Trust-wide Document

NHS
Great Western Hospitals
NHS Foundation Trust

Consent for Medical Treatment for All Patients at the Great Western Hospital (GWH) (including Endoscopy) Policy

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Target Audience- who does the document apply to and who should be using it. - The target audience has the responsibility to ensure their compliance with this document by: • Ensuring any training required is attended and kept up to date. • Ensuring any competencies required are maintained. • Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.	All employees directly employed by the Trust whether permanent, part-time or temporary (including fixed-term contract). It applies equally to all others working for the Trust, including private-sector, voluntary-sector, bank, agency, locum, and secondees. For simplicity, they are referred to as 'employees' throughout this policy		
Special Cases	Advise any cases where this document does not apply.		
Accountable Director	Medical Director		
Author/originator – Any Comments on this document should be addressed to the author	Legal and Inquest Manager		
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Review period. This document will be fully reviewed every three years in accordance with the Trust's agreed process for reviewing Trust -wide documents. Changes in practice, to statutory requirements, revised professional or clinical standards and/or local/national directives are to be made as and when the change is identified.			

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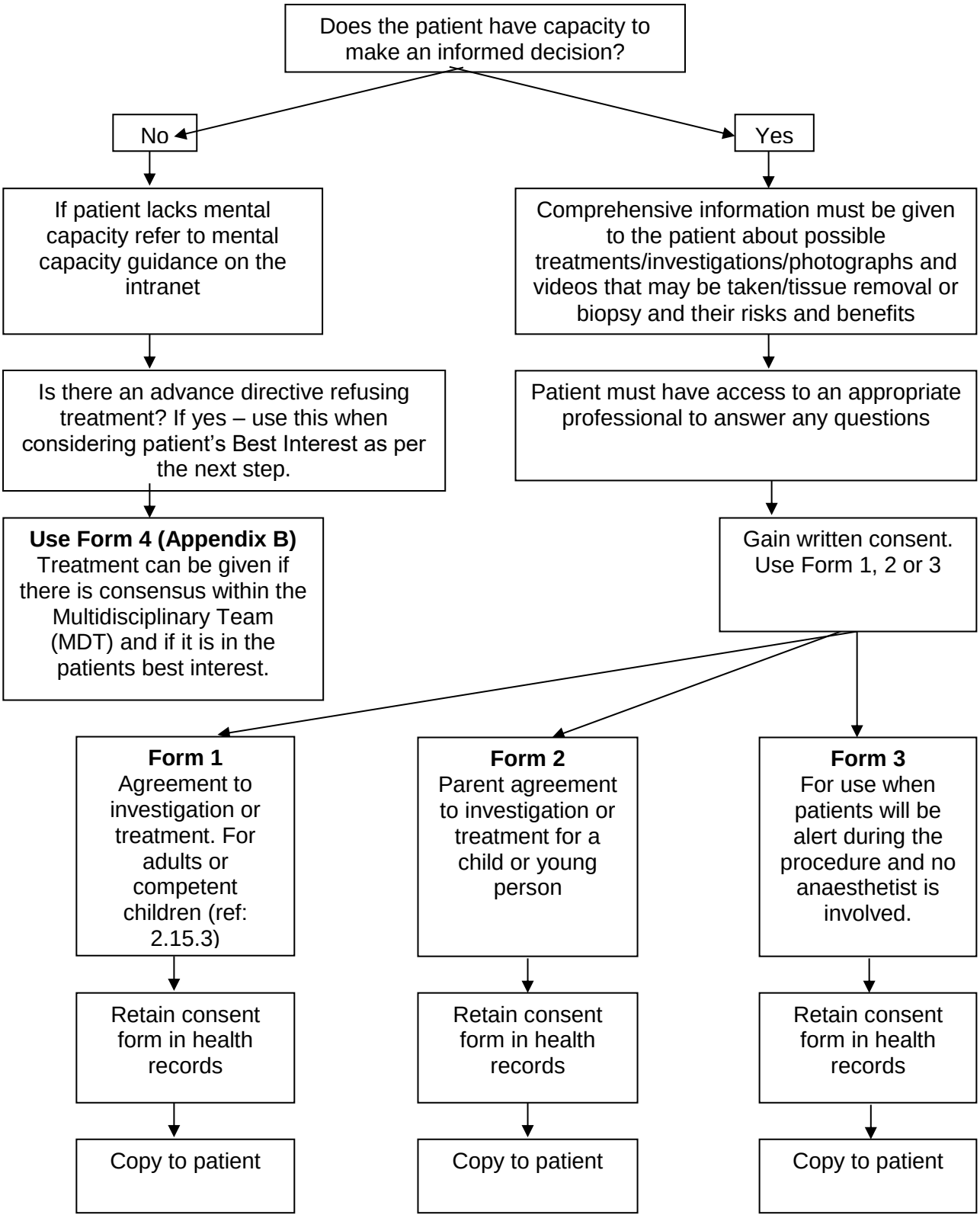


1 Introduction & Purpose

1.1 Introduction & Purpose

In 2009 the Department of Health and Social Care (DHSC) updated its *Good practice in consent implementation guide: consent to examination or treatment* and renamed it A *Reference Guide to Consent for Examination or Treatment* (Ref 2). Although there is no longer an explicit requirement to adopt the DHSC policy and model consent forms, trusts are responsible for ensuring that their Consent Policy and associated consent forms reflect the latest legal and regulatory requirements.

The purpose of this document is to set out the policy of the Great Western Hospital NHS Foundation Trust (The Trust) with respect to patient/parent/guardian consent for care and treatment, including post-mortem examination. The policy applies to all employees of the Trust.

This policy does not include guidance on how to obtain consent for matters other than for clinical treatments and procedures. The Trust's Information Disclosure Policy (Ref 24) describes the consent process for the sharing of personal, confidential information.

1.2 Glossary/Definitions

The following terms and acronyms are used within the document:

Competent child	Person under 16 who meets the Gillick competence guidance (section 5.5.2) for competence to consent to treatment
COREC	Central Office of Research Ethics Committees
CQC	Care Quality Commission
DHSC	Department of Health and Social Care
DoLS	Deprivation of Liberty Safeguards
EIA	Equality Impact Assessment
GMC	General Medical Council
GP	General Practitioner
HIV	Human immunodeficiency virus
HTA	Human Tissue Authority
Human Tissue	Defined by the HTA as 'relevant material', meaning material other than gametes, which consists of or includes human cells.
IMCA	Independent Mental Capacity Advocate
IP&C	Infection Prevention and Control
LPA	Lasting Power of Attorney
MCA	Mental Capacity Act
MDT	Multidisciplinary Team
NHS	National Health Service
NHSR	NHS Resolution
NMC	Nursing and Midwifery Council
Parent	The term parent in this document is used broadly and includes all those deemed to have parental responsibility in the eyes of the law.
Placement Information Plan	A local authority documents which provides clarity for the child and the child's carer and has been agreed by all parties.

2 Main Document Requirements

2.1 Why is Consent Crucial?

Patients have a fundamental legal and widely-accepted ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health care professionals and patients. Failure to obtain consent for treatment may result in prosecution for assault or battery.

In August 2009, the DHSC issued the 2nd edition of its *Reference Guide to consent for examination and treatment* (Ref 2), and this must be consulted for details of the law and good practice requirements on consent. This policy sets out the standards and procedures in this Trust which aim to ensure that clinicians are able to comply with the guidance.

2.2 What is Consent?

'Consent' in a medical context is a patient's agreement for a clinician to provide care or treatment. Patients 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 patient must:

- Be competent to take the particular decision;
- Have received sufficient information to take the decision; and
- Not be acting under duress.

2.3 The Context of Consent

The context of consent can take many different forms, ranging from the active request by a patient for a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional's advice. In some cases, the Clinician/health professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. In other contexts, there may be a number of ways of treating a condition, and the clinician will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. In many cases, 'seeking consent' is better described as 'joint decision-making' which means that the patient and the clinician come to an agreement on the best way forward, based on the patient's values and preferences and the clinician's clinical knowledge.

