University Hospitals of Derby and Burton NHS Foundation Trust

CONSENT POLICY

POL-CL 1903/02	**Version:** V1	**Status:** Final		**Author:** Richard Falerio **Job Title:** Medical Patient Safety Specialist
	Version	**Date**	**Author**	**Reason**
	1	Feb 2024	Sandra Coates and Nicola Smith	Separation of Previous Consent and MCA Policies.

Intended Recipients: All healthcare professionals

Training and Dissemination: Publicised on Intranet and disseminated via Medical Directors Office

To be read in conjunction with:

- Interpreting and Translation Services Policy
- Photographic & Video Recording Consent and Confidentiality Policy
- Trust Policy and Procedures Relating to the Death of an Adult Patient
- Radiological Interventional Procedures Consent Document
- Managing Requests of Exclusion from Treatment with Blood Components / Products Policy
- ReSPECT click here for access to UHDB Trust Policy
- Trust Mental Capacity Act Policy

In consultation with:

- Task and Finish Group - Consent

EIRA Stage One Completed **Yes**
Stage Two Completed **Yes**

Approving Body and Date Approved	Trust Delivery Group
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Contact for Review	Medical Directors Office Manager
Executive Lead Signature	Executive Medical Director
Approving Executive Signature	Executive Medical Director

Contents

Key Consent principles from Royal College of Surgeons (RCS) 2016 and General Medical Council (GMC) 2020)

The following 6 key principles underpin the consent process:

- The aim of the discussion is to give the patient the information they need to decide what treatment or procedure (if any) they want.

- The discussion must be tailored to the individual patient. You need to find out what matters to the patient about their health. You must explore their needs, values, and priorities.

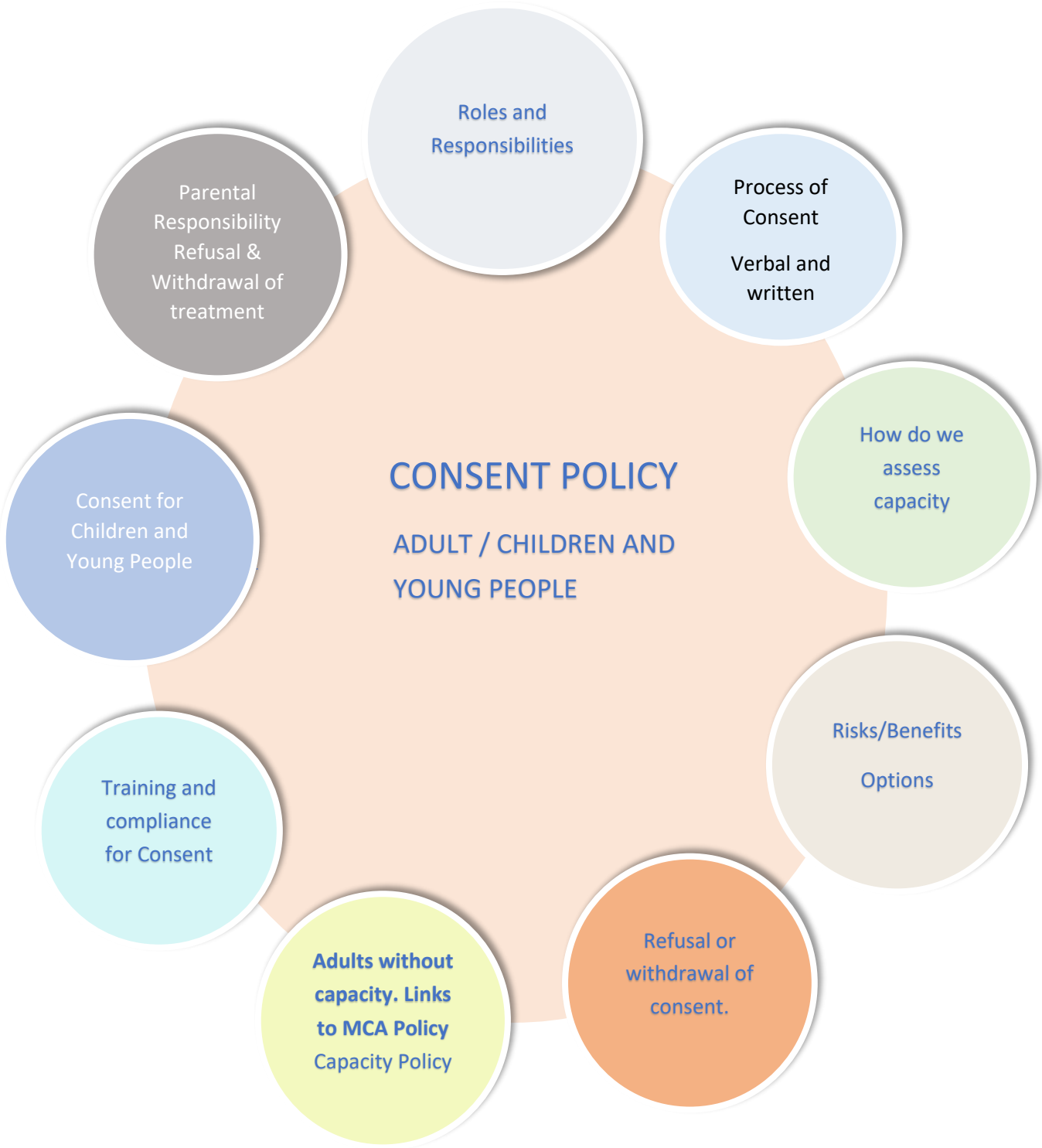
- All reasonable treatment options, along with their implications, should be explained to the patient. This should include benefits, risks and alternatives including the option to decline treatment.

- Material risks for each option should be discussed with the patient. **The test of materiality is twofold: *whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should be aware that the particular patient would likely attach significance to it*.**

- Consent should be written and recorded. If the patient has **made a decision**, the consent form should be signed at the end of the discussion. The signed form is part. of the evidence that the discussion has taken place, but provides no meaningful information about the quality of the discussion.

- In addition to the consent form, a record of the discussion including contemporaneous documentation of the key points of the discussion, hard copies or web links of any further information provided to the patient, and the patient's decision should be included in the patient's case notes. This is important even if the patient chooses not to undergo treatment.

Consent Policy Infographic



1.0 Introduction

1.1 Rationale

This policy has been developed to standardise the consent process and improve patient safety and patient experience across the five sites which make up the University Hospitals of Derby and Burton (UHDB): Royal Derby Hospital (RDH), Queen's Hospital, Burton (QHB), Florence Nightingale Community Hospital (FNCH), Sir Robert Peel Community Hospital (SRP) and Samuel Johnson Community Hospital (SJH) referred to in this document as "The Trust".

The aim of the Policy is to ensure that the Trust is operating effective controls that protect the human rights and safety of patients, respect autonomy and to support good practice. This Policy links closely with the Trust Mental Capacity Act Policy.

Healthcare Professionals taking consent must ensure that patients are aware of any "material risks" involved in a proposed treatment, and of reasonable alternatives, following the judgment in the case *Montgomery v Lanarkshire Health Board*. (Appendix 2)

This is a marked change to the previous "Bolam test", which asks whether a doctor's conduct would be supported by a responsible body of medical opinion. This test will no longer apply to the issue of consent, other than for determining what is a material risk, although it will continue to be used more widely in cases involving other alleged acts of negligence.

In a move away from the 'responsible doctor' to the 'reasonable patient', the Supreme Court's ruling outlined the new test: "The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

A person has a fundamental legal and ethical right to determine what happens to their own body. Valid consent is therefore absolutely central in all forms of healthcare, from undertaking a physical examination or providing personal care, through to performing major surgery. Seeking consent is also a matter of common courtesy between healthcare professionals and a person and staff must work in partnership with them.

The right to be given clear and transparent information about a recommended examination, treatment or investigation, including the risks and benefits associated with that treatment and available alternatives, and the right to accept or refuse examination, treatment or investigation is enshrined in the NHS Constitution.

This policy is issued and maintained by the Executive Medical Director on behalf of the Trust, at the issue defined on the front sheet, which supersedes and replaces all previous versions.

1.2 Objective

The purpose of the policy is the desire to ensure robust consent processes across the Trust and to provide supplementary local information to national guidance and professional training, setting out the standards that must be upheld. It aims to provide advice and guidance to ensure that all healthcare professionals, including those in training comply with professional and legal standards on seeking consent in their daily practice.

Healthcare professionals must work in partnership with their patients to ensure patients are involved in planning and making decisions in relation to their healthcare.

The Department of Health, National Institute of Health and Clinical Excellence (NICE) and various professional bodies such as the General Medical Council (GMC) have issued a range of guidance documents on consent, and these should be consulted for details of the law and good practice requirements on consent. The law relating to consent has its origins in common law, but other important legislation relating to this Policy includes the Mental Capacity Act 2005, Mental Health Act 1983, and Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

1.3 Roles and Responsibilities

Head of Safeguarding and Vulnerable People and the Trust MCA Lead - has the responsibility for:

- The MCA Lead who provides training for frontline staff in MCA and undertakes audit of performance and for ensuring that MCA action plans are implemented, monitored and followed up where necessary. To provide advice and guidance to General Managers / team leaders and frontline staff regarding the lawful authority for proposed examination, care or treatment. Also responsible for the Deprivation of Liberty Safeguards.

Divisional Clinical Directors - have the responsibility for ensuring that:

- The Service Leads/ Clinical Governance Leads discharge their duties as described below.

Medical/ACP/ Nursing/ AHP Service Leads/ Clinical Governance Leads - have the responsibility for:

- Ensuring that the policy is followed within their areas of work
- All staff within their specialty have undergone consent training as applicable

All staff seeking consent

- It is always best for the person treating the patient to seek the patient's consent. However, the person treating the patient may wish to delegate this to a health professional who can perform the procedure or have knowledge of the procedure in question. The health professional must be competent and have had generic training to seek consent.

