STANDARD OPERATING PROCEDURE FOR ESTABLISHING IDENTITY OF PARTICIPANTS IN CLINICAL RESEARCH

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1. PURPOSE

This document describes the process by which staff involved in clinical research establish the identity of a potential participant or participant in clinical research and comply with the principles of Good Clinical Practice (GCP).

2. SCOPE

Unless otherwise specified in a site agreement, this document applies to clinical research sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST).

This document applies to clinical research staff who are responsible for establishing the identity of a potential participant or participant in clinical research

3. RESPONSIBILITIES

UoD and NHST define establishing participant identity (ID) as the process of ensuring that the correct person is confirmed before sharing of information, communication and consultation or before the initiation of any procedure, care and/or treatment occurs as described in NHS Tayside Establishing Patient Identity Policy.

4. PROCEDURE

4.1 For clinical research studies involving healthy volunteers or volunteers with the condition under study

4.1.1 Potential participants and participants should provide identification at the initial study visit and throughout the study as necessary. Confirmation of identification should be documented each time. Some examples of identification are listed below:

- Current passport
- Current photographic identification driving licence
- Current matriculation card
- Young person's or senior citizen's railcard
- Proof of Address
- National Insurance Card
- CHI Number/Medical Card.

4.1.2 For residential studies all potential participants must be asked to provide proof of identification as described in 4.1.1. In addition, the actions described in 4.1.3 – 4.1.6 must be carried out.

4.1.3 An appropriate white or red (if known allergies) identity band must be placed on a wrist. The information on the identity band must include forename, surname, date of birth, NHS CHI number (if available) and gender written in full. **The patient must only wear one patient identity band.**

4.1.4 Verification of identity and the application of the identity band should be documented.

4.1.5 The identity band must remain in place throughout the stay. If it is damaged or requires to be removed or replaced, it should be documented.

4.1.6 If a person requires to be admitted to hospital during this residential stay, it is the responsibility of the admitting/receiving nurse to confirm identity and ensure that the participant is wearing an appropriate patient identity band. This procedure may be facilitated by the research study staff member accompanying the participant for admission.

4.2 For clinical research studies involving NHS patients attending clinic

4.2.1 The identity of potential participants must be confirmed using:

- Their medical case notes if one exists and is available **or**
- By accessing the appropriate NHS Tayside Electronic system **and**
- In line with the local NHS Board Policy on establishing patient identity.

4.3 For clinical research studies involving NHS patients in Primary Care

4.3.1 A check of information provided by the patient against their current NHS medical record should be conducted at study visits.

4.3.2 Potential participants should only be invited to take part in a study after their GP has confirmed that participation is appropriate. Confirmation of suitability should be documented within the GP practice.

4.4 Where identification is not possible in person

Under the General Data Protection Regulation and Data Protection Act, there is an obligation to take reasonable steps to confirm the identity of the person responding to a telephone call before proceeding with any conversation relating to personal information and there must be safeguards in place to ensure that the people responding to the call are who they say they are.

4.5 Verifying via phone

4.5.1 Verifying identity over the phone requires "something you know" methods and you must ask questions until you are satisfied the person is who they say they are.

4.5.2 Where possible these should be questions that another person (including family members) is not likely to know.

4.5.3 For example, if the person is already in a research project, then they should be asked to give their identification number. This can be verified on their personal copy of the Informed Consent Form.

4.5.4 Listen carefully to the voice and use common sense and intuition to help determine the validity and authenticity of the person; for example, if you are expecting to speak to an elderly person but the voice sounds young then you should be cautious.

4.5.5 Avoid giving confidential information before confirming identity.

4.5.6 If you are not satisfied that the person you are speaking to is who is they say they are, then ID is not confirmed. They must also be assured that you are genuine, therefore you must be prepared to confirm your own identity.

5. ABBREVIATIONS & DEFINITIONS

GCP	Good Clinical Practice
ID	Identity
NHST	NHS Tayside (Tayside Health Board)
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:
7	Patricia Burns (Senior Research Governance Manager)	02/12/2022	No changes required at this scheduled review.
8	Patricia Burns (Senior Research Governance Manager)	02/12/2024	No changes required at this scheduled review.

8. APPROVALS

Approved by:	**Date:**
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	02 Dec 2024