Scope

Will cover

Where to start

Different eConsent Scenarios

Brief intro to REDCap

Overview of making an eConsent form

Simple eConsent Demo

Useful external modules

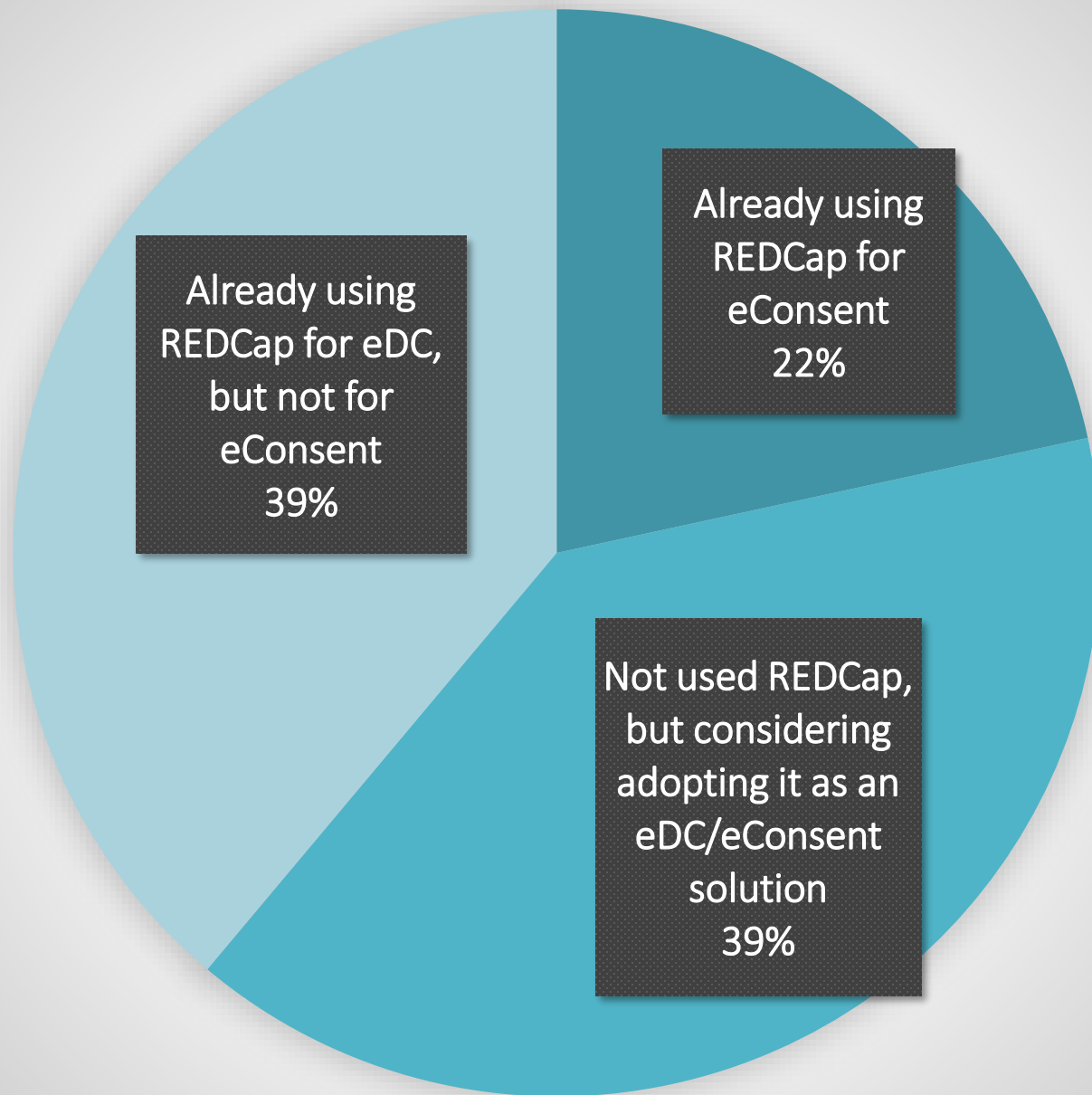## Won't cover

REDCap Cloud

Lots of technical detail of how to implement (can cover next week if requested)

Reminder

Not experts but most of our diverse trials use eConsent – worked through lots of issues and mistakes that you might come across!

Format

Questions

- Type in chat window
  - Can cover in this session at the end/break
  - Or in more detail at next weeks webinar
- Ask in the feedback form for answering in **next weeks session**

- Discuss on **Padlet**: https://tinyurl.com/5fn22zta

- Planning to add some of the questions to **Trialaborate** forum to aid further discussion
  www.trialaborate.org.uk/forums/

Guidance document

- We're creating a guidance **document** on eConsent coming out in next <u>few months</u>

- Planning to distribute via our website (will send an email when it's up), possibly also via UKTMN etc

Take home - What to get from this session

Knowing what types of eConsent are possible/suitable in REDCap

Where to start/questions to ask

Features that you might need and when to use them

Where to get more help

Implementing eConsent in REDCap

! Implementing eConsent isn't just turning a switch somewhere!

