Gloucestershire Hospitals
NHS Foundation Trust

SOP 04: Informed Consent for Research

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Author:	Chris Ford	
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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 & Development 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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https://www.gloshospitals.nhs.uk/about-us/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 Addition of '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4.0	Typographical error corrections Acknowledgment of use of electronic and paper-based medical notes Removal of out-of-date link Information on the National Data opt-out scheme Acknowledgement of use of interpreters Use of email to send out patient information sheets Insertion of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

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

Related Documents:

SOPs
SOP 02 - Research Documentation and File Management
SOP 03 - Training

Glossary

CI	Chief Investigator
CTIMP	Chief Investigator
GCP	Good Clinical Practice
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
IMP	Investigational Medicinal Product
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NMC	Nursing Midwifery Counsel
PI	Principal Investigator
PIS	Participant or Patient Information Sheet
REC	Research Ethics Committee
VIC	Valid Informed Consent

Contents

1. Introduction, Background and Purpose

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

1.1 Definition of Informed Consent (Declaration of Helsinki 2013[1])

"In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study."

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

This SOP describes the process for receiving Informed Consent from a study/trial participant. The use of study/trial are interchanged throughout depending on which is most applicable.

2. Who should use this SOP?

This SOP applies to all investigators and research team members involved in CTIMP and non–CTIMP studies.

The Sponsor will make the decision which staff groups are permitted to receive Informed Consent/ Assent and this information will be detailed in the REC application. Locally the decision will be made at set up who will be delegated the responsibility and this will be detailed in the submission paperwork sent to Trust for R&D approval. Below is a list of staff groups typically involved in the Informed Consent process this is not an exhaustive list (refer to study/trial protocol, Sponsor and Trust R&D department):

- Clinicians
- Research Nurses
- Research Co-ordinators
- Research Support Officers
- Research Radiographers
- Research Physiotherapists
- Midwives
- Students

3. When should this SOP be used

This SOP is applicable for all clinical studies/trials sponsored, co-sponsored and hosted by the Trust. It should be read alongside any study/trial specific requirements

as detailed in the study/trial protocol. It should be referred to during study/trial feasibility, set up and throughout the recruitment and follow up phase of the trial.

This SOP should be read alongside any study/trial specific requirements for individual studies/trials as stated in the study/trial protocol.

4. Which staff groups can receive consent?

The delegation of the responsibility for taking part in the Informed Consent process for each staff group will be decided on a trial-by-trialbasis. This will be confirmed at trial set up with the Sponsor and will follow the details in the REC submission and approved as part of the Trust Research Governance review.

Staff groups include but not exclusive to:

Job role	Type of study	Comments
Clinician	Interventional and non-interventional	PI having full responsibility for the consent process. Some sponsors only want PIs to receive consent others are happy for Sub-Investigators / Co-Investigators to receive consent.
Allied Health Professional	Interventional and non-interventional	May be PI having full responsibility for the consent process. Or may have full responsibilities in the informed consent process as agreed with the Sponsor/ REC

		submission, or take a given part in the consent process
Research Nurse	Interventional and non-interventional	May be PI having full responsibility for the consent process. Or may have full responsibilities in the 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	May have full responsibilities in the informed consent process as agreed with the Sponsor/ REC submission, or take a given part in the consent process
Research Support Officer	Non-interventional	Participants will be identified by senior member of research team, and Research Support Officer receives informed consent as agreed with the Sponsor

5. How to delegate responsibility for receiving informed consent

The Chief Investigator (CI) or Principal Investigator (PI) for the trial 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 NMC Code of Professional Conduct or other professional organisational guidelines
- The research team member has 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 clinical trial
- They are qualified by experience and/or should have received appropriate training for this study
- Research staff will only be delegated this responsibility after they have received trial 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 R&D Department.
- The delegation of responsibility should be documented on the Trials Delegation and Signature Log
- Research nurse or other non-clinician to receive informed consent has been specifically approved by the relevant Research Ethics Committee, Trial Sponsor and NHS organisation hosting the study
- 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 subjects have fully understood what they are consenting to
- Any other research personnel involved in giving information during the informed consent procedure should also sign and personally date the informed consent form

- All persons who obtain written and/or virtual informed consent must have a copy of their signed and dated CVs in the Study Site File and must have completed the Trial Delegation and Signature Log
- Delegation of informed consent for CTIMPs to non-clinicians 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 trial participants

There may be an element of pre-screening to ensure that the trial(s) being offered to a potential participant are appropriate. This pre-screening may take the form of reviewing patients' notes and associated imaging and laboratory results. No additional trial-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 trial 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.

Confirmation that participants who potentially fulfil the inclusion criteria for a CTIMP trial must be carried out 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. The clinician must record in the potential participant's medical notes that they are initially suitable to be approached.

