Consent to Examination, Treatment or Post Mortem Policy

'Delivering Excellence in Healthcare through Innovation and Collaboration'

Please be advised that the Trust discourages the retention of hard copies of policies and procedures and can only guarantee that the policy on the Trust Intranet is the most up to date version

Document Type:	**Policy**
Version:	**10**
Date of Issue:	**January 2019**
Review Date:	**January 2022**
Lead Director:	**Medical Director**
Post Responsible for Update:	**Associate Director of Quality Governance**
Approval Committee / Group:	**Executive Quality Governance Group**
Approved by them in the minutes of:	**16th January 2019**
Distribution to:	**All Trust staff via the Trust Intranet**

Contents:

Consent Policy

KEY POINTS

- ❖ Written consent must be obtained before the day of surgery / treatment with the following two exceptions:
  - When surgery is required as an emergency that day
  - For those patients who are subject to procedures via direct referral as a day case (e.g. endoscopy or interventional radiology). In such circumstances the patient should be provided with information prior to the day of procedure, and is then consented on the day of the procedure

- ❖ The healthcare professional obtaining consent must explain / discuss any material risks, which could be considered significant by an objective person, to the patient and should inform them of any alternative treatments

- ❖ The healthcare professional obtaining consent must be competent to do so because**:**
  - they carry out the procedure
  - they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit

- ❖ Any member of staff who feels pressurised to seek consent when they do not feel competent to do so should contact the Legal Services Department or the Associate Director of Quality Governance

- ❖ Ideally patients should not be listed for a procedure until they have given consent and that consent is documented on the appropriate consent form

- ❖ If the patient signs the form in advance of the procedure, a healthcare professional involved in their care on the day must countersign the form to confirm that the patient has been given the opportunity to have any further questions answered and still wishes to go ahead with the procedure

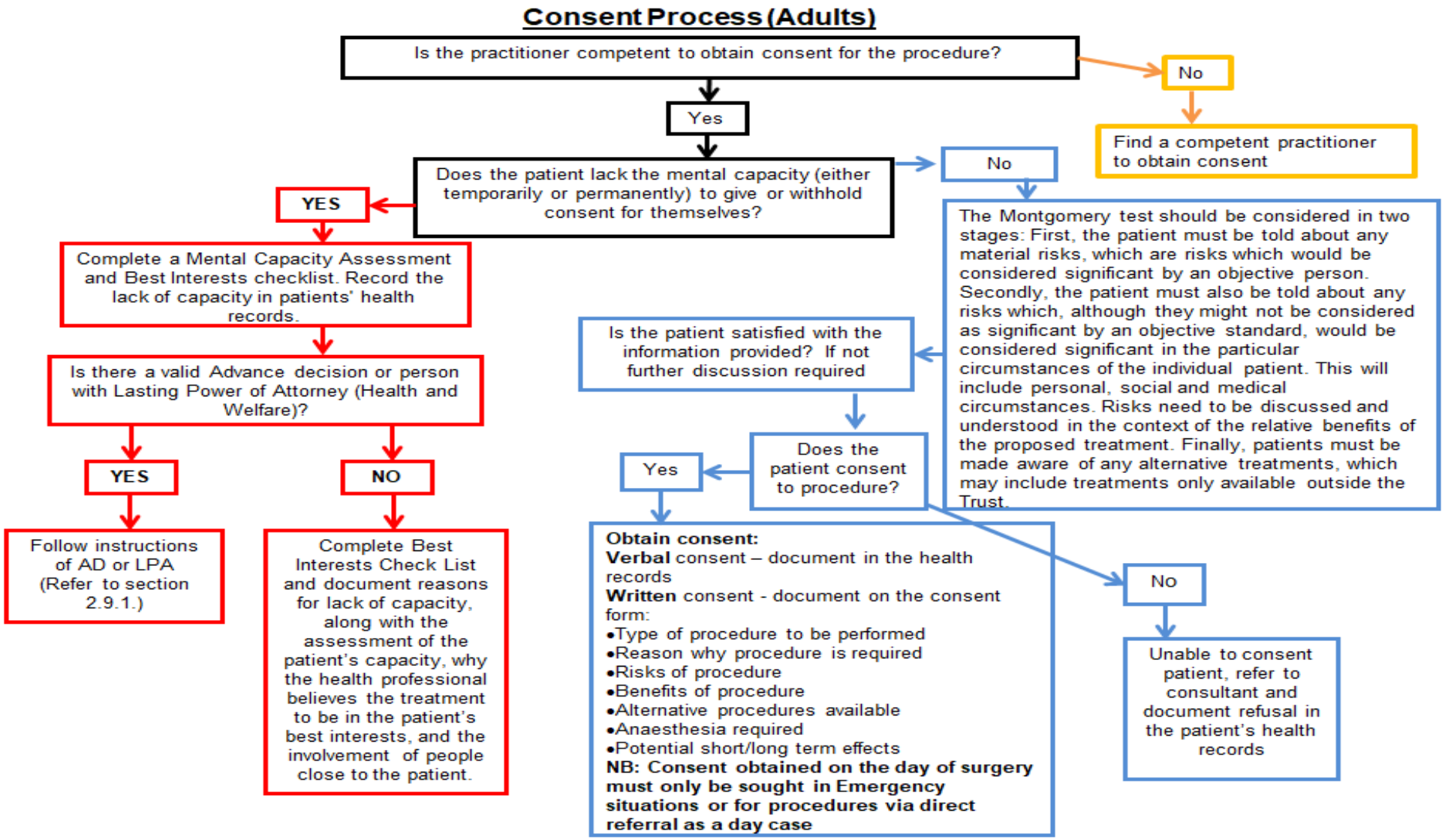
- ❖ For elective procedures a patient will receive information about anaesthesia prior to the procedure at the preoperative clinic and high risk patients are offered an appointment with the Consultant Anaesthetist at this time. On the day of the operation the patient is then seen by the anaesthetist who will anaesthetise them and a discussion about the anaesthetic then takes place and is documented on the anaesthetic charts. It is not good practice for a patient to receive information about anaesthesia for the first time at their pre-operative visit from the anaesthetist unless in an emergency situation

