

Clinical Consent Policy

Version No: 1

Document Summary:

This is a harmonised policy to encompass all sites in Mersey and West Lancashire Teaching Hospitals NHS Trust. This policy describes the correct processes to ensure that patients, or those lawfully acting on their behalf, have given consent before any care or treatment or procedure is undertaken. The policy guides staff on how to obtain consent lawfully and describes how staff taking consent must have the required knowledge and understanding of such care or treatment. It describes fundamental concepts and how they should be applied and also references special situations.

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Policy Author	Assistant Medical Director	
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Section 1 – Document Information	
Title	Clinical Consent Policy
Directorate	Medical
Brief Description of amendments	
Policy fully reviewed and harmonised from legacy organisations for the new organisation.	
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Are all mandatory headings complete?	Yes
Does the document outline clearly the monitoring compliance and performance management?	Yes
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Data Protection Impact Analysis completed?	Yes

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*Please remember to consult with all services provided by the Trust, including Community & Primary Care	
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Consultation end date	Click here to enter a date.

Section 3 – Version Control		
Version	Date Approved	Brief Summary of Changes
1	10/06/2024	Merged Consent Policy from STHK and S & O
	Click here to enter a date.	
	Click here to enter a date.	
	Click here to enter a date.	

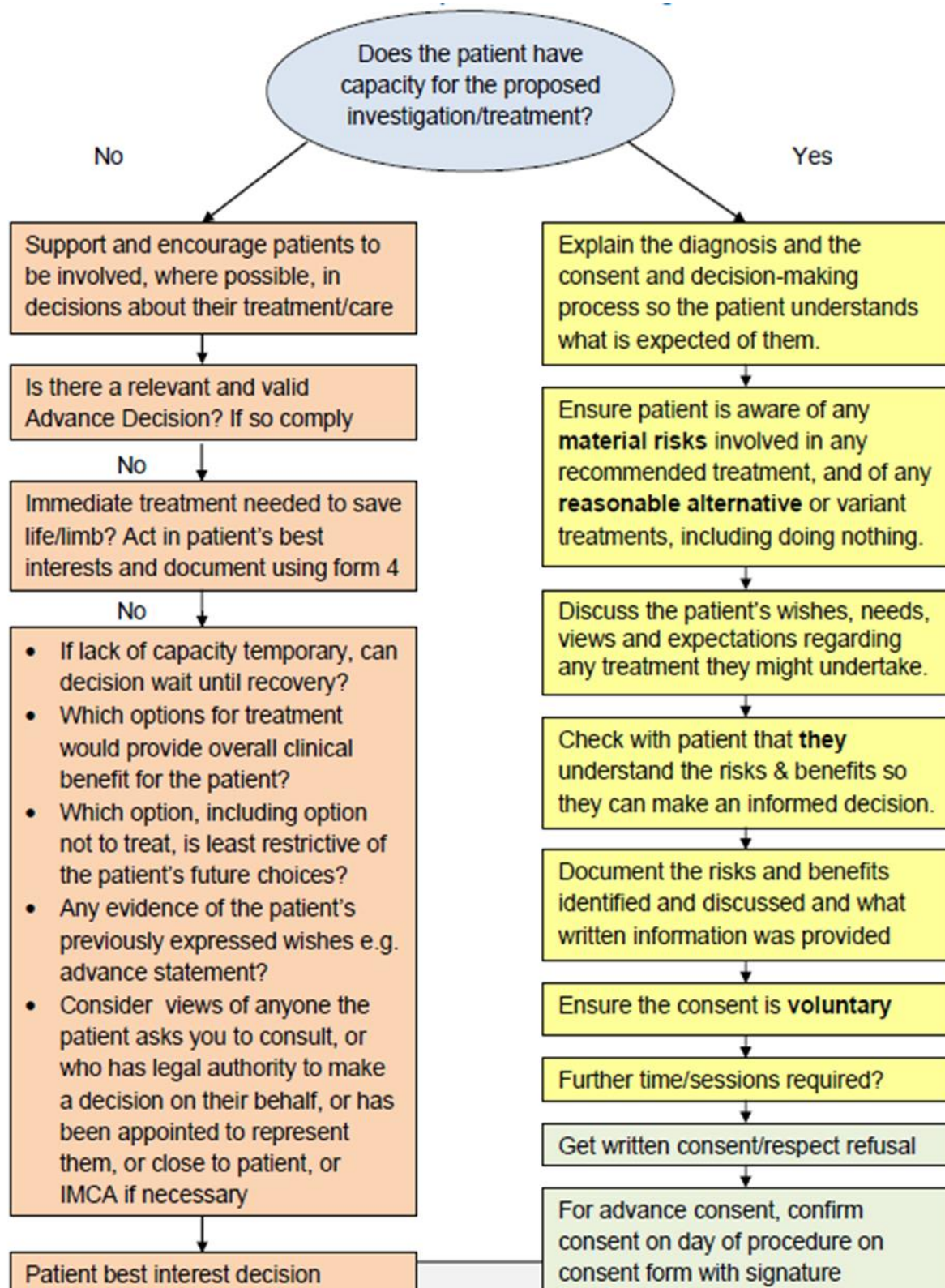
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Date approved	10/06/2024	Review date	30/06/2027

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Quick Reference Guide

Consent for a treatment or procedure should be given by patient (if they have capacity)/parent with support from clinical staff and sufficient information and time to make an informed decision.



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1. Scope

This Policy applies to all clinical staff at Mersey and West Lancashire Teaching Hospitals NHS Trust. It is appropriate for both planned and emergency situations for adults and children.

2. Introduction

It is a fundamental legal and ethical principle that valid permission (consent) must be obtained from the patient before starting treatment or physical investigation, or providing personal care, for a person; and that this is done based on an explanation by the clinician (doctor, nurse, other healthcare professional). The ethical principle of autonomy prevails, which is a person's ethical right to make decisions about themselves by themselves. This is a fundamental part of good practice. You must work in partnership with your patients and offer time and additional information where it is required. Case Law (Common Law) has established that touching a patient without consent or lawful authority can be considered as a civil wrong (battery) or criminal offence of assault.

