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<h1>Informed Consent for Research</h1>	
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1. PURPOSE

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 more vulnerable subjects (minors and incapacitated adults) and emergency research. This SOP uses the current HRA recommended guidance and fulfils transparency requirements under the General Data Protection Regulation for health and care research.

2. INTRODUCTION

Informed Consent is the process by which subjects voluntarily confirm 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. In exceptional circumstances verbal consent may be considered (refer to 9. VERBAL CONSENT)

Informed consent is a three-step process which involves:

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

The written documents consist of 3 elements:

- Medical notes
- Patient/participant information sheet
- Fully signed informed consent form

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 a copy filed in their medical records.

3. RESPONSIBILITIES

This SOP is applicable to all researchers, who are involved in designing patient information sheets, informed consent forms and obtaining informed consent for research studies.

It is the responsibility of the Head of Research Governance and Integrity (HORG) of the Research Governance and Integrity Team (RGIT) to ensure that this SOP is updated by the review date or as necessary.

4. INFORMED CONSENT OF ADULTS WITH CAPACITY

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:

- i. They are prepared to take on this additional responsibility AND feel confident to seek informed consent in line with their professional organisational guidelines.
- ii. 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.
- iii. This delegation of responsibility should be documented on the Study Delegation Log/Site Responsibility Log. This is a list of appropriately qualified persons to whom the investigator has delegated significant trial related duties. Sponsors/host organisations will usually provide a template for the Delegation Log/Site Responsibility Log to be signed and dated by the CI/PI.).
- iv. The process has been approved by the relevant Research Ethics Committee (REC).
- v. 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.

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 is also signed and dated by the CI. The CI/PI must maintain oversight of the consenting process.

4.2. Contents of Consent Form

4.2.1 The person(s) responsible for seeking Informed Consent must ensure they are completely familiar with all aspects of the clinical study as described in the latest version of the protocol and approved by the REC.

4.2.2 Copies of the Participant Information Sheet and Informed Consent Form must be approved by the REC. The Informed Consent Form must be checked for the following:

- i. It should be on departmental headed paper
- ii. The correct title and version number for the study is clearly visible and relates to the written information sheet given to the participant.
- iii. A statement to say the participant has had the study explained to them, the risks, benefits and alternative treatments have been discussed and all the subject's questions have been satisfactorily answered.
- iv. 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 or the loss of any medical care or legal rights.
- v. A statement that their medical records may be reviewed by authorised personnel and that confidentiality will be maintained at all times.

An example of an Informed Consent Form (for adults with capacity) is attached at Appendix 2. For Imperial sponsored studies, this template should be followed.

4.3. Procedure

4.3.1 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.

4.3.2 Subjects who potentially fulfil the inclusion/exclusion criteria will be identified and approached. It should be noted that normally only members of the clinical care team can identify and make the first approach to participants. A verbal explanation of the study must be given to the potential participant (and friends and family if appropriate). If necessary, diagrams should be used to explain the study. Time for questions throughout the discussion must be given and questions adequately addressed.

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

- I. The purpose of the study and any relevant background information.

- II. Why the subject has been approached and that confidentiality will be maintained throughout the study, should they decide to participate.
- III. 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 these procedures should be explained.
- IV. The number of people taking part in the study and how many have been recruited to date.
- V. 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.
- VI. 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.
- VII. The potential benefits and risks of participation in the study, and any alternative treatments available to the subject should be discussed.
- VIII. The availability of compensation should something go wrong
- IX. That the subject 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 subject that they have the right to withdraw them from the study in the interests of their safety.
- X. That a detailed discussion of the subject's medical history (including disclosure of all medication they are taking) will be required should they agree to participate.
- XI. If there are any payments made for participation in the study or for out of pocket expenses.
- XII. The responsibilities of the subject if they choose to take part, particularly if the study duration is lengthy.
- XIII. That giving informed consent does not necessarily mean the subject 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.

4.3.4 Once the above information has been verbally discussed with the subject, the subject should be provided with a written participant information sheet about the study (on departmental headed paper). An example of a Participant Information Sheet is attached at Appendix 1.

4.3.5 The subject 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 time period participants are allowed to

decide to participate in the study is normally approved by REC and outlined in the REC application, this should generally be a time period of more than 24 hours. The subject should not be coerced to participate and should be reassured that refusing to enter the study will not affect their care.

