Gloucestershire Hospitals
NHS Foundation Trust

SOP 04: Informed Consent for Research

SOP reference:	SOP 04	
Version:	5.0	
Author:	Gemma Race	
Approved by Trust Senior Responsible Officer for RIG:	Noel Peter 04/09/2026	
Implementation date of current version:		09/10/2026
Date of Review:		09/10/2029

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research, Innovation & Genomics Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the RIG website:

https://www.gloshospitals.nhs.uk/about-us/get-involved/support-our-trust/research-our-hospitals/

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	23/06/2014
2.0	Rebranding to GHNHSFT, updating of contact details and reference documents. Further definition of roles and level of freedom to act.	31/03/2018
3.0	Updating of website link. Reformatting of Training Log and Competency sheet. Typographical error corrections Addition of Flow Charts and 'Professional Legal Representative Guidelines' December 2019 and 'GHNHSFT Nominated Consultee Representative Guidelines' December 2019 Addition of remote consent processes	10/02/2021
4.0	Typographical error corrections. Removal of out-of-date link Acknowledgment of use of electronic & paper-based medical notes Information on the National Data opt-out scheme Acknowledgement of use of interpreters Use of email to send out patient information sheets Insertion of appendix containing legal representative guidelines and personal nominated consultee guidelines Removal of SOP categories and change of reference codes	30/10/2023
5.0	Departmental name change R&D to RIG Update Clinical Trial regs. Change 'trial' to 'study' where appropriate. Removing appendices to stand-alone guidelines	09/10/2026

This SOP will be reviewed every three years unless changes to any relevant legislation require otherwise

Related Documents:

SOPs
SOP 02 - Research Documentation and File Management
SOP 03 - Training
Guidelines
Guidelines 36 - Legal Representative Guidelines (Adults)
Guidelines 37 - Consultee Guidelines (Adults)
Guidelines 38: How to Document Valid Informed Consent in Health Records

Glossary

ALCOA+	Attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available
CI	Chief Investigator
CPRD	Clinical Practice Research Datalink
CTIMP	Clinical trials of investigational medicinal products
GCP	Good Clinical Practice
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
ICF	Informed Consent Form
IMP	Investigational Medicinal Product
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NMC	Nursing and Midwifery Council
PI	Principal Investigator
PIS	Participant or Patient Information Sheet
REC	Research Ethics Committee
RIG	Research, Innovation and Genomics
VIC	Valid Informed Consent

Contents

	Page No.
1. Introduction, Background and Purpose	5
2. Who should use this SOP?	6
3. When this SOP should be Used	6
4. Which staff groups can receive consent?	6
5. How to delegate responsibility for receiving informed consent	7
6. Identification of study participants	8
7. Information provided to the study participant	10
8. How will potential study participants be approached?	10
9. Receiving informed consent	12
10. Consent in Vulnerable Groups	15
11. Consent in Emergency Situations	21
12. Documentation	22
13. Training	24
14. References	24
Appendix 1: Examples of information to provide to a study participant	26
Appendix 2: Informed Consent Competency Sheet	28
Appendix 3: Informed Consent Training log	30
Appendix 4: Preparation during set up	32
Appendix 5: Individual staff training programme for receiving informed consent	33
Appendix 6: Informed consent process	34
Appendix 7: Adults lacking capacity to consent to research	35
Appendix 8: Consent Process with Minors (based on MRC Ethics Guide to medical research involving children)	36

1. Introduction, Background and Purpose

Informed consent is the process by which a person voluntarily confirms their willingness to participate in a research study, having been informed of all aspects of the study that are relevant to their decision to take part.

This SOP describes the ongoing process for receiving Informed Consent from a study participant. It outlines the informed consent procedures for adult participants and informed consent procedures for more vulnerable participants (minors and incapacitated adults).

Performing any research related procedure on someone without first obtaining their informed consent, is in breach of UK Regulations.

The use of study/trial are interchanged throughout depending on which is most applicable.

1.1 Description of Informed Consent (Declaration of Helsinki 2024)

“In medical research involving human participants capable of giving informed consent, each potential participant must be adequately informed in plain language of the aims, methods, anticipated benefits and potential risks and burdens, qualifications of the researcher, sources of funding, any potential conflicts of interest, provisions to protect privacy and confidentiality, incentives for participants, provisions for treating and/or compensating participants who are harmed as a consequence of participation, and any other relevant aspects of the research.

The potential participant must be informed of the right to refuse to participate in the research or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information and communication needs of individual potential participants as well as to the methods used to deliver the information.

After ensuring that the potential participant has understood the information, the physician or another qualified individual must then seek the potential participant’s freely given informed consent, formally documented on paper or electronically. If the consent cannot be expressed on paper or electronically, the non-written consent must be formally witnessed and documented.”

2. Who should use this SOP?

This SOP applies to all staff members involved in delivering CTIMP and non–CTIMP studies within Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT). The SOP should also be used by the Research, Innovation and Genomics (RIG) Professional Services team as required.

3. When should this SOP be used

This SOP is applicable for all studies sponsored and hosted by the Trust. It should be read alongside any study specific requirements as detailed in the study protocol. It should be referred to during study feasibility, set up and throughout the recruitment and follow up phase of the study.

4. Which staff groups can receive consent?

Consent can, in principle, be received by any member of the research or clinical team who is appropriately qualified by education, training and experience to undertake this task. The Sponsor will make the decision which staff groups are permitted to receive Informed Consent/ Assent and this information will be detailed in the Research Ethics Committee (REC) application. The delegation of the responsibility for taking part in the Informed Consent process for each staff group will be decided on a study-by study basis. This will be confirmed at study set up with the Sponsor and will follow the details in the REC submission and protocol.

Staff groups include but not exclusive to:

Job role	Type of study	Comments
Clinician, e.g., medical staff, nurses, midwives, AHPs	Interventional and non-interventional	The PI would have full responsibility for the consent process. Some sponsors only want PIs to receive consent, others are happy for Sub-Investigators / Co-Investigators, or other delegated staff to receive consent.

