REDCap eConsent Clinic

28th February 2022

Norwich Clinical Trials Unit

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NORWICH CTU

FUNDED BY

NIHR | National Institute for Health Research

Format

www.trialaborate.org.uk/forums/

Cover questions people asked at sign-up

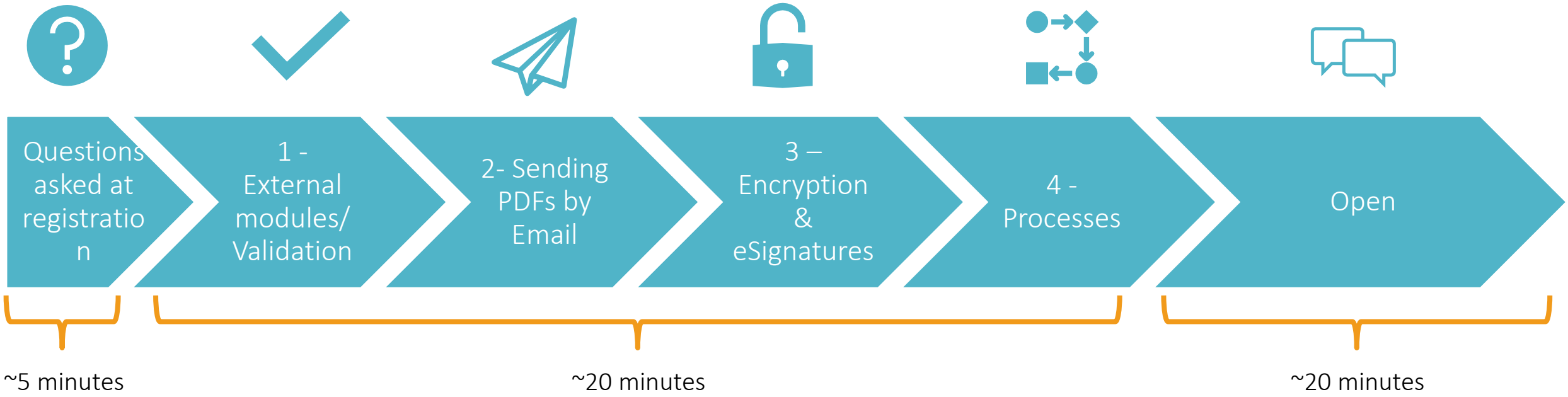
4 themes – based on questions at previous webinars

Open up to more questions

- External modules and Validation
- Sending PDFs of consent forms by Email
- Database Encryption and eSignatures
- Processes

Please use the raise hand function and then use mic/video to join in this session

Timeline



*timings not to scale/proportional

Registration questions

1. How to design **Assent** forms once Consent was given but assent is needed.
2. eConsent framework PDF file **header and footer**
3. What to do with eConsent data when a participant **withdraws** from the trial?

Registration questions

1. How to design **Assent** forms once Consent was given but assent is needed.

e.g. A Parent consenting for a child, but the child being able to assent

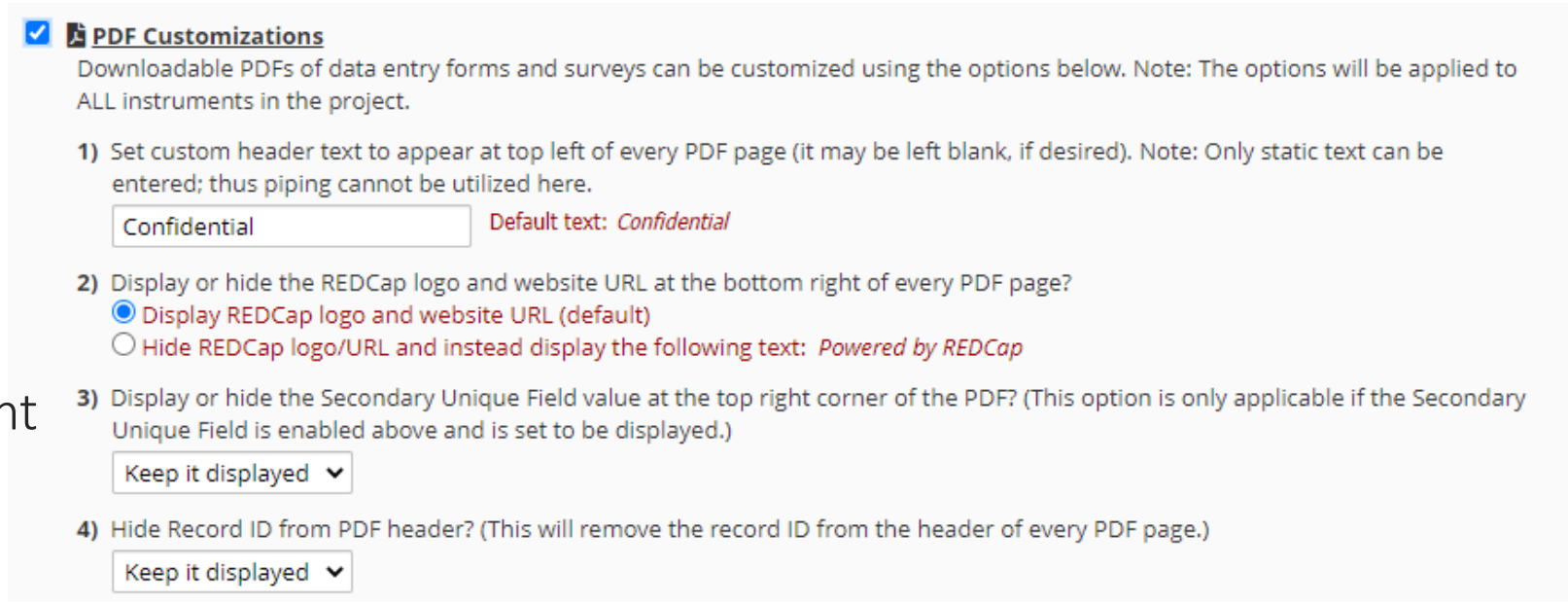
- Short study
  - 2 forms
    - *parental consent*
    - *child assent*
- For a longer study,
  - child might reach the age to consent during the study,
  - 3 forms
    - *Child consent*
    - *Child assent,*
    - *Parent consent,*
  - Report that shows a list of children who were minors when they joined, but have since reached the age where they can consent themselves, so that they can be **reconsented**. (automated email to site)

