<table>
<thead>
<tr>
<th>Title:</th>
<th>Gaining Valid Informed Consent from Participants for the Purpose of Research Studies</th>
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<tbody>
<tr>
<td>Outcome Statement:</td>
<td>Staff involved in gaining informed consent onto any research project (clinical or non clinical) being hosted/carried out within the Trust will be able to do so in a manner that complies with legal, professional and best practice requirements</td>
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<tr>
<td>Written By:</td>
<td>Research &amp; Development</td>
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<td>Reviewed:</td>
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<td>In Consultation With:</td>
<td>Kim Clipsham, DeNDRoN Senior Research Nurse</td>
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<tr>
<td>Approved By and Date:</td>
<td>V1.0 Research Governance Committee 31st May 2012 V1.1 Research Governance Committee, 26th September 2013</td>
</tr>
<tr>
<td>Associated Trust Policies:</td>
<td>Associated policies may differ depending on the type of study being carried out, please ensure that you are aware of any relevant documentation not already outlined in this section. Including Complaints procedure: Version 4 2010 C10 – Confidentiality C16 – Health Records..</td>
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<tr>
<td>Applicable To:</td>
<td>Trust wide</td>
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<td>For Use By:</td>
<td>Any staff involved in Trust wide research</td>
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<tr>
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<tr>
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<tr>
<td>Reason for Development/Review</td>
<td>Development: To inform researchers of the requirements and procedures to be undertaken when gaining valid informed consent from research participants Review: To clarify language, correct errors within body of text in consulting pathway, rearrange sections in order to flow in a more comprehensive way.</td>
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<tr>
<td>Implementation and Monitoring</td>
<td>a) To be sent out to all research teams b) Included in research training, supported by specific Informed Consent training session c) Reviewed annually or as required</td>
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1.1: Introduction:

Research is: “The attempt to produce generalisable new knowledge by addressing clearly defined questions with rigorous and systematic methods” (Gerrish and Lacey, 2010)

Research is regarded as a vital part of health care. Standards and governance have been built on many years of research practice and have led to the development of legal directives such as the Declaration of Helsinki which outlines the ethical responsibilities towards any persons engaging in research (WMA2000, Bosnjak2001,Tyebkhan 2003).

Norfolk and Suffolk Foundation Trust (NSFT) is committed to supporting health-care research to inform evidence-based practice. The Research and Development department manages all research projects within the Trust. The Trust also delivers national research projects through partnership with the Clinical Research Networks.

The main priority of NSFT Research and Development is to maintain the safety, rights and well being of the service user, carer or member of staff who are approached to participate in research.

1.2: Purpose:

The purpose of this policy is to set standards of practice for Trust staff who are involved in the Informed Consent process for Research.

The guidance requires that the process of seeking valid informed consent is well structured, transparent, properly documented and delivered in a way that protects the autonomy of the research participant and conforms to the Good Clinical Practice standards.

The policy and procedures stated below refer to all Trust-approved research studies which are both sponsored by the NSFT and external organisations.

1.3: Valid informed consent pertaining to research:

Informed consent relates to the detail of information given to enable a participant to objectively and, without bias, weigh up the risk, burdens and benefits of participating in research. Validity ensures that all the necessary steps have been taken to protect the participant in making that decision.

It is important to distinguish between the differences in relation to consent to research as oppose to consent to clinical care.

<table>
<thead>
<tr>
<th>Consent to research</th>
<th>Consent to Clinical Care</th>
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<tr>
<td>Research aims to gain new knowledge about a treatment, procedure, disease, equipment.</td>
<td>Risks involved are more predictable/known.</td>
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<tr>
<td>Research objectively evaluates risk vs benefit of potential new clinical interventions.</td>
<td>Treatment aimed at direct recovery or ease of distress/disease.</td>
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<tr>
<td>Individuals may or may not benefit directly from taking part in research.</td>
<td>Guided by professional code of conduct</td>
</tr>
<tr>
<td>Relies on the goodwill of participant.</td>
<td>Implied consent is more acceptable and used in treatment</td>
</tr>
<tr>
<td>Approved consent forms are usually required prior to commencement of study activity.</td>
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It is for these reasons that special considerations need to be in place to support the potential participant to make a fully valid and informed decision about participating in research.