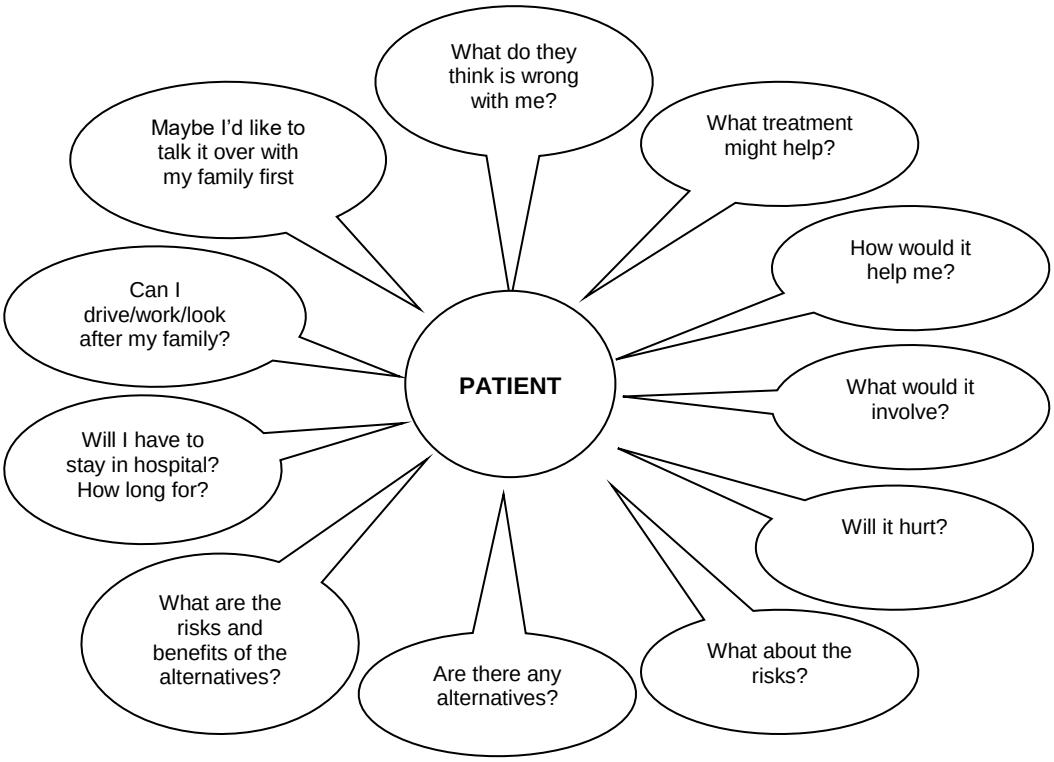
Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no-one else can give consent on their behalf. However, treatment may be given if it is in their best interests (note that the Mental Capacity Act 2005 (Ref 6) introduced legal requirements in respect of best interests), as long as it has not been refused in advance in a valid and applicable advance directive. For further details on advance directives see the DHSC *Reference guide to consent for examination or treatment*, chapter 1, paragraph 19 (Ref 2) and the Mental Capacity Act Policy (Ref 12).

2.4 Remembering the Patient's Perspective

In March 2015 there was a landmark legal case of Montgomery v Lanarkshire Health Board (Ref 4) which changed the requirement of consent law. The clinician responsible for taking consent is now legally required to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and any reasonable alternative or variant treatments. In

March 2017 Thefaut v Johnston (Ref 27) confirmed that doing nothing is an alternative which should be discussed with the patient. The Clinician must not decide to withhold from discussing a risk with the patient because the likelihood of it occurring is minimal. The clinician should also consider what the patient may class as an important factor to them and therefore personalising the consent to the individual. It is permitted to use percentage of a risk occurring. For example in Rogers v Whitaker (an Australian case) (Ref 29) a surgeon disclosed risks of 1% or more chance of occurring. There was a one in 14,000 chance of blindness in one eye. Although the risk was remote, the claimant was already blind in the other eye, making the risk of great significance to the claimant. The court found the doctor's failure to disclose this risk to be negligent.

Some points to consider relate to what the patient may be thinking when consent is being taken are below:



2.5 Guidance on Consent

The *Reference guide to consent for examination and treatment* (Ref 2) issued by the DHSC provides good advice but staff must also be aware of any guidance on consent issued by their own regulatory bodies.

Examples of other guidance available:

- Nursing and Midwifery Council *(*NMC*) Code: Professional Standards of practice and behaviour for Nurses , NMC 2015 (updated 2018) (Ref 8)*
- *Consent: patients and doctors working together,* General Medical Council (GMC), 2008 (Ref. 9).
- GMC Decision Making and Consent draft guidance (Ref 28)
- GDC Standards for the Dental Team (Ref 33)

2.6 Documentation

For 'significant procedures' for example a procedure involving general anaesthetic or a procedure which the patient feels to be significant, it is essential for clinicians / health care professionals to document clearly both the patient's agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient's medical records if necessary), or through documenting in the patient's medical records that they have given consent.

Whilst administrative arrangements will vary, it must always be remembered that for consent to be valid, the patient must feel that they have been fully informed, that it would have been possible for them to refuse, or change their mind.

For detailed information on consent forms, the type of consent forms available and the appropriate use of them, see Section 2.9.

2.7 Written Consent

Consent is often incorrectly equated with the provision of a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent, but is not proof of valid consent, see section 2.2. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

Although it is not a legal requirement to seek written consent, it is good practice to do so if any of the following circumstances apply:

- The treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some clinicians would describe as 'side-effects' or 'complications');
- The procedure involves general/regional anaesthesia or sedation;
- The procedure is sensitive in nature i.e. biopsy on face etc.
- Providing clinical care is not the primary purpose of the procedure;
- There may be significant consequences for the patient's employment, social or personal life;
- The treatment is part of a project or programme of research approved by this Trust;
- Post mortem activities such as the post mortem itself (unless requested by the Coroner) and the removal of organs or tissue for transplantation.

Completed forms must be kept with the patient's medical records. Any changes to a form, made after the form has been signed by the patient, must be initialled and dated by both patient and clinician.

Consent forms should be completed in handwriting. However, should there be a requirement to use a pre-printed sticker detailing the benefits, risks of the procedure and any alternatives, the patient must sign and date both the consent from and the sticker. Consideration should then be given to any additional patient specific risks which need to be included on the consent form.

Some departments will wish to use pre-printed forms. This is permitted providing that the minimum requirements discussed in this policy are met and there is free space to tailor the consent from to the patient i.e. to include patient specific risks.

If an information leaflet, where risks and benefits of the procedure are explained, is provided to the patient as part of the consent process, the consenting clinician must still record the risks and benefits on the consent form. The leaflet name and reference number must be recorded on the consent form.

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

2.8 Procedures to Follow when a Patient Lacks the Capacity to Provide Consent

Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact must be documented in Consent Form 4 (Appendix B). This section details the process for adults who are unable to consent to investigation or treatment, along with the assessment of the patient's capacity, why the clinician believes the treatment to be in the patient's best interests, and the involvement of those close to the patient. Consent Form 1 or 3 must never be used for adult patients unable to consent for themselves. For more minor interventions, this information must be entered in the patient's medical records.

2.8.1 The Mental Capacity Act 2005

The Mental Capacity Act 2005 (Ref 6) provides a statutory framework to protect those who are not able to make their own decisions and codifies many common law principles already widely in use.

Clinicians must ensure that a two stage assessment of capacity is clearly evidenced as having been completed. The first part of the assessment should clearly record the presence of an impairment of the mind or brain and stage 2, the functional element, whether this is sufficient to disrupt individual decision making by assessing the individual's understanding, retention, weighing of information and ability to communicate the decision. Without clear evidence of the presence of this level of assessment, practitioners and the Trust will not be protected from liability under section 5 of the Mental Capacity Act.

An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. The clinician must involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient's situation prevents this. If at all possible, the patient must be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

Where treatment continues over a long period, the patient's ability to give consent and whether treatment continues to be in their best interests must be reviewed at regular intervals (how often will be a patient-specific decision). Steps must be taken to ensure that any treatment does not amount to a deprivation of liberty under the European Convention of Human Rights. For more information see the Trust's Deprivation of Liberty Safeguards (DoLS and Mental Capacity Act) Policy (Ref 10).