Research Nurse, Research Radiographer	Interventional and non-interventional	The PI would have full responsibility for the consent process. Research Nurses/Radiographers may be able to complete the full informed consent process as agreed with the Sponsor/ REC submission, or take a given part in the consent process
Research Co-ordinator	Interventional and non-interventional	The PI would have full responsibility for the consent process. Research Coordinator may be able to complete the full informed consent process as agreed with the Sponsor/ REC submission, or take a given part in the consent process
Assistant Research Co-ordinator	Non-interventional	The PI would have full responsibility for the consent process. Participants will be identified by senior member of research team, and Assistant Research Co-ordinator receives informed consent as agreed with the Sponsor and demonstrates competency to receive consent for each allocated study

5. How to delegate responsibility for receiving informed consent

The Chief Investigator (CI) or Principal Investigator (PI) for the study running in the Trust can delegate the responsibility for the Informed Consent process after ensuring that the following criteria are met:

- The research team member is prepared to take on this additional responsibility AND feels confident and competent to receive informed consent in line with the Nursing and Midwifery Council (NMC) Code of Professional Conduct or other professional organisational guidelines
- They have a comprehensive understanding of the study, potential pharmacological interactions/treatment toxicities and the associated disease area. They are fully aware of the risks and potential benefits of taking part in the study
- They are qualified by experience and/or should have received appropriate training for this study. A signed and dated CV must be filed in the ISF.
- They have received study specific training and have a current GCP certificate and completed Informed Consent training (see SOP 03 - Training). All training must be documented.

- On a case-by-case basis, those staff working within their own area of expertise on a research study will undertake Informed Consent training that has been agreed with the Sponsor, PI and RIG Department.
- The delegation of responsibility should be documented on the study's Delegation and Signature Log
- Research nurse, or other non-medic, to receive informed consent has been specifically approved by the relevant Research Ethics Committee and study Sponsor.
- An effective line of communication is maintained back to the CI/PI who is ultimately the person responsible for the patient's care and for ensuring that participants have fully understood what they are consenting to
- Delegation of informed consent for CTIMPs to non-medics is permitted where, all the above criteria have been met, and the nurse has completed a Consent / Assent competency, with an appropriate assessor.

6. Identification of study participants

There may be an element of pre-screening to ensure that the study being offered to a potential participant is appropriate. This pre-screening may take the form of reviewing patients' notes and associated imaging and laboratory results. No additional study-specific screening activities, such as additional imaging procedures and laboratory tests, that do not form part of standard of care must take place until Informed Consent to participate in the study is obtained.

In certain circumstances it is permissible to interrogate anonymised NHS clinical data using the Clinical Practice Research Datalink (CPRD) which has a controlled way back to identify the person for recruitment. It is also permissible to interrogate local data bases within the Trust.

For a CTIMP, confirmation that participants fulfil the inclusion criteria for the trial, must be carried out, and documented, by medically qualified personnel with access to and a full understanding of the potential participant's medical history. The task of determining whether an individual meets the inclusion criteria for a study can NOT be delegated to non-medically qualified individuals within the trials team.

For non-CTIMP studies the participant may be identified by a non-medically qualified person where this has been agreed with the Sponsor. It is expected that there will be a health professional with the relevant qualification(s) as part of the study team and readily available to refer to.

6.1 National Data Opt Out

On the 25 May 2018, the national data opt-out was introduced, enabling patients to opt out from the use of their data for research or planning purposes. Patients are able to view or change their national data opt-out choice at any time by using the online service via www.nhs.uk/your-nhs-data-matters or NHS app. National data opt-out does not apply where the researcher is using data obtained by explicit consent. The responsibility for complying with national data opt-out policy rests with the data provider (e.g., hospital trusts). When an individual sets an opt out choice, it is recorded against their NHS number. If required, research staff can use the national data opt-out tool (available on the trust intranet) or contact Business Intelligence at GHNHSFT to determine participant preference.

7. Information provided to the study participant

The information should be as clear and concise, as possible, using simple language and avoiding unnecessary volume and complexity.

Varied approaches may be used to provide information to the participant or representative including text, images and videos. The suitability of the method of obtaining consent should be taken into consideration e.g. when computerised systems are used, if participants lack familiarity with computerised systems they may be given the option to use a paper alternative (if approved by the sponsor).

Patient information should be provided in language appropriate formats to potential study participants in both an oral and written form, usually a Patient Information Sheet (PIS) and Informed Consent Form (ICF) along with other appropriate supporting information wherever

possible. After checking with the Sponsor/protocol regarding eligibility, if a participant is identified who is unable to read an English language patient information sheet a hospital approved interpreter can be used. A written patient information sheet in the participant's first language will be requested from the Sponsor to be used alongside an interpreter if possible. (See Appendix 1)

8. How will potential study participants be approached?

8.1 Telephone

It is possible to make the initial approach by telephone conversation, using the ethically approved script if applicable, followed by a PIS sent through the post or via email. This may be appropriate for some forms of research and is acceptable as long as the application to the REC clearly stated this will be the case and favourable ethical opinion has been given.

8.2 Post

It is possible to make the initial approach by sending a letter to the potential study participant if this has been clearly stated in the REC submission and favourable ethical opinion has been granted.

8.3 Face to face

Typically, the potential research participant will be approached face to face in a clinical environment. The level of detail provided in the initial approach will vary as in some instances detailed discussions may not be considered appropriate, for example if the introduction to the study forms part of the consultation where the participant's diagnosis of the condition is presented.

The intended outcome of the initial approach is always the verbal presentation of study-related information and the provision of the correct version of the PIS to the prospective participant for their further consideration

8.4 Remote Consent

Receiving Valid Informed Consent (VIC) remotely is permissible where there is direct agreement and guidance from the Sponsor/TU. This will be decided on and agreed before a study is opened to recruitment or after a study modification.

When using video-conferencing for VIC the Trust's preferred method is Attend Anywhere. When using this method some Sponsors/TUs require a second member of the research staff to be present to witness the video conferencing VIC.

There will still need to be a record of this consent for the participants and again the delivery teams must use the Sponsor's/ TU's preferred form of providing this information which may be by posting out a hard copy, emailing an electronic copy or providing the online link for the participant. A record of each participants VIC will be kept for the ISF, again in the format agreed with the Sponsor/ TU.