4.3.6 Once the subject 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.

The informed consent form must be personally signed and dated in ink easily visible on photocopies by the person seeking consent and the participant. Each person signing 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. A copy of the above must be placed in the participant's medical notes and a copy kept by the study team.

4.3.7 All subjects must be provided with contact details where they may obtain further information about the study. This will either be the CI's number or a contact number of a member of the study team. Emergency/24-hour contact details should be provided where required

4.4. Ongoing Procedure throughout the study

4.4.1 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 is discovered. In these circumstances it may be necessary to re-consent the participant using an amended consent form, to continue their involvement in the study.

4.4.2 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.

5. INFORMED CONSENT OF MINORS

Clinical Trials Regulations 2004 defines a minor as under the age of 16 years and prohibits minors for giving consent to take part in a CTIMP (Clinical Trial of an Investigational Medicinal Product).

Those who are able to give consent on behalf of children / young people, to take part in a CTIMP, in the UK are:

- parent or someone with parental responsibility (agreement of only one parent is required)
- personal legal representative i.e. 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 child / young person, and is available and willing to do so
- a legal representative should only ever be approached if someone with parental responsibility cannot be contacted prior to the proposed inclusion of the child / young person, by reason of the urgent nature of the treatment provided as part of the trial.
- if a personal legal representative is not available, professional legal representative i.e. a doctor responsible for the medical treatment of the child / young person if they are independent of the study, or a person nominated by the healthcare provider.

For non-CTIMP research in England, Wales and in Northern Ireland a minor is a person under the age of 18 years; in Scotland that age is 16 years. There is no statute in England, Wales or Northern Ireland governing a child's right to consent to take part in research other than a CTIMP, i.e. consent for non-CTIMPs.

In the absence of law relating specifically to research, it is commonly assumed that the principle of 'Gillick competence' can be applied not only to consent for treatment, but also to consent for research.

A child / young person's right to give consent is dependent upon their capacity to understand the specific circumstances and details of the research being proposed, which in turn will relate to the complexity of the research itself. Children and young people's; competence may well be reflected in their ability or otherwise to understand and assess risk. Competence to understand will be heavily influenced by how the information is presented to the child or young person, and the language used. It is essential that the child / young person's has the best opportunity of understanding what is involved in the study.

In addition to the above, there are a number of factors that must be considered when seeking consent from minors:

- i. 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.
- ii. 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.

- iii. 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 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.
- iv. 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. Parental consent should reflect the wishes of the child and this may over-rule the parent's wishes.
- v. 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.
- vi. No incentives or financial inducements must be given except for compensation in the event of injury or loss.
- vii. If aged 16 or over, it is acceptable for minors to sign their own consent form.
- viii. 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.
- ix. 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.

6. INFORMED CONSENT OF INCAPACITATED ADULTS

The Medicines for Human Use (Clinical Trials) Regulations 2004 defines an incapacitated adult as "an adult unable by virtue of physical or mental incapacity to give informed consent".

For Non-CTIMP studies, for the purposes of the Mental Capacity Act 2005 (applies to England and Wales only) “a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain”. This will apply where a consultee should be sought if a patient is incapacitated. The PI should appoint legal representative/consultee.

In Scotland, the inclusion of adults lacking capacity in research is governed by the provisions of Section 51 of the Adults with Incapacity (Scotland) Act 2000. In Northern Ireland, it is currently governed by common law.

In regards to the Clinical Trials Regulations 2004, a legal representative should be approached to give informed consent on behalf of incapacitated adult prior to inclusion in the clinical trial and this can be:

a) Personal Legal Representative:

A person not connected with the conduct of the trial who is:

- i. suitable to act as the legal representative by virtue of their relationship with the adult, and
- ii. Available and willing to do so.

b) Professional legal representative

A person not connected with the conduct of the trial who is:

- i. the doctor primarily responsible for the adult’s medical treatment, or
- ii. A person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board).

A professional legal representative may be approached if no suitable personal legal representative is available.

When seeking consent from an adult that is unable to provide informed consent for themselves it is important that the Investigator ensures that:

- ii. 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.
- iii. 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.
- iv. The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risks to the subject. Continuous monitoring throughout the study of risks and/or distress must take place. The interests of the subject must always prevail over the interest of science.

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

6.1. 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.

6.1.1 Clinical Trials subject to UK Clinical Trials Regulations 2004

These relate to trials of medicinal products for human use. Currently 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. 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.