There are a number of supportive documents that outline good practice in relation to consenting participants onto research including Royal College of Nursing, British Psychological Society, and Good Clinical Practice (ICH).

This policy does not replace documentation or standards relating to clinical practice and consent to treatment or clinical investigations. Investigators should be aware that consent to clinical treatment pathways and consent into a research study are separate procedures, and are subject to different regulations.

1.4: Scope:

This standard of practice applies to all clinical and non clinical personnel that are involved directly or indirectly in the process of seeking valid informed consent relating to all study that is being undertaken within NSFT. This includes, but is not limited to Chief Investigators, Principal Investigators, Academic Supervisors, Assistant Psychologists, Research Assistants, Research Nurses, Clinical Studies Officers, and students. This applies to all staff members who are employed directly by the Trust and those who are working under an honorary contract or letter of access to help deliver research in the Trust.

2.0: Definitions and Abbreviations:

Chief Investigator (CI): The lead researcher who has overall responsibility for the conduct of the research study across all sites in a country, including maintaining study documentation.

Clinical Trial: A comparative evaluation of two or more treatments or interventions undertaken in accordance with approved standard protocols in a health-care setting.

Clinical Trial of an Investigational Medicinal Product (CTIMP): An investigational product or device is defined in the Medicines for Human Use (Clinical Trial) Regulations 2004 as any investigation in human subjects, other than a non interventional trial intended:

- To discover or verify the clinical, pharmacological or other pharmaco-dynamic effects of one or more medicinal products
- To identify one or more adverse effects of these medicinal products
- To study absorption, excretion or distribution of medicinal products with a view of ascertaining the safety or efficacy of such products.

Since May 2004 when the Trial Regulations came into force, CTIMPs have been regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) who needs to give explicit authorisation for a CTIMP to be conducted in addition to the standard approvals required for clinical studies. This is termed “Clinical Trial Authorisation” or CTA. The NSFT does not currently sponsor CTIMP studies.

Non-CTIMP Clinical Trial: Evaluation of an intervention/treatment that does not involve investigational medicinal products.
**Non-Interventional study:** An observational research project that does not involve a change to treatment or interventions for research purposes.

**Delegation (of Duties) Log:** A study-specific record of delegated roles and duties of the local study team involved in the conduct of the research. Each role identified in the log should be signed and dated by each named individual and counter-signed and dated by the PI.

**Informed Consent Form (ICF):** The form which research participants sign to confirm their understanding and willingness to participate in research studies.

Only the version of the ICF which is approved by REC and the NSFT should be used to take informed consent for research studies. All forms should contain the Trust logo header and include contact details of the local study team and should correspond with the approved Participant Information Sheet.

**Mental Capacity:** ‘Capacity’ is the ability of a person to make decisions that may have legal consequences for themselves and/or for others affected by the decision. (www.dls.org.uk)

**Minor:** An individual that is under the age of 16.

**Participant Information leaflet/Sheet:** The document that is provided to all potential participants that informs them of all the relevant and necessary information that is needed to make a fully informed decision as to whether to participate in the research. Participant information leaflets should include what will be expected of them during the study, risks and benefits, duration of the study, support that is available.

**Personal or Professional Consultee:** A professional or personal consultee is a person who, by the nature of their relationship with the individual, is able to offer advice regarding a prospective participant’s presumed will to consent into a research study. A personal or professional consultee is required when an eligible individual is assessed to lack capacity to make an informed decision about their participation in a non-CTIMP. The personal and professionals consultee is required to be independent of the research team.

**Personal or Professional Legal Representative:** An authorised professional or personal legal representative, as defined under applicable law, to consent on behalf of a prospective participant. A legal representative is required when an eligible individual is assessed to lack capacity to make an informed decision about their participation in a CTIMP. The personal and professionals Legal representative is required to be independent of the research team.

**Principal investigator (PI):** A person that has overall delegated duty for the conduct of the research study at each individual participating research site.

**Research Nurse (RN), Clinical Studies Officer (CSO)/Research Assistant (RA):** A research practitioner employed by research team, Trust or research body with delegated duties to carry out specific allocated duties as identified in Trust approval documentation and supported by the delegation log.
Research Ethics Committee (REC). RECs safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. A favourable opinion from REC to conduct a research project involving NHS patients or identifiable patient data must be obtained prior to the start of any research activity involving direct contact with participants.