Whether the informed consent takes place in person or remotely, the identity of the patient or representative should be confirmed in accordance with applicable requirements.

8.5 Simplified arrangements for seeking and evidencing consent in low intervention CTIMP's

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 allow for simplified arrangements to seek and evidence informed consent in low intervention clinical trials of investigational medicinal products (CTIMPS).

The amended regulations do not permit consent to be waived or presumed. However, they do allow sponsors of eligible low intervention CTIMPs to use simplified arrangements for seeking and evidencing informed consent. These arrangements may include proportionate approaches to the information provided, the way consent discussions are undertaken, and the means by which consent is evidenced, provided that consent remains informed, freely given, explicit and prospectively obtained. Any such arrangements must be clearly described in the protocol and approved by a REC.

8.6 Recording contact for study purposes

It must be possible to reconstruct when and how the provision of information took place. This is required to demonstrate that the potential participant was given time to consider the study before Informed Consent was received by the researcher. The information given and the version of the PIS given must always be recorded in the patient's medical records and recorded in the study specific documentation (usually provided by the Sponsor).

9. Receiving informed consent

Respect and dignity of the patient should be taken into consideration prior to the consent process being performed and a private area sought if possible. Consideration should also be given as to whether it is even appropriate to approach a particular individual with a request to participate in a study. Those receiving consent should consider whether there are factors present which may impair a patient's capacity at that time point.

9.1 Written consent

- The person making the initial approach to a potential participant must have to hand copies of the PIS and ICF for the study approved by the REC/MHRA, together with any documents the participant may need to use e.g., diaries.
- A systematic verbal explanation of the study must be given to the participant (and friends and family if appropriate) taking the patient through the PIS. Time for questions throughout the discussion must be given and questions adequately addressed.
- Potential participant should be given adequate time, the study protocol will state the minimum length of time a participant must be given, to read the PIS and to discuss with any family and friends (if applicable), prior to deciding whether to take part. The potential participant should not be coerced in any way to participate in the study and the consent procedure must follow exactly that approved by the REC.
- Once the potential participant has had time to read the PIS and has had any questions regarding their participation answered satisfactorily, then the person receiving informed consent will ask them to complete and sign/date the written ICF relating to the study. This may be in the form of a physical or electronic signature. The ICF must be personally signed

and dated by the person receiving consent and the study participant. Each should also clearly print their name by their signature. Where the consent process has been performed remotely and witnessed by another member of staff then both members of staff will sign paper and/ or electronic devices and provide copies for the participant.

- Once all parties have signed the ICF, the participant should receive a copy of the signed and dated consent form, PIS and any other written information provided. Unless stated otherwise by the study protocol, the original consent form must be placed in the Investigator Site File and a second copy placed in the participant's medical records and any additional copies as specified by the study protocol.
- No participant should undergo any study related procedures (including screening) until written informed consent has been provided UNLESS the matter has been presented to and approved by the REC.
- The timing of the signing of the consent form relative to study registration and the initiation of study procedures is subject to audit by governing bodies and regulatory authorities. It is therefore essential to record dates correctly on both the ICF and in the participant's medical notes.
- All participants must be provided with contact details where they may obtain further information about the study. This will either be the CI/PI's number and a contact number of a member of the study team and where possible a 24-hour help line number

9.2 Oral Consent

Oral consent is an acceptable alternative when a participant cannot provide written consent. All the points in section 9.1 above should be followed up to the point of the potential participant signing the consent form. At this point an independent witness is required in cases where potential participants, who have capacity, are not able to read and write, who are visually impaired or whose physical condition prevents them from signing a consent form.

Witnessed consent should be on an approved form for the witness and researcher to sign. If this is not already provided, contact the Sponsor for clarification on whether the potential participant can take part in the study before approaching the patient.

9.3 Ongoing consent

The informed consent process does not cease once the consent form has been signed. At each time of contact between the research team and the study participant, when treatment is being given and/or data is being collected specifically for research purposes, the member of the research team must check that the participant is happy to continue on study treatment/ have data sent to the CI/ Sponsor. This must be recorded in the patient's medical records.

9.4 Re-consent

The practice of giving information about the study to participants will be an ongoing process performed by all members of the research team. This is particularly significant with the introduction of protocol modifications and the availability of important new information (interim results/ safety measures) that may be relevant to the participant's willingness to continue participation in the study. In these circumstances it may require the study participant to re-consent on the amended consent form in order to continue involvement in the study.

Re-consenting will only be carried out by the research teams on receipt of written instructions from the Sponsor (letter or email, including the associated substantial modification favourable opinion/ letter of acceptance/ Trust approval). This will detail which participants need re-consenting and the time scale it is to be done in, whether at their next standard appointment or, in the case of safety alerts, as soon as possible.

The assigned research team member receiving the informed consent will go through the points in 9.1 and 9.2 above. When they are satisfied that the participant has been fully informed and understands the changes to the study/ new information available, the consent form should be signed and personally dated by the participant and by the authorised person who conducted the re-consenting discussion.

If the patient decides that they no longer wish to continue in the study as a result of the changes or the new information available, this should be documented in the patient records and the necessary withdrawal procedures undertaken. This will be fully documented in the patient's medical notes and on a site file note in the site file or screening log depending on study requirements.

10. Consent in vulnerable groups

The UK Clinical Trials Regulations permit legal representatives to give informed consent on behalf of minors and adults who are unable to consent for themselves (referred to as “incapable adults”). The roles and responsibilities and definitions are dependent upon which vulnerable group the potential participant is within.

Common to the definition of the legal representative in any scenario is that the individual concerned must not be “a person connected with the conduct of the trial”. This is defined as:

- The sponsor of the trial
- A person employed or engaged by, or acting under arrangements with, the sponsor and who undertakes activities connected with the management of the trial
- An investigator for the trial
- A healthcare professional who is a member of an investigator’s team for the purposes of the trial
- A person who provided health care under the direction or control of a person referred to above, whether in the course of the trial or otherwise.

The consent obtained from the legal representative should follow the usual requirements of obtaining informed consent. Consent obtained from a legal representative must be informed, documented and conducted in accordance with Good Clinical Practice (GCP) principles and applicable regulatory requirements.

