STANDARD OPERATING PROCEDURE FOR OBTAINING INFORMED CONSENT

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1. PURPOSE

This document describes the procedures for obtaining informed consent from adults and children considering participation in clinical research in NHS Fife.

It is the responsibility of all staff using this Standard Operating Procedure (SOP) to ensure they are using the latest version. The latest version is available via StaffPoint (Research and Development), the Research, Innovation and Knowledge (RIK) section of the NHS Fife website (www.nhsfife.org/research) and EDGE (Management | Edge).

For guidance, contact the R&D Department at fife.randd@nhs.scot.

2. APPLICABILITY

This SOP applies to all research studies in which it is necessary to obtain informed consent for a participant's involvement.

This SOP is intended for use by staff of all grades and disciplines (scientific, technical, and clinical) who are involved in obtaining informed consent for clinical research participation.

3. PRINCIPLES

3.1 Informed consent is a key element in ensuring the ethical conduct of clinical trial research. The consent process must align with the International Council for Harmonisation Guideline for Good Clinical Practice (ICH GCP E6(R3) 2025) and the Research Team must follow procedures specified in the study protocol.

3.2 Informed consent is a continuous process that begins with the initial approach of a potential participant or their representative. It remains active throughout the individual's involvement in the study and participants are free to withdraw their consent at any time throughout that time, with or without giving a reason. If substantial changes are made to a study protocol affecting the rights, safety, or well-being of participants then the research team will be required to obtain the participants' re-consent.

3.3 Informed consent can be obtained face to face, remotely or electronically. The method of obtaining consent will be specified in the protocol and appropriate to the specific study.

3.4 The key requirements of the consent process are:

- the participant has the capacity to consent or has a legally acceptable representative to consent on their behalf.
- the participant or their representative understands what they are consenting to.
- the consent is voluntary.
- the consent is properly documented.

3.5 The Chief Investigator (CI) is responsible for specifying the consent procedures permitted within the study protocol. Decisions to include alternative approaches to written consent – such as verbal or deferred consent - are based on factors specific to the study design and participant population e.g.

- **Health Condition**
  Potential participants may be unable to provide written consent due to their health condition (e.g. in severe pain or require urgent treatment). However, if they can understand the study and communicate, verbal consent may be allowed.

  See **4.5 Verbal Consent.**

- **Physical Ability to Read or Sign Documents**
  Potential participants may be unable to read or to sign a form (e.g. due to blindness, illiteracy, or manual dexterity problems) but be able to understand the study and communicate. In these circumstances, witness consent may be obtained. A third party provides written confirmation that the participant received information on the study, which they appeared to understand, and that they gave their voluntary consent to join the study.

  See **4.6 Witnessed Consent.**

- **Logistics**
  If potential participants or the participant's representatives cannot attend in person, remote consent options may be allowed.

  See **4.7 Remote Consent.**

- **Age**
  Consent procedures for minors (or individuals under legal guardianship) depend on the type of trial.
  - CTIMPs - Parental or guardian consent is required
  - non-CTIMPs - Assessment of competence is required, to determine the minor's capacity to consent

  See **4.8 Consent and Assent of Minors.**

- **Capacity**
  Individuals with permanent, temporary, or fluctuating cognitive capacity are considered adults with incapacity (AWI). In Scotland, studies involving AWI must have Scotland A Research Ethics Committee (SAREC) approval. Consent procedures for this type of study will typically include processes for loss of

capacity, recovery of capacity, and consent by a legal representative.

See **4.9 Consent and Vulnerable Adults.**

- **Emergency Situation**
  Clinical trials conducted in emergency settings may include participants enrolled without prior consent, provided that specific legal and ethical conditions are met, and the study protocol has received REC approval.

  See **4.10 Consent in an Emergency Situation**.

4. PROCEDURE

4.1 Who can obtain informed consent?

4.1.1 Informed consent must be obtained by a physician or another appropriately qualified individual involved in the research (Declaration of Helsinki, 1964).

4.1.2 The job titles of research team members authorised to obtain consent (e.g. research nurses, clinicians, trained staff) must be specified in both the Research Ethics Committee application (IRAS form) and the study protocol.

