Sheffield Teaching Hospitals NHS
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Clinical Research & Innovation Office

STANDARD OPERATING PROCEDURE

STH Researcher

Informed Consent

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Signature:			

Standard Operating Procedure: Clinical Research & Innovation Office

Informed Consent

This SOP has been produced in accordance with **Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments, ICH Good Clinical Practice (GCP), UK Policy Framework for Health and Social Care Research, The Declaration of Helsinki and Human Tissue Act (2004).**

This SOP will outline the procedure for when participants consent to take part in research.

Background

A participant may only be entered into a research project after they have received detailed information about the trial and they have given their informed consent (certain exemptions do apply, please see section 10 of this SOP for these). Where consent is required no study related procedure should take place prior to informed consent. The explanation of the study will be given by the Principal Investigator (PI) or delegate, and will be provided in verbal and/or written format (through ethically approved study documents).

The person giving information and receiving consent must possess an in-depth knowledge of the proposed research and should be suitably qualified with appropriate evidence of consent training and maintenance of competency. The PI maintains overall responsibility for the consent process but the task may be delegated to other staff members who meet the stated criteria. This delegated task must be recorded in the study delegation log and signed by the PI.

Consent must be given freely and voluntarily by the participant with no coercion from any party. It must be made clear that should consent be given, the participant has the right to withdraw from the study at any time, without giving a reason for their withdrawal. The decision to withdraw will not prejudice future medical treatment.

Where a research project requires written informed consent a participant information sheet must be provided with a consent form for completion by the participant with or without completion by the individual receiving consent. Regardless of whether consent is written or in another format, the consent procedure to be followed and the documents associated with it must be approved by the Research Ethics Committee responsible for reviewing the project (which will be an NHS REC in the case of research involving NHS patients or service users or their tissue, data or carers and in some other cases see https://www.hra-decisiontools.org.uk/ethics/ for further information) and, where relevant, by the Health Research Authority. Following the consent procedure for a clinical trial a potential participant must have their eligibility confirmed and documented in their medical notes, the consent process must also be documented here in accordance with STH CRIO SOP A108 “Recording research information in patient notes”.

Depending on the design of a study (for example observational research) a non-medical professional may be eligible and skilled to receive informed consent. The Declaration of Helsinki states that the person receiving informed consent should be a ‘physician or another appropriately qualified individual’. ICH Good Clinical Practice (ICH GCP) guidelines revision 3 state that ‘The informed consent process should be conducted by the investigator, or other investigator site staff delegated by the investigator, in accordance with regulatory requirements’ and the written informed consent form should be signed and dated by the ‘investigator or delegated investigator site staff who conducted the informed consent discussion’ (ICH GCP 2.8.5 and 2.8.8). The Good Clinical Practice Guide compiled by the MHRA state “The UK regulations allow for the interview with a potential subject to be undertaken by any member of the investigational team at the site. The IRAS application form submitted to the REC must set out the policy for the trial in terms of what types of personnel will be involved and the procedures that will be followed. All personnel involved in the consent process must have had appropriate training for this role”. Only those with a good knowledge of the research protocol and the risks and benefits to participants from participation in the research should seek consent. In the case of a CTIMP this should normally be a qualified physician, unless agreed by the main Research Ethics Committee and the Sponsor.

When a project involves participants who may be deemed as lacking capacity added protection is required. When a participant is unable to consent for themselves it is essential that their presumed will as determined by their representative informs any decisions made on their behalf. According to Medicines for Human Use (Clinical Trials) Regulations (2004) to consent adults lacking capacity into a CTIMP a personal legal representative or professional legal representative will need to be appointed in order to represent the presumed will of a participant. A personal legal representative is a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the incapacitated adult and is willing to do so. A professional legal representative is a person not connected with the conduct of the trial who is the doctor primarily responsible for the medical treatment of the incapacitated adult.

