NHS
Gloucestershire Hospitals
NHS Foundation Trust

Trial Delivery 03 – Informed Consent for Research

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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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

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

Contents

1. Introduction, Background and Purpose

This SOP describes the ongoing process for receiving Informed Consent from a 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 trial participant.

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 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 trial protocol, Sponsor and Trust R&D department):

- Clinicians
- Research Nurses
- Trials Co-coordinators
- Research Support Officers
- Research Radiographers
- Research Physiotherapists
- Midwives
- Students

3. When should this SOP be used

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

This SOP should be read alongside any trial specific requirements for individual trials as stated in the 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 trial basis. 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
Trial 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 take 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 R&D SOP TD 02 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 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.

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. (See Appendix 2)

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. 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 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 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.
- 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 representatives 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 (eg 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.

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.

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 :

Patient Medical Records

- Patient Information Sheet
- Signed Consent Form/ Assent Form (photocopy in the legal section of the notes)
- GP letter (where applicable)
- Written diary of consent process for each individual

Confirmation that the subject has been given a copy of the consent form should also be documented and dated in the medical records.

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, example 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 R&D SOP TD 02 Training along with competency / training sheets.)

12.0 Related SOPs and other documents

https://www.nihr.ac.uk/our-faculty/documents/NRES%20Decision%20Tree.pdf

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

Appendix 1: Associated Trust policies

Gloucestershire wide

Gloucestershire Mental Capacity Act Multi-Agency Policy, Procedure and Guidance V8 April 2014 http://www.gloucestershire.gov.uk/extra/CHttpHandler.ashx?id=46026&p=0

GHNHSFT

Capacity Assessment and Decision Making Flow Chart
http://glnt313/sites/ghnhsft_policy_library/Procedures/A2048.pdf

Capacity Act & Guidelines
http://glnt313/sites/ghnhsft_policy_library/Procedures/A0251.pdf

Mental capacity best interests card

http://glnt313/sites/ghnhsft_policy_library/ActionCards/A0251%20MC2.pdf

Appendix 2 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