St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Signature of Authorisor			

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Standard Operating Procedure (SOP)

Informed Consent

SOP Chronology		
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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

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1. Background

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 informed consent form.

Informed consent is a three step process which involves:

1. The giving of information.
2. The discussion and clarification of the information and.
3. Taking the subject's verbal and written consent.

All participants entering into a clinical study/research project must have given informed consent before any aspect of the project starts (interventional or non-interventional) and the original signed version should be filed in their medical records or study notes (for healthy volunteer studies) together with a copy of the Participant information Sheet (PIS). A copy of the signed consent form should be given back to the participant together with the PIS and a copy retained in the study file.

2. Joint Research and Enterprise Office (JREO) Policy

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

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). 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 minors and incapacitated adults.

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4. Definitions

4.1. Responsible Personnel

The Declaration of Helsinki states that the person seeking informed consent should be a qualified physician: 'The **physician** should then obtain the subject's freely given informed consent, preferably in writing' (1996 version). However 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 informed consent form 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 Chief Investigator (CI) or Principal Investigator (PI) are to accept responsibility for the informed consent process, it is important the following criteria are met:

1. They are prepared to take on this additional responsibility AND feel confident to seek informed consent in line with their professional organisational guidelines.
2. They have 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.
3. This delegation of responsibility should be documented on the Study Delegation Log/Site Responsibility Log (title can vary from Sponsor to Sponsor, 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 JREO has a template delegation log available on their website. Alternatively, researchers can contact their assigned JREO Governance contact, who will be able to send them the template.
4. The process has been approved by the relevant Research Ethics Committee (REC)
5. An effective line of communication is maintained back to the CI/PI who is the person ultimately responsible for the subject's care.

It is ultimately the responsibility of the CI/PI to ensure that subjects have fully understood what they are consenting to, and it is usual practice for the CI/PI or Co-Investigator to sign/countersign the Consent Form.

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It is best practice for any other research personnel involved in giving information during the informed consent procedure to sign and date the Informed Consent Form, e.g. if a translator was used, they should also sign and date the consent form. All those responsible for obtaining written informed consent must have a copy of their signed and dated CVs in the Trial Master File (TMF), and must have completed the study Delegation Log/Site Responsibility Log, which must also be signed and dated by the CI.

4.2. Informed Consent Form Contents

Copies of the Participant Information Sheet and Informed Consent Form must be approved by the REC and should be used, together with any documents the subject may need to use e.g. subject diaries. The Informed Consent Form must be checked for the following:

1. It should be on localised Trust headed paper.
2. The correct title, date and version number for the study is clearly visible and relates to the written Information Sheet given to the participant.
3. A statement to say the participant has had the study explained to them and by whom. The risks, benefits and alternative treatments have been discussed and all the subject's questions have been satisfactorily answered.
4. A statement that their participation is voluntary and they are free to withdraw at any time, without the loss of any treatment to which they would otherwise have been entitled.
5. A statement that their medical records may be reviewed by authorised personnel and that confidentiality will be maintained at all times.
6. That compensation arrangements have been discussed.
7. That their data and/or samples may be included or used in further ethically approved research studies

The JREO has template consent forms available on their website. Alternatively, researchers can contact their assigned JREO Governance contact, who will be able to send them the templates.

5. Responsibilities

It is the responsibility of the Chief Investigator and anyone delegated the responsibility of taking informed consent to read, understand and follow this SOP.

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6. Procedure

The procedure of taking consent within this SOP is split into Adults with Capacity, minors, 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 verbal explanation of the study must be given to the potential participant (or friends and family if appropriate) by the researcher. If necessary, diagrams or pictures should be used to explain the study. For example, it is much easier to show a picture of a person lying in an MRI than it is to write a description of this. Time for questions throughout the discussion must be given and questions adequately addressed.

The informed consent process should not end once the Informed Consent Form 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 Participant Information Sheet and consent form, to continue their involvement in the study.

The timing of the signing of the Consent Form, 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 Informed Consent form and in the subject's medical notes. The consent form 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.

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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 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 Participant Information Sheet about the study (on localised Trust headed paper).

The participant should be given adequate time to read the Participant Information Sheet 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.

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Once the participant has had time to read the information sheet and has had any questions regarding their participation answered satisfactorily, then they should be asked to sign the written Informed Consent Form 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 Informed Consent Form must be personally signed and dated in ink easily visible on photocopies by the person seeking consent, the CI/PI or Co-Investigator (if different) and the participant. Each should also clearly print their name by their signature.

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

All participants must be provided with 24 hour contact details where they may obtain further information about the study (only applicable for CTIMP studies). This will either be the CI's number or a contact number of a member of the study team.

6.2 Taking consent from minors

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 minors:

It is essential that the clinical study either relates directly to a clinical condition from which the minor suffers, or that the study can *only* be carried out on minors.

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).

The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development. Continuous monitoring throughout the study of such risks and/or distress must take place.

A full explanation of the study (including the objectives, risks/inconveniences) must be given to the parent/legal guardian of the minor. That person may then provide consent for the minor to

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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 minors) 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 minors to sign their own consent form.
5. The Participant Information Sheet should be written in a language that the minor can understand i.e. 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.

Whereever 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:

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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.

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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. This amendment allows the recruitment of patients in an emergency situation into clinical trials before consent is obtained from personal/legal representatives. 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 minors in emergency situations. Where the treatment to be given to a minor 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.

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 Participant Information Sheet and clauses added to the consent form:

1. Consent should be in writing from the donor, legal representative or next-of-kin as appropriate.

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2. Ethics approval or a statement that approval is not required should be obtained.
3. The participant information sheet 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 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 going 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 (1996)

Declaration of Helsinki (1996 Version)

Research Governance Framework for Health and Social Care 2005 2nd Edition

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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.

8. Appendices

There are no associated appendices for this SOP.

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