and conducting qualitative interviews on both prostate cancer patients and refugees.
  - Sarah Weber, MPH Project Management Specialist in Infectious Diseases
    - Project Management Specialist at BMC with Dr. Karen Jacobson's research group. Primary role is the management of domestic and international research studies on tuberculosis and COVID-19. Currently manages two large cohort studies in South Africa focused on the relationship between alcohol/substance use and tuberculosis.
  - · Kayla Brown, MS, MS Psychiatry
    - Fourth year PhD student in the Behavioral Neuroscience program at Boston University and completed a dual MS degree in Medical Sciences and Clinical
      Research from Boston University in 2019. Serves as the Clinical Research Coordinator for Dr. Ann Rasmusson's investigator-initiated multi-site Phase II
      clinical trial studying the effects of allopregnanolone on memory processes involved in recovery of posttraumatic stress disorder. Primary research
      interests include the role autoimmune diseases, infections, and neuroinflammation play in psychiatric disorders.
- Panel session for all questions hold all questions until all presenters are complete
  - Put questions in chat and they'll get answered when the panel convenes
  - Use the "raise your hand" function and we'll call on you to ask your question during the panel session



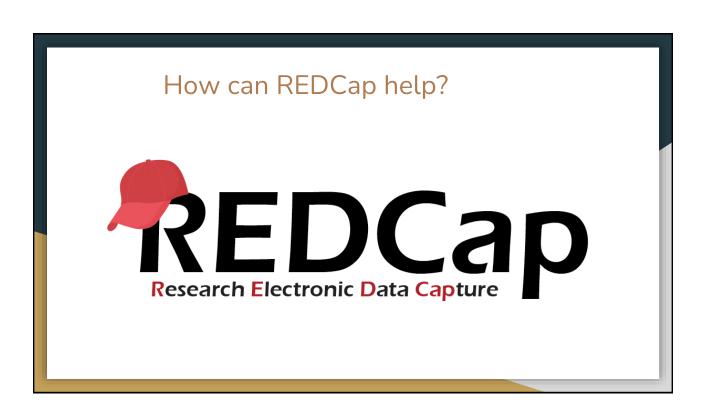
# REDCap: Minimizing the Language Gap in Research

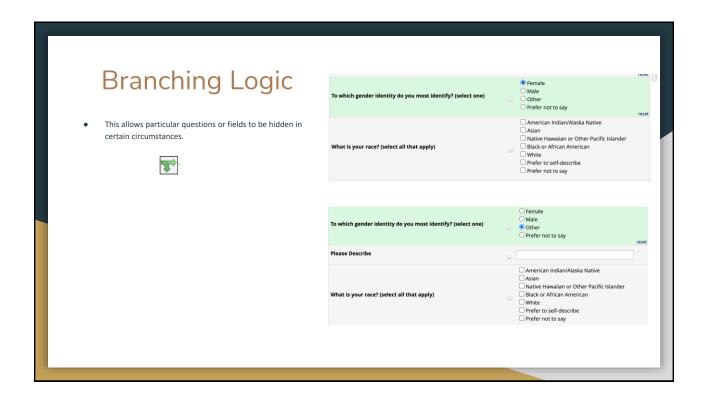
Sarah Brédy B.A. BMC Research Assistant



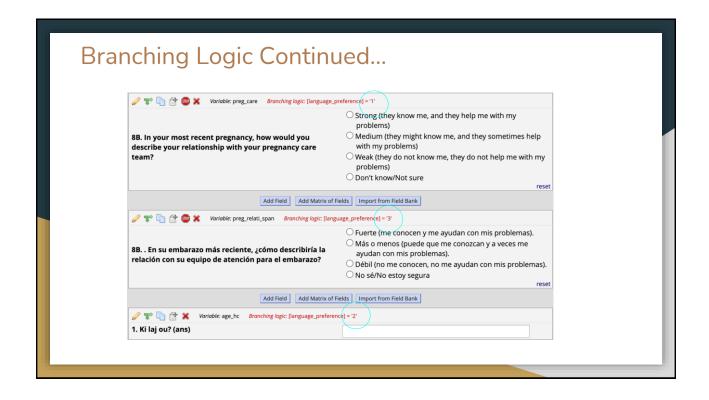
# Language Gap in Research

- A significant percentage of adult US clinical trials exclude individuals who cannot communicate in English or are not native English speakers.
- Diverse samples in clinical trials can make findings more generalizable to the overall population
- Diverse samples may also provide more insight into treatment efficacy in a wider population