4.1.3 The CI/PI retains overall responsibility for ensuring that the consent process enables participants or their representative to make an informed decision about their involvement. However, the Chief Investigator (CI) or Principal Investigator (PI) may delegate the task of obtaining consent to a suitably trained and qualified member of the research team. This must be conducted in line with General Medical Council (GMC) guidance on Good Practice in Research and Consent to Research.

4.1.4 All members of the Research Team involved in obtaining consent must be appropriately trained in Good Clinical Practice (GCP). (Refer to FWP-GCPT-01 – NHS Fife Wide Procedure for GCP Training for further guidance) and any other study specific training identified by the Sponsor.

4.1.5 For Clinical Trials of Investigational Medicinal Products (CTIMPs), if informed consent is obtained by someone who is not a medically qualified doctor, a medically qualified doctor from the study team must be contactable during the consent process to address any medical queries from the participant or their representative.

4.2 When to obtain consent

4.2.1 Consent is to be sought only after Local Management Approval (LMA) has been granted and the 'Research Team - Study Summary Checklist' workflow completed on EDGE.

4.2.2 Consent may take place prior to eligibility assessment and confirmation, or it may be taken after eligibility is confirmed, as specified the study protocol.

4.2.3 Consent (verbal, written or both) must be obtained prior to undertaking any study-specific procedures, unless otherwise permitted by the protocol.

4.2.4 Consent may only be obtained after a potential participant or their representative has been provided with information about the study e.g. a

Patient Information Sheet (PIS), audio, or video recordings. A minimum 24-hour consideration period is recommended between the provision of information and the obtaining of informed consent, unless otherwise specified in the study protocol.

4.2.5 Consent should be obtained once the research team member is satisfied that the participant or their representative fully understands what participation involves and voluntarily agrees to take part in the study.

4.2.6 Participants must be re-consented in the event of a substantial amendment to the study protocol (or associated documentation) that impacts participants' rights, safety, or well-being.

4.3 Obtaining written consent

4.3.1 The participant or their representative must be provided with information containing a clear and comprehensive explanation of the study's purpose, associated risks, and potential implications (e.g. Participant Information Sheet).

Where appropriate, patients must be offered translation services for study visits (see R&D SOP44). Information on how to access translation services is available via the NHS Fife Equality and Human Rights Department (fife.equalityandhumanrights@nhs.scot).

4.3.2 The CI/PI or any member of the research team must not coerce or unduly influence an individual (or their representative) to participate or continue participating in a study. All information provided—whether written or verbal—must avoid language that could be interpreted as waiving the participant's legal rights or releasing the CI or Sponsor from liability for negligence.

4.3.3 The participant or their representative should be given sufficient time to review the study information, to discuss it with others, and to ask questions of a suitably qualified member of the research team.

Discussions with the research team should take place in private, and in an appropriate setting, unless otherwise specified in the study protocol.

Language used should be clear, concise, and understandable to the participant or their representative.

4.3.4 The Research Team is responsible for regularly confirming the participant's continued willingness to take part in the study. This process is known as obtaining "ongoing consent".

4.4 Documenting consent

4.4.1 Prior to the study opening, the Research - Study Summary Checklist workflow must be completed to describe the study specific consent procedures to be implemented at NHS Fife and must also describe how the consent process will be documented.

4.4.2 If the sponsor does not provide a consent process documentation template for adding to the participant's medical notes, then the research team should agree documentation requirements with the Sponsor, and where necessary, draft a template. Any locally devised template must be sent to the Sponsor for review before use. The template can include prompts for key data* and must

be version controlled. *See Appendix 2 for examples of key data to be included in the template and Doc Ref 14-01 for an example of a Consent Process Documentation Template.

4.4.3 If the study has more than one way to obtain consent, the research team must ensure that the correct study documents (PIS and ICF) are used e.g. “Legal Representative” documentation for proxy consent.