Within a non-CTIMP study the Mental Capacity Act (2005) affords the appointment of a personal consultee or nominated consultee to reflect the presumed will of a participant. However, if the person shows signs of resistance or indicates in any way they do not wish to take part they must be withdrawn. A personal consultee can be defined as someone who knows the person who lacks capacity in a personal capacity who is able to advise the researcher about the person who lacks capacity's wishes and feelings in relation to the project and whether they should join the research. A nominated consultee can be defined as someone who is appointed by the researcher to advise the researcher about the person who lacks capacity's wishes and feelings in relation to the project and whether they should join the research.

When a project involves the collection and use of human tissue samples, the donor (or the person giving consent in the case of material obtained after death) must be made aware during the process of informed consent that they are making a donation of a tissue sample for use in research. The Human Tissue Act (2004) and Human Tissue Authority's codes of practice require that consent is necessary for the removal, storage and use of material from deceased bodies, and to store and use relevant material from the living.

In some cases explicit consent is not required or sought. For example, if a person receives, completes and returns a postal questionnaire, the act of completion and return implies that they have consented to participate in the research. In addition to this some research may require to access patient identifiable information without consent. Under these circumstances an application to the Confidentiality Advisory Group (CAG) should be made alongside the IRAS application. Further information on CAG can be found on the HRA website.

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1. Acronyms

CAG	Confidentiality Advisory Group
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CV	Curriculum vitae

HRA	Health Research Authority
HTA	Human Tissue Act
ICH GCP	International Conference on Harmonisation of Good Clinical Practice
IRAS	Integrated Research Approval System
ISF	Investigator Site File
MHRA	Medicines & Healthcare Products Regulatory Agency
MRC	Medical Research Council
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STH	Sheffield Teaching Hospitals

2. Definitions

Informed consent is a process by which a participant voluntarily confirms his or her willingness to partake in a particular study after having being informed of all aspects of the study that are relevant to their decision to participate. Informed consent may be documented by means of a written, signed and dated informed consent form or in other formats as approved by the ethics committee.

3. General procedure for face to face written informed consent

3.1 It is the responsibility of the CI or delegate to create the consent forms. Consent forms should conform to the example templates provided by the HRA. Best practice would be to ensure the consent form explicitly states that each statement should be initialled rather than ticked by the participant and for the consent form to collect the signature, printed name and date of the participant and of the person receiving the consent.

3.2 The CI or delegate is responsible for providing written information in the form of a participant information sheet. The information should be written in lay terms which are easy to understand. The format should be that of question and answer as per example templates provided by the HRA.

3.3 Both the consent form and the participant information sheet must be reviewed and approved by the Study Sponsor and the reviewing Ethics Committee. The ethics committee application should describe the planned processes for seeking and recording informed consent. Where the project does not require review by an NHS REC, review by a University Research Ethics Committee may be an appropriate alternative as determined by the study sponsor in accordance with national policy and legislation.

3.4 The PI is responsible for the conduct of the informed consent process. The PI can delegate this duty to another suitably qualified member of the Research Team within the terms of the ethics application and approval (see section 4). For all clinical trials, the suitably qualified member of the Research Team must have valid GCP Certification. This training must be clearly recorded within the Investigator Site File (ISF).

3.5 The PI records which individuals are appropriately qualified and have been delegated the conduct of the informed consent procedure. This is recorded in the ISF using a Delegation Log. Only those individuals named on the delegation log and delegated appropriately by the PI may obtain informed consent from participants.

3.6 The PI or delegate allows the participant adequate time to decide whether to take part in the study. Ideally the participant should be sent the patient information sheet in advance or be given it to take away to consider it and to take the opportunity to discuss it with others; family, friends or General Practitioner. The specific timelines will vary according to the nature of the research, and are confirmed within the ethics application and the respective approval.

3.7 The PI or delegate ensures that the Informed Consent Form refers to the current sponsor-approved Patient Information Sheet, ensuring the correct version and date of this document is recorded.

3.8 The PI or delegate is responsible for ensuring the participant receives a comprehensive explanation of the research.

3.9 The PI or delegate gives the participant every opportunity to ask questions before deciding to consent into the study.