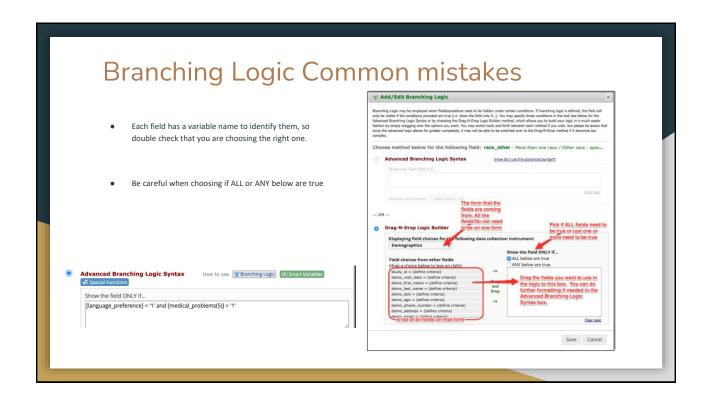


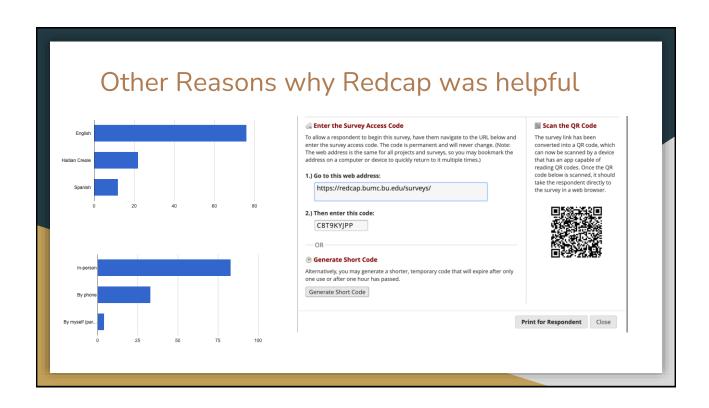


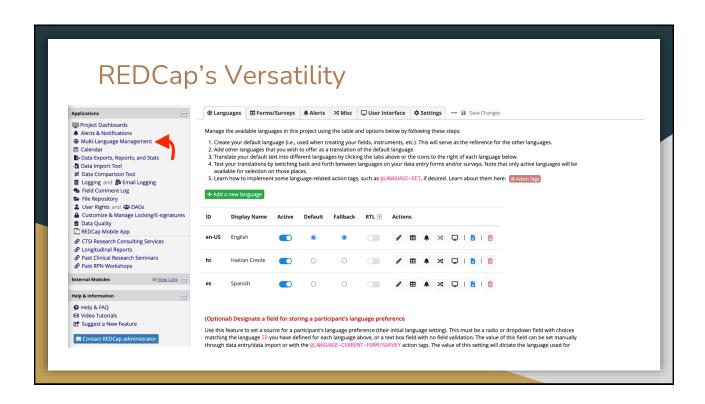
#### Branching Logic Continued... Which language are you most comfortable reading and English speaking in? O Haitian Creole O Spanish \* must provide value reset Add Matrix of Fields | Import from Field Bank Add Field Branching logic: [language\_eligibility] = '1' English Which language do you prefer to take the survey in? O Haitian Creole \* must provide value O Spanish reset Add Field Add Matrix of Fields Import from Field Bank



# Let's go into REDCap!







# Thank you!

#### References:

- Frayne SM, Burns RB, Hardt EJ, Rosen AK, Moskowitz MA. The exclusion of non-English-speaking persons from research. J Gen Intern Med. 1996;11(1):39-43. doi:10.1007/BF02603484
- Muthukumar AV, Morrell W, Bierer BE. Evaluating the frequency of English language requirements in clinical trial eligibility criteria: A systematic analysis using ClinicalTrials.gov. PLoS Med. 2021;18(9):e1003758. Published 2021 Sep 14. doi:10.1371/journal.pmed.1003758
- Egleston BL, Pedraza O, Wong YN, et al. Characteristics of clinical trials that require participants to be fluent in English. Clin Trials. 2015;12(6):618-626. doi:10.1177/1740774515592881
- https://www.bmc.org/medical-professionals/office-minority-physician-recruitment
- https://www.ctsi.ufl.edu/wordpress/files/2017/06/Branching-Logic-in-REDCap-%E2%80%93-How.pdf



#### Transmission of Tuberculosis Among illicit drug use Linkages (TOTAL)

- Recruiting 750 people who smoke illicit drugs in Worcester, South Africa to assess TB exposure and disease prevalence
- Data captured in REDCap:
  - Questionnaires on substance use and social network, a TB symptom screening, medical history, and behavioral assessments
  - Test results including rapid HIV testing, Xpert Ultra testing for TB disease, Mtb culture, Mtb whole genome sequencing, host RNA sequencing
  - For individuals with possible TB disease, an interview to identify individual social contacts and places of social aggregation to estimate social epidemiologic links



# **REDCap Features**

- 1. Field embedding
- 2. Secondary REDCap for tracking samples ("Sample Tracking System")