Consent may be given verbally or in writing.

For consent to be valid, it must be voluntary and informed, and the person consenting must have the **capacity** to make the decision. The key terms are explained here:

- Voluntary – the decision either to consent or not to consent to treatment must be made by the person themselves and must not be influenced by pressure from clinical staff, friends or family.
- Informed – the person must be given all of the information they require, including the benefits and **material** risks, whether there are reasonable alternative treatments and what will happen if treatment does not go ahead.
- Mental Capacity – the person must be capable of giving consent, which means they understand the information given to them; retain the information long enough to make a decision; weigh up the information available to make a decision and communicate their decision (this could be by talking, using sign language, or simple muscle movements like blinking or squeezing a hand) and they can use it to make an informed decision.

If an adult has the capacity to make a voluntary and informed decision to consent to or refuse a particular treatment, their decision must be respected.

A healthcare professional (or other healthcare staff) who does not respect this principle may be liable to legal action by the patient and to action by their professional body and the Trust. Employing bodies may also be liable for the actions of their staff.

Additional information is available from the General Medical Council's guidance 'Decision making and consent – November 2020.

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3. Statement of Intent

This policy has been written to ensure that clinical staff understand all aspects of patient consent so that the rights of patients regarding permission for examination and treatment are protected at all times. It describes the process of seeking consent, what documentation to use, what valid consent means, how to ensure consent is voluntary, what information must be given and what to do in emergency situations. It also covers a number of special situations including what to do when a patient lacks capacity, what the issues are for children and young adults and what to do when consent is refused.

4. Definitions

Term/Abbreviation	Definition/meaning
Mental Capacity	Is the ability to make a decision by having: <ul style="list-style-type: none"> • A general understanding of what decision they need to make and why they need to make it; • A general understanding of the likely consequences of making, or not making, this decision; • The ability to understand, retain, use and weigh up the information relevant to the decision; • The ability to communicate their decision, with support if necessary
Informed consent	The person must be given all of the information about what the treatment or examination involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment does not go ahead
Voluntary consent	The decision to either consent or not to consent to treatment must be made by the person, and must not be influenced by pressure from medical staff, friends or family
Presumed consent	Generally for low risk and complexity interventions; where a patient for example holds out their arm for blood pressure assessment.
Delegated consent	The task of seeking consent may be delegated to another person, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require.
Inappropriate Delegated Consent	Inappropriate delegation (for example where the clinician seeking consent has inadequate knowledge of the procedure) may mean that the 'consent' obtained is not valid. Clinicians are responsible for knowing the limits of their own competence. If any member of staff feels pressurised to seek consent when they do not feel competent to do so, they must contact their immediate clinical supervisor/line manager. If this person is the one applying pressure, then contact should be made with the Executive Medical Director of the Trust or the Director of Nursing, Midwifery and Governance and/ or Deputy Director of Governance.
IMCA	Means an Independent Mental Capacity Advocate. Their role is to provide independent safeguards for the person who lacks capacity and who has no one else (other than paid staff) to support and represent them or be consulted. An IMCA must be

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	consulted where an NHS body is proposing to provide serious medical treatment
Lasting Power of Attorney	(Health and Welfare) - means a person who has been legally empowered to make health and welfare decisions on behalf of a patient who lacks capacity. A financial lasting power of attorney is different and does not give this legal power.
Gillick Competence	Means, in the context of a child/young adult, a child has sufficient understanding and intelligence to fully understand a proposed examination/treatment. In updated legislation, there is now no longer a minimum age specified.
The Fraser ruling	This is updated legislation that stems from the Gillick case, it is not interchangeable as Fraser only applies to contraceptive advice for a child. This is no minimum age specified.
Material risk	Defined in law as a risk to which a reasonable person in the patient's position would be likely to attach significance or a risk that the doctor should reasonably know would probably be deemed as significant by the particular patient
Montgomery ruling	This is a ruling from case law that explains that consent must take into account any material risks that the patient may understand to be significant to their personal circumstances.
ANH	Artificial Nutrition and Hydration

5. Duties, Accountabilities and Responsibilities

5.1 Chief Executive

The Chief Executive Officer has overall responsibility for the strategic and operational management of the Trust including and ensuring that this policy complies with all legal, statutory and good practice requirements and is implemented effectively and efficiently.

5.2 The Medical Director

The Medical Director is responsible for the accuracy of the policy and that it complies with current legal and professional requirements. They are also responsible for ensuring that appropriate training and auditing processes are in place. These functions may be delegated to the appropriate Assistant/Deputy Director.

5.3 Divisional Medical Directors, Clinical Directors, Divisional Directors of Nursing/Midwifery/Allied Health Professional, Matrons and Directorate Managers

Divisional Medical Directors, Clinical Directors, Divisional Directors of Nursing/Midwifery/ Allied Health Professional, Matrons and Directorate Managers are responsible for ensuring that this policy has been disseminated within their division/directorate and that the policy is complied with. Clinical Directors are also responsible for ensuring that a register of delegated consent is kept up to date. Any breaches must be recorded on the Datix system, reported to the Medical Director or assistant/deputy and the directorate governance meeting.

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5.4 Clinical staff

All clinical staff who are involved in patient care have a responsibility to ensure that they comply with the law, this Trust policy and any appropriate professional regulator advice.

6. Process

See quick reference guide at beginning for a flow chart. When seeking consent to treatment, the question of whether the information given to a patient is adequate is judged from the perspective of a 'reasonable' person in the patient's position. The amount of information given to a patient will depend on the individual patient and what they want or need to know. Whether a risk is 'material' does not only depend on how frequently it occurs. Be aware that simply providing the information or getting a signature on a consent form may not be enough to evidence proper consent, but can be helpful as part of the consent process. See section 6.2 for more details.