The key principles of the act are as follows:

- There is a presumption of a patient having full mental capacity;
- 'All practical steps' must have been taken to assist a person to gain capacity before decisions are made on their behalf;
- Unwise decisions do not imply that a person does not have capacity;
- Any act done with regards to an incapacitated person must be done in their best interests;

- Consideration must be given to any less restrictive forms of treatment able to achieve the same purpose.

Under the Act, a person will be said to lack capacity if, on a balance of probabilities, they are unable to:

- Understand information relevant to the decision;
- Retain that information;
- Use or weigh that information as part of the process of making the decision;
- Communicate their decision

2.8.2 Best Interests

Importantly the Act also provides for a (statutory) best interests test. All healthcare professionals are now legally required to take the following steps when assessing what is in a patient's best interest for medical treatment and for the Treatment Escalation Plan (Ref 7):

- Encourage the patient to participate in decision making;
- Identify all relevant circumstances (what things would the person who lacks capacity have taken into account when making their decision);
- Find out the patient's views (past and present wishes and feelings, expressed verbally, in writing or by conduct; beliefs and values; and other relevant factors);
- Avoid discrimination;
- Assess whether the person might regain capacity and if so, when;
- If the decision concerns life-sustaining treatment not to be motivated in any way by a desire to bring about the person's death;
- Consult others (anyone previously named by the patient as someone to be consulted with, anyone engaged in caring for the patient, close relatives and friends who take an interest in the patient welfare, attorney appointed under a Lasting Power of Attorney or Enduring Power of Attorney; deputy appointed by the Court of Protection to make decisions for the person);

N.B. For decisions about major medical treatment where a patient should survive and where there is no-one who fits into these categories, an Independent Mental Capacity Advocate (IMCA) must be consulted.

- Avoid restricting a patient's rights – are there other options that may be less restrictive of a patient's rights;
- Take all of the above into account; weigh up all of the factors in order to make a decision about what would be in a patient's best interests.

2.8.3 Independent Medical Capacity Advocates (IMCA)

NHS bodies must instruct IMCAs to represent and support patients without capacity and who have no family or friends that it would be appropriate to consult about decisions.

IMCAs must be instructed where decisions in the following key areas need to be made:

- Serious medical treatment, but excluding treatment under the Mental Health Act 1983 (amended by the Mental Health Act 2007) (Ref 11) for mental disorders which do not require consent;
- NHS-arranged accommodation or change in accommodation in hospital for 28 days or more or in care home for eight weeks or more;
- Local Authority accommodation for eight weeks or more, except in an emergency.

It is important that IMCAs are independent. Those with responsibility for caring for a person without capacity must not be made an IMCA.

An IMCA's role is to represent a person's best interests; as such they must also follow the statutory best interests test outlined in the MCA 2005. Any information or reports provided by an IMCA to clinicians must be taken into account in reaching a decision about whether a treatment is in a patient's best interests. If an IMCA disagrees with the decision made by clinical employees, they are entitled to challenge the decision, ultimately to the Court of Protection. Where disagreements arise between the clinicians and an IMCA, legal advice must be sought at the earliest opportunity.

IMCAs are entitled to meet the patient in private and to view confidential medical records.

Employees wishing to instruct an IMCA or seek advice about the IMCA service must contact the Swindon Advice Movement on 01793 616562.

For more information see the Mental Capacity Act 2005 Policy and Procedures (Ref 13).

2.8.4 Occasions where there is No Agreement on Best Interests

An application should be considered to the court in cases where you have any doubt or dispute about whether a proposed treatment is in the best interests of the person without capacity. Where the consequences of having, or not having, the treatment are potentially serious/life threatening, a court declaration may be sought. In the first instance advice must be sought from Legal Services on 01793 604928.

2.9 Availability of Consent Forms

Consent forms are available by searching for 'consent' on the 'policy and procedures' page of the intranet and are available as pre-printed forms which can be requisitioned via the Trust's purchasing systems.

There are four standard consent forms:

- **Form One** for adults or competent children (see section 2.15.3) for a definition of a competent child); (pre-printed)
- **Form Two** for parental consent concerning a child or young person;(pre-printed)
- **Form Three** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care; (available on intranet) and
- **Form Four** for patients who lack capacity. Please see Appendix B

The use of Form three is optional but it may be more appropriate than Form one in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary.

Some departments will choose to have some consent forms partly completed with risks, benefits already pre-printed. In these cases there must be room to personalise the consent form. The individual department is responsible for liaising with the external printing company to process this. These forms must be approved at the department committee. Which committee is more relevant can be decided by the division.

An exemption from the use of these four consent forms is available in the Child and Family Services, Speech and Language and School Nursing services (when undertaking vaccination of children as part of an NHS vaccination scheme). Within these services the lead manager will work with the Legal and

Inquest Manager to ensure that a consent form that is fit for purpose is used and that this policy is followed.

A further exemption is where standard consent forms have been developed by nationally recognised organisations. Where there is a standard form available it is appropriate for these to be used eg consent forms for cancer treatments developed by Cancer Research (Ref 26). If the department wish to use such a form, they should seek local approval from the appropriate departmental committee and inform the Legal and Inquest Manager.

2.10 Process for Obtaining Consent

When a patient formally gives their consent to a particular intervention, this is only the endpoint of the consent process.It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

2.11 Ammendments to Consent

Any amendments to consent documentation must be signed and dated by the treating clinician.

2.12 Single-stage Process

In many cases, it will be appropriate for a clinician to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given verbally.

If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and the clinician must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the clinician may then proceed.

2.13 Two or More Stage Process

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital outpatient 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, discussions of options and initial decision which must be documented either in the patients medical records or on a consent form. The second stage being confirmation that the patient still wants to go ahead. This must be documented on the consent form.

Patients receiving elective treatment or investigations for which written consent is appropriate must be familiar with the contents of their consent form before they arrive for the actual procedure, and must have received a copy of the page 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 outpatients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patients arrive for treatment, a member of the healthcare team must check with the patient at this point whether they have any further concerns and whether their condition has changed. There is a section on the orignal consent form to document this. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When

confirming the patient's consent and understanding, it is advisable to use an open question: for example 'Can you tell me what you're expecting to happen', rather than 'is everything OK?'

2.14 Seeking Consent for Anaesthesia

Where an Anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks.

As regards elective treatment it is not acceptable for the patient not to receive any information about anaesthesia until their pre-operative visit from the Anaesthetist; at such a late stage the patient will not be in a position to make a decision about whether or not to undergo anaesthesia. Patients must therefore either receive a general leaflet about anaesthesia in outpatients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. Where the patient has a discussion with the Anaesthetist, the Aneasthetist must ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's medical records or on the consent form.

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

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

2.15 Emergency Surgery or Treatment

Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's medical records to document any discussion and the patient's consent, rather than using a form. The urgency of the situation may limit the quantity of information that they can be given, and must not affect its quality.

In some cases where Emergency Surgery is required the patient may not have capacity to consent ie if they are unconscious. In these situations treatment can be provided in the patient's best interests and consent form 4 must be used (Appendix B)

2.16 Seeking consent for Gastrointestinal Endoscopy

The rest of this policy still applies to endoscopy procedures.

2.16.1 Who can take consent

Within the Endoscopy Department at the Great Western Hospital, obtaining consent for a gastrointestinal endoscopy for an elective patient has been delegated by the Competent Endoscopist to an appropriately trained and competent employee – British Society of Gastroenterologists (BSG) Guidance for obtaining valid consent (Ref 34).

The Trust requires staff to complete the Obtaining Consent for Endoscopic Procedures Competency (Ref 36) before they are deemed competent. Sections 2.30 and 2.31 of this policy still apply to endoscopic procedures, namely that the clinician undertaking the procedure is ultimately responsible

for ensuring effective consent. There is also responsibility on this person to escalate to the responsible clinician if they do not feel they have enough knowledge of the procedure to take consent or the patient asks questions beyond their knowledge.

Annual revalidation of knowledge and skills through appraisal, and evaluation of nurse-led consent from patient satisfaction surveys, are essential.

Those who may have delegation of consent to them include Nurse Endoscopists, and Registered Nurses. This delegation does not include, inpatients and those patients who lack capacity to consent nor those who are aged under 18 years of age.

