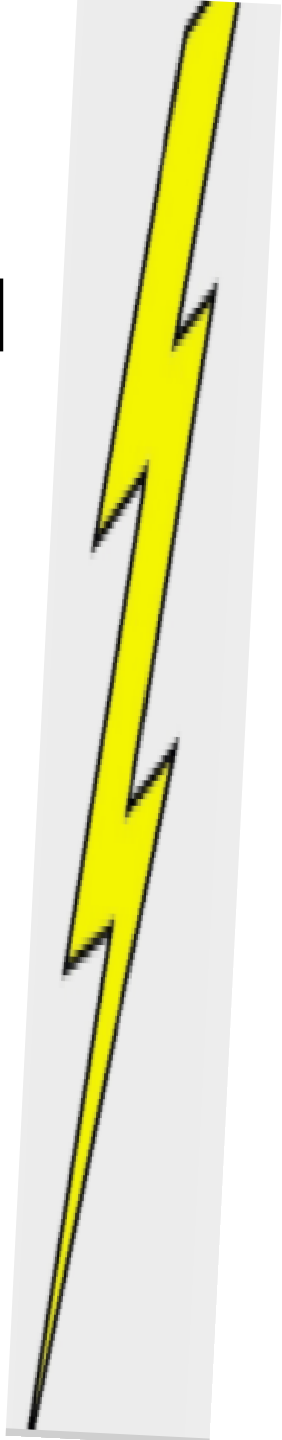


Remote and eConsent Lightning Talks and Group Discussions

December 11, 2020

Lightning Talk Presenters:

- Sara Ardren, PA, UVM
 - Ethan Jones, MPH, UVM
 - Jung Lee, BU
 - Darci Miller, MPH, UF
 - Cindy Montero, MS, CCRC, UF
 - Hira Shrethsa, MA, BMC
 - Tonia Toon, BA, CCRP, UF
- 

Agenda

- Introduction
- Lightning talks:
 - Building REDCap e-consent: Jung
 - **3 cases:** Ethan, Tonia, Cindy
 - Questions
 - **3 cases:** Sara, Hira, Darci
 - Questions
- Breakout room discussion
- Full group discussion

Goals of Informed Consent in Research

Ensure that research participants...

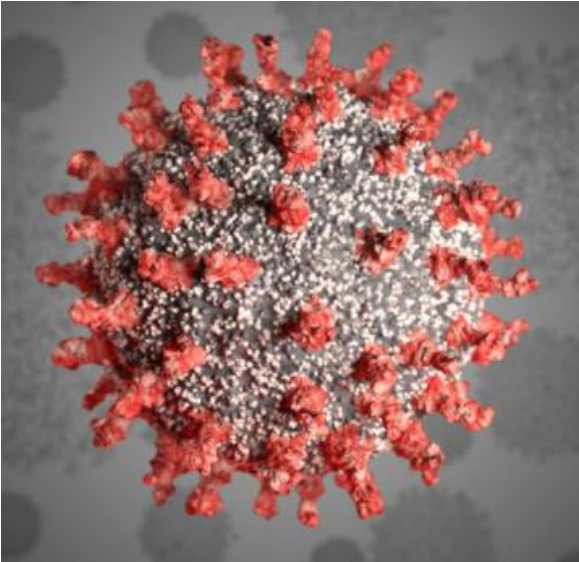
- Have the necessary info (i.e. required elements)
- Understand the necessary info
 - Form: complete information; readability
 - Process: constructive dialog → assessment of understanding
→ constructive dialog, and-so-on.... → signing/documenting

... to make an *informed decision* regarding participating in a research study.

...to make the decision that is right for the subject....



COVID-19 – Necessitated rapid changes



- Remote and e-consent were used prior to COVID-19
- New processes to conduct remote consent were needed for research with COVID+ subjects/LARs
 - Limit potential for viral transmission and use of PPE
 - Remote consent with witness
- New processes needed for research that could move to remote enrollment and/or follow-ups
- Increased openness to adopting e-consent process
 - IRB, study teams, subjects, etc.