Research and Development Offices (R&D): Research and Development Offices review the local feasibility of conducting research studies in the relevant NHS premises. The research review is a risk-assessment based approach, evaluating the availability of support to conduct research studies and safeguarding current policies and practice. Approval from NSFT Research & Development must always be obtained prior to any research activity for all studies starting in the Trust.

Valid Informed Consent: Informed Consent is an on-going process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subjects decision to participate. Informed consent is documented by means of a written signed and dated informed consent form.

3.0: Legal frameworks:

3.1 “Freely given informed consent is at the heart of ethical research, and the national and international governance frameworks - including the Declaration of Helsinki” – RCN Informed consent in health and social care research 2011.

There are 3 main government frameworks that provide legal and governance guidance for seeking valid informed consent. These are:

- The Medicines for Human Use (Clinical trials) regulations 2004,
- Research Governance Framework 2005
- Mental Capacity Act 2005. [Detailed in Appendix 2]

3.2 Adults with Capacity

CTIMPs: The Medicines for Human Use (Clinical trials) regulations 2004 provides the legal framework for consent procedures for all trials involving CTIMPs and new medical devices.

Non-CTIMPs: The Research Governance Framework 2004 provides guidance for consent procedures for all other studies being carried out within health and social care settings.

3.3 Adults lacking Capacity

CTIMPS: The Medicines for Human Use (clinical trials) Regulations 2004 provide the legal framework for involving persons who lack capacity to consent to research and outlines the responsibilities and scope of Personal and Professional Legal representatives.

Non CTIMPS: Where capacity issues are involved, the Mental Capacity act 2005 will provide the guidance for involving persons who lack capacity to consent to research and outlines the responsibilities and scope of Personal and Professional Consultees.

4.0: Duties:

4.1 All staff involved in research: Everyone involved with the valid informed consent process must be aware of their duties in ensuring that practice is in line with legal, professional and good practice requirements. Any member of the Research Team that will be engaged in obtaining ‘Informed consent’ should ensure that they have the appropriate and up to date training to enable them to carry out this duty competently and confidently. They must also be:
• Familiar with the study
• Able to communicate effectively to the participant, taking into consideration participants’ individual needs and circumstances.
• Knowledgeable of optional/alternative clinical treatments
• Aware of the need for informed consent
• Having time for full discussion with the participant
• And have completed the necessary Good Clinical Practice (GCP) training within the previous 24 months.
• Assure that Informed Consent procedures adhere to specific study protocols, Trust policies and professional codes of conduct.

4.2 Sponsor: The organisation with overall responsibility for the conduct of the clinical trial.
The sponsor will arrange:

• Indemnity, financial and contractual arrangements for the whole study.
• Necessary approvals required to be in place by the start of the study.
• Study set-up and provide full trial documentation and study training to local research teams.
• Appropriate emergency reporting procedures are in place at each site.
• To provide study medication to be sent to local Pharmacy sites where required.
• Comprehensive monitoring and audit functions throughout the study by arrangement with local teams.

4.3 Chief investigator:
The lead researcher with responsibility for the conduct of the clinical trial across all research sites, including but not limited to the following areas.

• Qualifications and agreements (Good Clinical Practice (GCP) Training, delegation of trial-related duties)
• Adequate Resources to conduct the overall study – time, funding, demonstrate ability to recruit (via pilot etc)
• Medical care of trial subjects: A qualified clinician, who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical decisions
• On-going communication with research approving bodies throughout the trial (amendments, annual reports etc)
• Ensure full compliance with protocol and document deviations and submit amendments to Research approving bodies.
• Investigational Product (if applicable) - responsible for IMP accountability at site/s (can be assigned to appropriate pharmacist)
• Randomization Procedures and Unblinding – responsible for following trial’s randomization and
  blinding/unblinding procedures (if applicable)
• Informed consent – responsible for following GCP guidelines on informed consent
• Records and Reports – follow GCP guidelines on Case Report Forms and source documentation, maintenance of trial documentation, financial agreements and archiving
• Progress Reports – provide written summaries to research approving bodies (annually or more frequently if requested) and sponsor regarding substantial changes to trial
• Serious Adverse Events (SAEs)- responsible for ensuring all SAEs reported to sponsor
• Premature Termination or Suspension of Trial – Responsible for ensuring trial subjects, institution sponsor and research approving bodies are promptly informed if trial ends prematurely or is suspended
• Final Report – ensure that final report is provided to research approving bodies and sponsor

The CI will be responsible for the integrity of the study protocol and publications resulting from the study

4.4 Principal Investigator (PI);
The lead researcher with delegated responsibility for the conduct of the clinical trial aligned with the responsibilities of the chief investigator (listed above) across the local site only.