Adding appropriate components, forms, fields, addons to build an eConsent process which reflects requirements, follows regulations and mitigates risk appropriately.
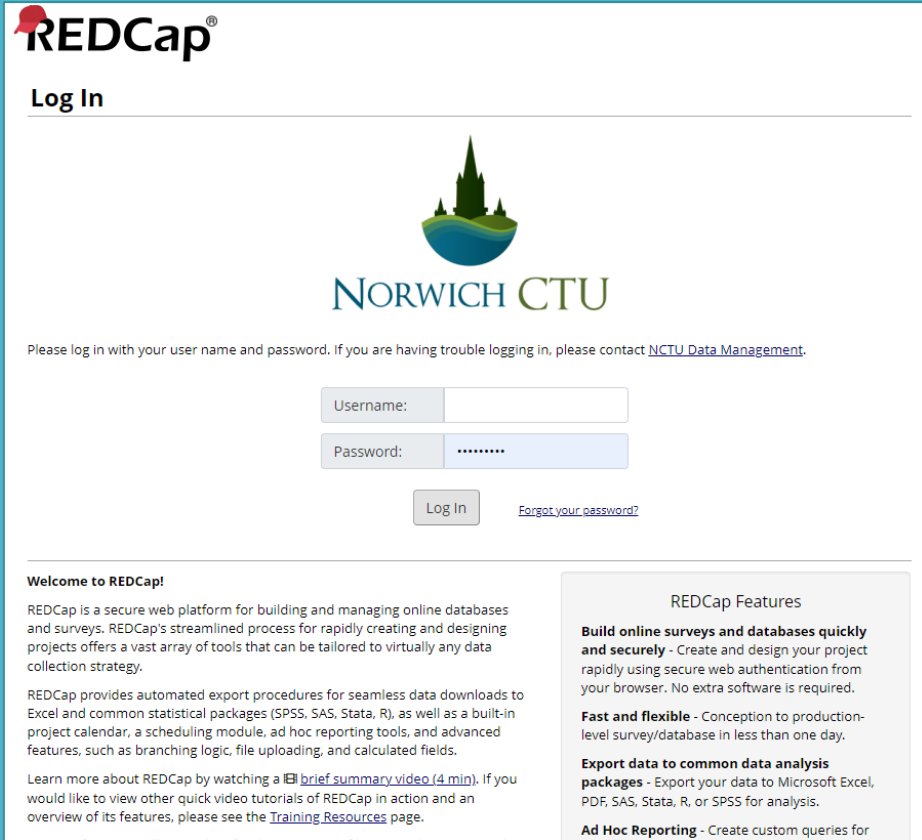

ONE SIZE DOES NOT FIT ALL

What is REDCap

Research Electronic Data Capture

Secure web application for building and managing online surveys and databases.

Developed by team at Vanderbilt University

Free for non-commercial research purposes

Widely used

(2m researchers at over 5000 institutions in 145 countries.)

Active community in REDCap consortium (thousands of users worldwide)

Lots of useful features

Flexible

Extensible

REDCap®

Log In

NORWICH CTU

Please log in with your user name and password. If you are having trouble logging in, please contact NCTU Data Management.

Username:

Password:

Log In   Forgot your password?

Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a 🎬 brief summary video (4 min). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the Training Resources page.

NOTICE: If you are collecting data for the purpose of human subjects research

REDCap Features

Build online surveys and databases quickly and securely - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.

Fast and flexible - Conception to production-level survey/database in less than one day.

Export data to common data analysis packages - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.

Ad Hoc Reporting - Create custom queries for

Obtaining and Hosting REDCap

How to get permission

Join the REDCap consortium at
https://projectredcap.org/partners/join/

Contact team at Vanderbilt

Prove you are non-profit

Hosting Requirements

Webserver with PHP (>=7.2.5) and MySQL (5.5.5+), SMTP email server

Options:

IT dept at your institution

Amazon Web Services

Microsoft Azure

Other options are available

Which option available depends upon **technical capacity** in your team – e.g. AWS/Azure you will need someone to set it up, IT department might have that already

REDCap glossary

Instrument

- The electronic form or survey for capturing data

Branching logic

- Logic used to hide and show fields based upon values of other fields/current user role etc

External module

- Individual packages of software that can extend REDCap's functionality, behaviour, and appearance

Email alerts & notifications

- Allows user to construct alerts and send customized email notifications based upon triggers

Open as a survey

- Open the data collection page as an online form for participant to complete without being logged into REDCap system

REDCap and eConsent – useful features

AUTOMATED EMAILS

AUDIT TRAIL

ECONSENT FRAMEWORK

GENERATE PDF

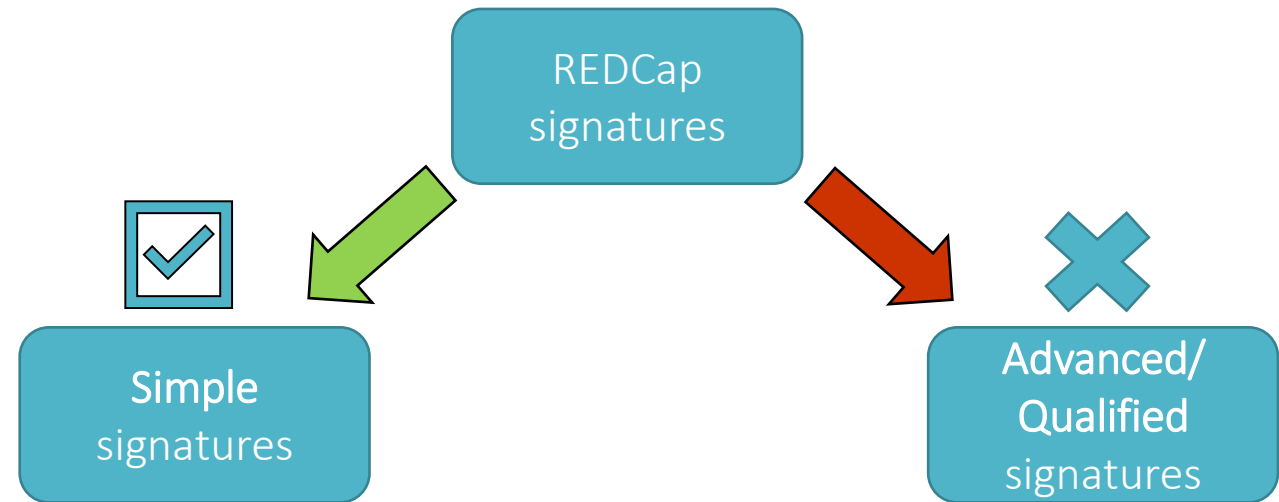**ESIGNATURE**

SECURE/ PERMISSIONS

EXTERNAL MODULES

COMMUNITY FOR SUPPORT

eConsent – what signature do I need?

