Standard Operating Procedure (SOP)

E-Consent for Clinical Research

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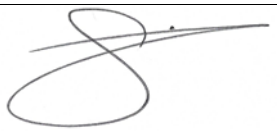
Signature of Authoriser:			

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SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Joe Montebello

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0004 Final Sponsorship for CTIMPs JRESGOVSOP0039 Protocol Design JRESGOVSOP0028 Applying for Sponsorship for Non-CTIMPs JRESGOVSOP0027 Informed Consent			

Contents

1. Background

The UK Policy Framework for Health and Social Care 2017 outlines a number of principles which serve as benchmarks for good practice for the management and conduct of health and social care research in the UK. Informed consent is a key aspect of Principle 12- "Choice".

ICH-GCP defines Informed Consent as the process by which a participant voluntarily confirms their willingness to participate in a study, having been informed of the full details of the project. Informed consent is documented by means of a written, signed and dated ICF.

Informed consent is an ongoing process. It involves giving information to the potential participant, discussing and clarifying the information, seeking their written consent and subsequently providing any new information that might affect their willingness to continue to participate in the study. In UK law 'in writing' is defined as '**typing, printing, lithography, photography and other modes of representing or reproducing words in a visible form**'.

St George's (SGUL and SGHFT) both sponsors and hosts several CTIMP and non-CTIMP research projects. Following the 2020 COVID-19 pandemic, large-scale changes have been made to clinical research protocols to align with social distancing and reduced face-to-face contact between patients and the care team. As the adoption of virtual clinics is rolled-out across the NHS, consent taken electronically ("eConsent") is likely to be the new standard for which potential research participants consent to take part in clinical research studies. eConsent has demonstrated the potential for increased patient recruitment, enhanced engagement with research participants and a greater understanding of clinical research when the information is provided in a multimedia format.

In 2018, the MHRA and HRA published a joint statement on eConsent, with basic principles that are broad enough to cover all types of clinical research and this SOP draws on the relevant guidance.

In the changing landscape that is the current patient care pathway in the health service, Sponsors should always make a provision for virtual recruitment and eConsent in order to access all potentially eligible patients to continue to deliver clinical research.

2. Joint Research and Enterprise Service (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This Standard Operating Procedure (SOP) describes the process for obtaining eConsent from a study subject and additional considerations around study design that need to be considered when undertaking a Sponsorship review. This SOP should be read in conjunction with JRESGOVSOP0027 Informed Consent.

4. Definitions

For general research-related acronyms used in this SOP, refer to the General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

JRESGOVSOP0027 Informed Consent outlines the roles and responsibilities of those taking consent, as well as the process of obtaining and recording informed consent in writing from research participants. The information provided in this SOP only seeks to provide additional guidance for obtaining eConsent and does not supersede or alter the process of obtaining informed consent according to the existing SOP.

It is the responsibility of the Chief and/or Principal Investigator and anyone delegated the responsibility of taking eConsent to read, understand and follow the eConsent procedures outlined in the study protocol and this SOP.

All participants entering into a clinical study/research project which is not classed as emergency research must have given informed consent in writing before any aspect of the project starts (interventional or non-interventional) with the original signed (either wet-ink or electronically) version filed in the Investigator Site File (ISF). A direct copy should be provided back to the participant with a copy added to their medical records together with a copy of the PIS (PIS).

For any type of clinical research study, the Chief and/or Principal Investigators and anyone delegated the responsibility of obtaining eConsent must be able to:

- trust that the person who signed is who they say they are
- trust that the consent form they signed hasn't been altered
- trust when the signature was applied

- demonstrate that trust if required

A proportionate approach to consent should be taken, in line with the HRA guidance. Dependent on the nature of the research, the perceived risk: benefit ratio and any other pertinent ethical issues, the Chief and/or Principal Investigator must ensure the appropriate type of electronic signature is sought in order to appropriately validate its' authenticity. There are three recognised groups of electronic signatures:

1. **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.

2. **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. An example of a service that can be used to provide advanced electronic signatures is DocuSign.

3. **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. An example of a service that can be used to provide qualified electronic signatures is DocuSign.