Remote Consent



- Not in the same physical location
 - Not able to sign the same hardcopy consent form
 - Not able to use the same device for e-consent
- Remote consent can be a hardcopy OR e-consent process

Electronic informed consent...E-Consent

- Use of electronic systems and processes
- Convey information about the study
- Obtain and document informed consent
 - E-platform captures valid e-signature
- Process can be in-person or remote
 - In-person: consent on a tablet; passed back and forth to sign
 - Remote: Link to e-consent sent (email etc.) to subject who signs electronically; investigator then signs electronically



Remote Consent: How to conduct consent process?



Remote process using hardcopy forms

- Consent discussion by phone or video-conference
- COVID+ subject signs his form in hospital room
- Witness signs a different copy on behalf of and as directed by subject
- Investigator signs form after witness; this version kept for records

Remote process using e-consent

- Consent discussion by phone or video-conference
- No witness required to sign on behalf of subject
 - May need witness for other reasons
- Documentation via electronic signature
 - Subject then investigator sign electronically

Platforms for e-consent

- Sponsor-provided platform
- For investigator-initiated studies

AdobeSign

DocuSign *(BU Med Campus/BMC)*

- FDA-regulated research (part 11 compliant)
- In-patient drug trials with COVID+ subjects

REDCap e-consent platform

- Tools to obtain and store consent
- FDA-regulated research: must be validated Part 11 compliant at the institution/ site



Considerations

- Research level of risk and other factors may dictate what e and remote consent options are appropriate
- Details related to FDA regulated research – validation of the subject's identification
- Loss/limited available cues that we would normally have with an in-person interaction
- The use of these processes is new, and will likely evolve with experience
- Ultimately the IRB is evaluating the compliance with regulations regarding informed consent, and if the process and documentation are appropriate and adequate

References

Institutional Guidance Using E-consent at:

- BMC/BU Medical Campus: <http://www.bumc.bu.edu/crro/tools/e-consent-tools-and-guidance/>
- UVM/UVM Medical Center: https://www.uvm.edu/rpo/irb-policies-and-procedures#Electric_Consent
- University of Florida: <http://irb.ufl.edu/wp-content/uploads/Electronic-Informed-Consent.pdf>

Regulatory Guidance:

- Use of Electronic Informed Consent Questions and Answers: Guidance for IRBs, Investigators, and Sponsors, joint FDA/OHRP, Dec. 2016: <https://www.fda.gov/media/116850/download>
- Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11, Questions and Answers, Guidance for Industry (Draft), FDA, June 2017: <https://www.fda.gov/media/105557/download>
- Guidance for Industry: Part 11, electronic Records; Electronic Signatures – Scope and Application, FDA, August 2003: <https://www.fda.gov/media/75414/download>
- Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and IRBs, FDA, March/Dec 2020: <https://www.fda.gov/media/136238/download>

REDCap e-Consent

JUNG LEE, HUMAN RESEARCH QUALITY MANAGER

Outline

1. REDCap Terminology

2. Core elements of REDCap e-Consent

3. In-Person e-Consent vs. Remote e-Consent

4. Method of e-Consent Distribution

5. Updating e-Consent

1. Terminology

Instrument – A data collection tool that can be left as a form or enabled as a survey.

(Data Entry) Form – An instrument in which data can only be entered or collected by a REDCap user. (viewing method)

Survey – An instrument in which a research participant can enter data or answer questions without a REDCap account. Instrument is accessed through a URL. (viewing method)

Record - A record contains all the information for a unique participant. One record may contain many instruments

Record ID – A unique identifier for each record in a project.

Survey Login – A way to increase security on private surveys by requiring participants to enter 1 to 3 specified login credentials in order to begin a survey. The credentials must already exist in the system for the survey login feature to be utilized, either by pulling them from a survey that has already been completed or by entering them on a form.

Online Designer – A way to build and edit instruments through a point-and-click interface.

Data Dictionary – CSV file that holds the architecture of a project. An alternative to the Online Designer for building or editing projects. Mainly use to save the project for future reference or project duplication.