2.16.2 Taking of consent

There are pre-printed consent forms available within the endoscopy department for common endoscopic procedures. The Consent form along with information (Ref 37) must also be sent with the information about the appointment date and time, thus providing the patient time to read, evaluate and seek any further information if they require. This includes those patients who are sent “straight to test”.

For high risk patients or high risk procedures as identified by the Endoscopy Department the procedure must be discussed with the patient in advance of the day of the procedure by the pre-assessment nurses or an Endoscopist. If this is a face to face discussion at a separate pre-assessment appointment the Consent may be taken at this time. If at time of pre-assessment the patient is found to be high risk, this must be identified on the “to come in list”.

Inpatients must be given written information before the consent is obtained, so that they have time to read the information, unless the procedure is an emergency one and where the procedure is performed in the patient’s best interests. Where ever possible written consent must be obtained. If required an interpreter must be obtained.

If a patient declines to receive written information or engage in discussion regarding the endoscopic procedure their wishes must be respected. The person who has attempted to provide the information must document in the patient’s notes or care plan that they were unable to provide guidance. However information must be given so that the patient can consent for their procedure, this should include the aims of the procedure, expected level of pain, discomfort and the steps to be taken to minimise it. In addition, the level of risk related to the procedure that the patient wishes to know must be ascertained and documented on the consent form.

Final validation of that process should occur in the procedure room before the procedure starts as part of the safety checklist (Ref 34) and National Safety Standards for Invasive Procedures (NatSSIPs). (Ref 35)

2.16.3 Withdrawing Consent

For patients who are not sedated section 2.26 of this policy must be followed.

For sedated patients. Sedation used for all endoscopic procedures is ‘conscious sedation’.
When a patient has been sedated it is a reasonable assumption that the patient has impaired ability to give valid consent. The anticipated effect of sedation is that the patient will be able to communicate, but is in a relaxed state. However, sedation is unpredictable and patients are unreliably affected.
If a sedated patient, characteristically, begins to struggle, and by physical and verbal act withdraws consent, the situation is entirely different. It is the responsibility of the Endoscopist to act in the patient’s best interests. If this event occurs at a crucial time, which will have an impact on a successful outcome, for example, removal of a bile duct stone, then it would be wise to pause,

attempt to regain co-operation and complete, perhaps with additional sedation. If the situation deteriorates, is irretrievable, and patient safety is likely to become compromised, then termination of the procedure is recommended.

A written record must be made.

Assessing capacity during a procedure can be difficult. Therefore, the decision to stop the procedure is a matter of clinical judgement. There needs to be a balance between the level of distress being experienced by the patient and the need to complete the endoscopy at that time as it is in the patient's best interests.

2.17 Treatment of Young Children

When babies or young children under 16 years of age are being cared for in hospital, it will not usually seem practicable to seek their parents' consent on every occasion for every routine intervention such as blood or urine tests or x-rays. However, clincians must remember that consent is required.

Where a child is admitted to hospital, clincians must discuss with their parent(s) what routine procedures will be necessary, and ensure that the clincian has gained their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, the clincian must do so, unless the delay involved in contacting them would put the child's health at risk.

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. Clinicians/health care professionals must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If clincians are in any doubt about whether the person with the child has parental responsibility for that child, they must check with the parents.

2.17.1 Parental Responsibility

Children over the age of 16 are assumed to be competent to make decisions about their own treatment and care. However those with parental responsibility are still able to consent on behalf of a child up until the age of 18. If there is conflict between parent and a child over the age of 16, the child's wishes must take precedence.

The following classes of person automatically have parental responsibility:

- The biological mother of the child (unless parental responsibility has been removed by a court order);
- Married biological parents of a child;
- Parents of a jointly adopted child.

For children born before 1 December 2003, unmarried biological fathers can obtain parental responsibility by:

- Marrying the mother or obtaining a parental responsibility order from the court;
- Registering a parental responsibility agreement with the court or by an application to court

For children born after 1 December 2003, unmarried biological fathers can obtain parental responsibility by:

- Registering the child's birth jointly with the mother (i.e. the father appears on the birth certificate);Obtaining a parental responsibility order from the court;

- Registering a parental responsibility agreement with the court or by an application to court.

2.17.2 Absent Responsible Parent

Non Urgent Medical Treatment - When a child requires non-urgent medical treatment and the Responsible Parent is not present, for example the child is in foster care consent is still required, the following paragraphs apply:

Where the child has routine medical matters it is the health care professionals' responsibility to check whether the Placement Information Plan delegates the consent rights to the foster parents. The health care professional can check by asking the foster parents or the appropriate Local Authority. Consideration must also be given as to whether there is a Child Arrangements Order (given by a court) in place which may permit other people to give consent on behalf of the child.

If either of these provisions are not in place, employees must obtain consent from the responsible parent. If the responsible parent is not able to be present for discussions, a telephone conversation discussing the procedure, risks, benefits and alternatives must be undertaken, with full documentation of this in the patient's medical records. Verbal consent is enough to proceed with the surgery.

As with all children consideration must be given to Gillick Competence see 2.15.3 and when appropriate it may not be necessary to obtain consent from the responsible parent.

Urgent Medical Treatment - In non-routine situations where a child requires urgent surgery/treatment and no one with parental responsibility is available to give consent, the procedure can be undertaken in the child's best interests. This decision must be recorded and consent form 5 can be used.

2.17.3 Gillick Competence

Children below the age of 16 are assumed not to have capacity to consent to treatment, unless they are able to demonstrate otherwise. If a child below the age of 16 is deemed to have 'sufficient understanding and intelligence to enable him or her to understand fully what is proposed' then they can be described as being Gillick competent. This concept originated from the case of Gillick v West Norfolk & Wisbech HA (Ref 31) where it was deemed that it would not be unlawful to offer children advice and contraceptive treatment without consulting their parents, provided they could demonstrate understanding of the nature and implications of the treatment.

If a Gillick competent child and those with parental responsibility for that child disagree about a proposed treatment option, the wishes of the competent child must again override those of the parents.

N.B. Gillick Competence does not extend to the withdrawal of life-sustaining treatment. In this case, those with parental responsibility can override a child who wishes to withdraw life-sustaining treatment, provided the treatment is in the best interests of the child.

N.B. Gillick Competence covers all medical treatment, however if the required treatment is for contraception and sexual health, Fraser Guidelines should be used. (Ref 32)

2.17.4 Disagreement between Parents and Clinicians

If there is disagreement between clinicians and parents about what is in the best interests of a non-competent child, particularly in respect of life-sustaining treatment, then legal advice must be sought as soon as possible. In the first instance advice must be sought through the Legal and Inquest Manager who will refer onwards to Trust Solicitors if appropriate. If advice is needed out-of-hours the on-call manager should be contacted.

2.18 Consent for Blood Transfusion

Where possible, informed verbal consent from the patient must be obtained prior to blood transfusion.

- This should include discussion about the risks, benefits and possible alternatives of transfusion. The patient should also be informed that they will no longer be able to donate blood.
- The consent conversation must be documented in the medical records along with the reason for transfusion, pre-transfusion haemoglobin level, target haemoglobin level, the number of units to be given and any special requirements.
- To assist with this discussion, leaflets produced by NHS Blood and Transplant are available in all clinical areas. Contact the blood transfusion team for leaflets in other languages.
- In some circumstances, where patients are unaware that they have received a transfusion, it is important that they are retrospectively given information. An information leaflet for this can be obtained by contacting the blood transfusion team.

When a patient refuses blood or blood products separate consent should be obtained using the Appendix to consent form 1 which is available on the intranet. For more information please see Jehovah's Witnesses and other Patients who Refuse Transfusion of Blood or Blood Components Clinical Guideline (Ref 25).

2.19 Consent for Post Mortem Activities

It is important to establish clearly when consent has been given to ensure the removal, storage and use of any tissue is lawful. However, giving consent must not be seen as a single act – the signing of a consent form. Rather, it must be seen as part of a continuing process, in which individuals and their relatives or close friends can discuss the issue fully, ask questions, and make an informed choice.

It is good practice, where possible, for discussions to take place with the relatives prior to a person's death. Relatives may know the patient's wishes.

