STANDARD OPERATING PROCEDURE FOR OBTAINING INFORMED CONSENT

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1. PURPOSE

This document specifies the procedures for obtaining written informed consent from adults and children considering participation in clinical research and complies with the principles of Good Clinical Practice (GCP).

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research) or for guidance, contact the R&D Office (fife-uhb.randd@nhs.net).

2. APPLICABILITY

Unless otherwise specified in a clinical study site agreement, this SOP applies to all research studies in which it is necessary to obtain informed consent from participants.

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. POLICY

Informed consent is defined as "The process by which a participant voluntarily confirms their willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form."

It is important to remember that informed consent is not merely getting someone to sign a form, it is a process of information exchange. The informed consent process involves the giving of information, the discussion and clarification of the information and taking the participant's verbal and written consent.

The process begins when the initial contact is made with the potential participant in the study and continues throughout the time the person participates.

4. PROCEDURE

4.1 Who can take informed consent?

4.1.1 The Declaration of Helsinki states that the person obtaining the informed consent should be a physician or another appropriately qualified individual.

4.1.2 The Chief Investigator (CI) or Principal Investigator (PI) may delegate the responsibility of taking informed consent to another appropriate member of the research team. The General Medical Council (GMC) recommends that when physicians delegate the task of informed consent they need to act in accordance with the GMC Guide Good Practice in Research and Consent to Research (http://www.gmc-uk.org/guidance/ethical_guidance/5992.asp). The UK Clinical Trials regulations allow for the consent process to be undertaken by any member of the research site, however the application form submitted to the Research Ethics Committee must set out the general policy for the study in terms of what types of personnel will be involved (for example, the Principal Investigator, medical Sub Investigators and/or research nurses) and the procedures that will be followed.

4.1.3 For Clinical Trials of Investigational medicinal Products (CTIMPs), where taking informed consent has been delegated to someone who is not a medically qualified doctor, it is expected that a medically qualified doctor who is part of the study team is readily available during or following the consent process if the subject requires or requests further discussion relating to the medical care to be provided as part of the trial.

4.1.4 If staff other than the CI or PI accept responsibility for the informed consent process and/or being the sole signatory on the Informed Consent Form (ICF) it is important that the following criteria are met by the designee:

- Is prepared to take on the additional responsibility AND feels confident to take informed consent in line with appropriate Professional Conduct Code(s) or other professional organisational guidelines. Will adhere to the relevant professional codes of conduct and seek advice from them if necessary.
- Is fully trained in the specific study for which they are giving the verbal and written information to the potential study participant.
- Has sufficient knowledge of the proposed investigation, or treatment or intervention, and understands the risks and has sufficient knowledge of the associated disease area, including potential pharmacological interactions / treatment toxicities, where appropriate.
- Is qualified by training, skills and experience. All relevant training, including study-specific and GCP, must be documented on a signed and dated CV and in a Research Training Log, or equivalent.
- Ensures an effective line of communication is maintained back to the CI/PI.
- Ensures that the delegation is documented in a study-specific Delegation Log (see R&D SOP13 - Completion of Delegation of Duties and Signature Log).

4.1.5 All staff taking informed consent (and/or otherwise participating directly) in CTIMPs must be GCP trained and this training is strongly recommended for those taking consent in (or participating directly) in other types of clinical research (see FWP-GCPT-01 - NHS Fife Wide Procedure for Good Clinical Practice (GCP) Training).

4.1.6 It is ultimately the responsibility of the CI/PI to ensure that participants have fully understood what they are consenting to and the CI/PI is ultimately responsible for the participant's care. For CTIMPs, the CI/PI is legally responsible for the conduct of the study.

4.2 When to take consent

4.2.1 Consent can only be taken after all study approvals (Sponsor, REC, Medicines and Healthcare Products Regulatory Agency (MHRA) if appropriate, NHS Local Management Approval and any others) have been received in writing. Evidence of written consent must also be in place before any study specific procedures can take place.

4.2.2 Information regarding the study, such as the Patient Information Sheet (PIS), should be provided to the potential participant prior to written informed consent being taken. Where appropriate, a period of at least 24 hours between providing the information and obtaining informed consent is desirable.