Where the health professional obtaining consent is not capable of performing the procedure

- Where the health professional providing the information and obtaining consent is not capable of performing the procedure, local arrangements will be put in place to ensure the patient has proper access to the delegating clinician / appropriate colleagues so that any problems or queries which cannot be answered by the person explaining the treatment can be easily and speedily addressed.

  All Healthcare professionals seeking delegated consent must have received specific training for seeking consent.

Health professional carrying out procedure

- The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.

All staff undertaking routine everyday care

- Have the responsibility for gaining consent prior to implementing any routine care. Although these examples are not exhaustive this may include: taking a blood pressure reading, assisting with personal care such as washing, dressing and feeding, facilitating the transfer of patients from a chair to a wheelchair and taking samples of blood. All staff have the responsibility to undertake mandatory and update training on mental capacity including consent.

1.4 Scope

This Policy applies across the Trust and to all individuals involved with seeking consent to examination, treatment or investigation.

1.5 Glossary / Terms Used

The following terms and abbreviations have been used within this document:

Term	Definition
Person	An individual seeking or undergoing treatment, investigation or examination within UHDB. This individual may also be known as a patient.
Healthcare Professional	All individuals involved with seeking consent to examination, treatment or investigation under employment within the Trust.

Healthcare Records	Electronic and/or paper health documentation forming an individuals' record.
Children	People aged below 16 years.
Young People	People aged 16 and 17 years.

2.0 Consent Processes

2.1 What is Consent?

The GMC (09 November 2020, page 6) describes consent as *"a fundamental legal and ethical principle. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can. The exchange of information between doctor and patient is essential to good decision making. Serious harm can result if patients are not listened to, or if they are not given the information they need - and time and support to understand it - so they can make informed decisions about their care."*

Consent must be sought by all healthcare professionals. It is a continuous process, and a person has the right to change their mind. Healthcare professionals must work in partnership with the person, listen to and respond to concerns and preferences. Different approaches may be necessary, and the amount of information shared will vary dependent on the individual person's circumstances.

Healthcare professionals must be satisfied that they have a person's consent or other valid and lawful authority before examination, treatment or investigation.

Consent is a person's informed agreement for a health professional to undertake a physical examination, provide care and/or treatment. A person may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), verbally, or in writing.

For the consent to be valid, the person must have capacity to make the decision with sufficient and appropriate information and not be acting under duress. Where they lack capacity the framework of the Mental Capacity Act (2005) must be followed.

2.2 When do we need to assess capacity?

The Mental Capacity Act (MCA) 2005 and Codes of Practice sets out the statutory framework for making decisions for people who lack capacity to make decisions themselves. Where a person lacks capacity, any decision must be made following the principles and processes of the MCA

A standard principle of the MCA is the presumption that the person is able to make their own decisions. All efforts should be made to support and encourage the person to make their own decisions. If, during discussion with the patient, there is reason to doubt the patient's capacity, the 2-stage test as required in the MCA 2005 should be adopted. The professional should use the Trust Template to record the assessment. Click the link below:
https://neti.uhdb.nhs.uk/download.cfm?doc=docm93jijm4n21147.docx&ver=57463

A person is entitled to make a decision which may be perceived by others to be unwise or irrational, as long as they have the capacity to do so.

Under the MCA, the healthcare professional is required to make an assessment of capacity before carrying out any care or treatment if there is a reasonable belief someone lacks capacity.

Mental capacity is not fixed and may change over time, a person may still have the capacity to make a decision on another issue.

2.3 Process for Obtaining Consent

The provision of information is central to the consent process. Before patients can come to a decision about examination, care or treatment, they need comprehensible, comprehensive and in some cases very specific information of rare risks and risks pertinent to their individual health / circumstances (Montgomery) about their condition. This will also include information about possible care, treatments and investigations and their

risks and benefits (including the risks / benefits of doing nothing) (See Briefing Note at Appendix 1, p29). They also need to know whether additional care, treatment or procedures are likely to be necessary as part of the original proposal, for example a blood transfusion, or the removal of particular tissue. As part of making a decision about examination, care or treatment patients will need information about what will happen: where they will go, how long they will be in hospital, how they will feel afterwards and so on.

There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented. Click link for Royal College of Surgeons Tips: https://rcpsg.ac.uk/college/speaking-up-for-the-profession/policy-reports-and-publications/consent/tips-for-foundation-doctors-trainees-and-their-supervisors

The Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English. Sign Language, telephone and face to face interpreters are available. For information relating to interpreting services and booking please click here for access to the Trust Processes and Procedures for Interpreting and Translation Services Policy (POL-CL/2233/18)
Trust Policies Procedures & Guidelines catalog › Details for: Interpreting and Translation Services - Trust Policy and Procedure (koha-ptfs.co.uk).

There may be other considerations around the provision and communication of information:

- Communicating in an appropriate way. For example, could the information be explained or presented in a way that is easier for the person to understand?
- Simple language should be used, avoiding jargon. Use of pictures or objects could be helpful.
- Making the person feel at ease. For example, are there particular times of the day when a person's understanding is better, or will a particular environment make them feel more at ease?
- Supporting the person. For example, can anyone else help or support the person to understand information and to make a choice?
- Family, carers and others who know the person well can advise on the most effective methods of communication.

Information will normally be provided verbally through discussion, but a patient (and carers) may also be offered written information in the form of information leaflets or printed sheets to aid in the decision-making process. It may also be appropriate to direct patients/ carers to particular websites/ external organisations where further information is available.

In most cases where a consent form signed by the patient is required. Treatment options will generally be discussed **well in advance of the actual procedure being carried out**. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have **at least two stages:** the first being the provision of information, discussion of options and initial decision, and the second being confirmation that the patient still wants to go ahead, which can be completed on the day of surgery. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

PLEASE NOTE: Patients are required to have a pregnancy status check if they could be physiologically pregnant, even if they don't identify / present as a female, if a planned procedure could harm or impact a pregnancy. A refusal by a patient to have a pregnancy check - even once the

risks have been explained - may result in the cancellation of a planned procedure because of the risk of harm to the foetus.

Clearly in urgent situations, the discussion of options and confirmation that the patient wishes to go ahead will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a 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.

The process for obtaining consent will vary depending on the clinical situation and the person's circumstances. In many cases, it will be appropriate for a healthcare professional to initiate an examination, investigation, or treatment immediately after discussing it with the person.

The gaining of consent in these circumstances is therefore a **Single stage process.**

For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the person's condition and whether there are any significant risks. If the person is willing for the technique to be used, they will then give their consent and the intervention can go ahead immediately. In many such cases, it is entirely appropriate for consent to be given verbally but it will still need to be recorded in the healthcare records.

In **most cases** where written consent is being sought, investigation and/or treatment options will be discussed well in advance of the actual intervention being carried out and in a **two or more-stage process** over a whole series of consultations with a number of different health professionals.

Patients receiving elective treatment or investigations for which a consent form signed by the patient is required should be familiar with the contents of their consent form before they arrive for the actual procedure and should have received the patient copy of the page from the consent form documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment.

Consent forms can be, and often are, signed before a person arrives for treatment or investigation. However, a member of the healthcare team must check with the person if they have any further concerns, their condition has changed, and to confirm they still consent to the treatment or investigation. This check must be recorded on the Consent Form.

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 time to respond to the person's questions and provide adequate information. Clinicians should then check before the procedure starts that the person still consents.
In no circumstances should a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment.

All the stages of the consent process must be documented in the healthcare records.

If new information becomes available regarding the proposed intervention between the times when consent was obtained and when the intervention is undertaken, the healthcare professional must inform the person and re-assess their consent or refusal.

It must be remembered that for consent to be valid, the person must always feel that it would have been possible for them to refuse, or able to change their mind. It will rarely be appropriate to ask a person to sign a consent form after they have begun to be prepared for treatment or investigation unless this is unavoidable because of the urgency of the person's condition.

The consent form can be used as a means of documenting the information stage(s), if appropriately designed to do so, as well as the confirmation stage. Healthcare professionals must ensure they record the detail of discussions with the person in the medical notes and/or in a letter to the person and/or on the consent form all of which is then kept with the person's healthcare records. The quantity and detail must be proportionate

to the clinical situation and procedure. This must include the information discussed, any specific requests by the person, any written, visual, or audio information given to the person and their responses, and details of any decisions that were made.

People increasingly want to participate in choosing their care, and literature for patients is a useful resource. Written information leaflets can be read and absorbed at a patient's own pace. Good written patient information can give patients confidence and thus improve their overall experience as a patient and also remind them of what their health care professional told them. It gives people time to go away, read the information and think about the issues involved.

The Trust's internally produced patient information leaflets can be located on the internal intranet and/ or the external website using these links:

- Patient information leaflets (intranet)
  - Adult Information Leaflets | z UHDB Intranet
  - https://neti.uhdb.nhs.uk/patient-leaflets-childrens

- Patient information leaflets (external website)
  - Patient leaflets | Adults | UHDB Trust | University Hospitals of Derby and Burton NHS
  - Information leaflets | Children's | UHDB Trust | University Hospitals of Derby and Burton NHS

Please remember it is the responsibility of the person offering the written information to ensure that it is the most appropriate and up-to-date information for the patient.

In some circumstances, a patient may not wish to be given as much detail as would usually be explained. In these cases, the patient choice should be respected but the patients' request for limited information only **MUST** be documented on the Consent Form and within the Medical Notes.

2.4 Verbal or Written Consent?

There are very few occasions where the law specifically requires written consent – for example, in relation to the storage and use of gametes and embryos in fertility treatment. But in the main, a verbal consent is just as valid as written consent. Consent is a process – it results from open dialogue, not from getting a signature on a form.

Completed consent forms provide some evidence that consent was obtained but mean little beyond that – it is important to realise that they do not constitute proof that the consent was valid. If there is any dispute over whether valid consent was obtained, the key issue will not be whether the patient signed a form or not, but whether they were given all the information they needed to make a considered decision. It is, therefore, crucial that the essential elements of discussions with the patient are documented in the medical record.