# 1. Field Embedding

#### **Social Contact Survey**

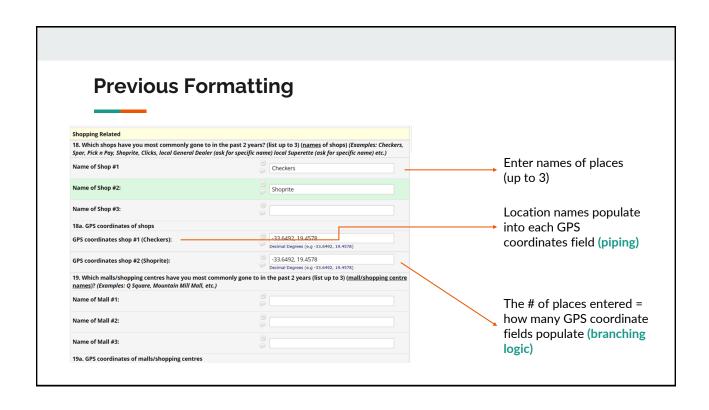
Ask participants where they have spent time within the last 1-2 years, including:

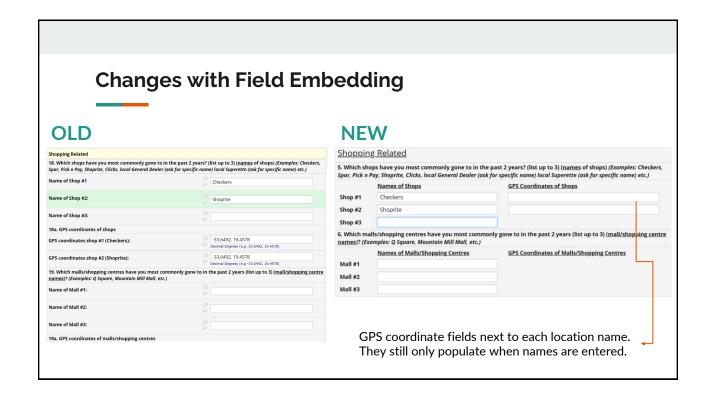
- Household information Work
- School
- Grocery stores, malls and other retail
- Hairdressers/barbers
- Places of worship Gyms/recreation centers
- Bárs/shebeens/taverns/clubs/restau
- Friends and family members' houses
- Places they smoke drugs
- Transport
- Incarcerations

For each place, we record the name, GPS coordinates, and frequency of time spent there.

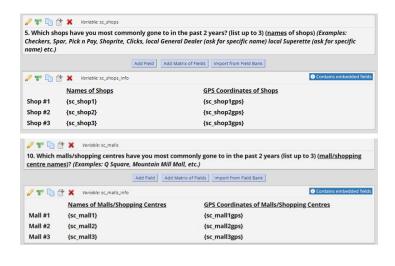


Assess overlap as potential hot spots for TB transmission.





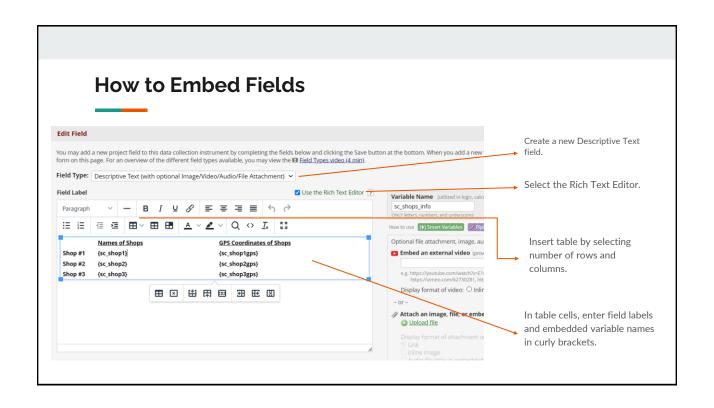
#### **Embedded Fields in Designer Mode**

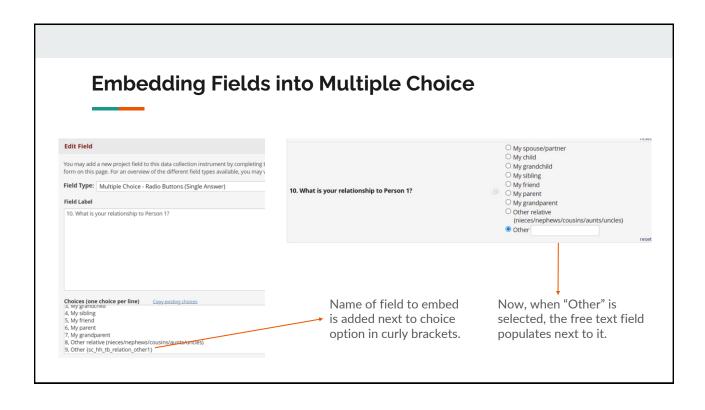


#### **How to Embed Fields**



- Each individual field must be created on the instrument before being embedded into another field.
- Here, we have separate fields for each of the shop names and gps coordinates.