In the event of seeking consent for post mortem examination care must be taken regarding the possible disclosure of information, such as genetic information or Human immunodeficiency virus status, which the deceased person may not have wished to be disclosed, or which may have significant implications for other family members.

The way in which a post mortem examination is discussed with the deceased patient's relatives or close friends is extremely important. They need to be given:

- Honest, clear, objective information;
- An opportunity to talk to someone they can trust and of whom they feel able to ask questions;
- Reasonable time to reach decisions (about hospital post mortem and about any donation of organs or tissue;
- Privacy for discussion between family members;
- Support if they need and want it including the possibility of further advice or bereavement counselling or psychological support.

For more detailed or specialist information regarding post mortem examination relatives or close friends will be directed to the Mortuary Manager or Anatomical Pathology Technician on-call if after hours. These employees will be able to provide support and information to the bereaved.

2.20 Provision of Information

The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need easy-to-understand information about their condition and about possible treatments/investigations and the risks and benefits (including the risks or benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue.

Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where they will stay, how long they will be in hospital, how they will feel afterwards and recovery time. Where relevant, information about anaesthesia must be given alongside information about the procedure.

Although not a legal requirement, it is important that the patient is informed if the procedure is to be undertaken by a student or trainee.

Patients (and those close to them) will vary in how much information they want; from those who want as much detail as possible, including details of rare risks, to those who ask clinician to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally and non-verbally) that they do not wish to be given this level of information, this must be documented.

2.21 Patient Information Available in the Trust

2.21.1 Information Available in the Great Western Hospital

See Trust Production of Patient Information Policy (Ref 13) for guidance on creating new patient information.

Information for relatives and parents in relation to post mortem examination can be found on the Department of Health and Social Care Website (Ref 30).

2.21.2 Information Available in the Trust's Community Settings

Each community service provides information about the service and treatment provided. This is available in clinics, on the wards, from professionals providing patient care or from the patient's General Practitioner (GP).

N.B. The information a patient has been provided with and any discussions that take place on risks, benefits and alternatives must be documented fully on the Consent Form.

2.22 Provision for Parents whose First Language is not English

This 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 employees. Leaflets are available in the languages prevalent within Wiltshire. Additionally all employees can access translation and interpreting services and should refer to the Trust's Translation and Interpretation Services pages on the Customer Services section of the intranet (Ref 14) for further information.

Trust employees or family members should not be used as a translator unless it is an emergency situation. The exception to this is where staff members have been signed up as official translators. The Patient Advise and Liaison team can assist further with identifying these staff members.

2.23 Services Available for People with Communication or Hearing Difficulties

The Trust is committed to ensuring that patients with communication or hearing difficulties receive the information they need and are able to communicate appropriately with healthcare employees.

Refer to the Trust's Translation and Interpretation Services pages on the Customer Services section of the intranet (Ref 14) for further information.

2.24 Access to More Detailed or Specialist Information

Patients may also be directed to specialist information via the Specialist Nurses, where available, who can offer details of support or self-help groups, along with contact numbers for further supporting literature which normally includes website addresses and email/telephone details. It is important to guide the patient to appropriate sites for accurate information.

2.25 Access to Health Professionals between Formal Appointments

After an appointment with a clinician in primary care or in outpatients, patients will often think of further questions which they would like answered before they make their decision. Where possible, it will be much quicker and easier for the patient to contact the clinician's secretary by telephone to pass on any questions or queries than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice).

Following an initial outpatient appointment, patients are given details of Specialist Nurses where appropriate.

Contact telephone and/or pager numbers should given to enable the patient to seek further advice during normal office hours. Where a card has not been given directly to the patient, Specialist Nurses may be contacted through the main hospital switchboard.

2.26 Open Access Clinics

Where patients access clinics directly, it must not be assumed that their presence at the clinic implies consent to particular treatment. Clinicians must ensure that they have the information they need before proceeding with an investigation or treatment.

2.27 Refusal of Treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983 (Ref 11). The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* (Ref 15) for more detail.

The following paragraphs apply primarily to adults:

If, after discussion of possible treatment options, a patient refuses a treatment, this fact must be clearly documented in their health records. If the patient has already signed a consent form, but then changes their mind, the clinician (and where possible the patient) must note this on the consent form.

Where a patient has refused a particular intervention, the clinician must ensure that they continue to provide any other appropriate care to which they have consented. The clinician must also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they must be advised accordingly.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, the clinician must explain to the patient the possible consequences of their partial refusal. If the clinician genuinely believes that the procedure cannot safely be carried out under the patient's stipulated conditions, they are not obliged to perform it. The clinician must, however, continue to provide any other appropriate care. Where another clinician believes that the treatment can be safely carried out under the conditions specified by the patient, they must on request be prepared to transfer the patient's care to that health professional.

2.28 Human Tissue

2.28.1 The Living

Consent for treatment and examination including the removal of tissue is a common law matter dealt with in the Department of Health's *Reference Guide to Consent for Examination and Treatment* (Ref. 2). Under The Human Tissue Act 2004 (Ref 3) tissue may be taken for a variety of circumstances, for example:

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

Consent is needed for the storing and use of tissue for:

- Obtaining scientific or medical information which may be relevant to any other person, now or in the future (i.e. where the purpose is storage or use in relation to another person, rather than where it might, incidentally, be of future relevance to another person);
- Research in connection with disorders or functioning of the human body (see exceptions in specific circumstances below);
- Public display;
- Transplantation.

2.28.2 Expectations

Consent is NOT needed for storage and use of tissue for:

- Clinical audit purposes;
- Education or training relating to human health (including training for research into disorders, or the functioning of the human body);
- Performance assessment;
- Quality assurance.

Tissue from the living may be stored for use and/or used without consent provided that:

- The research is ethically approved;
- The tissue is anonymised such that the researcher is not in possession of information identifying the person from whose body the material has come and is not likely to come into possession of it.

2.28.3 The Deceased

Consent is needed:

- Where, after a Coroner's post mortem, the continued storage and use of material is no longer required to be kept for the Coroner's purpose;
- For the removal storage and use in the following scheduled purposes:
    - Anatomical examination;
    - Determining the cause of death;
    - Establishing, after a person's death, the efficacy of any drug or other treatment administered to them;
    - Obtaining scientific or medical information, which may be relevant to any other person now or in the future;
    - Public display;
    - Research in connection with disorders or functioning of the human body;
    - Performance assessment;
    - Public health monitoring;
    - Quality assurance.

This applies to all tissue removed at post mortem, including small samples such as blocks and slides, and samples that might be kept as part of the record.

2.28.4 Exceptions

Consent is NOT needed for:

- Carrying out an investigation into the cause of death under the authority of the Coroner;
- Keeping material after a post mortem under the authority of the Coroner for as long as the Coroner requires it;
- Keeping material in connection with a criminal investigation or following a criminal conviction.

Any tissue required for research purposes will be part of a separate consent process. This will have been approved by the Trust's Ethics Committee in advance and the relevant information and consent forms will be available.

2.29 Consent for Research

All research involving human participants requires approval from an appropriate Ethics Committee. Central Office of Research Ethics Committees (COREC) issue detailed guidelines on seeking informed consent from participants involved in research. These guidelines must be followed. Further information is available from the Research and Innovation team.

2.30 Clinical Photography and Conventional or Digital Recordings

For information on clinical photography and digital recordings refer to the Trust's Medical Photography Storage Policy (Ref 16).

2.31 Who is Responsible for Seeking Consent?

The clinician 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 on.

Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the clinician responsible. However, team work is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

It is usually the responsibility of the treating clinician to seek consent for post mortem examination, knowing the medical problems and unresolved aspects that merit investigation. There may be different options for who actually discusses the post mortem and obtains consent, but most will involve a team approach. Anyone seeking consent for a hopsital post mortem examination must be sufficiently senior and well informed, with a thorough knowledge of the procedure. They must have been trained in the management of bereavement and in the purposes and procedures of post mortem examinations and they must have witnessed a post mortem examination.

2.32 Completing Consent Forms

The standard consent form provides space for a clinician to provide information to patients and to sign confirming that they have done so.

If the patient signs the form in advance of the procedure (for example in outpatients or at a pre-assessment clinic), a clinician involved in their care on the day must sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot answer themselves.