10.1 Research Involving Minors

The term Minor refers to anyone under the age of 16 years.

The Regulations prescribe a hierarchy for determining who should be approached to give informed consent on behalf of a minor prior to their inclusion in a clinical trial. In emergency situations, where the nature of the treatment provided as part of the trial requires urgent action and it is not reasonably practicable to obtain consent prior to inclusion, recruitment may proceed

in accordance with the UK Clinical Trials Regulations, subject to the conditions set out in the approved protocol and favourable opinion from a REC.

The hierarchy for consent is as follows:

1. **Parent:** A parent or person with parental responsibility (a mother automatically has responsibility from birth. A father may not have parental responsibility if not married to the minor's mother at the time of the birth) http://www.gov.uk/parental-rights-responsibilities
2. **Personal legal representative:** A person not connected with the conduct of the trial who is suitable to act as a legal representative by virtue of their relationship with the minor, and available and willing to do so.
3. **Professional legal representative:** A person nominated by the relevant healthcare provider (e.g. an acute NHS Trust) who is not connected with the conduct of the trial.

Gillick Competence

In addition to the above, a minor under the age of 16 may be considered capable of providing consent if assessed as Gillick competent. Gillick competence refers to a child who has sufficient understanding and intelligence to comprehend the nature, purpose, risks, and benefits of the research and to make an informed decision regarding participation.

Where a minor is assessed as Gillick competent, their consent should be sought in addition to, and not in place of, any required parental or legal representative consent, unless otherwise specified in the approved protocol and REC favourable opinion.

Assessment of Gillick competence must be undertaken by appropriately trained and delegated research or clinical staff and documented in the participant's study records.

Areas to consider and be aware of are:

- It is best practice wherever possible and appropriate, to receive assent from the minor in addition to the consent of the parent/guardian
- Assent: a minor agrees and accepts participation in the study
- Parental consent should reflect the wishes of the minor and this may over-rule the parent's wishes

- There should be different versions of patient information sheets and assent forms to reflect a minor's level of understanding
- Consent must be received from the participant once they reach their 16th birthday.
- Consent and assent should be received by appropriately trained and delegated personnel

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. The amendment allows minors to be entered into a trial prior to informed consent being obtained provided that:

- It is not reasonably practicable to obtain informed consent from a person with parental responsibility or a legal representative prior to enrolment; and
- The procedure is conducted in accordance with a protocol approved by a REC.

In such cases, consent from a person with parental responsibility or a legal representative must be sought as soon as possible following enrolment. Where consent is refused, the participant must be withdrawn from the trial in accordance with the protocol.

All the considerations listed in section 9.1 to 9.4 apply with the following additions:

- that the minor will receive information according to his or her capacity of understanding about the trial and its risks and benefits. This information will be given by staff with experience working with minors.
- The research must consider the explicit wish of the minor capable of forming an opinion and assessing the information provided. This applies both to the wishes of a minor to refuse to take part, or to withdraw from the trial at any time
- No incentives or financial inducements are given either to the minor or to the parent or legal representative, except the provision of compensation for injury or loss.
- The clinical trial relates directly to a condition from which the minor suffers or is of such a nature that it can only be carried out on minors.
- Some direct benefit for the group of patients involved in the trial is to be obtained from the trial.

- The trial is necessary to validate data obtained (a) in other clinical trials involving persons able to give informed consent, or (b) by other research methods.
- Informed consent by a parent or legal representative shall represent the minor's presumed will.

10.2 Research Involving Incapacitated Adults

Legally, adults must be presumed to have capacity to make decisions unless it is established otherwise for a specific decision, in accordance with the Mental Capacity Act 2005.

The potential participant should be provided with information, according to their capacity of understanding, about the study and its risks and benefits.

A person with capacity has:

- the capacity to make a choice about a proposed course of action;
- knows about the risks, benefits, alternatives;
- understands that consent is 'voluntary and continuing permission';
- understands that consent 'can be withdrawn at any time';
- retain information long enough to make a decision

An adult is deemed to lack legal capacity to consent or refuse consent only when they cannot be helped to reach their own decision using their usual means of communication. Researchers must ensure that appropriate versions of PIS and ICF, including accessible formats, are used to support decision making wherever possible to aid potential participants to make an independent informed choice.

Adults incapable of providing informed consent may still be included within a clinical trial where there are grounds for expecting that administering the medicinal product to be tested will produce a benefit for the participant.

It is permissible in the research setting for a third party to make decisions about participation on behalf of an adult lacking capacity, based on the individuals presumed will, wishes and feelings with regards to participating in research.

10.2.1 Research involving CTIMPs

For CTIMP's, governed by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, a legal representative may give consent on behalf of an adult lacking capacity

Those who can act as a legal representative in CTIMPs, in England and Wales are:

- Personal legal representative i.e., a person not connected with the conduct of the trial who is suitable by virtue of their relationship with the adult and is available and willing to do so (Next of kin, nearest relative, power of attorney).

If one is not available:

- Professional legal representative i.e., a doctor responsible for the medical treatment of the adult, if they are independent of the study, or a person nominated by the healthcare provider. At GHNHSFT the decision regarding which staff group may act as professional legal representative/s will be made on an individual study basis. The nominated staff will be provided with local guidelines.

The legal representative must be:

- Informed that they are being asked to give consent on behalf of the incapacitated adult,
- Informed that they are free to decide whether they wish to make this decision or not,
- Informed that they are being asked to consider what the adult would want, and to set aside their own personal views when making this decision,
- Given sufficient information, in an understandable form, about the trial to ensure that they can make an informed decision.

See RIG Guidelines 36 - Legal Representative Guidelines (Adults), for further details.

10.2.2 Research not subject to Clinical Trials Regulations (non-CTIMP's)

Non-CTIMP research involving adults lacking capacity is governed by the Mental Capacity Act 2005. Non-therapeutic studies may still involve incapacitated adults when the study objective cannot be met without participants who cannot provide consent personally.

Advice should be sought from a consultee on whether an adult lacking capacity to consent would wish to be included in the research. Consultees are not asked to give consent on behalf of the adult, but to provide an opinion on the views and feelings of the potential participant.