4.4.4 If a patient agrees to participate in a study (or their representative agrees on their behalf), consent is documented by the patient (or their representative) signing and dating an ICF. The ICF will be counter signed and dated by the member of the research team obtaining consent. (Exceptions to this process are covered in later sections.) In cases where the patient or their representative cannot sign the form themselves, an annotation should be added to explain the reasons for this.

4.4.5 The original ICF should be filed in the Trial Master File (TMF) or Investigator Site File (ISF). If securely stored elsewhere then a filenote must be added to the ISF to identify their location.

4.4.6 One copy of the signed ICF and the PIS should be provided to the participant.

4.4.7 If specified in the protocol or by the sponsor, a further copy of the ICF and PIS should be filed in their paper or electronic medical notes (Sci-Store).

4.4.8 The research team must record a contemporaneous* and accurate clinical note of the consent process that was followed and the discussion that took place, in the participant’s medical record (or for studies where this approach may not be suitable, discuss with the Sponsor to agree on an appropriate alternative)

The text within the study-specific consent process template will provide prompts for writing the clinical note but the template should be edited and expanded upon then saved in one of the following formats:

- As a Clinical Note added to an appointment (one that cannot be cancelled) in the Electronic Patient Record (EPR) section of TrakCare medical notes and “authorised”
- Text added to “Appointment Details” or in the ***Comments*** in the Patient Details section in EDGE.

*This must ideally be completed in the same shift that consent is obtained.

4.4.9 Most ICFs ask for a participant’s consent to inform their GP of their involvement in a study. If the participant or their representative agrees for the participant’s GP to be informed, the CI / PI or delegate must ensure that the GP is notified using the approved GP letter template or via a secure, NHS compliant approach.

4.4.10 If specified in the Protocol or confirmed by the sponsor, a copy of the GP letter should be filed in their paper or electronic medical notes (Sci-Store).

4.4.11 If re-consent is necessary, documentation should be processed and filed as above.

4.5 Verbal Consent

4.5.1 Verbal consent may be specified in the trial protocol for use in defined circumstances e.g. time critical treatment. This is usually followed up later by written consent.

Although there may not be an ICF, verbal consent must still be documented either in the patient's electronic patient record (Trakcare annotation) or paper medical notes (then scanned to SCI-Store).

4.6 Witnessed Consent

4.6.1 Witnessed consent may be required in a number of different situations:

- Participant is unable to provide written consent due to factors such as blindness, illiteracy, or physical inability to sign the form.
- Where consent is obtained remotely or verbally from a participant.

4.6.2 When a participant is unable to provide written consent due to factors such as blindness, illiteracy, or physical inability to sign the form. the witness must be impartial i.e. an individual who is not directly involved in the trial. This may be a staff member not involved in the study or a participant's relative. They must be provided with the study information and be present during the consent discussion.

The researcher must complete the ICF, and the witness must sign and date to confirm their presence. The witness must not provide consent on behalf of a competent adult. Their responsibility is to verify that the discussion between the researcher and the patient accurately reflects the Patient Information Sheet and to ensure the participant has received all the required information to make an informed decision.

If the situation is unexpected and the ICF lacks designated fields for witness and researcher signatures, both should sign directly on the form and annotate the circumstances. Even if unable to provide a signature, the participant should mark the form, if possible.

4.6.3 Where consent is obtained remotely or verbally from a participant, the role of the witness is to attest that a competent participant has been provided with appropriate study information, has had the opportunity to ask questions, and has voluntarily agreed to participate. Witnessed consent may be documented either to confirm agreement during a remote consent discussion, or to confirm that a consent conversation has taken place and participation has been agreed where no formal written consent form is required. This includes low-risk studies where consent is recorded only within the electronic health record (EHR) or study documentation.

Unless agreed with the Sponsor, the witness must be independent of the research team working on the study and must document the date, method of consent, and confirmation that consent was freely given.

4.7 Remote Consent

4.7.1 Remote consent may be specified in the trial protocol, to allow a prospective participant or the participant's representative to provide consent without attending the site in person.

The study protocol will specify how study information (i.e. PIS) must be provided to the participant or their representative. The protocol will also describe the procedure and requirements for documenting consent.

e.g.