Piping – Allows answers from previous questions to auto-populate or “pipe” into another place in a survey/form.

Action Tags – A method of customizing data entry for individual fields in a survey or form.

2. Core elements of e-consent

- Approved e-consent form
- Entry fields for name, signature, and date
- E-consent framework (REDCap specific)
 - Certification step
 - Adds extra certification page to end of the survey in which participants will be asked to confirm that all information in the document is correct.
 - Auto-archive step
 - Completed e-Consent survey will be stored as a PDF in the project's File Repository.
- Consent documentations to consider:
 - Confirmation that a copy of informed consent was given to participant
 - Verbally instruct participant to download a copy of the completed ICF and document this in comment field
 - Automate sending of completed ICF to participant

3. In-Person e-Consent vs. Remote e-Consent

- In-Person e-Consent Form:
 - Study teams need to create 1 instrument
 - Participant and Study Personnel signature section exist on the same instrument

- Remote e-Consent Form
 - Create 2 instruments
 - Participant e-Consent and Study Personnel e-Consent forms will be 2 separate instruments
 - The 2 completed e-Consents will be linked by the same Record ID
 - Paper Trail Module – combines two separate PDFs into one PDF file within REDCap

4. Method of e-Consent Distribution

- E-mail
 - Enable module to designate an email field for sending survey invitations
 - Invitation can be automated
 - Use Survey Login for added security (e-mail alone is not a secure form of communication)
 - Twilio (via text message)
 - Survey as webpage – survey URL provided by SMS (similar to invitation via email)
 - via hospital patient communication portal
 - Video conference chat
- *Make sure you get IRB approval on your method of distribution

5. Updating e-Consent instrument

➤ Things to consider:

- Are you using the Automated Survey Invitation feature?
 - Then you need to carefully think about what exactly you should set as your conditional field that will trigger this invitation

- Consider utilizing a version tracking instrument to keep track of ICF versions
 - Utilize the field in this instrument to set up the Automated Survey Invitation trigger
 - i.e. create a Yes/No field where staff will confirm whether or not to email the consent survey and specify which e-consent instrument version to email to the participant

COVID Serology Study: A UVM Case Study

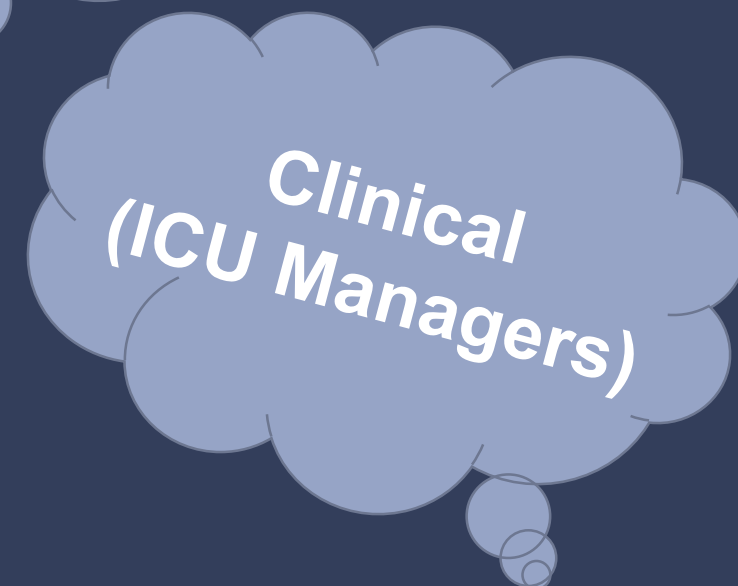
Ethan Jones, MPH – Clinical Research Coordinator,
Office of Clinical Trials Research, UVM/ UVM Medical Center