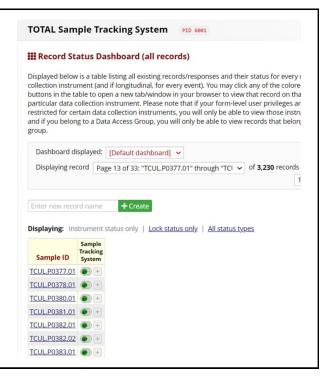




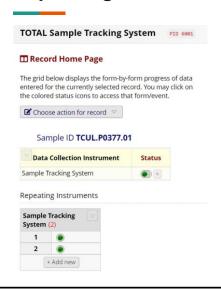
# 2. Sample Tracking System

# Sample Tracking System

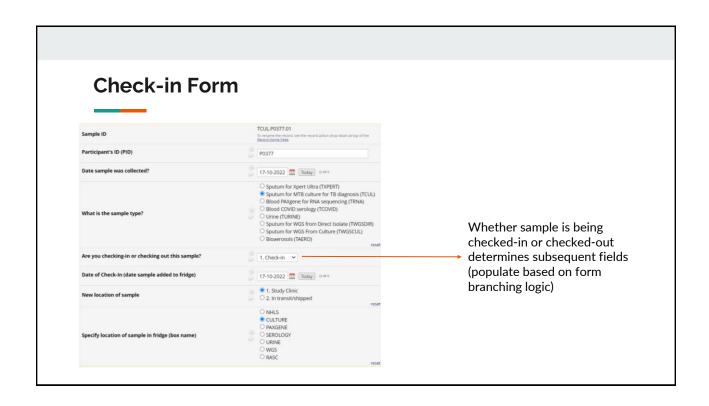
- <u>Purpose</u>: to track location of study samples and transport to labs.
- Every sample collected and entered into the main study REDCap is given a sample ID.
- Sample tracking system REDCap contains one record for each sample, named by sample ID.

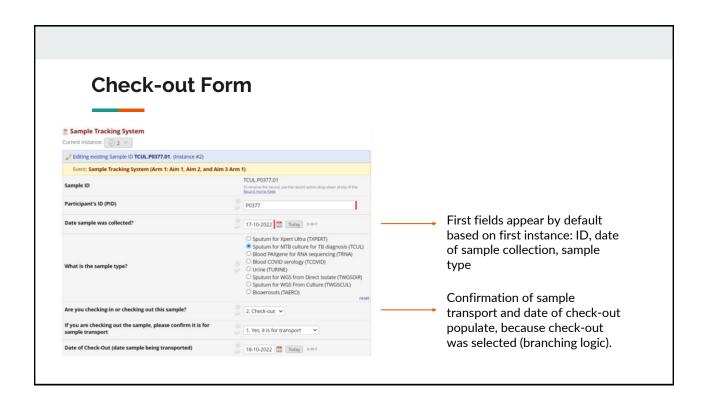


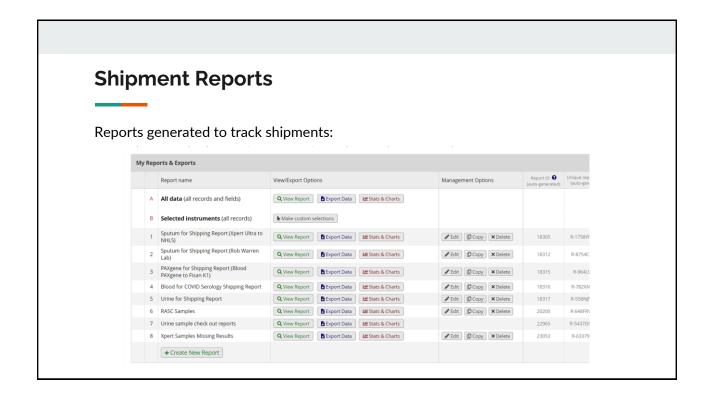
#### Repeating Forms to Check-in & Check-out Samples