A consent discussion may take place by telephone or video, the participant or their representative may be required to complete the previously provided ICF, sign, date and return it to the site by post or email. Any discrepancies in dates caused by postal or email consent delays must be documented with an annotation on the ICF or a file note, as agreed with the Sponsor.

or

A second member of the research team might need to be present to witness the participant or their representative give consent.

The ICF may be completed, signed, and dated by the member of the research team taking consent and signed and dated by the witness on behalf of the participant.

4.8 Consent and Assent Procedures Involving Minors

4.8.1 The procedures previously described in this SOP are applicable to minors; however, in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 for CTIMPs, and the Age of Legal Capacity (Scotland) Act 1991, additional provisions are required to ensure that consent is lawfully obtained.

In accordance with GCP principles for the protection of vulnerable participants, age-appropriate assent should be sought wherever feasible. If a minor chooses not to provide assent, their decision must be respected even when parental or legal-guardian consent has been obtained. This approach ensures that the minor's autonomy and best interests are upheld.

4.8.2 Where the parent or legal representative is competent, but unable to read or write, the sponsor may specify that the Witnessed Consent method be used.

4.8.3 CTIMP Studies

- Legal Capacity to Consent >16

  Under the Medicines for Human Use (Clinical Trials) Regulations 2004, children under the age of 16 cannot legally provide consent to participate in a Clinical Trial of an Investigational Medicinal Product (CTIMP).

- Authorised Consent Providers

  Instead, consent must be provided by:

  - parent or someone with parental responsibility (one parent required)

- personal legal representative
- professional legal representative

See Appendix 1. Table - Hierarchy of informed consent for a minor.

- Competent Minor - Assent

  When the child is deemed competent to understand the nature of the research, assent from the child should also be sought, in line with ethical best practice and the Age of Legal Capacity (Scotland) Act 1991.

4.8.4 Non-CTIMP Studies

- Legal Capacity to Consent

  There is no specific statutory provision in Scots law governing a child's right to consent to participate in non-CTIMP research. However, the Age of Legal Capacity (Scotland) Act 1991 states that a child under 16 may consent to medical procedures and by extension, **non-CTIMP** research, if a qualified medical practitioner deems them capable of understanding the nature and consequences of the procedure or study.

- Assessment of Competence

  For studies involving surgical, medical, or dental procedures, or treatments that may result in a diagnosis, competence must be assessed by a qualified physician.

  For all other studies, competence may be assessed by another suitably qualified professional.

- Competent - Minor Consent / Parental Assent

  Written consent may be obtained from a competent minor. This decision must be discussed thoroughly with the child's parent, guardian, or legal representative.

  Alongside consent by a competent minor, assent should be sought from a parent, guardian, or legal representative. In specific contexts e.g. sexual health studies, where parental involvement may influence the child's decision-making, it is not necessary to inform parents of the child's participation.

- Absence of Competence - Parental Consent / Minor Assent

  If a child is judged not to be competent to provide consent, assent should still be obtained from the child, and consent must be secured from a parent, guardian, or legal representative. The child's views and preferences must be respected, even where parental consent is provided.

  Guidance on consent of minors at the Health Research Authority (HRA) website.

4.9 Consent and Vulnerable Adults

4.9.1 The consent procedures previously described in this SOP are applicable to vulnerable adults; however, in accordance with the Mental Capacity Act 2005 and the Adults with Incapacity (Scotland) Act 2000, additional provisions are required to ensure that consent is lawfully obtained, and that the individual's autonomy and best interests are safeguarded.

4.9.2 If an individual explicitly refused consent before losing capacity, that decision remains binding, and they must not be enrolled in a trial under any circumstances. In such cases, the provisions allowing consent via a legal representative do not apply. This position is reinforced by ethical guidance and the Adults with Incapacity (Scotland) Act 2000.

4.9.3 If a competent adult consents to participate in research and subsequently loses capacity, their prior consent remains legally valid (unless the protocol changes significantly).

