Standard Operating Procedure RD SOP08:
Obtaining 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 R&D Department website 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Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use.

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This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.1	3/01/2014	Minor changes following Research Forum Review
2.0	11/12/2018	Changed NRES to HRA Section 4. SOP and documents updated with current policies. Pg. 7 Changed RIO to SystmOne Changed BDCT to BDCFT Generally updated expired website links

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1. Introduction, Background and Purpose

A critical step in the research process is the researcher seeking the consent of participants to take part or to refuse. The process of obtaining voluntary and informed consent involves two complementary and reciprocal decisions:

1. The **participant makes a decision** about whether to take part or to refuse to be involved in a research project.
2. The **researcher judges the quality of that decision.** If the quality of that decision meets certain ethical standards, the person is considered to have consented to participate or to have refused.
   (BPS, 2008, pg 11)

In order to make this decision, it is necessary for researchers to provide their potential participants with **appropriate information**, and then to engage in a **process** of assessment of the participant's responses to determine the willingness of that person to become involved in that particular research project.

This process is referred to as the Informed Consent and is **specific to the project being discussed with that participant, and at the time of that discussion**. As such this 'process' may require:

- **Confirmation** of a participant's decision throughout the life of the project in question
- **Adaptation** for participants with specific needs eg. children, adults without mental capacity

Informed consent is defined in ICH as:
A 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 subject's decision to participate. Informed consent is documented by means of a written signed and dated informed consent form.
(ICH Guideline for Good Clinical Practice, E6, 1.28)

This SOP describes the procedure for receiving written informed consent from a participant in a research study, with particular reference to the difference in procedure between:

- Clinical Trials of an Investigational Medicinal Product (CTIMP) study[1]
- Other research studies.

Because of their nature, CTIMPs have a specific set of regulation that influences the consent process. Where this differs from other research studies it will be highlighted.

The intention of the procedure is to ensure that practice is of the highest standard and will comply will all regulations and Good Clinical Practice guidance for research.

Note: Clinical trial regulation refers to those recruited into those trials as 'subjects'. Other studies may use the term 'participants'. As such these terms are used interchangeably within this document.

This document is for guidance purpose only and should be read in conjunction with the Trust Patient Information and Consent Policy. This notes Trust policy for consent procedures, including those for children and adults that lack capacity, and more generally for provision for consent for patients whose first language is not English.

However, research should be seen as a **special and separate** activity to routine clinical care. As such the contents of **this procedure MUST be operationalised** when considering enrolling a participant into a research study **in addition to** any other guidance for consent for clinical purposes.

[1] See GCP Guidance for definitions of a CTIMP

2. Who Should Use This SOP

This SOP applies to all investigators, Clinical Studies Officers/Research Nurses, and other research team members involved in research studies.

3. When this SOP Should be Used

This SOP is applicable for all research projects, including clinical trials that do not have their own procedures for consent, although this document may supplement and add to those procedures. The SOP relates to participants able to give informed consent for participation in a research project and also sets out the consent procedures for more vulnerable participants (minors and Adults Lacking Capacity).

Individuals should refer to the HRA website https://www.hra.nhs.uk/ for further information on consent form layout and requirements for patient information sheets and consent forms if they are involved in their design.

Further information and detail for specific circumstances can be found in the related documents listed in Section 5 below, and from project specific consent SOPs where appropriate.

4. Procedure(s)

The Declaration of Helsinki clearly states that the person seeking informed consent should be a qualified physician: '*The **physician** should then obtain the subject's freely given informed consent, preferably in writing'* (1996 version).

However ICH GCP guidelines state that '*The **investigator, or, a person designated by the Investigator** should fully inform the subject*' (ICH GCP 4.8.5) and the written informed consent form should be signed and dated by the '***person who conducted the informed consent discussion***'.

Although ICH GCP has no legal status it is referred to in the UK Clinical Trial Regulations and must be taken into account by anyone conducting clinical trials with medicinal products.

The delegation of Informed Consent to an appropriate, suitably qualified member of the research team should therefore be considered reasonable for non-CTIMPS and on a trial-by-trial basis for CTIMP[2]s, taking account of local circumstances and in accordance with ICH Good Clinical Practice Guidelines.