3.10 The PI or delegate makes it clear to the participant that declining to take part in the research will not affect their future care or treatment.

3.11 The PI or delegate ensures that participants understand that they are free to withdraw from the study at any stage without providing a reason.

3.12 On the Informed Consent Form the participant must initial in the box next to each corresponding statement. The participant then signs and dates the consent form in the presence of the PI or delegate who will also sign and date the form if the form requires this.

3.12.1 If the participant is unable to write, they must mark the consent form with an “X” and this must be signed by a witness other than the PI or delegate taking the consent. If required, information on consent must be available in suitable formats such as large print. Interpreters can be used if required dependent on the information on the IRAS form and funding availability.

3.13 The PI or delegate must ensure all signatories also print their name clearly. The PI or delegate must also ensure the correct date has been recorded.

3.14 The PI or delegate must ensure one or two copies (see section 3.14.3) of the consent form are taken from the original.

3.14.1 The original consent form is filed in the ISF and the details of the participant are recorded on the enrolment log.

3.14.2 One copy of the consent form and participant information sheet is given to the research participant to take away with them.

3.14.3 Where the study is a clinical trial and/or where the study involves the storage of human tissue samples, a copy of the completed consent form and a written record of the consent process is filed in the participant’s medical records or source data file in accordance with the STH CRIO SOP A108 “Recording of research information in patient case notes”.

3.15 The PI or delegate is responsible for ensuring the information process continues throughout the participation in the study; this may involve re-consenting patients if any amendments to the study have a potential effect on the participants.

3.16 The PI or delegate is responsible for ensuring that all original consent forms are filed in the ISF.

3.17 The PI or delegate is responsible for monitoring the presence of consent forms by cross checking against the enrolment log.

3.18 The PI or delegate will ensure all consent forms are available on request for inspection and audit by the Clinical Research & Innovation Office, Sponsor and Regulatory Authority as appropriate.

4. Consent by Non-Medical Professionals in clinical research

If the consent process in a clinical research project is to be delegated to a non-medical professional then the following requirements must be adhered to:

4.1 Research Ethics Committee and Sponsor agreement must be in place through the REC application and/or protocol. Ideally content specifying that informed consent can be obtained by non-medical professionals and specifying the roles of those who will be permitted to obtain consent should be contained in documents reviewed by the ethics committee. Where documentation is not explicit the advice of the Sponsor must be sought.

4.2 The PI must be willing to delegate the task of receiving informed consent and the non-medical professional must agree to this task.

4.3 The responsibility for receiving informed consent can only be delegated on a study by study basis. Study staff who are to be delegated to receive informed consent must have a good knowledge of the research protocol and the risks and benefits of participation in the research. The task can only be delegated to an individual that has had appropriate training. Please refer to section 12 for training requirements.

4.4 The task of receiving informed consent for a CTIMP or device trial can only be delegated to a non-medical professional if a medically qualified doctor who is part of the trial team is readily available if required during the consent process. If the participant requires or requests further discussion relating to the medical care to be provided as part of the trial then this must be documented as part of the consent process.

4.5 A medically qualified doctor must confirm in writing prior to dosing that the participant is eligible for the trial. As this is considered to be a medical decision it is therefore integral that the confirmation is made by a medically qualified doctor.

5. The Consent Procedure – Adults Lacking Capacity – CTIMP studies

5.1 An adult lacking capacity can be defined as an adult unable by virtue of physical or mental incapacity to give informed consent. Where it is suspected that a person may lack capacity an assessment must be made. The PI or another suitably qualified clinician (delegate) must undertake the assessment. The assessment and its results must be recorded in the patients' medical notes. Adults lacking capacity must only be included where the REC approvals cover their involvement.

5.2 If the patient is deemed to lack capacity the PI or delegate must receive written informed consent from either a Personal or Professional Legal Representative (see background section for full definitions).

