Standard Operating Procedure (SOP)
Informed Consent

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SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Lucy H H Parker
V2.0	Updated with new Trust Logo and Foundation Trust. Update with Clinical Trials Regulations Amendment 2008 re minors and consent in emergency research.	Nadia Azzouzi
V3.0	Updated to add reference to UK Policy Framework for Health and Social Care. Change term of "minor" to Children and Young Person. Additional clarification in emergency situations. Additional consideration for consent in the deceased. Addition of link to general definitions document	Subhir Bedi & Prof Heather Jarman
V4.0	Update to outline on individuals able to take consent. Addition consideration of non-English speaking consent. Administrative updates.	Subhir Bedi

Contents

1. Background

The UK Policy Framework for Health and Social Care 2017 outlines a number of principles which serve as benchmarks for good practice for the management and conduct of health and social care research in the UK. Informed consent is a key aspect of Principle 12- "Choice".

ICH-GCP defines Informed Consent is the process by which a participant voluntarily confirms their willingness to participate in a study, having been informed of the full details of the project. Informed consent is documented by means of a written, signed and dated ICF.

Informed consent is an ongoing process. It involves giving information to the potential participant, discussing and clarifying the information, seeking their written consent and subsequently providing any new information that might affect their willingness to continue to participate in the study.

All participants entering into a clinical study/research project which is not classed as emergency research must have given informed consent before any aspect of the project starts (interventional or non-interventional) with the original signed version filed in the Investigator Site File (ISF). A direct copy should be provided back to the participant with a copy added to their medical records together with a copy of the PIS (PIS).

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This Standard Operating Procedure (SOP) describes the process for obtaining informed consent from a study subject. It outlines the informed consent procedures for adult subjects with capacity who are able to give informed consent, and informed consent procedures for those groups considered vulnerable such as children and incapacitated adults.

4. Definitions

For general research management related acronyms refer to "Definitions" working practice document (JREOWPD0020).

5. Responsibilities

It is the responsibility of the Chief and/or Principal Investigator and anyone delegated the responsibility of taking informed consent to read, understand and follow the consent procedures outlined in the study protocol and this SOP.

The PI should only delegate the task of taking consent to any member of the research team who is appropriately qualified by education, training and experience to undertake this task.
ICH GCP guidelines state that '*The **investigator, or, a person designated by the Investigator** should fully inform the subject*' (ICH GCP 4.8.5) and the written ICF should be signed and dated by the '***person who conducted the informed consent discussion***'.

The delegation of Informed Consent to an appropriate, suitably qualified member of the research team should be considered on a study-by-study basis. If staff other than the PI are to accept responsibility for the informed consent process, it is important the following criteria are met:

- S/He is prepared to take on this additional responsibility AND feels confident to seek informed consent in line with their professional organisational guidelines.
- S/He has a full understanding of the study, potential risks/benefits and the associated disease area. They should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.
- This delegation of responsibility should be documented on the Study Delegation Log/Site Responsibility Log (title can vary from centre to centre, but is essentially a log that captures each member of the study team and their individual responsibilities in the management and conduct of the study and is signed and dated by the CI/PI).
- The process is in accordance with the consent process outlined in the approved ethics application.
- Effective communication is maintained back to the CI/PI who is ultimately responsible for the subject's care.

For St George's sponsored CTIMPs and Clinical Investigational (Device) Trials, informed consent may be taken from other clinically qualified personnel, e.g. Research Nurse. However, each study will be assessed on a case by case basis by the CI and JRES, informed by the outcome of the risk assessment, and this arrangement must comply with the conditions in the favourable opinion of the NHS Research Ethics Committee (REC) and the approval of the Medicines and Healthcare products Regulatory Agency (MHRA).

For hosted studies, the sponsor has the final decision on whether to allow nurse consent on CTIMP and or Clinical Investigational (Device) Trials.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigational (Device) Trials eligibility of potential subjects must be determined by medically qualified personnel (i.e. doctor or dentist). This responsibility cannot be delegated to non-medically qualified individuals within the study team. The assessment of the eligibility of the potential participant must be documented in the subject's medical notes

6. Procedure

The procedure of taking consent within this SOP is split into Adults with Capacity, children, adults without capacity to consent for themselves, consenting in an emergency research situation and consent for relevant material, as defined under the Human Tissue Act, to be supplied to an external organisation.

