

Guidance: Seeking consent by electronic methods (eConsent)

This guidance is applicable to all researchers seeking informed consent by electronic methods (other than those conducting Clinical Trials of Medicinal Products (CTIMP) – see separate HRA guidance).

Electronic methods may be used for seeking, confirming and documenting informed consent in research studies.

Electronic signatures are classified as 'simple,' 'advanced' or 'qualified'. The type of electronic signature that should be used in a study depends on whether the recruitment and consent procedures taken as a whole (and considered as part of a proportionate approach) mean that you:

- can trust that the person who signed is who they say they are
- can trust that the consent form they signed has not been altered
- can trust when the signature was applied
- can demonstrate that trust if required

Introduction

Seeking informed consent is central to the conduct of ethical research and properly respects a person's right to determine what happens to them. Wherever possible and appropriate, potential research participants should be provided with the information they need to help them decide whether they wish to take part in the research or not. This information is traditionally provided in the form of a paper participant information sheet (PIS) and a face-to-face discussion with one of the investigating team. If the individual agrees to take part, they are usually asked to sign a paper consent form.

Electronic methods for seeking, confirming and documenting informed consent are increasingly being adopted by researchers: either to supplement the traditional paper-based approach or, where appropriate, as a replacement for it.

Whilst it is acceptable to use online text or multimedia material as the primary means of informing potential participants, researchers should be mindful of the possibility that the use of such methods may unintentionally discriminate against people who are not comfortable with or who cannot use such technology. Alternative methods for the provision of information and/or documentation of consent should be available for those unable or unwilling to use electronic methods.

Regardless of whether paper or multimedia formats are used, it is often the face-to-face communication between one or more members of the research team and the potential participant that will be the most effective way of improving potential research participants' understanding of what is involved.

Whilst a consent form provides an important audit trail and assurance that the consent process was conducted appropriately, a signature on a consent form (regardless of whether it is wet-ink or electronic) does not determine that the consent given has been sufficiently informed and is legally valid. Researchers should always assure themselves that the participant (or their legal representative) has actually understood the information provided.

Electronic signatures

What is an electronic signature?

The UK eIDAS regulation (which refers to the EU eIDAS regulation: Regulation (EU) 910/2014) establishes a legal framework for electronic signatures and defines an electronic signature as "data in electronic form which is attached to or logically associated with other electronic data and which is used by the signatory to sign".

Electronic signatures can include signatures that are:

- Tick box plus declarations
- Typewritten
- Scanned
- An electronic representation of a handwritten signature

- A unique representation of characters
- A digital representation of characteristics, for example, fingerprint or retina scan (*where technology allows*)
- A signature created by cryptographic means

Electronic signatures can be divided into three groups:

- 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
- 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
- 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

The use of ‘advanced’ or ‘qualified’ electronic signatures provides:

- Authentication – the signatory can be linked to the information
- Integrity – changes to the information can be detected more easily
- Non-repudiation – legal assurance regarding where the electronic signature has come from

Whilst any type of electronic signature is admissible as court evidence by virtue of the UK eIDAS regulation, some are more reliable and carry greater evidential weight and assurance than others.

Legal requirements for seeking consent

For research (that is not a CTIMP), it is not a legal requirement to provide written information or document consent in writing. Nevertheless, for the majority of research with human participants it is considered best practice and researchers should document consent unless not doing so can be justified (and approved by a Research Ethics Committee).

Participants with capacity who are unable to physically sign a paper or electronic document may provide consent orally or by any other means of communication (such as using augmentative and alternative communication methods).

What type of electronic signature should I use for my study?

The method of authentication of electronic signatures used in a study should be proportionate to:

- the nature and the complexity of the research
- the risks, burdens and potential benefits (to the participants and/or society), and
- the ethical issues at stake

In deciding which form of electronic signature is best for your study, the key question to ask will be whether your recruitment and consent procedures taken as a whole mean that you can:

- trust that the person who signed is who they say they are
- trust that the consent form they signed has not been altered
- trust when the signature was applied, and
- adequately demonstrate that trust is justified, if required (for example, in an inspection, audit or court proceeding)

The answer to this question (considered as part of a proportionate approach) will help you to decide whether a simple electronic signature may be used and, if so, what type would be appropriate. In rare cases an advanced or qualified eSignature may be more suitable.

For the majority of research involving only negligible or minimal risk (for example, face-to-face surveys or non-sensitive qualitative research) any simple electronic signature is normally adequate where it is appropriate to seek consent.

Where the research involves more than minimal risk, burden or intrusion, simple eSignatures that involve the participant tracing their handwritten signature using a finger or a stylus, or biometric eSignatures, should be considered, as they allow for direct comparison with eSignatures and/or wet-ink signatures previously used by the participant for the purpose of audit or where the consent is contested.

For postal/online surveys or self-administered questionnaire-based research where identifiable personal data are collected, and 'consent' is used as the legal basis for the purposes of compliance with the General Data Protection Regulation (GDPR), then the participant must be able to actively signify their consent. This can be achieved by providing an explicit consent statement and a tick box within the survey/questionnaire that the participant can complete if they are in agreement. A handwritten or biometric eSignature is not required.

Things to think about when using electronic methods to seek and document informed consent

- Can the signature be dated? Either manually by the participant or automatically by the eConsent system?
- Is it possible to verify to which versions of the information sheet and consent form the electronic signature applies? Note: The participant should be provided with a copy of the participant information sheet for reference.
- Are there methods in place to ensure that the person signing the electronic consent form is the person who will be participating in the research study?

Further Information

Legislation

EU Regulation on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (No 910/2014)

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2014.257.01.0073.01.ENG

EU Regulation No 910/2014 is supplemented by the Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (SI 2016/696) (the UK eIDAS Regulations)

http://www.legislation.gov.uk/uksi/2016/696/pdfs/ukxi_20160696_en.pdf

The Electronic Identification and Trust Services for Electronic Transactions (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/89) <http://www.legislation.gov.uk/uksi/2019/89/made>

Electronic Communications Act 2000 <http://www.legislation.gov.uk/ukpga/2000/7/contents>