Newcastle REDCap Electronic Consent

NJRO-INF-SOP-003

Contents

1. Background/Introduction

Electronic Consent (eConsent) is the process of seeking, confirming and documenting informed consent in research studies using electronic means. Remote Electronic Consent is an extension of this, using electronic systems to consent without the patient being required to physically attend a research appointment.

The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) offers the facility to electronically and remotely consent via Newcastle REDCap for research projects in accordance with HRA and MHRA guidance **(7.1)**.

This SOP should be used in conjunction with Newcastle REDCap Data Security SOP **(8.1)**.

2. Purpose

To describe the responsibilities of NuTH, Newcastle REDCap Administrators and Newcastle REDCap users when using Newcastle REDCap to conduct electronic consent in person and/or remotely.

3. Scope of Document

Applicable to all staff using Newcastle REDCap to electronically consent.

4. Definitions

CTIMP - Clinical Trial of an Investigational Medicinal Product
HRA – Health Research Authority
MHRA – Medical and Healthcare products Regulatory Agency
NJRO – Newcastle Joint Research Office
PIS – Patient Information Sheet

5. Roles & Responsibilities

It is the responsibility of the researcher(s) to ensure their eConsent process meets the guidance set out by relevant health and research organisations. The NJRO Governance Team are responsible for signing off the appropriate consent process based on risk level.

6. Procedures

6.1. System

- eConsent should be conducted on Newcastle REDCap.

6.2. Local approvals

- The intended type of eConsent must meet requirements dependent on the nature of the project/study, as set out by the HRA and MHRA **(7.1)**

- Remote eConsent processes must be appropriate for the risk level of the study, as confirmed by the NJRO Governance Team. The risk levels and process descriptions are as follows:
  - Low-risk: Participants can choose to self-consent, but are always given the opportunity to ask questions
  - Medium-risk: Participants can choose to self-consent, but must prove that they have read the PIS and answer questions about it
  - High-risk: Participants must always have a consent phone/video call
- The intended eConsent process must receive all usual approvals (e.g. ethical approval, Caldicott) before consent can take place via REDCap.

6.3. Authentication

- Authentication of patient identity must be appropriate for the risk level of the study as in section **6.2**.
- All eConsent forms in REDCap must use the 'signature' field type to capture a digital representation of the patient's usual signature, regardless of risk level.

6.4. Devices

- NuTH sponsored studies should use pre-configured NuTH Clinical Research Participant Tablets when electronically consenting in a face-to-face setting
  - Devices other than this may be suitable if agreed by local governance, but it should be demonstrated that functionality which could risk patient confidentiality (such as Autofill, access to drives, etc.) is disabled.
- When handing a device to a participant for use in face-to-face eConsent, staff must always use the 'Open survey and log out' function to ensure all other areas of REDCap are inaccessible to participants.

6.5. Form design

- eConsent forms will be created with support from the Newcastle Research Informatics Team
- There is no prescriptive eConsent form design, however they must include as a minimum:
  - Project title
  - Consent form version number
  - Patient information sheet version number (where applicable)
  - Consent questions
  - Patient's full name
  - Patient's signature
  - Date of consent

6.6. Staff signatures

- When necessary, signatures from staff taking consent will be captured on the eConsent form or in an accompanying attestation form(s)
- Accompanying attestation form(s) will be automatically combined with the signed patient consent form via the 'Multi Signature Consent' or 'Paper Trail' **(7.2)** external module **(7.3)** to form a fully consented PDF document, stored in a file upload field in the REDCap project or in the REDCap File Repository.

6.7. Patient copies

- Finalised consent forms are stored as PDF files in a file upload field in the REDCap project or in the REDCap File Repository.
- The final PDF version of the consent form should be considered as the actual consent form, **not** the REDCap data collection instrument.
- It is the responsibility of researchers to ensure the participant is provided with a copy of the consent form.
- The REDCap alert module will optionally send out an automatic e-mail copy of the fully consented PDF document to the participant upon creation, if requested in the project design.

6.8. Additional PDF copies

- It is the responsibility of researchers to ensure additional copies of the consent form are downloaded and utilised when necessary (e.g. patient notes)
- As consent forms are considered identifiable, additional PDF copies can only be downloaded by nominated individuals. It is the responsibility of these individuals to ensure PDF copies are downloaded only to devices in accordance with local data protection and data security compliance.

6.9. Version control

- New versions of the eConsent form will be created as a new eConsent instrument within REDCap
- Expired versions of the eConsent form will be deactivated upon activation of a new eConsent form

7. References

7.1 MHRA and HRA Joint statement on seeking consent by electronic methods

7.2 Multi-Signature Consent REDCap External Module

7.3 Paper Trail REDCap External Module

8. Appendices

8.1 NJRO-INF-SOP-002 Newcastle REDCap Data Security SOP