4.9.4 If re-consent is required following substantial protocol changes, a participant who has lost capacity since they consented may continue in the trial only if proxy consent is permitted within the protocol and ethical approval, and if their personal or professional legal representative agrees to their continued involvement.

4.9.5 The research team must ensure that the correct study documents are used for proxy consent e.g. specific “Legal Representative” documentation.

Guidance on consent of adults lacking capacity at the Health Research Authority (HRA) website.

4.10 Consent in an Emergency Situation

4.10.1 The general rule for consent of incapacitated adults is that they may be enrolled in research by proxy i.e. with the consent of a legal representative. This method of consent must be documented in the Protocol and approved by an appropriate Research Ethics Committee REC) who are authorised to review research involving adults lacking capacity (AWI) in Scotland, as defined by the Adults with Incapacity (Scotland) Act 2000

4.10.2 The 2006 amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 introduced an exception to this rule that applies only in emergency situations. This includes trials involving first line treatments where immediate administration of the study intervention is essential. In these cases, eligible patients may be enrolled before consent is obtained, with consent deferred to a more appropriate time. This provision applies exclusively to CTIMP studies and does not extend to non-CTIMPs.

Deferred consent can only be undertaken where:

- Action must be taken urgently for the purpose of the study.
- It is not reasonably practicable to obtain informed consent beforehand.
- The procedure is conducted in accordance with a REC approved protocol.

A Research Ethics Committee (REC) will only approve this approach if it is clearly justified that:

- Consent cannot be obtained from a personal or professional legal representative.
- The research intervention is likely to benefit the participant.

4.10.3 Once the urgent circumstances no longer apply, this exemption ceases. The standard requirements for obtaining informed consent must then be followed.

4.10.4 In the event that such a participant regains capacity, they should be provided with a tailored Participant Information Sheet (PIS) and Consent Form, seeking their ongoing consent. This process must be clearly outlined in the ethics application and follow guidance from the Health Research Authority (HRA).

4.11 Consent for Human Tissue

4.11.1 Consent is required for the collection of human tissue, including blood, for research. The Human Tissue (Scotland) Act 2006 is applicable only to tissue from the deceased. The Human Tissue Act (2004), which covers England and Wales, is only applicable in Scotland where there is intent to analyse DNA. However, in Scotland it is considered good practice to follow the provisions of this Act and to obtain consent for the use of all tissue samples obtained for clinical research purposes.

4.11.2 If tissue is to be taken as part of a clinical research study, information should be included in the PIS and a separate consent statement should be included in the ICF. It should be made clear to the participant or their representative whether they can participate or not in the research without giving additional, separate consent for tissue.

4.11.3 In instances where consent cannot be obtained or is not available then all samples must be anonymised to the researcher and a REC favourable opinion is required or an application to a Tissue Bank.

4.11.4 Guidance for good practice, including instances where individuals are unable to consent, is available via the Human Tissue Authority Code of Practice on Consent. A Summary of Human Tissue (Scotland) Act 2006 requirements and the DNA analysis section of the Human Tissue Act 2004, applicable for Scotland, is available from the MRC website - https://www.mrc.ac.uk/publications/browse/human-tissue-and-biological-samples-for-use-in-research/.

5. ASSOCIATED DOCUMENTS

Doc Ref 14-01 - Example Consent Process Documentation Template
FWP-GCPT-01 - NHS Fife Wide Procedure for GCP Training
R&D SOP13 - Completion of Delegation of Responsibilities and Signature Log.
R&D SOP44 - Use of Translation Services for Research
R&D WI22 - Recording Details of Research in Medical Records
R&D SOP41 - Procedure for Obtaining Approval for the Provision and Use of Human Tissue
R&D WI42 - Adding Clinical Notes (to Trakcare)
R&D WI45 - Uploading Documents to Sci-Store

6. ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Product
GMC	General Medical Council
GCP	Good clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
IRAS	Integrated Research Application System
ISF	Investigator Site File
LMA	Local Management Approval
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator.
PIS	Participant Information Sheet
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File

7. REFERENCES

International Council for Harmonisation, Harmonised Guideline for Good Clinical Practice, E6(R3), adopted 06 January 2025
ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf

World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

Medicines for Human Use (Clinical Trials) Regulations 2004
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.
http://www.legislation.gov.uk/uksi/2004/1031/contents/made.