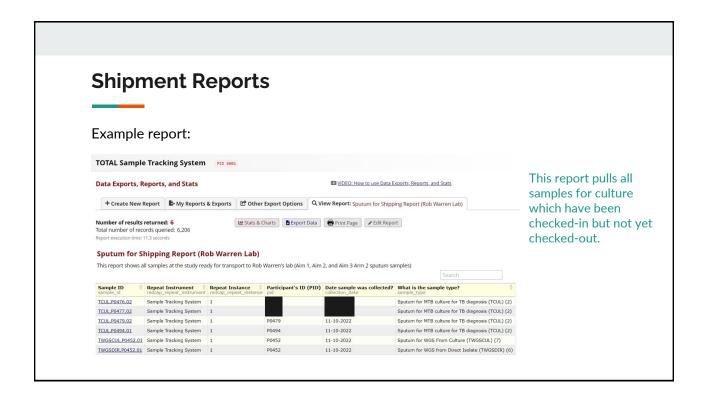


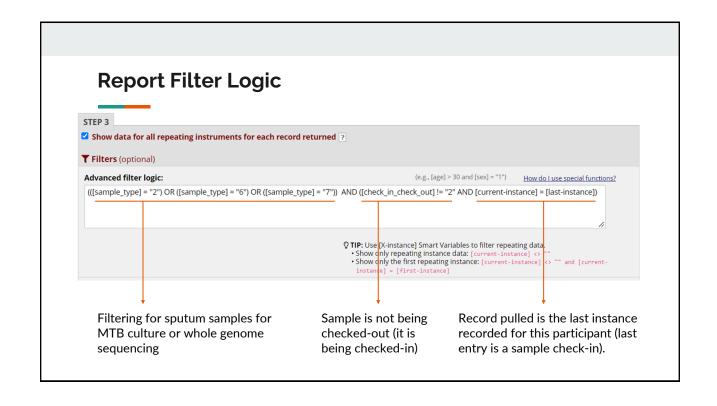
- Each sample record has one repeating form with two instances.
- Instance #1: checking the sample into the study clinic after collection
- Instance #2: checking the sample out of the study clinic when it is transported to the lab











# One other random tip...

- Each time our team creates a new REDCap project, we copy the project and create a "training portal."
- Training portals are identical projects without real data.
- Before a project is implemented, field staff are given access to the training portal to familiarize themselves with the forms and practice data entry.
- When we make moderate to major changes to a REDCap project (new instrument, major structural changes or additions to an instrument, etc.), we first add them to the training portal so we can test the changes and give the team opportunity to practice.

# REDCap for an Investigator-Initiated Multi-site Phase II Clinical Trial

BY KAYLA BROWN, MS, MS

CLINICAL RESEARCH COORDINATOR & PHD STUDENT

### Prior REDCap Experience

- 3 years at Stanford University
- 6 months in the Psychiatry Department at Boston Medical Center

# Study Design

Facilitation of Extinction Retention & Reconsolidation Blockade by Intravenous Allopregnanolone in Posttraumatic Stress Disorder

• PI & FDA IND Sponsor: Ann Rasmusson, MD

Multi-site studies within REDCap database:

- 1. PK Study 1: Extinction Retention
- 2. PK Study 2: Reconsolidation Blockade
- 3. Main Study 1: Extinction Retention
- 4. Main Study 2: Reconsolidation Blockade

## Study Design

#### Each study has 3 subgroups:

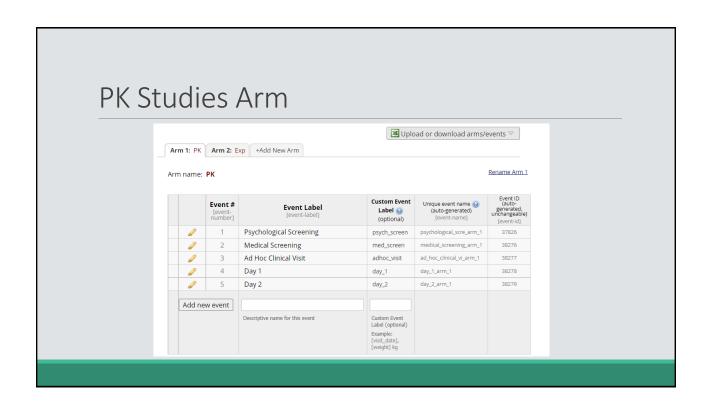
- 1. Women in early follicular menstrual phase
- 2. Women in mid-luteal menstrual phase
- 3. Men

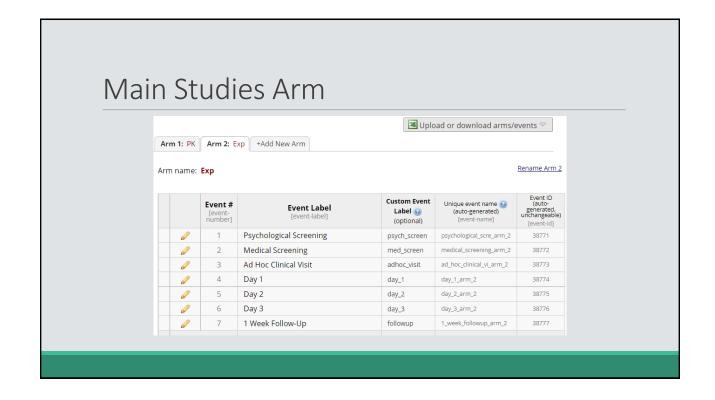
#### Main Studies:

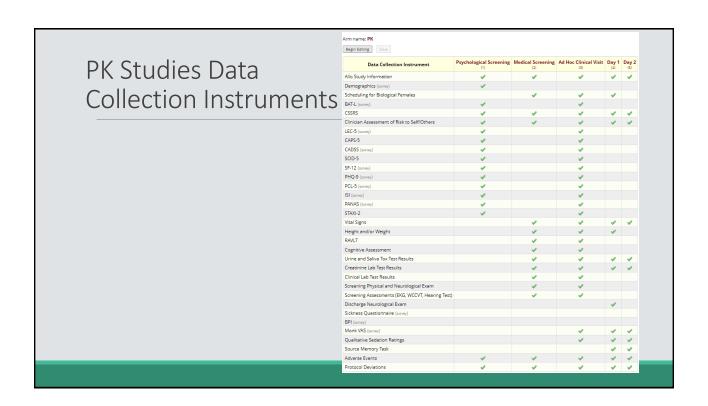
- 1. Double blind placebo-controlled phase II clinical trials
- 2. Stratified randomization by both site & subgroup

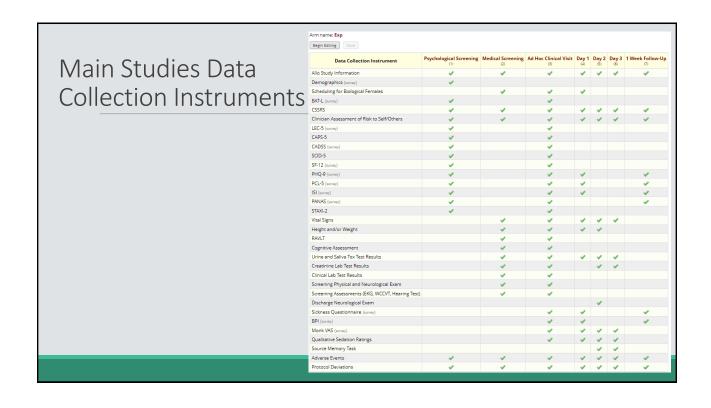
# REDCap Implementation

- Define arms
- Define events for each arm
- 3. Designate data collection instruments to events on each arm
- Designate repeatable events or repeatable instruments for each event
- Harmonize REDCap variables to be consistent with NIMH Data Archive (NDA) variables