For non-CTIMP trials/ studies the participant may be identified by a non-medically qualified person where this has been agreed with the Sponsor and the Trust Research Governance Manager at trial set up. It is expected that there will be a health professional with the relevant qualification(s) as part of the trial 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 at www.nhs.uk/your-nhs-data-matters. 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). Research staff can use the national data opt-out tool, or contact Business Intelligence at GHNHSFT to determine participant preference.

7. Information provided to the trial participant

Patient information should be provided in language appropriate formats to potential trial participants in both an oral and written form, usually a Patient Information Sheet and Informed Consent Form 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)

8.0 How will potential trial participants be approached?

8.1 Telephone

It is possible to make the initial approach by telephone conversation using an ethically approved script followed by a Participant Information Sheet (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 trial participating 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 trial 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 trial forms part of the consultation where the subject's diagnosis of the condition is presented.

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

8.4 Remote consent processes

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 trial is opened to recruitment or after a trial amendment.

When using video-conferencing for VIC the Trust's preferred method is Attend Anywhere. When using this method some Sponsor's/ 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.

8.5 Recording contact for trial purposes

It must be possible to reconstruct when the provision of information took place. This is required to demonstrate that the potential participant was given time to consider the trial before Informed Consent was received by the researcher. This information and the version of the PIS given must always be recorded in the patient's notes, currently electronic for inpatients and paper-based for outpatients and recorded in the trial specific documentation (usually provided by the Sponsor).

9. Receiving informed consent

Respect and dignity of the subject 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 taking consent should consider whether there are factors present which may impair a subject'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 Participant Information Sheet and Informed Consent Form for the study approved by the REC/MHRA, together with any documents the subject may need to use e.g., diaries.
- A systematic verbal explanation of the study must be given to the subject (and friends and family if appropriate) taking the patient through the Patient Information Sheet. 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 (usually at least 24 hours), to read the information sheet 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 (see section A28 of the ethics application).

- Once the potential participant has had time to read the information sheet and has had any questions regarding their participation answered satisfactorily, then the person taking informed consent will ask them to sign the written informed consent form relating to the study. The informed consent form must be personally signed and dated by the person taking consent and the trial 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 informed consent form, the participant should receive a copy of the signed and dated consent form, information sheet and any other written information provided. The original consent form must be placed in the Trial Master File and a second copy placed in the participant's medical records and any additional copies as specified by the trial 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 Informed Consent form and in the participant's medical notes.
- All subjects 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 trial 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 trial 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 trial treatment/ have data sent off to the CI/ Sponsor, this must be recorded in the patient's notes.

9.4 Re-Consent

The practice of giving information about the trial to participants will be an ongoing process performed by all members of the research team. This is particularly significant with the introduction of protocol amendments and the availability of important new information (interim results/ safety measures) that may be relevant to the subject'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

amendment 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 satisfied that the subject 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 subject and by the authorised person who conducted the re-consenting discussion.

If the patient decides that they no longer wish to continue in the trial 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.

9.5 Consent in vulnerable groups

The 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.

9.5.1 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 the trial. The provisions for informed consent by a legal representative only apply if by reason of the emergency nature of the treatment provided as part of the trial no person with parental responsibility can be contacted prior to the proposed inclusion of the minor.

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.

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:

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

Having regard to the nature of the trial and the particular circumstances of the case, it is necessary to take action for the purpose of the trial as a matter of urgency but

- It is not reasonably practicable to obtain informed consent prior to entering the subject, and
- The action to be taken is carried out in accordance with a procedure approved by the ethics committee.

Where a minor is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent from a person with parental responsibility or a legal representative as soon as practicable after the initial emergency has passed. Where consent is withheld, the subject must be withdrawn from the trial.

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.

If aged 16 or over, it is acceptable for minors to sign their own consent form.

9.5.2 Research Involving Incapacitated Adults

Legally, adults must be presumed to be capable of taking decisions unless the opposite had been determined for a particular decision. The 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 that consent is 'voluntary and continuing permission';
- understands that consent 'can be withdrawn at any time'.

A patient 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 be aware of the various forms of PIS and ICF applicable to the specific study 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 subject.

It is possible in the research setting for a third party to act in the incapacitated patient's best interest with regards to participating in research.

9.5.2.1 Research involving CTIMPs

A legal representative can be asked to give consent on behalf of an adult lacking capacity to do so themselves.

Those who are able to 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 to act as the legal representative 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:

- Told that they are being asked to give consent on behalf of the incapacitated adult,
- Told that they are free to decide whether they wish to make this decision or not, and
- Told 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 your trial to ensure that they can make an informed decision.

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

Non-therapeutic trials may still involve incapacitated adults when the trial 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 Clinical Trials of Investigational Medicinal Products (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:

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

The advice given by consultees should be recorded on a Consultee Declaration form (rather than a consent form).