- ❖ Healthcare professionals must follow an advance decision if it is valid and applicable, even if it may result in the person's death

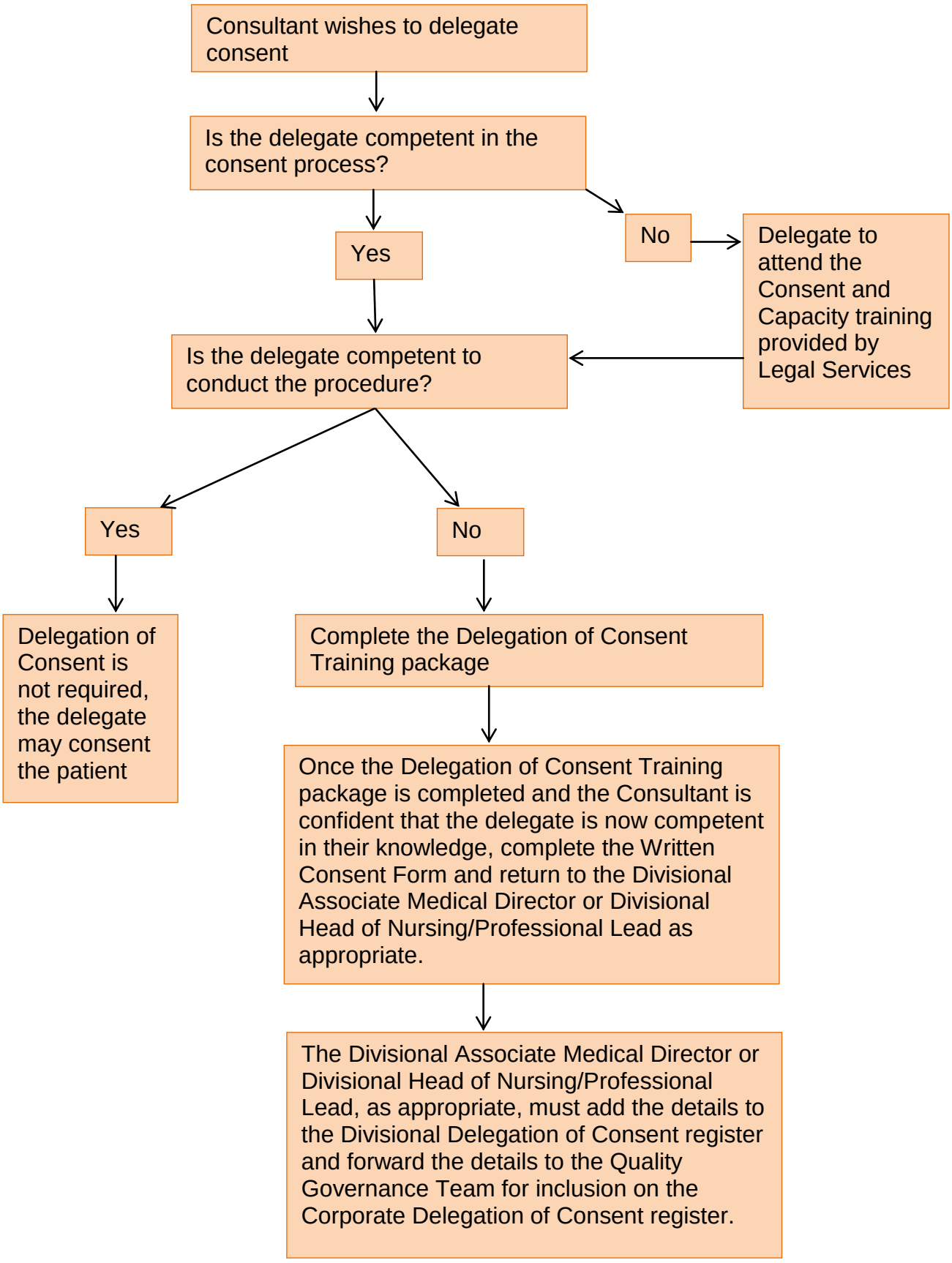
- ❖ If a patient is identified or suspected of lacking capacity a mental health capacity and best interests checklist must be completed (refer to the "*Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy*")