First question – I need eConsent, what type of signature do I need?

REDCap signatures

Simple signatures

Advanced/ Qualified signatures

- Typed names, drawing signature with mouse/finger
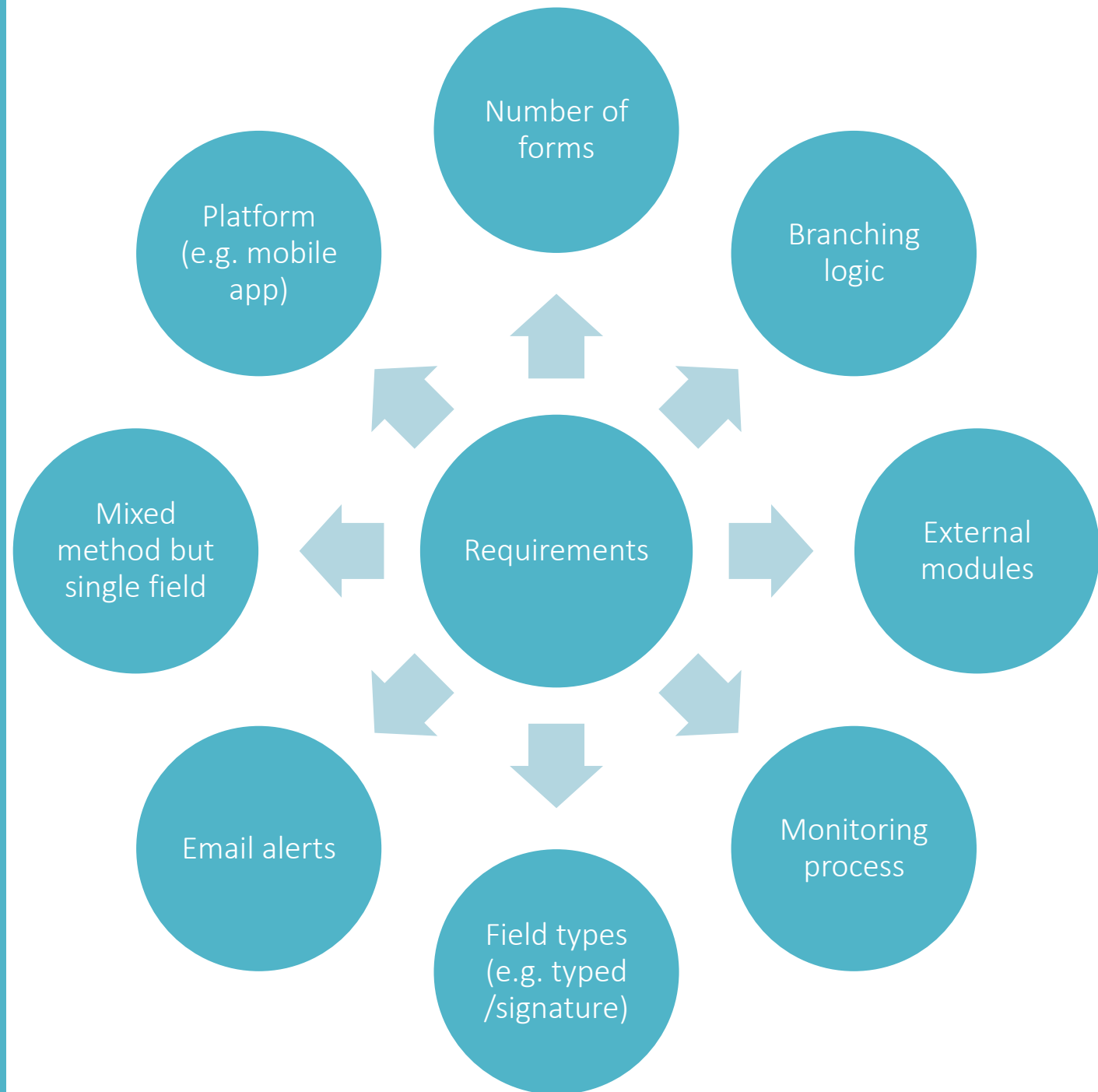- Sufficient for majority of non-CTIMPS and CTIMPS