5.3 When involving a Legal Representative the PI or delegate must follow the consent process that has received a favourable opinion from an appropriate NHS REC. The Legal Representative must be given sufficient verbal and written information about the study to enable them to make an informed decision and they should be told that they are:

- Being asked to give consent on behalf of the incapacitated adult
- Free to decide whether they wish to make this decision or not
- Being asked to consider what the incapacitated adult would want

5.4 The PI or delegate must ensure that adults lacking capacity who are conscious should receive information about the study even if a Legal Representative is providing consent. The PI or delegate should judge the format and level of information that is appropriate for the Adult lacking capacity.

5.5 During the study the PI or delegate must ensure that the Legal Representative who provided consent should be informed of all material changes to the study and the participant's condition.

The Legal Representative has the right to withdraw the participant at any point in the study without it affecting the participant's care.

5.6 If a participant regains capacity during a study, the consent provided by the Legal Representative remains valid, however at this point the PI or delegate must provide the participant with verbal and written information. If the participant refuses consent following regaining capacity or withdraws consent the PI must immediately withdraw them from the study unless this would pose a significant risk to their health.

5.7 Where the treatment to be given to an incapacitated adult as part of the trial needs to be given urgently, time may not allow for the written consent of a legal representative to be obtained first. The incapacitated adult can be entered into a trial prior to consent being obtained from a legal representative provided that:

- Having regard to the nature of the trial and the particular circumstances of the case, it is necessary to take action for the purposes of the trial as a matter of urgency but
- It is not reasonably practicable to obtain informed consent prior to entering the participant and
- The action to be taken is carried out in accordance with a procedure approved by the Research Ethics Committee.

5.8 Where an incapacitated adult is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent from either the participant (if capacity has been recovered) or from the legal representative as soon as practicable after the initial emergency has passed in accordance with the procedures described in the trial protocol and/or ethics application. Where consent is withheld, the participant must be withdrawn from the trial.

6. The Consent Procedure – Adults Lacking Capacity – Non-CTIMP studies

6.1 Where it is suspected that a person may lack capacity an assessment must be made. The PI or another suitably qualified clinician (delegate) must undertake the assessment. The assessment and its results must be recorded in the patients' medical notes.

6.2 If the patient is deemed to lack capacity the PI or delegate must seek an opinion from a Consultee. The Consultee may be a Personal Consultee or a Nominated Consultee. The PI or delegate must take reasonable steps to identify a Personal Consultee before approaching a Nominated Consultee (please refer to Background section for full definitions).

6.3 The PI or delegate must ensure that the Consultee is told that they are:

- Being asked to provide an opinion for the adult lacking capacity to enter into a study
- Being asked whether the Adult Lacking Capacity might wish to participate in the study
- Free to decide whether they wish to provide this opinion or not

6.4 The PI or delegate must ensure that the involvement of the Consultee must follow the consent processes that have received a favourable opinion from an appropriate NHS REC.

6.5 The PI or delegate must ensure that the opinion provided by a Consultee is recorded on a Consultee Declaration Form that has received favourable opinion from an appropriate NHS REC.

6.6 During the study the PI or delegate must ensure that the Consultee is informed of all material changes to the study and the participant's condition. The Consultee has the right to withdraw the participant from the study at any point without it affecting the participants care.

6.7 If a participant regains capacity during a study, the opinion provided by the Consultee remains valid, however at this point the PI or delegate must provide the participant with verbal and written information. If the participant refuses consent following regaining capacity or withdraws consent the PI must immediately withdraw them from the study unless this would pose a significant risk to their health.

6.8 Where the research is being delivered in an emergency setting and it is not possible to consult in the usual way, then the person who lacks capacity can be entered into an ethically approved study with either the agreement of a doctor who is not connected to the research or in accordance with a procedure previously agreed by the REC where it is not reasonably practicable to obtain agreement from a doctor who has no connection with the project.

6.9 Any doctor identified to agree to the inclusion of a person in an approved project must have no connection to the research. They must be provided with appropriate information about the nature of the study, the inclusion/exclusion criteria and their duties. In the absence of any contrary information it is justifiable for the doctor to assume that a potential participant would wish to receive an intervention that has the greatest chance of saving their life or improving their health. Where there is genuine uncertainty about the relative benefits or harms of the standard treatment and the research treatment, it may be reasonable to assume that a potential subject would wish to enter the approved research project.