4.3 How to take consent

4.3.1 The CI, or delegate, should fully inform the participant in person, unless otherwise permitted, by the study protocol. In certain circumstances, and if permitted by the study protocol, if the participant is unable to consent for themselves, consent may be obtained from the participant's legally acceptable representative.

4.3.2 Participants must be informed of all pertinent aspects of the research and provided with the written information given a favourable opinion by the REC.

4.3.3 When discussing a clinical research study with a potential participant, discussion should take place in a private and appropriate surroundings. The following elements of informed consent should be covered:

- That the study involves research
- The purpose of the study
- The study treatment(s) or intervention(s), and whether random assignment to the intervention will occur
- The study procedures to be followed, including all invasive procedures
- The participant's responsibilities
- Those aspects of the study that are experimental
- The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, foetus or nursing infant
- The reasonably expected benefits - when there is no intended clinical benefit to the participant, the participant should be made aware of this
- The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks
- The compensation and/or treatment available to the participant in the event of a study-related injury
- The anticipated payment, if any, to the participant for participating in the study
- The anticipated expenses, if any, to the participant for participating in the study
- That the participant's participation in the study is voluntary and that the participant may refuse to take part if they wish, without their medical care being affected.
- That authorised representatives from regulatory bodies, the REC or the Sponsor, as appropriate will be given access to the participant's records for the purpose of verification of the study procedures and data collected, without violating the confidentiality of the participant. By signing the informed consent form, the participant is authorising such access.

- That the participant's GP will also be informed in writing of their participation in the study, if appropriate.
- That records identifying the participant will be kept confidential and will not be made publicly available. If the results of the study are published, the participant's identity will remain confidential.
- That the participant or their legal representative will be informed in a timely manner if any information becomes available that may be relevant to the participant's willingness to continue to participate in the study.
- The person(s) to contact for further information regarding the study (where appropriate provide a 24 hour 'phone number where the participant can receive advice out of office if required).
- The foreseeable circumstances under which their participation in the study may be terminated.
- The expected duration of the participation in the study.
- The approximate number of participants involved in the study.

4.3.2 Neither the CI/PI nor any member of the research team should coerce or unduly influence a person to participate or to continue to participate in a study.

4.3.3 Any information imparted to the participant (written or verbal) should not contain any language that causes the participant to waive (or appear to waive) any legal rights, or that releases (or appears to release) the CI or Sponsor from liability for negligence.

4.3.4 The language used in the oral and written information about the study including the ICF, should be as clear and concise as practical and should be described in layman's terms so as to be understandable to the participant.

4.3.5 Where appropriate, patients who cannot read or write in English must be offered translation services for the purposes of the consent visit and any other appropriate 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-UHB.EqualityandHumanRights@nhs.net).

4.3.6 Unless the study protocol states otherwise, participants must be given a minimum of 24 hours to review the study information, to discuss with others, and to ask questions of the research team. All questions should be answered by an appropriate member of the research team prior to the participant signing the consent form.

4.3.7 When the person taking informed consent is satisfied that the participant has been fully informed and understands what study participation entails, has had all concerns addressed, and had time to consider their decision, the consent form should be signed and personally dated by the participant and then by the authorised person who conducted the informed consent discussion.

4.3.8 The ICF and PIS should be identifiable by date and version number and be printed on headed paper associated with the particular Sponsor and/or Board and/or Institution where the study is being conducted.

4.3.9 The timing of the signing of the ICF relative to study screening/ registration/ randomisation and the initiation of study procedures is subject to monitoring and/or audit by Sponsor, REC and regulatory authorities.

4.4 Documenting Informed Consent

4.4.1 One original copy of the ICF should be signed and dated by the participant and the person obtaining consent. The original should be filed in the Study Master File or Investigator Site File (ISF), in the case of a multi centre study. A copy of the signed ICF should be given to the participant and, if appropriate, a copy filed in their medical notes (see R&D WI22). Participants should be provided with copies of all updated and new information regarding the study, where relevant to them, throughout their participation. If re-consent is necessary, re-consent forms should be filed in the same manner.

4.4.2 The CI/PI or delegate must ensure that, where appropriate and where consent is in place to do so, the participant's GP is informed about their participation in the study and receives appropriate information regarding the study.