- Links signature to person using advanced methods
- Needed for research that involves high risk e.g. higher risk than standard care, type b or c
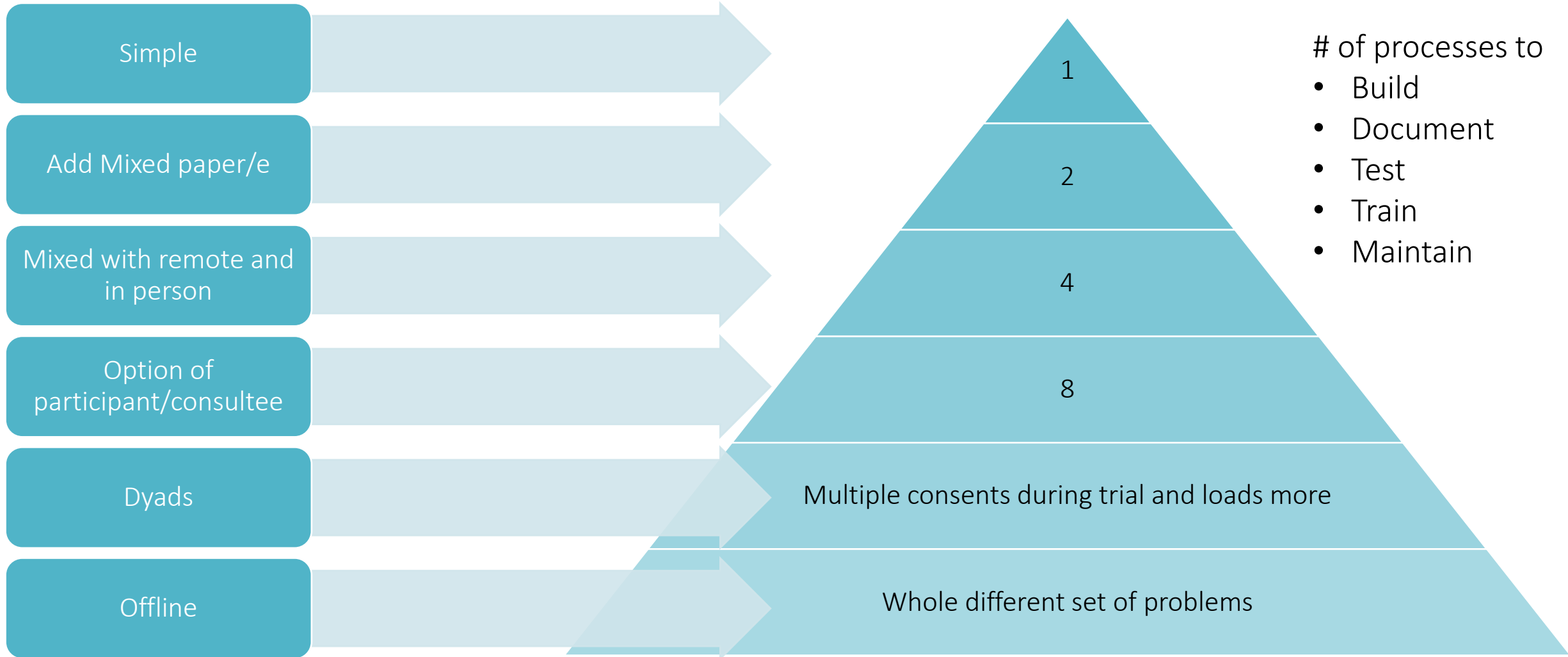
Different eConsent System Requirements

Different types of eConsent (multiple can be used in one system)

- 'Simple' (participant only)
- With researcher countersigning
- Remote and in-person
- Hybrid/mixed paper and eConsent
- Open online recruitment and eConsent
- Dyads (e.g. Patient and Carer)
- Offline eConsent (with mobile app. *)
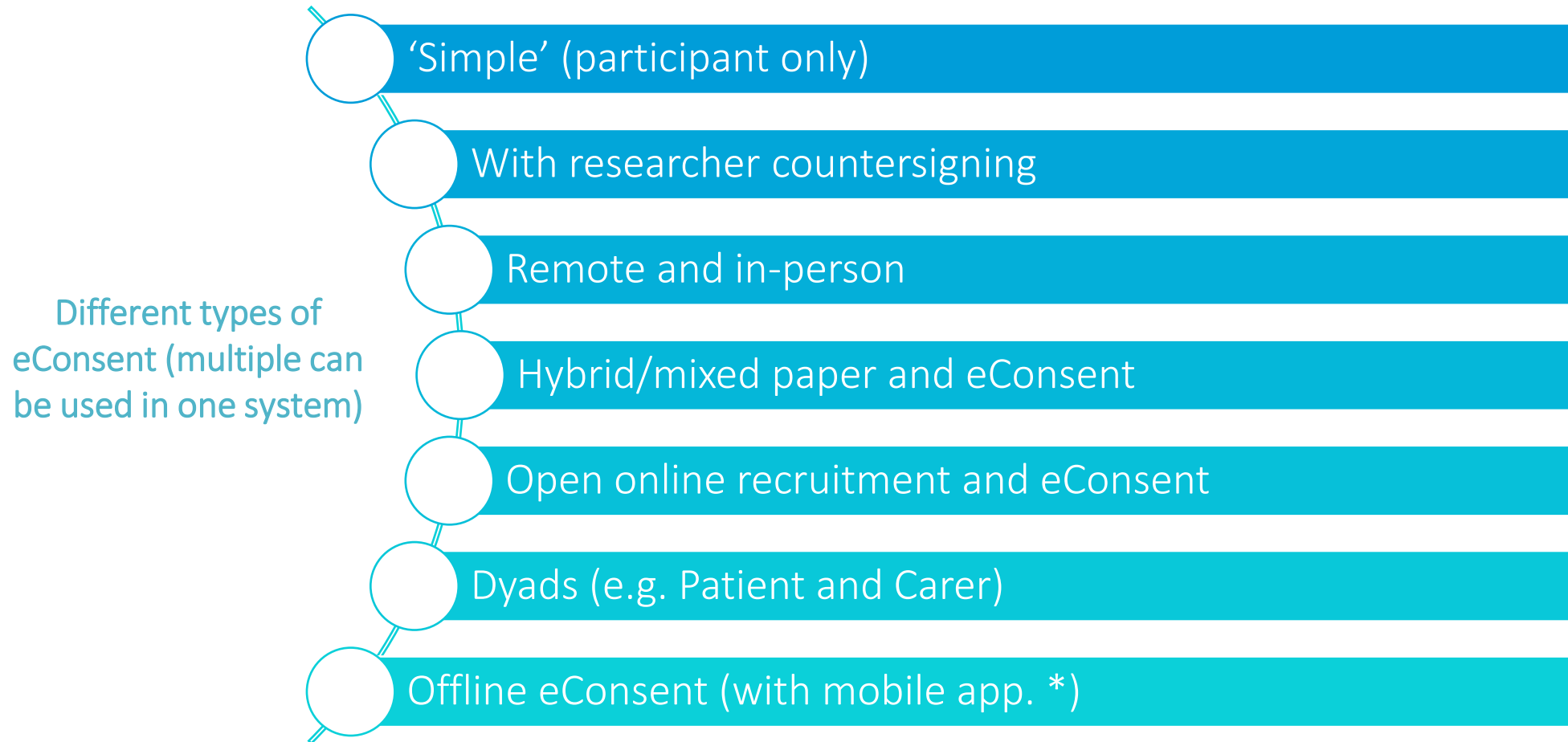
*requires extra – app and setup

"Can you just add eConsent"

Simple

Add Mixed paper/e

Mixed with remote and in person

Option of participant/consultee

Dyads

Offline

1

2

4

8

Multiple consents during trial and loads more

Whole different set of problems

# of processes to
- Build
- Document
- Test
- Train
- Maintain

Importance of requirement gathering

Different requirements result in different:

⏰	Amount of time to build
☢	Weighing up risks/testing
⚒	Maintenance required
🧑‍🏫	Staff training to use

⚠ WARNING – harder to retrospectively add things on to an already built system

Checklist

- ☐ Will consent be on **paper** as well?