- ❖ If photographs are taken by staff they must be taken using a digital camera. The use of personal mobile telephone cameras is prohibited under any circumstances. Any clinician who does use a personal mobile telephone camera to take a photograph or video recording of a patient will be:
  - liable for the risk of such an action
  - face disciplinary action

  (refer to the "*Clinical Photography/ Images Policy*")


Consent Process (Adults)
Is the practitioner competent to obtain consent for the procedure?
No
Find a competent practitioner to obtain consent
Yes
Does the patient lack the mental capacity (either temporarily or permanently) to give or withhold consent for themselves?
No
YES
Complete a Mental Capacity Assessment and Best Interests checklist. Record the lack of capacity in patients' health records.
Is there a valid Advance decision or person with Lasting Power of Attorney (Health and Welfare)?
YES
Follow instructions of AD or LPA (Refer to section 2.9.1.)
NO
Complete Best Interests Check List and document reasons for lack of capacity, along with the assessment of the patient's capacity, why the health professional believes the treatment to be in the patient's best interests, and the involvement of people close to the patient.
The Montgomery test should be considered in two stages: First, the patient must be told about any material risks, which are risks which would be considered significant by an objective person. Secondly, the patient must also be told about any risks which, although they might not be considered as significant by an objective standard, would be considered significant in the particular circumstances of the individual patient. This will include personal, social and medical circumstances. Risks need to be discussed and understood in the context of the relative benefits of the proposed treatment. Finally, patients must be made aware of any alternative treatments, which may include treatments only available outside the Trust.
Is the patient satisfied with the information provided? If not further discussion required
Does the patient consent to procedure?
Yes
No
Obtain consent:
Verbal consent – document in the health records
Written consent - document on the consent form:
•Type of procedure to be performed
•Reason why procedure is required
•Risks of procedure
•Benefits of procedure
•Alternative procedures available
•Anaesthesia required
•Potential short/long term effects
NB: Consent obtained on the day of surgery must only be sought in Emergency situations or for procedures via direct referral as a day case
Unable to consent patient, refer to consultant and document refusal in the patient's health records