The notes do not need to be exhaustive but should state the nature of the proposed procedure or treatment and itemise the risks, benefits and alternatives brought to the attention of the patient. Any particular fears or concerns raised by the patient should also be noted.

Verbal consent means that **the individual obtaining consent reads/explains a verbal version of a consent form** (i.e. an information sheet), and subjects give their verbal consent in place of written consent to participate.

An explicit consent can be given in writing or verbally. However, **you can only rely on a verbal consent if you make a written record of: the name of the individual who gave the consent**.

If you are obtaining a verbal informed consent, you must **submit script containing all of the elements of informed consent that will be presented verbally to the patient**: research/purpose/procedures, risks and benefits.

2.5 Remote Consent

Where a person is not physically present (e.g., in a virtual or telephone consultation) to sign a consent form for an agreed treatment or investigation, the agreement must be documented within the healthcare record and the consent form must be completed in person on or before the day of the intervention. It is best practice to send a copy of all information including a blank consent form for the procedure to the person.

2.6 Cross-site Consent

The Trust is a multi-sited Trust. Therefore, there are circumstances whereby a patient will be consented for a procedure, e.g., at Queens Hospital, that is due to be carried out at another site, e.g., Royal Derby Hospital.

In this event the consent form can be completed at Queens Hospital with the following advice:

- The consent form is scanned into Meditech V6 for the Royal Derby Hospital clinician to review pre-procedure. Confirmation of consent can then occur which must be documented in the patient record.
- The notes, containing the hard copy of the consent form, follow the patient to the procedure site for the clinician to complete the requisite confirmation of consent.
- In exceptional circumstances the consent form can be given to the patient, and they can give this to the clinician at the procedure site for confirmation of consent.

In situations where it is appropriate to formally record the capacity assessment undertaken the Trust request that staff use the mental capacity assessment form to record the capacity assessment and the outcomes. Click on the link to access the form:
https://neti.uhdb.nhs.uk/download.cfm?doc=docm93jijm4n21147.docx&ver=57463

2.7 Open Access Clinics and consent

Where a person accesses clinics directly, it should not be assumed that their presence at the clinic implies consent to a particular examination, treatment or investigation. The healthcare professional must ensure that they have the information they need before proceeding with an examination, treatment or investigation.

2.8 Risks

2.8.1 Aspects of Risk in the consent process

The provision of information is central to the consent process. Before a person can come to a decision about treatment or investigation, they need comprehensive information about their condition. This should include potential or alternative treatments and investigations and the associated risks and benefits. The person may also need to know whether additional procedures are likely to be necessary, e.g., a blood transfusion.

Unless all these elements are appropriately addressed, this may invalidate consent.

2.8.2 Discussing Benefits and Risks

Taken from decision making and consent (GMC: 09 November 2020, page 14):

"You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.

It wouldn't be reasonable to share every possible risk of harm, potential complication or side effect. Instead, you should tailor the discussion to each individual patient, guided by what matters to them, and share information in a way they can understand.

You should include the following information when discussing benefits and harms:

- *Recognised risks of harm that you believe anyone in the patient's position would want to know. You'll know these already from professional knowledge and experience.*

- *The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient's medical history, you'll know some of what you need to share already, but the dialogue could reveal more.*

- *Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during discussion with the patient about what matters to them.*

- *Any risk of serious harm, however unlikely it is to occur.*

- *Expected harms, including common side effects and what to do if they occur.*

You should consider using visual or other explanatory aids to support patients to understand their personalised risk, taking account of their individual clinical and personal circumstances, compared with population level risk."

This is likely to be easier to discuss in advance where possible.

2.8.3 Communication of Risk
When communicating information about risk, use clear language. If the person's first language is not English, use an approved translator.
Some people prefer descriptive words (common, rare etc.) to numbers. The healthcare professional must clarify what these words mean to an individual as interpretation may change depending on the risks involved. When using numbers, natural frequencies with the same denominator (1 in 1000, 15 in a 1000) are usually more easily understood than percentages or fractions. Pictorial descriptions can sometimes help make numbers clearer. At the end of the discussion, it is good practice to check the person's understanding, for example by asking them to repeat what has been explained.

Taken from decision making and consent (GMC: 09 November 2020, page 16):

"You must answer patients' questions honestly and accurately, and as fully as is practical in the circumstances. You must be clear about the limits of your knowledge and, if you can't answer a question, explain whether it is something you are uncertain of or something that is inherently uncertain.

If you are uncertain about the diagnosis, or the clinical effect a particular treatment might have, or if the available evidence of benefits and harms of an option is unclear, you should explain this to the patient. Some things will become clearer after treatment starts, so you should discuss in advance what the arrangements will be for monitoring the effect of the treatment and reviewing the decision to provide it. You should also explore in advance what options the patient might prefer in the future, depending on how treatment progresses, and the factors that might influence their choice."

If the person insists, they do not want to know about the risks of a treatment or investigation (including anaesthesia), the consequences of this should be explained. This discussion should be recorded in writing and the person given the opportunity to change their mind. A person should understand that there may be risks but should not have a detailed explanation forced upon them if unwilling.

2.8.4 Exceptional circumstances where not all relevant information is shared
Taken from decision making and consent (GMC: 09 November 2020, page 13):

"There may be circumstances in which you decide not to share all relevant information with a patient straight away. If you delay sharing information necessary for making a decision, you should let the patient know there's more to discuss and make sure arrangements are made to share the information as soon as it's appropriate to do so. You must make a record of the information you still need to share, your reasons for not sharing it now, and when it can be shared.

You should not withhold information a patient needs to make a decision for any other reason, including if someone close to the patient asks you to. In very exceptional circumstances you may feel that sharing information with a patient would cause them serious harm and, if so, it may be appropriate to withhold it. In this context 'serious harm' means more than that the patient might become upset, decide to refuse treatment or choose an alternative. This is a limited exception…." and legal advice must be sought from the Trust's Legal Services Department

2.9 Additional Procedures

On rare occasions it may become apparent during an operation that the person would benefit from an additional procedure that was not within the scope of the original consent. **It may be justified to perform this additional procedure if a delay would be unreasonable because there is a significant threat to that person's wellbeing, but it should not be done as a matter of convenience.** The GMC states it is good practice to seek the views of the person on possible additional procedures when seeking consent for the original intervention. **If a person has refused certain additional procedures before the anaesthetic, then this must be respected if the refusal is applicable to the circumstances**.

2.10 Clinical Photography and Visual / Audio Recordings
Photographic and video / audio recordings form an important part of a patient's healthcare record, and are used to treat, diagnose and monitor a patient's condition. Gaining informed consent for these recordings is a very important part of the process.

There are 3 levels of consent:

1. For use in Health Records
2. For use in Teaching
3. For Publication

It is good practice for informed consent to be taken by the healthcare professional making the visual recording. This can be in writing, verbal or non-verbal.

Further clarification can be found from the following sources.

The Trust policy can be found at:

Photographic & Video Recording Consent and Confidentiality Policy (koha-ptfs.co.uk)

Institute of Medical Illustrators (IMI), Confidentiality and Consent, A Guide to Good Practice (2020), can be found at:

https://www.imi.org.uk/wp-content/uploads/2020/06/NG_Conf_Consent_2_0.pdf

Medical Photography, Guidelines for Clinicians can be found at:

Medical Photography guidelines for clinicians | z UHDB Intranet

2.11 Who is Responsible for Seeking Consent?
The named consultant or healthcare professional in charge of the person's episode of care will remain ultimately responsible for the quality of medical care provided including obtaining consent. The task of obtaining consent may be delegated to another competent healthcare professional.

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.

2.12 All Healthcare Professionals
The healthcare professional carrying out the intervention is accountable for ensuring the person taking consent is competent to do so.

It is a health professional's own responsibility to work within their own competence and not to agree to perform tasks which exceed that competence.

All regulated healthcare professionals must work within their scope of practice regardless of pressures that may be experienced. If a healthcare professional feels they are being pressurised to seek consent when they do not feel competent to do so they should first contact their responsible Consultant and/or The Clinical Lead for Consent.

All incidents concerning consent must be reported on the Trusts' Incident Management system. (Datix)

2.13 Process for following up those who have obtained consent for a procedure without being authorised to do so
If staff believe that a member of staff has signed a consent form but is not authorised to do so, this should be raised in the first instance to the healthcare professional's line manager and/or the Divisional Management Team, who will initiate a full investigation.

Following the investigation, if it has been identified that clinical staff have obtained consent when not authorised to do so notification will be forwarded to the appropriate governing bodies as detailed below:

- General Medical Council – Registered Doctors
- Local Education and Training Board – for trainee doctors not registered with GMC
- Nursing and Midwifery Council – Registered Nurses
- General Dental Council - Registered Dental Practitioners
- General Pharmacy Council - Pharmacists
- Health And Care Professions Council - Allied Health Professionals

2.14 Does it matter how the person gives consent?
Consent can be given in written, verbal, or non-verbal format. The purpose of a consent form is to record the person's decision and provide evidence of the consent process. It is not a binding contract but will confirm that discussions have taken place.

A person may withdraw consent at any time after they have signed a form.

2.15 Access to Health Professionals between formal appointments
After an appointment with a healthcare professional in any setting, a person may think of further questions which they would like answered before they make their decision. Where possible, the patient should contact their clinical team by telephone or make another appointment via the relevant secretary to discuss the concerns directly. Contact details should be noted on the consent form or provided as separate written patient information. It should be possible to easily access further information without necessarily making another appointment or waiting until the date of treatment or investigation.

2.16 Radiology

2.16.1 Consent to Interventional Radiology
In these technical treatments or investigations, the referring healthcare professional must take responsibility for the first elements of informed consent. They must explain to the person how the intervention fits into the plan of care, any alternatives, and the material risks associated with the intervention for which they are being referred. This information should be included in any patient information leaflet and any delegated consent procedure specific consent form.