NOTE: If you are required to obtain written informed consent for a CTIMP study and are <u>not</u> medically qualified then it is your responsibility to:

- **Ensure that the Ethics Committee, study Sponsor and the NHS Organisation hosting the study have approved you to take informed consent for the study.**
- **Ensure you have been entered on the study delegation log appropriately, and approved by the local study lead/Principal Investigator**
- **If you are a nurse and/or a member of a professional organisation ensure that the organisation is aware, and if necessary has advised you.**
- **Adhere to your professional codes of conduct.**
- **Be fully informed and familiar with the verbal and written information you are giving to the potential study participant.**
- **Seek advice from the R&D Department if unsure**

[2] CTIMP – Clinical Trial of Investigational Medicinal Products; including drug trials

The General Medical Council (GMC) recommends that when doctors delegate the task of informed consent it is **their responsibility** to ensure that the person delegated is:

- suitably trained and qualified
- has sufficient knowledge of the proposed investigation or treatment, and understands the risks.
- acts in accordance with guidance as set out in GMC "Seeking Patients Consent ; the ethical considerations"

4.1 How to delegate responsibility for taking informed consent

If you are the Chief Investigator (CI) or Principal Investigator (PI) for a research study you *may* delegate responsibility for the informed consent process and/or responsibility for being the sole signatory on the Informed Consent Form (refer to GCP Guidance). It is the responsibility of the CI/PI to ensure that the following criteria are met:

- The designee is **prepared** to take on this additional responsibility AND feels **confident** to take informed consent in line with the NMC Code of Professional Conduct or other professional organisational guidelines.
- S/He has a **comprehensive understanding of the study,** potential pharmacological interactions/treatment toxicities and the associated disease area (as appropriate).
- The designee should be fully aware of the **risks and potential benefits** of taking part in the research project/clinical trial.
- S/He should be **qualified** by experience and/or should have received appropriate training for this study. All training must be documented.
- The delegation of **responsibility should be documented** on the Study Delegation and Signature Log
- The **process has been approved** by the relevant Research Ethics Committee (REC), 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 participants 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 Study Delegation and Signature Log. Valid GCP certificates should also be included where appropriate.

CTIMPs – staff **must** present evidence of current, valid GCP certification (where 'current' is less than 2 years from date of that certification)

4.2 Information provided to the research study participant

According to Schedule 1 of the Clinical Trials Regulations, a person gives informed consent to take part in a clinical trial only if his/her decision:

(i) is freely given after that person is informed of the nature, significance, implications and risks of the trial; and either

(ii) (a) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his/her consent, or
(b) if the person is unable to sign or to mark a document so as to indicate

consent, is given orally in the presence of at least one witness and recorded in writing.

Patient information should be provided to potential study participants in both an oral and written form, and in a **format best suited to their needs/level of understanding**.

This forms good practice and should be applied, in principle, to all research studies undertaken in Bradford District Care NHS Foundation Trust (BDCFT)

ICH GCP (4.8.10) describes what you should explain to the research participant during the discussion prior to them consenting to participate in a trial and in the patient information sheet (or any other written information relating to the trial).

[NOTE: ICH GCP refers specifically to clinical trials, but its principles should be applied to all research projects]

You should check that any oral information reflects the written information provided and includes:

1. A statement that the clinical study involves research
2. The purpose of the clinical study
3. The clinical study treatment(s) and the possibility of random assignment to each treatment (if applicable)
4. The clinical study procedures to be followed, including all invasive procedures
5. The subject's responsibilities
6. The experimental aspects of the clinical study
7. Any foreseeable risks or inconveniences for the clinical study subject
8. The reasonably expected benefits. If there is no clinical benefit intended, the subject must be made aware of this
9. Alternative treatments and procedure(s) that may be available and the potential benefits and risks
10. The compensation and/or treatment available to the subject in the case of any injury relating to the clinical study
11. Anticipated pro-rata payment, if any, to the subject for participating in the clinical study
12. The anticipated out of pocket expenses, if any, to the patient for participating in the clinical study
13. That the subject's participation in the clinical study 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
14. 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 clinical study 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
15. That record 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
16. That the subject/legal representative[3] 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 clinical study

[3] See later sections on consent from persons other than the participant/subject themselves

17. The person(s) to contact for further information regarding the clinical study (if applicable/possible record a 24hour phone number where the subject can receive advice out of office if required)
18. The foreseeable circumstances under which the subject's participation in the clinical study may be terminated
19. The expected duration of the subject's participation in the clinical study
20. The approximate number of patients involved in the clinical study

Written information must be presented in an **appropriate format** (**approved by the Research Ethics Committee (REC)**) for the participant group being approached to take part.