6.10 As soon as the emergency is over, arrangements must be made to seek consent in the usual manner or to seek advice from a Consultee on the continued participation of the person who lacks capacity in the study in accordance with the processes described and approved in the REC application. This should not compromise the provision of important clinical information, which must take priority over the consultation regarding any research.

7. The Consent Procedure – HTA

7.1 Investigators intending to use human tissue taken specifically for research must always obtain informed consent from the donor for this use. The signed informed consent forms must be kept in both the ISF and in the medical notes of the patient.

The only exceptions to obtaining consent are if:

- the tissue was collected before 1 September 2006
- the tissue has been taken from a living person and the researcher is not able to identify the donor and the research is ethically approved by a Research Ethics Committee
- it is imported tissue.

Appropriate consent is always required under the Human Tissue Act to remove tissue from the deceased for research purposes.

7.2 Where investigators are required to obtain a donor's consent, investigators must ensure that Participant Information Sheets state clearly the intention to use tissue samples taken at clinic or surgery in research. The Participant Information Sheet should contain sufficient information so that it is clear to the participant, within the description of study procedures, the nature of the tissue sample to be donated and state:

- whether new tissue samples will be taken as part of the research (e.g. blood, tissue, specifically for this study)
- whether tissue samples excess to a clinical procedure will be asked for
- access to existing stored samples will be asked for
- the security procedures in place for collecting, using and storing samples
- whether there will be any possible intended use in the future for research that cannot yet be specified (a separated or two part consent form is recommended if future use is intended, and it should be clear if further ethical approval will be sought)
- whether tissue samples will be used for genetic testing
- who will have access to use the tissue sample
- the level of confidentiality (for this study and for storage for future studies)
- provision for disposal of the tissue sample after use in research
- procedures for possible feedback of individually significant information from their use
- whether tissue samples will be transferred outside the UK

7.3 There must be a section on the Consent Form which allows for the recording of a donor's explicit consent for the use of their tissue. Investigators taking consent should record the process in the patient's notes and file a copy of the Participant Information Sheet and signed Consent Form in the patient notes. The original signed Consent Form should be kept in the study ISF.

7.4 Where an investigator wants to obtain tissue samples from children, the consent process must include assent from the child (if applicable age) and consent from the parent or legal guardian if under 16 years of age.

7.5 Where an investigator cannot obtain written consent from a donor due to the disability of that individual, the consent process must be witnessed by another party independent of the research team. The Human Tissue Act details those individuals with 'qualifying relationships' allowing those individuals to give consent on behalf of the incapacitated donor.

7.6 Where an investigator wishes to use tissue samples from the deceased, consent is always required unless the tissue samples were obtained before 1 September 2006. A person may consent for their tissue to be used for research after their death. If there is no record of the deceased wishes, consent can be obtained from relatives or a person acting on the deceased's behalf.

7.7 Consent forms must be accessible to those using or releasing tissue for research and for those needing to conduct an audit.

8. The Consent Procedure – Paediatric Setting

For research involving those under the age of 16 years the initial approach for informed assent/consent of a child must be done through the parent. If a parent is unavailable a guardian/legal representative may be approached.

8.1 The PI or delegate must ensure that prior to discussing a research study with a child the parent/guardian (non-CTIMP) or legal representative (CTIMP) of the child has had the opportunity to review the REC approved information sheets. There would usually be a PIS/ICF for Parents/Guardians, and an age appropriate PIS/Assent Form for children (e.g. <6, 6-10, 11-15). The PI or delegate must also allow sufficient time for the parent/guardian or legal representative to consider participation. This process will ensure the parent/guardian or legal representative is given the opportunity to understand the objectives and risks of the study and the environment and conditions which it is to be conducted.

8.2 The PI or delegate must ensure that the parent/guardian or legal representative has been provided with a contact point where further information about the trial can be sourced.

8.3 The PI or delegate must receive informed consent from the parent/guardian or legal representative for the child to take part in the research project.