All potential participants should be given information about the study prior to inclusion in the study. The dignity of the potential participant should be taken into consideration, and a private area used for the consent process if required.

Subjects who **potentially** fulfil the inclusion/exclusion criteria will be identified and approached. A verbal explanation of the study must be given to the potential participant (or friends and family if appropriate) by the researcher.

The informed consent process should not end once the ICF has been signed. The practice of giving information about the study to participants should be an ongoing process performed by all members of the research team and any associated healthcare professionals. This is particularly important if protocol amendments are introduced, or if important new information that may be relevant to the participant's willingness to continue taking part in the study or wellbeing is discovered. In these circumstances it may be necessary to re-consent the participant using an amended PIS and consent form, to continue their involvement in the study.

The timing of the signing of the ICF, relative to study registration and the initiation of study procedures, is subject to audit by regulatory/approval bodies. It is therefore essential to record dates correctly on both the ICF and in the subject's medical notes. The ICF must be signed by the study participant before any aspect of their involvement in the study begins.

6.1 Taking consent from Adults with the capacity to consent

When describing the study, the person seeking consent should explain:

1. What the purpose of the study is and any background information that may be relevant.
2. Why the participant has been approached and that confidentiality will be maintained throughout the study, should they decide to participate.
3. Details of the study design and details of any drugs used (including any known safety profiles). If there is a placebo arm or randomisation involved then these procedures should be explained.
4. The number of people taking part in the study and how many have been recruited to date.

5. The duration of the study and the number of study visits involved. It should be explained where the subject will be seen and by whom.
6. All procedures, such as blood tests, electrocardiograms (ECGs) etc. that are required as part of the study should be included and explained in lay language e.g. 10mls (2 teaspoons) of blood.
7. The potential benefits and risks of participation in the study, and any alternative treatments available to the subject should be discussed.
8. The availability of compensation should something go wrong.
9. That the participant enters the study voluntarily and can withdraw at any time without any prejudice to them or their future care. Similarly, if the Investigator feels that the study medication/treatment/procedure is not suiting the participant that they have the right to withdraw them from the study in the interests of their safety.
10. That a detailed discussion of the participant's medical history (including disclosure of all medication they are taking) will be required should they agree to participate.
11. If there are any payments made for participation in the study or for out of pocket expenses.
12. The responsibilities of the participant if they choose to take part, particularly if the study duration is lengthy.
13. That giving informed consent does not necessarily mean the participant will be enrolled into the study if it is discovered they do not meet the inclusion/exclusion criteria e.g. a study specific diagnostic test.

Once the above information has been verbally discussed with the subject, the participant should be provided with a written PIS about the study (on localised Trust headed paper).

The participant should be given adequate time to read the PIS and to discuss with any family and friends (if applicable), prior to agreeing to participate. The participant should not be coerced to participate, and should be reassured that refusing to enter the study will not affect their care.

Once the participant has had time to read the PIS and has had any questions regarding their participation answered satisfactorily, then they should be asked to sign the written ICF relating to the study.

Each box following each statement on the consent form should be personally initialled by the participant to affirm agreement with the corresponding statement. The ICF must be personally signed and dated in ink easily visible on photocopies by the person seeking consent or the CI/PI or Co-Investigator and the participant. Each should also clearly print their name by their signature.

Once all parties have signed the written ICF, the participant should receive a signed and dated copy, together with a PIS and any other written information provided to the participants. The original copy of the above must be placed in the Site File and a copy in the participant's medical notes by the study team.

For interventional studies participants must be provided with 24-hour contact details where they may obtain emergency information/support if needed.

6.2 Taking consent from children & young persons

In addition to the procedure stated above in section 6.1, there are a number of factors that must also be considered when seeking consent from children & young persons. Under the Regulations a child is a person under the age of 16 years.

It is essential that the clinical study either relates directly to a clinical condition from which the patient suffers, or that the study can *only* be carried out on child/young person.

The wishes of the child must always be considered. If the child does not want to participate in the study, their opinion should be respected. If there is discord between the parents or guardians and the child, the wishes of the child should take precedence.
It should be shown that there will be some direct benefit for the research participants, and that the clinical study is necessary to validate data obtained in other clinical studies involving those able to give informed consent (or by other research methods).