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

9.5.3 On-going Consent and Participants Who Regain Capacity

If it is possible 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 Participant Information Sheets and Consent Forms 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.

9.6 Informed Consent in Emergency Situations

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 amended 2006 or not.

9.6.1 Clinical Trials subject to UK Clinical Trials Regulations amended 2006

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 into the trial. This amendment allows the recruitment of patients in an emergency situation into clinical trials before consent is obtained from personal/legal representatives.

In the UK the law allows adults not able to consent for themselves to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if:

- Treatment needs to be given urgently;
- It is also 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 a NHS Research Ethics Committee;
- 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.

9.6.2 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 (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 research ethics committee.

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.

Capacity must be constantly assessed and if regained informed consent sought from the patient. If the patient refuses, they must be withdrawn.

10.0 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 will contain the items listed below for both inpatient and outpatient trials.

- Patient Information Sheet
- Signed Consent Form/ Assent Form (photocopy in the legal section of the notes)

GP letter (where applicable)The following will occur for inpatient based trials, the written diary of consent process for each individual andconfirmation that the subject has been

given a copy of the consent form will be documented and dated in the electronic medical records. Outpatient based trials will record this information in the paper-based medical notes.

Participant

– Patient Information Sheet

- Consent Form/ Assent Form (photocopy)

Subjects 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)
- Written diary of consent process for each individual participant to be kept within 'patient pack'

Supporting departments

- Consent Form/ Assent Form (photocopy, sample copy of consent form to Histology Department to inform them the participants has agreed for archival tissue sample to be sent off site to a central laboratory for micro array sampling/ analysis)

Consent forms 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 notes. A site file note to explain the event is to be completed and filed in the site file alongside the consent form.

11.0 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. Checking staff competencies may be delegated to senior research staff within a given research team and/ or Trust senior R&D staff. (Further information is in SOP 03 - Training along with competency / training sheets.)

12.0 References

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/
Mental Capacity Act (2005)
EMERGENCY RESEARCH The Medicines for Human Use (Clinical Trials) (Amendment No.2) Regulations 2006
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 trial participant

- A statement that the trial involves research
- The purpose of the trial
- The trial treatment(s) and the possibility of random assignment to each treatment
- The trial procedures to be followed, including all invasive procedures
- The subject's responsibilities
- The experimental aspects of the trial
- Any foreseeable risks or inconveniences for the trial subject
- The reasonably expected benefits. If there is no clinical benefit intended, the subject 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 subject in the case of any injury relating to the trial
- Anticipated pro-rata payment, if any, to the subject for participating in the trial
- The anticipated out of pocket expenses, if any, to the patient for participating in the trial
- That the subject's participation in the trial is completely voluntary and that the subject can withdraw or refuse to participate, at any time, without penalty or loss of benefits to which they would otherwise be entitled and without affecting their future care
- 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 subject's records for the purpose of verification of the trial procedures and data collected, without violating the confidentiality of the subject
- That the subject's General Practitioner will also be informed in writing of their participation in the study
- By signing the informed consent form, the subject is authorising such access
- That records identifying the subject will be kept confidential and will not be made publicly available. If the results of the study are published, the subject's identity will remain confidential

- That the subject /legal representative will be informed in a timely manner if any information becomes available that may be relevant to the subject's willingness to continue to participate in the trial
- The person(s) to contact for further information regarding the trial (if possible, record a 24 hour phone number where the subject can receive advice out of office if required)
- The foreseeable circumstances under which the subject's participation in the trial may be terminated
- The expected duration of the subject's participation in the trial
- The approximate number of patients involved in the trial

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 - 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 IC training sheet) - Written reflection for portfolio			

Appendix 3: Informed Consent Training Log

Observation 1

Name	
Trial	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	
Trial	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	
Trial	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 trial' 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 trial procedures.

Evidence of the patient understanding the study, including
potential toxicities, side effects and trial procedures.

A working knowledge of the Trust Informed Consent SOP
and adherence to this SOP during the Informed Consent Process.

Appendix 4: Informed Consent Annual Competence Review

Name:……. Job Role:……..…….

Measures:
It is assumed that the research delivery staff member will perform both the 'Informing the patient about the trial' and 'Taking informed consent' during this review process and as a minimum, the following measures should be met.

	Yes	No
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 trial procedures.		
Evidence of the patient understanding the study, including potential toxicities, side effects and trial procedures.		
A working knowledge of the GHNHSFT Informed Consent SOP and adherence to this SOP during the Informed Consent Process.		

Trial……. Date……..

Supervised by…… ……
Name Job Title

Informed Consent Measures met?* YES/NO
(If measures are not met, the reviewee should be supervised in the Informed Consent Process until the reviewer is satisfied that the measure have been met. A separate form should be completed for each review).

Supervisor/Trainer: ……..…… continues to perform Informed Consents to a high standard and therefore may continue to perform Informed Consents unsupervised.