8.4 The parent/guardian or legal representative of the child may, without the child being subject to any resulting detriment, withdraw the child from the research project at any time by revoking the informed consent.

8.5 The PI or delegate must ensure that the child has full age appropriate information about the research in order receive their full assent to take part. Assent must be freely volunteered by the child. The REC application will set out what age groups of children are expected to provide assent in addition to parent/guardian or legal representative consent.

8.6 The PI or delegate must ensure that the information presented to the child and parent explains fully what will happen in the research, what is being asked of the child and it must be conveyed that the child or parent can refuse to take part without adverse consequences.

8.7 The PI or delegate must ensure that the information given is in a clear, understandable language which the child and parent can comprehend.

8.8 If the PI or delegate deems the child incapable of understanding the implications of taking part in a research project or where the child is regarded as incompetent to assent, parental consent alone is acceptable.

9. Consent for Research in Emergency Settings and Situations

9.1 In some cases research will involve a need to act upon recruitment during a short period of time due to the nature of the project/investigation. In an emergency situation it is not always possible to get consent to involve a person in research using the standard consent procedures.

9.2 In designing such emergency research projects the CI and sponsor must carefully consider what level of consent it may be possible to obtain prior to the intervention taking place. Except in cases where the patient is incapacitated it is usually possible to provide limited information about the research and gain at least verbal consent before including the participant in the study. The CI and sponsor are responsible for specifying the consent process to be used in the REC application and for designing suitable brief information sheets which will provide shortened guidance on what will happen to the patient if they participate.

9.3 The Mental Capacity Act 2005 permits urgent research in emergencies to start when it is not practical to consult someone about involving a person who lacks capacity in research. In this situation you must either get agreement from a doctor not involved in the research, or follow the procedure approved by a Research Ethics Committee

9.4 For details on research involving adults lacking capacity in emergency situations please refer to sections 5 and 6 respectively, depending upon the nature of the research.

9.5 In emergency research where the patient does not lack capacity the PI or delegate will follow the abbreviated consent procedure specified in the protocol using the study documents approved by the REC/HRA and sponsor. The PI or delegate will provide the patient with an abbreviated information sheet as approved by the ethics committee and Sponsor or, where a brief information sheet is not provided otherwise follow the process for gaining emergency consent that has been approved by the REC (for example, perhaps verbally delivering an ethically approved script) as specified in the protocol and IRAS form.

9.6 Following the patient receiving the brief information sheet the PI or delegate will ensure the patient provides any relevant form of consent as approved by the REC prior to receiving any study related intervention. Where written consent is required the participant will sign and date the form to indicate they are willing to receive the treatment. The PI or delegate will then countersign the document to indicate they bore witness to the patient agreeing to take part in the research. Alternatively, depending on what has been approved by REC as specified in the protocol and IRAS application verbal consent may be taken instead following the patient receiving the brief information sheet. Verbal consent should be recorded in the patient notes and/or study case report form as specified by the CI and study sponsor

9.7 Once the emergency situation is over it is the responsibility of the PI or delegate to follow the full retrospective consent procedure as specified in the protocol and IRAS application and as outlined in section 3 of this SOP.

9.8 If the participant decides they do not wish to continue in the research after the emergency situation has passed the process outlined in section 11 of this SOP should be followed.

10. Alternative Processes

Not all research will require face to face written informed consent. In some situations it will be more appropriate to obtain verbal consent, telephone consent, postal consent or electronic consent from participants. Any plan to obtain consent via alternative means should be clearly described within the application submitted to the Research Ethics Committee and subsequently approved by the committee.

It is advisable to undertake the procedure of verbal consent or telephone consent with a colleague who can verify the process.

10.1 **Telephone (or video call) consent**

10.1.1 When telephone consent is planned for the research it is the responsibility of the CI and sponsor to plan how telephone consent will be documented and to describe this fully in the ethics application, providing a suitable template for the recording of the telephone consent process for ethical review as appropriate.