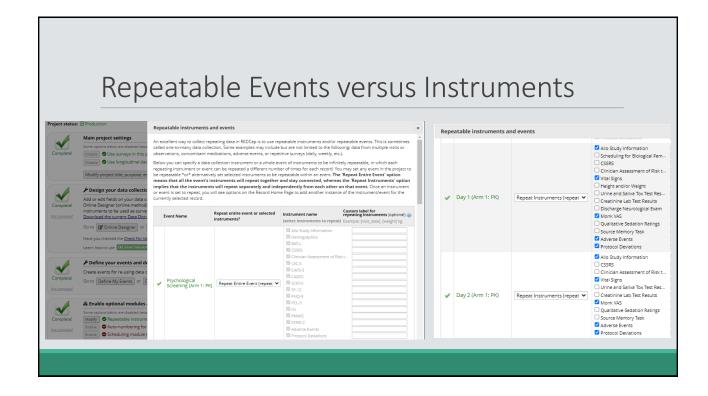


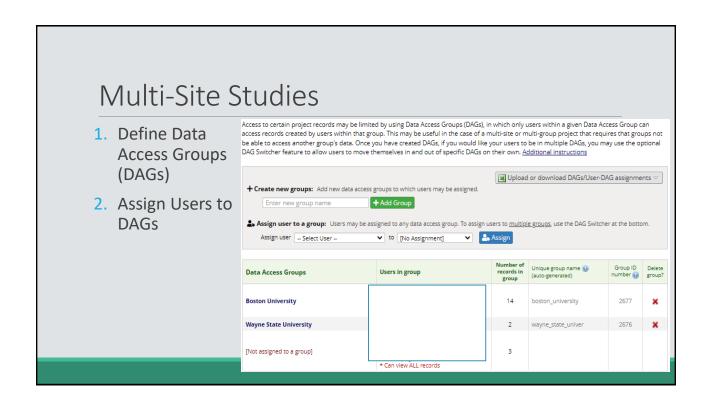


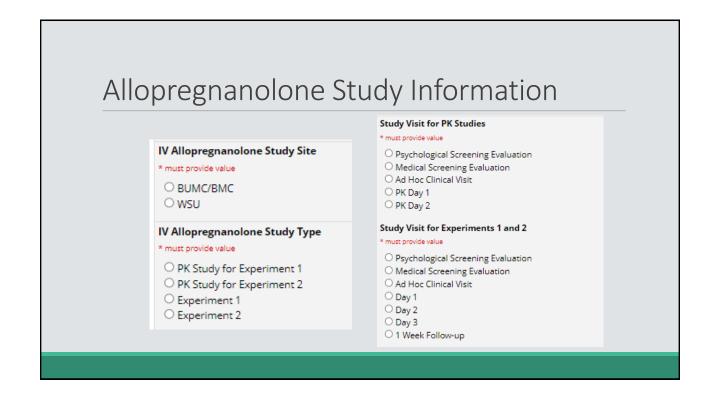


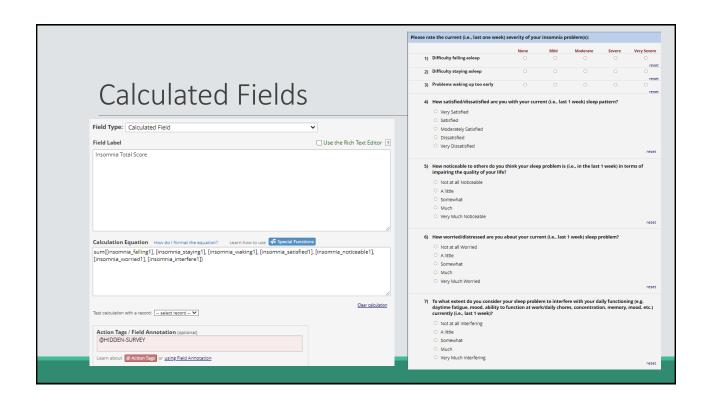
#### Repeatable Events versus Instruments

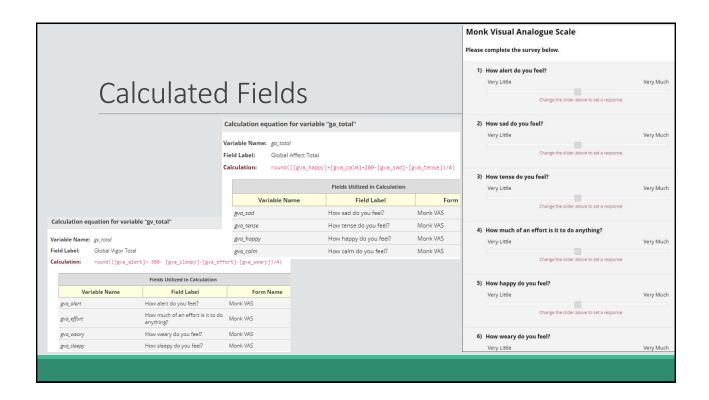
- 1. Repeat event if study visit could be conducted more than once
- Repeat instrument if data collection instrument will be collected more than one time during a study visit







