Using REDCap for e-Consent

Meyad Baghezza, Associate Director IRB

&

Robert Geller,

IT Project Mgr & REDCap Administrator Population Health Sciences

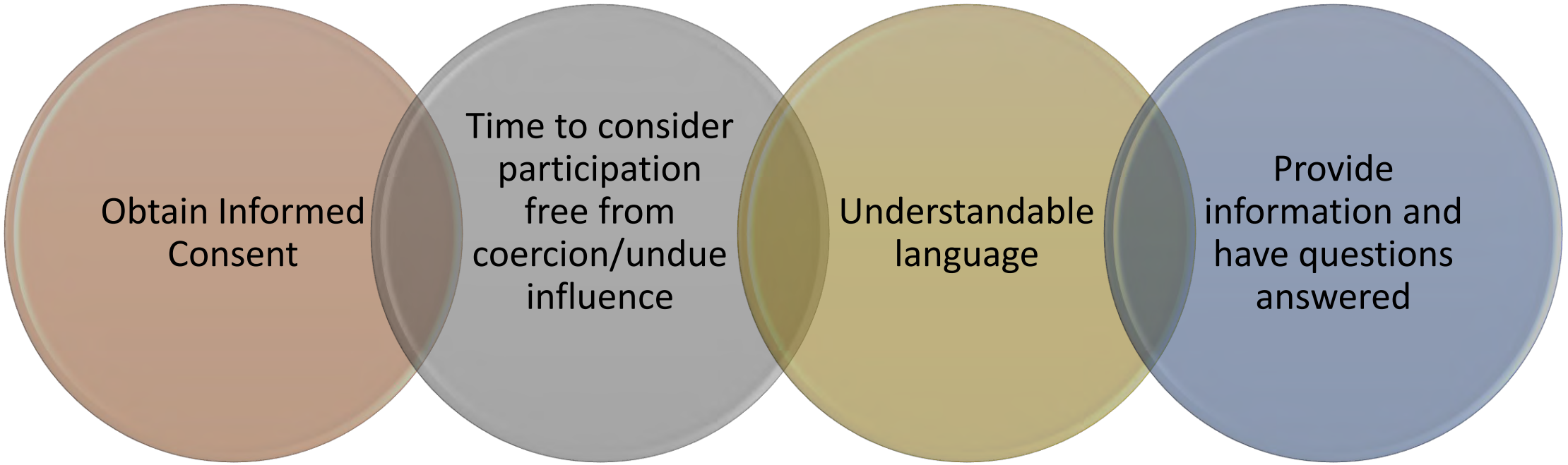
During the Forum

- Mute your mics to avoid echoing or background noise
- Do not activate your camera to preserve bandwidth
- In lieu of voicing your questions, use the chat function, a moderator will respond to your question.