Duties will include:

- Set-up and maintenance of trial documentation,
- Participant identification and recruitment,
- Participant follow-up assessments
- Arrangement and collection of prescribed study medication from Pharmacy
- Ensuring that the study is being conducted to study protocol, trust policy and GCP standards.
- Reporting of adverse events or serious adverse events to the sponsor/CI,
- Responsible for the set-up and conduct of the study at the local site and ensure that all trial documentation and appropriate training has been received and passed onto the study team.

4.5 Local Research Team

Clinical Studies Officer/Research Nurse/Research Assistant, if delegated by the PI and supervised appropriately, support the conduct of the research study at the local site, if recorded on the study delegation log:

Duties could include:

- Set-up and maintenance of trial documentation.
- Participant identification and recruitment.
- Participant follow-up assessment.
- Arrangement and collection of prescribed study medication from Pharmacy.
- Ensuring that the study is being conducted to study protocol, trust policy and GCP standards.

4.6 Trust R&D office:

The participating NHS organisation is required to have procedures in place for conducting the trial locally. These procedures include:

- Provision of adequate training for all site staff to conduct the study confidently and competently;
- Ensuring clarity of roles and responsibilities (e.g. contracts and agreement, delegation log)
- Appropriate knowledge of the trial and quality systems in all peripheral departments (e.g. laboratories, radiology, medical records);
- Ensure systems and facilities are fit for purpose (e.g. computer systems, equipment)
- Conducting the trial in accordance with the protocol, including: informed consent; reporting of adverse events / reactions as per protocol (and urgent safety measures); unblinding procedures; and IMP accountability at the trial site; and adequate trial documentation and archiving of trial documentation.
- Compliance with GCP guidance, Clinical Trial Regulations and any other relevant frameworks as assessed through local approval procedures and audit/monitoring of the study as required.

4.7 Complaints:

Complaints about Informed Consent procedures related to research should be directed through the standard Trust complaints procedures within the Trust see Trust Policy. Complaints CS002

5.0 Guidance to Good Practice.
Gaining informed consent should be perceived as a process not a single act (ICH GCP) and should be free from any coercion (inference of intimidation or threat) and undue influence (inference of favouritism or bribery.). Appendix 1 shows a flow-chart for the procedures required for obtaining consent from research participants.

The consent process commences at a time when a potential participant is being identified. This may be either pre or post screening against the inclusion criteria outlined in the approved protocol and continues throughout the life of the study ensuring that consent is sought prior to each study activity and that “willingness to continue” is established and documented.

Systems for identifying potential participants may vary dependent on the type of research [Appendix 3 shows a flow-chart for the different procedures dependent on the type of study being undertaken]. These systems should be agreed with the research team and be in line with the study protocol, Norfolk and Suffolk NHS Foundation Trust and Department of Health policies and where applicable agreed with the relevant clinical team.

Any methods of approaching potential candidates and seeking consents should adhere to the practices outlined in the approved up to date version of the research proposal or as discussed and agreed by appropriate members of the research team including the CI and PI. Any discussions with local research team, CI or PI regarding additional procedures for seeking consent should be clearly documented and should include why the discussion happened and the outcome.

**Under no circumstances should any potential candidates be approached regarding the research study prior to the study being given both ethical and Trust approval, and other regulatory approvals as determined by the type of study being undertaken.** (Medicines for Health Act 2004 Section 3 Paragraph 12 (1) & (2)).

5.1 Consent process: Prior to initial contact

5.1.1 Documentation

It is important to ensure that approved documentation is in place this includes (but is not limited to)

- Consent forms for research
- Assent forms (Minors)
- Patient information leaflets
- Process Recording Forms for recording discussions, questions and capacity assessments etc.

5.1.2 Use of approved documentation:

Any information used in the process of receiving informed consent should be approved through the REC and R&D approval system and display the research body and hosting trusts logo. The documentation in use should only be the current version approved. Any superseded versions should have a line placed through the form, marked as superseded, signed, dated and held in the site file.