On the day of the procedure, the validity of the consent previously given is to be checked and any additional questions or changes in circumstances must be addressed.
Click here to access Trust Guideline:

RADIOLOGICAL INTERVENTIONAL PROCEDURES CONSENT DOCUMENTATION (koha-ptfs.co.uk)

2.16.2. Consent for Investigation or Treatment involving Radiation Exposure
Informed consent is required for all Imaging examinations and procedures and a person or their representatives must be provided with adequate information relating to the benefits and risks associated with the radiation dose from exposure, prior to the exposure taking place.

Consent for non-invasive and diagnostic examinations is verbal consent and is implicit as the patient agrees to undergo the examination. It is reliant on the patient being provided with information by the referrer as well as information provided by the Imaging department. Wherever practicable, referrers should provide patients with information on the examination requested, its risks and benefits. Imaging staff will then provide patients with information as part of the appointments process, when applicable, and when they attend for examination.

Interventional Radiology and other invasive procedures require documented consent. This is a 2-part process:

1. Part 1 - Initial risk and benefit information, particularly relating to the options, alternatives, and any material issues for their specific patient; is provided by the referrer in advance of the procedure.
2. Part 2 - Understanding of risks and benefits is confirmed, and any specific questions answered, by the Interventional Radiologist when the patient attends for their procedure.

Please see Trust Clinical Guideline CG-T/2014/146. Via this link: RADIOLOGICAL INTERVENTIONAL PROCEDURES CONSENT DOCUMENTATION (koha-ptfs.co.uk)

When radiation exposure is included as part of another investigation or treatment these risks must be documented in the consent form.

For some diagnostic scanning the only intervention is the anaesthetic. It is the responsibility of the referring clinician for seeking formal written consent for the imaging under general anaesthetic (GA), as (s)he will have discussed other options including not performing the imaging, and the impact on diagnosis and prognosis of that omission.

The anaesthetist explains the anaesthesia to facilitate the scan, but currently this does not require separate written consent in addition to that taken for the scan.

If patients are referred from another hospital, consent should be taken by the referring clinician and a written agreed policy developed to avoid problems on the day of the scan. In exceptional circumstances, the anaesthetist may seek consent for the scan itself if they understand the reasons for performing the imaging. Each unit should develop their own local written consent procedures to ensure that the scan proceeds as smoothly as possible.

2.17 Consent for Anaesthesia
Where an Anaesthetist is involved in a person's care, it is their responsibility to ensure that appropriate consent for anaesthesia is taken, having discussed the benefits and risks. The Anaesthetist must document the discussion with the person and record consent in the person's healthcare records such as on an anaesthetic chart.

Where the healthcare professional providing the care is responsible for anaesthesia (e.g., where local anaesthesia or sedation is being used), they are responsible for ensuring that the person has consented to it.

2.18 Capture, Storage and Retention of Gametes
Special conditions apply to the consent for the capture, storage and retention of gametes, please refer to the Human Fertilisation and Embryology Acts.

2.19 Consent to Screening
Consent to participation in national screening programmes will follow the relevant national guidance

2.20 Consent to Post-Mortem Examination
The Human Tissue Authority license requires that the undertaking of a post-mortem examination and any retention or use of tissue from the deceased requires formal consent except when performed under the jurisdiction of the coroner or the police.
Further information can be found within the Trust Policy - click on this link: opac-retrieve-file.pl (koha-ptfs.co.uk) and at: https://www.hta.gov.uk/guidance-professionals/hta-legislation/human-tissue-act-2004

A Consultant, Speciality Registrar or Speciality Doctor who has a) received appropriate training and b) previously witnessed post-mortem examination should be identified to discuss the possibility of a post-mortem with the family of the deceased patient.

The Consultant, Speciality Registrar or Speciality Doctor, along with an appropriate member of the Bereavement service (who is trained to provide support during post-mortem consent), should discuss the reasons for suggesting a post-mortem and the potential value with the Next of Kin and any other relevant family members
Where agreement to post-mortem is received this should be documented on Consent Form 1, which the Next of Kin should be asked to sign.

The family must be informed of the date and time of the post-mortem and advised of the Bereavement Service number in case they have any queries or wish to stop the post-mortem before it takes place.

The family must be allowed a cooling off period (at least overnight)

If the family refuses to consent to a post-mortem, they should not be pressurised into it and the threat of referral to the Coroner should NEVER be used in an attempt to persuade the family to give consent.

The family's refusal should be documented in the deceased person's medical records.

Post-mortem staff in the bereavement service will receive additional training in relation to the Human Tissue Act recommendations surrounding hospital post- mortem examinations, to ensure all requirements are met.

See also UHDB Policy for Death of an Adult Inpatient at: opac-retrieve-file.pl (koha-ptfs.co.uk)

2.21 Human Tissue
The Human Tissue Act (2004) regulates the removal, storage and use of human tissue from the living and from the deceased with consent being the fundamental principle underpinning the lawful retention and use of such. It does not apply to therapeutic samples such as blood for tests or tissues taken for histological diagnosis only. Any intervention involving the use of human tissue must be consented to in accordance with the requirements of the Act.

Prior to an intervention, it is the duty of the healthcare professional seeking consent to discuss all aspects of the intervention with the person, including the use of tissue where appropriate. Such details should be recorded in the healthcare records and/or on the consent form. A person should be given the opportunity to refuse permission for tissue taken to be used for educational or research purposes during surgery or another procedure.

The Human Tissue Act (2004) lists the 'scheduled purposes' for which consent is required and that consent must be 'appropriate' i.e., from an appropriate person as identified in the Act. Additional information is available at the Human Tissue Authority's (HTA) website. https://www.hta.gov.uk/guidance-professionals/hta-legislation/human-tissue-act-2004

2.22 Consent to Transfusion
For an acute transfusion or a chronic transfusion programme valid consent must always be obtained and documented in the person's healthcare record by the healthcare professional.

Consent must include informing the person of the risks, benefits and alternatives to blood transfusion and that they can no longer donate blood.

When valid consent is not possible prior to transfusion the person must be informed of the transfusion at the first clinically appropriate opportunity.

Prior to discharge all those who have received a transfusion should be provided with the relevant blood transfusion patient information leaflet.

Please click on the link below to access the Trust Policy and Procedures for Managing Requests of Exclusion from Treatment with Blood Components / Products - opac-retrieve-file.pl (koha-ptfs.co.uk)

For further reading:
Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) *Consent for Blood Transfusion Oct 2020.*
Available at: https://www.transfusionguidelines.org/transfusion-practice/consent-for-blood-transfusion

NICE Blood transfusion NICE guideline [NG24] published 18 November 2015
https://www.nice.org.uk/guidance/ng24/chapter/Recommendations

2.23 Consent to Research
For information on appropriate methods of Consent for Research, please refer to the Health Research Authority website- Informing participants and seeking consent - Health Research Authority (hra.nhs.uk).

All Research taking place at UHDB should have the relevant regulatory approvals in place and should have been submitted to Research and Development (R&D) and "Confirmation of Capacity and Capability" issued. For any queries, please contact uhdb.researchgov@nhs.net

2.24 Duration of Consent
When a person gives valid consent to an intervention, that consent remains valid for an indefinite period, unless it is withdrawn by the person, or circumstances have changed such that the process must be revisited.

If new information becomes available regarding the proposed treatment / intervention between the time when consent was sought and when the intervention if undertaken, GMC guidance states that "a doctor or member of the healthcare team should inform the patient and reconfirm their consent discussing all material risks and benefits with them". A clinician is under a legal duty to take reasonable care to ensure that the patient is aware of any material risk involved in the recommended treatment, and of any reasonable alternative or variant treatments. **Similarly, if the patient's condition has changed significantly in the intervening time, it may be necessary to seek consent again.**

There is no legal directive as to the duration of consent but this Trust recommends any consent be renewed after a 3-month period has elapsed.

2.25 Refusal of Consent to Care and Treatment
An adult with capacity is entitled to refuse any treatment or investigation at any time. A person can make irrational and unwise decisions, but this does not mean they lack capacity. The only exceptions are the circumstances governed by the Mental Health Act 1983 (amended 2007). When a person is assessed as having a mental disorder which may impair informed consent, further specialist assessment should be sought from the Trust Safeguarding Team to ascertain whether there is need for intervention under the Mental Health Act.

The situation for consent and refusal of consent in children is more complex. This is explained in Section for Consent in Children and Young People, pages 24-27.

The following paragraphs apply primarily to adults:
Any refusal of treatment or investigation, at any time, must be clearly documented in the healthcare records.

Where a person has refused a particular treatment or investigation, the healthcare professional must continue to provide all other appropriate care. The healthcare professional must also ensure that the person understands they are free to change their mind and accept treatment or investigation in future; but they must be advised of the consequences of any delay.

If a person gives consent to a particular procedure but refuses certain aspects of the intervention, the healthcare professional must explain to the person the possible consequences of their partial refusal. If the healthcare professional genuinely believes that the procedure cannot be safely carried out under the person's stipulated conditions, the healthcare professional is not obliged to perform it. The healthcare professional must, however, continue to provide all other appropriate care. Where another healthcare professional

believes that the treatment or investigation can be safely carried out under the conditions specified by the person, the initial healthcare professional must be willing to transfer the person's care.

2.26 Withdrawal of Consent
A person with capacity is entitled to withdraw consent at any time, including during the performance of the procedure. It is important to agree in advance how a person might indicate withdrawal of consent during the procedure such as by raising a hand.

Where it appears that a person is or maybe withdrawing consent, it is good practice, if possible, to stop the procedure and establish what the person's concerns are and explain the consequences of not completing the procedure. Withdrawal of consent may reflect the effects of discomfort or pain which could be ameliorated. A healthcare professional may be justified in completing the procedure if in the person's best interests. Assessing capacity during a procedure is difficult and involving the wider team in making this assessment is important. If stopping the procedure at that point would genuinely put the person's life at risk, the healthcare professional may be entitled to continue until that risk no longer applies.
Where consent is withdrawn, the healthcare professional must review the clinical situation with the person and agree a forward plan.

