SOP 25 Associated Document 2

Guidance document on seeking consent by electronic methods

The Joint Research Management Office (JRMO), covers the consent process in *SOP 25 Informed consent* and although e-consent is mentioned, there are no specific details relating to this, therefore this guidance should support the review of any e-consent process and is an associated document to SOP 25.

Health Research Authority (HRA) produced guidance in 2017 on consent https://www.hra.nhs.uk/about-us/news-updates/hra-publishes-new-proportionate-consent-guidance/ which lays out a proportionate approach which the JRMO supports.

In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) and HRA produced in 2018 a joint statement on E-consent and follows this same principle to help researchers with new approaches to consent: *https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/*

The statement outlines that electronic signatures can be divided into three groups:

a. Simple electronic signatures – examples are a stylus or finger drawn signature, a typed name, a tick box and declaration, a unique representation of characters and a fingerprint scan.
b. Advanced electronic signatures – these are uniquely linked to the signatory, are capable of identifying the signatory, allow the signatory to retain control, and are linked to data within the signature that can detect any changes made. (eSignatures traced with a finger or a stylus or biometric eSignatures)
c. Qualified electronic signatures – an advanced electronic signature, uniquely linked to the signatory, that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures.

In addition to this guidance the Chief Investigator (CI) and JRMO teams should consider and discuss the ability of the studies target population to interact with electronic consenting.

1. Queen Mary University of London (Queen Mary) and Barts Health NHS (Barts Health) Sponsored research

Study type	Additional risk type	JRMO risk score	Type of E consenting permitted
MHRA Regulated Studies*	Type A	Low risk	Simple electronic signatures
	Type B and C	Moderate and high risk	Advanced electronic signatures or Qualified electronic signatures
Interventional studies		Low risk	Simple electronic signatures
		Moderate risk	Simple electronic signatures permitted but advanced electronic signatures or Qualified electronic signatures may be preferable and should be considered in the light of the importance of future audit.
		High risk	Advanced electronic signatures or Qualified electronic signatures
Research studies		Low risk and Moderate	Simple electronic signatures
		High risk	Simple electronic signatures permitted but advanced electronic signatures or Qualified electronic signatures may be preferable and should be considered in the light of the importance of future audit. For further guidance please see *Guidance Documents for e-Signatures.*

The advice given is based on risk and below we have transcribed this into JRMO terminology for local application:

a. For clinical trials of investigational medicinal products (CTIMPs) the methods used to inform and document the consent of participants need to comply with the requirements of The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) (also referred to as the 'Clinical Trials Regulations'). The MHRA and HRA statement focuses on face to face consent with e-documentation and suggests that remote e-consenting is rare. In current climate this is no longer the case with more researchers wishing to conduct remote consenting and using e- documentation.

b. Where face-to-face verification is possible, and can be completed prior to the participant receiving any research intervention, a simple electronic signature (such as a handwritten signature using a finger/stylus or biometric eSignature) will normally be acceptable to document consent (face to face verification of identify i.e. in person using information from official photo ID/ Hospital notes).

c. Where it is not possible to verify that the participant is who they say they are, for example by checking official photo ID, it may be preferable (though not legally required) to use an advanced or qualified electronic signature that uniquely identifies the individual signing and thus provides greater assurance.

Requirements for any e-consenting system

a. Full compliance with Computer system validation process outlined in *SOP 38 series:*
    i. MHRA regulated: Documentation to be reviewed by GCP team as part of sponsorship process set up.
    ii. Interventional and research studies- study team to provide statement of compliance during Sponsorship process.
b. Written agreement, or contract in place with Software provider or System provider (this includes AWS, DocuSign and all other service providers). In some cases the researcher will 'merely' be asked to set up an account with the provider and standard T&C implemented. If this is the case the account details and a copy of the T&C should be downloaded and retained in the TMF.
c. Barts Health and Queen Mary DPIA screening form completed and process signed off by the relevant IG team as part of the sponsorship set up process.
d. Provide written explanation how system will be archived for 25/5years (see *SOP 20 Archiving*) and how site will retain direct access to consents both during the study and archiving period.

2. Hosted or externally sponsored research

a. Use of e-consenting must be flagged at capability and capacity review stage.
b. Sponsor must provide written explanation of compliance with MHRA and HRA statements and that the system in use has been validated. JRMO does not need to see or review documentation.
c. Sponsor must explain how system will be archived for 25/5years (see *SOP 20 Archiving*) and how site will retain direct access to consents both during the study and archiving period.