4.3 The receiving of informed consent

Participants who potentially fulfil the inclusion criteria for a study **must be initially identified by appropriately 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-qualified individuals within the study team. If eligibility has been assessed and documented by appropriately qualified personnel then the process of taking informed consent may be delegated and documented as described in section 4.1.

NOTE: For CTIMP studies, participant identification and checking against inclusion/exclusion criteria for the trial MUST be undertaken by a medically qualified person.

Respect and dignity of the participant should be taken into consideration prior to the consent process being performed and a private area sought if required. 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 participant's capacity **at that time point**.

The person taking Informed Consent must have to hand copies of the Participant Information Sheet and Informed Consent Form for the study approved by the REC/MHRA (as applicable), together with any documents the participant may need to use e.g. diaries.

A verbal explanation of the study must be given to the participant (and friends and family if appropriate), and if necessary diagrams may be used to explain the study. Time for questions throughout the discussion must be given and questions adequately addressed.

The person taking informed consent should then provide the participant with a written information sheet (which should be on appropriately headed paper) about the study. Participants should be **given adequate time, related to the nature of the study, and outlined in the study protocol**, 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.

Once the participant has had time to read the information sheet and has had any questions regarding their participation answered satisfactorily, then the person receiving 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 study 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/Investigator Site File and a second copy placed in the participant's medical records. This may involve scanning and uploading documents onto SystmOne.

No participants should undergo any study related procedure (including screening) until written informed consent has been provided UNLESS the matter has been detailed in the protocol 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 participants must be provided with contact details where they may obtain further information about the study. This will either be the CI/PI's number or a contact number of a member of the study team.

4.4 Ongoing consent procedures throughout the study

The informed consent process does not cease once the consent form has been signed, the practice of giving information about the study to participants should be an **ongoing process** performed by all members of the research and/or multidisciplinary team (as appropriate).

It is expected that confirmation of consent will be undertaken at **every patient visit/contact**, and details of this place in the patient's medical notes and research record as appropriate.

This is particularly significant with the introduction of protocol amendments and the availability of important new information that may be relevant to the participant's willingness to continue participation in the study. In these circumstances it may require the study participant to re-consent on an amended consent form in order to continue involvement in the study.

4.5 Consent in vulnerable groups

People can only give consent if they are **capable of choosing between alternative courses of action at the time that the decision must be made**. This means they must be able to understand the information given by researchers.

Including participants with impaired capacity to decide is more acceptable where research is necessary to promote the health of that particular group, and cannot be performed on legally competent people instead.

CTIMPS:

The *Medicines for Human Use (Clinical Trials) Amendment Regulations 2006/1928* encompass situations where it is not possible to obtain informed consent for participants to be involved in Medicinal Clinical Trials. The Regulation describes provisions relating to giving informed consent on behalf of minors and adults who are unable to consent for themselves (referred to as "incapable adults"[4]), including the role and responsibilities of legal representatives.

Under the UK Medicines for Human Use (Clinical Trials) Regulations 2004, the definition of a legal representative depends on whether the subject is a minor or an adult with incapacity. The definition also varies where the subject is an adult with incapacity in Scotland.

[4] Referred to also as Adults Lacking Capacity

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.

NOTE: the opinion of the legal representative is taken as the **presumed will** of the participant, and as such holds the same status as if the consent were given by the **participant themselves**. However, it would be expected that the participant's participation **would not** be enforced against their will, and that objections would be respected.

Other types of studies (non-CTIMPs):

The legal status of consent for other studies is not prescribed for non-CTIMPs, and these sorts of studies have differing roles for patents/carers/others as outlined specifically below.

NOTE: Whilst the following gives general principles for the consent process for vulnerable groups, and specific processes must be approved by the Research Ethics Committee, along with all documentation used for the consent process/es.

4.6 Consent of Minors

Children and their parents or guardians should be involved in the research consent process in proportion to the child or young person's competence to weigh the risks and benefits, and they may need extra time to do so; the child must also indicate that they do not object to the research activity.