6.1 Consent documentation

You should seek written consent if any of the following circumstances apply:

- The treatment or procedure is complex.
- The treatment or procedure may result in even a small chance of significant side effects or complications including death.
- The procedure involves general/regional anaesthesia or sedation.
- Providing clinical care is not the primary purpose of the procedure.
- There may be significant consequences for the patient's employment, social or personal life.
- The treatment is part of a project or programme of research approved by Mersey and West Lancashire Teaching Hospitals NHS Trust
- The National Institute for Health and Care Excellence defines a significant interventional procedure as any procedure used for diagnosis or treatment that involves incision; puncture; entry into a body cavity; or the use of ionising, electromagnetic or acoustic energy
- **If in doubt, get written consent**

If a patient information leaflet has been used to give information it must be reflected in the medical records or referred to on the consent form in the appropriate section should a future disagreement arise about a procedure or treatment. A copy, if possible, and preferably signed should be in the patient notes. Patient information leaflets should comply with GMC standards including the reasons for, the nature of the benefits, the risks, the discomforts, the alternatives to and consequences of not having the clinical procedure. **An information sheet does not replace the need for discussion, therefore, make sure you discuss the issues on the information sheet with the patient.**

There are 6 consent forms in use throughout the Trust:

- **Consent Form 1**

Patient agreement to investigation or treatment

- **Consent Form 2**

Parental agreement to investigation or treatment for a child or young person

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- **Consent Form 3** – withdrawn as this is now covered by Consent Form 1
Patient/Parental agreement to investigation or treatment (procedures where consciousness is not impaired)
- **Consent Form 4**
Form for adults who lack capacity and are unable to consent to investigation or treatment
- **Consent Form 5**
Consent for a hospital post mortem examination on an adult
- **Consent Form 6**
Medical photography – this has been revised to combine the request for medical photography and video recording request and consent
- **Consent Form 10**
Foetal histological examination

6.2 Guidance on consent

The Department of Health, General Medical Council and Care Quality Commission have issued guidance on consent and this should be consulted for advice on the current law and good practice requirements in seeking consent. Health professionals must be aware of any guidance on consent issued by their own regulatory bodies.

Following the UK Supreme court ‘Montgomery’ judgement, (March 2015) the law now requires that doctors and practitioners take ‘reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments’. Material risks means that in the circumstances of a particular case, a reasonable person in the patient’s position would be likely to attach significance to it including specifically avoidable, frequent and serious risks.

You **MUST** ask yourself as the patient’s clinician the following questions:

1. Does the patient know about the material risks of the treatment I am proposing?
2. What sort of risks would a reasonable person in the patient circumstances want to know?
3. What sorts of risks would **this particular patient** want to know?
4. Does the patient know about reasonable alternatives?
5. Have I taken reasonable care to ensure that the patient actually knows all of this?
6. Do any of the exceptions to my duty to disclose apply here?
7. Have I properly documented my consent process?

An example would be this: a patient is blind in one eye and requires an operation on the other eye. The risk of blindness in the other eye from the operation is very remote (1 in 14000), but the risk would be very significant to this patient and must be disclosed. Remember that it is the legal and ethical duty of care for the clinician to seek consent to perform a clinical intervention, by request, after explanation. The burden of proof that consent was taken properly lies with the clinician.

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Exceptions to the duty to disclose include:

1. The patient tells the practitioner that he or she does not want to know the risks
2. Telling the patient something that would directly harm the patient's health (this must be only used sparingly, if at all and may be challenged legally)
3. When a patient needing life-saving treatment is unconscious or lacks capacity

The use of any of these exceptions must be explained in the patient notes

6.3 Written consent

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent; but is not proof of valid consent. If a patient 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 patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment, but this must be clearly documented in the notes. Patients with (for example) learning disabilities may be able to give consent, but may require special assistance or arrangements. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent giving, not a binding contract.

If a person cannot read or write then they can make their mark on the form preferably witnessed by someone other than the clinician who is seeking consent, or if they cannot the signature can be left blank and this issue recorded in the notes. The patient can direct someone to sign the form on their behalf if they are unable to, but this is not a legal requirement.

Completed forms must be kept with the patient's notes. Any changes to a form, made after the form has been signed by the patient, must be initialled and dated by both patient and health professional or a new form drawn up and appropriately signed if the changes are significant. On completion of an episode of care the patient's health records and consent form will be sent for electronic scanning and merged into the patient's electronic health record.

It will not usually be necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about, similar care in the past), it would be advisable to do so.

6.4 Procedures to follow when a patient lacks capacity to give or withhold consent

Where an adult lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves for a specific treatment or intervention, any treatment given must be in their best interests and according to the requirements of the Mental Capacity Act 2005 - refer to the Trust Mental Capacity Act page on the intranet.

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Essentially and simply, capacity is about the decision making ability of a patient. If a patient lacks capacity to give or withhold consent the procedures set out in the Mental Capacity Act must be followed. The fact that they do not have the capacity to give or withhold consent to a significant intervention should be documented in **Form 4** (form for adults who are unable to consent to investigation or treatment), along with the assessment of the patient's capacity, why the health professional believes the treatment to be in the patient's best interests and the involvement of people close to the patient. The standard consent forms must **never** be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient's notes.

If a patient who lacks capacity to give or withhold consent for **serious medical treatment** does not have any family, friends or unpaid carers who can assist in determining their best interests, then an Independent Mental Capacity Advocate (IMCA) must be appointed on their behalf. Serious medical treatments are defined as:

- Treatment where there is a fine balance between benefits/burdens and risks;
- The decision on the choice of treatments is finely balanced;
- And/or the treatment would be likely to involve serious consequences for the patient.
- The potential complications or recovery may have a serious effect on the patient's wellbeing.

An IMCA is not required for emergency or urgent medical procedures, though a referral should still be made for any serious treatment that follows emergency treatment. If an IMCA is required, see the Trust Mental Capacity Act intranet page for details.

It must be noted that an apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity, as with a patient with learning disabilities.

You are advised to involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient's situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate. Please document Mental Capacity decision and consider a best interest meeting including the Safeguarding Team if the patient lacks capacity and reasonable adjustments are required. Careflow referrals, 0151 290 4946 (Whiston Hospital) 01704 705248 (Southport Hospital) or email the Safeguarding and Learning Disability Team to access this resource.

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Where the consequence of having, or not having, the treatment is potentially serious, a court declaration may be sought. Further advice is available from the Trust's Legal Department.

