Liverpool Women's NHS Foundation Trust

Consent

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The Trust is committed to a duty of candour by ensuring that all interactions with patients, relatives, carers, the general public, commissioners, governors, staff and regulators are honest, open, transparent and appropriate and conducted in a timely manner. These interactions be they verbal, written or electronic will be conducted in line with the NPSA, 'Being Open' alert, (NPSA/2009/PSA003 available at www.nrls.npsa.nhs.uk/beingopen and other relevant regulatory standards and prevailing legislation and NHS constitution)

It is essential in communications with patients that when mistakes are made and/or patients have a poor experience that this is explained in a plain language manner making a clear apology for any harm or distress caused.

The Trust will monitor compliance with the principles of both the duty of candour and being open NPSA alert through analysis of claims, complaints and serious untoward incidents recorded within the Ulysses Risk Management System.

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1 Executive Summary

1.1 Policy Scope

i. This policy applies to all staff who are responsible for taking consent or, after appropriate training, have been delegated consenting responsibilities for specific procedures.

ii. This policy also applies to all staff involved in peoples care, who have a duty to understand the principles of this policy and ensure they are applied according to 'best practice' standards and report any breaches of these standards via the incident reporting process, or the whistle blowing process.

2 Introduction

i. People have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

ii. It must be borne in mind that the consenting process encompasses advice, options of treatments and incumbent risks and benefits of the various treatment options, including no treatment, and takes into consideration the impact of the treatment on the personal circumstances of the individual.

3 Policy Objectives

i. To ensure staff are aware of their responsibility to people in respect of obtaining consent before providing advice, care or treatment.
ii. To ensure staff are aware of the process for obtaining valid consent.
iii. To ensure staff are appropriately trained to take consent
iv. To promote ways for healthcare professionals and people using services to work together to make shared decisions about treatment and care.
v. To ensure staff are aware of their legal duties under the Mental Capacity Act (MCA) and Deprivation of Liberty Safeguards (DOLs) in respect of care or treatment afforded to people who lack the mental capacity to make decisions for themselves
vi. To ensure clear guidance and reference to the law and good practice documents are available to all staff
vii. To ensure the interests of people, staff, researchers and the Trust are safeguarded
viii. To ensure compliance with external regulation, i.e. NHS Litigation Authority and Care Quality Commission Regulations and associated outcomes.

4 Duties / Responsibilities

4.1 Chief Executive

i. Has overall accountability for ensuring correct patient consent is taken and that the systems and processes to support this are in place

4.2 Medical Director

i. Has delegated Executive responsibility for development of this policy. In addition they are responsible for ensuring the policy is reviewed at least every 3 years or whenever relevant legislation, national policy or guidance changes.

4.3 Chief Nurse and Midwife

i. Has delegated responsibility for development and review of this policy at least every 3 years or whenever relevant legislation, national policy or guidance changes.

4.4 Doctors, Nursing, Midwifery and Allied Health Professionals

i. This policy applies to all clinical Trust employees, irrespective of grade, level, location or staff group, including locum and agency staff, students and those employed on honorary contracts. It is the responsibility of staff providing advice, treatment or care to people with capacity to ensure that valid consent has been obtained from the person before providing that treatment or care. In addition staff have a legal duty pursuant to the provisions of the MCA and DOLs to ensure compliance with the MCA in respect of decision making for people who lack the required mental capacity to consent to the index treatment or care. All clinical staff are also under a contractual obligation to attend relevant training in line with the Training Needs Analysis (TNA).

4.5 Safety and Effectiveness Sub-Committee

i. The Safety and Effectiveness Sub-Committee is responsible for assuring the Trust Board that the standards within this policy are followed and where exceptions are found through audit, the Committee will performance manage actions plans until all actions are completed. This assurance will be provided to the Quality Committee, a sub-committee of the Board which provides Board assurance.

5 Main Body of Policy

5.1 Guidance on Consent

i. It is the responsibility of health practitioners to have a working knowledge of any guidance on consent published by the Department of Health (DH), the General Medical Council (GMC), and their own colleges and regulatory bodies.

5.2 Documentation

i. It is essential that health professionals clearly document the discussions including the reason for treatment, any options or alternatives for treatment, the risks and benefits of treatment, the impact of the treatment on the personal circumstances of the individual, and the person's decision/agreement. This may be done either through

the use of the consent form (with further detail in the person's notes if necessary), or through documenting in the person's notes that they have given verbal consent.

5.3 Valid Consent

i. Consent is often wrongly equated with an individuals person's signature on a consent form. A signature on a form is merely evidence that the individual has given consent. It is not proof of *valid* consent. If a person is rushed into signing a form, on the basis of too little information, the consent may not be valid despite the signature. Similarly if a personhas given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. People may, if they wish, withdraw consent at any time after they have signed the consent form: the signature is evidence of the process of consent , it is not a binding contract.

ii. It is rarely a legal requirement to seek written consent, but it is good practice to do so if any of the following circumstances apply:
    a. The treatment of procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'recognised complications or 'side-effects' ')
    b. The procedure involves general/regional anaesthesia or sedation
    c. The provision of clinical care is not the primary purpose of the procedure
    d. The person has requested a specific treatment contrary to clinical recommendation
    e. There may be significant consequences for the person's employment, social or personal life
    f. The treatment is part of a clinical study or research project approved by the Trust.

iii. Completed consent forms must be kept in the person's medical records. Any changes to a consent form, made after it has been signed by the person, should be initialled and dated by both the individual and a health professional.

iv. It will not usually be necessary to document a persons consent to routine, low risk procedures/interventions, e.g blood taking or personal care. However if you have a reason to believe that the consent may be disputed later, or if the procedure is of a particular concern to the person, it would be prudent to do so.

v. The Mental Health Act 1983 (Amended 2007) and the Human Fertilisation and Embryology Act 2008 required written consent in certain circumstances.