- **Perspective: March 2020**
 - Onset of initial pandemic wave, national effort to protect capacity of healthcare system
- **Goal: Use a newly developed and experimental enzymatic assay to:**
 - Determine presence or absence of SARS-COV-2 antibodies in a high risk healthcare population (blood draws at Baseline, 6-Months, 12-Months)
 - Prospectively collect data on experiences with exposure or illness for one year as pandemic unfolded (surveys at Baseline, 6-Months, 12-Months)
 - Assess durability (duration) and efficacy (protection) of SARS-COV-2 antibodies in a high risk healthcare population (ICU staff)

Our team:

- **Gary An, MD FACS**
 - Surgeon, Department of Surgery, UVMMC
 - Vice Chair of Research, Department of Surgery, UVMMC
 - Professor, LCOM UVM
- **Kimberly Luebbers, MSHS, RN, BSN, OCN®**
 - Assistant Dean for Clinical Research, LCOM UVM
 - Director, OCTR, UVM
 - Administrative Director, CRC, UVMMC
- **Jennifer Holmes, CCRP**
 - Research Navigator, OCTR, UVM
- **Annie Penfield-Cyr, MS**
 - Research Navigator, OCTR, UVM
- **Ethan Jones, MPH**
 - Clinical Research Coordinator, OCTR, UVM

..Must include these perspectives!



THE CHALLENGE:

- Minimizing risk of COVID-19 transmission to both:
 - ICU clinical staff
 - Research staff

Meanwhile..

- Enroll up to 250 participants
- Achieve data collection (both surveys and blood collection) towards your objective

THE SOLUTIONS:

- Email Recruitment
- eConsent Framework
- REDCap Enrollment Process

REDCap Instrument & Study Design:

eRecruitment: (Email)

Email Distribution of IRB approved invitation letter

- To: ICU email listservs (MICU, SICU/PICU)

Containing:

- Study background, study contact Information
- Invitation to participate
- **REDCap Link** to study REDCap Survey Instruments

eScreening: (REDCap)

Screening Instrument:

- 1) Age Verification
- 2) Healthcare Worker Verification
- 3) Increased risk of exposure due to nature of their clinical duties

e(Informed) Consent: (REDCap)

eICF Instrument:

- (Read Only) **PDF eICF available** for download
- Each page IRB Approved ICF inserted as JPEG
- 3 Opt-in/Opt-out points (future research contact, etc.)

Entered by participant:

- 1) Full Name
 - 2) Electronic Signature (eSignature line feature)
 - 3) Date of Signature
- Completion -> Notification

eEnrollment: (REDCap)

Demographics:

- Contact Information (Email*)

Baseline Questionnaire:

- Exposure History
 - Diagnosis/Symptom History
- Completion -> Notification

At the conclusion:

- 1) Copy of eSigned ICF sent to each individual after completion
- 2) Participant was sent an automated confirmation email with unique Study ID & instructions for blood collection

Making the case for eConsent..

Make sure an eConsent framework works for the population of interest!

Involve all stakeholders.. For us, both clinical and research perspectives!

If eConsent still makes sense..

REDCap offers great functionality.. Use it!

Some lessons learned:

- 1) Build a diverse planning team and use the institutional resources available to you (REDCap admins)
- 2) Allowing participants to interrupt the process to take more time for consideration is required.
 - Therefore.. anticipate that one person may generate multiple Study IDs! (logistical/reporting consideration)
- 3) Test-Test-Test all scenarios!
 - Test: Participants who sign consent and end there..
 - Test: Participants who sign consent, complete demographics form, but entered email with a typo..
 - ..And then test some more!

Assorted Conditions in eConsent

NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study

- Adult and Pediatric oncology patients
- Documented positive viral SARS-CoV-2 test
- Outcomes of COVID-19, including symptoms, severity, and fatality, in adult and pediatric cancer patients undergoing treatment.
- Cancer treatment modifications made in response to COVID-19

It's All in There

- Pediatric cancer patients with COVID-19
 - Parental consent
 - Assent
- People with severe symptoms of COVID-19 may be or become unable to consent
 - LAR to provide consent on their behalf.
- Yes / No Optional Research Questions
- Separate HIPAA form
- Demographics (optional in electronic format)

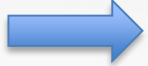
Obtaining & Documenting Informed Consent for NCCAPS

- In-person
 - Wet ink
 - eSignature

- Remotely
 - Phone
 - Audio Video Conferencing
 - Wet ink
 - eSignature

Divergent Policies

Difference in IRB of Record & Institutional Policy

- Best Practice  follow most rigorous policy
- eSignature by REDCap is required by our Institution & not by IRB of Record (NCI CIRB)
- Witness is required by NCI CIRB for remote consent & not by our institution
- Consent to communicate electronically – institution requires this documentation prior to email communication.