- ☐ Is this a **CTIMP**?

- ☐ Does consent need a **counter-signature** from a researcher?

- ☐ Will consent be done **remotely** (e.g. emailed/in person/both)?

- ☐ Does a carer or someone related to participant need consent (e.g. **dyad**)

- ☐ Will **internet access** always be available? (i.e. otherwise mobile app offline)

- ☐ Is it **open** recruitment?

- ☐ Are there **multiple sites**?

- ☐ Is **monitoring** done centrally?

- ☐ Is the consent date or info in the consent form **used elsewhere**? (e.g. optional consent parts, or reports depending upon a single date)

- ☐ Will consent need to be taken **more than once**? (e.g. change of carer during study, child participant changes category)

Conveying information

eConsent gives you more options for how to do this

- Include a summary of PIS on the web page

- Highlight key terms with a tooltip

- Add audio descriptions to help participants with vison or reading difficulties

- Link to download full PIS, or link to study website for further information

- Embed video explaining study

- Can even include an information review in the form of a short multiple choice questionnaire

Documenting informed consent

Consent form (TEST — Testing Econsent System Trial)

Header to identify study

Mandatory statements
- Radio buttons, rather than checkboxes or initials
- Guidance for eConsent doesn't require initials, and they can create monitoring issues
- Checkboxes more complex to analyse

Optional statements

Field for name
- eSignature fields tricky with mouse/finger
- Better on tablet than pc
- Guidance allows text fields often and aren't gaining much from squiggle

Consent date field

Documenting Informed consent: Researcher Counter-signing

- **Separate** counter-signing form

- **Enabled** once participant eConsent form complete

- Researcher can counter-sign electronically either:
  - As a **logged-in user**
  - Sent a **survey link** by email

Member of site research team Sign-off	
Name of Person Taking Consent	
Date	📅 Today D-M-Y
Signature	〜 Add signature

Storing consent

- PDF copies generated:
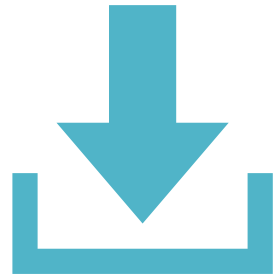
Saved to a file upload field

Saved to the REDCap file Repository

Downloaded by sites and saved or printed and filed in site file

Participant copies

- Good practice to provide participant with a copy of their completed consent form

For simple eConsent, the participant can download as PDF via eConsent module.

Can give option to download pdf version at end of any survey

PDF copy can be sent to participant by email, or printed and posted/handed over

Monitoring

- ICF monitoring can all be done centrally within REDCap
- Forms can be automatically checked for completion, so should be fewer errors
- Trial/Data Manager can log into REDCap and view completed consent form
- Can mark it as reviewed, and then either delete or retain PDF copy.
- Paper forms can be scanned and uploaded for monitoring in once place

Questions & Demo

Demo of an "open" online signup process in REDCap

Link in chat or scan this QR code:

https://redcap.link/7dzvyxbz

Has:

- Short form PIS
- Optional sections
- Automated email copy back to you
- Uses the REDCap eConsent framework
- External modules to extend functionality (6 in this example!)

Note – we will delete this example and your data 48 hours after the final webinar

REDCap – toolkit of useful features to add flexibility

REDCap eConsent Framework

Additional features built in:

- End-of-survey certification & archival of PDF consent form
  - Adds review, confirmation and download step to end of eConsent (see demo!)

- Version of ICF in footer of PDF

- Has been around a while but now EMs have added a lot more functionality

"referred to as a 'framework' because enabling this option alone does not provide an e-Consent process but merely provides the general framework or mechanism to allow you to provide e-Consent to patients/subjects"

Quick mention – REDCap mobile app
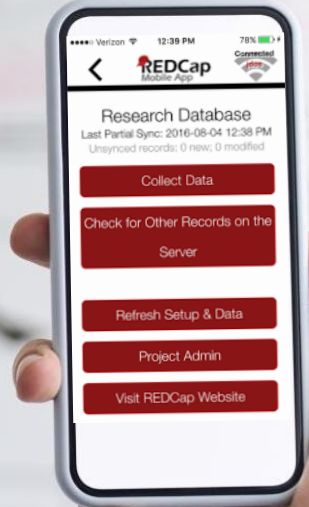
- We don't mean opening on a mobile which is fine generally

- **Offline data collection** via an **app** on mobile/tablet etc, but still must have REDCap project installed to **sync** to

- Requires a very careful setup and very clear processes to follow

- Not app on participant device (which would be MyCAP), but for **researcher devices**

- We have used it before including eConsent, and can discuss our experiences another time, but in general our advice would be

Don't (unless really well thought through!)