A Lasting Power of Attorney (LPA) is a legal format that allows one person to give another person the legal authority to make a decision on behalf of another person who has lost capacity. Such a person is usually referred to as a donor; as in donating that authority to another. Under an LPA the chosen person (the attorney or 'donee') can make decisions that are as valid as one made by the

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person (the donor). A 'Health and Welfare' LPA allows the attorney to consent to medical treatment on behalf of the donor if the donor lacks capacity to consent to that treatment.

6.5 Is the consent given voluntarily?

To be valid, consent must be given voluntarily and freely, with no pressure or influence being exerted on the person. Be aware of patients who are detained as prisoners or under the Mental Health Act to ensure that such patients do not interpret treatment offers as coercion. Be also alert to family members putting pressure on patients.

6.6 When should consent be sought?

When a patient formally gives their consent to a particular intervention, this may be the formal documentation of a continuing consent process (unless the patient then changes their mind). It is helpful to see the whole process of information provision, discussion and decision making as part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

6.6.1 Single stage process

In many cases, it will be appropriate for a health professional to perform a procedure immediately after discussing it with the patient. For example, during an on-going episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient 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.

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 understand the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then carry out the procedure.

6.6.2 Two or more stage process

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (for example at a hospital outpatient clinic), or it might be over a whole series of consultations with a number of different health professionals. During all the stages of investigation and treatment, the original consent form will be provided by the Trust at each outpatient visit, even if partially completed and scanned. Final scanning occurs once the procedure has been completed. If the consent form is not available in the clinic then contact the Scanning Department via switchboard

A) First Stage:

Provision of information, discussion of options and initial (oral) decision.

Page 2 of the consent form should be filled in and the white carbon copy given to the patient as evidence that the discussion has taken place. For elective procedures, this should happen before the patient is admitted for the procedure or treatment.

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Document on the form which patient leaflet has been provided. The benefits and risks section can refer to the relevant patient information form, or detailed in a letter sent to the patient if appropriate, but you must ensure that anything else relevant to the particular patient is documented in this section. The patient does not sign the consent form at this stage. In some clinics it is not possible to provide the consent forms for logistical and technical reasons (e.g. long distance peripheral clinics); in these circumstances the clinician should send a copy of the GP letter to the patient detailing the proposed procedure, risks/benefits etc. so that the patient has all the information required, and then fill in page 2 when the patient is admitted.

B) Second Stage:

Confirmation that the patient still wants to go ahead with the procedure having had the opportunity to read and discuss the information provided to inform the consent process. The patient must sign if they are able on **page 3** of the consent form which is used to document that consent is given. This can be in out-patients or at a pre-admission clinic or when they arrive for treatment. Consent can be withdrawn at any appropriate point before the procedure. This means the induction of general anaesthesia where used. If local anaesthesia is used, consent may be withdrawn at any time but the patient must be advised of any harmful consequences of abandoning a procedure that has commenced. For patients under sedation having endoscopy who withdraw consent, follow the endoscopy protocol.

When a form is signed before a patient arrives for treatment procedure a member of the healthcare team **must** check with the patient (or advocate) at this point whether they have any further concerns and whether their condition has changed. This is particularly important when there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?" This is known as reaffirmation and a healthcare professional (doctor or nurse) should sign the 'Confirmation of consent' at the bottom of **page 3** of the consent form.

While administrative arrangements will vary, it should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse, or change their mind. It is, therefore, inappropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment (for example, by changing into a hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

The seeking and giving of consent is usually a process, rather than a one-off event. Where possible for major interventions, it is good practice where possible to seek the person's consent to the proposed procedure well in advance, when there is more time to consider the treatment options and senior staff are more readily available to support the patient in deciding the most appropriate treatment. This means obtaining the consent signature before the day of admission if practicable. Clinicians should then check, before the procedure starts that the person still consents. Patients should not be admitted for elective major procedures where the risks and

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benefits have not already been discussed unless this is unavoidable. **In no circumstances should a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment.**

6.7 E-Consent

The Trust is committed to a Digital Maturation Strategy to minimise the use of paper in medical record keeping. An E-consent solution is being developed to facilitate this. Currently, this is only available in limited areas through a pilot project. It is envisaged that this will be developed in the future to enhance the consent process.

6.8 Endoscopy Consent

Following the issue of the Department of Health (DH) guidance on the process of obtaining consent in 2001, the Endoscopy Committee of the British Society of Gastroenterology (BSG) established a working party to consider the possibility of obtaining remote or postal consent.

This produced a set of procedure-specific booklets to provide information and consent forms for most of the common procedures carried out in outpatient endoscopy units. The postal information booklets and their unique, procedure-specific accompanying consent forms were designed both to improve the consenting process and also to conform to Department of Health guidelines.

All of the consent forms and information booklets that are used by the Treatment Centre, Ormskirk District General Hospital (ODGH) and the Endoscopy Unit at Southport District General Hospital (SDGH) comply with the Guidelines for Postal Consenting for Outpatient Endoscopic Procedures produced by the working party of the BSG.

These consent forms are only to be used for outpatient endoscopy procedures that are carried out on the Treatment Centre, ODGH and the Endoscopy Unit, SDGH. These will be checked prior to the procedure as part of the two stage consent as confirmation.

For inpatient endoscopy, delegated consent for gastroscopy, sigmoidoscopy and some colonoscopy should be performed prior to the procedure by the inpatient teams that are appropriately trained. Advanced and more complex procedures such as Endoscopic Cholangio-pancreatography or full thickness polypectomy must be consented using the appropriate Trust consent forms that are available on the hospital intranet and this would usually be by the Endoscopy specialist. Inpatient teams that are trained or delegated to take this consent should do so and the Endoscopist will confirm this prior to the procedure. For endoscopy for inpatients; the patient should receive an information leaflet and the referring clinician should discuss the risks and benefits and document this discussion and this should include the benefits, alternatives and risk of the procedure.