There must be clear documentation in the healthcare records in all cases.

2.27 Advance Decisions to Refuse Treatment
Advance decisions to refuse treatment (ADRT) that are both valid and applicable under the requirements of the MCA will be legally binding for everyone involved in the care of the individual. The MCA and Code of Practice clearly define that the responsibility for making an advance decision lies with the person making it.

For an ADRT to be valid, the person must have had full capacity at the time it was made, and the decision must specifically apply to the current circumstances.

Other provisions also apply:

- The person who made the ADRT must specifically acknowledge that they intend to refuse treatment even where their life may be at risk.
- The ADRT must be in writing.
- The decision must be signed by the person making the ADRT.
- The signature must be witnessed.
- An ADRT made after the appointment of a personal welfare Attorney takes precedence (though consider MCA provisions alongside this also).
- A person with capacity can withdraw an ADRT at any time by any means. Where a patient who now lacks the requisite capacity provides a view inconsistent with the ADRT, seek legal advice.
- Where there is doubt about the applicability or validity of an ADRT, further advice should be sought from the Trusts' Legal Services department.

A member of staff may be involved in the process of helping a person to make an ADRT by providing relevant information as they would in any consent process, but the decision must be the person's own. Staff should not be involved in the witnessing of such documents but should advise the person to find an independent witness.

If a member of staff is made aware of an ADRT or Power of Attorney this must be easily visible in the person's healthcare records.

To raise a query or make a change in a patient record regarding Lasting Power of Attorney please consult the Subject Access Team within Health Records.

2.28 Recommended Summary Plan for Emergency Care and Treatment (ReSPECT)
The ReSPECT process creates personalised recommendations for a person's clinical care and treatment at a future point in time including emergencies.

The ReSPECT document does not constitute a legally binding consent to or refusal of care or treatment. It is used by healthcare professionals to guide decision making about care and treatment (including potentially life sustaining treatments). Where such treatments are declined in advance by a valid and applicable ADRT, e.g., blood products, this is legally binding on treating healthcare professionals.

Where a ReSPECT form includes a decision not to attempt cardiopulmonary resuscitation (DNACPR), there should be a discussion with the person (or their representative/ independent mental capacity advocate (IMCA) should they lack capacity) as part of the consent process for any procedure or operation about any circumstances where this may not be followed.

If a person wishes to maintain a decision not to attempt CPR during any operation or procedure, the healthcare professional proposing that procedure must ensure the person is clear about the risks associated with the procedure and may need to reconsider whether such a procedure remains a valid option in these circumstances.

The ReSPECT form can be used during the consent process to discuss what is most important to the person, including any particular priorities and preferences the person has for their care. This might include certain treatments that they might not wish to receive during or post procedure.

For more information regarding ReSPECT click here for access to UHDB Trust Policy
opac-retrieve-file.pl (koha-ptfs.co.uk)

2.29 Ceiling of Care – Discontinuance of Treatment
The principles around consent are the same for all interventions including the decision not to continue with a course of treatment. Persons with capacity may make this decision on their own behalf either at the time or via an advance decision to refuse treatment.

If the person lacks capacity, the decision not to continue must be made in the best interests of the person.

No person has the right to demand and receive any treatment that is not clinically indicated or is futile, including CPR. In the event of significant disagreement, a second opinion must be sought by consulting with colleagues. If this is inconclusive, please consult the Trusts' Legal Services Department.

2.30 Emergency Situations
In event of an emergency the initial healthcare professional should do what is necessary to sustain life, limb or organ. If possible, consultation with the person or more senior healthcare professional should take place. In life-threatening emergency situations consent is not always necessary when immediate action is required, and the person temporarily lacks capacity to make the decision. The rationale for the decision and the action taken must be documented.

In an emergency situation, where there is doubt as to the appropriateness of treatment, there should be a presumption in favour of life-sustaining treatment until time is available for all those concerned with the care of the person to assess the situation and contribute to a multi-disciplinary decision involving the relatives, carers.

When a person has capacity in an emergency, it may be appropriate to use the person's healthcare records to document any discussion and the person's consent, rather than using a form. The urgency of the person's situation may limit the quantity of information that they can be given but should not affect its quality.

3.0 Adults Without Capacity

3.1. General Principles

Where there is a reasonable belief that an adult may lack capacity, a full mental capacity assessment must be undertaken and be clearly documented in the person's health record. If it is identified that they lack capacity then a Best Interest process must be undertaken. The Trust proforma must be used. https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=a422b8f90b7b26552ea9f311c29061ad

4.0 Provision of Information

The provision of information is central to the consent process.

- The information must be what the reasonable person can expect to be told rather than what the reasonable healthcare professional would be expected to say.

- A person needs sufficient and appropriate information about their condition and about possible treatments/investigations before they can come to a decision. The associated risks and benefits of all options must be explained, including doing nothing.
  A person also needs to know whether additional procedures that may be necessary as part of the procedure, for example a blood transfusion, or the removal of tissue.

4.1.0 Communication

Some people may need special consideration to ensure understanding of the information provided; and high quality, two-way communication is essential in the consent process.

4.1.1 Learning Disability

All efforts must be made to communicate with person with learning disabilities using media suitable to that individual, for example via Easy-read literature and pictures Further advice can be sought from the Trust Learning Disability and Neurodiversity Lead via 01332 340131 ext: 87547.

4.1.2 Communication Difficulties

All efforts must be made to maximise the ability for healthcare professionals to communicate with a person with communication difficulties. These people may need extra time to understand the information and enable them to reach and communicate their decision.

4.1.3 People Whose First Language is Not English

The Trust is committed to ensuring that a person whose first language is not English receives the information they need and are able to communicate appropriately with healthcare professionals. It is not routinely appropriate to use family members or friends to interpret for those who do not speak English unless it is imperative.
For information relating to interpreting services and booking please click here for access to the Trust Processes and Procedures for Interpreting and Translation Services Policy (POL-CL/2233/18)
Trust Policies Procedures & Guidelines catalog › Details for: Interpreting and Translation Services - Trust Policy and Procedure (koha-ptfs.co.uk)

4.2. Access to More Detail

Healthcare professionals must check that a person has had all their questions answered. If a person requests more detailed information than an individual can provide, access to additional support must be obtained. Any members of staff who do not feel competent to provide sufficient information must not do so.

4.3. People Who Decline Information

Taken from decision making and consent (GMC: 09 November 2020, page 30):

"If a patient has chosen an option but doesn't want to discuss the details, you should explain they will need to have some information about what it would involve before you can proceed, such as:

a) *whether the procedure is invasive*

b) *what level of pain or discomfort they might experience and what can be done to minimise this*

c) *anything they should do to prepare for the intervention*

d) *if it involves any risk of serious harm.*

You should try to find out why they don't want to be involved in decision making and explore whether you can do anything to reassure and support them. They might be anxious about the decision or overwhelmed by the information and need time or support to process it.
If, after trying to discuss options with them along the lines set out above, your patient insists that they don't want even this basic information, you will need to judge whether their consent is valid so that you can proceed. This is more likely to be the case if the proposed option is a well-established intervention commonly used for treating the condition they have, and there's reason to believe the patient wants to be treated or cared for rather than take no action…"

In rare circumstances, Healthcare Professionals may seek advice from a second opinion, multiple disciplinary team or the Trusts' legal services department.

Where a person declines to receive the information from a healthcare professional, this must be documented in the healthcare records.

5.0 Training to Take Consent
All healthcare professionals must understand the core principles of consent. Healthcare professionals who are required to obtain consent must receive appropriate generic and specific training which must be readily available. Training content will include updates to the consent policy, relevant legal framework and guidance. Specific training must cover the relevant scope of practice and appropriate delegation with defined accountability and responsibility.

Consultants and SAS doctors should access and complete Essential to Role Training incorporating 'Treatment with Lawful Consent via MLP.

Nurses and AHP's are able to access Consent and Refusal by Adults with Capacity Training via My Learning Passport (MLP) which is recorded on the Learning Management System.

To access the Consent Training package, please contact Learning and Education at UHDB.mandatorytraining@nhs.net

6.0 Seeking Consent for Students and Training
A person must be made aware and consent sought and documented by a healthcare professional before an examination, treatment or investigation is going to be undertaken, assisted or observed by a student or for training purposes. Where a student proposes to conduct a physical examination that is not essential to the person's care then it is mandatory to explain that the purpose of the examination is to further the student's training. The involvement of students and trainees for this purpose may be declined and the refusal must not impact on the person's care.

7.0 Monitoring Compliance
A unified audit of the consent process must be undertaken annually and reviewed by the Consent Steering Group to agree recommendations for further action.

PART TWO - CHILDREN & YOUNG PEOPLE

Term	Definition
Children	People aged below 16 years.
Young People	People aged 16 and 17 years.

8.0 Children and Young People
There are different legal rules governing consent and refusal of treatment for children and young people depending on their age, ability to give consent and their family circumstances. These rules are different from those which govern adults and advice from the local Trust's Legal Services Department should be sought in any difficult circumstances.

For the purposes of this policy and in line with the Department of Health's Reference guide to consent for examination and treatment second edition (2009), 'children' refers to people aged below 16 years and 'young people' refers to people aged 16 and 17 years.

The arena of deprivation of liberty is complex and advice should be sought from the Trust's legal department where it is felt that the care arrangements amount to a deprivation of liberty.

8.1 Consent in Young People
Young people are presumed in law to be capable of consenting to their own investigation or treatment. (The Mental Capacity Act 2005 applies to those 16+). A young person may lack capacity because of an impairment or disturbance in the functioning of the mind or brain in the same way as an adult and the MCA and best interest decisions apply

Parental consent is not required for young people (16 & 17yrs). Best practice states that Healthcare professionals should encourage young people to inform their families and consultation should take place with the young person's parents/those close to them where appropriate. However, if a competent child requests confidentiality this should be respected unless the healthcare professional considers that failing to disclose information would result in significant harm to the child.