A full explanation of the study (including the objectives, risks/inconveniences) must be given to the parent/legal guardian of the child. That person may then provide consent for the minor to participate in the study. If the study involves emergency treatment and the parent/guardian cannot be contacted in time to provide consent, then consent from a legal representative can be obtained. The legal representative must receive the same full explanation of the study so that they can provide consent to the minor taking part. A contact number for the research team must be given so that they can obtain further information about the study should they wish to do so.

1. The minor should be given information about the study according to his/her level of understanding (from staff that have experience in dealing with children) and the person seeking consent must respect their wishes.
2. The minor, parent/legal guardian of the minor (or the legal representative of the minor) must be made aware that they can withdraw from the study at any time without any detriment to future care.

3. No incentives or financial inducements must be given except for compensation in the event of injury or loss.
4. If aged 16 or over, it is acceptable for young people to sign their own consent form.
5. The PIS should be written in a language that the minor can understand and there should be different versions, for e.g. under 5s, 6-12 year olds, 13-15 year olds and over 16. There should also be a version produced for the parent/guardian/legal representative.
6. It is best practice to obtain the assent of the child in addition to the consent of the parent/guardian, if the child is deemed competent to understand the research being explained to them. In such circumstances a signature should be obtained from both the minor and the parent/guardian on the consent form.

If a minor becomes an adult during the life of the study, it is important that they are then consented into the study. This is common in long term studies and should form part of the ongoing consent process.

Wherever possible consent should be sought from both parents. If there is a difference of opinion between the two parents then consideration should be given as to whether that child should indeed be included in the study.

6.3 Taking Consent – Incapacitated Adults

When seeking consent from an adult who is unable to provide informed consent for himself or herself, it is important that the Investigator ensures that:

1. The study relates directly to a life threatening or debilitating clinical condition from which the participant suffers, and it is expected that the study will produce a benefit to the participant. This benefit should outweigh the risks or produce no risks at all.
2. The clinical study must be essential to validate data obtained in other clinical studies involving persons able to give informed consent, or by other research methods.
3. The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risks to the participant. Continuous monitoring throughout the study of risks and/or distress must take place. The interests of the participant must always prevail over the interests of science.
4. The participant's legal representative must have the objectives, risks, inconveniences/discomforts and associated conditions for the study explained to them. A contact number for the study team should be provided in case they wish to ask further questions about the study. The legal representative must be informed of their right to withdraw the participant at any time resulting in no detriment to care or treatment for the subject. They must then give informed consent on behalf of the subject.

5. The participant must also be given information about the study according to their level of understanding. Participants who are able to form an opinion based on the information provided, their wish to participate (or not) must be respected by the person seeking consent.
6. No incentives or financial rewards must be used to influence a participant to participate (or the participant's legal representative to consent on their behalf), other than provision for compensation in the event of loss or injury.

6.4 Informed Consent in Emergency Research

Where research involves adults that temporarily or permanently lack capacity to consent, and there is a need to initiate recruitment within a short timescale due to the nature of the investigation e.g. stroke studies, the situation differs depending on whether the research falls under the UK Medicines for Human Use (Clinical Trials) Regulations 2004 or not.

6.4.1 Clinical Trials subject to UK Clinical Trials Regulations 2004

These relate to trials of medicinal products for human use. An adult is anybody over the age of 16 years for the purposes of these regulations. Consent is required (before recruitment) from the personal representative of the participant, or if there is no such person, from a professional representative. In December 2006 the regulations were amended to give provisions for emergency research. This amendment addresses the problem that in trials involving emergency treatment there may not be enough time to contact a representative before entering the patient onto the trial. Where an incapacitated adult is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent either from the subject (if capacity has been recovered) or from a legal representative (personal or professional) as soon as practicable after the initial emergency has passed. Where consent is withheld, the subject must be withdrawn from the trial. Such recruitment would be subject to approval from a research ethics committee.

The Medicines for Human Use (clinical trials) and Blood Safety and Quality Amendment Regulations 2008 made additional provision relating to trials involving children in emergency situations. Where the treatment to be given to a child as part of the trial needs to be administered urgently, time may not allow for the written consent of a person with parental responsibility or a legal representative to be obtained first however steps must be taken to seek informed consent from a person with parental responsibility (in the first instance) and or legal (personal or professional) representative as soon as practicable after the initial emergency has passed. Where consent is withheld, the subject must be withdrawn from the trial.