Consultees for intrusive research other than CTIMPs, in England and Wales are:

- Personal consultee, i.e., a person who cares for the adult lacking capacity or is interested in that person's welfare, but is not doing so for remuneration or acting in a professional capacity.
- If not available or unwilling to give advice then a nominated consultee i.e., a professional who is independent of the study can do so. At GHNHSFT the decision regarding which staff group may act as nominated consultee/s will be made on an individual study basis. The nominated staff will be provided with local guidelines.

The consultee must be:

- Informed that they are being asked to advise on the views and feelings that they believe the adult would have towards participation in the study.
- Informed that they are free to decide whether they wish to provide this advice or not.
- Given sufficient information, in an understandable form, about the study to ensure that they provide you with informed advice.

The advice given by consultees should be recorded on a Consultee Declaration form (not a consent form).

See RIG Guidelines 37 - Consultee Guidelines (Adults) for further details.

The researcher should also provide the participant with information, according to their capacity of understanding, about the study and its risks and benefits.

10.3 On-going Consent and Participants Who Regain Capacity

If it is possible that participants might regain capacity during the course of a study, there should be provision made for the on-going consent process.

In most cases it is appropriate to ask patients to give their own consent when and if they are

able. Approved PIS and ICF for participants who regain capacity should be used according to the study protocol.

The protocol should describe the process for participants withdrawing consent at any stage of the study.

11. Informed Consent in Emergency Situations

Where research involving 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) (Amendment) Regulations 20025 or not.

11.1 Clinical Trials subject to UK Clinical Trials Regulations

In the UK the law allows adults not able to consent for themselves to be recruited into CTIMPs without prior consent in emergency situations if:

- Treatment needs to be given urgently;
- It is necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by an NHS REC;
- Consent is sought from a legal representative as soon as possible.

Such recruitment would be subject to favourable opinion from a REC. Trial specific procedures for consent in emergency situations may include brief versions of Patient and Representative Information Leaflets and Consent Forms or Telemedicine consent.

11.2 Research not included under UK Clinical Trials Regulations (non-CTIMPs)

Under the Mental Capacity Act (2005), where a potential participant lacks capacity, researchers are required to seek advice from a consultee (i.e. a person who knows the participant well and is able to advise on their likely wishes and feelings regarding participation). This may include

a family member, carer, or someone interested in the adult's welfare, or a nominated 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 however).

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 REC.

Where an incapacitated adult is recruited in an emergency situation without prior informed consent, as soon as possible after the emergency, steps must be taken to seek informed consent from a legal representative.

The participants' capacity must be constantly assessed throughout the study and if regained, informed consent for ongoing participation must be sought from the participant t. If consent is not given, the participant must be withdrawn from the study in accordance with the protocol.

12. Documentation of consent process

All contact or discussions with participants or potential participants regarding a study must be documented as per section 8.5 above. The informed consent process must also be clearly documented in medical records, including dates and times, following the ALCOA+ principles.

See Guidelines 38: How to Document Valid Informed Consent in Health Records

12.1 Location of consent documentation

Copies of the documentation will be typically stored at the following locations but may differ according to instructions from the Sponsor:

Paper-based Patient Medical Records currently contain the items listed below for both inpatient and outpatient studies.

- Participant Information Sheet
- Signed Consent Form/ Assent Form (photocopy in the legal section of the notes)
- GP letter (where applicable)

The Trust is transitioning to electronic health records across all clinical services with some specialties accessing a combination of electronic and paper-based records for both inpatient and out-patient-based care. Consent documentation may be scanned to electronic systems for some research studies or filed in paper-based records for others. Ideally, consent documentation will be filed in the most appropriate patient health record and corresponding format.

Participant

- Participany Information Sheet
- Consent Form/ Assent Form (photocopy)

Participants should get copies of all relevant, updated and new information, regarding the study throughout their participation.

Site File

- Patient Information Sheet
- Consent Form/ Assent Form (wet copy)
- GP letter (copy where applicable)

Supporting departments

- Consent Form/ Assent Form as required, e.g. for the transfer of tissue samples

ICFs for patients who are then found to be ineligible before randomisation / starting treatment must be filed in the site file and the patient's medical records. The event will be documented in the patient's medical records and, if required by the study team, a site file note to explain the event is to be completed and filed in the site file alongside the consent form

13. Training

The CI/PI are responsible for ensuring that all staff involved in the Informed Consent process are delegated the responsibility only after due training and experience following the Sponsor and Trust's training programme. Staff new to consent in research must complete the consent competency which will then be maintained on an individual basis through NIHR training materials and NIHR Research Delivery Competencies. Checking staff competencies may be delegated to senior research staff within a given research team and/or Trust senior RIG staff. (Further information is in SOP 03 - Training along with competency / training sheets.)

14. References

Declaration of Helsinki 2024: WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

Mental Capacity Act 2005: https://www.legislation.gov.uk/ukpga/2005/9/contents

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/

ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf

MHRA: Guidance on GxP data integrity

http://www.gov.uk/parental-rights-responsibilities

Associated Trust policies:

Mental Capacity Act 2005 Trust polices and action cards:

- http://glnt313/sites/ghnhsft_policy_library/WPP/A0251.aspx

Mental Capacity and Safeguarding Trust guidance:

- https://intranet.gloshospitals.nhs.uk/departments/corporate-division/safeguarding/mental-capacity/