Children can give consent to participate in research themselves provided they have the capacity to do so, although for **CTIMPs this is not the legally binding process;** this must come from someone with **parental responsibility** for the child, or the child's **legal representative** (see below).

To give consent, this means the child is able to understand the nature and consequences of their participation in the research.

It is necessary to assess the individual child's capacity, depending on their maturity and understanding.

Gaining a child's views and desires can require the use of creative ways of providing information and alternative means for them to express their thoughts.

Please refer to the BDCFT Patient Information and Consent Policy for information on the determination of capacity and recording in clinical notes.

4.6.1 CTIMPS

Under the Regulations a 'minor' is a person under the age of 16 years. (SI 2004/1061). There is **no provision** for *'Gillick Competence'* within CTIMPs.

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[5]. 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.

Parent: A parent or person with parental responsibility[6][7]

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 is both available and willing to do so.

Professional legal representative: A person nominated by the relevant healthcare provider (eg an 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:

- 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 participant, 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 participant must be withdrawn from the trial.

NOTE: If a child is enrolled in a study that goes beyond their 16th birthday, then they should be consented at that point of their birthday, according to their now (for research purposes) adult status.

[5] See Appendix 1

[6] Mothers automatically have parental responsibility for their children. Fathers do not automatically have parental responsibility. Those taking consent must establish whether fathers have 'Joint Parental Responsibility'. This is achieved by:

- Being married to the mother at the time of the child's birth
- Formal agreement with the mother
- Subsequent marriage to mother
- Order of court
- The holding of a residence order in relation to the child.

Once achieved, a father's parental responsibility remains following divorce from the mother.

[7] Mothers under 16 DO HAVE parental responsibility for their children.

4.6.2 Conditions and principles which apply to the inclusion of a minor in a CTIMP

The following conditions and principles are listed in Part 4 of Schedule 1 of the Regulations.

Conditions

1. The **parent or legal representative** has had an **interview** with the investigator, or another member of the investigating team, in which opportunity has been given to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
2. The parent or legal representative has been provided with a contact point where further information about the trial may be obtained.
3. The parent or legal representative has been informed of the **right to withdraw** the minor from the trial at any time.
4. The parent or legal representative has given informed consent to the minor taking part in the trial.
5. The parent or legal representative may, without the minor being subject to any resulting detriment, withdraw the minor from the trial at any time by revoking the informed consent. *[Note: Paragraphs 1-5 do not apply where treatment is being, or is about to be provided for a minor as a matter of urgency and, having regard to the nature of the clinical trial and of the particular circumstances of the case:*
   (a) It is also necessary to take action for the purposes of the trial as a matter of urgency, but
   (b) It is not reasonably practicable to meet the conditions set out in paragraph 1-5, and
   (c) The action taken is carried out in accordance with a procedure approved by the ethics committee.]
6. The **minor** has received information, according to his or her capacity of understanding, about the trial and its risks and benefits. **The information must be given by staff with experience with minors.**
7. The investigator must consider the explicit wish of a minor **capable of forming an opinion** and assessing the information provided. This applies both to the wish of a minor to refuse to take part, or to withdraw from the trial at any time. For **capable minors** it is expected that their **assent** will be taken and recorded in patient notes and research records accordingly.
8. 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.
9. 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.
10. Some direct benefit for the group of patients involved in the trial is to be obtained from the trial.
11. 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.
12. The corresponding scientific guidelines of the European Medicines Agency (EMEA) are followed.

Principles

13. Informed consent by a parent or legal representative shall represent the minor's presumed will.
14. The trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development.
15. The risk threshold and the degree of distress have to be specially defined and constantly monitored.
16. The interests of the patient always prevail over those of science and society.

4.6.3 Non-CTIMP Studies

The guidance for non-CTIMP studies is not as clear as for CTIMPs. However:

- Declaration of Helsinki - requires permission from the responsible relative to consent on behalf of a minor.
- Medical Research Council – If a child is able to give assent to a decision about participating in research, the investigator must obtain it.

The process for CTIMPs is rigorous and accepted as good practice. The process for non-CTIMP studies should therefore resemble, **as closely as possible,** the CTIMP process above.