Refusal by a competent young person may in certain circumstances be overridden by either a person with parental responsibility or a court. (See Section 8.3 Parental Responsibility).

8.2 Consent in Children
In order to give consent to examine, investigation or provide treatment to a child, consent must be given by a person with the legal authority to do so. There may be more than one person who can consent. It is important that the health professional identifies who is legally able to give consent on behalf of the child. It can, for example, extend to Local Authorities in certain circumstances - see below

Children under the age of 16 are not deemed automatically legally competent to give consent. The courts have determined that such children can be legally competent if they meet Gillick competency. That is, having sufficient understanding and intelligence to understand fully what is proposed and to be able to make an informed decision. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made as the understanding for different interventions will vary.

8.2.1 Children who are Gillick Competent
If the child is Gillick competent and is able to give consent voluntarily after receiving appropriate information, then that consent is valid and additional consent by a person with parental responsibility will not be required. It is however, good practice to involve the child's family in the decision making process if the child agrees. This decision should be respected unless there is a clear risk of harm to the child. In that situation, please consult the Trusts' Legal Services Department.

If a child seeks advice or treatment related to contraception or an abortion, the Health Care professional should advise the child to inform their parents or responsible person and should seek that consent where possible. If the child declines to inform their parents - the health professional should consider the child's competence, the nature of the sexual relationship (and be alert for indications of an abusive relationship), provide advice on implications of sexual activity, the individual's mental health and that it is in their best interest to be given advice and/or treatment without parental authority.

8.2.2 Children who are Not Gillick Competent

Where a child under the age of 16 years is not Gillick competent, consent can be given on their behalf by a person with parental responsibility, where the decision is in relation to things normally within the parental zone of decision making. It is good practice even where a child lacks capacity to involve the child in the decision-making process.

8.3 Parental Responsibility

Persons with 'parental responsibility' (PR) are entitled to give consent on behalf of their children. PR may also be held by the Courts (via the Local Authority) for children subject to an interim care order, emergency protection order or child assessment order, or by the Local Authority for children on a care order. The law emphasises the need for parents (or others) to work actively for what is best for the child, not themselves.

PR means all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his/her property.

It must be noted that not all parents have parental responsibility for their children. If there is any doubt whether an individual has parental responsibility for that child, this must be checked. See appendix A within this policy.

In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity and be acting according to the welfare and best interests of the child. If the healthcare professional is concerned that either is not the case, then advice should be sought from the Trust Safeguarding Team

In an emergency if it is impossible to obtain consent in time and the treatment is vital to the survival or health of the child, it is justifiable to treat a child who lacks capacity without the consent of a person with parental responsibility.

If a child is the subject of a care or supervision order from the Court, treatment decisions can be taken by the Social Services Department, the Social Worker or any appropriate person named in the Order. Urgent treatment may be given in the best interests if delay in obtaining consent as above is experienced.

A local authority acquires parental responsibility for a child when it is granted a care order under The Children Act (1989). It shares PR with those other people who have PR for the child. Other relatives can also be granted PR by the Court such as stepparents, or grandparents. Health professionals should ask to see the Court Order which details this.

More than one person may have PR for the same child at the same time. A person who has PR for a child at any time shall not cease to have that responsibility solely because some other person subsequently acquires PR for the child. Where more than one person has PR for a child, each of them may act alone and without the other (or others) in meeting that responsibility, however it must be considered whether there is a decision which requires the consent of more than one person in a matter affecting the child. The court has determined that certain clinical decisions are so serious that they cannot be made without obtaining consent from all those with PR for a child, e.g.: circumcision in an example of a procedure that the court has determined cannot be performed without the consent of all those with PR for the child. (see **APPENDIX A** for further information) Please note, that whilst rare, the courts do have the power to remove PR also.

8.4 Consideration of Voluntariness

It is important to establish that the decision given by a child or young person is being given voluntarily because children may be more prone to undue influence by adults around them. A healthcare professional who suspects this is the case must discuss it with the Trusts' Safeguarding Team.

8.5 Refusal of Treatment
Where a young person or a child under 16 years old who is Gillick competent, refuses treatment, it is possible that such a refusal could be overruled by those with PR or the court if the refusal would lead to the death or severe permanent injury. You are advised to contact the Trust Safeguarding Team and Legal Department in relation to MCA and issues of children and young people.

Where the treatment required is connected to mental disorder, lawful authority for that treatment can be obtained via the MHA and consideration must be given to ensuring MHA assessment and applying the powers of that legislation.

8.6 Withdrawal of Treatment
It is not a legal requirement to continue a child's life-sustaining treatment in all circumstances. For example, where the child is suffering an illness where the likelihood of survival even with treatment is extremely poor, and treatment will pose a significant burden to the child, it may not be in the best interests of the child to continue treatment.

The decision not to continue with life-sustaining treatment must be made in the best interests of the child. All best interests' decisions should be interpreted more broadly than medical interests and should include emotional and other factors. There is a strong presumption in favour of preserving life, but not where treatment would be futile. There is no obligation on healthcare professionals to give treatment that would be futile. If there is disagreement between those with parental responsibility for the child and the healthcare team concerning the appropriate course of action, seek advice from the Trusts' Legal Services Department.

8.7 Research
There are many ethical and legal issues to consider when involving children and young people in research. For information on Consent of Children and Young People for Research, please refer to the Health Research Authority website - Informing participants and seeking consent - Health Research Authority (hra.nhs.uk)
All Research taking place at UHDB should have the relevant regulatory approvals in place and should have been submitted to Research and Development (R&D) and "Confirmation of Capacity and Capability" issued. For any queries, please contact uhdb.researchgov@nhs.net (Added by JT - Research Governance Lead

9.0 References

- Department of Health (2009). Reference guide to consent for examination or treatment (second edition). [online] GOV.UK. Available at: https://www.gov.uk/government/publications/reference-guide-to-consent-for-_examination-or-treatment-second-edition

- GMC (2020) Decision making and consent. [online] Available at: Decision making and consent - ethical guidance - GMC (gmc-uk.org)

- IMI National Guidelines Consent to Clinical Photography. (2006). [online]. Available at: https://www.imi.org.uk/wp-content/uploads/2020/06/NG_Conf_Consent_2_0.pdf

- Ionising Radiation (Medical Exposure) Regulations 2017 reg 6 schedule 2 (i)

- Ltd, T.I.S. (n.d.). JPAC - Transfusion Guidelines. [online] transfusionguidelines.org.uk. Available at: https://www.transfusionguidelines.org/redbook

- Mental Capacity Act 2005
- Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (General) Regulations 2006
- Mental Health Act 1983

- NHS Constitution

- Nice.org.uk. (2015). Recommendations | Blood transfusion | Guidance | NICE. [online] Available at: https://www.nice.org.uk/guidance/ng24/chapter/recommendations.

- Office of the Public Guardian (2013). Mental Capacity Act Code of Practice. [online] GOV.UK. Available at: https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice.

- Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

- The Children Act (1989)

APPENDIX 1 - Guidance re: Lawful Authority for Undertaking Examination, Care or Treatment for Children: Parental Responsibility (PR)

Births Registered in England and Wales	• If the parents of a child are married when the child is born, or if they've jointly adopted a child, both have PR. • They both keep PR if they later divorce.
Unmarried parents	An unmarried father can acquire PR for his child in 1 of 3 ways: • Jointly registering the birth of the child with the mother (from 1 December 2003) • Getting a PR agreement with the mother (A PR Agreement under the Children Act 1989 is an agreement to which all other people with PR consent. This is a formal document which needs to be signed by all the parties and then registered at court). • Getting a PR order from a court (A PR Order is an order under the Children Act 1989, which unmarried fathers can apply for when the mother refuses to allow the father to be registered or re-registered on the birth certificate or refuses to sign a PR Agreement with him). You must ask for evidence of any of the above in the event that an unmarried father attends with the child on his own.
Step-Parents	A step-parent can only acquire PR for a child in very specific circumstances including: • When the court makes a Child Arrangements Order that the child lives with the step-parent either on their own or with another person. • When the step-parent adopts a child which puts him / her in the same position as a birth parent. • Through the signing of a PR Agreement to which all other people with PR consent. This is a formal document which needs to be signed by all the parties and then registered at court. • When the court has made a PR Order following an application by the step-parent. On acquiring PR, a step-parent has the same duties and responsibilities as a natural parent. In all cases you should ask for evidence of any of the above in the event a step-father attends with a child and consent to treatment is required.
Same-sex parents - Civil partners	Same-sex partners will both have PR if they were civil partners/married at the time of the treatment, e.g., donor insemination or fertility treatment.
Same-sex parents - non-civil partners	For same-sex partners who aren't civil partners/married, the second parent can get PR in the following circumstances: • If a PR Agreement was made. (This would be with the mother's agreement and evidenced in the form of an Order from the Court.) • Civil partnership/marriage of the other parent and making a PR Agreement or jointly registering the birth.