Appendix 1: Example of information to provide to a study participant

- A statement that the study involves research
- The purpose of the study
- The study treatment(s) and the possibility of random assignment to each treatment
- The study procedures to be followed, including all invasive procedures
- The participant's responsibilities
- The experimental aspects of the study
- Any foreseeable risks or inconveniences for the participant, and partner (when applicable).
- The reasonably expected benefits. If there is no clinical benefit intended, the participant must be made aware of this
- Alternative treatments and procedure(s) that may be available and the potential benefits and risks
- The compensation and/or treatment available to the participant in the case of any injury relating to the study
- Anticipated pro-rata payment, if any, to the participant for participating in the study
- The anticipated out of pocket expenses, if any, to the participant for participating in the study
- That the participant's study participation is completely voluntary and that they can withdraw from the study or stop the investigational product, at any time, without penalty or loss of benefits to which they would otherwise be entitled.
- Participants who stop an investigational product or discontinue study participation should have their follow up procedure explained.
- That authorised representatives from regulatory bodies, pharmaceutical company (or other commercial company, if appropriate to the study), sponsor or the Research Ethics Committee (as appropriate) will be given access to the participant's records for the purpose of verification of the study procedures and data collected, without violating the confidentiality of the participant
- That the participant's General Practitioner will also be informed in writing of their participation in the study
- By signing the informed consent form, the participant is authorising such access
- That records identifying the participant will be kept confidential and will not be made publicly available. If the results of the study are published, the participant's identity will remain confidential
- That the participant/legal representative will be informed in a timely manner if any information becomes available that may be relevant to the participant's willingness to continue to participate in the study

- The person(s) to contact for further information regarding the study (if possible, record a 24 hour phone number where the participant can receive advice out of office hours if required)
- The foreseeable circumstances under which the participant's involvement in the study may be terminated
- The expected duration of the participant's involvement in the study
- The approximate number of participants involved in the study

Appendix 2: Informed Consent Competency Sheet

Competency	Date	Assessor Signature	Staff Signature
Principles of gaining consent/assent for participation in research			
Demonstrate an awareness of the Declaration of Helsinki and Good Clinical Practice in relation to gaining consent and assent			
Demonstrate detailed understanding and can explain types of observational and interventional studies			
Demonstrates detailed understanding and can explain the need for inclusion and exclusion criteria			
Demonstrates detailed understanding and can explain randomisation, equipoise and blinding			
Provides evidence of training and understanding of the consent process			
Can define valid informed consent and assent and explain the difference			
Demonstrate awareness of when and how to gain consent/assent (adult representative/child)			
Mental Capacity in Research			
Demonstrate understanding of mental capacity act and the legal requirements related to gaining and maintaining valid informed consent, especially when participants lack capacity.			
Demonstrate ability to define when a person lacks capacity			
Demonstrate ability to assess for mental capacity			
Undertaking consent/assent			
Demonstrate an awareness of the ideal physical environment within which to receive informed consent/assent			
Demonstrates an awareness of the factors contributing to a participants decision making during the consent process			
Complies with the informed consent processes as described in the approved protocol, including use of approved versions of PIS and ICF			
Aware of the ongoing nature of informed consent			
Adults Lacking Capacity (if applicable)			
Demonstrate awareness of the different requirements for research with incapacitated adults in relation to - CTIMP - Non CTIMP - Emergency			
Can explain the difference between - Personal Legal Representative - Professional Legal Representative - Personal Consultee - Nominated Consultee			
Understands what steps to take if patients regain capacity			
Research involving children (if applicable)			
Can define valid informed consent and assent and explain the difference *			
Documentation			
Demonstrates and understanding of the documentation required to underpin a capacity assessment			
Demonstrates an ability to accurately assess and record eligibility for the study or record why the patient is ineligible within the research and medical documentation			
Can explain why it is important to accurately record the participants understanding of the study			Continued overleaf

Demonstrates ability to complete a consent/assent form with participant in accordance with GCP			
Demonstrates understanding and compliance with the recording and retaining of consent/assent documentation in accordance with the protocol			
Reflection			
Able to demonstrate reflective practice with regard to gaining informed consent/assent - Verbally to Manager (recorded on ICF training sheet) - Written reflection for portfolio			

Appendix 3: Informed Consent Training Log

Observation 1

Name	
Study	Date
Supervised by Name	Job Title
Suggested improvements incorporated	Yes/ No
Informed Consent Measures met? *	Yes/ No
Further improvements to be made: Signed…… Supervisor	

Observation 2

Name	
Study	Date
Supervised by Name	Job Title
Suggested improvements incorporated	Yes/ No
Informed Consent Measures met? *	Yes/ No
Further improvements to be made: Signed…… Supervisor	

Observation 3

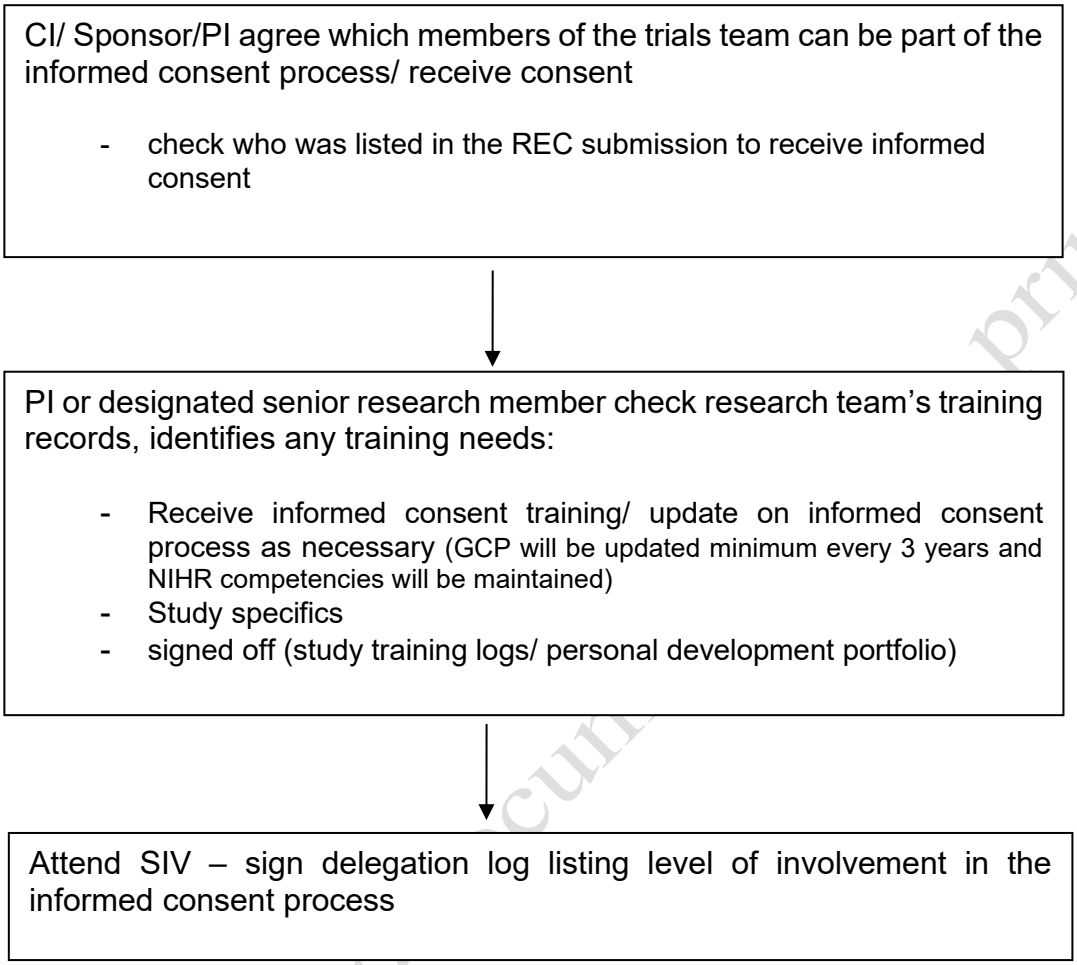
Name	
Study	Date
Supervised by Name	Job Title
Suggested improvements incorporated	Yes/ No
Informed Consent Measures met?*	Yes/ No
Further improvements to be made: Signed…… Supervisor	