Delegation of Consent Flowchart



QUICK REFERENCE GUIDE

12 Key Points on Consent – the Law in England

When do health professionals need consent from patients?	1. Before you examine, treat or care for competent adult patients you must obtain their consent. 2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation. 3. Patients may be competent to make some health care decisions, even if they are not competent to make others. 4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.
Can children give consent for themselves?	5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, someone with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent **cannot** over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.
Who is the right person to seek consent?	6. It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.
What information should be provided?	7. Montgomery – The patient must be told of any material risks which could be considered significant by an objective person, or for that individual patient, including personal, social and medical. Risks need to be discussed and understood in the context of the relative benefits of the treatment and be made aware of any alternative treatments, including those available outside the Trust. 8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.
Does it matter how the patient gives consent?	9. No: Consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.
Refusal of treatment	10. Competent adult patients are entitled to refuse treatment, even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the foetus.
Adults who are not competent to give consent	11. Except for a person holding a Lasting Power of Attorney (for Health and Welfare) which includes the power to consent to treatment, no-one can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences. 12. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances and has signed an 'advance decision to refuse treatment' (known as an advanced directive or living will), and those circumstances arise, this refusal must be abided by.

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment,* available from the NHS Response Line 08701 555 455 and at
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf

1 Introduction / Purpose

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between healthcare professionals and patients. Healthcare professionals who do not respect this principle may be liable both to legal action by the patient and to action by their professional body. Employing bodies may also be liable for the action for their staff. Whilst there is no English statute setting out the general principle of consent, case law (common law) has established that touching a patient without valid consent may constitute the civil or criminal offence of battery.

The Supreme Court case of Montgomery vs Lanarkshire Health Board in 2015 was a landmark decision for the doctor-patient relationship and the process of informed consent. The Montgomery case closed the gap between regulatory guidance and case law by shifting the focus of consent towards the specific needs of the patient. Accordingly, doctors must take reasonable steps to ensure that patients are aware of any risks that are material to them, and they should inform their patients of alternative treatments. It should be noted that the Bolam principle still applies in all other aspects of clinical practice apart from consent.

This policy has been developed to give guidance to staff on consent to examination, treatment and post mortem. The Department of Health has issued a range of guidance documents on consent (available from the Department of Health website) and these should 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 health professionals are able to comply with the guidance.

It is the policy of the Trust that no one will be discriminated against on the grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. The Trust will provide interpretation services or documentation in other mediums as requested and necessary, to ensure natural justice and equality of access.

1.1 Guidance on Consent

The Department of Health has issued a number of guidance documents on consent, and these should be consulted for advice on the current law and good practice requirements in seeking consent. Healthcare professionals must also be aware of any guidance on consent issued by their own regulatory bodies.

For example the document “Reference guide to consent for examination or treatment” provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies may be accessed on the internet at www.dh.gov.uk/consent and clicking on ‘Consent Key Documents’.

In addition “12 key points on consent: the law in England” has been distributed widely to health professionals working in England. This one-page document summarises those aspects of the law on consent which arise on a daily basis. Further copies are available at www.dh.gov.uk/consent

Specific guidance, incorporating both the law and good practice advice, is available for healthcare professionals working with children, with people with learning disabilities and with older people. Copies of these booklets are available on the internet at **www.dh.gov.uk/consent** and clicking on ‘Consent Key Documents’

2 Consent Policy

NOTE: This policy must be read in conjunction with the "Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy" and the "Clinical Photography / Images Policy". Consent for children is within the "Consent to Examination and Treatment for Children and Young People Policy".

2.1 What is Consent?

For the consent to be valid, it must be based on the following criteria:

- Voluntariness. This describes the willingness of a patient or parent to agree to themselves or their child undergoing health care intervention.
- Capacity. This term describes that the patient or parent is able to understand the nature of the proposed treatment.
- Knowledge. The patient or parent must have received sufficient information about the nature of the proposed treatment or intervention including risks and benefits.

<u>If any of these factors are missing, the patient is not considered to have given permission to proceed to treatment.</u>

The validity of consent does not depend upon the form in which it is given. It can be verbal, implied or written. Implied consent is not in itself sufficient to demonstrate an understanding about the proposed intervention without evidence that sufficient information has been provided to a capacitous patient. Acquiescence where the person does not know what the intervention entails is not consent.

