

Title: Informed Consent	
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1. Scope

This Standard Operating Procedure (SOP) applies to all Bournemouth University (BU) staff and other collaborators involved in receiving informed consent.

2. Responsibilities

The *Chief Investigator (CI)/Researcher* is responsible for ensuring that the informed consent form is fit for purpose and has received a valid REC favourable opinion. They are also responsible for ensuring sites have received any amended informed consent forms so that participants are recruited using the correct version.

The *Principal Investigator (PI)* is responsible for ensuring that written information provided to participants is the REC approved documentation, and is the correct version for that time. They are also responsible for ensuring that informed consent is received prior to any research procedures and any testing or data is collected from participants.

3. Procedure

3.1 ICH Good Clinical Practice (ICH GCP) guidelines define informed consent 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, 1996)

3.2 Informed consent is implemented so as to protect the research participant's rights and wellbeing. Informed consent should be ongoing, with willingness to participate being confirmed at every study visit and recorded in the participant's record.

The Research Team

3.3 The PI should receive informed consent unless this duty has been delegated to a member of their research team. The PI should inform the Sponsor if they are delegating staff to receive informed consent.

3.4 The delegation log should explicitly identify who has been attributed the task of receiving informed consent. Staff undertaking this duty should be confident in doing so, and supported by appropriate training. The Clinical Governance Advisor (CGA) is able to deliver informed consent training to staff, locally.

Providing Information to Potential Participants

3.5 All individuals being approached to participate in research should be given as much information about the study as appropriate, and in a form that they can understand. Participant information must include a REC approved Participant Information Sheet (PIS) as a minimum.

3.6 The potential participant should be given enough time to read the PIS and any other documents. The timeframe in which to do so is often 24 hours, but this depends on the nature of the study, and also whether the study is being conducted in an acute or emergency setting.

3.7 The potential participant must be allowed the opportunity to ask questions about the research, ideally answered by the staff member who will receive their consent. If the potential participant requires additional information or time then this should be provided prior to obtaining informed consent. If appropriate you may offer them the option of speaking to another member of the research team, or advise they speak to a GP or relative.

The Informed Consent Form (ICF)

3.8 The ICF must be on headed paper, with the approved version number and date, along with the project's IRAS I.D. If the ICF is for a Clinical Trial of an Investigational Medicinal Product (CTIMP) then the EudraCT number must be stated. The ICF must also state the study title and the name of the researcher or CI.

Receiving Informed Consent

3.9 Only Investigators and staff delegated the duty of receiving informed consent may obtain it.

3.10 The potential participant must not be pressured into taking part.

3.11 The staff member receiving informed consent should assess the participant's understanding, ensuring they are aware of all the risks associated with the project, the study procedures/design, and that they may withdraw at any time without their future or current treatment being affected.

If there is doubt as to the participant's understanding, they should **not** be recruited to the study.

3.12 Informed consent must be received before any procedures, tests, or treatments are carried out as per the study protocol, and which are not considered routine standard care.

3.13 The person receiving the informed consent should instruct the participant to read each point on the form, initialling each box (*not ticking*, unless this method was NHS REC approved), then writing their own name before signing and dating their section. The person receiving the consent must then countersign and date the form, in the participant's presence.

3.14 Written consent is most often obligatory (always with CTIMPs), however in some cases, telephone, consent via post, or verbal consent is allowed. If this is the case, a SOP and the study protocol will detail the procedure, and it will be included in the application to the REC on the IRAS form.

3.15 The PI or delegate must document the date that the participant was given the PIS, along with the version and date of the document. Once informed consent has been received, the person receiving the consent must document the date of this event in the clinical notes, alongside the date and version of the ICF used. They must also document eligibility and that the participant met all of the inclusion criteria and none of the exclusions.

3.16 The ICF covers the participant's consent to participate in the study, it is not intended to be used to obtain the participant's consent to process their personal data in connection with the study. This is because consent as the basis for processing personal data can only be relied upon if the withdrawal of consent could be acted upon by removing a participant's data from the research project and outputs. Often this is not possible in the context of a research project as it would affect the validity and integrity of the research process and/or the outputs from the research. The PIS and our Research Participant Privacy Notice confirm the legal basis on which the participant's personal data is collected but generally the following conditions under the General Data Protection Regulation (GDPR) will be relied upon to collect and process participants' personal data:

- Article 6.1(e), i.e. the processing is necessary for the performance of a task carried out in the public interest;
- Article 9.2(j), i.e. the processing is necessary for research purposes or statistical purposes (this condition applies as long as we are applying appropriate protections to keep the participants data secure and safeguard their interests).