Measures:

It is assumed that the trainee will perform both the 'Informing the patient about the study' and 'Taking informed consent' for each of the three assessments on the previous page and that, as a minimum, the following measures should be met.

- Description of randomisation
- Voluntary nature of consent
- All questions raised by the patient answered
- Explanation of the study equipoise
- Comprehensive understanding (by the trainee) of the study, including trial history, study question/aim, potential toxicities, side effects and study procedures.
- Evidence of the patient understanding the study, including potential toxicities, side effects and study procedures.
- A working knowledge of the Trust Informed Consent SOP and adherence to this SOP during the Informed Consent Process.

Appendix 4: Preparation during study set-up



Appendix 5: Individual staff training programme for receiving informed consent

A new member of the research team will attend an NIHR Informed Consent training course as soon as possible after joining the research team

↓

New member of staff will buddy up with a clinician or an experienced research nurse/ research co-ordinator:

- Initially sit in (with the participants permission) / shadow / work alongside the experienced team member to observe the informed consent process
- After agreed number of observations the new team member will take on an agreed section of the informed consent process alongside the experienced researcher
- When in the opinion of the experienced researcher, the new member if staff is competent and confident then the new researcher can take the lead on the informed consent process, however the experienced research does the final confirmation and signs the ICF
- When in the opinion of the experienced researcher the new member of staff is competent and confident then the new researcher can take the lead on the informed consent process and does the final confirmation and signs the ICF observed by the experienced member of staff. 3 complete consent conversations must be observed before the new member of staff is signed off to undertake the whole consenting process.
- The new member of the research team is now ready to approach and see participants but must remember that they can still call upon other members of the team to assist with the informed consent process when the participant asks for information, they do not have confidence or knowledge in.
- Following initial training and assessment, Assistant Research Coordinators will be observed at least once for each subsequent study when delegated the duty of receiving informed consent

↓

All research staff involved in the consenting process will undertake 3 yearly GCP updates and maintain NIHR competencies that include informed consent. An individual review can be arranged by the line manager as required.

Appendix 6: Informed consent Process

Preparation before approaching potential participants; each staff member must:

- Be prepared to take on the additional responsibility and feel confident and competent to receive informed consent in line with their professional code of conduct where applicable
- Have a comprehensive understanding of the research study including
    - the disease area
    - standard treatments and their potential toxicities
    - the research treatment/ intervention and its pharmacological interactions/ toxicities/ side effects
    - risks and benefits of participating in the research study
- Be qualified by experience and training in the research process and the specifics of the research study (GCP and VIC) and able to provide documentary evidence of this training
- Have signed the delegation log and it be countersigned by the PI
- Have provided a research CV for the site file

↓

Plan how and where to approach potential participants:

- Identification by pre –screening can only take place by reviewing patient notes/ results taken as part of standard care or a standard Trust data base. Check if clinician eligibility check required.
- Check room availability for the meeting/ internet connectivity for eInformed Consent
- Check what is the current Trust approved version of the protocol, PIS(x2) and ICF
- It may be possible depending on the submission to REC to make the first contact by telephone or post – if this is the case, remember to document and keep copies of information sent/ telephone transcript.

↓

Information giving with documentation in notes: (electronic for or paper-based in line with clinical setting)