5.1.3 Information communication:

Initial communication about the study is usually performed with the aid of a participant information leaflet. This may take a variety of formats and must take into account the capabilities, age, language and capacity of the potential participants being approached.
Good Clinical Practice guidelines outline all the relevant information that should be discussed and outlined to potential participants and should be used as guidance to ensure that practice is in line with GCP standards and includes:

- Purpose of the trial
- Trial treatments and study processes i.e. the potential outcomes and different research pathways of randomisation
- Trial procedures including any screening study procedures required prior to entry into the study after consent has been granted.
- Risks and Benefits including safety reporting measures
- Alternative procedures available
- Anticipated expenses for the subject including time, travel etc and reimbursement arrangements.
- Regulatory information
- Data management/storage and confidentiality
- Contact numbers, including emergency/24-hour contact details where required.
- Reasons why a trial may be terminated and the follow-up procedures.
- Expected duration of participation in a study and the level of commitment expected from the participant.
- Accountabilities and responsibilities of the sponsor organisation.

If any recruitment materials are to be seen publicly i.e. newspaper advertisements, posters etc, these materials must also be approved by the relevant bodies. Any contact details on these materials should enable potential participants successful access to the research team.

5.1.4 Quality of information:

Every means possible must be available to ensure that the information is communicated in a way that is easily understandable to the target group and must take into consideration: Age, disability, equality and diversity issues. The language used in the oral and written information about the trial, including the written informed consent forms should be appropriate for the age and condition of the participant, and should also be understandable to the subjects’ legal representative or personal/professional consultee where applicable.

5.1.5 Ensuring understanding:

Where necessary every effort must be made to provide appropriate resources/equipment to allow full availability and understanding of information.

5.1.6 Method of Communication:

Methods of initial contact and gaining informed consent may vary depending on the study, the participant group and the services from which participants are identified. Procedures for contacting potential candidates should be clearly identified in the protocol and/or documented and approved in the Trial site file where additional local arrangements are required. Sponsor agreement should be sought for any other methods of initial contact not identified in the protocol i.e. emailing the Participant Information Leaflet upon request from the participant.

5.2 Seeking consent

5.2.1 Initial contact:

To comply with the Data Protection Act, initial identification of potential research participants can only occur by the clinical care team using routine clinical pathways. It is expected that the clinical care team will liaise with the local research team as required to identify suitable research participants.
Initial discussion of research with the potential participant may also occur by the treating clinical care team after discussion with the local research team. Under these circumstances, the clinical team will need to record that the potential participant is happy for their personal contact details to be passed to the research team. To facilitate this, a “Consent to Contact” form, provided by the study sponsor, should be completed by the clinical team and participant and given to the research team. In the absence of a “Consent to Contact” form, the discussion should be recorded in the clinical notes of the participant.

If Participants are to be self-referring to the research team through public advertisement, the research team must ensure that there are resources in place to accommodate the enquiries or telephone screening procedures.

Other methods of initial participant identification may not comply with Data protection regulations and require discussion and agreement with the sponsor of the study. This should be evidenced and placed in the site file.

Consideration should be made as to the timing of initial contact taking into account the circumstances that potential participants may find themselves in ie. Patients or carers having just received distressing news following a clinic.

Potential participants should not be coerced or unduly influenced to participate or consent into a research study.

5.5.8 Pre-Consent Contact and Activities

No screening or research assessment activities should be undertaken prior to Valid Informed Consent being obtained.

Such contact should aim to reduce the distress and burden on the potential participant and any carers and may include:

- Courtesy phone calls the day prior to the screening appointment to clarify the requirements, and seek verbal consent to attend the pre screening appointment.
- Provision of early and timely appointments in a location which is mutually agreeable and approved.
- Offer to answer any initial questions about the study.

It is allowable that some eligibility screening questions can be done verbally over the telephone if stated explicitly in the protocol and approved by the sponsor.

Attendance may be regarded as implied consent to that specific appointment but does not provide consent onto the study. Formal written consent should therefore be obtained at the earliest possible time during the screening visit.

5.2.2 Timelines for Informed Consent:

Each participant should be given adequate time to read, digest, discuss and think the decision over. Adequate time can be regarded to be as much time that individual needs to make that decision without pressure or fear of reprisal. Support and time to ask questions must be offered until the individual is comfortable that they have explored all aspects of the study.