In the absence of valid consent, an intervention may be lawful:

- Under the Mental Capacity Act 2005
- Under the Mental Health Act 1983
- With the consent of someone who holds parental responsibility (where the decision is "within the scope" of parental responsibility)
- Following a decision of the Court of protection or the High Court.

Consent is often (wrongly) equated with a patient's signature on a consent form. A signature on a form is evidence of valid consent, not proof. 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 also withdraw consent after they have signed a form. The signature is not a binding contract.

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves <u>no one else can give consent on their behalf.</u> If the patient has appointed a person as their attorney under a Health and Welfare Lasting Power of Attorney (LPA), they may only make decisions about life-sustaining treatment if the patient has specifically stated this in their Health and Welfare LPA. However, treatment may be given if it is in their best interests, as long as the requirements of the Mental Capacity Act 2005 are adhered to and it has not been refused in advance in a valid and applicable advance directive or advance decision. If consent is gained from a person with LPA for Health and Welfare, the document must be seen and registered with Legal Services before consent can be given, to ensure that it is a valid document and the attorney has the power for such decisions. **Please refer to the "*Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy*".**

There are two categories of formal consent within the Trust:

1. **Standard Consent** – Consent taken by someone who is able to perform the procedure that the patient is consenting to

2. **Delegated Consent** – The healthcare professional obtaining the consent must be competent to do so because:

    - they themselves carry out the procedure

    - they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations, are registered on the Trust Delegation Register and are subject to audit

The latter is known as delegated consent as the healthcare professional has been given delegated authority to obtain consent.

(**See section 2.5.2 for the process of Delegation of Consent**)

2.2 Process for Obtaining Consent

2.2.1 Responsibility for Obtaining Consent

The healthcare professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done. Any issues in understanding caused by language, understanding, and/or special requirements must be addressed. It is the healthcare professional carrying out the procedure that will be held responsible in law if this is challenged later.

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

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

In an exceptional situation where delaying treatment would constitute a breach of care, and in which there is no member of staff immediately available who is able to take consent, the clinical team should not delay treatment in order to ensure consent is obtained, and must continue with clinically appropriate treatment if it is in the patient's best interests (e.g. during acute life-threatening emergencies when there is no-one able to take consent until the operating clinician arrives on site, and delaying preparation for surgery would be a life-threatening breach of care).

2.2.2 Stages of Gaining Consent

The "consent seeking" process consists of information provision, discussion and decision making. When a patient formally gives their consent to a particular intervention (examination or treatment) this is the endpoint of a 'consent seeking' process. This process may take place on more than one occasion, depending on the seriousness of what is proposed and the urgency of the patient's condition.

- **Single stage process (Verbal)**

In many cases, particularly with routine or low-risk procedures, it will be appropriate for a healthcare professional to initiate a procedure immediately after discussing it with the patient. For example, during an on-going episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In

many such cases, consent will be given orally but this **must** be documented in the patients' health records by the healthcare professional.

If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and healthcare professionals 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 healthcare professional may then proceed. This **must** be documented in the health records by the healthcare professional.

- **Two or more stage process (Written)**

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 out-patient clinic), or it might be over a whole series of consultations with a number of different healthcare professionals. The consent process will therefore have at least two stages.