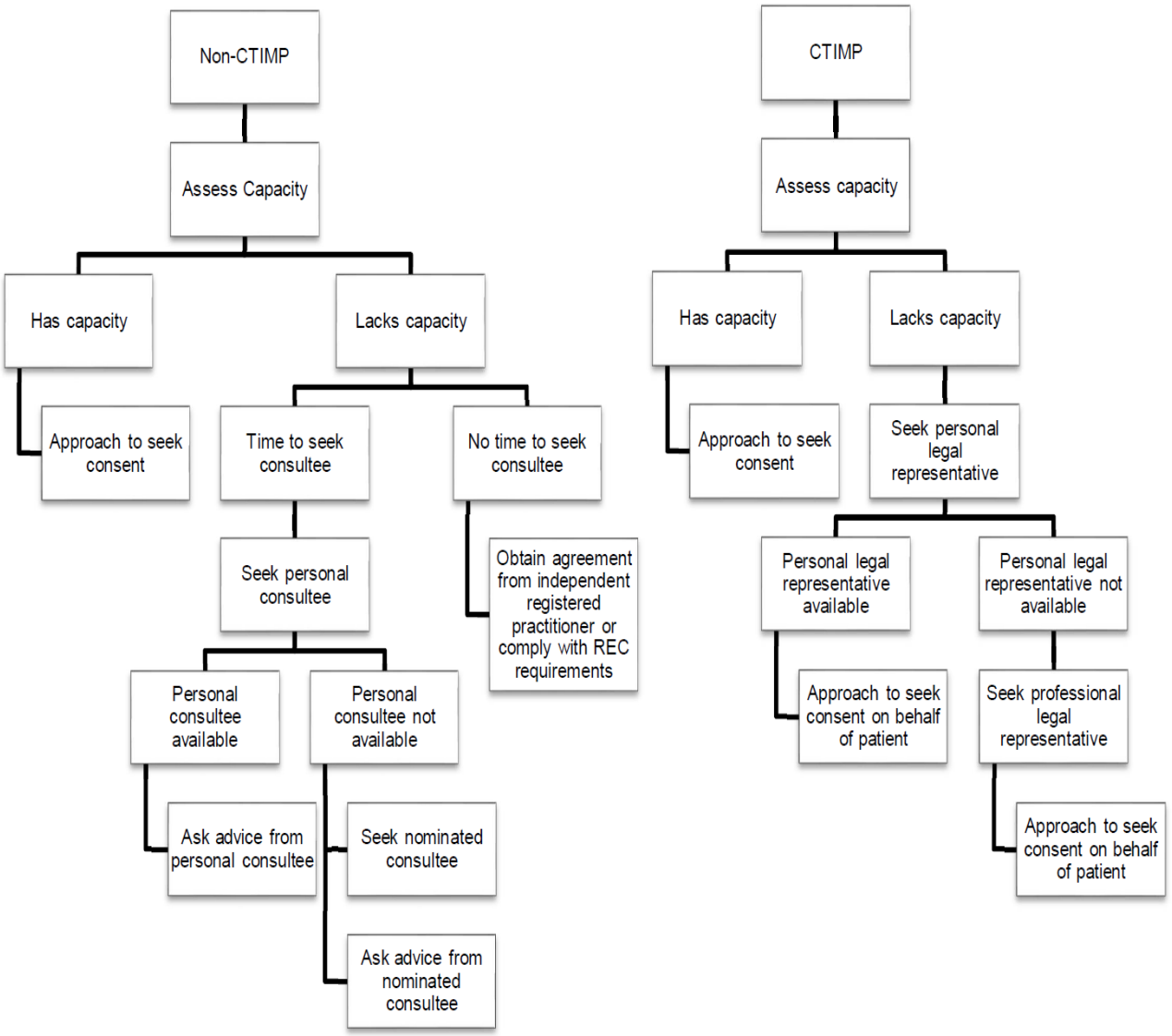
- Introduction and discussion to help participant achieve full knowledge and understanding
- Review participant's understanding answer questions/ concerns
- Provide time for the participant to make a considered decision (check REC and protocol)

↓

Receiving/ withdrawal of informed consent with documentation in notes (electronic or paper-based in line with clinical setting)

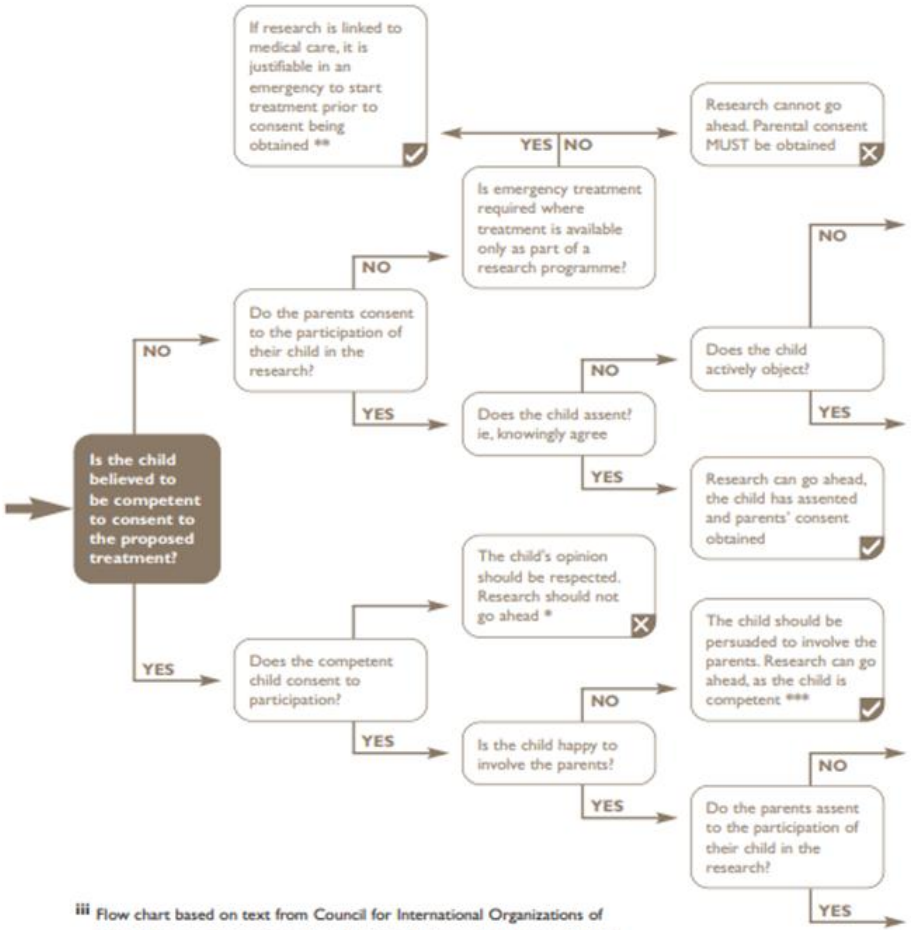
- Receive consent, participant's decision to voluntarily accept and provide permission, ICF full executed
- Consent is a continuous ongoing process, the researcher must check each time they meet with the participant that they wish to continue in the research study
- The participant can withdraw at any time without giving a reason
- On occasion the Sponsor will have new information they wish the participants to have which may involve reconsenting and the due process should be gone through again

Appendix 7: Adults lacking capacity to consent to research decision tree (based on NRES document)



Appendix 8: Consent process with minors (based on MRC Ethics Guide to medical research involving children)

5.1.6 Seeking consent – a summary[iii]



[iii] Flow chart based on text from Council for International Organizations of Medical Sciences *International ethical guidelines for biomedical research involving human subjects.*[5]