The study team should be aware that time to consider participation in a research study will be variable according to individual participant and Protocol requirements and that a minimum period for decision-making may be stipulated in the Protocol.

It is recognised as good practice to offer a minimum of 24-48 hours reflection time for participants to decide whether to take part in the research study, this time should be proportionate to the risks and
complexity of the study and the needs of the participants i.e. being able to participants as long as they need to make an informed decision.

5.6 Emergency provisions for Gaining Informed Consent:
The Mental Capacity Act identifies that “In some circumstances, it may not be possible to separate the research from the urgent treatment”

In circumstances such as life threatening events, where a person is unconscious due to an acute illness, accident or operation and where consent cannot be sought by that person, consent should be sought as soon as possible from

- A legal representative such as a medical practitioner who is not directly involved within the research
- The person, themselves, once they have regained the capacity to give valid informed consent in that situation to that request.

The protocol should clearly outline procedures to be followed in relation to managing urgent situations and special considerations regarding consent and should have the appropriate approval.

5.2.3 Informed Consent Visit:

Only those investigators named on the Delegation of Responsibility Log and authorised by the Principal Investigator are allowed to obtain informed consent from study participants.

In Clinical Trials of Investigational Medicinal Products (CTIMPs), only an authorised health care professional (MHA 2004 Part 1 Paragraph 2(1)) should conduct the informed consent procedure unless delegation to a local research team member has been agreed by the sponsor. Any additional training undertaken for this role should be recorded in the Trial Master File, the local site file and the individual’s Training Log.

The Informed Consent visit should include adequate time for questions, reassurance and offer of further time if the individual is still unsure. If the participant is confident in their wish to participate, then an approved consent form should be completed.

5.5 Special Considerations

5.5.1 Vulnerable participants:

“Every recipient of health care is in some way vulnerable, but those with more limited ability to act autonomously can also be more vulnerable to the impact of research activity” (RCN, 2009)

Each potential participant must be regarded in terms of their own situation and circumstances which may not always be obvious at first. The eligibility criteria may outline the desired cohort of suitable candidates that will support the research study but will not be able to cater for individual circumstances such as geographical location, familial, employment responsibilities and economic circumstances etc. Such consideration needs to be taken into account when regarding vulnerability and ensuring correct protective measures are in place when seeking consent.

Some other considerations include:

5.5.2 Sensory deficit: including visual and auditory impairment.

Materials that enhance ability to fully understand all necessary aspects of research should be made available.
5.5.3 **Older Age:**
Ability to process information may slow down with age therefore adequate time and explanation should be offered.

5.5.4 **Culture and language:**
Any persons seeking consent from individuals with cultural diversity need to ensure that they are well informed as to the needs and expectations of this cultural group.

If required interpreters should be made available where necessary and if practical.

Persons of differing cultural backgrounds should not be excluded from the research project if they satisfy the inclusion criteria or otherwise specified within the Protocol as to their exclusion.

5.5.5 **Adults lacking Capacity:**

“A person must be assumed to have capacity unless it is established that he lacks capacity” Principle 1
MCA Code of Practice 2005

If there is any doubt about the mental capacity of a potential participant to provide informed consent onto a research study, the individual should not be recruited. Participants lacking capacity may be entered into a research study if:

- The research relates to the condition causing the incapacity, or to a condition resulting from or attributed to the incapacity.
- The research cannot be done as effectively using people who have mental capacity;
- The research must produce results relevant to the condition (or a similar condition) affecting the person and have small risks or low adverse impact on the person, or it must have potential benefits to the person without disproportionate risk

The researcher must stop the research if at any time they think that one of the above criteria is not met at any time during the research, unless withdrawal of any treatment as part of the research would impose a significant health risk

In these situations dependent on whether the study is a CTIMP or Non-CTIMP either the Medicines for Human use (2004) (CTIMP) or the Mental Capacity Act (2005) provide the legal framework to consent onto a study.

These acts should be adhered to, to ensure that the individual’s rights are upheld and that any decision made is done so in their best interest. The individual has a right to be assessed as to ability to consent onto the study at that particular time by an appropriate person who is able to assess capacity.