4.7 Consent in Adults Who Lack Capacity

Mental 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. Where a person does not have capacity to make decisions, the law provides safeguards and protection, including giving limited powers to third parties to take decisions on their behalf.

The **Mental Capacity Act (MCA) 2005** provides a statutory framework to empower and protect vulnerable people who may not be able to make their own decisions. It sets out who can make decisions in which situations and how they go about it. It can be seen to work in tandem with the Clinical trials Regulations. It is required that staff work in line with the MCA code of practice[8].

Legally, adults must be **assumed to be capable of taking decisions** unless the opposite has been demonstrated for a **particular decision** and at that **given time**.

Key indicators in judging whether a person lacks capacity are:

- the presence of an impairment or disturbance (disability, condition) that affects the way the person is able to think;
- whether the impairment is permanent, temporary or fluctuating;
- the nature of the decision – the person may be able to make decisions about some things but not others; and
- the timing of the decision – the person may be able to make a decision on the matter in question if the decision is delayed for another time.
  (BPS, 2008, pg 14)

Where doubt exists, the CI/PI or another experienced and independent clinician should **formally assess the capacity of the individual** to make an informed decision about participation in a research project. This assessment and the conclusions should be recorded in the medical records. A patient is deemed to lack legal capacity to consent or refuse only when they cannot be helped to reach their own decision with memory aids or sign language for example.

In order to have capacity, a potential participant should be able to:

- Understand information presented to them
- Retain information
- 'weigh up' and evaluate the information
- Communicate their decision (this may not necessarily be via speech or writing).

[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf

If researchers involved in the consent process, or others involved in the person's care believe the person may not have capacity, then a capacity assessment should be undertaken by a person qualified to make such an assessment

See the BDCFT Patient Information and Consent Policy for further detail of undertaking these assessments and recording in clinical notes.

The term used in the Clinical Trial Regulations is *"an adult unable by virtue of physical or mental incapacity to give informed consent"*.

A hierarchy prescribed in the Regulations for determining what type of legal representative should be approached to give informed consent on behalf of an Adult Lacking Capacity prior to inclusion of the participant in the trial[9]. The provisions in England, Wales and Northern Ireland differ from those in Scotland.

The Medicines for Human Use (Clinical Trials) (Amendment No.2) Regulations 2006 made additional provision relating to trials involving Adults Lacking Capacity in emergency situations. Where the treatment to be given to an Adult Lacking Capacity 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 Adults Lacking Capacity to be entered into a trial prior to consent being obtained from a legal representative provided that:

- 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 participant, and
- The action to be taken is carried out in accordance with a procedure approved by the research ethics committee.

Where an adult lacking capacity is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent either from the participant (if capacity has been recovered) or from a legal representative **as soon as practicable** after the initial emergency has passed. Where consent is withheld, the participant must be withdrawn from the trial.

For non-CTIMP studies there is a similar process, involving consultations with others, but the nature of consultations is significantly different from CTIMP studies.

4.7.1 Conditions and principles which apply to the inclusion of an adult lacking capacity in a CTIMP

The following conditions and principles are listed in Part 5 of Schedule 1 to the Regulations and implement Article 5 of the EU Directive.

Conditions

1. The **legal representative** has had an **interview** with the investigator, or another member of the investigating team, in which opportunity has been given to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.

[9] See Appendices 2 and 3

2. The legal representative has been provided with a contact point where further information about the trial may be obtained.
3. The legal representative has been informed of the right to withdraw the participant from the trial at any time.
4. The legal representative has **given informed consent** to the participant taking part in the trial. This shall be taken as the **presumed will** of the participant.
5. The legal representative may, without the participant being subject to any resulting detriment, **withdraw** the participant from the trial at any time by revoking the informed consent.
   [Note: Paragraphs 1-5 do not apply where treatment is being, or is about to be provided for a participant who is an Adult Lacking Capacity as a matter of urgency and, having regard to the nature of the clinical trial and of the particular circumstances of the case: (a) It is also necessary to take action for the purposes of the trial as a matter of urgency, but
   (b) It is not reasonably practicable to meet the conditions set out in paragraph 1-5, and (c) The action taken is carried out in accordance with a procedure approved by the ethics committee.]
6. The **participant** has received information, **according to his or her capacity of understanding**, about the trial and its risks and benefits.
7. The investigator **must consider the explicit wish of a participant capable of forming an opinion** and assessing the information provided. This applies both to the wish of a participant to refuse to take part, or to withdraw from the trial at any time.
8. No incentives or financial inducements are given either to the participant or to the legal representative, except the provision of compensation for injury or loss.
9. There are grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit.
10. The 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 participant suffers.