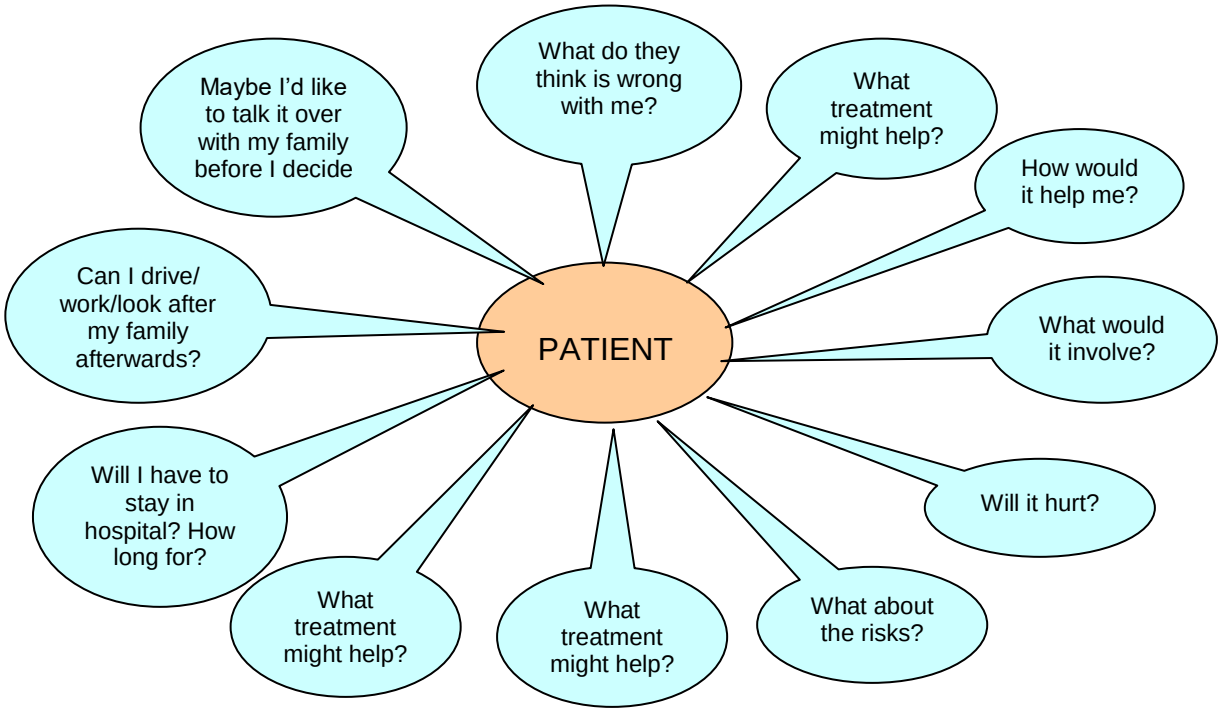
  - The first is the provision of information, discussion of options, risks, benefits and alternatives (if relevant) and initial (oral) decision
  - The second is the confirmation that the patient still wants to go ahead

The consent form should be used as a means of documenting the stages of consent. Discussions should be noted in the health records by the healthcare professional.

To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the person either to accept or refuse treatment. Such pressure can come from partners or family members as well as healthcare professionals. Healthcare professionals should be alert to this possibility and, where appropriate, arrange to see the person on their own in order to establish that the decision is truly alone. Coercion invalidates consent. Coercion should be distinguished from providing the person with appropriate reassurance concerning their treatment, or pointing out the potential benefits of treatment for the person's health. Threats such as withdrawal of any privileges or similar may well invalidate consent given.

The Trust expects that written consent will be obtained in the out-patient setting prior to the patient being listed for the procedure. Confirmation on consent on the day of the procedure gives the patient time to reflect and then raise any questions or concerns.

2.2.3 **Gaining Consent: Remembering the Patient's Perspective**



2.2.4 Gaining Consent in Emergency Situations (Doctrine of Necessity)

When a clinical emergency arises, and it is not possible to find out a patient's wishes, the patient can be treated without their consent, provided the treatment is immediately necessary to save the patient's life or to prevent a serious deterioration in their condition. The treatment provided must be the least restrictive on the patient's future choices. On-going care should be provided for as long as the patient lacks capacity. If the patient regains capacity they must be told what has been done and why, as soon as they have recovered sufficiently to understand. This communication **must** be recorded in the patient's health records.

Clearly in emergencies, the two stages of gaining consent (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 health care records to document any discussion and the patient's consent, rather than using a consent form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

2.2.5 Seeking Consent for Anaesthesia and Sedation

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

A patient for an elective procedure should be seen in the preoperative clinic where patient national approved leaflets are given around the general anaesthetic. If the patient is deemed to be high risk (using national guidance on preoperative assessment) then these patients are invited to see a Consultant Anaesthetist in the preoperative clinic, where a discussion around their individual risk can take place. The patient should then be highlighted as a Consultant only case and the Consultant given correspondence around this. On the day of the operation the patient is then seen by the anaesthetist who will anaesthetise them and a discussion about the anaesthetic then takes place and is documented on the anaesthetic chart.