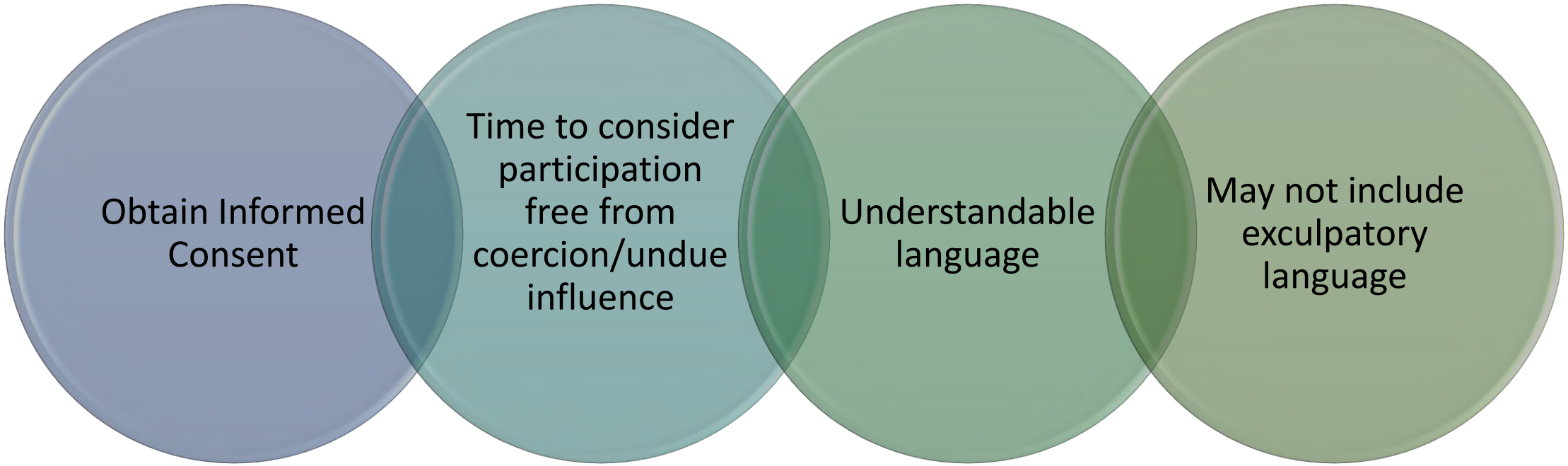
eConsent Regulatory Considerations

Meyad Baghezza, Associate Director IRB

Informed Consent Requirements – DHHS
45 CFR §46.116



Informed Consent Requirements – FDA
21 CFR §50.20



What is eConsent?

- Electronic informed consent (eConsent) is the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent.

IRB Considerations

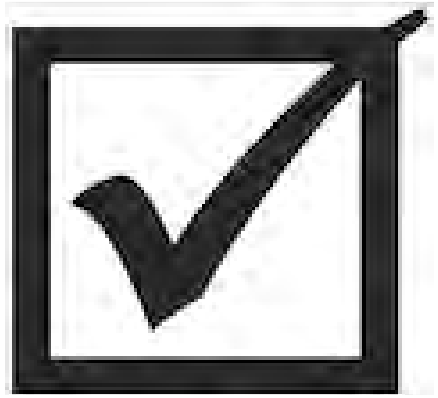
Ensuring safeguards regarding privacy and confidentiality

Ability to display the most current version of the consent form

Ability to reconsent

Allow subjects to download/save a copy of the consent for that was signed – also meets HIPAA requirements

IRB Considerations



Mechanisms for subject or subject's LAR to document willingness to participate (i.e. check box or mouse pad signature box)

Must have a way to address patient questions

Ensuring that the subject signing/checking the box is the subject participating in the research

Plans to ensure visually/motor impaired or those who are unfamiliar with working technology will be able to provide informed consent

Protocol Review – Inst Form

Item 29

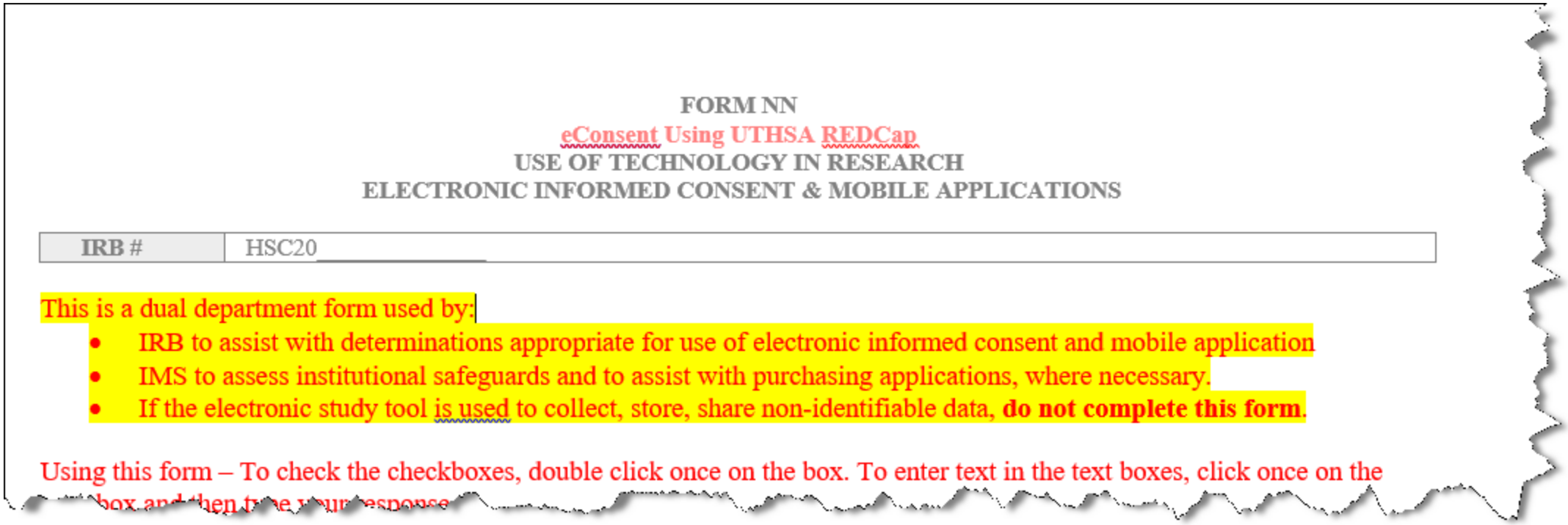
Does the study employ the use of electronic study tools to collect, store, and/or share identifiable data such as online platforms (e.g. XNAT), mobile applications (*e.g. electronic diaries)* or electronic informed consent *(e.g. MyTrus)*?