Principles

12. Informed consent given by a legal representative shall represent the presumed will of an Adult Lacking Capacity.
13. The 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.

Legal Representatives (CTIMPs)

A Legal Representative (LR) gives informed consent which legally represents the subjects presumed will. Who can act as a Legal Representative?

- Someone suitable by virtue of their relationship to the Adult Lacking Capacity (personal LR)

Or if there is no such person available or willing to act

- The doctor primarily responsible for their treatment (professional LR), and not involved in the trial, or
- a person nominated by the healthcare provider (nominated LR), again independent of the trial

4.7.2 Conditions and principles which apply to the inclusion of an Adult Lacking Capacity in a non-CTIMP

The process for CTIMPs represents good practice, and should be followed as closely as possible for non-CTIMPs. However, the role of others, acting on behalf of the patient is **not legally binding**.

A researcher must take reasonable steps to identify a **personal consultee or nominated consultee** to give **advice**, not consent.

A '**personal consultee'** means a person who is:

- engaged in caring for the subject
- person with 'Lasting Power of Attorney'
- a court appointed deputy
- prepared to be consulted

A **'nominated consultee'** can be:

- an Independent Mental Capacity Advocate
- the participant's usual doctor or paid carer
- another nominated person

4.7.3 Enduring consent

In both CTIMPs and non-CTIMPs the LR and Consultee has the right to withdraw the participant from the trial at any time without affecting care.

Researchers must always respect the advice of the LR and/or Consultee.

The LR and the Consultee should be informed of all material changes to the trial or the patient's condition.

4.7.4 Regaining Capacity

In **CTIMPs**, given consent, i.e. presumed will, remains valid after the participant may have regained capacity. In practice, it is expected that researchers would confirm consent to participate with the participant, and document the outcome in clinical notes/research records as appropriate.

In **non-CTIMPs**, a Consultee may be asked to sign a 'Consultee Consent form'. They cannot consent for a patient.

In non-CTIMPS, if the participant regains capacity, they should then sign a consent form or decide to withdraw from the research **as soon as is practicable**.

4.8 Participants whose first language is not English

Bradford District Care Trust (BDCFT) is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with health care staff. This service is provided by bi-lingual link workers or interpreters who act as a conduit between the professional and service user. **It is not appropriate to use family members, especially children, to interpret for family members who do not speak English.**
(Taken from BDCFT Patient Information and Consent Policy, 2012) Check this policy for updates to this information.

4.9 Participants with Communication Problems/Comprehension Difficulties

The legal position is that adults must be presumed capable of taking decisions unless the opposite has been demonstrated. This applies just as much to people with learning disabilities as to any other adult. Where there are comprehension or communication difficulties then participants must be given **all appropriate help** to enable them to make their own decisions eg. using visual aids, sign language etc.

If a decision is taken to enrol participants with communication problems or comprehension difficulties then investigators must have a **clear plan** about how these matters will be managed and **documented in the consent process**. Any such plan should be approved by the ethics committee. For example, if the difficulties are due to visual impairment then the information sheet can be read to the potential participants and audio recorded at the same time to provide a copy for the participant to keep.

Where there are communication difficulties, a relative or an independent patient's advocate should be involved in the consent process. The latter's role is to help the prospective participant express their views. Therefore two types of information sheet may be required: one for the relative and one for the patient. The latter should be designed to overcome or minimize some of the communication problems, for example, a pictorial information sheet for the research participant. Sufficient time must be allowed for the person seeking consent to explain and discuss the proposal with the participant and the relative or advocate, and for the relative or advocate to discuss with the prospective participant.

For the consent to be valid the research participant must always be able to communicate their decision. If the **person is unable to sign or to mark the consent form** so as to indicate his/her consent, then consent may be given orally in the **presence of at least one witness**, usually a relative or patient advocate. The role of the relative or advocate in the consent process, for example, acting as a witness or explaining the trial to the participant, must be **documented in the medical records**. Consent could also be recorded to provide a complete record with a copy of the tape for the participant.