The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's health 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 procedure.

2.2.6 Additional Procedures

During an operation it may become evident that the person could benefit from an additional procedure that was not within the scope of the original consent. It may be justified to perform the procedure on the grounds that it is in the person's best interest, for example because there is a threat to the person's life. However, the procedure should not be performed merely because it is convenient.

If a person has refused certain additional procedures before the anaesthetic (for example, specifying that a mastectomy should not be carried out after a frozen section biopsy result), then this must be respected if the refusal is applicable to the circumstances. The GMC guidance states that it is good practice to seek the views of the patient on possible additional procedures when seeking consent for the original intervention.

2.2.7 Verbal / Non-Verbal (Implied) Consent

Verbal consent should be limited to those procedures where the risk is low (both in terms of percentages and that any potential injury is trivial or minor), and the agreement of the procedure to take place must always be recorded in the patient's health records by the professional conducting the procedure.

Whether or not the consent process is formally documented, the principles of valid consent apply. For routine and low-risk procedures, such as providing personal care or taking a blood sample, the patient's understanding can usually be assessed during an informal discussion immediately prior to the procedure, as part of the care process. Verbal or non-verbal consent is appropriate for these routine and low-risk procedures. Consent is stated (verbal) by the patient or implied (non-verbal) by, for example, the patient rolling up their sleeve and putting out their arm in response to a request from a clinician to take blood.

If there is 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), the consent process should be documented in the patient's health records.

Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to a particular treatment. You should ensure that they have the information they need before proceeding with an investigation or treatment. Suitable leaflets are available from healthcare professionals and any information given to patients should be documented in the patients' health records.

2.3 Consent of Children and Young People

Please refer to "Consent to Examination and Treatment of Children and Young People Policy"

2.4 Documentation of Consent

For clinical intervention procedures, it is essential for healthcare professionals to document clearly both a 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 health records if necessary), or through documenting in the patient's health records that they have given oral consent.

2.4.1 Written Consent

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent, but is not proof of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment.

Patients may, if they wish, withdraw consent after they have signed a form. Their signature is evidence of the process of consent-giving, not a binding contract.

It is rarely a legal requirement to seek written consent (The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances), but 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 health professionals would describe as 'side-effects' or 'complications')
- The procedure involves general / regional anaesthesia or sedation
- Providing clinical care is not the primary purpose of the procedure e.g. research trials, student observation
- There may be significant consequences for the patient's employment, social or personal life e.g. HIV and Hepatitis B testing, pregnancy testing, stress testing
- The treatment is part of a project or programme of research approved by this Trust

Completed consent forms **must** be kept with the patient's health 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 healthcare professional.

Completed consent forms **must** be checked before the patient leaves the ward or department for a procedure. In the unlikely event that a patient arrives at the operating theatres or appropriate department without a signed consent form, if required for the procedure, they must be taken back to their ward, and the Consultant informed. An electronic incident form should be completed by the clinician responsible for performing the procedure and an investigation conducted into the event, co-ordinated by the Quality Governance Manager for the Division concerned.

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

Standard consent forms and forms for adults who are unable to consent for themselves are available in the clinical areas. There are three versions of the consent form:

- **Form 1:** for adults or competent children
- **Form 2:** for parental consent for a child or young person
- **Form 3:** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 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

- **Best Interest Check List:** for adults who are unable to consent to investigation or treatment

2.4.2 Delegation of Consent

Clinical, legal and professional responsibility for ensuring that valid consent has been obtained before treatment is provided rests with the person carrying out the procedure. The GMC's (General Medical Council) guidance states:

"If you are the doctor undertaking an investigation or providing treatment, it is your responsibility to discuss the procedure, risks and benefits with the patient. If this is not practical, you can delegate the responsibility to someone else, provided you make sure that the person you delegate to:

a. is suitably trained and qualified
b. has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved
c. understands, and agrees to act in accordance with, the GMC's guidance".

Only a Consultant can delegate consent. If the Consultant delegates the consent process, they are still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before they start any investigation or treatment. Therefore the Consultant should ensure that when they require a colleague to seek consent on their behalf, they are confident that their colleague is competent and trained to do so.