There may be circumstances when a mobile app meets the definition of a mobile medical application and may be subject to FDA regulations. Please refer the FDA guidance here

☐ No, skip to *Item 30*	Complete this section, but do not submit Form NN for **External IRB studies**
☐ Yes, select study tools that will be used *(check all that apply)*:	
UTHSA REDCap	
☐ Data collection ☐ Obtaining informed consent *(complete Form NN)*	
UTHSA secure server-based system, specify:	
☐ Data collection ☐ Obtaining informed consent *(complete Form NN)* ☐ Mobile App *(complete Form NN)*	
Sponsor study tools, specify: ☐ Confirm understanding that the sponsor study tools are FDA 21 CFR Part 11 compliant and the company providing the study tools to the sponsor has been named as a disclosure in the HIPAA authorization	
☐ Data collection ☐ Obtaining informed consent *(complete Form NN)* ☐ Mobile App *(complete Form NN)*	

Protocol Review – Form NN

- Form NN – partially completed form available



FORM NN

eConsent Using UTHSA REDCap

USE OF TECHNOLOGY IN RESEARCH

ELECTRONIC INFORMED CONSENT & MOBILE APPLICATIONS

IRB #	HSC20_____

This is a dual department form used by:

- IRB to assist with determinations appropriate for use of electronic informed consent and mobile application
- IMS to assess institutional safeguards and to assist with purchasing applications, where necessary.
- If the electronic study tool is used to collect, store, share non-identifiable data, **do not complete this form**.

Using this form – To check the checkboxes, double click once on the box. To enter text in the text boxes, click once on the

Protocol Review – IRB Form

Item 12 How will you consent subjects to participate in the research? *Select all applicable*	☐	Will not obtain consent from: *(select one)* ☐any participant ☐some participants	*If some participants selected, which ones?*	☐ *Submit Form F (complete the Waiver of Consent section)* **OR** ☐ *Waiver of Consent is not needed because subjects will provide informed consent or informed consent will be waived as part of their participation in a contributing protocol (i.e. data coordinating center activities).*
			If selected, Is the information collected for the study health information?	☐ No ☐ Yes *submit Form J – HIPAA Waiver* ☐ Yes *but a HIPPA Waiver is not needed because subjects will provide authorization or a waiver of authorization will be obtained as part of their participation in a contributing protocol (i.e. data coordinating center activities).*
	☐	Will obtain consent **without a signature**	*If selected, select at least one of the following describing how you will obtain consent:* ☐ Verbal in person ☐ Telephone ☐ Online ☐ Survey (or other data collection tool) ☐ Other	*submit Form F (complete the Waiver of Documentation section)* *Also submit either:* *the text of the information that will be provided (i.e., script, consent paragraph)* *or an Information sheet -Form D-IS*

Is REDCap FDA 21 CFR Part 11 Compliant?

- Currently, PHS does not support use of REDCap for FDA-governed clinical trial.
- PHS has provided guidance on how projects may become 21 CFR Part 11 Compliant here: https://rc.partners.org/kb/article/2732
  - Each project requires validation and include a minimum of:

Does the REDCap eConsent build need to be completed before IRB submission?

- No, the IRB approved stamped consent form will need to be uploaded to the REDCap tool.