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6.9 Pre-printed consent forms

Some clinical teams have chosen to adopt pre-printed consent forms that are supplemented by information leaflets. This can enhance the process as legibility can be a cause of concern in handwritten consent forms (particularly on the white carbon copy paper). The process of consent should be individualised and these types of information should be presented as a guide to ensure that all the appropriate material risks are discussed rather than a 'tick list'. Annotation or amendment is encouraged to facilitate a thorough consent process.

6.10 Seeking consent for where consciousness maybe impaired (General Anaesthesia and Sedation)

It is unacceptable for patients having elective procedures to receive no information about anaesthesia until their preoperative visit by the anaesthetist; at such a late stage the patient will not be in a position to genuinely make a decision about whether or not to undergo anaesthesia. Patients should, therefore, receive relevant information about anaesthesia in outpatients and have the opportunity to discuss anaesthesia at their preoperative assessment clinic visit.

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of the team carrying out the intervention) to seek consent for anaesthesia, having discussed the risks and benefits. There is a separate anaesthetic consent form. The consent process in anaesthesia can be taken as a form of verbal or written consent as part of a surgical procedure as outlined below. If the process for gaining consent to anaesthesia is a verbal process, taking place between the patient and the anaesthetist, that must be subsequently documented on the Anaesthetic Record sheet filed within the patient's case record. The anaesthetist must complete the relevant section on the Trust Anaesthetic Record sheet marked under: "Anaesthetic Plan: Verbal consent to GA/SAB/Epidural/RA (risks/benefits discussed)" and record any relevant information.

Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then they will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will, therefore, share that responsibility.

With children aged up to 16 years, the anaesthetist should be familiar with and comply with the Trust's Children's Surgical Policy which states which procedures are performed on children at this Trust and which anaesthetists, by name, anaesthetise which age groups of children.

6.11 Interventional radiology

The initial process of information and consent for interventional radiology (minimally invasive imaged guided procedure) starts with the referring clinician explaining the need for the procedure, the risks involved and giving the patient an information leaflet regarding the procedure. Page 2 of the consent form should be completed if the clinician has sufficient knowledge and training of the

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procedure. Page 3 of the consent form should be completed just before the procedure after the radiologist has discussed the procedure further with the patient. This should take place outside the procedural room except in emergency life-saving procedures.

Clinicians referring patients for radiological imaging involving intravenous contrast media must explain the risks and benefits of the use of contrast media and follow the Trust guidelines for prevention of contrast induced nephropathy.

6.12 Emergencies

Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other as a single process, and it is requisite to use the patient's notes to document any discussion and the patient's consent, rather than only using the consent form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

6.13 Provision of information

Give the patient information in clear terms; avoid technical jargon which a patient cannot reasonably be expected to grasp. Abbreviations should be avoided.

The legal duty of care to a patient requires that the person needs to understand not only the nature and purpose of the procedure but also other relevant information, especially all significant possible adverse outcomes. Section 6.2 details the seven essential questions. It is no longer the case that clinicians can argue that they do not have enough time to give information. The law now reminds all clinicians that 'even those doctors who have less skill or inclination for communication, or are more hurried, are obliged to pause and engage in the discussion which the law requires'.

For the process for developing patient information leaflets refer to the Trust Patient Written Information Policy and Procedures.

6.14 Provision for patients whose first language is not English

Mersey and West Lancashire Teaching Hospitals NHS Trust is committed to ensuring that patients whose first language is not English or who communicate using British Sign Language (BSL) receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use family members or children to interpret for a patient who does not speak English or who communicates using BSL unless no interpreter can be obtained or in an emergency situation

The Trust has access to telephone interpreters as well as face-to-face interpreters. Refer to the Trust's Policy to meet the communication needs of patients (previously known as Interpreter Policy) on how to arrange for an interpreter to attend in person.

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6.15 Access to health professionals between formal appointments

After an appointment with a clinician regarding a proposed investigation or procedure, patients will often think of further questions which they would like answered before they make their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure, therefore, ensure that the patient knows how to contact the healthcare team when needed.

6.16 Who is Responsible for Seeking Consent?

The clinician carrying out the procedure is ultimately responsible for ensuring that the patient has given valid consent before treatment begins, although the consultant in overall charge of the patient remains responsible for the quality of medical care.

The seeking of consent can only be delegated to another person as long as they are suitably trained and qualified. This person must have sufficient knowledge of the proposed investigation or treatment and the risks involved otherwise the consent will be invalid. Clinicians are responsible for knowing the limits of their competence and asking for senior advice where necessary. It is the responsibility of consultant supervisors and their trainees to ensure that such training has occurred and is logged in on a departmental register.

6.16.1 Training to obtain consent (delegated consent)

There must be recorded evidence that training has occurred. Examples include:

- Formal training in a classroom setting or completion of a training module
- A local induction on consent for key procedures
- The completion of a procedure based assessment (PBA) where there is a record that consent has formed part of the assessment.
- Informal bedside teaching on consent for a procedure is perfectly acceptable but there has to be a record of this taking place

How much training is required will depend on the level of experience of the proposed consent taker. An experienced trainee may require a simple logged discussion of a few essential points, whereas a more junior doctor may require a lecture or workshop on a particular range of procedures. In determining whether training is adequate, senior staff should consider whether they could defend its adequacy in a court of law.

No doctor at ST2/CT2 level or below, or nurse (any grade) must consent a patient for a procedure or treatment without evidence of delegated consent training which covers the procedure or treatment, except in unavoidable and exceptional emergency situations.

A senior trainee doctor with a final 'exit exam' will be deemed to have sufficient training to undertake delegated consent in their own specialist area without further documented training unless any specific need is identified by the trainee or supervising consultant.

6.16.2 Maintaining the departmental consent register

Each department will maintain a departmental consent register to ensure that the delegation of authorisation to take consent is kept up to date. This is the responsibility of the clinical audit lead to maintain and individual educational/clinical supervisors and trainees must log changes as their

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trainees gain experience and training increases. The register will cover those procedures (or related groups of procedures) for which written consent is normally taken. Documented evidence of previous training at other trusts is acceptable as long as trainees provide this. The register will be audited annually by the departmental clinical audit lead and upon request at other times.

