



STANDARD OPERATING PROCEDURE FOR RECEIVING INFORMED CONSENT FROM POTENTIAL PARTICIPANTS IN CLINICAL RESEARCH

SOP NUMBER:	TASC SOP07 v10
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1. PURPOSE

This document specifies the procedures for receiving written informed consent from individuals considering participation in clinical research sponsored or co-sponsored by NHS Tayside (NHST) and/or the University of Dundee (UoD).

This SOP does not apply to receiving consent from adults with incapacity or children; both of which require study specific consent process/documents.

2. SCOPE

This SOP applies to all staff, involved in the informed consent process, employed by UoD/NHST.

Research staff employed externally may follow their own institution's SOP if fit for purpose and agreed by the Sponsor at Site initiation.

This SOP applies to any research staff not employed by UoD/NHST who do not have a local SOP that is fit for purpose.

3. RESPONSIBILITIES

Chief Investigator: Ensure all written information provided to participants has been approved by the Research Ethics Committee (REC) prior to the study commencing.
Ensure all staff receiving informed consent are adequately trained and on the Delegation Log.
Ensure that informed consent is received before the initiation of any procedures, tests or treatments required by the study protocol and which are not considered part of routine clinical care.

Delegated staff: Ensure they are trained in the protocol and procedure.
Be prepared to take on this responsibility and feel confident to receive consent in line with codes of professional conduct.

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4. PROCEDURE

4.1 Information provided to participants

- 4.1.1 All information provided to potential participants must be presented in terms and in a form that is easily understood, generally this is in a Participant Information Sheet/Leaflet (PIS/L). The PIS must adhere to the specific guidance and template available from the Health Research Authority (HRA) website (search for online consent guidance tool). The HRA recommended wording for General Data Protection Regulations (GDPR) compliance must be used. With regard to insurance, Sponsor will provide the appropriate text. The document must be version controlled and approved by a REC.
- 4.1.2 A record must be kept of the version of the PIS/L given or sent to the participant and the date when this occurred. This is to ensure that the participant has as much time as required to read and understand the information or to seek advice from others.

4.2 Who can receive Informed Consent?

- 4.2.1 The protocol must set out the consent process- who is contacting the participants and who is receiving written informed consent. This can be by defining the role i.e. Principal Investigator or research nurse.
- 4.2.2 Each individual who is delegated the task of receiving informed consent must receive documented protocol training and be named on a Delegation Log.
- 4.2.3 All staff responsible for receiving informed consent must be Good Clinical Practice (GCP) trained.

4.3 The process of informed consent

- 4.3.1 Discussion with a potential participant should take place in confidential and appropriate surroundings.
- 4.3.2 Only the individuals named on the Delegation Log are permitted to receive informed consent from participants.
- 4.3.3 Investigators, co-investigators and staff named on the Delegation Log cannot be consented into the study.
- 4.3.4 The participant's name and date of birth should be verified and documented, and the participant asked to confirm that they have had time to read and understand the PIS/L.
- 4.3.5 The participant is to be invited and encouraged to ask questions about the research and should be able demonstrate an understanding of the risks and their responsibilities, i.e. potential side effects, dosing requirement, visit schedules.
- 4.3.6 If a potential participant is unsure about participation, then they cannot be consented.
- 4.3.7 Pressure must not be put on a participant to take part.
- 4.3.8 The participant must be fully aware that they are under no obligation to take part that they can withdraw at any time, and that where relevant, this would not affect their treatment, now or in the future.

4.4 Informed Consent Form

- 4.4.1 Once satisfied that all questions have been answered and the participant understands the study, the researcher must enter the version number and date of the PIS/L into the Informed Consent Form (ICF). The ICF must adhere

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to the specific guidance and template available from HRA website (search for online consent guidance tool). The participant must be asked to:

- read the statements on the ICF
- initial the boxes against each of these
- write their name in full
- sign and date.