2.32.1 Who is permitted to Take Consent?

The health professional carrying out the procedure is ultimately responsible for ensuring the patient is genuinely consented. He/she may be held responsible in law if this is challenged later.

However, teamwork is a crucial part of the way the NHS operates, and where written consent is sought it may be appropriate for other members of the team to participate in the process of seeking consent.

The following groups of employees are permitted to take consent in this Trust:

- Healthcare professionals that are competent and capable of carrying out the procedures unsupervised.
- Clinicians who have knowledge of the procedure. There is also responsibility on this person to escalate to the responsible clinician if they do not feel they have enough knowledge of the procedure to take consent or the patient asks questions beyond their knowledge.

2.33 Training

All clinical staff receive training in Safeguarding Adults and Children, which includes specific training on the Mental Capacity Act 2005.

All clinical staff are required to complete the Training Tracker module, Consent, Mental Capacity and DOLS

2.34 Audit and Monitoring

From October 2019 an on-going audit of the consent process is undertaken by the Clinical Audit and Effectiveness Department to ensure compliance with this policy.

During the audit a sample of health records will be reviewed in order to ensure that they meet the required criteria.

2.35 Following up those who are unauthorised to Take Consent

Invalid consent maybe identified from audits, as part of a complaint, incident or the legal process. During the audit process, if it is identified that a clinician has obtained consent for a procedure without being authorised to do so the consent is invalid. The Legal and Inquest Manager will report the matter to the Clinical Lead who will then decide whether an incident form is required to be completed and whether duty of candour applies.

Where the Legal and Inquest Manager is made aware of repeated and deliberate disregard for this policy (repeated in this context meaning on three separate occasions) or there is a serious lack of understanding of the consent process, this will be reported to the Medical Director.

Depending on the severity of the situation the above will be dealt with in accordance with the Medical and Dental Revalidation and Appraisal Policy (Ref 21) and in some cases the matter will be referred to the General Medical Council (GMC).

3 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	Monitoring or audit method	Monitoring responsibility (individual, group or committee)	Frequency of monitoring	Reporting arrangements (committee or group the monitoring results is presented to)	What action will be taken if gaps are identified
That the consent is taken and meets all the legal requirements	Random sample of case notes of patients who had given consent for a procedure/treatment	Legal and Inquest Manager/Clinical Audit team – audit starts October 2019	On-going	Synopsis presented at Patient Quality Committee.	Legal and Inquest Manager will meet with individual clinicians or department were required.
Compliance with Consent being obtained outside the procedure room.	Audit of compliance by observation of the consent process.	Endoscopy Unit Manager	6 Monthly	Reports to the Endoscopy User Group	Investigated by the Unit Manager and the Clinical Lead
Revalidation of knowledge and skills for Nurses who are	Annual revalidation at appraisal	Endoscopy Unit Manager	Annually	Reports to the Endoscopy User Group	Further training and assessment prior to continuation

consenting					of obtaining the consent from the patients

4 Duties and Responsibilities of Individuals and Groups

4.1 Chief Executive

The Chief Executive is ultimately responsible for the implementation of this document.

4.2 Ward Managers, Matrons and Managers for Non Clinical Services

All Ward Managers, Matrons and Managers for Non Clinical Services must ensure that employees within their area are aware of this document; able to implement the document and that any superseded documents are destroyed.

4.3 Document Author and Document Implementation Lead

The document Author and the document Implementation Lead are responsible for identifying the need for a change in this document as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and resubmitting the document for approval and republication if changes are required.

4.4 The Endoscopy Clinical Lead, Endoscopy Unit Manager & Matron

The Endoscopy Unit Clinical Lead, Unit Manager and the Matrons must ensure that employees within their area are aware of this document; able to implement the document and that any superseded documents are destroyed. The lead must also advise the author of this policy when the Endoscopy section requires updating.

4.4 The Medical Director

The Medical Director has Executive responsibility for ensuring that consent is undertaken in accordance with the legislative and regulatory framework.

4.5 The Legal and Inquest Manager

The Legal and Inquest Manager is responsible for reviewing the consent policy every three years to ensure, so far as is reasonable and practicable, that it complies with all relevant legislation and the regulatory framework.

The Legal and Inquest Manager is also responsible for updating Consent Forms 1-4 and delivering training on consent.

4.6 All Employees

All employees are responsible for ensuring that they act in accordance with this policy when consenting patients for treatment including recognising when they are not permitted to take consent.

4.7 Patient Quality Committee

The Patient Quality Committee is the committee with delegated responsibility from the Trust Board for overseeing the consent policy and associated processes.

5 Further Reading, Consultation and Glossary

5.1 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which employees should refer to for further details:

Ref. No.	Document Title	Document Location
1	Health Service Circular 2001/023	www.dh.gov.uk
2	Reference guide to consent for examination and treatment (2nd edition)	www.dh.gov.uk
3	The Human Tissue Act 2004	www.legislation.gov.uk
4	MDU guidance on Montgomery Consent changes	http://www.themdu.com
5	CQC Standards for Hospitals	www.cqc.org.uk
6	Mental Capacity Act 2005	www.legislation.gov.uk
7	Treatment Escalation Plan and Resuscitation Decision Policy	T Drive/Trustwide Documents
8	NMC Code: Standards of Conduct	https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf
9	Consent: patients and doctors working together	www.gmc-uk.org
10	Deprivation of Liberty Safeguards (DoLS and Mental Capacity Act) Policy	T Drive/Trustwide Documents
11	Mental Health Act 1983 (amended by the Mental Health Act 2007)	www.legislation.gov.uk
12	Mental Capacity Act 2005 Policy and Procedures	T Drive/Trustwide Documents
13	Production of Patient Information Policy	T Drive/Trustwide Documents
14	Translation and Interpreting Services	T Drive/Trustwide Documents
15	Reference Guide for Consent for examination or treatment edition 2	www.dh.gov.uk
16	Medical Photography Storage Policy	T Drive/Trustwide Documents
17	Human Tissue Authority Code of Practice 1: Consent (2006)	www.hta.gov.uk

Ref. No.	Document Title	Document Location
18	Human Tissue Authority Code of Practice 2: Donation of organs, tissue and cells for transplantation (2006)	www.hta.gov.uk
19	Human Tissue Authority Code of Practice 3: Post mortem examination (2006)	www.hta.gov.uk
20	Human Tissue Authority Code of Practice 5: The Removal, Storage and disposal of Human organs and tissue (2006)	www.hta.gov.uk
21	Medical and Dental Revalidation and Appraisal Policy	T Drive/Trustwide Documents
22	Mandatory Training Policy	T Drive/Trustwide Documents
23	BMJ Update on UK consent law	www.bmj.com
24	Information Disclosure Policy	Intranet
25	Jehovah's Witnesses and other Patients who Refuse Transfusion of Blood or Blood Components Clinical Guideline	T Drive/Trustwide Documents
26	Consent forms for SACT (Systemic Anti-Cancer Therapy)	http://www.cancerresearchuk.org
27	Thefaut v. Johnston (2017) EWHC 497 QB	http://ukhealthcarelawblog.co.uk
28	GMC draft guidance on Consent	https://www.gmc-uk.org/-/media/ethical-guidance/related-pdf-items/consent-draft-guidance/consent-draft-guidance.pdf?la=en&hash=920B435518160455840473FA316D7BEEBDFBB332
29	Rogers v Whitaker	https://www.ncbi.nlm.nih.gov/pubmed/11648609
30	Department of Health and Social Care Website	www.dh.gov.uk
31	Gillick v West Norfolk & Wisbech HA	www.bailii.org
32	Fraser and Gillick guidelines	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1432156/pdf/bmj33200807.pdf
33	GDC guidence on consent	https://www.gdc-uk.org/information-standards-guidance/standards-and-guidance/standards-for-the-dental-team/
34	Guideline for obtaining valid consent for gastrointestinal endoscopy procedures June 2016	www.bsg.org
35	National Safety Standards for Invasive Procedures (NatSSIPs)	www.england.nhs.uk
36	Trust wide documents - Leaflets → Endoscopy i.e. Oesophagoscpy, Colonoscopy, Flexible Sigmoidoscopy	T:\Trust-wide Documents

Ref. No.	Document Title	Document Location
37	Obtaining Consent for a Endoscopic Procedure Competency	T:\Trust-wide Documents

5.2 Consultation Process

The following is a list of consultees in formulating this document and the date that they approved the document:

Job Title / Department.	Date Consultee Agreed Document Contents
Claims and Inquest Officer	April 2019
Medical Director	18 June 2020
Safeguarding Adults at Risk Team	9 April 2019
AMD	16 April 2019
AMD - USC	9 June 2020
Clinical lead – endoscopy	10 June 2020
Governance lead – endoscopy	9 June 2020

6 Equality Impact Assessment

An Equality Impact Assessment (EIA) has been completed for this document and can be found at Appendix A.