Registration questions

2. eConsent framework PDF file **header and footer**

Unsure what exact requirements are for question. Lots of posts on community forum about this

Can have some options as in screenshot – e.g. removing patient ID, but other things have to stay, e.g. “powered by REDCap” or the logo



Registration questions

3. What to do with eConsent data when a participant **withdraws** from the trial?

a) **Keep it**. Your protocol should detail how long you will keep details of consent on file.

b) However, you may need to **delete** any associated information such as **contact details**, if you no-longer have a justification for keeping these

c) Use a **separate withdrawal form** to record the date and reason for withdrawal. You can include the fields from this form in the logic on reports and email triggers etc to **ensure the participant does not receive any follow-up messages** once they have withdrawn.

External modules

List of external modules:

https://redcap.vanderbilt.edu/consortium/modules/index.php

Not all **compatible** with all versions of REDCap – logged in your list will only show compatible ones

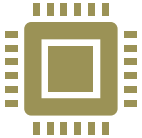
Can **write own-** can share if you want, or just use yourself

Check out our Webinar 2 for list of useful EMs for eConsent (12 mentioned)

External modules and Validation

Do you need to do own validation on External modules? Yes!

For each project



At upgrade of REDCap, Module and PHP version. All can break functionality.

Suggest upgrading modules and REDCap at same time to reduce work

Have a plan to work through for testing all functions.

Document results of testing

Sending PDFs by email- is it secure?

It's true that unencrypted email is potentially vulnerable to hackers, but in reality this is very unlikely.

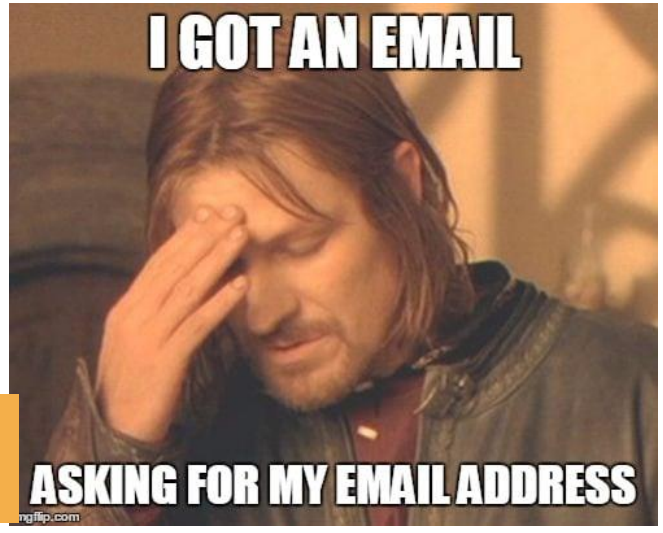
Main sources of email data breaches:

- Sending to wrong email address
- Participant having poor password on account

Encryption won't help either of these scenarios unless you password protect and send a password by alternative method.

Need a method to confirm the address

Participant's responsibility and not much we can do about that.