5.4 Forms

i. There are 4 versions of the standard consent form:
    a. **Form 1** for adults or competent children whose treatment involves general and/or regional anaesthesia, local anaesthesia or sedation
    b. **Form 2** for parental agreement to investigation or treatment for a child or young person who lacks the requisite understanding required for valid consent (Fraser Competency)
    c. **Form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care
    d. **Form 4** for adults who are unable to consent to investigation or treatment.

ii. **Consent Form 3:** The use of this form is optional but may be thought more appropriate than Form 1 in situations where people do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make such decisions at the time if necessary. The treating clinician must however be satisfied that the person has retained capacity to consent and that only necessary treatment is provided. What must be avoided is performing additional procedures that may be viewed as being performed for the convenience of the clinician.
iii. It is recognised that there will be circumstances where individual departments will need to add further details to the standard consent form in order to meet specific criteria. In general terms it is acceptable to customise the forms in this way providing the existing information is not modified or removed. However, any changes and/or additions to the universally required information on consent forms will have to be reviewed and approved by the Safety Senate.
iv. All new consent forms will be subject to scrutiny and approval be the Safety Senate
v. Standard Consent forms are available in clinical areas
vi. Procedure specific consent forms are also available on the intranet
vii. The following consent forms are available:
    a. Consent for Post Mortem for Adults
    b. Consent for Post Mortem – children and babies
    c. Consent for Care of Pregnancy Remains (also part of Medical Management of Miscarriage, Surgical Management of Miscarriage and Laparoscopy for Ectopic Pregnancy consent forms)

5.5 Responsibilities of Health Care Professionals in Obtaining and Documenting Consent

i. The health professional carrying out the procedure is ultimately responsible for ensuring that the person is genuinely consenting to what is being done.
ii. Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this must be done by the health professional undertaking the procedure.
iii. The consent forms provide space for the health professional to provide information to people. It is good practice to document the information provided including the risks and benefits of all treatment options in the person's records.
iv. The health professional providing the information must be competent to do so. If this is a delegated responsibility this competence must be evidenced by their completed competency assessment to take consent for the procedure in question

5.6 Delegation of Consent

i. The task of seeking consent may be delegated to another professional. They must have sufficient knowledge of the proposed investigation or treatment, and understand the risks and benefits involved, and alternatives forms of treatment in order to be able to provide any information the person may require.
ii. Health care professionals must ensure that when they request colleagues to seek consent on their behalf they are confident that the colleague is competent to do so.
iii. S/he must have been trained in obtaining consent for the specific procedure have a designated mentor for procedure specific consent, and be subject to annual

PDR assessment and at least triennial review of consent competency with their mentor (Appendix 3).

iv. Health care professionals must be aware of the limits of their own knowledge and competence and must not perform tasks that exceed that competence (including taking consent). If all questions not answered to the person's satisfaction then consent should be referred onto more senior clinician/

5.7 Completing Consent Forms

i. The consent form provides space for a health professional to provide information to people and to sign confirming that they have done so.
ii. If the person signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a health professional involved in their care on the day of the procedure should sign the form to confirm that the person still wishes to go ahead and that they have had any further questions answered.
iii. It will be appropriate for any member of the healthcare team (for example a nurse admitting the person for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot answer themselves.
iv. The Health Professional undertaking the procedure is responsible for ensuring that consent has been taken and should confirm this with the person.
v. For elective procedures, the health care professional should provide the information at outpatient consultation or in the pre-operative assessment clinic, and follow this up with a letter to the person's GP [copied to the person],
vi. The consenting clinician must explain to the person how the procedure fits into the plan of care, the risks and benefits and what alternatives exist and discuss the impact of the treatment on the personal circumstances of the individual. The practitioner performing the procedure (or an appropriately trained and delegated individual) must also explain the procedure itself, any relevant risks, benefits or alternatives
vii. Adequate literature describing the procedure, its benefits and risks, and any alternatives must be given to the person where available. (Appendix 2)

5.8 Postal Consent

i. The Trust is aware of a practice, advice by some of the Royal Colleges and in relatively widespread use, whereby literature concerning a particular procedure / treatment / investigation is posted to the person with their appointment letter. The consent form may also be sent to the person at the same time. Whilst the early provision of information is often very useful it is NOT a substitution for discussion in clinic. Practitioners cannot provide on literature alone as the basis of informed consent. To do so would necessitate various assumptions, such as the person having been able to read the literature, having read it and having understood it. Such assumptions are not appropriate in the context of obtaining informed consent. Where literature is being relied upon, the medical records should be annotated to reflect this and to confirm that the person has advised they have read and understood the literature, and that they have been given the opportunity to ask questions in clinic.

5.9 Procedures to Follow When Persons Lack Capacity to Give or Withhold Consent

i. Please refer to the Mental Capacity and Deprivation of Liberty for Safeguarding Policy. Further assistance can be obtained from the Safeguarding Team. Out of hours advice can be obtained by following the procedure described in Appendix 1.

5.10 Person Information

i. The provision of information is central to the consent process. Before people can come to a decision about treatment, they need comprehensible information about their condition, the treatment offered, the risks and benefits of that treatment, the alternative treatments options (including no treatment) and the impact of the treatment on the personal circumstances of the individual. They also need to know whether additional procedures are likely to be necessary as part of the procedure.
ii. People and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the person wishes to be well informed about the risks and benefits of the various options.
iii. It is recognised that in a clinical setting people will sometimes specifically ask not to be told about risks of a procedure. This can place health practitioners in a difficult position. Efforts should be made to explain why such a discussion is necessary, but if the person does not want to be given information it cannot be forced upon them. The medical records should be annotated to reflect the wishes of the person. Best practice would be for them to be asked to counter-sign the note.
iv. Discussions should actively promote shared decision making, for example, offering training, and using posters or other media (such as appointment letters or websites) to prompt people to ask questions such as:
    What are my options?
    What are the possible benefits and risks of those options?
    How can we make a decision together that is right for me?
v.