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Appendix A - STAGE 1: Initial Screening For Equality Impact Assessment

At this stage, the following questions need to be considered:			
1	What is the name of the policy, strategy or project? Consent for Medical Treatment		
2.	Briefly describe the aim of the policy, strategy, and project. What needs or duty is it designed to meet? To provide a guidance on how to take consent for medical treatment. Based on case law and legal requirements.		
3.	Is there any evidence or reason to believe that the policy, strategy or project could have an adverse or negative impact on any of the nine protected characteristics (as per Appendix A)?		**No**
4.	Is there evidence or other reason to believe that anyone with one or more of the nine protected characteristics have different needs and experiences that this policy is likely to assist i.e. there might be a *relative* adverse effect on other groups?		**No**
5.	Has prior consultation taken place with organisations or groups of persons with one or more of the nine protected characteristics of which has indicated a pre-existing problem which this policy, strategy, service redesign or project is likely to address?		**No**

Signed by the manager undertaking the assessment	Lesley Biles
Date completed	16 May 2019
Job Title	Legal and Inquest Manager

On completion of Stage 1 required if you have answered YES to one or more of questions 3, 4 and 5 above you need to complete a STAGE 2 - Full Equality Impact Assessment

Equality Impact Assessment

Are we Treating Everyone Equally?

Define the document. What is the document about? What outcomes are expected?

Consider if your document/proposal affects any persons (Patients, Employees, Carers, Visitors, Volunteers and Members) with protected characteristics? Back up your considerations by local or national data, service information, audits, complaints and compliments, Friends & Family Test results, Staff Survey, etc.

If an adverse impact is identified what can be done to change this? Are there any barriers? Focus on outcomes and improvements. Plan and create actions that will mitigate against any identified inequalities.

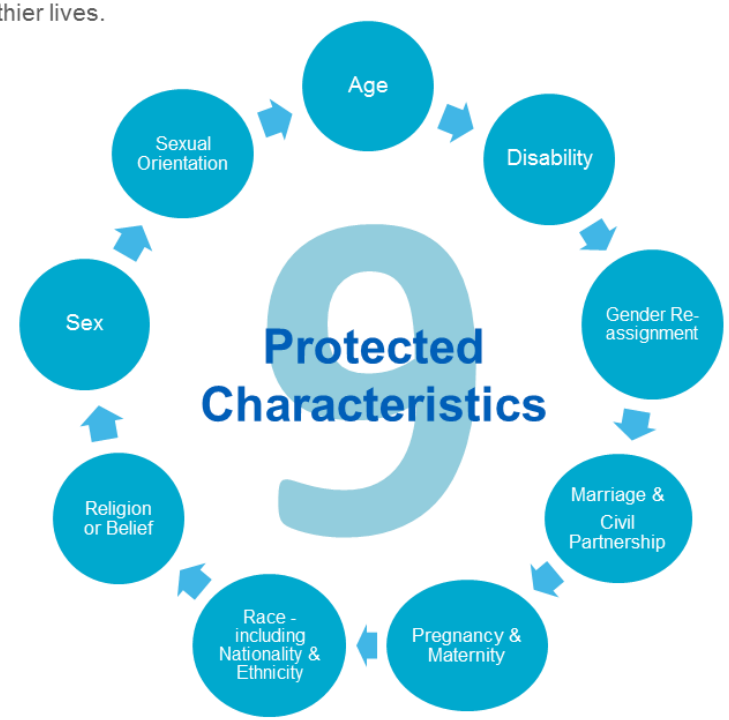
If the document upon assessment is identified as having a positive impact, how can this be shared to maximise the benefits universally?

Trust Equality and Diversity Objectives

Better health outcomes for all	Improved patient access & experience	Empowered engaged & included staff	Inclusive leadership at all levels

Our Vision

Working together with our partners in health and social care, we will deliver accessible, personalised and integrated services for local people whether at home, in the community or in hospital empowering people to lead independent and healthier lives.



Great Western Hospitals NHS Foundation Trust

Appendix B - Consent Form 4

For adults who lack capacity to consent to investigation or treatment

Patient details (or addressograph)

Patient's surname/family name _____
Patient's first names_____
Date of Birth _____
Responsible health professional_____
Job Title _____
NHS number (or other identifier)_____
Male ☐ Female ☐

Special Requirements_____
(eg other language requirements/ other communication method)

All sections are to be completed - The original must be kept in patient's notes

A) Details of procedure or course of treatment proposed (include brief explanation if medical term not clear)

_____
_____

The intended benefits are

_____
_____
_____

Significant, unavoidable or frequently occurring risks are

_____
_____
_____

Alternative treatments are

_____
_____
_____

The proposed treatment is the least restrictive for the patient **Yes** **No**

Note: see guidance to health professionals overleaf for details of situations where court approval must first be sought

I confirm that I have explained the procedure, the intended benefits, risks and alternatives to the patient, their family, and other relevant persons involved with making this decision. I also confirm that:

I am trained and competent to do the procedure; or
I am trained to take consent for this procedure.

signed _____

designation _____

date _____

(to be used if a second person is undertaking treatment)
I am trained and competent to do the procedure; or
I am trained to take consent for this procedure.

signed _____

designation _____

date _____

B) Assessment of patient's capacity (in accordance with the Mental Capacity Act 2005)

Stage One

i) Is there an impairment of, or disturbance in the functioning of the person's mind or brain? **Yes** **No**

ii) Details of the impairment or diagnosis (for example, a disability, condition or trauma, or the effect of drugs or alcohol)

_____

Is this of a nature or degree which might be sufficient to affect their capacity for this decision? **Yes** **No**
If yes please record details

_____

NOTE: If the answer to either question is no, do not complete this form, please use Consent Form 1

Stage Two

i) Is the person able to understand the information relevant to the decision? **Yes** **No**
If yes please record details

_____

(Ensure you have provided the person with sufficient relevant information and that this is included in your consideration of the person's understanding. Ensure you have presented the information in ways which can enhance the person's likelihood of understanding)

ii) Can the person retain the information for long enough to reach a decision? **Yes** **No**

If yes please record details

_____

(Ensure you have presented the information in ways which can enhance the person's likelihood of retaining the information)

iii) Can the person use or weigh the information as part of the process of reaching a decision? **Yes** **No**

If yes please record details

_____

iv) Can the person communicate their decision by any means? **Yes** **No**
If yes please record details

_____

v) Further details (excluding where patient unconscious): for example how above judgements reached; which colleagues consulted; what attempts made to assist the patient make his or her own decision and why these were not successful.

_____

_____

NOTE: If the person is assessed as 'no' for any of the stage two domains they will lack capacity for the specific decision and then you should proceed to the Best Interest Decision section below.

If all the stage two domains are assessed as 'yes' the person is capacitated. Please use Consent Form 1.

I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment

Signed _____

Designation _____

Date _____

C) Assessment of patient's best interests

Will the patient regain capacity? **Yes** **No**

If yes the treatment cannot wait until the patient regains capacity because:

_____
_____
_____

Has everything reasonably practical been done to encourage the patient's participation? **Yes** **No**

Has everything reasonably practical been done to improve the patient's ability to participate? **Yes** **No**

Has consideration been given to the patient's wishes, feelings beliefs and values? **Yes** **No**

What is known to be the most important to the patient regarding this decision?