Useful External Modules

Saving PDFs of eConsent forms:

- Save PDF to field
- Multi Signature Consent
- Papertrail
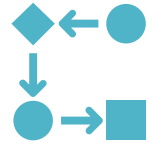
Controlling the flow of your eConsent process

- Autocontinue logic
- Form render skip logic
- Auto Form Status *
- HideSubmit

Improving appearance/usability

- Survey UI Tweaks
- Complete Row
- CSS Injector

Monitoring

- Image Viewer
- showByRole

* Currently unreleased – internal EM

Alerts and Notifications ✉@

- Use to send emails and SMS messages (requires Twilio - outside scope of this presentation)

- To study team and to participants

- Triggered by values in database, events (e.g. saving pages) and dates

Use cases:
➡ Sending survey links to participants
➡ Sending copy of completed eConsent form to participant
➡ Alerting Study team that consent form ready to monitor

- Built into REDCap with an easy to use interface

Reports

- REDCap has built in reporting which is useful for some aspects of consent

- Consider what you want to report on when you design eConsent forms

- Quick view and easy export to e.g. excel

- Example reports which can be useful:
  - Consent forms which are ready to monitor
  - Participants consented and date, including site

Consented but not randomised

Participant consented but abandoned baseline before randomisation

Record ID record_id	Event Name redcap_event_name	I agree to take part in the above study. cons_agree	Today's Date: consent_date
165	Baseline	Agree (1)	28-11-2020
170	Baseline	Agree (1)	28-11-2020
171	Baseline	Agree (1)	28-11-2020
172	Baseline	Agree (1)	28-11-2020
180	Baseline	Agree (1)	29-11-2020
202	Baseline	Agree (1)	30-11-2020
205	Baseline	Agree (1)	01-12-2020
208	Baseline	Agree (1)	01-12-2020
211	Baseline	Agree (1)	01-12-2020
225	Baseline	Agree (1)	02-12-2020

Audit trail

e-consent feb 2022 test project PID 345

📕 **Logging** | Export all loggi...

This module lists all changes made to this project, including data exports, data changes, and the creation or deletion of use...

Filter by event: Record created-updated-deleted
Filter by user name: All users
Filter by record: 7
Filter by time range from [ ] to [ ]
Displaying events (by most recent): 1 - 4 (Page 1 of 1)

Time / Date	Username	Action	List of Data Changes OR Fields Exported
08-02-2022 12:13	[survey respondent]	Updated Response 7	consent_form_complete = '2'
08-02-2022 12:13	[survey respondent]	Updated Response 7	cons1 = '1', cons2 = '1', cons3 = '1', cons4 = '1', cons5 = '1', cons6 = '1', cons7 = '1', cons_emailyesno = '1', cons_email = [ ], first_name = 'Antony', last_name = 'Colles', signature = '22035', cons_date = '2022-02-08 12:12:21', consent_form_complete = '0'
08-02-2022 12:12	[survey respondent]	Updated Response 7	elig_1 = '1', elig_2 = '1', elig_3 = '1', elig_calc = '3', eligibility_complete = '2'
08-02-2022 12:12	[survey respondent]	Created Response 7	pis_notint = '1', record_id = '7', pis_complete = '2'

...ging system built in

...a history button on each field

...require reasons if field data changed

...get page views as well as edits

H
Agree

Data History for variable "cons4" for record "1"

Listed below is the history of all data entered for the variable "**cons4**" for Record ID "**1**". The data history results are sorted from earliest to most recent.

| Date/Time of Change	User	Data Changes Made
07-02-2022 17:13:28 (most recent data change)	[survey respondent]	Agree (1)

Close

Making things look nice

Some things to consider/you can do:

- Localising for sites – site logos and names

- Matching branding, colour schemes and logos to create continuity

- Including images, e.g. on PIS

- Making buttons bigger, enhanced radio buttons

OOOOO PRETTY
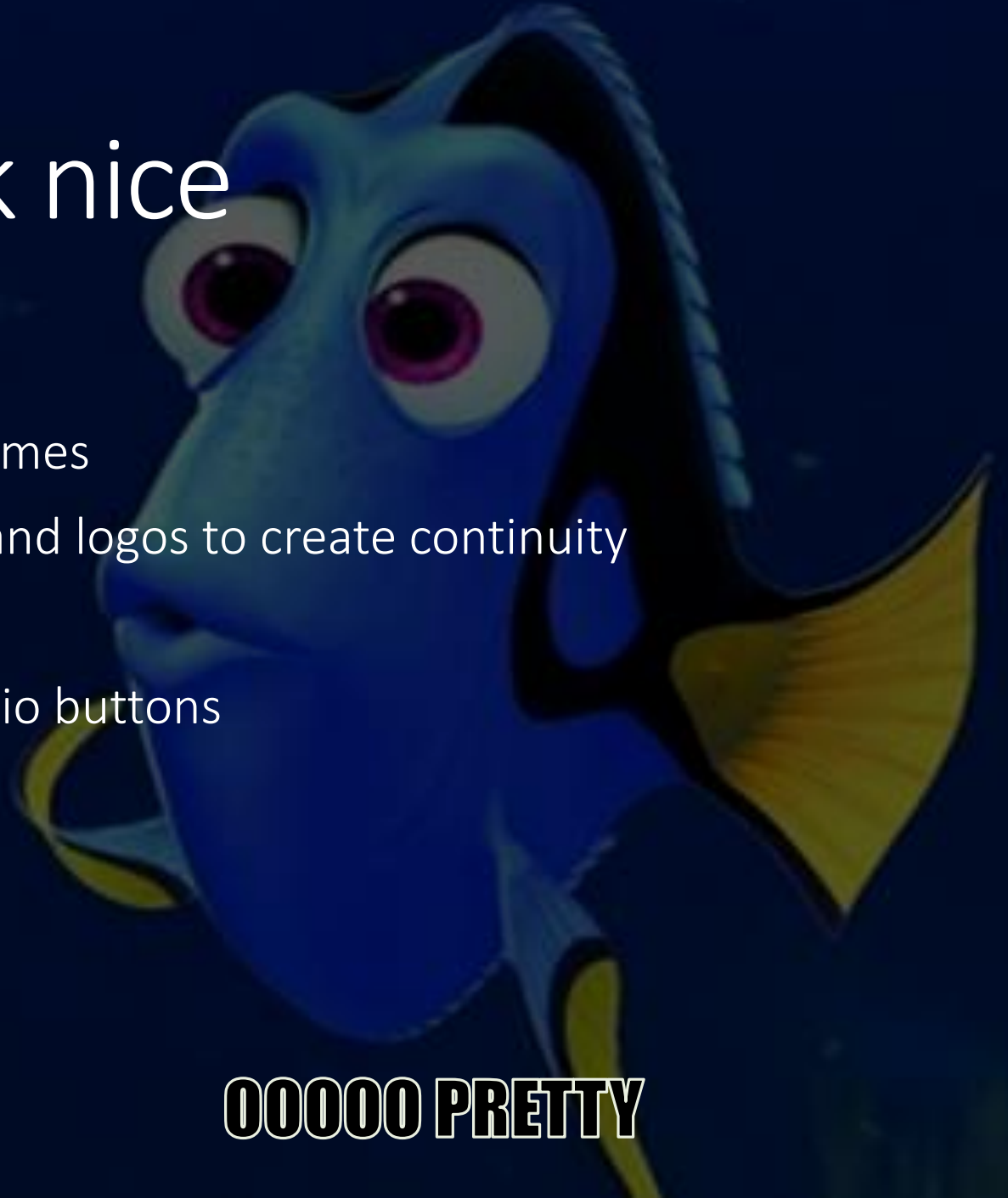
Examples

Note – these are suggestions only, there's more than one way to do things and one solution won't fit all
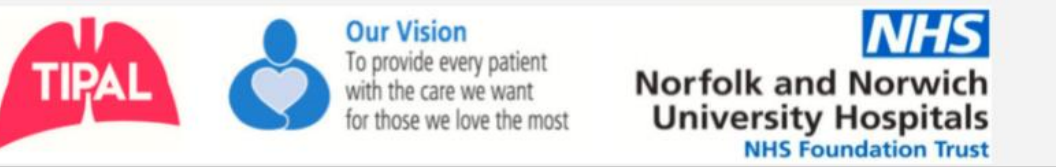
Localising for sites

- Descriptive field with header and site logo
- Branching logic/smart variable to display only at site

Logic to only show image if record is in e.g. the Norwich site:

`[record-dag-name]='01_norwich'`

Counter-signing

Suggest separate forms for participant and researcher to sign:

Stops accidental overwriting

Allows more control over permissions and timing (e.g. can stop researcher signing before participant)

External modules

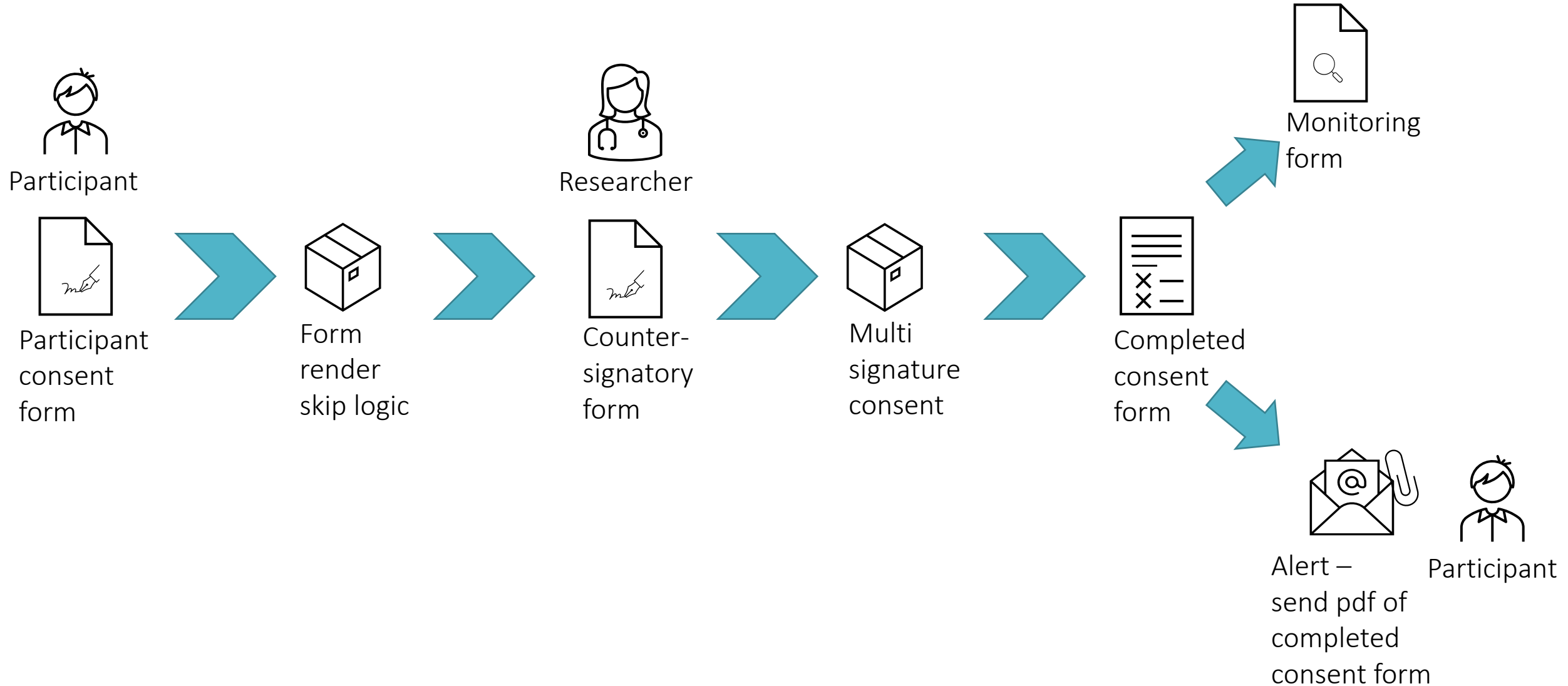Form Render Skip logic – enable counter-signature form once participant form completed