5.11 Shared Decision Making

i. Support shared decision making by offering interventions at different stages, including before, during and after discussions, so that people are fully involved throughout their care.
ii. Tailor the methods used to support shared decision making to the care setting and context in which the decision is being made, including whether the discussion is happening in person or remotely by video or phone.
iii. Ask the person if they want to involve family members, friends, carers or advocates (being aware of safeguarding). If so, include them as a way to help the person:
    - actively engage in the discussion
    - explain what matters to them
    - make decisions about their care
    - remember information they have been given during the discussion.
iv. When providing information and resources:

- only use reliable, high-quality sources such as NICE-accredited information, links to the NHS website, information from appropriate patient organisations, or relevant NICE guidelines and quality-assured patient decision aids
- take into account accessibility and the requirement to meet the NHS Accessible Information Standard.

5.12 Use of Patient Decision Aids

i. Use patient decision aids as one part of an overall 'toolkit' to support shared decision making. If a relevant decision aid is not available, continue to use the shared decision-making principles outlined in this guideline.

ii. Only use a patient decision aid if it is:
    - quality assured and reflects evidence-based best practice
    - relevant to that discussion and the decision that needs to be made
    - relevant to that clinical setting.

iii. Before using a particular decision aid, healthcare professionals should make sure they are familiar with it, including how it will help people to understand which option is best for them

5.13 Communicating risks, benefits and consequences

i. Discuss risks, benefits and consequences in the context of each person's life and what matters to them. Be aware that risk communication can often be supported by using good-quality patient decision aids or graphical presentations such as pictographs.

ii. Personalise information on risks, benefits and consequences as much as possible. Make it clear how the information you are providing applies to them personally and how much uncertainty is associated with it. For more on dealing with uncertainty, see the General Medical Council's guidance on decision making and consent.

iii. Ensure that staff presenting information about risks, benefits and consequences to people have a good understanding of that information and how to apply and explain it clearly

iv. If information on risks, benefits and consequences specific to the person is not available, continue to use the shared decision making principles outlined in this guideline.

5.14 Discussing numerical information

i. Think about using a mixture of numbers and pictures, for example, numerical rates along with pictograms or icon arrays, to allow people to see both positive and negative framing at the same time.

ii. Use numerical data to describe risks if available. Be aware that different people interpret terms such as 'risk', 'rare', 'unusual' and 'common' in different ways.

iii. Use absolute risk rather than relative risk. For example, the risk of an event increases from 1 in 1,000 to 2 in 1,000, rather than the risk of the event doubles.

iv. Use natural frequencies (for example, 10 in 100) rather than percentages (10%).

v. Be consistent when using data. For example, use the same denominator when comparing risk: 7 in 100 for one risk and 20 in 100 for another, rather than 1 in 14 and 1 in 5.
vi. Present a risk over a defined period of time (months or years) if relevant. For example, if 100 people have treatment for 1 year, 10 will experience a given side effect.
vii. Use both positive and negative framing. For example, treatment will be successful for 97 out of 100 people and it will be unsuccessful for 3 out of 100 people
viii.

5.15 Provision for People Whose First Language is not English

i. The Trust is committed to ensuring that people whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. Using a trained interpreter (in person or via telephone) Please refer to interpreters policy should always be offered to aid communication; if this is declined this should be documented in the Health Records. It is not advisable to use family members as translators; however it is acknowledged, that in the absence of telephone interpretation, this may be necessary in emergency situations.

5.16 Sensory or Motor Impairment/Illiteracy

i. If the person is incapable of signing a consent form because of sensory or motor impairment, arrangements should be made to document the witnessing of consent. When difficulties occur, help and support can also be obtained from the Safeguarding Team.

5.17 Access to More Detailed or Specialist Information

i. People should be informed of how they can obtain more detailed information about their condition or a proposed treatment than that provided in general leaflets. They should be provided with contact details for the relevant doctors, nurses, midwives or allied health professionals responsible for their care.
ii. Alternative forms of information should also be available e.g. Braille, audiotapes, which can be facilitated by the Patient Experience Team.

5.18 Single Stage Process

Routine Procedure:

i. It is appropriate for a health professional to initiate a procedure immediately after discussing it with the person. If the person is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given verbally.

Complex procedure:

i. If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to

make their decision. The more significant the risk, the greater the need for a “cooling off” period may become.

Emergency Procedure:

i. In emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other. The discussion and the person’s consent should be documented in the notes whether or not a form is used. The urgency of the patient’s situation may limit the quantity of information that they can be given, but should not affect its quality. Consideration should be made of whether any advanced directives are in place at the time the procedure is being proposed. If there are concerns with respect to the person’s capacity to consent, advice should be sought from the safeguarding team.

Seeking Consent for Anaesthesia

i. The requirement to obtain informed consent for anaesthesia is no different to that in relation to any other treatment or investigation. Every effort should be made to provide as early as possible the provision of information in relation to the risks / benefits / alternatives of anaesthetic care.
ii. People receive a general leaflet about anaesthesia in outpatient’s preoperative assessment clinic and will have the opportunity to discuss anaesthesia during the pre-anaesthetic assessment visit.
iii. The anaesthetist should discuss the anaesthetic options including risks, benefits and where possible, alternatives with the person and document in their health records; this is usually provided within the pre-operative assessment records.
iv. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she should also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

5.19 Treatment of Children

i. Where a child is admitted, you should discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, you must do so, unless the delay involved in contacting them would put the child’s health at risk.
ii. Only people with ‘parental responsibility’ are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.
iii. When a child attends without a parent or legal guardian, efforts should be made to contact them and obtain oral consent, which is then recorded in the notes. In the case of a Fraser competent child this should be done with the child’s consent.
iv. If the parent or legal guardian of the child is unavailable and the treatment required is urgent, consent should be obtained from the child if he/she is able to understand what is involved in the treatment proposed (i.e. Fraser competent). In this case a “full note should be made of the factors taken into account by the healthcare

professional in making his/her assessment of the child's capacity to give a valid consent". [Section 10, HC (90) 22].

v. In an emergency, if the child is alone and is unable to give consent or lacks capacity it is justifiable to treat a child .Treatment must be given in the best interests of the child House of Lords decision in Re. F [1989] 2WLR 1025[1989] 2A11ER545 Section 5). Detailed notes must be made of attempts to obtain consent and of the urgency of the treatment required.