If the participant loses capacity during the course of the study, the protocol should state clearly whether the participant and/or their data should be withdrawn and this should be stated explicitly in the Participant Information Leaflet and Consent Forms. Any clarification required about individual participants’ continued consent and involvement in a specific research study should be referred to the sponsor organisation.

Appendix 3 shows a flow-chart detailing the different situations and pathways to be adhered to when seeking the appropriate party to advise about presumed will or giving consent on behalf of the participant.

5.5.6 **Children and young people. (Minors)**

“Research involving children and young people can benefit all children, but they may be vulnerable because they cannot always recognise their best interests, express their needs or defend their rights.”
The Mental Capacity Act does not usually apply to children younger than 16 who do not have capacity. Generally, people with parental responsibility for such children can make decisions on their behalf under common law. For 16 or 17-year-olds who lacks capacity to consent, the person providing care or treatment must follow the Act’s principles and act in a way that they reasonably believe to be in the young person’s best interests. Parents, others with parental responsibility, or anyone else involved in the care of the young person should be consulted unless the young person does not want this or this would otherwise breach their right to confidentiality. Any known views of the young person should also be taken into account.

If a Minor is participating onto a study and during that time attains the age of 16, then the consent process needs to be repeated in order for that minor to continue in the study.

5.5.7 People who are detained under the Mental Health Act

Although people who are detained under the Mental Health Act do not necessarily lack capacity to consent, time and appropriate information should be made available to these participants and thought may need to be given as to the presentation, manner and timing of the sharing of this information dependent on the individuals presentation at the time of seeking consent. Liaising with the care team is vital, as is the need for time and ensuring that consent, if given, has been done so with confidence.

5.6.8 Health Care Staff as Research Participants

Awareness of time and workload pressures that may impact on willingness to contribute to research is important. Adequate information and time should be available to enable them to make a fully informed decision regarding consent. It is also important not to assume that individual staff members will understand the benefits of participating or that they share the same level of knowledge as colleagues therefore adequate time and support is important.

5.3 Willingness to continue

Ongoing consent or “willingness to continue” should be checked/obtained prior to any trial related procedure or appointment taking place. This may be verbal consent but recorded in the appropriate manner. This may be particularly relevant when capacity for continued consent may be a consideration.

If information about study intervention or treatment has changed since the initial consent into the study i.e. changes to safety of medicinal products, this information should be communicated to the participant and, where appropriate, re-consent procedures undertaken.

5.4 Right to withdraw:

Research participants should be clearly informed of their right to withdraw from a study at any time prior to initial consent onto the study and that this is supported in the approved documentation such as the participant information leaflet and the participant consent form.

Participants should be free to withdraw without having to give any reason and with the confidence that the decision will have no negative impact on their standard clinical care or future access to services and research studies.

If stated in the protocol, participant information leaflet and consent form, participants may be invited to attend any follow up or termination research appointments. Consent for this should be sought at the point of withdrawal and supported by an appropriate and approved withdrawal consent form.
In a situation where participants leave a study early a request may be made to continue using the data already. This should be clearly documented and explained at the time of initial consent into the study and highlighted on the consent form.

5.7: Recording and documentation

5.7.1 Recording Consent:

Consent should be recorded on the authorised ICF documentation with the signature of the participant, guardian (where appropriate), and staff member seeking consent. All Consent forms should be dated (on each page where the ICF is more than 1 page in length) and each individual statement signed using initials. The ICF should also be dated by the participant and staff member who witnessed/took the informed consent, and full names written in block capitals.

Telephone and verbal consents are not permitted unless written consent has been deemed not practical, has been explicitly documented within the protocol, the process has been clearly justified and has been given specific approval by REC and R&D committees and regulatory authorities where appropriate. All communication and consent processes should be fully documented and signed by the research team, and placed in the site file. Any deviation from the protocol in terms of the approved informed consent procedure will be regarded as a violation and may result in the suspension of the study.

Fully signed copies of the consent form(s) should be given to each participant. Additional copies of the consent form and Participant Information Sheet are to be placed in the site file and at the front of Trust medical notes. Good practice also recommends that details about the study start and end-date and contact details (either local team, lead institution or sponsor details) are additionally included at the front of medical notes in case of emergency.

ICFs, which contain identifiable information, must not be kept in the same physical location as anonymised Study Case Report Forms.