Potential workaround: send a link to a password protected survey page

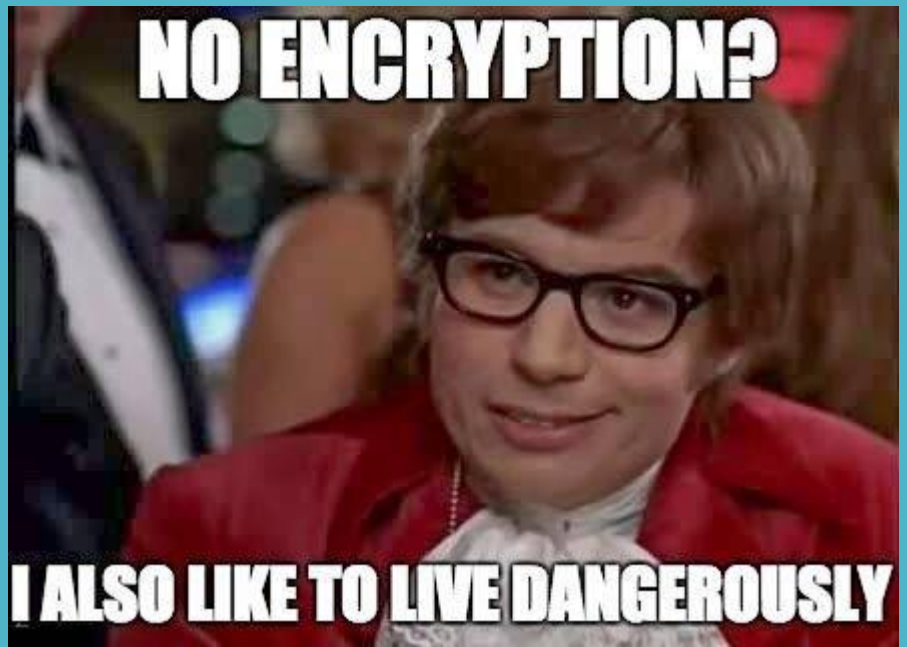
Encryption more important for **removable/portable media** (Laptops, Phones, Memory Sticks)

Less useful on server, where people should not have **physical access** to disks

REDCap does not encrypt data, but if you **host on an encrypted server**, then your data are encrypted.

Good **server security**, and good **user management** and **authentication** most important.

Database Encryption of Typed Signatures/PDFs



Processes

Pre-consent stage needed for contact details?

- **Remote** eConsent
  - Often have a clinic visit first to discuss trial and interest before link is sent, researcher can get then
- **In clinic**
  - Can either get in advance as above, or as part of consent process if need to send follow-ups etc via email. Only in advance if emailing link to consent remotely.

Preventing participants inadvertently consenting twice

- **Public** survey
  - Will need to try to design process to limit this by e.g. checking unique email/mobile number. Will be a lower risk trial if public
- Via **email/in person**
  - Once completed via email link, link will no longer let them complete again. In clinic, form needs to be reopened as a survey and set to editable by researcher to do again

Processes

Mid Study Amendments to PIS or Consent form

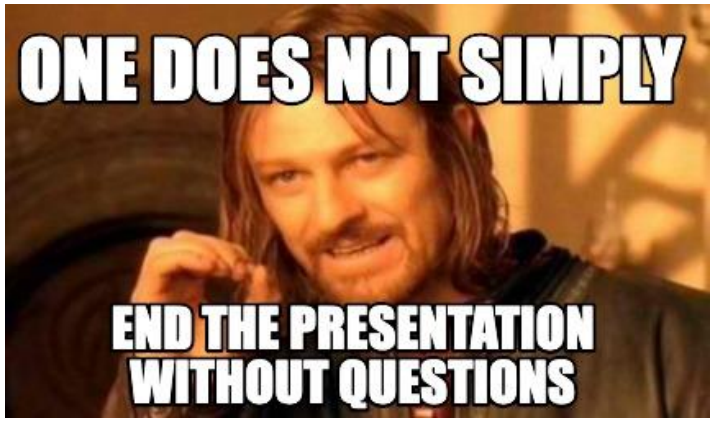
PIS version changes

- Agree **date** to change over and make old version unavailable
- If mixed methods we **pipe** in version from control form, so update that and make old version unavailable
- If only eConsent, may just need to change wording of **descriptive** field

Consent form amendments

- **Affects study data**
- Can be more awkward as can **affect other processes**, e.g. could base ability to randomise on consent form completion, so updates needed elsewhere.
- Can depend if **optional** or **mandatory** statements changed, and even sometimes **site specific**
- **Hide** existing fields using **action tags**, so data isn't changed, and add new fields? Document what was done, when and why
- Add **field annotation** with when added/removed too

Questions


ONE DOES NOT SIMPLY
END THE PRESENTATION
WITHOUT QUESTIONS

NORWICH CTU

Thank you!

Please complete our feedback form:
https://norwichcrtu.uea.ac.uk/redcap/surveys/?s=CMMCD4KWYT