If it *can* happen....

- Six participants have given consent electronically
 - One participant signed the LAR line via REDCap
 - We made adjustments in REDCap
 - One participant used Adobe sign
 - Does not violate IRB Policy, local issue
- Educate and support
 - Ongoing education regarding pertinent policies
 - Availability during eConsent for assistance



Using eICF with a Legally Authorized Representative (LAR)

- Sara Ardren, Clinical Research Coordinator, Pulmonary & Critical Care, UVM Larner College of Medicine

Objectives & Requirements

- ◆ Identify the LAR
- ◆ Contact and communicate with the LAR
- ◆ Explain, explain, explain!
- ◆ Demonstrate understanding
- ◆ Obtain written consent

How objectives are achieved

- ♦ Work with the medical team to assess the patient's capacity to consent and then identify the LAR
- ♦ Make initial contact with the LAR and verify their relationship to the patient
- ♦ If the LAR is receptive, introduce the study and send a copy of the ICF. Explain the process of eConsent and schedule the next call.
- ♦ Review the study in greater detail, explain all topics in the consent, answer questions, offer call with the PI. If they wish to proceed, send the link to the eICF and walk them through the form.
- ♦ Ask questions to demonstrate the LAR's understanding. Obtain electronic signature.

Challenges to using eICF with LARs

- ◆ LAR is frequently under-informed
- ◆ Loss of non-verbal communication
- ◆ Requires technology—smart phone at minimum
- ◆ Often requires multiple contacts with the LAR, coordination of contact with the PI and/or clinical team.
- ◆ Can be difficult to assess understanding

Benefits to using eICF with LARs

- ◆ LAR is not required to be at the bedside
- ◆ Documents are secure and organized
- ◆ Establishes regular communication which can be utilized throughout the study
- ◆ Allows study enrollment to continue during COVID-19 restrictions

UF Emergency Medicine Research

Electronic Consent in Emergency Medicine Research

An fast paced evolution in response to COVID-19

Cindy Montero MS, CCRC
Lead Clinical Research Coordinator



Who we are and what we do!

- Team of 12 Coordinators and research assistants
- 24/7 Research Infrastructure working in Emergency Department (ED) at UF
- Recruit for clinical trials in the ED and follow patients throughout the hospital
- Specialties include cardiac arrest, TBI, and drug intervention clinical trials
- BSL2+ lab and workspace in the Trauma bay of the ED



The Problem: COVID 19 Research

- **March 13, 2020** : research focus shifted to COVID-19 studies while other studies were on hold
- *How do you consent without face to face interaction?*
- **How do you consent for new COVID drug trials without physical interactions?**
- Get verbal consent over the phone with participant
 - Participant still need copy of consent to review over the phone
 - Digital
 - Paper
 - Impartial Witness will need to sign consent
- Switch to remote electronic consent (e-consent)
 - Participant can review consent electronically and sign on their smart device
 - Participant can review consent electronically and sign on one of our IPADs

Consenting COVID Positive Patients

Patient Population:

- COVID Positive Inpatient/Outpatient
- Mostly on supplemental oxygen
- Anxious
- Mostly between the ages of 30-95yo

Standard Approach:

- Call patient room or discuss with care team to ask for permission to call personal cell phone
 - LAR contact information can also be discussed with care team
- Soft approach participant in order to engage interest in study
- Discuss smart device usage
 - Provide IPAD if patient does not have a smart device
- Provide physical/digital copy of ICF for review