In the case of a withdrawal from a study or a pre-entry screen failure, a participant’s ICF should not be discarded but retained in study and clinical files.

5.8: Deviations and Violations

5.8.1 Protocol deviations:

Any deviation from the protocol, which is beyond the control of the research team, should be recorded in a file note and the sponsor informed.

5.8.2 Protocol Violations:

It is the responsibility of all Trust employees to report incidents of wilful protocol violations in the Informed Consent Process, in accordance with the Research Integrity, Fraud and Misconduct Policy. Any staff member found or reported to be violating the study protocol in a way which may cause harm or increase risk to participants may be subject to an investigation by the Research Integrity Officer.

5.9: Amendments:

When approval for Amendments to the consent form and/or Participant Information Sheet has been obtained from approving bodies, participants who are actively participating in the study should be re-consented by the research team to the new version and dated documents at the nearest feasible opportunity (i.e. the next follow-up research assessment).
Appendix 1: Flow chart of process of gaining informed consent

TRUST APPROVAL
Once trust approval has been gained, the team begin to identify potential candidates and seek informed consent.

WORKING TOGETHER
Research teams, R&D depts and clinical teams will work together to identify the best routes of identifying suitable candidates; how to make initial contact in a way that supports the service users/clinicians rights.

INITIAL CONTACT & INTRODUCTION TO THE STUDY
Initial contact is to introduce yourself and the idea of the research study, to offer a time to meet to discuss further and begin informing the individual of the requirements of the study.

INFORMATION IS MADE AVAILABLE
Through appropriate communication all information relating to the project that will enable the potential participant to make a fully informed decision as to whether participating in the research project is in their best interest.

ACCESS TO SUPPORT AND TIME
Potential candidates should be offered as much time as is needed to make their decision without concern as to their current treatment or working conditions. Adequate time and support to answer outstanding questions should be made available if required.

CONSENT OR NOT?!
Any persons withholding consent should be supported in this decision so that their rights to dignity and respect are upheld. When a person has consented, approved forms should be used, signatures of all relevant individuals gained and copies placed in appropriate files and given to consented candidate.

INFORMATION REGARDING CONSENT IS PASSED ONTO RESEARCH TEAM READY FOR COMMENCEMENT OF PROJECT
## Appendix 2: Frameworks Covering Consent And Incapacity

<table>
<thead>
<tr>
<th>Research involving drugs or new medical devices. (CTIMP)</th>
<th>Research involving non drug related interventions. (NON-CTIMP)</th>
<th>Mental Capacity Act (2005)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines for Human Use (Clinical Trials) regulations (2004)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Any research needs to be specific to the impairing condition that has contributed/caused the state of incapacity.</td>
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</tr>
<tr>
<td>2. Research can only be carried out effectively within people who lack capacity.</td>
<td>2. Research can be carried out effectively involving people who lack capacity.</td>
<td>2. Research can be carried out effectively involving people who lack capacity.</td>
</tr>
<tr>
<td>3. The potential benefits to the person who lack capacity are not disproportionate to the burden or distress endured.</td>
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<td>3. The potential benefits to the person who lack capacity are not disproportionate to the burden or distress endured.</td>
</tr>
</tbody>
</table>

### 1. Personal Legal Representative

A person who is willing and able to act as a Personal Legal Representative and who has a personal relationship with the individual

### 2. Professional Legal Representative

A person who holds professional status such as a doctor involved in patients care or a person nominated by the NHS Trust and has no involvement or financial interest in the trial.

### Other points:

1. Provides consent onto study
2. Legally represent the presumed will of the person.
3. Consent remains legally valid if/when person regains capacity until they are able to express own opinion as to offer own consent or wish to withdraw from the study.
4. Data may be retained for audit purposes but not be used for research purposes if person once regained capacity expresses wish to withdraw consent.

### 1. Personal Consultee:

A person who provides unpaid care, a family member or a nominated person who holds a lasting power of attorney or a court appointed deputy.

### 2. Professional Consultee:

A person who may hold professional (Doctor), or advocate status and is independent of the research.

### Other points:

1. Consultation offers opinion. Consent is not provided.
2. Should reflect the presumed will of the potential participant.
3. Capacity should be reviewed at each point of research intervention.
4. No legal status.
Appendix 3: Flow-chart showing the differences between CTIMPs and non-CTIMPs for obtaining consent