GMC Guide Good Practice in Research and Consent to Research
(*http://www.gmc-uk.org/guidance/ethical_guidance/5992.asp*).

FWP-GCPT-01 - NHS Fife Wide Procedure for Good Clinical Practice (GCP) Training).

Human Tissue Act 2004

The Age of Legal Capacity (Scotland) Act 1991.

HRA online guidance for researchers and ethics committees on consent
http://www.hra-decisiontools.org.uk/consent/principles-children.html.

Human Tissue Act (Scotland) Act 2006

The Mental Capacity Act 2005

The Adults with Incapacity (Scotland) Act 2000

MRC Ethics Guide on Medical research involving Children, 2004 (updated 2007).

Human Tissue Authority (HTA) Code of Practice on Consent, revised July 2014.

MRC Summary of Human Tissue (Scotland) Act 2006 requirements and DNA analysis section of HT Act 2004, applicable for Scotland.

Governance Arrangements for Research Ethics Committees: A Harmonised Edition, 2011 (updated May 2012).

UK Policy Framework for Health and Social Care Research
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/.

8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of editions made:
1	Isla Smith R&D Research Nurse	31 Oct 2014	New
2	Julie Aitken R&D Trials Facilitator	22 Mar 2018	Updated to reflect current practice. Information regarding translation services included.
3	Julie Aitken R&D Quality & Performance Lead	29 Apr 2020	Updated in line with format of Current SOP template. Text refreshed throughout for clarity.
4	Karen Gray R&D Lead Research Nurse	06 July 2026	Updated throughout for clarity and to cover different processes for obtaining and documenting informed consent.

9. APPROVAL

APPROVED BY	Date
Kirsty Pine, Associate Director RIK, NHS Fife Signature: 	06 July 2026

APPENDIX 1

Hierarchy of informed consent for a minor

Hierarchy of informed consent for a minor			
Person who may give consent		Definition	Commentary
1.	Parent	A parent or person with parental responsibility.	Should always be approached if available.
2.	Personal legal representative	A person not connected with the conduct of the study who is: (a) suitable to act as the legal representative by virtue of their relationship with the minor, and (b) available and willing to do so.	May be approached if no person with parental responsibility can be contacted prior to the proposed inclusion of the minor, by reason of the emergency nature of the treatment provided as part of the study.
3.	Professional legal representative	A person not connected with the conduct of the study who is: (a) the doctor primarily responsible for the medical treatment of the minor, or (b) a person nominated by the relevant health care provider (e.g. an NHS Board).	May be approached if no person suitable to act as a personal legal representative is available. Informed consent must be given before the minor is entered into the study.

APPENDIX 2

Contents of Consent Process Trakcare Note, AKA EPR Clinical Note Annotation

Header	
1. Template title e.g. Consent Process Template	
2. NHS Fife R&D reference number and study title	
3. PI	
4. Participant ref ID	
Identification (if relevant)	
1. How the potential participant was identified	
2. Who identified the participant	
3. When the participant was identified	
Identity	
Confirm participant's identity was verified (using their name, address, and date of birth)	
Approach	
1. Date the participant was approached.	
2. Who approached the participant	
3. How was the participant approached.	
PIS	
1. Date provided	
2. Time provided (if same day as day of consent)	
3. Who provided the PIS	
4. Role of person who provided the PIS	
5. PIS Title	
6. Version number	
7. Version date	
Consent	
1. Date of consent discussion	
2. Who discussed consent with the participant	
3. Role of person discussing consent with the participant	
4. Was the participant was informed of the study requirements?	
5. Was the participant was given sufficient time and opportunity to ask the R&D Research Team questions about the study?	
4. Date consent provided by participant	
5. Time signed (if on same day PIS provided)	
6. ICF Title	
7. Version number	
8. Version date	
9. Was the participant was provided with copies of the relevant PIS and signed Consent Form, where relevant.	
10. Description of the consent process	