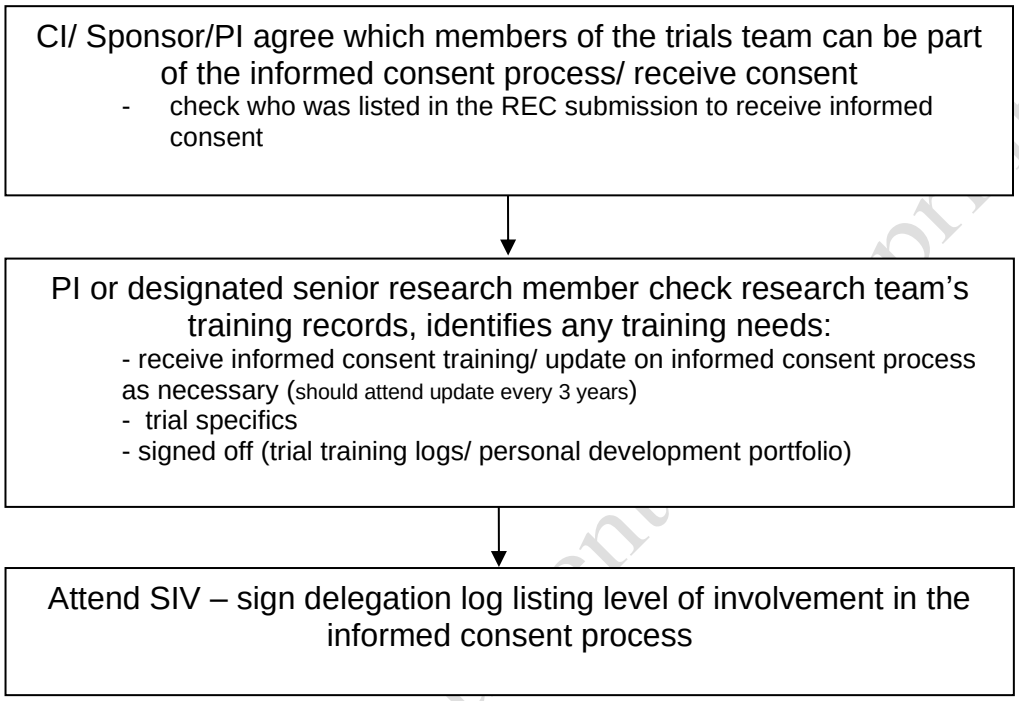
Signed…… Date……

Supervisee: I understand that I may perform Informed Consents unsupervised, but will only do so when I feel confident and competent to do so.