6.4.2 Research not included under UK Clinical Trials Regulations 2004

Following the introduction of the Mental Capacity Act (2005), researchers are required to consult a carer or someone interested in the adult's welfare, or an independent nominee for their advice and opinion on whether the patient should be recruited. It would broadly be expected that this advice is followed. Studies that are subject to the Clinical Trials Regulations are excluded from the Mental Capacity Act as the Clinical Trial Regulations contain provision for this.

The Act also allows an adult to be enrolled in a research study in an urgent situation without such consultation, providing there is an agreement from an independent clinician. Alternatively if this is not practical, then the protocol must be approved by the appropriate research ethics committee. These arrangements only apply for the duration of the emergency. Consent and consultee input must be sought as soon as practically possible. Arrangements for this procedure should be clearly set out in the IRAS application and study protocol and approved by an ethics committee.

6.5 Consent to supply relevant material to external organisations

Most external organisations require assurances that informed consent has been appropriately and legally obtained.

If tissue samples are to be stored for future use and/or external collaboration there are key points that should be included in the PIS and clauses added to the consent form:

1. Consent should be in writing from the donor, legal representative or next-of-kin as appropriate.
2. Ethics approval or a statement that approval is not required should be obtained.
3. The PIS and consent form explains the actual or potential use of tissue samples.
4. Statements regarding withdrawal, data protection and duration of storage (if any) are clearly stated in the participant information sheet.

Researchers should consider which clauses in relation to future use should be made optional so that the participant can participate in a study without having to consent to their samples being used for future use.

6.6 Consent of the deceased

Consent given prior to death, is believed to extend beyond death however the opinions of their relatives need to be considered. This should be handled sensitively with relatives being encouraged to respect the deceased person's wishes. If consent from the patient was not sought prior to death (due to lack of capacity), then consent can be gained from the deceases legal

(personal) representative. Consent for children who have died should be gained from the party with legal parental responsibility.

The Data Protection Act no longer applies to identifiable data that relate to a person once they have died. However, any duty of confidentiality does extend beyond death. It is important to maintain confidentiality to ensure that trust in services and institutions are not undermined. Disclosure of confidential information post mortem therefore requires consent.

Tissue collection from a deceased person or to conduct a post mortem purely for research purposes requires consent

6.7 Obtaining consent from those whose first language is not English

ICH GCP guidelines require that '*the information that is given to the subject or their representative shall be in language understandable to the subject or their representative'*.Therefore, when recruiting participants whose first language is not English and who cannot demonstrate sufficient comprehension and or understanding in English, the PIS and PCFs may need to be translated into a language the participant does understand. Accurate translation is required. An explanation of the translation process should be provided to the REC. Some RECs may wish to see the translated and back- translated versions of the PIS and PCF. This the responsibility of the clinical project sponsor.

During the consent process a certified translator may be required to sit in on the meeting to ensure the potential participant has a full understanding of all the issues, risks and benefits of the trial prior to consenting. A certified translator would not include a family member and or individual accompanying the patient/participant.

6.8 Withdrawal of consent

Many studies will have participants "drop out" of participating in the study. Indeed, many studies plan for a certain percentage of their participants to remove themselves from the study. It is important therefore, to have a process in place for recording the removal of consent from a study.

Researchers are allowed to ask the participants for the reason of withdrawal of consent. This may help the design of the study, e.g. if they are dropping out because they feel there are too many visits or too many questionnaires to complete, the study team may then go through the correct procedure for amending the study design. However, the participant does not have to give them a reason.

There are a number of options available should a participant choose to stop taking part in the study. Are they going to give permission for all of their data and samples to be collected until the point of withdrawal to be used or do they wish everything to be removed? There should be a discussion with the participant and their wishes recorded in their notes and in the study records.

If the participant wishes all data/samples to be removed/destroyed then their wishes must take precedence over the wishes of the researcher.

7. References

ICH GCP

Declaration of Helsinki (1996 Version)

UK policy framework for health and social care research v3.3 07/11/17

The Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument 2004/1031

The Human Tissue Act (2004)

MRC Research in emergency settings involving adults who lack capacity

The Mental Capacity Act (2005)

UK Medicines for Human Use (Clinical Trials) Regulations 2004

The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006

The Medicines for Human Use (clinical trials) and Blood Safety and Quality Amendment Regulations 2008

HRA Information Sheets and Consent Forms – Guidance for Researchers and reviewers http://www.hra-decisiontools.org.uk/consent/index.html

8. Appendices

There are no associated appendices for this SOP.