All **hospital staff** that provide information and request consent from patients with communication problems or comprehension difficulties must be **appropriately trained and experienced** with such patients.

The research ethics committee and the sponsor must agree the plan, including the delegation of responsibilities. Any such agreement should be documented in the investigator site file.

5. Related SOPs and Documents

- **BDCFT Patient Information and Consent and Consent Training Policy, (2018) (http://connect.BDCFT.local/docs/policies/pubdocs/Pt_Infrmtn_Cnsnt_Tng_Policy_v3-03_Final_PDF_10-08-2018.pdf)**
- **Code of Human Research Ethics** (British Psychological Society, 2014) **(https://www1.bps.org.uk/system/files/Public%20files/inf180_web.pdf)**
- **Conducting research with people not having the capacity to consent to their participation; A practical guide for researchers,** (British Psychological Society, 2008)
- **Declaration of Helsinki** (2013 Version)
- **Guidance on nominating a consultee for research involving adults who lack capacity to consent** (DH, 2008)
- **Informed Consent in CTIMPs** (HRA, 2008)
- **Mental Capacity Act (2005) Code of Practice** (TSO, 2007)
- **MRC Ethics Guide: Medical research Children** (MRC, 2004)
- **MRC Ethics Guide: Medical research involving adults who cannot consent** (MRC, 2007)
- **NRES Shared Single Issue Ethical Debate - Issue Paper One -Time To Consent** (National Research Ethics Service, 2010)
- **Patient Information and Consent Policy**, Bradford District Care Trust (2012)
- **Research Ethics: RCN Guidance for Nurses (Revised),** (RCN, 2011)
- **Research Governance Framework for Health and Social Care** (2nd Edition February 2017)
- **The Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument 2004/1031**, implemented on the 1st May 2004 as amended
- **The Mental Capacity Act** 2005 (HMSO)

6. Appendices

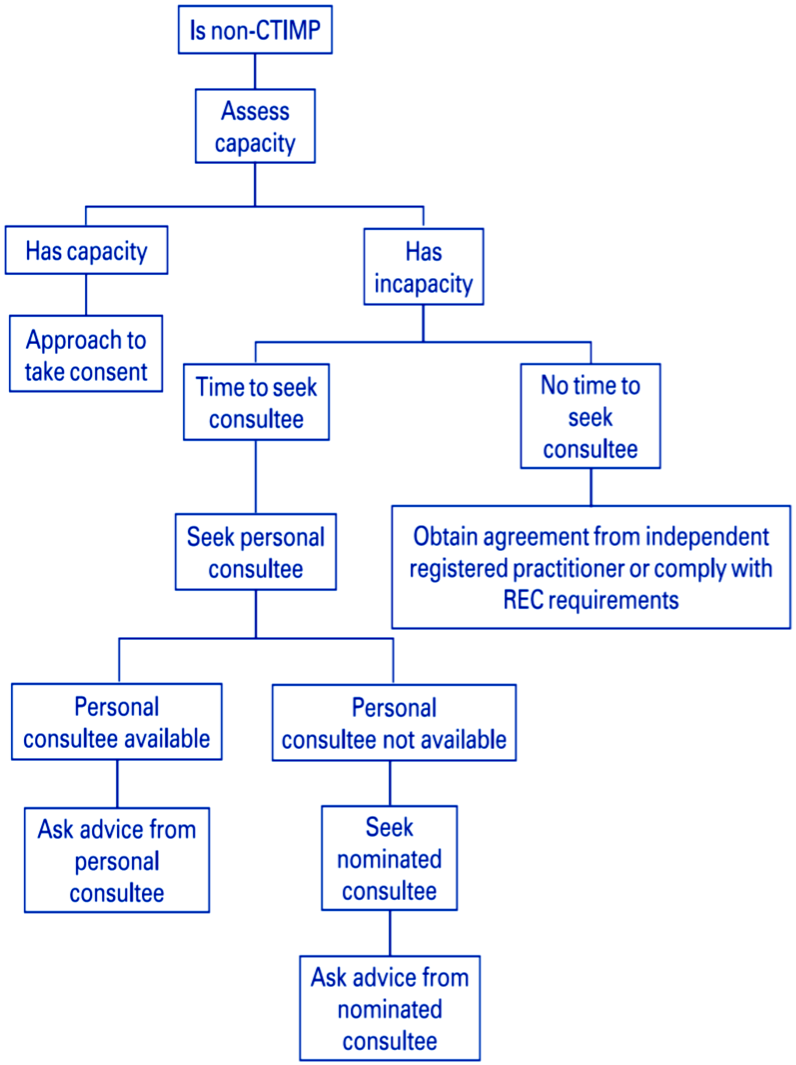
6.1 Appendix 1 - Hierarchy of informed consent for a minor