Signed……. Date……

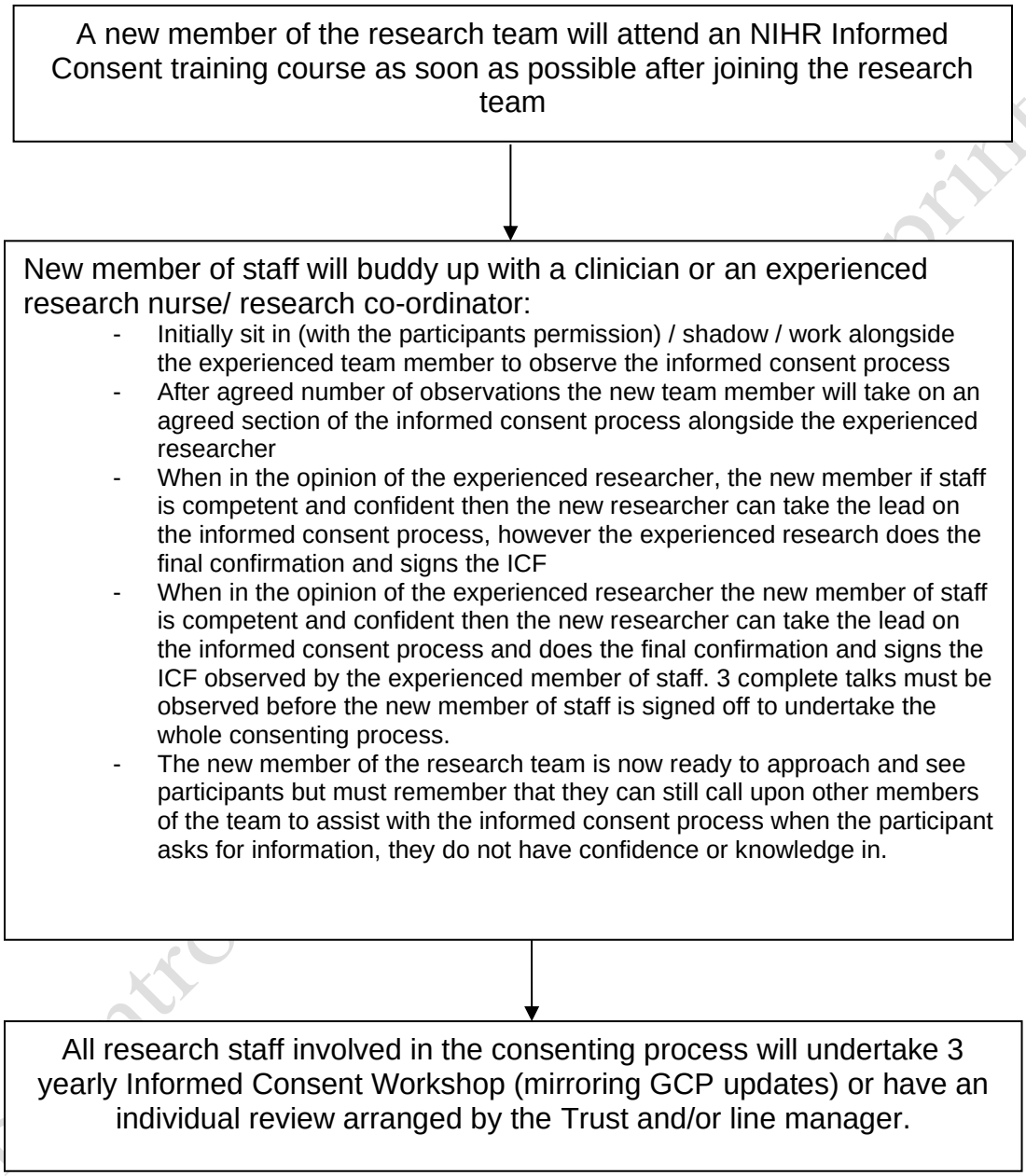
Appendix 5

Preparation during set up of trial



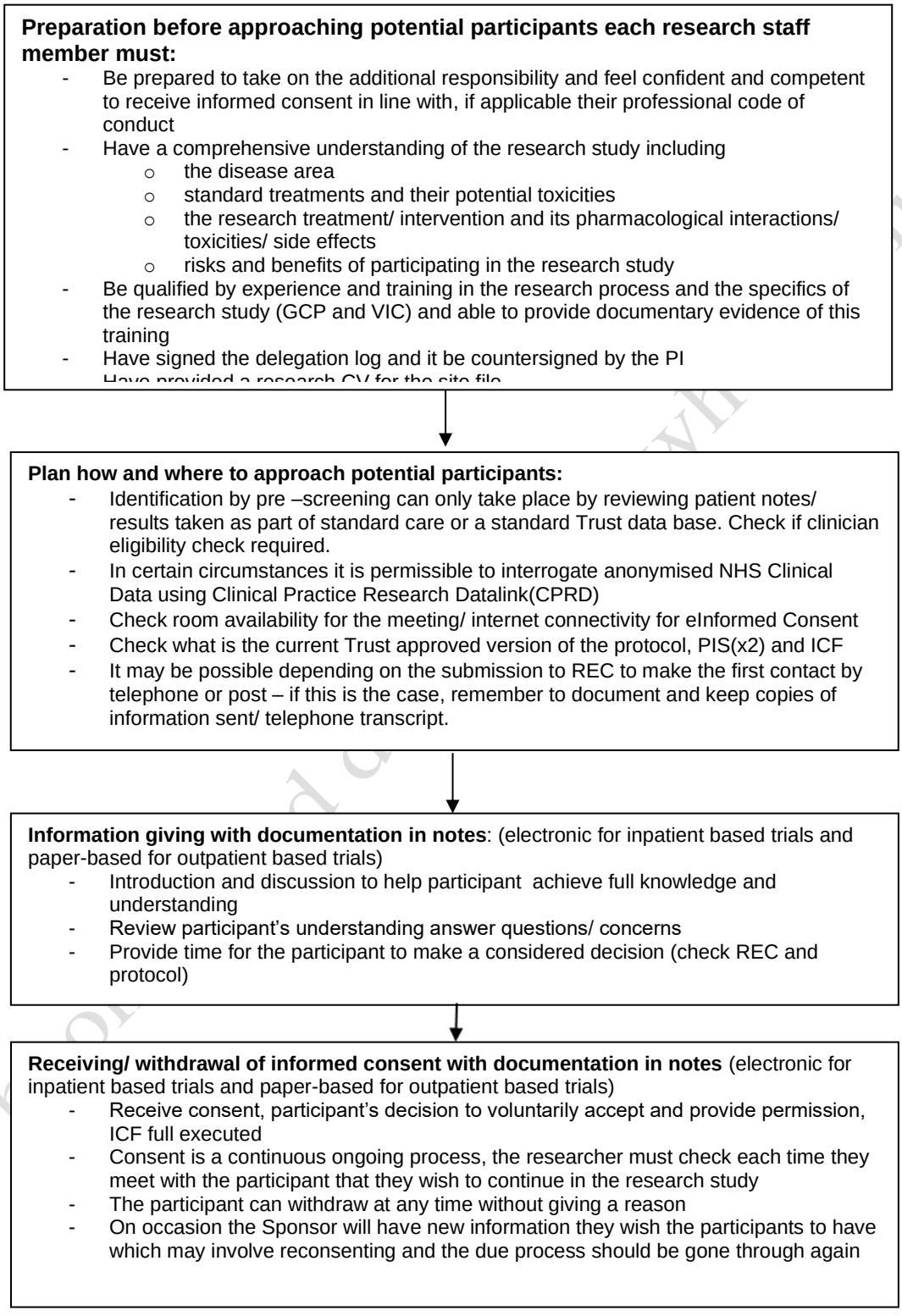
Appendix 6

Individual staff training programme for receiving informed consent

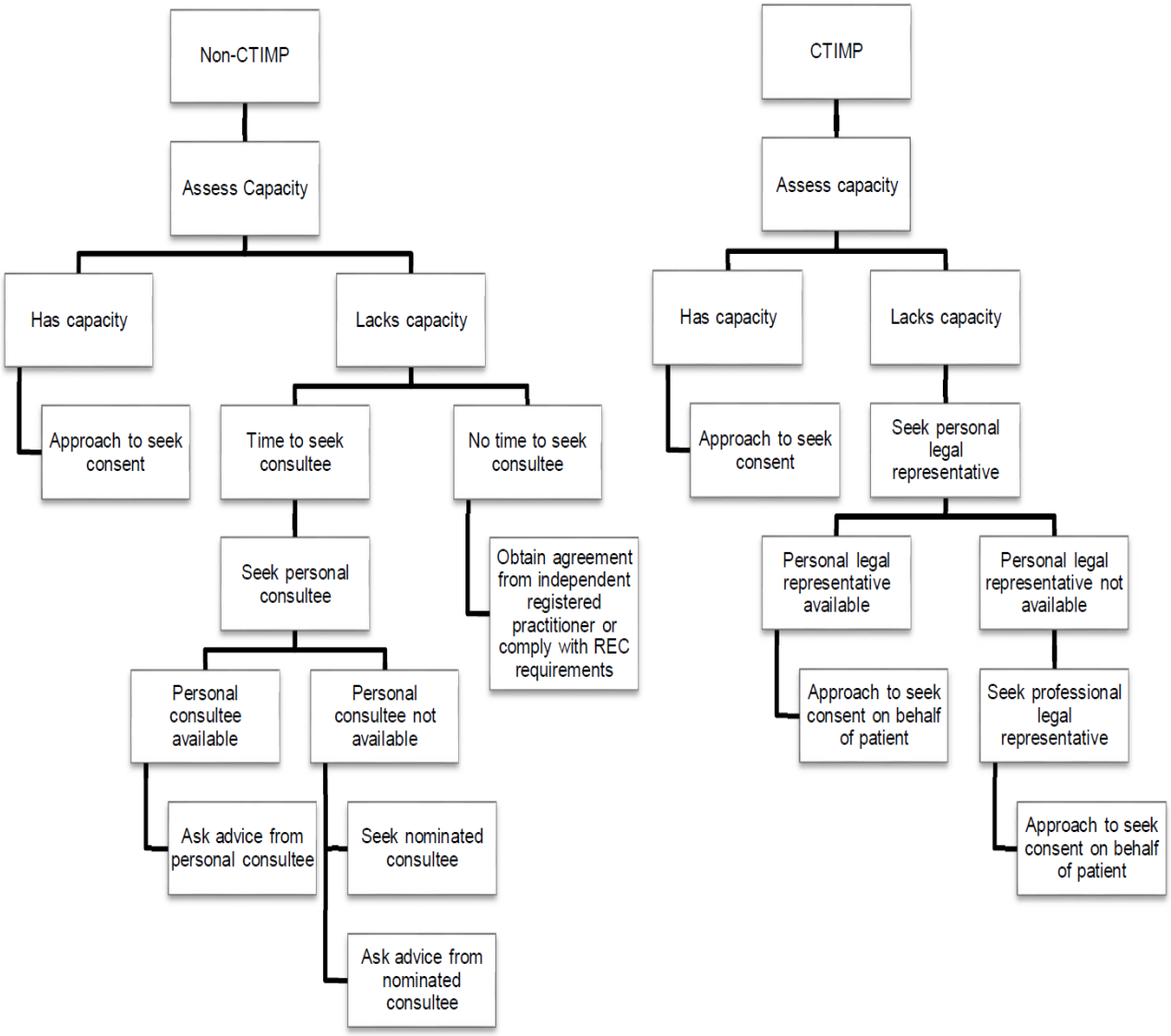


Appendix 7

Informed Consent Process



Appendix 8: Adults lacking capacity to consent to research decision tree (based on NRES document)



Appendix 9: Legal Representative Guidelines

Legal Representative Guidelines (Adults)

(CTIMPS - Clinical Trial of an Investigational Medicinal Product)

The Medicines for Human Use (Clinical Trials) Regulations 2004 profoundly changed the legal basis for consent for vulnerable subjects (minors and incapacitated adults). One of the key requirements is that the researcher obtain the written informed consent of a Legal Representative for all incapacitated adults and also, for minors.