4.4.3 If a participant is unable to read (e.g blind, illiterate etc.) an impartial witness is required to ensure that the verbal information given correlates to that written on the information sheet. The impartial witness must sign the consent form as witness to the process. The participant is required to mark the consent form if able to do so.

4.4.4 For the consent to be valid the participant must always be able to communicate their decision. That decision having been given freely after the person is informed of the nature, significance, implications and risks of the trial. They must either (i) evidence this in writing, date and sign, or otherwise mark, by the person so as to indicate his consent, or (ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing in the medical notes.

4.5 Consent and Children

4.5.1 All guidance, advice and statutory provisions previously documented in this SOP apply to children and, in addition extra care and consideration must be applied.

4.5.2 Arrangements must be made to ensure that relevant information is provided in age appropriate written or pictorial form and that the role and responsibilities of parents or guardians, carers or supporters are clearly explained and understood.

4.5.3 Non-CTIMPs

There is no specific provision in Scots law governing a child's right to consent to take part in research, except in a Clinical Trial of an Investigational Medicinal Product (CTIMP).

It is reasonable to follow the Consent for Treatment guidelines in the Age of Legal Capacity (Scotland) Act 1991 which states that;

"A person under the age of 16 years shall have legal capacity to consent on his or her own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment".

- A minor is defined in Scots Law as a person under the age of 16 (Age of Legal Capacity (Scotland) Act 1991.
- Written consent should be given by a minor if the CI or other appropriate member of the research team adjudges that the child is competent to consent. The CI or delegate should discuss consent given by a child carefully with a parent, guardian or other person with legal responsibility for the child.
- Only a qualified physician should make an assessment of competence with regard to studies that involve surgical, medical or dental procedures or treatments that may lead to a diagnosis. For studies that do not involve these, assessment of competence may be made by another appropriate professional.
- Where a child gives consent, a parent, guardian or other person with legal responsibility for the child should also be asked to give their assent. However, in situations where parental involvement may affect the young person's decision-making, such as sexual health studies, then parents do not require to be informed of participation.
- Where it is judged that a child is not competent to consent then assent should be obtained with consent taken from a parent, guardian or other person with legal responsibility for the child. Even if the parent or guardian gives consent, the child's wishes should be taken into account.
- Where the parent is competent to decide for their child but unable to read or write, the PIS and other relevant information should be read to the parent who should be afforded sufficient time to consider study participation and have any questions answered. An impartial witness should sign the consent form to say that the PIS and ICF have been read to the parent and verbal consent has been given.
- Guidance on the ethical and legal issues to consider when involving children and young people in research is available from the Health Research Authority (HRA) website - http://www.hra-decisiontools.org.uk/consent/principles-children.html.

4.5.4 CTIMPs

- A minor is defined under the Medicines for Human Use (Clinical Trials) Regulations 2004 as a person under the age of 16.
- Written consent must be given by a parent or guardian or other person with legal responsibility for the child, but competent children should also give their consent (under the 1991 Act). Where a child is not competent, assent should be sought.
- Where the parent or guardian is competent to decide for their child but unable to read or write, the PIS and other relevant information should be read to the parent

or guardian who should be afforded sufficient time to consider study participation and have any questions answered. An impartial witness should sign the consent form to say that the PIS and ICF have been read to the parent or guardian and that verbal consent has been given.

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.

4.6 Consent and Vulnerable Adults

4.6.1 All guidance, advice and statutory provisions previously documented in this SOP apply to vulnerable adults and, in addition extra care and consideration must be applied.

4.6.2 Any adult with a permanent, temporary or fluctuating mental capacity to consent is considered vulnerable. In addition, some adults with capacity may be vulnerable to pressure to take part in research. You should be aware that their health or social circumstances might make them vulnerable to pressure from others. Vulnerable adults may include, for example, living in care homes or other institutions, or have learning difficulties or mental illness. Arrangements must be made to ensure that relevant information is provided in appropriate written or pictorial form and that the role and responsibilities of parents, guardians, carers or supporters are clearly explained and understood.

4.6.3 Participants who are unable to consent for themselves can only be included in a study if:

- the study has been approved by a REC to allow inclusion of incapacitated adults
- the research cannot be performed on any other population and
- if it is the condition that is preventing them from consenting which forms part of the research, for example research on Alzheimer's disease.