Remote E-Consent Over Phone/Zoom

- Consent process can be over the phone/zoom
- Two Methods:
 - Consent Review Only (PDF)
 - Consent Review and Signature (E-Consent)
- Participant emailed signed consent

Phone:

- Consent process over the phone while participant follows on smart device



ZOOM:

- Send Participant Zoom link or
- Share Screen
 - See what they are seeing
- Multiple IPADs cleaned and rotated in order to prevent exposure to staff

Dealing with Sponsors with Non-COVID Research

- Are you providing an E-consent platform?
- Do we need to create one for you?
 - REDCAP
- What is the charge?
- Do you accept our remote consent SOP?



REMOTE CONSENT FOR “MOTHERS AND
INFANTS AFFECTED BY SIGNS AND
SYMPTOMS OF COVID-19 (MASC)
STUDY”

Hira Shrestha, MA

Elisha Wachman, MD

12/11/2020

RESEARCH CORE TEAM

Primary Personnel:

- Elisha Wachman, MD (PI)
- Elizabeth Barnett, MD (Co-I)
- Vishakha Sabharwal, MD (Co-I)
- Tina Yarrington, MD (Co-I)
- Elizabeth Taglauer, MD (Co-I)
- Jeffery Boateng, MBBS (Lead RA)
- Nurses, doctors, and admin staff

Departments:

- Pediatrics Infectious Disease
- Neonatal Intensive Care Unit
- OB/GYN
- Labor & Delivery
- Postpartum Care Units

INTRODUCTION

- There are limited information about the impact of COVID-19 on pregnant women and babies
- Guidelines on how to best care for mom and baby are unclear
- **MASC:** A longitudinal Observational Study to learn about how the COVID-19 virus is transmitted from mothers to their babies
- Purposes:
 - To look at viral markers in the placenta, blood, urine, and breast milk to understand if the baby has been exposed to the virus and at what time point this exposure occurred
 - To check medical outcomes of mother and baby related to COVID-19

STUDY PROCEDURES

- **Enrollment Timeline:**
 - Prenatal or at Delivery
- **Eligibility:**
 - 18+ years old, tested positive for COVID-19 at any point during a viable pregnancy, delivering at BMC
- **Study Timelines:**
 - Study Introduction by clinicians or RA
 - **Informed Consent Visit (remote or in-person)**
 - Delivery Visit:
 - Placenta sampling; cord blood sample; mom and baby blood samples; infant urine collection; infant rectal swab or stool collection; breastmilk sample (if breastfeeding)
 - 6-Week Postpartum Visit:
 - Breastmilk sampling (if breastfeeding); brief questionnaire; wellness check; mom and baby blood sample collection;

CHALLENGES WITH ENROLLMENT AND RETENTION

- Patient access (inpatient or outpatient)
- Coordination of visits/procedures with clinical team
- Obtaining Consent of interested patients
- Proper PPE training of staff for sample processing
- Communication
- Language barrier – non-English speaking patients

COORDINATION WITH CLINICAL TEAM

- Created and shared with IRB trained research staff this Google Spreadsheet with all roles and weekly dates

ROLES	Jan 26	Jan 27	Jan 28	Jan 29	Jan 30
Consent - day (note, RAs)	Jeffery				
Consent - night / weekend					
Primary in person facilitator		Elisha			
Consent witness					
Mom blood					
Infant samples					
Breast milk					

CONSENTING OPTIONS

Basic Identifying Information

Editing existing Study ID (MASC01, etc) **test 2**

Event Name: **Enrollment**

Study ID (MASC01, etc) test 2
To rename the record, see the record action drop-down at top of the [Record Home Page](#).