5.20 Teenage Sexual Health

i. It is recognised that Fraser competent children under 16 years old attend the hospital and may not give their permission to parental contact being made to obtain consent. As previously stated, healthcare professionals working with these patients should seek to persuade them to inform their parent.
ii. Where treatment of sexually transmitted infection is required however, and parental consent cannot be obtained, the treatment should be carried out.
iii. Similar judgements are made regarding the provision of contraceptive services to this client group in the interest of avoiding unwanted pregnancies. The healthcare professional working in this area should be mindful of the potential medico-legal dilemmas to be considered with regard to the Fraser ruling. Legal opinion suggests the principle that the welfare of the child is paramount as contained in the Children Act (2004), must prevail.

5.21 Safeguarding Children and Consent

i. Consent should be sought from the parent/carer in all cases. Children must not be medically examined or photographed without parental/carer consent, unless a legal order, which permits such an examination, is in place, or where there is a need for urgent medical attention and, in the judgement of the doctor, the best interest of the child must be served. The appropriate Safeguarding Children Procedure must be followed. Refer to Safeguarding Children Policy.
ii. It is good practice that discussions should take place with experienced colleagues, and it should be noted that healthcare professionals must be prepared to justify their decision to the parent(s) and, if necessary, to others.

5.22 Limited Consent (e.g. Jehovah's Witness)

i. A competent patient may choose to limit the consent given, which must be respected by the healthcare professional involved. Except for any unanticipated measures that may become necessary in order to save life or prevent irreversible damage, the healthcare professional should not carry out any procedure that has not been agreed in principle with the patient. If the patient has actually considered and refused consent to any procedure, having understood the potential consequences of his/her decision, then that decision must be respected. This could be evidenced by the provision of a valid advanced directive.

ii. In situations where the patient is a child under 16 who is not Fraser competent, and where parental refusal conflicts with the best interest of the child, then it is permissible to consider treatment despite parental refusal.
iii. The area of limited consent most likely to be encountered is a refusal to receive blood or blood products, whatever the circumstances or effects may be.
iv. It is important that a senior clinician makes clear to the patient, preferably in the presence of another clinician, the possible consequences of this limited consent, and a detailed record must be documented in the case notes, together with the completion of the consent form. Please refer to Management of women who decline blood products with the appropriate consent form.
v. The patient should also be given the opportunity to have a relative and/or representative of his/her religious organisation present.
vi. For further information please refer to section 5.24.iii.

5.23 Refusal of Treatment

i. If the process of seeking consent is to be a meaningful one, refusal must be one of the person's options. A competent adult is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983 (amended 2007). The situation for children is more complex: see the Department of Health's Seeking consent: working with children for more detail. The following paragraphs apply primarily to adults.
ii. If, after discussion of possible treatment options, a person refuses all treatment, this fact should be clearly documented in their notes. If theyhave already signed a consent form, but then changes their mind, this must be clearly documented
iii. Where a person has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

5.24 Consent for Research

i. All research projects must have a favourable ethical opinion from a Research Ethics Committee, and full Trust R&D approval before any project can commence. This includes collation of pilot data, patient identification and screening etc. Consent issues will be specific to each project. The protocol for studies should be followed in accordance with Good Clinical Practice.
ii. The Patient Information Sheet and Consent Form used for the purpose of seeking informed consent must be approved by an Independent Research Ethics Committee and Trust R&D. The documents must be written in accordance with guidance for preparing research information sheets and consent forms provided by the National Research Ethics Service; the R&D Office can provide further details.
iii. All staff taking consent for research MUST be trained in Good Clinical Practice (GCP). Details of GCP training can be sought from the R&D Office; GCP training is mandatory for all researchers before they start recruiting participants to studies. The delegation of seeking informed consent to an appropriate, suitably qualified person on the research team should be considered on a study-by-study basis. If staff other than the Chief Investigator (CI) or Principal Investigator (PI) are to accept

responsibility for the informed consent process, it is important that the following criteria are met:

iv. S/he is prepared to take on this additional consent in line with their professional organisational guidelines;
v. S/he has a full understanding of the study, potential risks/benefits and the associated disease area. They should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.
vi. This delegation of responsibility should be documented on the study delegation log/site responsibility log (title may vary from study to study, but this is essentially a log that captures each member of the study team and their individual responsibilities in the management and conduct of the study and is signed and dated by the CI/PI).
vii. The process has been approved by the relevant Research Ethics Committee (REC)
viii. An effective line of communication is maintained back to the CI/PI who is the person ultimately responsible for the participant's care.
ix. If a PI / CI delegates the informed consent process to a Research Nurse or Research Midwife, the nature of the research procedure(s) the participant is being asked to consent to, must be in accordance with the Nurse / Midwife's clinical competency, i.e. a nurse or midwife should not be expected to take informed consent for research for a procedure they would not consent for / or perform, in their clinical duties.
x. Staff of all healthcare professions, e.g. nurses and midwives, taking consent for research must work within the boundaries of their competence and in accordance with their professional code of practice, any staff member experiencing problems working to the requirements of their professional code because of the research demands placed upon them, should report to someone in authority. It is important that staff have professional indemnity insurance, and therefore individuals should check that their indemnity insurance covers research duties.
xi. All participants entering into a clinical study or trial must have given informed consent before any aspect of the research begins (interventional or non-interventional). Exemptions apply for emergency research only. For emergency research please consult the Legal Representative Policy available via the Research & Development Department. The individual taking consent must explain clearly in language comprehendible to the potential participant, the nature and purpose of the research, who is organising and funding the research, what the potential risks and benefits of the interventions/procedures are and what the participant will be expected to do as part of the research, which is in addition to standard clinical procedures, for example, have an extra blood sample taken, or complete a questionnaire. The potential participant must be informed that their participation is entirely voluntary, that if they refuse their care will not be compromised, and that they are free to withdraw from the research at any time, without having to give an explanation.
xii. A copy of the signed consent form must be given to the participant to keep, a copy must be filed in their medical records and a copy must be kept with the data record sheets/case report forms held by the researcher.
xiii. The fact that the patient is participating in the research project and the information that has been given to them must be noted in the case notes. The informed consent process may be monitored by the study Sponsor, who will review consent forms and clinical notes where necessary.