Using REDCap for eConsent on external IRB studies

- Applies when using UTHSA's REDCap
- Form NN is not required to be submitted

Technical Components: Building the REDCap eConsent

Bob Geller, *IT Project Mgr & REDCap Administrator Population Health Sciences*

What is REDCap e-Consent?

- e-Consent is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet.
- Provides the framework. You must create the survey with all appropriate questions including name and DOB.
- Framework adds a certification page to your survey and handles automatic creation and storage of archive copies of the consent

e-Consent Signatures and versions/types

- Patients can sign their consent by typing their name in a text field or by utilizing REDCap's signature field to trace their 'wet signature' on a trackpad or using a computer mouse.
- the signature process will NOT be implemented by REDCap automatically, so it is your responsibility as a survey administrator to construct your survey using one of the methods above for the signature to get captured appropriately.
- e-Consent version and type are both free-form text fields whose value will be inserted at the footer of each page in the PDF.

PDF Auto-Archiver

Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

- ○ Disabled
- ○ Auto-Archiver enabled
- ◉ Auto-Archiver + e-Consent Framework — What is the e-Consent Framework?

(includes end-of-survey certification & archival of PDF consent form)

e-Consent Framework Options: For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey, after which that PDF 'hard-copy' will be archived in the File Repository. Read more

e-Consent version: 1.0 e.g., 4

First name field: first_name_part "Participant Fi

Last name field: last_name_part "Participant La

Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):

e-Consent type: Multiple Signat e.g., Pediatric

Date of birth field: dob "Date of Birth"

Participant Multi-Signature Consent Form

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

Participant Multi-Signature Consent Form

Please note That this message is for the study team only and needs to be deleted before Moving to Production.

The EXACT language must be IRB approved prior to using the eConsent. This note is meant to provide instruction on how to develop this. Please highlight the underline then type the appropriate content for those blanks.

View the eConsent by going to the Manage Survey Participant and open the Public Survey Link. Then make the PDF from the on-screen version to be included in your electronic protocol. Note the Making the PDF from within REDCap is not the Version the IRB will approve.

Management of Consents

The management of your consent is very [illegible]

Please consider the following:
1. Use eSignature on the EDC forms from a REDCap account
2. If you are uploading a new version, the best way to manage this is to add a new upload field with a new version of your approved consent. Then hide the previous version so that it does not get accidentally used.
3. Use record locking (review the online video)

☐ **I confirm that all the information in the document above is correct, and I understand that signing this form electronically is the legal equivalent of a signed physical document.**

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous Page

Submit

Show 10 entries Displaying all records Download all (zip) Search

Survey Completion Time	Record	Survey	Identifier (Name, DOB)	IP Address	Version	Type	Download
05/09/2018 4:20pm	3	Participant Multi-Signature Consent Form	Teresa Bosler, 2000-05-09	129.112.115.42	1.0	Multiple Signatures	PDF
05/09/2018 3:57pm	2	Participant Multi-Signature Consent Form	Teresa2 Bosler, 2000-05-09	129.112.115.54	1.0	Multiple Signatures	PDF
05/09/2018 3:22pm	1	Participant Multi-Signature Consent Form	Teresa Bosler, 2018-05-09	129.112.115.41	1.0	Multiple Signatures	PDF

Previous 1 Next

Contactless Consenting for virtual consenting

https://www.youtube.com/watch?v=vvf5QXAeBFQ

CTO Staff Announcement

- ***NEW Team Member*** – Anna Stewart, Budget Analyst – Intermediate
- Jason Bates – Director, Clinical Trials Office
- Patricia Miranda – Manager, Research Operations
- Brandi Weaver – Manager, Clinical Trials Development
- Cathy Haegelin - Budget Analyst – Senior
- Lynda Schrack – Clinical Trials Specialist
- Cristina Morales – Clinical Trials Specialist
- Laura Martinez – Administrative Assistant

UT Health San Antonio
Clinical Trials Office

Virtual Concierge

Concierge Dates for Fiscal Year 2020-2021

Date	Time
September 1, 2020	1pm - 4pm
September 9, 2020	9am - 12pm
September 23, 2020	9am - 12pm
October 6, 2020	1pm - 4pm
October 7, 2020	9am - 12pm
October 21, 2020	9am - 12pm
November 3, 2020	1pm - 4pm
November 4, 2020	9am - 12pm
November 17, 2020	9am - 12pm

November's Research Forum

- November 19, 2020
- General Research Updates