Date of informed consent 10-12-2020 Today D-M-Y

Informed consent process used

Witness Form
 REDCap E-Consent
 In-Person Consent (For patients not on COVID-19 precaution)

Interpreter used for informed consent process Yes No

Participant's primary language Spanish

Interpreter ID number for consent process 1234567

Consented for (select one): Full study Placenta and cord blood only

Participant email hira.shrestha@bmc.org

Form Status

- We utilized:
 - ✓ Witness Form
 - ✓ **REDCap e-Consent**
 - ✓ In-person Consent (for patients not on COVID-19 precaution)
- Criteria for choosing remote eConsent
 - ✓ Patient on COVID-19 precaution at the time of enrollment
 - ✓ Admitted to L&D for delivery during statewide shutdown.

REDCAP E-CONSENT SET UP

Enable optional modules and customizations

Some options below are disabled because they may not be modified once the project is created.

- Repeatability instruments and events [?](#)
- Auto-numbering for records [?](#)
- Scheduling module (longitudinal only) [?](#)
- Randomization module [?](#)
- Designate an email field for sending survey invitations [?](#)
Field currently designated: **email** ("Participant email")

- BUMC CTSI eConsenting guidelines – separate forms for patient and research staff for remote REDCap eConsent purposes only.
- Used Survey and Longitudinal Data Collection Features
- Designated an email field for sending survey invitations.

Main project settings

Some options below are disabled because they may not be modified once the project is created.

- Use surveys in this project? [?](#)
- Use longitudinal data collection with defined events? [?](#)

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

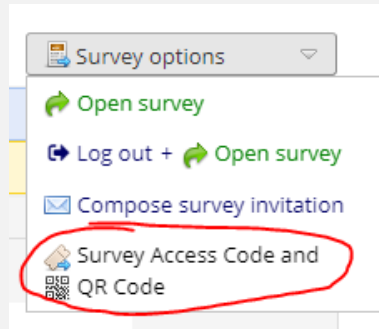
- Incomplete
- Incomplete (no data saved) [?](#)
- Unverified
- Partial Survey Response
- Complete
- Completed Survey Response

Study ID (MASC01, etc) **MASC-01**

Data Collection Instrument	Study ID (MASC01, etc) MASC-01				
	Enrollment	Delivery Hospitalization	Six Week Visit	Repeated Forms	Data Collection Chart Review
Basic Identifying Information	<input checked="" type="radio"/>				
Informed Consent Signature Form (English) - Participant (survey)	<input checked="" type="radio"/>				
Informed Consent Signature Form (English) - Researcher (survey)	<input checked="" type="radio"/>				
ClinCard Signature Form (English) - Participant (survey)	<input checked="" type="radio"/>				
ClinCard Signature Form - Researcher (survey)	<input checked="" type="radio"/>				
Delivery Samples		<input checked="" type="radio"/>			
Follow-up 6 week visit Samples			<input checked="" type="radio"/>		
Follow-up 6 week visit questionnaire (English) (survey)			<input checked="" type="radio"/>		
Follow-up 6 week visit questionnaire (Spanish) (survey)			<input type="radio"/>		
Follow-up Call Form				<input checked="" type="radio"/>	
Protocol Deviation				<input type="radio"/>	
Serious Adverse Event Form				<input type="radio"/>	
Delete all data on event:	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	

IMPLEMENTATION

- Survey link and access code
 - Sent to participant's email directly via REDCap
 - In a text message via study cell phone
- Documentation
 - Once signed by both parties, download the signed consent forms to include in the regularity binder



Survey Access Code or QR Code

Survey title: "MASC Study Informed Consent Signature Form"

A Survey Access Code and a QR Code both allow respondents to begin a survey on another computer or device without someone having to email them an invitation. This is especially useful if the respondent is currently nearby or if you will be sending the survey invitation to a physical mailing address (i.e. 'snail mail'). You may click the Print button at the bottom if you wish to print out the instructions for the respondent.

Enter the Survey Access Code

To allow a respondent to begin this survey, have them navigate to the URL below and enter the survey access code. The code is permanent and will never change. (Note: The web address is the same for all projects and surveys, so you may bookmark the address on a computer or device to quickly return to it multiple times.)

1.) Go to this web address:

2.) Then enter this code:


OR

Generate Short Code

Alternatively, you may generate a shorter, temporary code that will expire after only one use or after one hour has passed.