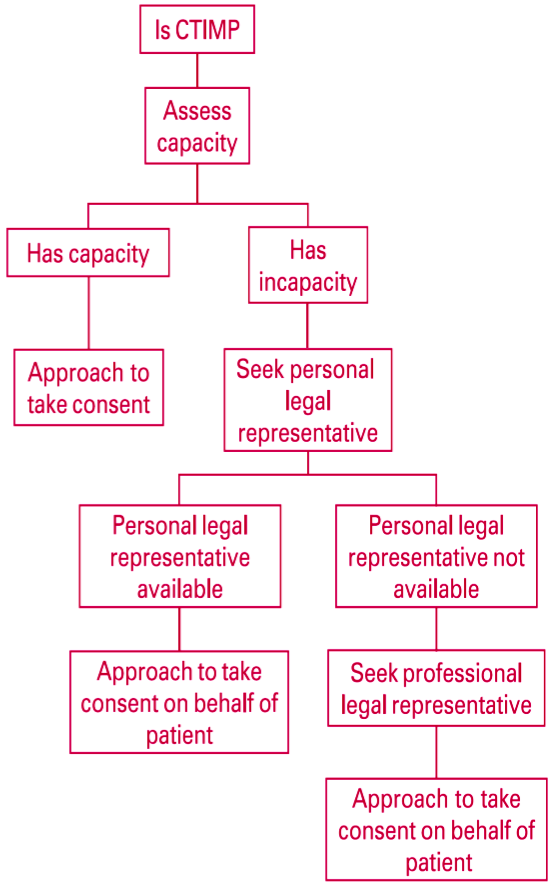
Rank Order	Person who may give consent	Definition	Commentary
1	Parent	A parent or person with parental responsibility.	Should Always be approached if possible
2	Personal legal representative	A person not connected with the conduct of the trial who is: (a) suitable to act as the legal representative by virtue of their relationship with the minor, and (b) available and willing to do so.	May be approached if no person with parental responsibility can be contacted prior to the proposed inclusion of the minor, by reason of the emergency nature of the treatment provided as part of the trial.
3	Professional legal representative	A person not connected with the conduct of the trial who is: (a) the doctor primarily responsible for the treatment of the minor, or (b) a person nominated by the relevant health care provider (eg. a NHS Trust or Health Board	May be approached if no person suitable to act as a personal legal representative is available. Informed consent must be given before the minor is entered into the trial

6.2 Appendix 2 - Hierarchy of informed consent for an Adult Lacking Capacity (England)

Rank Order	
1	**Personal legal representative**
	A person not connected with the conduct of the trial who is: (a) suitable to act as the legal representative by virtue of their relationship with the adult, and (b) available and willing to do so.
2	**Professional legal representative**
	A person not connected with the conduct of the trial who is: (a) the doctor primarily responsible for the adult's medical treatment, or (b) a person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board). A professional legal representative may be approached if no suitable personal legal representative is available.
Note: Other devolved Nations may have different regulations	

6.3 Appendix 3 - Flow chart for selection of consultees/legal-representatives for research with Adults without Capacity


Is non-CTIMP
Assess capacity
Has capacity
Approach to take consent
Has incapacity
Time to seek consultee
No time to seek consultee
Seek personal consultee
Obtain agreement from independent registered practitioner or comply with REC requirements
Personal consultee available
Personal consultee not available
Ask advice from personal consultee
Seek nominated consultee
Ask advice from nominated consultee


Is CTIMP
Assess capacity
Has capacity
Approach to take consent
Has incapacity
Seek personal legal representative
Personal legal representative available
Personal legal representative not available
Approach to take consent on behalf of patient
Seek professional legal representative
Approach to take consent on behalf of patient