For such studies:

- justification of inclusion of such participants should be documented in the protocol
- the study must be expected to produce benefit to the participant, outweighing risk or producing no risk at all
- the interest of the participant must prevail
- the study must be designed in a way that produces the minimum pain, discomfort or other foreseeable risk
- a full explanation of the study must be given to the person with parental responsibility, carer or legal representative
- the information must also be presented to the participant in a format that they, as far as possible, can understand.

4.6.4 If a capable adult becomes incapacitated their previous wishes remain legally binding and if they consented before losing capacity this remains valid. If they refused to give consent before losing capacity this equally remains valid and under no circumstances can this person be entered into a clinical study - the provisions of legal representatives cannot apply.

4.6.5 The Adults with Incapacity (Scotland) Act 2000 Section 5 and The Mental Capacity Act 2005 dictates the requirements for consent in incapacitated adults involved in research, in Scotland and in England and Wales, respectively.

Refer to the HRA website - http://www.hra-decisiontools.org.uk/consent/principles-ALC.html.

4.7 Consent in an Emergency Situation

4.7.1 There is clearly a need to carry out research into emergency situations where the potential participant may be unconscious or otherwise unable to give fully informed consent. Usually the study will allow for a legal representative to provide consent, but it may be necessary to proceed without this.

4.7.2 A REC will only approve this arrangement if the reasons why it is not possible to gain consent from a personal or professional legal representative and that the research treatment will be of benefit to the participant can be clearly explained and justified. Consent is always the preferred option, and entry into a study without consent will only be permitted when there is no person who qualifies as a personal or professional legal representative. For example, it may be possible for a physician who retains responsibility for the care of a participant, but does not have involvement in the trial, to provide temporary consent.

4.7.3 For CTIMPs, the provisions for Consent in an Emergency Situation are described in Amendment no. 2 to the Medicines for Human Use (Clinical Trials) Act (S.I.2006:2984). An unconscious patient or incapacitated adult in an emergency situation can be administered a medicinal product without prior written consent only when the following applies:

- Having regard to the nature of the study and the particular circumstances of the case, it is necessary to take action for the purpose of the study as a matter of urgency
- But it is not reasonably practicable to obtain informed consent prior to entering the participant
- The action to be taken is carried out in accordance with a procedure approved by an NHS/NRES REC.

4.7.4 When it is no longer necessary to take action as a matter of urgency this exemption does not apply and the usual conditions for obtaining informed consent need to be met.

4.8 Consent for Human Tissue

4.8.1 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.

4.8.2 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 whether they can participate or not in the research without giving additional, separate consent for tissue.

4.8.3 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.

4.8.4 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/.

4.9 Ongoing consent

4.9.1 The informed consent process should not cease once the ICF has been signed. The practice of giving information about the study to participants should be an ongoing process performed by appropriate member(s) of the research team.

4.9.2 This is particularly significant with the introduction of substantial protocol amendments and the availability of important new information, such as safety information, that may be relevant to the participant's willingness to continue participation in the study.

4.9.3 Where there is a substantial amendment to the protocol or other study document which affects participants' rights, safety or wellbeing they should be provided with the relevant amended information and asked to re-consent.

4.9.4 The Sponsor, REC and/or the MHRA, where appropriate, and NHS R&D Office(s) must approve all substantial amendments prior to them being implemented.

5. ASSOCIATED DOCUMENTS

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

6. ABBREVIATIONS

CI	Chief Investigator
GMC	General Medical Council
GCP	Good clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator.
PIS	Participant Information Sheet
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
TMF	Trial Master File

7. REFERENCES

ICH Harmonised Tripartite Guideline, Guideline For Good Clinical Practice E6(R1)
Dated 10 June 1996
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.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:
1.0	Isla Smith R&D Research Nurse	31 Oct 2014	New with adaptations from TASC SOP07
2.0	Julie Aitken R&D Trials Facilitator	22 Mar 2018	Updated to reflect current practice. Information regarding translation services included.
3.0	Julie Aitken R&D Quality & Performance Lead	29 Apr 2020	Updated in line with format of Current SOP template. Text refreshed throughout for clarity.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	29 April 2020