Scan the QR Code

The survey link has been converted into a QR code, which can now be scanned by a device that has an app capable of reading QR codes. Once the QR code below is scanned, it should take the respondent directly to the survey in a web browser.



PARTICIPANT PAGE

RESEARCHER PAGE

I give my permission to participate in the following aspects of the study (select one): H 🗨

* must provide value

FULL STUDY including blood, urine, and/or breast milk collection, with 2 study visits at delivery and 6 weeks after delivery (full study payment of \$70)

Placental and Cord Blood collection (discarded samples) with medical record review (no payment) reset

I give my permission for study staff to contact me about future related research studies H 🗨

Yes

No reset


CONSENT FORM SIGNATURE

By signing this consent form, you are indicating that:

- You have read this form (or it has been read to you)
- Your questions have been answered to your satisfaction
- You are providing consent for yourself and permission for your child to voluntarily participate in this research study; AND to permit the use and sharing of information that may identify you and your child as described, including health information.

First Name H 🗨 * must provide value

Last Name H 🗨 * must provide value

SIGNATURE H 🗨  [signature_2020-12-10_2158.png\(0.01 MB\)](#) Remove file or Send-It

IF POSSIBLE, SIGN WITH FINGER, STYLUS, OR MOUSE

Date and Time of Consent H 🗨 M-D-Y H:M * must provide value

After reviewing attached ICF, patient would select all provided options and type in their full name. Signature is optional and date is automatically stamped.

Study ID (MASC01, etc) test 2

Participant Name
Hira Shrestha

Date of informed consent signature
12-10-2020 21:58

Communication method used for consent (check one) H 🗨

Phone

BMC Zoom

BU Zoom Meetings for HIPAA

BU Teams reset

RESEARCH STAFF SIGNATURE FOR CONSENT FORM

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and free agrees on participation for herself and her child. I consider that the above-named subject (check one): H 🗨

* must provide value

is providing parental consent and permission.

is capable of understanding what is involved in the study and is providing assent.

is not capable of understanding what is involved in the study. reset

First name H 🗨 * must provide value

Last Name H 🗨 * must provide value

Signature (if possible, sign name with finger, stylus, or mouse) H 🗨 [Add signature](#)

Date and Time of researcher signing consent H 🗨 M-D-Y H:M * must provide value

Form Status

Patient's full name and basic info would automatically populate into researcher's signature form. Researcher would select relevant options and type in their names, sign and save it.



e-Consenting for an Adolescent Behavioral Intervention

- Procedures, Lessons Learned, & Challenges during the COVID-19 Pandemic •

Darci Miller, MPH
Research Coordinator III
University of Florida



e-Consent in the Adolescent Population

NIH-funded Behavioral Intervention



- Acceptance-Based Therapy Weight Loss Intervention in Adolescents: A Randomized, Controlled Trial
- Previously in-person, but has moved to remote delivery

Target Population



- Adolescent girls ages 14-19
 - Participant ages in both adult/child ranges, so sometimes using consent only (participant), sometimes using consent/assent (parent/legal guardian and child participant)
- Overweight/obesity (BMI \geq 85th percentile for sex-and-age)



e-CONSENTING PROCEDURE

- 1** Phone screen is conducted with potential participant (or parent/legal guardian, depending on age) to determine study eligibility.
- 2** If potential participant qualifies, a Zoom meeting is set up to discuss further study details and go over the e-Consent form (sent in email prior to meeting).
- 3** At the Zoom meeting, the study/e-Consent form (developed on REDCap) is discussed and consent is signed during the meeting.



PROS AND CONS

Pros



- Schedule availability (my own and participant's)
- Participant attendance
- Streamlined through REDCap with all other study data

Cons



- Uncertainty of participant proficiency with Zoom/online signatures prior to meeting
- Study seems to inevitably target a higher SES group



LESSONS LEARNED

- Infographics can be a more effective/easier way to explain your study to participants.
- Using the remote control feature improves the overall process for remote e-Consent.





Questions?

Email: dmiller5@ufl.edu