6.16.3 Deliberate breaches of consent will be taken seriously

Any doctor or other clinician who inappropriately delegates or puts pressure on another clinician who does not feel competent to do so risks being referred for investigation under the Trust disciplinary procedure, and referral to their professional body in serious cases. Likewise, any junior doctor or clinician who wilfully consents a patient without the required delegated permission may also risk being referred for investigation. These events must be reported on the Datix system.

6.17 Duration of consent

In general, when a patient gives valid consent then that remains unless the patient withdraws it. However, if new information becomes available regarding the proposed treatment in the interim, then the patient should be alerted by the treating clinician and consent should be reconfirmed. The same applies if the patient's condition has significantly changed. It is good practice to reaffirm the consent if a significant time interval has elapsed between the original consent and the procedure.

6.18 Additional procedures

During an operation it may become apparent that the patient may benefit from a procedure that was not within the scope of the original consent. If the situation is an immediately life threatening emergency then the additional procedure may be justified if it is in that person's best interests. However, the additional procedure must not be performed merely because it may be convenient to the surgeon or patient. If possible seek the views of the patient regarding possible specified additional procedures when seeking consent for the original proposed procedure. Any refusals must be respected provided the patient is fully awake and aware. Except to save life, removing body parts (for example reproductive organs) or doing other procedures outside the scope of the agreed consent is likely to lead to a complaint and litigation and may be regarded as assault.

6.19 Refusal or Restriction of Treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in certain circumstances governed by the Mental Health Act. The situation for children is more complex: see advice below. The following paragraphs apply primarily to adults.

If, after discussion of possible treatment options, a patient refuses **all** treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind you (and where possible the patient) should note this on the form. Where a patient 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. If a patient consents to a particular procedure but refuses certain aspects of the intervention (restriction), you must

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explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

6.20 Children and Young People

6.20.1 Introduction

The basic principle when considering consent and children (including young people) is that there is an overriding duty to act in the best interests of the child. It is essential that children and young people are involved as much as possible when making decisions regarding treatment. Once a person reaches their 18th birthday they are assumed to be a competent adult capable of consenting and refusing, unless other factors prevent them making informed choices.

6.20.2 Age 16 and 17

Once a young person has reached aged 16, their consent to investigation and treatment deemed in their best interest, once made cannot be overruled by anyone with parental responsibility, although this could be overridden by the court.

6.20.3 Age younger than 16

Children under age 16 can consent to investigation or treatment only if they can understand what is being proposed. It is up to the clinician to decide whether the child has sufficient intelligence and maturity to fully understand the nature, risks, benefits and options of the investigation or treatment proposed. Maturity and understanding varies enormously between young persons and the ability to decide will also depend on the complexity, risks and importance of the proposed procedure. A child who has such understanding is described as Gillick competent and this consent cannot be overruled by those with parental responsibility. Children who are not Gillick competent require those with parental responsibility to take investigation and treatment decisions on their behalf. In emergency situations when those with parental responsibility are not available, consider what the child's best interests are and act accordingly; limiting treatment to what is reasonably required to deal with the emergency.

6.20.4 Fraser guidelines

These apply to contraceptive advice and treatment as well as treatment for sexually transmitted infections and termination of pregnancy. Bear in mind that children under the age of 16 cannot consent legally to any sexual activity. Advice and treatment can be given for contraception and sexual health if:

1. They have sufficient intelligence and maturity to understand the nature and implications of the proposed treatment
2. They cannot be persuaded to tell her parents or to allow the doctor to tell them
3. They are very likely to begin or continue having sexual intercourse with or without contraceptive treatment

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4. Their physical or mental health is likely to suffer unless he/she received the advice or treatment
5. The advice or treatment is in the young person's best interests

Beware: all the conditions must be met. If any suggestion of exploitation or abuse refer to safeguarding.

6.20.5 Refusal of treatment by a child/young person

If a child is not Gillick competent and refusing treatment then those with parental responsibility can consent on the child's behalf. Clearly, sufficient time should be taken to encourage the child to accept the intervention or treatment working in partnership with the child, parents and the multidisciplinary team.

If a young person up to the age of their 18th birthday refuses treatment, then their best interests must be weighed up. If the proposed treatment or procedure is to save life or prevent serious deterioration in health then every effort must be made to try and resolve such refusals informally, by involving other members of the multidisciplinary team if necessary. If time allows, it is good practice to obtain a court order to support the intervention. The Trust solicitor can be contacted via the Legal Department in hours or on call general manager out of hours to begin this process in or out of hours which takes approximately 4 hours and requires lengthy discussions with the patient's consultant to brief the judge. If parents refuse treatment that is clearly in a child or young person's best interests who lacks capacity, or if both a young person and their parents refuse such treatment, involve other members of the MDT to try to resolve informally as best as possible before resorting to legal advice where required.

6.20.6 Parental responsibility

The Children Act 1989 sets out persons who may have parental responsibility. These include:

- The child's mother
- The child's father, if he was married to the mother at the time of birth
- The child's legally appointed guardian
- A person in whose favour the court has made a residence order concerning the child
- A local authority designated in a care order in respect of the child
- A local authority or other authorised person who holds an emergency protection order in respect of the child
- Unmarried fathers, who can acquire parental responsibility in the ways outlined below:

For children born after 1 December 2003, unmarried fathers will have parental responsibility if they:

- Register the child's birth jointly with the mother at the time of birth or re-register the birth if they are the natural father
- Marry the mother of their child or obtain a parental responsibility order from the court
- Register with the court for parental responsibility
- Provide written evidence of the above criteria if not married and a copy must be taken for the health records

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The person with parental responsibility must attend in person to give consent; this must not be done over the telephone except in a life threatening situation.

Consent given by one person with parental responsibility is valid, even if another person with parental responsibility withholds consent. However, some 'important decisions' should not be taken by one person with parental responsibility against the wishes of another and referred to the court, for example non-therapeutic male circumcision, immunisation and possibly major experimental treatment. If in doubt seek legal advice.

Where there is doubt about whether a parent is acting in the interest of the child or young person, then the healthcare practitioner would be unwise to rely on the parent's consent, for example if a child alleges abuse and the parent supports psychiatric treatment for the child. Refer to the Children's Safeguarding Team and gain expert advice.

