Joint TMRP Health Informatics Working Group, UKTMN & UKCRC CTU Network e-Consent Survey

The Highlights
Survey Steering Committee

The study steering committee comprises:

- **TMRP HI WG:**
  - Matt Sydes (UCL)
  - Amanda Farrin (Leeds)
  - Duncan Appelbe (Oxford)
  - Carrol Gamble (Liverpool)

- **TMRP:**
  - Paula Williamson (Liverpool)

- **UKTMN:**
  - Eleanor Mitchell (Nottingham)

- **UKCRC**
  - Helen Evans (Leeds)
  - Sharon Love (UCL)
  - Lucy Culliford (Bristol)
  - Katie Gillies (Aberdeen)
  - Kerry Hood (Cardiff)

With the survey being developed by DA, AF, MS, EM, SL & Judith Bliss (ICR).
Background

• Definition of eConsent (MHRA):

“The use of any electronic media (such as text, graphics, audio, video, podcasts or websites) to convey information related to the study and to seek and/or document informed consent via an electronic device such as a smartphone, tablet or computer”

• Survey opened 27Apr2021 and closed 14Jul2021

• The Survey asked
  • CTU level questions around plans, preparations and guidance used
  • CTU level questions around processes
  • CTU level Information Systems approaches/issues/validation/solutions
  • CTU level QA queries
  • If CTU’s could provide data from example CTIMP/ATIMP/non-CTIMP studies with
    • Trial specific questions on implementation/operational aspects
  • At each level asked if there were outstanding questions/what did you wish you had known
Responses

- Thirty-four (64%) of 53 UKCRC CTU’s completed the survey.

- Of the 34 responses received, 21 CTUs (62%) stated that they were currently using any form of eConsent in any trials or were currently integrating eConsent into an existing trial.

- Of the 13 CTU’s who responded that they were not using eConsent, seven (54%) stated that they planned to implement eConsent in the next 6-12 months.
What Studies were reported on ....?

Number of CTU's reporting (N=21)

- CTIMP
- non-CTIMP
- CTIMP Non-CTIMP
- CTIMP ATIMP

What are you using eConsent to record

- Consent of patients lacking capacity
- eSignature
- Paediatric Assent
- Provision of PIS
- Record of Discussion
- Sending Consent form to participant

CTIMP  nonCTIMP
### Reasons why CTU’s are not implementing eConsent in the next 6-12 months

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of Responses</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waiting for more mature technology</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Worried about regulatory issues</td>
<td>1 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Patient population may not wish to use eConsent approaches</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Would like more guidance before implementing</td>
<td>3 (50%)</td>
<td></td>
</tr>
<tr>
<td>Worried about security</td>
<td>1 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Lack of resource</td>
<td>2 (33.3%)</td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td>3 (50%)</td>
<td></td>
</tr>
<tr>
<td>Need to know a tried and tested method is available</td>
<td>2 (33.3%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (33.3%)</td>
<td></td>
</tr>
</tbody>
</table>

- Six CTU’s
- More than one answer allowed

These themes are repeated in the questions attendees have posed

- Looking to purchase a system
- No suitable trials in this period
Preparatory Work from CTU’s looking to implement or have implemented eConsent

- Suitable Software
- Available Guidance
- PPI
- Data Protection
- Fit in study pathways
- Cost
- Comply with regulations

Looking to Implement: Suitable Software - 6, Available Guidance - 25, Data Protection - 8, Comply with regulations - 4
Implemented: Suitable Software - 2, Available Guidance - 5, Data Protection - 4
Guidance Referenced
Challenges ....

Top Challenges

- Resources
- Practicality
- Not determined yet
- New way of working
- IT Equipment
- How to ensure site engagement
- Governance of remote eConsent
- Change management process
- Interpretation with guidance
- Audit Trails
- Patient understanding of study
- Data Protection
- Cost - limited funding
- Compliance with regulations around consent
- Acceptable to sites/ppts
- Acceptable to or Approval of Sponsor
- Software

Looking to implement vs Implemented
How does the Consent Discussion Take place?

- Face-to-Face e replacing paper
- No researcher contact
- Phone/Video call

CTIMP | non-CTIMP
Identity Checks

The identity of the participant was confirmed in several different ways (more than one option could be specified) ranging from direct contact (either in clinic [N=17] or phone/video call [N=20]) to sending the participant an electronic link to their phone/eMail (N=21).

Given that the use of electronic systems has the potential for automating checks between delegation logs and eConsent forms, CTU’s were asked how they confirmed that researchers taking consent were on the delegation log. Responses here (multiple allowed) ranged from electronic check between systems (N=5), enabled based on role when they log in (N=10) to manual checks (N=18).
Feedback from Approval Bodies

At the time of the survey the MHRA had not inspected any responders using eConsent
How have Sites taken to your approach

- Learning Curve
- Mixed
- Not yet known
- Like it
- Prefer it to paper

CTIMP vs non-CTIMP
How do you ensure that site retains a copy of the ICF

Central Monitoring | Checked at site closure | Still to be finalised | Retained in electronic system

CTIMP | non-CTIMP

0 | 3 | 1 | 5
Systems utilised to provide eConsent

- Bespoke
- Docusign
- Medidata RAVE
- MedSciNet
- OpenClinica (Participate Module)
- Qualtrix
- REDCap
- REDCap Cloud
- Sealed Envelope (Red Pill)
Security of data

The security of consent form data (including PID) is in the main based on the security of the server hosting the application and roles within the eConsent software/server. Only five CTU’s stated that the consent data was encrypted at rest.