It is the Sponsor's responsibility to ensure that the appropriate type of electronic signature is sought, which should be commensurate with the nature of the research to be undertaken.

6. Procedure

6.1 CTIMP/Device trials sponsored by St George's

Written informed consent must be obtained for all CTIMP/Device trials. Electronic documentation of consent is considered to be 'written'.

All participants must be provided with a Patient Information Sheet (PIS) which may be provided electronically, where appropriate to the patient population. Participants must also be able to discuss the trial with the investigator prior to consent being obtained. Where it is not possible to do this in person, it may be conducted via a telephone conversation or video call (following approval by an ethics committee). Confidentiality must be maintained and the method must be secure.

It is essential that the identity of a participant is confirmed where the consent process is conducted remotely and that an audit trail is present to confirm that the person providing the electronic signature is actually the participant.

The type of electronic signature will depend on the nature and risk level of the trial. For lower risk trials (categorised as Type A by the MHRA), a simple electronic signature is acceptable. Higher risk trials (Type B and C) should use an advanced or qualified electronic signature. Signatures must also be dated manually or automatically by the system.

Participants must be provided with a copy of the signed/dated consent form which can be provided electronically.

The following must be considered when using electronic methods for obtaining informed consent in CTIMPs/Device trials:

- Access to the e-consent system for regulatory inspections/audits.
- Assessment of any third party vendor providing the e-consent service, for GCP compliance and maintenance of participant confidentiality. Availability of the source consent documentation for monitoring visits and for regulatory inspections.
- Provision of the consent documentation, including the signed consent form, to the participant.
- Retention of the consent documentation in the Investigator Site File (ISF).

More guidance on e-consent specifically for CTIMPs can be found here: https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

6.2 Non-CTIMP/Device studies sponsored by St George's

Although it is not a legal requirement, written informed consent must be obtained for all non-CTIMP/Device research studies. Electronic documentation of consent is considered to be 'written'.

At the point of protocol design, the Chief Investigator should consider which type of electronic signature is most appropriate in line with the nature of their research and should seek advice from JRES for the avoidance of doubt.

For observational studies deemed to be low-risk to patients, such as questionnaire or data collection studies that do not impact the patient's care pathway and are perceived to have a very low burden on patients, a simple electronic signature should be sufficient. An appropriate simple electronic signature could entail a tick-box *in lieu* of a wet-ink signature or a space to allow the patient to trace their name with a finger or stylus.

For interventional studies or observation studies that are deemed to be of higher risk to patients, an advanced or qualified signature should be sought. For example, using a third party electronic signature service such as DocuSign meets the eIDAS EU Regulation criteria for both advanced and qualified signatures.

Information should be provided to potentially eligible participants in exactly the same format (Patient Information Sheet (PIS)) but this can be provided to patients electronically. An electronic consent form (eICF) should use exactly the same format and wording as the current JRES template ICF but can be modified to allow for its' use as an eICF, for example by converting it into a PDF fillable form.

The Principal Investigator or delegated member of staff, who is also part of the direct clinical care team should first contact the potentially eligible patient by telephone to introduce themselves and to explain the study. If the patient is amenable, the PI or delegate will verify the patient's email address to send them an electronic copy of the PIS and eICF for their review by email and will agree a time to call the patient back to obtain consent. If the patient has a shared/family email account, the PI or delegate should make the patient aware of potential risk of a breach of confidentiality by sending information to this account.

The PI or delegate should call the patient back at the agreed date and time, to further discuss the study and answer any questions that the patient has. If the patient is still willing to participate, the PI or delegate will ask the patient to sign the eICF remotely and return to them by email. The PI or delegate will countersign the eICF and return a fully-signed copy to the patient, while retaining one copy for the ISF and another for upload to the patient's electronic medical records.

Should potential research participants be unable or unwilling to provide written informed consent electronically, alternatives such as postal consent or seeking consent at the next face-to-face outpatient appointment should be sought.

6.3 All studies hosted by St George's

Principal Investigators and delegated members of the research team should follow the procedure as outlined in Section 6 of the JRESGOVSOP0027 Informed Consent and the Sponsor's protocol.

7. References

ICH GCP

https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

8. Appendices

None.