4.4.2 The staff member must review the form for accuracy and completeness, and when satisfied, countersign and date.

4.4.3 The original consent form must be placed in the investigator site file, a copy of the consent form is given to the participant and another placed in the clinical notes or sent to the participant's GP (dependent on REC approval).

4.5 Electronic Consent (eConsent)

4.5.1 eConsent includes multimedia components which can be used to develop an interactive informed consent process (e.g., auditory, visual).

The intent to use any form of econsent within a project must be clearly described in the Protocol and PIS.

The following list provides details of what must be considered – the list is not exhaustive:

Provision of audit trail

Whether the system can be amended manually

Assurances on version control

Verification of participant identification

Who is providing the system

How is eConsent retained in the trial master file

How does the participant receive a copy

How withdrawal of eConsent is processed.

Note 1:

Appropriate processes are required to ensure that any statements not consented to by the participant are managed correctly.

Note 2:

For Clinical Trials of Investigational Medicinal Product (CTIMP) and for any other project as required by the Sponsor, a detailed description of the consent process is required to be documented in the medical notes.

This includes the date that the participant was given the PIS/L (including version number and date); confirmation of eligibility; participant questions answered, date of consent and who received it.

This provides an audit trail showing that no study specific activities occurred prior to obtaining consent.

Note 3:

The paper ICFs must not be stored together with data from Case Report Forms.

Note 4: Loss of capacity:

If consent has been freely given by a capable adult who subsequently loses the capacity for consent, the original consent remains valid.

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If consent has been refused by a capable adult who subsequently loses the capacity to give informed consent, their previous decision remains valid. The individual cannot be entered into the study by seeking consent from a legal representative.

Note 5: Withdrawal of Consent:

The processes to be followed regarding withdrawal of consent must be stated in the Protocol, with consideration being given as to any safety follow up and data and sample analysis. It is recommended that the PIS/L state that samples and data collected up to the point of withdrawal will be retained and used for analysis.

4.6 Ongoing consent

- 4.6.1 Confirmation that the participant wishes to remain in the study should be obtained at each visit.
Where there is new information or a substantial amendment to the protocol or other study document which affects participants’ rights, safety, wellbeing, or responsibilities, they should be provided with the relevant amended information and asked to re-consent on the updated, approved version of the PIS/L on the ICF.
- 4.6.2 The process must be the same as when original consent obtained to ensure the participants’ full understanding.

5. ABBREVIATIONS & DEFINITIONS

CTIMP	Clinical Trial of Investigational Medicinal Product
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
HRA	Health Research Authority
ICF	Informed Consent Form
NHST	NHS Tayside
PIS/L	Patient Information Sheet/Leaflet
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

None.

7. DOCUMENT HISTORY


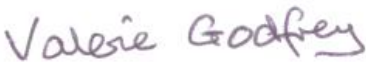
Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
History of reviewers prior to 2014 is detailed in the archived SOPs.			
5	June Gardner (CRM) & Catrina Forde (RGM)	29/03/2015	General update. Amended dates (effective and review).
6	Catrina Forde (SRGM)	29/03/2017	Scheduled review. Section on adults with incapacity 4.7 updated. Minor changes to the layout of text.

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7	Patricia Burns (Senior Research Governance Manager)	02/04/2019	Revised in line with current recommendations. Removal of consent for children or adults with incapacity. Change of title, to 'receiving informed consent' New TASC SOP format implemented.
8	Vera Nuritova (Research Governance Manager)	29/04/2020	TASC PIS/L (Doc Ref 117) and ICF (Doc Ref 009) templates removed. Use HRA templates instead.
9	Tracy Petrie (Quality Assurance Support Officer)	25/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
10	Patricia Burns (Senior Research Governance Manager)	21/04/2022	eConsent included.

8. APPROVALS

Sign	Date
<p>APPROVED BY: Professor Russell Petty, R&D Director, NHS Tayside</p> <p>Signature </p>	19 April 2022
<p>APPROVED BY: Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee</p> <p>Signature </p>	18 Apr 2022

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