Legal Order Guidance	
Private Fostering	It is an arrangement whereby a child under the age of 16 (or 18 if the child has a disability) is placed for 28 days or more in the care of someone who is not the child's parent(s) or a 'connected person' (someone who has a pre-existing relationship with the child, for example, a teacher who knows the child in a professional capacity). Those caring for a child(ren) under these arrangements will not have PR for the child(ren), therefore consent from the person with PR is required.
Section 20 Children Act 1989	The Local Authority (LA) does **NOT** have PR for a child subject to section 20 care provision.
Interim Care Order (section 38 Children Act 1989)	This is an interim order prior to the final Care Order being made and gives the LA PR for a child. However, the LA MUST consult with and inform other PR holders about important decisions they make for the child.
Care Order (section 31 Children Act 1989)	A Care Order gives the LA PR for a child (the LA MUST consult with and inform other PR holders about important decisions they make for the child i.e., medical treatment).
Emergency Protection Order	Gives the LA PR for the child while at the same time does not remove it from anyone else who has PR in respect of the child.
Supervision Order (section 35 Children Act 1989)	Does not give the LA PR for a child; PR remains with the parent(s).
Child Arrangement Order (section 8 Children Act 1989)	If child arrangements order states that the child will live with a person, that person will have parental responsibility for that child until the order ceases. The parent(s) also retain PR as stated above under PR guidance.
Special Guardianship Order (Adoption and Children Act 2002)	This order discharges any existing care order and grants PR to the Special Guardian(s). Although parents do not lose their right to PR, the Special Guardians will have a higher level of PR than the birth parent(s) should conflict arise.
Placement Order (Adoption and Children Act 2002)	Prospective adopters will acquire PR for the child as soon as the child is placed with them, to be shared with the birth parents and the adoption agency making the placement (i.e., this could be the LA).
Adoption Order (Adoption and Children Act 2002)	When a child is adopted, the PR of their biological (birth) parents as well as any other person who holds PR will end. PR will be held solely by the adopter/s.
Looked After Children	When children and young people become accommodated by the LA, parents are asked to sign a Placement Plan which also has Consent to Medical Treatment section (NB: this does not give authority to anaesthetics). Social Workers should contact parent(s) when children and young people are required to undergo routine examination or treatment. They should involve the parent(s) in discussion regarding the examination or treatment prior to consent being given. Where a child is in need of surgery, a general anaesthetic or other specific medical treatment, the child's Social Worker should actively seek to involve the parent(s) with PR.

	• Consent should be given in writing by the parent and the local authority delegated person as above (but is equally valid if given verbally, provided it was informed and freely given). • Children's wishes and feelings where possible should be obtained, considered and accounted for. • If a Looked After child under 16, who is subject to a Care or Interim Care Order, the Team Manager should give consent if the parent(s) are unable or unwilling to do so. • If a Looked After child requires serious medical treatment, this should be brought to the attention of the LA senior management, who can then give consent and delegate a Social Worker or Team Manager to attend the hospital, discuss the surgery, anaesthetic and risks with the doctor(s). • In a 'life or limb' situation, a Doctor must act in the child's best interest and may proceed without consent. Children receiving medical treatment who are Looked After by another LA should follow the same process as Looked After children locally.

What happens when those with PR disagree?

Disputes between parents can be difficult for everybody involved in the child's care. Health professionals must take care to concern themselves only with the welfare of the child and to avoid being drawn into extraneous matters such as marital disputes.

Generally, the law only requires doctors to have consent from one person in order lawfully to provide treatment (though see above in context of some decisions regarding consensus). However, doctors may feel reluctant to override the dissenting parent's strongly held views, particularly where the benefits and burdens of the treatment are finely balanced, and it is not clear what is best for the child. If the dispute is over a controversial and elective procedure (for example: male infant circumcision for religious purposes), doctors must not proceed without the authority of a court judgement in the case.

In other cases, discussion aimed at reaching consensus should be attempted. If this fails, a decision must be made by the clinician in charge whether to go ahead despite the disagreement.

If you are in any doubt about whether the person with the child has PR for that child, you must check. Others (such as adopted parents, step-parents or the Local Authority) may acquire parental responsibility via specific legal processes.

When babies or young children are being cared for in hospital, it will not usually seem practicable to seek a parent's consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, you must remember that, in law, such consent is required. Where a child is admitted, you must therefore 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.

APPENDIX - 2

BRIEFING NOTE - CONSENT

One of the most controversial areas of medical law is the issue of how much information a patient should be given about the risks of a particular procedure during the consent process.

The decision in ***Montgomery v.Lanarkshire Health Board (2015)*** fundamentally alters the answer to that question.

The new test now requires an explanation of all **material risks** to a patient. A risk is said to be material if it is one to which **the patient is likely to attach significance**.

In this respect, the Judgment brings the law into line with current GMC guidance, as well as guidance provided by other bodies such as the AAGBI (The Association of Anaesthetists of Great Britain and Ireland).

Mrs Montgomery's Case

Mrs Montgomery brought a claim on behalf of her son in respect of his birth in 1999.

As Mrs Montgomery suffered with diabetes, the pregnancy was deemed to be high risk, by virtue of the fact that diabetic mothers are likely to have babies that are larger than normal, with a particular concentration of weight around the shoulders. This creates a 9-10% risk that during delivery the shoulders are too wide to pass through the birth canal, leading to shoulder dystocia.

If this occurs there is a small risk (put at 0.1%) that the umbilical cord will become occluded, causing hypoxia and resulting in consequential cerebral palsy or death.

Mrs Montgomery was not informed of the risk of shoulder dystocia. She claimed that if she had been warned she would have opted for a delivery by caesarean section.

At birth, shoulder dystocia did occur and the cord became occluded, causing hypoxia and resulting in her son sustaining severe brain injury. A claim was brought against the health authority on the basis of the failure to explain the risk of shoulder dystocia.

The Obstetrician's Approach to Consent

The Obstetrician accepted in evidence that she had not warned Mrs Montgomery of the risk of shoulder dystocia. She said she had not done so because *"if you were to mention shoulder dystocia to every [diabetic] mother…then everyone would ask for a caesarean section and it is not in the maternal interests for women to have caesarean sections"*

The Trust in turn relied on expert opinion that there was a responsible body of obstetricians who would not have warned Mrs Montgomery of the risk.

The Law as it Stood

For the last 30 years lawyers and doctors have been taught that the decision in ***Sidaway v. Board of Governors of the Bethlem Hospital (1985)*** set out the law on consent. In Sidaway, the Court said that the issue was to be considered by reference to the famous "**Bolam**" test. In other words, was the consent process one which a responsible body of medical opinion would support? If the failure to warn was supported by a responsible body of opinion, then under the old law, the

Trust would have a defense.

Applying that test, the lower courts had dismissed Mrs Montgomery's claim on the basis that the obstetrician was indeed supported by a responsible body of opinion.

The Appeal to the Supreme Court Judgement and the New Test for consent

The Supreme Court overturned Sidaway unanimously. The old "*responsible body of opinion"* test no longer applies to consent.

The test now to be applied in consent cases was outlined by Lord Reed:

1. In all adults of sound mind, there is a duty to take reasonable care to ensure that the patient is aware of any **material risks** involved in any recommended treatment.

2. A risk is material if it is one where, in the circumstances of the particular case, a **reasonable person in the patient's position would be likely to attach significance to the risk** or the particular individual patient has attached significance to a risk.

The patient is required to understand the seriousness of the risk and the anticipated benefits of the proposed treatment and reasonable alternatives.

Applying this new test, the Supreme Court held that Mrs Montgomery should have been warned of the risk of shoulder dystocia and offered a caesarean section. The Court pointed out that the risk must be regarded as one which would have been significant to Mrs Montgomery. Indeed, the very reason why she had not been told of the risk was that the obstetrician assumed that she would then have asked for a caesarean section.

It is important to remember that the new test only applies to consent. The Supreme Court made it clear that the Bolam test will still apply to the issue of whether the treatment itself was carried out to an appropriate standard.

Implications

This case has far reaching implications for your practice when consenting a patient.

1 In cases of informed consent, there is no longer a defence that you failed to explain a risk on the basis that a reasonable body of opinion would support that omission. The law now requires explanation of **all material risks**.

2 The law now requires that:
- A patient should be told of all material risks
- A risk is material if that patient would attach significance to it.

3. This means that when you are consenting your patient, you must consider their individual circumstances and explore with them what risks are of significance to them personally. It will not be enough on its own for you to rely on patient information leaflets or pre-printed consent forms.

In practice, many legal cases are not about whether or not it was reasonable for a clinician not to warn of a particular risk. Instead, the dispute is usually about whether a particular complication was discussed at all, with a doctor who is adamant that the patient was told about a risk and a patient who is equally adamant that they were not.

These cases often boil down to what was written (or not written) in the medical records. If the

