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

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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 Standard Operating Procedure (SOP) does not apply to receiving consent from adults with incapacity or children; both of which require study-specific consent process/documents.

This SOP describes the process for obtaining and documenting informed consent in accordance with applicable regulatory requirements, ethical principles, and Good Clinical Practice (GCP).

This SOP does not apply to studies involving adults lacking capacity, children, or emergency research where alternative consent processes apply.

2. SCOPE

This SOP applies to all staff, involved in the informed consent process, employed by UoD/NHST and is applicable to all study types including:

- Clinical Trials of Investigational Medicinal Products (CTIMPs)
- Medical device studies
- Non-interventional studies.

Staff from external organisations must comply with their own institution's SOP where approved by the Sponsor or otherwise follow this SOP.

3. RESPONSIBILITIES

Sponsor: Ensure appropriate systems are in place to safeguard participants' rights and wellbeing.

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 with appropriate permissions.
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.

Principal Investigator: Responsible for obtaining consent at the location.

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.

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, 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 investigator is responsible for ensuring the consent process is conducted appropriately even if delegated.

4.2.2 Delegation must be appropriate to the individual's training, experience and professional role.

4.2.3 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.

4.2.4 Each individual who is delegated the task of receiving informed consent must receive documented protocol training and be named on a Delegation Log with appropriate permissions.

4.2.5 All staff responsible for receiving informed consent must be GCP trained.

4.3 The process of informed consent

4.3.1 Provision of written information must be accompanied by a discussion with the participant, provided in formats accessible to the participant where required (e.g. translated versions, large print).

This discussion with a potential participant should take place in confidential and appropriate surroundings.

4.3.1 Only the individuals named on the Delegation Log are permitted to receive informed consent from participants.

4.3.2 Investigators, co-investigators and staff named on the Delegation Log cannot be consented into the study.

4.3.3 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.

4.3.4 The participant is to be invited and encouraged to ask questions about the research and should be able to demonstrate an understanding of the risks and their responsibilities i.e. potential side effects, dosing requirement, visit schedules.

4.3.5 If a participant requires additional time to consider participation, the consent discussion should be deferred. and participants must be given sufficient time to consider participation.

4.3.6 Pressure must not be put on a participant to take part.

4.3.7 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.

4.3.8 Where appropriate and approved, consent discussions may take place remotely (e.g. telephone or video consultation).

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

- read the statements on the ICF
- initial the box against each statement
- write their name in full
- sign and date.

4.4.2 The researcher 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:

- System validation
- Secure authentication
- 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.

eConsent systems must be validated, secure, and maintain a complete audit trail.

Note 1:
Appropriate procedures must be in place to ensure that any elements of consent declined by the participant are documented and that the associated activities are not undertaken.

Note 2:
For (CTIMPs) and any other project as required by the Sponsor, a detailed description of the consent process is required to be documented in the participant's 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.
An audit trail should show that no study-specific activities occurred prior to obtaining consent**.**

Note 3:
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.
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 states 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 modification to the protocol or other study record which affects participants' rights, safety, wellbeing, or responsibilities, they should be provided with the relevant amended information and asked to re-consent to the updated, approved version of the PIS/L on the ICF.

4.6.2 The process must be the same as when the original consent was 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

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
10	Patricia Burns (Senior Research Governance Manager)	21/04/2022	eConsent included.
11	Patricia Burns (Senior Research Governance Manager)	21/04/2024	Scheduled review. No updates required.
12	Patricia Burns (Senior Research Governance Manager)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

8. APPROVALS

Approved by:	**Date:**
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	08 Apr 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	07 Apr 2026