6.1.2 Research not included under UK Clinical Trials Regulations 2004

Following the introduction of the Mental Capacity Act (2005) which applies to England and Wales only, researchers are required to consult a carer/consultee, or someone interested in the adult's welfare, or an independent nominee consultee for their advice and opinion on whether the patient should be recruited. It would

broadly be expected that this advice is followed (this excludes research that falls under the Clinical Trials Regulations 2004). The consultee does not give consent, only advise.

In Scotland, the inclusion of adults lacking capacity in research is governed by the provisions of Section 51 of the Adults with Incapacity (Scotland) Act 2000. In Northern Ireland, it is currently governed by common law.

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 REC application.

7. CONSENT TO SUPPLY HUMAN TISSUE AND RELEVANT MATERIAL TO EXTERNAL ORGANISATIONS

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

If you plan to store samples for future use and/or external collaboration there are key points that should be included in the participant information sheet and consent documentation:

- i. Consent should be in writing from the donor, legal representative or next of-kin as appropriate.
- ii. Ethics approval or a statement that approval is not required should be obtained
- iii. The participant information sheet and consent form explains the actual or potential use of tissue samples.
- iv. Statements regarding withdrawal, data protection and duration of storage (if any) are clearly stated in the participant information sheet.
- v. To ensure transparency on areas of public concern, for example where research is known or is likely to involve the commercial sector, genetic testing or the use of human tissue in animals, these should be covered in the information used to support the consent process. Where there is an expectation that samples may be exported for use abroad, the HTA also advises that donors are provided with adequate information as part of the consent process.
- vi. If identifiable tissue is to be used for research, donors should be informed about any implications this may have. For example, they may be contacted by researchers, given feedback, or be asked for access to their medical records.
- vii. A statement explaining that donated samples supplied to external non-commercial and commercial organisations do not infer the right of the donor to financial gain from any

commercially viable outcomes to the use of their tissue in
commercial research and development.

8. ELECTRONIC CONSENT

Electronic consent is an approach sponsors and researchers are increasingly keen to adopt and enables potential research participants to be provided with the information they need to make a decision via a tablet, smartphone or digital multimedia. It also enables their informed consent to be documented using electronic signatures. This approach can supplement the traditional paper-based approach or, where appropriate, replace it.

Using electronic consent offers a number of potential benefits, such as:

- improving understanding
- testing and reinforcing participant comprehension
- providing feedback on how consent materials could be improved
- improving patient recruitment process and reducing dropout rates
- enabling process efficiencies.

The Health Research Agency (HRA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) have produced a [statement setting out the legal and ethical requirements for seeking and documenting consent using electronic methods](#). It also sets out the joint expectations regarding the use of electronic signatures in CTIMPs.

The process and procedure for taking the electronic declaration (including an arrangement for telephone discussion and answering questions) should be detailed in the IRAS form, protocol and PIS and should be approved by the REC and/or HRA.

9. VERBAL CONSENT

If a verbal consent process is to be used, the following details should be provided:

- The justification for verbal, rather than written consent
- Documentation of the procedure and process, including details on how the verbal consent will be recorded

The process should be included in the IRAS form and protocol and be REC and/or HRA approved.

10. REFERENCES

ICH (1996) Guidelines for Good Clinical Practice – ICH Harmonised Tripartite Agreement

Declaration of Helsinki (1996 Version)

[UK Policy Framework for Health and Social Care](#) (v3.3 07/11/17)

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

[MRC guidance on Patient Consent](#)

[HRA guidance on research in emergency settings
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](#)

[HRA guidance on participant Information and Consent](#)

[HRA guidance on GDPR](#)

[HRA/MHRA statement on electronic consent](#)

[CT Toolkit](#)

[HRA guidance on GDPR and consent in Research](#)

[HRA guidance on research involving children](#)

[Human Tissue Act \(HTA\) codes of practice](#)

11. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP which can be found on the [SOP, Associated Documents & Templates page](#).

Appendix 1: Guide to Writing a Participant Information Sheet – RGIT_TEMP_031

Appendix 2: Template Informed Consent Form for Adults with Capacity - RGIT_TEMP_032

Appendix 3: Template Informed Consent Form for Adults without Capacity (For CTIMPS) - RGIT_TEMP_033

Appendix 4: Template Informed Consent Form for Parent/Legal Guardian/Representative of Minor - RGIT_TEMP_034

Appendix 5: Guide to Writing a Participant Information Sheet for non-healthcare research - Refer to link [Imperial College London - Human Research Ethics - Application Process](#) (cited 21/09/2020)