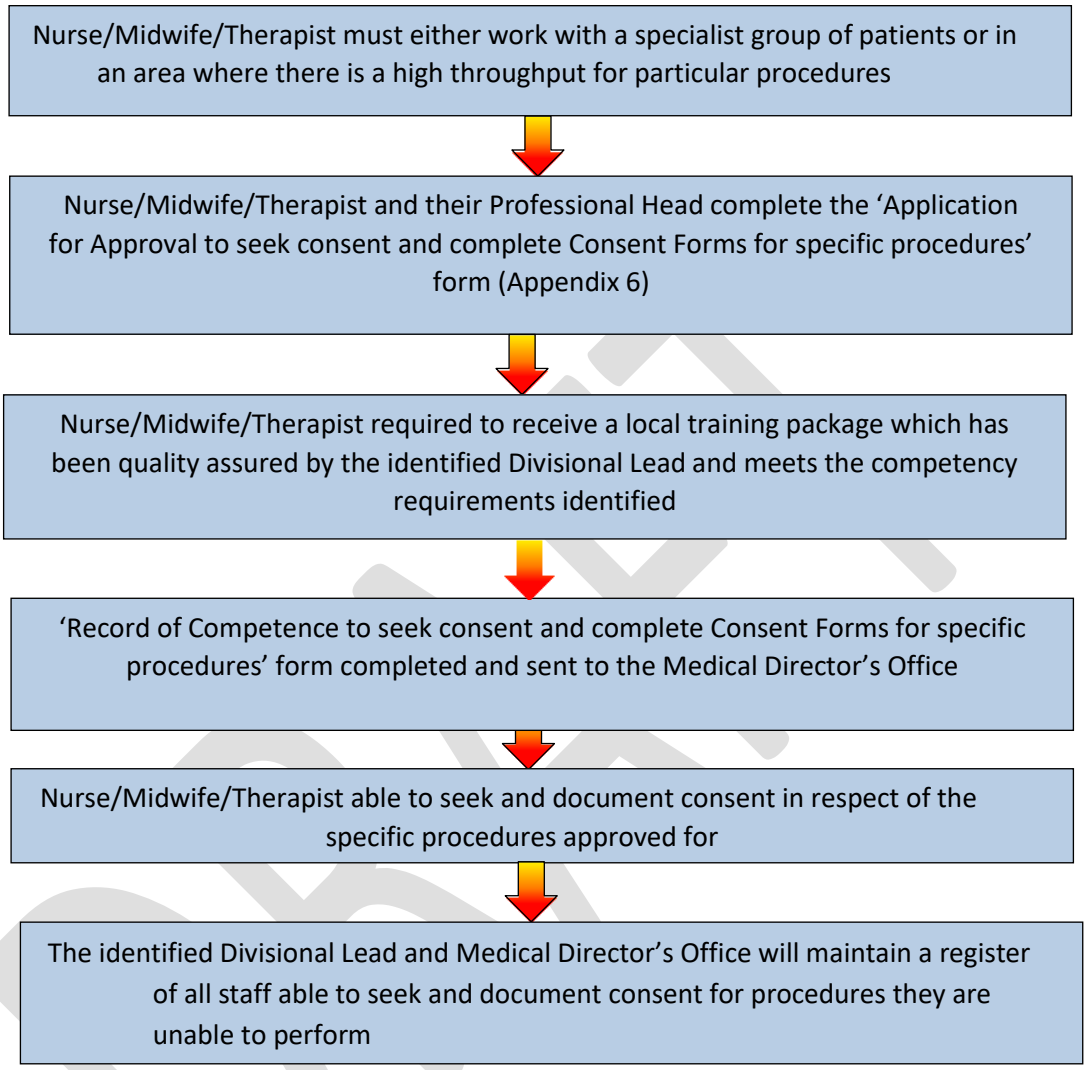
records are silent as to whether the patient was warned of a complication of treatment it is likely that the Court will believe the patient, for whom the treatment is a once in a lifetime experience, rather than the Doctor, recalling one consultation, possibly many years later.

Experience within the Trust makes it clear that where a doctor has clearly and fully set out the risks in the records, and where there is clear evidence that information has been provided in well drafted information leaflets, we are much less likely to face these sorts of claims.

Legal Services
dhft.legalservices@nhs.net
01332 785419 / 786333

APPENDIX 3

Process for Obtaining Delegated Authority for Seeking Consent and Completing Consent Forms – Nurses and AHPs



APPENDIX 2 contd.

UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS FOUNDATION TRUST
Scope of Professional Practice

Application for Approval to seek consent and complete Consent Forms for specific procedures

This document should be used to apply for approval to seek consent and complete consent forms for specified procedures.

Name of registered nurse / midwife / therapist:	
Status:	
Directorate:	
Department:	

Please identify procedures for which consent would be sought and consent forms completed:

Please state supporting case for seeking consent and completing consent form for specified procedures: Where supporting case involves high throughput of procedure state numbers per month

I understand that should this application be approved I cannot commence seeking consent and completing consent forms until such time as I have successfully completed the related Scope of Professional Practice requirements

Applicant's Signature:	
Date of Application:	

Approval of Professional Head:
Status:
Date:

APPENDIX 2 contd.

UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS FOUNDATION TRUST

Scope of Professional Practice

Record of Competence to seek consent and complete Consent Forms for specific procedures

This document reflects the training received and systems in place to support registered nurses / midwives in seeking consent and completing Consent Forms for procedures that they are not capable of undertaking.

Name of registered nurse / midwife / therapist:	
Status:	
Directorate:	
Department:	

Criteria	**Responsibility / Signature**	**Date achieved**
Principles of Consent	Trust Patient Safety and Risk Manager	
Quality Assurance of Consent Resource Package	Trust Patient Safety and Risk Manager	

Following the above criteria being fulfilled the assessor (Health Care Professional competent to undertake the procedure being consented for) must ensure understanding of the principles and witness the registered nurse / midwife / therapist seeking valid consent prior to deeming the registered nurse / midwife competent to seek consent and complete the Consent Form

Assessment of Competence	***Achieved*** ***Assessor's Signature***	***Date***
Knowledge of the key principles of valid consent.		
Knowledge of the information the patient requires in order to give valid consent.		
Knowledge of what must be routinely documented to provide evidence of valid consent.		
Knowledge of how to assess capacity.		
Knowledge of action to be taken where a patient lacks mental capacity.		
Clarity around the procedures a consent form should be completed for (after competence assessment).		
Practical observation of the registered nurse / midwife / therapist seeking consent and completing the consent form, applying the above knowledge appropriately.		

1 x copy in consent resource pack, 1x copy to manager, 1x copy to registered nurse / midwife / therapist, 1x copy to Trust Patient Safety Lead

Assessor's Name:	
Assessor's Grade:	
Assessor's Signature:	
Date of Competence Assessment:	

APPENDIX 4

TABLE OF CONSENT FORMS IN USE AT UHDB

TRUSTWIDE	GENERAL CONSENT FORMS	ORDER NO.
	Patient Agreement to Investigation or Treatment	WPH0056
	Patient / Parental Agreement to Investigation or Treatment	WPH0057
	Form for Adults who are Unable to Consent to Investigation or Treatment	WPH1112
SPECIALITY	**PROCEDURE SPECIFIC CONSENT**	**ORDER NO.**
OBSTETRICS (1)	Elective Caesarean Section	WPH
	Urgent Caesarean Section	WPH1547
	Operative Vaginal Delivery	WPH2587 (QHB)
	Trial in Theatre	WPH2588
	Pertussis Vaccination	QHB913A (QHB)
	Flu Vaccination	QHB914A (QHB)
	Sterilisation	WLZ105A (QHB)
GYNAECOLOGY (24) General (4)	Hysteroscopy	WPH2296
	Diagnostic Laparoscopy	WPH2378
	Total Laparoscopic Hysterectomy	WPH2379
	Laparoscopic Bilateral Salpingo-Oophorectomy	WPH2381
Urogynae (4)	Pelvic Floor Repairs +/- Mesh Insertion, Vaginal Hysterectomy, Sacrospinus Fixation	WPH2416
	Abdominal Sacrocolpoopexy / Sacrohysteropexy	WPH2415
	Cystoscopy / Urethral Bulking Agent Injection (Bulkamid) or Botulinium Toxin Injection to Bladder	WPH2413
	Autologous Fascial Sling	WPH2587
Gynaeoncology (8)	Staging Laparotomy	WPH2377
	Total Laparoscopic Hysterectomy for the treatment and Staging of Cancer	WPH2376
	Cytoreductive surgery	WPH2475
	Cytoreductive Ultra-radical Surgery for Advanced Intra-abdominal Cancer	WPH2375

	Laparoscopic Radical Hysterectomy	WPH2380
	Radical Hysterectomy (Open)	WPH2380
	Radical Vulval Surgery for Vulval Cancer	WPH2587
Pregnancy Advisory (2) & GAU (6)	Medical Management Pathway of Care (Booklet)	WPH0836
	Surgical Management Pathway of Care (Booklet)	WPH0835
	Laparoscopy and removal of tubal ectopic pregnancy	WPH2503
	Medication Management of Tubal Ectopic Pregnancy with Methotrexate	WPH2504
	Expectant Management of Tubal Ectopic Pregnancy	WPH2505
	Consent for Laboratory Examination & Sensitive Cremation	WPH2160
	Consent for disposal of pregnancy remains	WPH2216
	Bartholin's Cyst/Abscess Treatment using Word Catheter	WPH2502
UROLOGY (1)	Transrectal Ultrasound Scan (TRUS) Biopsy (Stickers on Generic Form)	n/a
ENDOSCOPY (1+5)	Endoscopic Retrograde Cholangio Pancreatography (ERCP)	WPH0061
	Bronchoscopy (Combined Patient Information & Consent Booklet)	
	Endoscopic Ultrasound (EUS) with or without fine needle aspiration/biopsy (FNA/FNB) (Combined Patient Information & Consent Booklet)	
	Gastroscopy (Combined Patient Information & Consent Booklet)	WPH0058
	Flexible Sigmoidoscopy (Combined Patient Information & Consent Booklet)	WPH0060
	Colonoscopy (Combined Patient Information & Consent Booklet)	WPH0059
SURGERY (1+1+5) (Bariatric, Vascular, Upper GI and Colorectal)	Laparoscopic Cholecystectomy	WPH2313
	Endovascular Radiological Procedures (Arteriogram +/- Angioplasty/Stent). (Patient Care Pathway Incl.Consent)	WPH
	Bariatric/Metabolic Surgery (Additional Consent Sheet)	n/a
	Laparoscopic (+/-Open) repair of Abdominal Incisional Hernia (Additional Consent Sheet)	n/a
	Laparoscopic (+/-Open) Oesophago-Gastrectomy (Additional Consent Sheet)	n/a

	Laparoscopic Paraoesophageal Hernia Repair (Additional Consent Sheet)	n/a
	Laparoscopic (+/-Open) Gastrectomy (Additional Consent Sheet)	n/a
OPTHALMOLOGY (1)	Cataract Surgery	WPH1095
HANDS (1)	Needle Aponerotomy (Sticker attached to Generic Consent Form)	n/a
HEAD & NECK (2)	Fluoride varnish	WPH2584
	Retainer Consent & Information	WPH0999
ORTHOPAEDICS & SPINAL (0)	Nil	n/a
PAEDIATRICS (0)	Nil	n/a
CARDIAC CATH LAB (3)	Coronary Angiography	WPH1333
	Coronary Angiography & Stenting	WPH1334
	DC cardioversion	WPH2395
PARENTERAL THERAPY (1)	PICC consent form	WPH2350
PHOTOGRAPHY (2)	Clinical Photographic Consent Card	WPH0529
	Clinical Photographic Consent Card	WPH0535