In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity. Where the person with parental responsibility for a child is themselves under 18, they will only be able to give valid consent for the child's treatment if they themselves are Gillick competent (see paragraph 6.2.3 above). Whether or not they have capacity may vary, depending on the seriousness of the decision to be taken.

Where a child is a ward of court, no important step may be taken in the life of the child without the prior consent of the court. This is likely to include more significant medical interventions but not treatment for minor injuries or common diseases of childhood.

If a local authority has the parental responsibility to give consent then they must sign any form by personal attendance, not by fax or e mail.

6.20.7 Research

Where children lack capacity to consent for themselves, parents may give consent for their child to be entered into a trial where the evidence is that the trial therapy may be at least as beneficial to the patient as the standard therapy. It may also be compatible with the welfare principle for a person with parental responsibility to give consent to a research intervention that is not strictly in the best interests of the child, but is not against the interests of the child either. Such an intervention must involve only minimal burden to the child. Decisions about experimental treatment must be made in the child's best interests.

6.20.8 Using children as bone marrow donors

This is covered by the Human Tissue Authority's code of practice on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation and this must be followed.

6.21 Specialist Consent Issues

The Human Tissue Act 2004 makes consent the fundamental principle in the lawful retention and use of body parts, organs and tissue from the living and deceased. It does not cover the removal of tissue from living patients and the usual consent principles apply to this. Human tissue can be very valuable in education and research and its use may lead to developments in medical

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knowledge and improvements in healthcare for all. At present, the Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes. A patient's refusal **MUST** be clearly documented in the patient's case record and signed and dated entry by the clinician.

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out process must apply. Information sheets are to be placed in local areas, e.g. out-patient clinics, phlebotomy areas, explaining to patients that their anonymised sample/s may possibly be used with their agreement only in areas other than diagnosis, e.g. public health monitoring, teaching, audit and quality assurance. Patients are to be given the opportunity of opting-out if they so wish by informing the person obtaining the sample. The latter is to record this information on the laboratory request form to alert laboratory staff to this request.

The Department of Health believes that tissue samples may be used for quality assurance purposes without requiring specific patient consent provided there is an active policy of informing patients of such use. [Refer to the Human Tissue Act or Head of Quality Laboratory services for guidance]

This is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudo-anonymised.

Foetal tissue is regarded as the mother's tissue. However, because of the sensitivity attached to this subject, consent should be obtained for the examination of foetal tissue and for its use for all scheduled purposes, regardless of gestational age.

Consent is required for a post-mortem (unless under the authority of the coroner) and removal, storage and use of any tissue including slides for a variety of purposes - see the HTA consent code of practice for details.

6.22 Limited Consent

A 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 or her decision, then that decision must be respected.

In situations where the patient is a child under 16 who is not Gillick competent and where parental refusal conflicts with the best interest of the child, then it is permissible to consider treatment despite parental refusal.

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. It is important that a senior clinician

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makes clear to the patient, preferably in the presence of a clinical witness, the possible consequences and hazards of this limited consent and a detailed record must be documented in the case notes.

The patient should also be given the opportunity to have a relative and/or representative of their religious organisation present.

6.23 Clinical photography and conventional or digital video recordings

Consent should be obtained for any visual or audio recording, including photographs or other visual images. The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made. If it is to be used for teaching, audit or research, people must be aware that they can refuse without their care being compromised and that when required or appropriate it can be anonymised. Consent form 6 should be used in this case.

Careflow Connect has functionality for taking of medical images on personal devices. This is only for the purpose of medical care and these photographs require verbal consent to be given by the patient. These images are not to be used for education, teaching or publication without prior written permission from the patient.

It is not permissible to record, transmit or publish any patient images without prior written consent.

7. Training

The Trust offers generic training for clinicians who are responsible for taking consent. This has been provided as a classroom based learning session but will move to an e learning package which is being prepared. As described previously, directorates are responsible for organising delegated consent.

What aspect/s of this policy will require staff training?	Which staff groups require this training?	Is this training covered in the Trust's Statutory & Mandatory Training Policy?	If no, how will the training be delivered?	Who will deliver the training?	How often will staff require training	Who will ensure and monitor that staff have this training
Full content	Any clinical staff who are required to take consent	No	Individual training requirements must be identified by the clinician and their line manager	There are a range of training options as identified in section 6.16.1	As required and identified by the clinician and their line manager	Line manager

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8. Monitoring Compliance

8.1 Key Performance Indicators (KPIs) of the Policy

No	Key Performance Indicators (KPIs) Expected Outcomes
1	All audit forms to be fully and correctly completed
2	No litigation occurring due to failure of consent process

8.2 Performance Management of the Policy

Minimum Requirement to be Monitored	Lead(s)	Tool	Frequency	Reporting Arrangements	Lead(s) for acting on Recommendations
A standardised consent audit pro forma is used to audit compliance with consent forms	Clinical Audit Lead and QICA consent audit lead	Consent Audit tool, using a PDSA cycle	Annually	CEC, as part of the annual Quality Improvement and Clinical Audit Report	Chair of Clinical Audit Leads Group
Delegated consent audit	Random sample	Departmental Clinical audit lead	Annually for each speciality	Clinical Audit Leads Group	Clinical Audit Leads Group
Litigation arising from failure to adhere to consent process	Chair of Claims Governance group	Medical director monthly report	Monthly	CEC	Chair of claims governance group