The definition of an incapacitated adult used in the Regulations is *a) an adult unable by virtue of physical or mental incapacity to give informed consent, and b) did not prior to the onset of incapacity, give or refuse to give informed consent to taking part in the clinical trial.*

A legal representative can be asked to give consent on behalf of an adult lacking capacity to do so themselves. Those who are able to act as a legal representative in CTIMPS in England and Wales are;

1. A **Personal Legal Representative (PeLR)** 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 adult, and is available and willing to do so.

2. A **Professional Legal Representative (PrLR)** 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.

In circumstances where it has not been possible to obtain the consent of a PeLR, the Principal Investigator (PI) or delegate, will approach the PrLR.
If, having assessed the information given, the PrLR agrees that a subject should be entered into the trial; they will then be asked to give their written informed consent.

How is the decision to give consent made?

In the absence of any information to the contrary, it is justifiable for a PrLR to assume that a patient being considered for a clinical trial would wish to enter the trial. In order to arrive at a decision, the PrLR should consider:

- Is there any information about the patient that might influence their decision? For example, race, religion or an Advanced Directive.

- Has the Principal Investigator/ delegate confirmed that the patient meets the eligibility criteria and has received information according to their capacity for understanding?

What happens if a personal legal representative becomes available?

It is good practice that responsibility for continued participation in the study be transferred up the chain. In other words, if a **PeLR** becomes available, the PrLR should transfer the responsibility for substituted judgement over to that individual if they are willing to give their consent, this should be documented on a consent form. If the subject regains capacity, their consent should be sought.

Emergency Situations

The Medicines for Human Use (Clinical Trials) (Amendment No.2) Regulations 2006 makes additional provision relating to trials involving incapacitated adults in emergency situations. Where the treatment to be given to an incapacitated adult as part of the trial needs to be given urgently, time may not allow for the written consent of a Legal Representative to be obtained first. The amendment allows incapacitated adults to be entered into a trial prior to consent being obtained from a Legal Representative provided that:

- Treatment needs to be given urgently;
- It is not reasonably practicable to seek advice from a consultee;
- The procedure is approved by a NHS Research Ethics Committee; and
- A consultee is consulted as soon as possible to seek advice on the participant's likely views and feelings.

NOTE: Even if an ethics committee has approved the above provision for a particular trial, in circumstances where it is possible to obtain the consent of a Legal Representative before inclusion of the subject, it should be obtained.

Conditions and principles which apply to the inclusion of an incapacitated adult in a clinical trial

1. The Legal Representative has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
2. The Legal Representative has been provided with a contact point where he may obtain further information about the trial.

3. The Legal Representative has been informed of the right to withdraw the subject from the trial at any time.
4. The Legal Representative has given informed consent to the subject taking part in the trial.
5. The Legal Representative may, without the subject being subject to any resulting detriment, withdraw the subject from the trial at any time by revoking his informed consent.
6. The subject has received information according to his capacity of understanding regarding the trial, its risks and its benefits.
7. The explicit wish of a subject who is capable of forming an opinion and assessing the information referred to in the previous paragraph to refuse participation in, or to be withdrawn from, the trial at any time is considered by the investigator.
8. No incentives or financial inducements are given to the subject or their legal representative, except provision for compensation in the event of injury or loss.
9. There are grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit to the subject outweighing the risks or produce no risk at all.
10. The clinical trial is essential to validate data obtained (a) in other clinical trials involving persons able to give informed consent, or (b) by other research methods.
11. The clinical trial relates directly to a life-threatening or debilitating clinical condition from which the subject suffers.

Principles

12. Informed consent given by a legal representative to an incapacitated adult in a clinical trial shall represent that adult's presumed will.
13. The clinical trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.
14. The risk threshold and the degree of distress have to be specially defined and constantly monitored.
15. The interests of the patient always prevail over those of science and society.

Indemnity Arrangements for NHS Staff Delivering Research

There are schemes in place to provide cover for NHS staff conducting research, whether that activity is taking place within NHS premises, patients' homes, care homes, hospices or other spaces in which NHS researchers undertake NHS research.
Research is a core NHS activity. NHS staff undertaking research as part of their job role are covered by NHS Resolution indemnity schemes if working for a member of those schemes, subject to the usual scheme terms and conditions.

