Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

STH Researcher

Informed Consent

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Approved by (name & role)	Dipak Patel	**Date**	27 July 2017
Signature:			

Standard Operating Procedure: Research Department

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), Research Governance Framework, 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). No study related procedure should take place prior to informed consent. The explanation of the study will in the first instance be given by the Principal Investigator (PI) or delegate, and will be provided in either 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 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 and the individual receiving consent. The consent procedure and the documents associated with it must be approved by the Research Ethics Committee responsible for reviewing the project 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.

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 asserts that the person receiving informed consent should be a qualified physician. However, ICH Good Clinical Practice (ICH GCP) guidelines posit that 'The Investigator, or a person designated by the investigator, should fully inform the participant' and the written informed consent form should be signed and dated by the 'person who conducted the informed consent discussion' (ICH GCP 4.8.8). In the Good Clinical Practice Guide compiled by the MHRA it states "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". It is considered best practice that only those with a good knowledge of the research protocol 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 volunteer 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 wish 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. It may also be implied, for example when a completed questionnaire is returned.

3. The General procedure for written informed consent

3.1 It is the responsibility of the CI or Sponsor 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.

3.2 The CI or delegate is responsible for providing written information in the form of a participant information sheet approved by the reviewing Ethics Committee and the Study Sponsor. The information should be written in lay terms which are easy to understand. The format should be that of question and answer as approved by both the HRA and NRES (National Research Ethics Service). Where the project does not require review by an NHS REC, review by a University Research Ethics Committee may alternatively be required. It is the responsibility of the PI and Sponsor to ensure the correct version of the participant information sheet and informed consent form are used.

3.3 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. For CTIMPS and Device 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). This can be evidenced through the staff members CV, GCP certificate, or can be documented on the training log.

3.4 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 may obtain informed consent from participants.

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

3.6 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.

3.7 The PI or delegate allows the participant adequate time to decide whether to take part in the study. Ideally the participant should be able to take the information 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.

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

3.9 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.

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

3.11 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. Under circumstances where the approved process for receiving informed consent consists of postal consent the presence of the PI or delegate is naturally not required. Under circumstances where the approved process for receiving consent consists of telephone consent the PI or delegate must be party to this conversation.

3.11.1 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.

3.12 The PI or delegate must ensure all signatures have the name of the person signing printed clearly. The PI or delegate must also ensure the correct date has been recorded.

3.13 The PI or delegate must ensure two copies of the consent form are taken from the original.

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

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

3.13.3 The final copy of the consent form is filed along with a copy of the participant information sheet in the participant’s medical records. This is filed in accordance with the Research Department SOP A108 “Recording of research information in patient case notes”. This however is not necessarily required when the research is purely observational and human tissue is not stored.

3.14 The PI or delegate must ensure the consent process is recorded in the medical records of each participant. Specifically the time and date of the initial approach, confirmation that the discussion took place and that the participant had an opportunity to ask questions needs recording in the medical records. This provides a clear audit trail to ensure no study specific activities occurred prior to consent being obtained. This however is not necessarily required when the research is purely observational and human tissue is not stored.

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 Research Department, Sponsor and Regulatory Authority as appropriate.

4. Non-medical professionals consent in clinical trials

If the consent process in a clinical trial 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 content specifying that informed consent can be obtained by non-medical professionals.

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. 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 can only be delegated to a non-medical professional if a medically qualified doctor who is part of the trial team is readily available during or following 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. 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 in Emergency Research

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 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 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 the 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 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 13 of this SOP should be followed.

10. Alternative Processes

Not all research will require written informed consent. In some situations it will be more appropriate to obtain verbal consent or telephone consent from participants. Any plan to obtain verbal consent or telephone consent 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 consent*

10.1.2 When telephone consent is planned for the research it is the responsibility of the PI or delegate to ensure an information sheet has been given or sent to a potential participant.

10.1.3 It is the responsibility of the CI or sponsor to create a script for the consent process. A consent script should include the same elements as would be in a consent form, but in a more conversational manner. This script will be approved by the reviewing Research Ethics Committee and the Study Sponsor.

10.1.4 The PI or delegate will ensure the potential participant is granted sufficient time to consider whether or not to participate in the research. After allowing the potential participant sufficient time, 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.

10.1.5 When documenting the consent process the PI or delegate should record the reading of a consent statement, and the answers of the participants indicating willingness to participate. The documented record of events verifies the telephone consent process.

10.2 *Verbal Consent*

10.2.1 The PI or delegate is responsible for providing written information in the form of a participant information sheet approved by the reviewing Research Ethics Committee and the Study Sponsor. The information should be written in lay terms which are easy to understand. The format should be that of question and answer. The PI or delegate must also explain the study to the potential participant verbally, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation), and must allow the potential participant suitable time and opportunity to ask questions.

10.2.2 It is the responsibility of the CI or sponsor to create a script for verbal consent. This script will include the same elements of consent as would be in a consent form. This script will be approved by the reviewing Ethics Committee.

10.2.3 The PI or delegate will ensure the potential participant is granted sufficient time to consider whether or not to participate in the research. After allowing the potential participant sufficient time, the PI or delegate should answer any additional questions the participant may have. The PI or delegate may then obtain verbal consent to participate in the research.

10.2.4 When documenting the consent process the PI or delegate should record the reading of a consent statement, and the answers of the participants indicating willingness to participate. The documented record of events verifies verbal or telephone consent.

11. Withdrawal of Consent

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

11.2 The PI or delegate must ensure that the process documented in the study protocol for early termination is followed.

11.3 The PI or delegate must documents in the medical notes whether the participant has withdrawn consent for all study follow up or confirm if the participant is willing to continue follow up until the study naturally ends.

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. Sponsors may advise two yearly renewals.

12.2 Where applicable, completion of the UKCRF informed consent competency training for research characterised as CTIMP or Device trials.

12.3 Full protocol training and study specific SOP training which is then to be documented via the signing of the signature log in the ISF.

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 3.0		To account for and incorporate national changes to research and to provide a more thorough guidance of the informed consent process	LB
PREVIOUS SOPs			
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		