9. References/Bibliography/Relevant Legislation/National Guidelines

No	Author	Year	Title	Ed	Place of Publication	Publisher
1	GMC	2020	Decision making and consent	1	London	https://www.gmcuk.org/ethicalguidance/ethical-guidance-fordoctors/decision-making-andconsent
2	GMC	2008	Consent: patients and doctors making decisions together	1	London	https://www.gmcuk.org/ethical-guidance/ethical-guidance-fordoctors/consent
3	RCR		Standards for patient consent particular to radiology	2	London	https://www.rcr.ac.uk/publication/standards-patient-consentparticular-radiology-secondedition
4	GMC	2017	0-18 years: guidance for all doctors	2	London	https://www.gmcuk.org/ethical-guidance/ethical-guidance-fordoctors/0-18-years
5	CQC	2017	Gillick competency and Fraser Guidelines	1	London	https://www.cqc.org.uk/guidance-providers/gps/nigelssurgery-8-gillick-competency-fraser-guidelines
6	Gov.uk	2018	Parental rights and responsibilities	1	London	https://www.gov.uk/parentalrights-responsibilities
7	HTA	2017	HTA codes of practice and standards	2	London	https://www.hta.gov.uk/htacodes-practice-and-standards0
8	NMC	2018	The Code	3	London	nmc-code.pdf
9	GMC	2010	Treatment and care towards the end of life: good practice in decision making	1	London	Treatment and care towards the end of life - GMC (gmc-uk.org)
10	Gov.uk	2019	Organ Donation (Deemed Consent) Act	1	London	Organ Donation (Deemed Consent) Act 2019 (legislation.gov.uk)

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10. Related Trust Documents

No	Related Document
1.	Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS) Policy
2.	Safeguarding Adults Policy
3.	Safeguarding Children & Young People Policy
4.	Policy to meet the communication needs of patients (previously Interpreter Policy)
5.	Procedure for Requesting a Hospital Post Mortem Examination previously Policy for Requesting an Autopsy
6.	Code of Confidentiality Policy
7.	Mobile Device Policy
8.	Children's Surgical Policy
9.	Patient Written Information Policy and Procedures

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11. Equality Analysis Screening Tool

The EIA screening must be carried out on all policies, procedures, organisational changes, service changes, cost improvement programmes and transformation projects at the earliest stage in the planning process. Where the screening identifies that a full EIA needs to be completed, please use the full EIA template.

The completed EIA screening form must be attached to all procedural documents prior to their submission to the appropriate approving body. A separate copy of the assessment must be forwarded to the Head of Patient Inclusion and Experience for monitoring purposes via the following email, cheryl.farmer@sthk.nhs.uk. If the assessment is related to workforce a copy should be sent to the workforce Head of Equality, Diversity and Inclusion for workforce equality&diversity@sthk.nhs.uk.

If this screening assessment indicates that discrimination could potentially be introduced then seek advice from either the Head of Patient Inclusion and Experience or Head of Equality, Diversity (Workforce) and Inclusion.

A full equality impact assessment must be considered on any cost improvement schemes, organisational changes or service changes that could have an impact on patients or staff.

Title of function	Clinical Consent Policy
Brief description of function to be assessed	Policy to ensure that clinical staff understand all aspects of patient consent so that the rights of patients regarding permission for examination and treatment are protected at all times. It describes the process of seeking consent, what documentation to use, what valid consent means, how to ensure consent is voluntary, what information must be given and what to do in emergency situations. It also covers a number of special situations including what to do when a patient lacks capacity, what the issues are for children and young adults and what to do when consent is refused.
Date of assessment	11/04/2024
Lead Executive Director	Peter Williams
Name of assessor	Anne Rosbotham-Williams
Job title of assessor	Deputy Director of Compliance

Equality, Diversity & Inclusion

Does the policy/proposal:

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- 1) Have the potential to or will in practice, discriminate against equality groups
- 2) Promote equality of opportunity, or foster good relations between equality groups?
- 3) Where there is potential unlawful discrimination, is this justifiable?

	Negative Impact	Positive Impact	Justification/ evidence and data source
Age	No	Yes	The Policy provides additional information to ensure that the rights of children and patients with disabilities, communication needs and specific beliefs are protected.
Disability	No	Yes	
Gender reassignment	No	No	
Pregnancy or maternity	No	No	
Race	No	Yes	
Religion or belief	No	Yes	
Sex	No	No	
Sexual orientation	No	No	

Human Rights

Is the policy/proposal infringing on the Human Rights of individuals or groups?

	Negative Impact	Positive Impact	Justification/ evidence and data source
Right to life	No	Yes	The processes outlined in the Policy ensure that lifesaving treatment can be provided
Right to be free from inhumane or degrading treatment	No	Yes	The Policy maintains the rights of patients to make their own decisions
Right to liberty/security	No	No	
Right to privacy/family life, home and correspondence	No	No	
Right to freedom of thought/conscience	No	No	
Right to freedom of expression	No	No	
Right to a fair trial	No	No	

Health Inequalities

Is the policy/proposal addressing health inequalities and are there potential or actual negative impact on health inequality groups, or positive impacts? Where there is potential unlawful impacts is this justifiable.

	Negative Impact	Positive Impact	Justification/ evidence and data source
Deprived populations	No	No	
Inclusion health groups	No	No	
5 child clinical areas	No	No	
5 adult clinical areas	No	No	

Outcome

After completing all of the above sections, please review the responses and consider the outcome.

Is a full EIA required?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Please include rationale: The Policy positively supports the rights of patients.
--------------------------------	--

Sign off

Name of approving manager	Alex Benson
Job title of approving manager	Assistant Medical Director
Date approved	

12. Data Protection Impact Assessment Screening Tool

If you answer **YES** or **UNSURE** to any of the questions below a full Data Protection Impact Assessment will need to be completed in line with Trust policy.

	Yes	No	Unsure	Comments - Document initial comments on the issue and the privacy impacts or clarification why it is not an issue
Is the information about individuals likely to raise privacy concerns or expectations e.g. health records, criminal records or other information people would consider particularly private?		X		
Will the procedural document lead to the collection of new information about individuals?		X		
Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?		X		
Will the implementation of the procedural document require you to contact individuals in ways which they may find intrusive?		X		
Will the information about individuals be disclosed to organisations or people who have not previously had routine access to the information?		X		
Does the procedural document involve you using new technology which might be perceived as being intrusive? e.g. biometrics or facial recognition		X		
Will the procedural document result in you making decisions or taking action against individuals in ways which can have a significant impact on them?		X		
Will the implementation of the procedural document compel individuals to provide information about themselves?		X		

Sign off if no requirement to continue with Data Protection Impact Assessment:

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Confirmation that the responses to the above questions are all NO and therefore there is no requirement to continue with the Data Protection Impact Assessment

Policy author

Alex Benson

Date 12/04/2024

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