10.1.2 The PI or delegate to ensures an information sheet has been given or sent to a potential participant well in advance of the consent telephone call to allow sufficient time to consider whether or not to participate in the research. The PI or delegate should answer any additional questions the participant may have. The PI or delegate may then obtain telephone consent to participate in the research, documenting the process using the ethically approved telephone consent template and/or procedure. Where no specific method of recording telephone consent is provided then the provision of consent should be documented as a note in the medical notes including the STH number of the study concerned.

10.2 **Verbal Consent**

10.2.1 Verbal consent alone is uncommon in the context of clinical research and is usually restricted to either simple permission for research observations of the delivery of usual care where the level of intrusion does not warrant written consent or in emergency scenarios where time or situation does not permit written consent processes. Sometimes verbal consent for the transfer of identifiable data for the participant to an external organisation is required in order to facilitate completion of the full written consent process by the external organisation or to facilitate the use of e-consent systems maintained by the external organisation

10.2.2 When verbal consent is planned it is the responsibility of the CI and sponsor to plan how information about the research will be provided. Where written information will be provided the information should be written in lay terms which are easy to understand. Since scenarios where verbal consent is appropriate are varied but specific appropriate formats for written information will vary and could include an information sheet, leaflet, poster, brief information sheet.

10.2.3 Where no written information is planned to be provided to the prospective participant in advance of verbal consent a script for the information which is to be delivered verbally or other guide listing points to be covered in the verbal discussion should ideally be provided for ethical review.

10.2.4 Methods of documenting verbal consent will also vary and should be appropriate to the scenario. A suitable template for the recording of the verbal consent should be provided for ethical review if appropriate.

10.2.5 The PI or delegate must explain the study to the potential participant as described in the ethics application using the approved study documents and must allow the potential participant suitable time and opportunity to ask questions.

10.2.6 The PI or delegate should document the consent process and provision of verbal consent according to the method approved by the ethics committee. Where no specific method of recording verbal consent is provided the provision of consent should be documented as a note in the medical notes including the STH number of the study concerned.

10.3 Implied Consent

10.3.1 Implied consent is generally only used in the context of questionnaire-based observational research. The CI should confirm with the sponsor where consent can be implied by the completion and return of a questionnaire and this format of consent must be approved by the reviewing ethics committee.

10.3.2 Complete written participant information, reviewed and approved by the relevant ethics committee, must be provided to the participants prior to their completion and return of the questionnaire. The information should provide participants with a point of contact should they wish to discuss their participation in the research prior to their completion of the questionnaire.

10.3.3 There should be no additional aspects of the research which would require explicit consent, such as use of samples, access to medical records by those outside the care team or onward transfer of participant identifiable details. Where explicit consent for these aspects is needed implied consent should not be used and alternatives such as written postal consent or electronic consent recorded as part of the electronic responses to the online questionnaire (which in the context of low-risk research could be the simple acceptance of tick-boxes within the online questionnaire) should be employed.

10.4 Postal Consent

10.4.1 This consent format can be completed independently by the participant in the case of simple observational research where it is anticipated that no discussion will be necessary with the majority of potential participants. Alternatively, the consent form can be completed by the participant during a telephone or video call with a member of the research team.

10.4.2 When postal consent is planned it is the responsibility of the CI and sponsor to prepare participant information sheet and postal consent form and to submit these for review by the relevant ethics committee, detailing the planned consent procedure (including whether any verbal discussion with the potential participant by the research team will be routinely required) in the ethics application. The information sheet should provide participants with a point of contact should they wish to discuss their participation in the research prior to their completion of the questionnaire. The consent form does not need to contain fields for the researcher receiving the consent where this is not pertinent to the planned consent process

10.4.3 The PI or delegate posts or otherwise sends the approved information sheet and consent form to the potential participant. The PI or delegate follows this up with a phone call and/or reminder in line with that described in the protocol and/or ethics application form only.