Those studies that send the consent form to the participant were further asked if they encrypt the consent form and if so, how they provide the key to the recipient. The responses provided were:
- No – not encrypted (N=18)
- N/A (N=3)
- Yes (N=2)
  - System generated code given to participant by site
  - E-Mail with link
- Downloaded direct (N=1)
What else would we still like to know?

- Better Guidance (CTU Level, QA, IS, TM)
- Practical Examples (CTU Level, QA, IS, TM)
- Expectations from Regulators
- What other CTUs have done
- Best mechanism for transferring Consent forms to participant

Next two speakers/other attendees

Opportunities today
Thanks to all of those CTUs that responded to the survey.

Any questions please contact me at: duncan.appelbe@ndorms.ox.ac.uk
eConsent in the VROOM Trial

Presented by
Lucy Cureton
Clinical Trials Manager
OCTRU (Oxford Clinical Trials Research Unit)
eConsent in the VROOM study

- **The Trial:** VROOM: vaccine response on/off methotrexate: does temporarily suspending methotrexate treatment for two weeks enhance covid-19 vaccine response? A Randomised Controlled Trial. Urgent COVID study!
- **Why eConsent?** A move towards paperless studies within OCTRU. Protocol states that paper consent can be used if needed – so far not happened.
- **How?** Consent taken electronically at face-to-face baseline clinic visit at participating centre. Sites provided with an iPad. VROOM ethically approved paper consent form converted into a data matrix which is then programmed into REDCap database. Consists of radio buttons, optional statements (Y/N), space for electronic signatures, date fields and validation to ensure no fields missed/completed incorrectly.

Once completed, a PDF version of the consent form is automatically emailed to the participant and becomes available in REDCap for sites to download for filing in site file and medical notes.
Nuances to eConsent system

- So many nuances! We refer to the VROOM database as having a lot of ‘bells and whistles’
- Part of VROOM is asking participants how they would like to be contacted with reminder messages and questionnaire - email/postal/telephone. These options have been included on the consent form and these fields ‘trigger’ certain actions e.g. if the participant selects that they wish to receive a text message to remind them what intervention they have been allocated to, the study database systems are programmed to send SMS text messages to the participant at the relevant time points.
- ‘Flow’ of forms: in REDCap’s survey mode, once a form is completed, the next form in the process automatically opens. Ensures no forms or missed or completed at the wrong time.

Baseline part 1 ➔ consent form ➔ baseline part 2 ➔ contact details ➔ participant questionnaire
Nuances to eConsent system

- Some fields in the eConsent are ‘piped’ through to other CRFs. Date of consent is used as validation on other date entries in later forms, e.g. date of blood sample cannot be before date of consent.
- Pre-populated read-only fields for ease of completion and QA: date set for today’s date, participating site and participant ID number.
- Using form render skip logic, other CRFs can’t be started until consent successfully completed.

Ability to run reports on consent form data, for example, to see patients’ contact preferences for receiving reminders about the VROOM study. Can’t do that with paper!
REDCap reports and OCTRU’s Study Information Management System (SIMS) make it easy to pull real-time data in this way.
Challenges with implementing or managing eConsent

- Linked CRFs, a mistake in one CRF can lead to it being cascaded to the CRFs it is linked to.
- Front loaded process; large amount of work required up front in building and testing the database, but saves time across whole of trial as many systems are automated.
- Process to send consent forms to participants’ email addresses, if entered incorrectly email bounces back and we have to send the consent form manually.
- Every time there is an amendment to the consent form, updating the form on REDCap, re-testing, and releasing is quite an involved process.

Quote from VROOM study nurse: Using the electronic consent has been really easy to use. The best part about it is it can be accessed from any iPad or computer and you don’t have to worry about which version the consent form is as it’s managed from CTU end. Patients have found it easy to use too and the electronic signature is always a talking point. I really think this should be used in all the studies I am involved in.
Bristol Trials Centre case study: including remote e-consent in the CO2 study

Rachel Todd
Senior Research Associate in Clinical Trials Management
Carbon Dioxide Insufflation and Brain Protection During Open Heart Surgery: A Randomised Controlled Trial

**Design:** Multicentre, parallel two-group placebo-controlled blinded Randomised Controlled Trial

**Study population:** Patients aged 50 years and above undergoing left side heart valve repair or replacement

**Aim:** To evaluate the efficacy and safety of CDI in patients undergoing planned open left side heart valve surgery.

**IMP:** Carbon dioxide insufflation

**Placebo:** Medical air insufflation

**Primary outcome:** Acute ischemic brain injury within 10 days post surgery
Remote e-consent process

Call the patient to discuss the study and answer any questions they have.

Ask patient for their email address

Enters patient’s email address into REDCap e-consent module.

Patient receives email with link to the electronic form

Each consent item discussed with the patient, patient initials and the electronically signs the form

Electronic consent form reviewed and electronically signs by person taking consent to confirm they obtained consent.

Patient receives email with link to download PDF of the consent signed by both parties, their records. Clinician/Research Nurse prints PDF of consent and files.

Reduced admin and paper usage

Dedicated ‘space’ and time for consent

Pandemic induced technical competence

Compliments other consent methods

‘Easier for patient’
Using an ‘off the shelf’ system

- REDCap e-consent module
- Modified to mirror paper consent process
- Fail safes added
- Very little remains the same
- Bespoke may have saved time
Challenges implementing

- HRA/MHRA guidance
- Centre uptake
- Sponsor
- Amendment required if not already implemented / changes to materials
- Development / testing time
- Transfer/storage of patient identifiable data
- Patient uptake