Further information can be found at: Indemnity cover for NHS staff delivering research - Health Research Authority (hra.nhs.uk)

References:

The Medicines for Human Use (Clinical Trials) Regulations 2004 (legislation.gov.uk)

Research in emergency settings - Health Research Authority (hra.nhs.uk)

NHS information governance: legal and professional obligations - GOV.UK (www.gov.uk)

Principles of consent: Adults Lacking Capacity (England and Wales) - Consent and Participant information sheet preparation guidance. (hra-decisiontools.org.uk)

Indemnity cover for NHS staff delivering research - Health Research Authority (hra.nhs.uk)

Appendix 10: Personal Nominated Consultee Guidelines

Personal/Nominated Consultee Guidelines (Adults)

(NON-CTIMPs)

The Mental Capacity Act (MCA) 2005 is a piece of legislation that protects the rights of people who are not able to make decisions for themselves. The MCA includes safeguards for the conduct of research involving people who may, temporarily or permanently, not be able to consent due to a medical problem. A person must be assumed to have capacity unless it is established that they lack capacity.

Following NHS Research Ethics Committee approval for each study, the MCA requires that before a person who is unable to consent is involved in research, another suitable person must be identified who can act on their behalf as a consultee. This consultee can advise the research team on what the participant's wishes and feelings would be if they were able to consent for themselves. The consultee does not give consent, only advice on whether, in their opinion, the person who lacks capacity would want to be involved in research.

The Mental Capacity Act in England allows research to proceed without the usual consent if no medicines or drugs are being tested. Clinical trials of investigational medicinal products (CTIMPs) are excluded from this Act. For CTIMPs see Gloucestershire Hospitals NHS Foundation Trust, Legal Representative Guidelines and Medicines for Human Use (Clinical Trials) Regulations 2004.
A consultee role can either be personal or nominated.

Personal Consultee

A Personal Consultee is someone who is unconnected with the conduct of the research project. They personally know the person who lacks capacity and they are able to advise on the person's wishes or feelings. A number of people may be capable of acting as a Personal Consultee, but they should be someone whom the person who lacks capacity would trust with important decisions about their welfare. Usually, it will be someone with a close personal relationship with the person, for example their next of kin, spouse or partner, adult child or parent. They must **not** be someone who is paid to look after the person who lacks capacity.

Duties of a Personal Consultee

A Personal Consultee must themselves have capacity and be prepared to be consulted by the researcher about the possible involvement in the research project of the person who lacks capacity. This means that they must be willing to take on this role and able to understand the information given to them. The consultee is not being asked to provide

their own personal views on participation in the specific project, or research in general. They must set aside any views they have about research and consider only the views and interest of the person who lacks capacity. The consultee should consider the past and present views of the person who lacks capacity on the overall nature of the research. At any stage, the consultee can advise the researcher that the person who lacks capacity would not want to remain the research project, and their advice must be respected by the researcher.

The main responsibility of a consultee is to advise the research team as to whether or not they think that the participant would be happy to take part in the research project
It should be made clear that they are not obliged to undertake the role of consultee if they do not want to. If this is the case and reasonable steps have been taken to identify another Personal Consultee and if one is not available then a Nominated Consultee should be approached.

Nominated Consultee

A Nominated Consultee is also someone unconnected with the conduct of the research project. However, this Consultee does not have to personally know the person who lacks capacity, but they can ask other people close to the person who lacks capacity about the person's wishes or feelings. A Nominated Consultee may have a professional knowledge of the person who lacks capacity, such as their doctor or lawyer. They can be someone who is paid to look after the person who lacks capacity.

Duties of a Nominated Consultee

A Nominated Consultee is required to perform the same role as the Personal Consultee in advising the researcher about the participation of the person who lacks capacity. The Nominated Consultee needs to receive information regarding the research project. They must also consider how the wishes and interests of the person who lacks capacity would incline them to decide if they had the capacity to make the decision.
The Nominated Consultee is not required to know the person who lacks capacity. In determining what the person's wishes and feelings about the research project would be if they had capacity, the Nominated Consultee should attempt to seek views from any family, friends or carers (if they are available) who may not be willing or able to act as a consultee. Where appropriate, other colleagues with a professional interest in the person who lacks capacity, such as members of the care team not involved in research, may be asked for their view. The Nominated Consultee must consider any possible potential or perceived conflict of interest in the outcome of the research when weighing up the views of family, friends or carers.

Mental Capacity Act 2005
Available at:
https://www.legislation.gov.uk/ukpga/2005/9/section/32/enacted (last accessed 15 June 2023)

Guidance on nominating a consultee for research involving adults who lack capacity to consent
Available at:
https://www.manchester.gov.uk/download/downloads/id/12218/guidance_on_nominating_ (last accessed 15 June 2023)

Gloucestershire Hospitals
NHS Foundation Trust

Appendix 11: Consent process with minors (based on MRC Ethics Guide to medical research involving children)