10.4.4 The participant returns the completed and signed consent form to the PI or delegate. The relevant member of the research checks and countersigns the returned consent form if required by the consent process, returning a fully signed copy to the participant if required, and then files the completed consent form in the ISF. Where the study is a clinical trial and/or where the study involves the storage of human tissue samples, a copy of the completed consent form and a written record of the consent process is filed in the participant's medical records or source data file in accordance with the STH CRIO SOP A108 "Recording of research information in patient case notes".

10.5 Electronic Consent

10.5.1 E-consent methods can be used in clinical research where it is within the scope of the ethics committee approval. E-consent may either be completed independently by the participant or may be completed during an interaction with either local or external investigators depending on the methods described in the ethics committee application and/or protocol. Where the consent is completed during an interaction with an investigator this interaction may take place within a face to face visit or may be undertaken remotely during a telephone or video call. The method to be used in the completion of e-consent should be described in the ethics committee application form and/or protocol and copies of documents and e-consent forms to be used in the process should be submitted for ethics committee review and approval

10.5.2 Ideally the e-consent system used should be able to provide verification that the consent provided is traceable to the participant themselves and verification of the date on which the consent was provided and of the identity of the person taking the consent (where applicable). Ideally the system should also be able to print a record of the informed consent form for insertion into the participant's medical notes where appropriate (refer to STH CRIO SOP A108). These requirements are especially important in the case of e-consent within a CTIMP or device trial.

10.5.3 Simpler forms of electronic consent can be used to record consent for low risk studies, for example as part of the responses returned for an online questionnaire, see 10.3.3 above.

10.5.4 Where e-consent will be used for a project the procedures and processes outlined in Section 3.1-3.11 and 3.14.3-3.18 must be followed in as much as they apply to the specific e-consent process described in the ethics committee application and/or protocol and provided by the study sponsor.

11. Withdrawal of Consent

11.1 Where a research participant, the legal representative, or parent/guardian wishes to withdraw their consent from a study, or where the PI responsible for the participant's care decides it is in the best interest of the participant to withdraw them from a study, the withdrawal process and reasons for withdrawal, where provided, must be fully documented in the participant's medical or case notes.

11.2 The PI or delegate must clarify the nature of the withdrawal of consent since the withdrawal of consent may relate only to the wish to stop receiving the intervention or stop in person attendance for study visits rather than withdrawing consent for all study follow up either by post or telephone or passively from medical records etc. The PI or delegate must document in the medical notes the nature and extent of the withdrawal of consent.

12. Training and Experience

While there are no national guidelines in place for what constitutes appropriate training and experience for the receiving of consent Sheffield Teaching Hospitals has set out the following criteria which can be followed as per best practice.

12.1 For research characterised as CTIMPs or Device trials either an accredited NIHR GCP training or a GCP training course approved by a study Sponsor is required; in line with the possible duration of STH granted Research Honorary Contracts, current GCP status is defined as three years since the date of last substantiated GCP education and experience. External Sponsors may advise two yearly renewals.

12.2 Where applicable, the UKCRF Network provides a template for informed consent competency documentation for research characterised as CTIMP or Device trials.

12.3 Full protocol training and relevant study specific SOP training which is then to be documented via the signing of the signature log in the ISF and/or completion of other study training record as required by the study sponsor.

12.4 Ideally an individual who will receive consent will also endeavour to attend either the NIHR Informed Consent Training Day which can be booked via LMS or another appropriate training approved by the Sponsor. It would also be encouraged for the individual to undergo shadowing with the PI.

Appendix 1 SOP revisions and history

SOP number & version	Effective date	Reason for change	Author
THIS SOP			
A106 Version 4.0	19 February 2024	To improve language and clarity throughout To revise sections on telephone and verbal consent To include implied, postal and electronic consent To account for alternate methods/processes needed during an urgent public health scenario	EW
PREVIOUS SOPs			
A106 Version 3.0	01 September 2017	To account for and incorporate national changes to research and to provide a more thorough guidance of the informed consent process	LB
A106 Version 2.4	15 June 2010		
A106 Version 2.3	20 August 2009		
A106 Version 2.2	15 November 2006		
A106 Version 2.1	03 August 2006		