



Implementation of REDCap eConsent in a multisite RCT

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Why REDCap eConsent?

- Flexibility in the consent process while retaining regulatory compliance
- Investigator availability on-site can limit opportunities for consent

Aim: Implement REDCap eConsent 2.0 in the OLAM multisite RCT to increase opportunities for recruitment through remote consent

What we built

- | | |
|---|---|
| eConsent 2.0 provided: | We added: |
| ✓ Electronic signatures + certification step (Fig. 1) | → Site-specific workflow |
| ✓ PDF snapshots | → Participant + investigator forms (Fig. 2) |
| ✓ Version management | → Witness + compliance fields |
| ✓ Multisite/DAG functionality | → PICF version checks |
| ✓ Logging/audit functionality | → Reconsent process |
| ✓ User access controls | → Training + monitoring processes |
| | → Extra DAG + PDF snapshot functionality (Fig. 2) |
| | → User Rights History external module* |

**Subject to REDCap administrator approval/testing. In our trial, logging and user permissions were highly restricted; User Rights History provides a record of changes to these settings.*

What we learned

- **FLEXIBILITY:** greatly improved investigator availability
- **TRAINING:** supported by an SOP, training video/workshops and a checklist
- **MAINTANANCE:** not ‘set and forget’ - PICF versions, user access, and monitoring require ongoing oversight
- **CUSTOMISATION:** study-specific adaptations were needed to meet ethics requirements* and improve useability

**Ethics approval of the eConsent process and associated documents is required; screenshots or database access may also be requested.*

☒ I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

Figure 1: added signature certification step not present in the previous (legacy) REDCap eConsent.

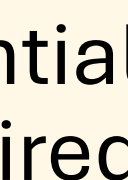
 Data Collection Instrument	Status
OPEN ME FIRST	
Participant eConsent - Main Study (survey)	
Person Obtaining eConsent - Main Study (survey)	
Participant eConsent - First Nations Sub Study (survey)	
Person Obtaining eConsent - First Nations Sub Study (survey)	
Signed eConsent PDFs	

Figure 2: the OLAM RCT eConsent instruments - the first form assigns the potential participant to the correct site/DAG. The potential participant (and witness, if required) then completes the relevant consent form(s), followed by investigator countersignature. Additional PDF snapshots combine the completed consent components, with the final PDF(s) available in the last instrument for download and filing.

Conclusion: REDCap eConsent 2.0 enabled remote investigator-supported consent in the OLAM multisite RCT, but implementation required study-specific workflows, training and ongoing maintenance.

**REDCap provides the technology.
The trial team builds the process.**

Want to know more or discuss REDCap eConsent?

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