_____
_____
_____

Has the patient named someone to be consulted on the decision being made? **Yes** **No**

If yes, please record their name and views

_____
_____
_____
_____

Has anyone been engaged in caring for the patient or interested in their welfare? **Yes** **No**

If yes, please record their name and views_____
_____
_____
_____

Is there an advanced decision which is relevant to the decision? **Yes** **No**

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D) Involvement of the patient's family and others close to the patient

Unless the patient has an attorney or deputy, the final responsibility for determining whether a procedure is in an incapacitated patient's best interests lies with the health professional performing the procedure. However, there is a positive requirement under the Mental Capacity Act to consult with those close to the patient (e.g. spouse/partner, family and friends, carer, supporter or advocate) as far as is practicable and appropriate.

Independent Mental Capacity Advocate (IMCA)

For decisions about serious medical treatment, where there is no one appropriate to consult other than paid staff, has an Independent Mental Capacity Advocate (IMCA) been instructed?

Yes **No**

Details

_____

_____

_____

Signed _____ Date _____

Patient's Family / Carer / IMCA

I/We have been involved in a discussion with the relevant health professionals over the treatment of_____ (patient's name). I/We understand that he/she is unable to give his/her own consent, based on the criteria set out in this form. I/We also understand that treatment can lawfully be provided if it is in his/her best interests to receive it.

Any other comments (including any concerns about decision)

_____

_____

_____

_____

Person 1

Name _____ Relationship to patient _____

Signed _____ Date _____

Person 2

Name _____ Relationship to patient _____

Signed _____ Date _____

Person 3

Name _____ Relationship to patient _____

Signed _____ Date _____

If a person close to the patient was not available in person, has this matter been discussed in any other way (e.g. over the telephone?)

Yes **No**

If yes, please provide details

_____

_____

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E) Signature of health professional proposing treatment

I have undertaken the 'best interests' checklist as laid out in the Mental Capacity Act 2005 and replicated in this form. It is my view, having had regard to the information gathered, that this procedure is in the best interests of the patient.

I have/have not sought a second opinion.

Signed _____

Designation _____

Date _____

Where second opinion sought, s/he should sign below to confirm agreement:

Signed _____

Designation _____

Date _____

F) The patient has an attorney or deputy

Where the patient has authorised an attorney to make decisions about the procedure in question under a Lasting Power of Attorney or a Court Appointed Deputy has been authorised to make decisions about the procedure in question, the attorney or deputy will have the final responsibility for determining whether a procedure is in the patient's best interests.

Signature of attorney or deputy
I have been authorised to make decisions about the procedure in question under a Lasting Power of Attorney / as a Court Appointed Deputy (delete as appropriate). I have considered the relevant circumstances relating to the decision in question (see section C) and they believe the procedure to be in the patient's best interests.

Any other comments (including the circumstances considered in assessing the patient's best interests)

_____
_____
_____
_____

Name _____ Relationship to patient _____

Address _____

Signed _____ Date _____

Where the patient's representative / consultee has been involved with the process as copy of this form should be given to them.

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Guidance to health professionals (to be read in conjunction with consent policy)

This form should only be used where it would be usual to seek written consent but an adult patient (16 or over) lacks capacity to give or withhold consent to treatment. If an adult **has** capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the *Mental Health Act 1983*, different legal provisions apply and you are required to adhere to: Mental Capacity two stage test and the Best Interested assessment, both have been included in this form.

If the adult now lacks capacity, but has made a valid advance decision to refuse treatment you must abide by that refusal. For further information on the law on consent, see the Department of Health's *Reference guide to consent for examination or treatment* (www.doh.gov.uk/consent).

The law on consent

See the Department of Health publications *Reference guide to consent for examination or treatment* and *Seeking consent: working with children* for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

When treatment can be given to a patient who lacks the capacity to consent

All decisions made on behalf of a patient who lacks capacity must be made in accordance with the Mental Capacity Act 2005. More information about the Act is given in the Code of Practice (www.publicguardian.gov.uk/mca/code-of-practice). Treatment can be given to a patient who is unable to consent, only if:

- the patient lacks capacity to give or withhold consent to this procedure AND
- the procedure is in the patient's best interests.

Capacity

A person lacks capacity if they have an impairment or disturbance (for example, a disability, condition or trauma, or the effect of drugs or alcohol) that effects the way their mind or brain works which means that they are unable to make a specific decision at the time it needs to be made. It does not matter if the impairment or disturbance is permanent or temporary. A person is unable to make a decision if they cannot do one or more of the following things:
Understand the information given to them that is relevant to the decision. Retain that information long enough to be able to make the decision.
Use or weigh up the information as part of the decision-making process.
Communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

You must take all steps reasonable in the circumstances to assist the patient in taking their own decisions (for example by involving more specialist colleagues). This may involve explaining what is involved in very simple language, using pictures and communication and decision-aids as appropriate. People close to the patient (spouse/partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates (as distinct from an IMCA as set out below) or supporters. Sometimes it may be necessary for a formal assessment to be carried out by a suitably qualified professional.

Capacity is 'decision-specific': a patient may lack capacity to take a particular complex decision, but be quite able to take other more straightforward decisions or parts of decisions. Capacity can also fluctuate over time and you should consider whether the person is likely to regain capacity and if so whether the decision can wait until they regain capacity.

Best interests
The Mental Capacity Act requires that a health professional **must** consider all the relevant circumstances relating to the decision, including, as far as possible considering:
The person's past and present wishes and feelings (in particular if they have been written down)

Any beliefs and values (e.g. religious cultural or moral) that would be likely to influence the decision in question and any other relevant factors
The other factors that the person would be likely to consider if they were able to do so.

When determining what's in a patient's best interests, a health professional must not make assumptions about someone's best interests merely on the basis of the person's age or appearance, condition of any aspect of their behaviour. If the decision concerns the provision or withdrawal of life-sustaining treatment the health professional must not be motivated by a desire to bring about the person's death.

The Act also requires that, as far as possible, health professionals must consult other people, if it is appropriate to do so, and take into account their views as to what would be in the best interests of the person lacking capacity, especially anyone previously named by the person lacking capacity as someone to be consulted and anyone engaging in caring for the patient and their family and friends. The best interests decision record is attached to the back of this form.

Independent Mental Capacity Advocates (IMCA)
The Mental Capacity Act introduced a duty on the NHS to instruct an independent mental capacity advocate (IMCA) in serious medical treatment decisions when a person who lacks capacity to make decision has no one who can speak for them, other than paid staff. IMCAs are not decision makers for the person who lacks capacity. They are there to support and represent that person and to ensure that decision making for
people who lack capacity is done appropriately and in accordance with the Act.

Lasting Power of Attorney and Court Appointed Deputy
A person over the age of 18 can appoint an attorney to look after their health and welfare decisions, if they lack capacity to make such decisions in the future. Under a Lasting Power of Attorney the attorney can make decisions that are as valid as those made by the person themselves. The LPA may specify limits to the attorney's authority and the LPA must specify whether or not the attorney has the authority to make decisions about life-sustaining treatment. The attorney can only, therefore, make decisions as authorised in the LPA and must make decisions in the person's best interests.

The Court of Protection can appoint a deputy to make decisions on behalf of a person who lacks capacity. Deputies for personal welfare decisions will only be required in the most difficult cases where important and necessary actions cannot be carried out without the court's authority or where there is no other way of settling the matter in the best interests of the person who lacks capacity. If a deputy has been appointed to make treatment decisions on behalf of a person who lacks capacity then it is the deputy rather than the health professional who makes the treatment decision and the deputy must make decisions in the patient's best interests.

Second opinions and court involvement
Where treatment is complex and/or people close to the patient express doubts about the proposed treatment, a second opinion should be sought, unless the urgency of the patient's condition prevents this. The Court of Protection deals with serious decisions affecting personal welfare matters, including healthcare, which were previously dealt with by the High Court. Cases involving:
Decisions about the proposed withholding or withdrawing of artificial nutrition and hydration from patients in a permanent vegetative state

- Organ, bone marrow or peripheral blood stem cell donation by an adult who lacks

capacity to consent;

- The proposed non-therapeutic sterilisation of a person who lacks capacity to consent to this (e.g. for contraceptive purposes); and
- Doubt or dispute about whether a particular treatment will be in a person's best interests (including

cases involving ethical dilemmas in untested areas) should be referred to the Court for approval. The Court can be asked to make a decision in cases where there are doubts about the patient's capacity and also about the validity or applicability of an advance decision to refuse treatment.