Once Consent has been received

3.17 The original consent form must be placed in the ISF and a copy given to the participant. An additional copy must be placed in the participant's clinical notes.

3.18 If any changes are made to the study protocol, PIS and/or ICF once the study is underway, the CI/Researcher must seek approval from the REC and HRA¹ (and MHRA if required), and discuss with the CGA whether any new consents are required from existing participants.

Consent in Adults Lacking Capacity (ALC)

3.19 The Mental Capacity Act (2005) (MCA) states that "A person must be assumed to have capacity unless it is established that he lacks capacity". A person's ability to make a decision at the point of which it is required, will allow the assessment of their capacity prior to obtaining their informed consent.

3.20 Participants, whether they have capacity or not, should be supported in making their own decision to participate in the research. Any information given should be appropriate to the potential participant's level of understanding. If the person is capable of reaching their own decision, and at any point states that they do not wish to participate, then the PI/researcher must respect their decision, and act upon it.

¹ Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval

Depending on the nature of the study, there are different steps to follow in order to gain the consent of an adult lacking capacity (ALC).

3.21 The presumed will of a participant should always be the basis for decision making, and a consultee or legal representative should be identified due to their ability to provide the potential participant's presumed will. This person should be able to identify what they believe the person's feelings and wishes would be with regard to taking part in the research, if they had the capacity to decide for themselves.

3.22 Non-CTIMP: Consultation Process - ALC

Seek Consultee —————> An appropriate person should be consulted with, in order to decide as to whether the potential participant should be recruited to the study. The consultee does not consent on their behalf, but their advice should be considered by the research team.

Personal or Nominated Consultee —————> A **personal** consultee is an individual that cares for the potential participant, or who is interested in their welfare (but not a paid professional), and who is prepared to be consulted. If a personal consultee is not available, then an appropriate **professional**, not connected to the research may be nominated as a consultee.

Document consultation process —————> The consultee must be given information with regard to all the aspects of the study that are relevant to their decision, and likewise given time to consider their decision. Ethically approved consultee information sheets should be provided by the Sponsor and information given clarifying their legal obligations under the MCA.

3.23 CTIMP: ALC Consent Process

Seek Legal Representative —————> The Medicines for Human Use (Clinical Trials) Regulations stipulate that an appropriate person should be found to act as a Legal Representative. This person will provide their consent on behalf of the participant and must represent the feelings and wishes of the potential participant. The legal representative should only provide their consent if they truly believe that the person would have agreed to participate in the trial, should they have had the capacity to consent for themselves.

Personal or Professional Legal Representative —————> A **personal** legal representative has a relationship with the participant which enables them to act as their legal representative, having been willing to assume the position. If a personal legal representative cannot be found then a **professional** legal representative, who is not connected to research, may be appointed instead.

Document consent process —————> The process of informed consent when a legal representative is consenting on behalf of the participant, is the same as if the participant was consenting for themselves. The legal representative, as with the participant with capacity, should be given information with regard to all the aspects of the study that are relevant to their decision, and likewise given time to consider their decision. Ethically approved

information sheets should be provided by the Sponsor.

Informed Consent in Paediatric Research

3.24 English law defines a minor as a person under the age of 18, whereas the Medicines for Human Use (Clinical Trials) Regulations, identifies a minor as a person under the age of 16 (SI 2004/1031, 2.1). Most non-CTIMPs will identify a minor as under 16, but the protocol should be checked in all cases.

3.25 In CTIMPs and non-CTIMPs in which minors cannot consent for themselves, consent to participate in the research is given on behalf of the child by an individual with parental responsibility. A mother will automatically have parental responsibility for her child from birth, but this may not be true for the father. This area should be treated with sensitivity.