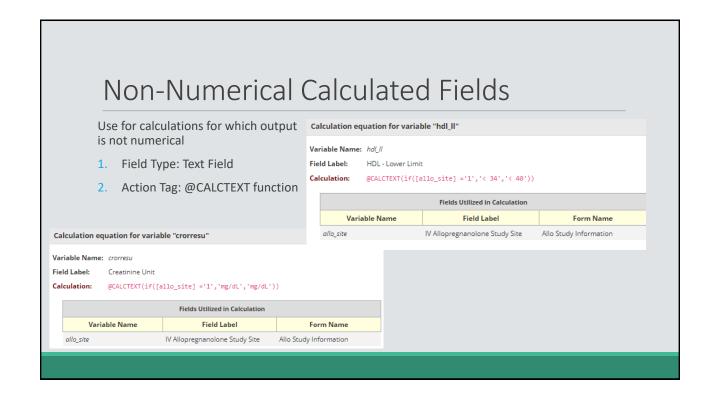


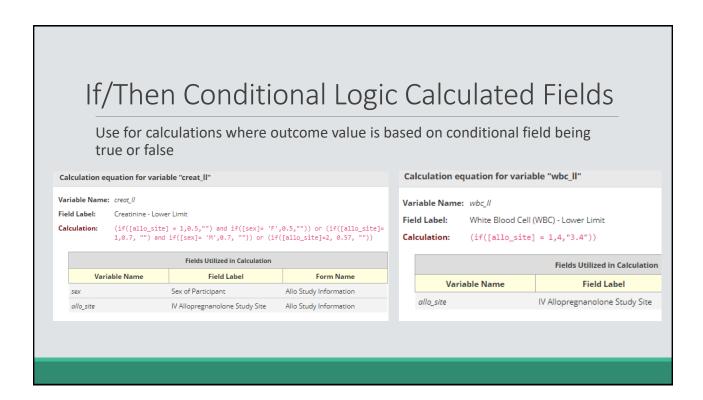


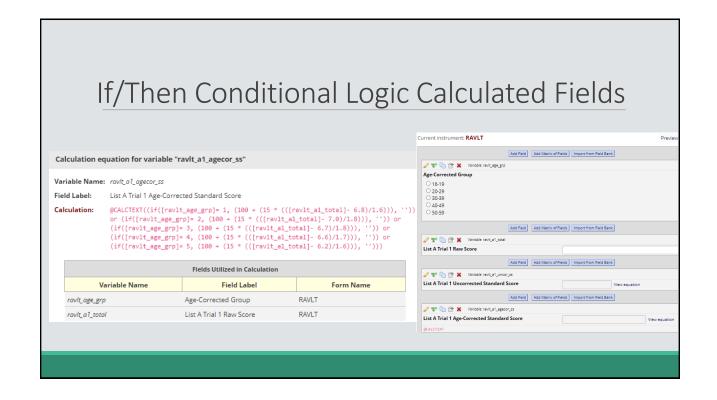
#### **Datediff Calculated Fields**

0 = round to nearest whole number









# Data Quality Checks

Use for data verification to check for potential data entry errors

1					_
3   Weight < 90 lbs or > 400 lbs   ([weight_lbs] < 90) or ([weight_lbs] > 400)	1	Participants below age 18 or greater than 55		•	Execute
4 Sitting Diastolic BP < 50 or > 120	2	Height < 48 inches or > 94 inches	([height_st]< 48) or ([height_st]> 94)		Execute
4 Sttting Diastolic BP < 30 or > 120	3	Weight < 90 lbs or > 400 lbs	([weight_lbs] <90) or ([weight_lbs] >400)		Execute
Sitting Systolic BP < 90 or > 120	4	Sitting Diastolic BP < 50 or > 120		•	Execute
Standing Diastolic BP < 40 or > 120	5	Sitting Systolic BP < 90 or >160			Execute
Standing Diastolic BP < 40 or > 120	6	Sitting HR < 50 or > 120		•	Execute
8 Standing Systolic BP < 80 or > 160	7	Standing Diastolic BP < 40 or > 120			Execute
9 Standing HK < 50 or > 130 ([heart_rate_stand]> 130)	8	Standing Systolic BP < 80 or > 160			Execute
	9	Standing HR < 50 or > 130			Execute
10 Respiration Rate < 8 or > 24 ([respct] < 8) or ([respct] > 24)	10	Respiration Rate < 8 or > 24	([respct]< 8) or ([respct]> 24)		Execute
11 Pulse Oximeter < 96% [pulse_ox] < 96 @ Execute	11	Pulse Oximeter < 96%	[pulse_ox] <96		Execute
12 Temperature < 95 or > 100 degrees F ([temperature] < 95) or ([temperature] > 100)	12	Temperature < 95 or > 100 degrees F			Execute
13 # of Blasts/Explosions within 10 ft > 400 ([batl_s1b10]> 400) or ([batl_s7b10]> (Execute	13	# of Blasts/Explosions within 10 ft > 400		•	Execute
14 # of Blasts/Explosions between 11 and 100 ft ([batl_s1b100]>1000) or ([batl_s7b100]> > 1000   Execute	14				Execute

# FDA Part 11 Compliance

REDCap functions that Require Validation Testing for FDA Part 11 Compliance:

- 1. Calculated, Signature, Slider/Visual Analog Scale, & File Upload Field Types
- 2. Text Fields that include validation (date, number, integer, letters only, min, max, etc.)
- 3. Embedded fields
- 4. Action tags/field annotation (@CALCTEXT, @HIDDEN-SURVEY, etc.)
- 5. Branching logic

# Thank you!

sarah.weber@bmc.org



PANEL DISCUSSION

- Use the chat function to ask questions
- Use the "raise hand" function to ask questions



- Sarah Brédy, BA Research Assistant in GIM
- Sarah Weber, MPH Project Management Specialist in ID
- Kayla Brown, MS, MS Psychiatry



#### WRAP UP AND FINAL REMINDERS · Today's session is being recorded. **Upcoming Events** 10/25: RPN Workshop - Multitasking and Managing a Coordinator's Varied Role · All recordings and slides of previous 11/2: Seminar – BMC SOP Implementation seminars are available on CRRO website. 11/TBD: RPN Workshop – Project Management 11/29: Fundamentals Sessions start weekly on Thursday Evaluation survey will be emailed and is 12/14: Seminar – Topic TBD linked in the chat - this is valuable to information for how seminars are 12/8: Principal Investigator Training presented and what topics are covered. 12/TBD: RPN Workshop – Topic TBD **CRRO Education** Always looking for presenters and speakers – please add suggestions on the evaluation! **CRRO Resources Study Documentation Tools** PI Training REDCap eConsent Guidance **RPN Workshops Consultation Requests**



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