5.25 Clinical Photography and Conventional or Digital Video Recordings

i. Photographic and video recordings made for clinical purposes form part of a person's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.
ii. Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in point iii below. Written consent must be sought to use such a recording for education, publication or research purposes, the person giving consent must be fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.
iii. Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this GMC guidance is well publicised. However, express consent must be sought for any form of publication
iv. If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.
v. In situations where a recording is made specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious, consent must be sought as soon as the patient regains capacity. The recording must not be used until consent is obtained. the recording must be destroyed if the patient does not consent to any form of use,
vi. If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of someone close to the patient. You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

5.26 Other Circumstances

Unconscious Patients

i. When a person presents as acutely unconscious because of injury or illness a clinician may undertake whatever treatment is reasonably necessary to ensure the patient's life or health is not at risk, after consideration of best interest.

ii. A note should be made in the clinical records to explain the absence of formal consent.
iii. Good practice should prevail and relatives or other carers should be involved in the decision, but in an emergency this should not delay the clinician taking such actions as the best interests of the patient demands.
iv. Where there is no advance directive or "living will" to refer to, the "best interest principle" should apply. There is no duty upon doctors to commence or continue treatment that would subject the person to discomfort or indignity. Such decisions must, however, be made with great care and will involve consultation with relatives, others close to the person, and healthcare professionals, as well as appropriate specialist consultations or second opinions.

Advance Decisions

i. A person may have made an advance decision to refuse particular treatment in anticipation of future incapacity (sometimes previously referred to as a 'living will' or 'advance directive'). A valid and applicable advance decision to refuse treatment has the same force as a contemporaneous decision to refuse treatment. This is a well-established rule of common law, and the Mental Capacity Act 2005 now puts advance decisions on a statutory basis. The Act sets out the requirements that such a decision must meet to be valid and applicable. Further details are available in chapter 9 of the Mental Capacity Act (2005) Code of Practice, but in summary these are:

- The person must be 18 or over
- The person must have the capacity to make such a decision
- The person must make clear which treatments they are refusing
- If the advance decision refuses life-sustaining treatment, it must be in writing (it can be written by someone else or recorded in healthcare notes), it must be signed and witnessed and it must state clearly that the decision applies even if life is at risk
- A person with capacity can withdraw their advance decision at any time.
- Healthcare professionals must follow an advance decision if it is valid and applicable, even if it may result in the person's death.

ii. While a decision is awaited from the courts, healthcare professionals can provide life-sustaining treatment or treatment to stop a serious deterioration in the person's condition.

Biological Material

i. The Human Tissue Authority (HTA) was established on 1 April 2005 to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of 'Scheduled Purposes set out in the Human Tissue Act 2004 (HT Act); this act came into force on 1 September 2006.
ii. The Human Tissue Authority Code of Practice – Consent, Code 1 was published in July 06.The Act, and the Hat's codes of practice, encompasses consent provisions on:

a. The storage and use of dead bodies
b. The removal, storage and use of 'relevant material' from a dead body and for example: the storage and use of relevant material from the living. Department

of Health's Reference guide to consent for examination and treatment (2009) Under the Act, tissue may be taken in a variety of circumstances

iii. The Act does not deal directly with the removal of tissue from the living. Although the process of seeking consent for the storage and use of tissue from person will often be undertaken at the same time as consent to investigation or treatment, the consent for removal itself in these circumstances remains a matter of common law.
iv. Consent under the Act relates to the purposes for which material might be stored or used. Anyone removing, storing or using material in circumstances for which the Act requires consent, must be satisfied that the consent is in place. They do not need to have taken or recorded the consent personally, but must ensure that procedures are in place giving the necessary assurance. These procedures should be robust and reviewed regularly. It is a defence that the person acts with a reasonable belief that consent is in place or is not necessary.
v. At the heart of the Act lies the need to obtain consent for the removal, storage and use of human tissue or organs and the storage and use of whole bodies for certain scheduled purposes. The code gives guidance on the need for consent, and also addresses the closely related issues of communication and consultation with person and their families, which should support the consent process.
vi. Consent for treatment and examination including removal of tissue is a common law matter dealt with in the Department of Health's Reference guide to consent for examination and treatment (2009). Under the Act, tissue may be taken in a variety of circumstances. For example:

    a. In the course of diagnostic procedures, e.g., taking a blood or urine sample, tissue biopsy, cervical screening, etc
    b. In the course of a treatment procedure, e.g., removing tissue (organs, tumours, etc.) during surgery
    c. When removed specifically for the purpose of research

vii. Once tissue has been taken from the person s, for whatever purpose, it can be stored and used without consent for a number of purposes.
viii. Consent from the living is needed for storage and use of tissue for:

    a. obtaining scientific or medical information which may be relevant to any other person, now or in the future (i.e. where the purpose is storage or use in relation to another person, rather than where it might, incidentally, be of future relevance to another person)
    b. Research in connection with disorders, or the functioning, of the human body
    c. Public display and transplantation.

ix. Consent from the living is not needed for storage and use of tissue for:

    a. Clinical audit
    b. Education or training relating to human health (including training for research into disorders, or the functioning, of the human body)
    c. Performance assessment
    d. Public health monitoring
    e. Quality assurance.

x. For the deceased, consent is needed:

   a. where, after a coroner's post mortem, the continued storage or use of material no longer required to be kept for the coroner's purposes
   b. For the removal, storage and use for the following scheduled purposes: anatomical examination
   c. Determining the cause of death
   d. Establishing, after a person's death, the efficacy of any drug or other treatment administered to them
   e. Obtaining scientific or medical information, which may be relevant to any other person now or in the future ('a future person')
   f. Public display
   g. Research in connection with disorders, or the functioning, of the human body
   h. Transplantation
   i. Clinical audit
   j. Education or training relating to human health
   k. Performance assessment
   l. Public health monitoring and quality assurance.

5.27 Consent to 'Do not Attempt Resuscitation' (DNAR) Decisions

i. Refer to the Trust DNAR Policy

5.28 Withdrawing or withholding lifesaving treatment in babies

i. Refer to the guideline for withdrawing or withholding lifesaving treatment in babies

5.29 Consent to Adult Post-Mortem Examination

i. The Trust consent form which is modelled on that recommended by the Royal College of Pathologists must be used to obtain consent for a Post mortem examination. A post-mortem examination may also legally be required under the direction of the coroner's office. An information sheet is available for relatives and should be provided to relatives.

5.30 Consent to Fetal, Perinatal or Infant Post-mortem examination

i. Alder Hey Children's NHS Foundation Trust (Alder Hey) form should be completed with the parents and senior clinician
ii. When parents agree to the post mortem they must state the storage/disposal details of blocks and slides.
iii. The witness signing the consent form must be somebody who is not the clinician and not the parent.
iv. More details contained within Post-mortem booklet.

5.31 The Consent Register

i. The Consent register contains:

   a. All clinical staff able to consent and perform the procedure independently

b. All clinical staff to who consent responsibility has been delegated for specific procedures. This will include junior medical staff, nursing and midwifery staff, and clinical laboratory staff in Genetics and Reproductive Medicine.

ii. For these staff the Register will contain

a. Staff name
b. Designated consent training mentor
c. Specific procedures the staff have been trained to take consent for
d. Date of update of training required.

iii. The Register will be updated and archived every 2-4 months with the rotation of the junior medical staff depending on their medical speciality.
iv. The Register is the responsibility of the Post Graduate Manager in conjunction with the Head of Nursing/ Midwifery. Those taking consent that are not on the consent register will be subject to Trust disciplinary procedures.

6 Key Reference

i. Reference Guide to consent for examination or treatment (2nd edition July 2009)
ii. Mental Capacity Act 2005.
iii. The Human Embryology Act (1990)
iv. What Happened After Death – Patient Information Leaflet
v. Human Tissue Authority Website – www.hta.org.uk
vi. The Children's Act 1989
vii. Working with Children – Seeking Consent (DoH)
viii. The Human Tissue Act (2004) (HT Act)
ix. Reference guide for withdrawing or withholding lifesaving treatment in babies
x. http://www.bsgm.org.uk/media/678746/consent_and_confidentiality_2011.pdf
xi. https://www.nspcc.org.uk/preventing-abuse/child-protection-system/legal-definition-child-rights-law/gillick-competency-fraser-guidelines

7 Associated Documents

i. Incident Reporting Policy
ii. Whistleblowing Policy
iii. Refer to the guideline for withdrawing or withholding lifesaving treatment in babies
iv. Do Not Attempt to Resuscitate (DNAR) Policy

8 Training

i. All staff involved in the formal recording of consent, including delegated consent, must possess the requisite knowledge and skills required. This may be evidenced via training documents (for junior doctors) or by completion of the Trust consent training programme.

9 Policy Administration

9.1 Consultation, Communication and Implementation

Consultation Required	Authorised By	Date Authorised	Comments
Impact Assessment	PGP	15/06/2022	Policy Guideline and Procedures group
GDPR	PGP		
Have the relevant details of the 2010 Bribery Act been considered in the drafting of this policy to minimise as far as reasonably practicable the potential for bribery?	Yes (√)		
External Stakeholders	Hill Dickinson's: Trust Solicitors		
Trust Staff Consultation via Intranet	Start date: May 22		End Date: May 2

Describe the Implementation Plan for the Policy (and guideline if impacts upon policy) (Considerations include; launch event, awareness sessions, communication / training via CBU's and other management structures, etc)	By Whom will this be Delivered?
Policy will be uploaded to staff Intranet and communicated to staff via 'staff track newsletter, and the Meditech bulletin board	Policy Officer

Version History

Date	Version	Author Name and Designation	Summary of Main Changes
May 22	12	Deputy medical Director	Full review undertaken
May 19	11	Acting Medical Director	Minimal changes to meeting titles and updated to new automated template
Apr 16	10	Deputy Director of Nursing and Midwifery	Policy now in new template; numbering therefore amended. Changes detailed below reflect the changes reflected in this version of the policy. 4.iii Title of post holder changed 4.v Title of post holder changed 5.1 Guidance shortened to responsibility of individual 5.2 Final sentence removed 5.3.ii.d Additional point added 5.3.v amendment to detail of Act

			5.5 Points 5.5.vi and 5.5.vii removed 5.6.i reference to consent register removed 5.6.v point removed 5.8 additional section on Postal Consent added 5.10 section strengthened to reflect Montgomery ruling 5.12 Amended role to Safeguarding Team 5.14.ii Addition of sentence to include 'cooling off' period 5.14.iii Additional reference to support for those lacking capacity 5.15.i Additional point 5.15.iii Amended to reflect current record keeping practice 5.16.i Reworded following legal advice 5.18.ii Amended to 'good practice' 5.19.ii Additional final sentence 5.19.iv word 'hazard removed 5.19.vi addition of a direction to section 5.24.iii 5.20.i Amendment to details of legislation 5.20.iv Paragraph removed 5.21 Section now details complete consent process for research 5.23.i word 'reasonably' added 5.23 old sections iii and iv removed 5.29.iii Frequency of update amended to reflect changes to medical staff rotation 6. Additional references added at points x and xi Old section 6.31 removed **9.2 All KPI's amended and committee reference updated** 10 Old Appendix A removed relating to 12 Key points of consent
Nov 12	9	Head of Governance	Minor revision no change to content
May 11	8.1	Assistant Director of Clinical Governance	Minor addition in section 6.27 relating to gaining consent for research in an emergency.
May 2010	8	Assistant Director of Clinical Governance	Changes and additions in this policy reflect changes identified in the Reference Guide to consent for examination (2009). In addition added clarity has been identified to 'Responsibilities of Health Care Professionals in Obtaining and Documenting Consent' at section 7.3.
Mar 08	7	Assistant Director of Clinical Governance	Minor revision no change to content

Mar 06	6	Trust Risk Manager	Minor revision no change to content
Mar 05	5	Trust Risk Manager	Minor revision no change to content
Mar 04	4	Trust Risk Manager	Minor revision no change to content
Mar 03	3	Trust Risk Manager	Minor revision no change to content
Mar 02	2	Trust Risk Manager	Minor revision no change to content
	1		Policy creation

9.3 Monitoring Compliance with the Policy

Describe Key Performance Indicators (KPIs)	Target	How will the KPI be Monitored?	Which Committee will Monitor this KPI?	Frequency of Review	Lead
The consent form is signed to indicate that information is provided to people to support their decision making, including risks, benefits and alternatives where appropriate	100%	Audit of key Performance indicator	Effectiveness Senate	Annual	Head of Governance and Quality
All areas of the consent form have been completed	100%	Audit of key Performance indicator	Effectiveness Senate	Annual	Head of Governance and Quality
Where consent forms are pre-signed and dated, there is evidence of countersignature and the date this has been completed	100%	Audit of key Performance indicator	Effectiveness Senate	Annual	Head of Governance and Quality
All staff taking consent must be trained in the LWH consent process and records of training retained on OLM	100%	Audit of key Performance indicator	Effectiveness Senate	Annual	Head of Governance and Quality
Where consent has been delegated there are local records indicating which procedures have been delegated and evidence of staff competency within these areas.	100%	Audit of key Performance indicator	Effectiveness Senate	Annual	Head of Governance and Quality

9.4 Performance Management of the Policy

Who is Responsible for Producing Action Plans if KPIs are Not Met?	Which Committee Will Monitor These Action Plans?	Frequency of Review (To be agreed by Committee)
Safety Senate	Effectiveness Senate	Annual

10 Appendices

10.1 Appendix A - How to seek a Court Declaration

During office hours please contact, Safeguarding team – 0151-702-4373.

Out of hours the Trusts solicitors operate an “on call” solicitor for legal advice in an emergency.
The contact number is 07715376624

B) Legal Advice

The Trust Solicitors are Hill Dickinson Solicitors (Please ask for the Healthcare Team), Telephone 0151 600 8000 (Core hours, or out of hours,07715376624) ; Fax 0151 600 8001.

- Clinicians should make initial contact with one of the Healthcare Team by telephone. A solicitor will always be available in the Healthcare Department who can deal with a high court declaration.
- Clinicians should make sure that any faxes sent (during core hours) are clearly marked urgent and made for the attention of a key contact or their deputy.
- A declaration as to the lawfulness of proposed treatment can be obtained at very short notice and judges will do their utmost to deal with cases as a matter of urgency. However the following needs to be noted:
- Applications to the courts have failed in the past because the courts have been given insufficient time to properly access the case.
- While the judge will abridge or dispense with procedural requirements where possible in an emergency, certain information will always be required to enable a judge decide a case.

- The minimum information required when contacting solicitors is as follows:
  - The time limit to which the professional is working/the gravity of the situation
  - The age and sex of the person
  - The circumstances of the case including whether the person is subject to the provisions of the Mental Health Act 1983.
  - The degree to which capacity has been accessed. Whether the person is able to consent to the proposed treatment and details of the attempts made to assess competence.
  - The Type of treatment which is proposed, alternative treatment options and the consequences of the person not having any or all of the treatment.
  - The type of treatment which is proposed, alternative treatment options and the consequence of the person not having any or all of the treatment.
  - Whether parents relatives nearest relatives have been consulted and if represented relevant contact details
  - Whether social services have been involved and if so relevant contact details.

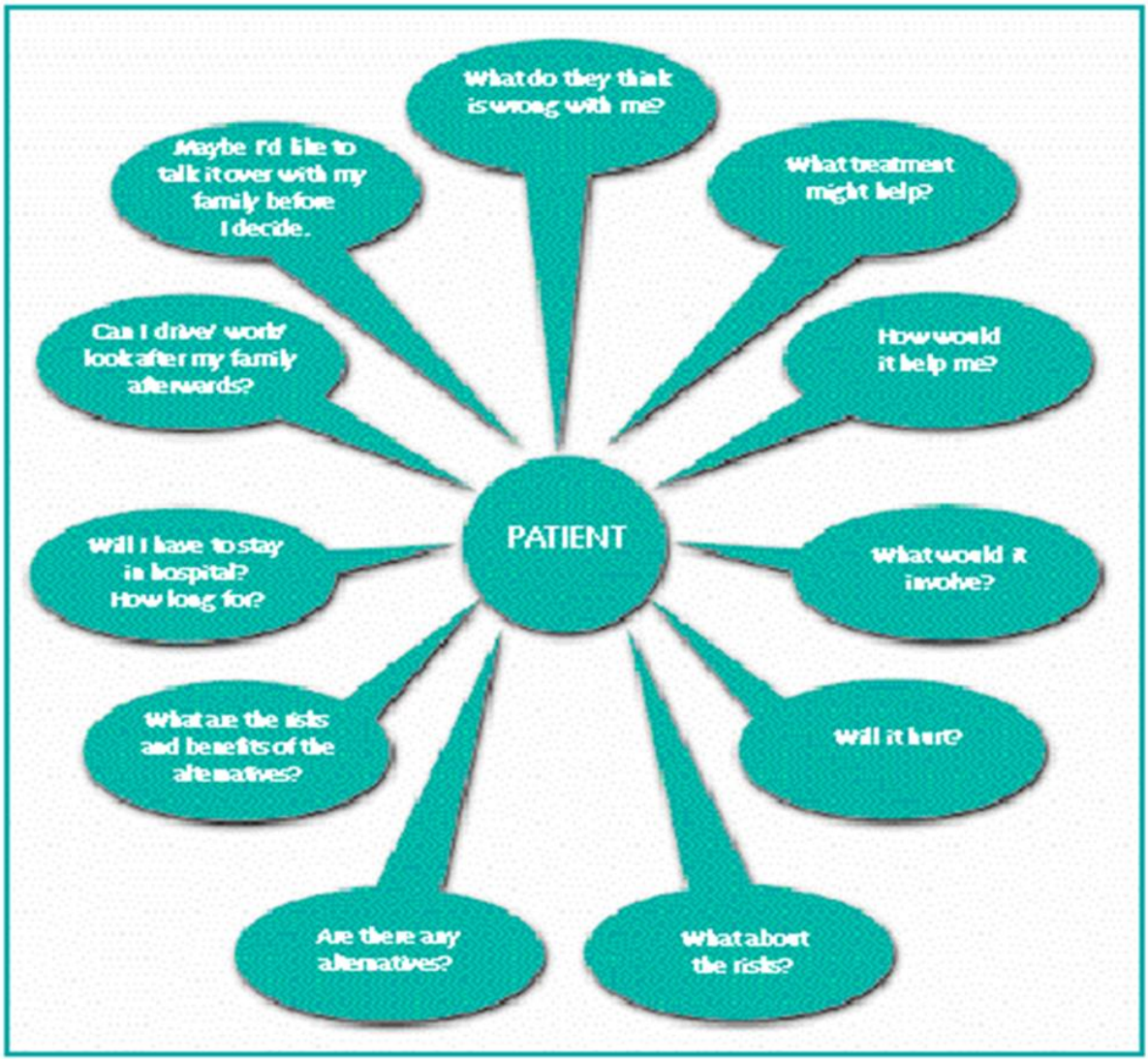
♦ Copies should be prepared of any relevant evidence including extracts of the case notes in readiness for faxing sending through to Trust Solicitors.

The above minimum information should be read in conjunction with the circular HSC20001/023, which expands upon the law on consent.

C) Documentation

As soon as an issue arises concerning consent, even if it not likely to lead to an application to the court for the declaration careful documentation should be compiled and retained including:
Minutes of meetings with the person
Meetings with relatives and social services
Discussions and meetings with clinicians and those requested to provide second opinions either on ‘competence’ or ‘best interest’.
Notes of discussions with advisors.
Case notes should be comprehensive, contemporaneous, clear and legible.
Copies of any research/medical literature in relation to the proposed treatment

10.2 Appendix B Seeking Consent: Remembering the Person's Perspective



10.3 Appendix C – Individual Competency Statement

Competency Statement:

…… Consent

…….has undergone a period of training, supervision and assessment and:

- Has compiled an assessment log to record her developing competency

- Demonstrated the ability and confidence to consent persons for the above procedure.

Signature ……. Date ……..

Mentor/Supervisor

Competency Statement
Procedure Specific, Delegated Consent taking
Revalidation

Name

Designation

Procedure +/- GA	Current Guidance RCOG/SIGN etc discussed	Risks discussed	Benefits discussed	Alternatives to procedure discussed

I confirm that my mandatory consent training is in date; and I have evidence of competency training and assessment for each Procedure Specific Consent.
I am confident in obtaining the persons consent for the above procedures.

signed/date

Consultant Mentor signed/date

11 Initial Equality Impact Assessment Screening Tool

Name of policy/ business or strategic plans/CIP programme: **Consent Policy**	**Details of policy/service/business or strategic plan/CIP programme, etc:** The Policy describes the legal requirements, roles and responsibilities and monitoring arrangements required to provide assurance relating to the safe and effective management of the consent process within the Trust	
Does the policy/service/CIP/strategic plan etc affect (please tick) **thes** ☐ **Staff** ☐ **Both X** ☐		
Does the proposal, service or document affect one group more or less favourable than another on the basis of:	**Yes/No**	**Justification/evidence and data source**
Age	No	Use this space to provide any supporting evidence to demonstrate how your decision was made or, justify the decision(s) you have made Consideration of all groups of staff has been undertaken during the development of this policy
Disability: including learning disability, physical, sensory or mental impairment.	No	
Gender reassignment	No	
Marriage or civil partnership	No	
Pregnancy or maternity	No	
Race	No	
Religion or belief	No	
Sex	No	
Sexual orientation	No	
Human Rights – are there any issues which might affect a person's human rights?		**Justification/evidence and data source**
Right to life	No	Human Rights considerations have been factored into the legal processes for obtaining consent and backed up in Statute
Right to freedom from degrading or humiliating treatment	No	
Right to privacy or family life	No	
Any other of the human rights?	No	
EIA carried out by: Devender Roberts Quality assured by: PGP	Date	Contact details of person carrying out assessment.