3.26 When a parent or guardian is consenting on behalf of the minor, the process is the same as though they were consenting for themselves; therefore they must be given all the required information about the study in order to make an informed decision and time to consider this information. Ethically approved information sheets should be provided by the Sponsor.

3.27 As part of the decision making process, the child's wishes and views must likewise be considered. The child must be given information about the study to their level of understanding, and asked to assent to the research study. If assent is not received, despite the child being able to give it, then there must be clear and convincing reasons as to why the minor was recruited to the study, despite their wishes.

3.28 Assent is not usually requested for a child under 7 years of age. Assent and children's information sheets are grouped by age (*young children* aged 5 and under, *children* aged 6 – 10 years and *young people* aged 11 – 15 years).

3.29 Parental Responsibility

3.29.1 A mother automatically has parental responsibility for her child from birth; however parental responsibility for the father differs throughout the UK. For births registered in England and Wales, if the parents are married to each other at the time of their child's birth, they both have parental responsibility. Similarly, if they have jointly adopted a child, the same applies.

3.29.2 In the case of divorce, the parents do not lose parental responsibility, applying to both resident and non-resident parents. Under current law, a mother will always have parental responsibility for her child.

3.29.3 If the mother is under 16 and has parental responsibility for her child, then it is advisable to include the child's maternal grandparents in the decision making process. The mother may consent on behalf of her child; however, being under 16, she would not usually be able to consent for herself if invited to a study.

3.29.4 For births registered in England and Wales, the father of the child only has parental responsibility if he is married to the mother when their child is born, or if he has obtained legal responsibility for his child:

- (from 1st December 2003) by jointly registering the birth of the child, with the mother;
- or, by a parental responsibility agreement with the mother;
- or, by a parental responsibility order, made by a court;
- or, by marrying the mother of the child.

Co-habitation, even for a long period of time, does not by itself give a father parental responsibility. If the parents are not married, parental responsibility does not automatically pass to the father if the mother dies, unless he already has parental responsibility.

3.29.5 By entering into a parental responsibility agreement, or through applying to court, a parent's Civil Partner may obtain parental responsibility for their partner's child. If the relationship were to end then their parental responsibility would still stand.

3.29.6 Same-sex civil partners will both have parental responsibility if they were civil partners at the time of treatment e.g. donor insemination or fertility treatment. In the case of same-sex couples who are not civil partners, the second parent can obtain parental responsibility by:

- applying for parental responsibility if a parental agreement was made;
- becoming a civil partner of the other parent and making a parental responsibility agreement;
- jointly registering the birth of the child.

3.29.7 If a surrogate was used, parental responsibility can be obtained through a parental order made by a court provided the applicant is genetically related to the child or, in the case of joint applicants; one applicant is genetically related to the child. If there is no genetic link to the child, parental responsibility can be obtained through adoption of the child.

3.29.8 It is important that both parents in possession of parental responsibility are both supportive of the child participating in the study. If the child was enrolled without the agreement of both parents, then this could lead to problems with compliance and their progress in the research project.

3.29.9 When a child is the subject of a care order in favour of a local authority, then the local authority shares parental responsibility with the mother or both parents. Rarely, the parents may lose parental responsibility and the local authority would take responsibility of the child, placing them in the care of a legal guardian, such as their grandparents, or alternatively placing them in care. When a child is in care voluntarily, then the parents still have parental responsibility.

4. Abbreviations and definitions

ALC	Adults Lacking Capacity
CGA	Clinical Governance Advisor
CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
EudraCT	European Clinical Trials Database
HRA	Health Research Authority
ICF	Informed Consent Form

ICH GCP	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice
IRAS	Integrated Research Application System
ISF	Investigator Site File
MCA	Mental Capacity Act
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee

5. Related documentation and references

Department of Health (2005). Mental Capacity Act. London, HMSO

GOV.UK. (n.d.). Parental rights and responsibilities. [online] Available at: <https://www.gov.uk/parental-rights-responsibilities> [Accessed 19 Jun. 2018]

ICH GCP 1.28, (1996),
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

Medicines for Human Use (Clinical Trials) Regulations, Legislation.gov.uk. (2004). [online] Available at: http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf [Accessed 19 Jun. 2018]

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) GCP 1.28, (1996),
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf