STANDARD OPERATING PROCEDURE FOR VERIFYING THE IDENTITY OF PARTICIPANTS IN CLINICAL RESEARCH

SOP NUMBER:	**Fife R&D SOP17**
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1. PURPOSE

This document describes the process by which staff involved in clinical research must verify the identity of a potential participant or participant.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D section of the NHS Fife website (www.nhsfife.org/research), EDGE (https://www.edge.nhs.uk) and Q-Pulse. For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This document applies to clinical research sponsored or co-sponsored by NHS Fife and to any clinical research where NHS Fife is a site.

This document applies to clinical research staff responsible for establishing and verifying the identity of a potential participant or participant in clinical research.

3. POLICY

The identity of study participants must be established and verified before sharing of information, communication, consultation and/or initiation of any procedure, care and/or treatment occurs'.

4. PROCEDURE

4.1 The identity of potential participants and participants should be confirmed at the initial visit and throughout the study at every interaction.

4.2 At a minimum, the name and date of birth provided verbally by participants or potential participants must be verified at every interaction using:

- Their medical case note, if one exists and is available **or**
- By accessing the appropriate NHS Fife electronic system

At the initial interaction, in addition to name and date of birth of the participant or potential participant, their address must also be verified.

4.3 Confirmation that the participant's identity has been verified must be recorded in the paper CRF, TrakCare or EDGE as appropriate.

4.4 If the participant or potential participant reports a change of name and/or address this must be updated on TrakCare.

5. ASSOCIATED DOCUMENTS

None

6. DEFINITIONS

R&D Research and Development
SOP Standard Operating Procedure

7. DOCUMENT HISTORY

Version Number	Edited by (job title)	Effective Date	Details of Revisions Made
1	David Chinn Senior Research Advisor	28/10/2014	New - *Adapted from TASC SOP 12, version 2.0*
2	Julie Aitken R&D Trials Facilitator	06/12/2018	Reformatted in line with current SOP template. Revised to reflect current practice.
3	Karen Gray Lead R&D Research Nurse	09/04/2021	Amended to clarify that Participant ID must be verified at every visit and this must be recorded.

8. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	09 April 2021