Multi signature consent – merge two pdfs together and save in a specified "file upload" field

Extras

Can then download, print or email pdf to participant and for site

Monitoring page can be used – image viewer external module, and reports to keep track of what needs to be checked/deleted as appropriate

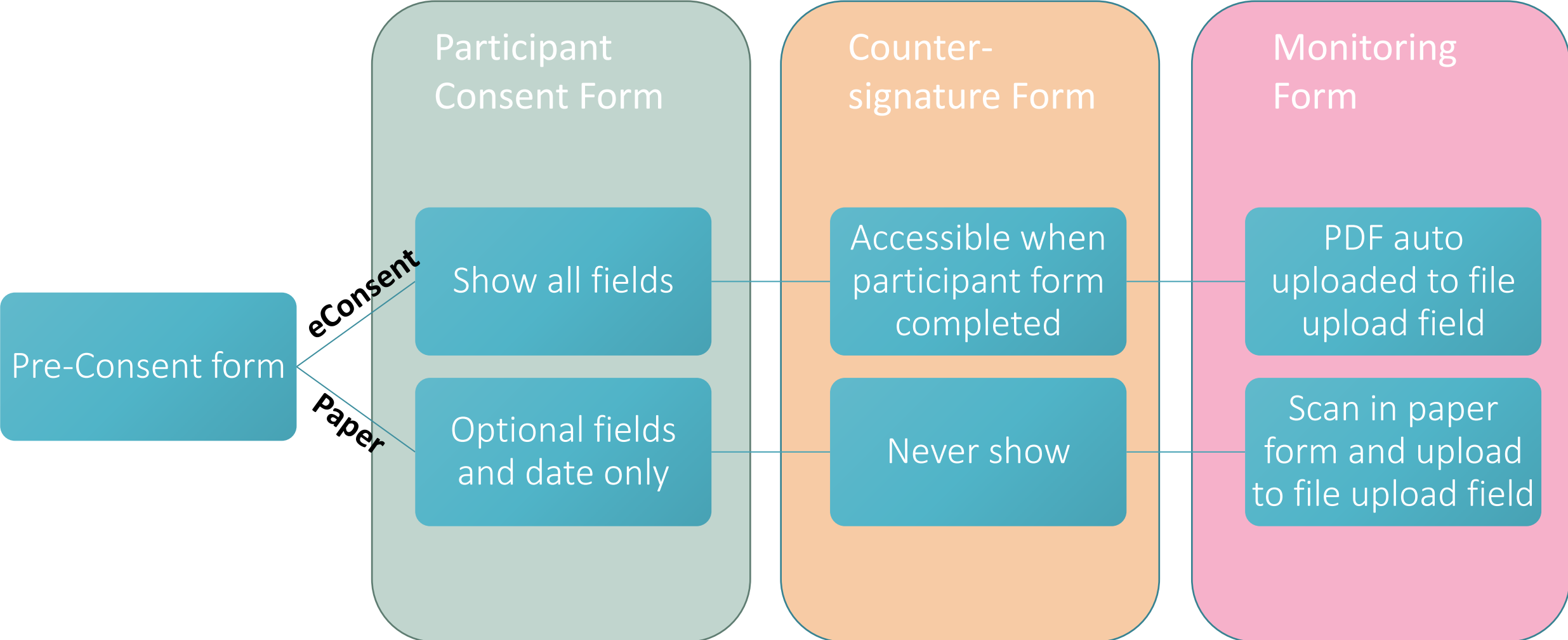# Counter-signing

Participant

Participant consent form

Form render skip logic

Researcher

Counter-signatory form

Multi signature consent

Completed consent form

Monitoring form

Alert – send pdf of completed consent form

Participant

Mixed/hybrid paper and eConsent

- Requires 4 forms
  - **Pre-consent form**, recording whether consent will be eConsent or paper, and drop down list with the version of PIS and ICF being used
  - **Participant consent** form – branching logic to show all questions if eConsent, and only optional consent questions and consent date if paper consent
  - **Countersigning** form – only shows if eConsent selected AND participant signature and name are in consent form
  - Consent form **monitoring** page – has 2 upload fields, one for eConsent and another for paper, which show depending upon which option selected in pre-meeting form, and fields to record the date reviewed by the monitor.

Mixed/hybrid paper and eConsent

Pre-Consent form

eConsent →

Paper →

Participant Consent Form

- Show all fields
- Optional fields and date only

Counter-signature Form

- Accessible when participant form completed
- Never show

Monitoring Form

- PDF auto uploaded to file upload field
- Scan in paper form and upload to file upload field

Things to consider – common issues

- Rolling out new PIS/ICF versions-process
- Browser compatibility –
  - some browsers (usually IE) don't play well with some Ems or inline PDF viewer
  - eConsent Framework can cause issues on mobile devices
- Researchers overwriting survey responses
- Participants misunderstanding process
  - downloading eConsent form and completing on paper,
  - using wife's details
- Resending emails process
  - e.g. if typo in address or caught in spam filter

Where to get help

- **REDCap forum** –www.community.projectredcap.org

- **UKCRC REDCap user group** – for current REDCap users, email regctus@leeds.ac.uk to join.

- Google! – lots of good resources, guides and videos e.g. ITHS website has lots of useful REDCap information

- Forums – www.trialaborate.org.uk/forums REDCap board Suggest we put some of our discussions on there.

- Our next webinar!

**"REDCap eConsent clinic" –
28th February 12:00-13:00**

Next session details

"REDCap eConsent clinic" – 28th February 12:00-13:00

Sign up - https://norwichcrtu.uea.ac.uk/econsentweb/

Ask questions/topics for the **next session** :

- o in the feedback form
- o come along and ask in the session

Please complete the **Feedback form** after this session – thanks!

Questions

- Session 2 feedback form, thanks!