The accountability of consent rests with the person taking consent and it is this process which will be considered as part of any legal proceedings in negligence claims.

In some cases, the treating doctor may be informed by the individual tasked with seeking consent that they have the necessary knowledge or skills to comply with the request. In such circumstances, the doctor carrying out the procedure is responsible for making alternative arrangements to ensure that valid consent is obtained from the patient before the treatment is provided. If doctors delegate responsibility for seeking consent to someone who does not have the necessary knowledge and skills, they must accept overall responsibility for any failings in the consent process.

Where the healthcare professional obtaining delegated consent is unable to answer specific patient queries, they should contact the healthcare professional carrying out the procedure (or a colleague competent to undertake such a procedure) to ensure the information is provided in a timely manner.

For those members of staff who are not capable of performing the procedure but who wish to be authorised to obtain consent, the following principles will apply:

(a) All staff seeking consent must be educated in the principles of consent

(b) Following the above education session the health professional must complete an assessment of competence form with their supervising Consultant or delegated nominee

(c) The Consultant and health professional will both agree what procedures can be delegated to the health professional. This will depend on the level of experience required

Appropriate training and Delegation of Written Consent Forms must be completed prior to staff being authorised to take consent and forwarded to the Integrated Governance Department for recording on the Corporate Delegated Consent Register. The only exceptions to this are the designated nursing staff within the Treatment Centre who

undergo the required level of training and on completion receive a covering letter signed by all relevant Consultants. Divisional records and updating of the Divisional Delegated Consent Register will be the responsibility of the Divisional Associate Medical Director and the Divisional Head of Nursing /Professional Lead. The Quality Governance Department must be informed of additions to the Delegated Consent Register.

It is the responsibility of the person to whom consent has been delegated to inform the Consultant concerned if they do not feel competent to take consent from a patient.

If the member of staff is not capable of obtaining consent then appropriate local training must be provided prior to authorisation via the Delegation of Written Consent Form.

As part of the appraisal process for designated nursing staff and speciality doctors, a review of their delegated consent practice must be undertaken to identify any issues or concerns. Doctors in training should take consent as appropriate to their level of training in accordance with their e-portfolios.

Any member of staff who feels pressurised to seek consent when they do not feel competent to do so should contact the Legal Services Department or the Associate Director of Quality Governance.

Where a member of staff is identified as having obtained formal delegated patient consent for a procedure when not authorised to do so, (e.g. via audits or spot checks), an electronic incident form must be completed and the matter must be brought to the attention of the Division's Quality Governance Manager. The Divisional Quality Governance Manager will then investigate what omission(s) has / have occurred in the delegated consent process.

If, for example, the investigation confirms that the member of staff has been taking consent without the required training or assessment, then the member of staff could undergo formal disciplinary action.

If any subsequent Disciplinary Hearing concludes that a medical practitioner has taken consent from a patient without the authority to do so, then the Trust's Medical Director will report the medical practitioner to the GMC.

2.5 Duration of Consent

In general, when a person gives valid consent to an intervention that consent remains valid for an indefinite duration, unless it is withdrawn by the person. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the times when consent was sought and when the intervention is undertaken, the GMC guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent.
The clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent repeated on the basis of this information. Similarly, if the patient's condition has changed significantly in the intervening time it may be necessary to seek consent again, on the basis that the likely benefits and / or risks of the intervention may also have changed.

If consent has been obtained a significant time before undertaking the intervention, a health care professional should confirm that the person who has given consent (assuming that they retain capacity) still wishes the intervention to proceed, and sign the consent form even if no new information needs to be provided or further questions answered.

2.6 Provision of Information

The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition, about possible treatments or investigations, and their risks, benefits and alternatives (including the risks and benefits of doing nothing). Patients also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, the removal of tissue, or recording images. They need to know, for example, what will happen, how long they will be in hospital, and how they will feel afterwards.

Staff must record the information given to the patient, either on the consent form or in the patient's health records.

Patients, and those close to them, will vary in how much information they want, ranging from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the 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 in the health records. If a hazard that should have been mentioned is not mentioned, the law will impose an obligation to compensate if that hazard occurs.

The clinician is entitled to withhold from the patient information as to a risk if they reasonably consider that its disclosure would be seriously detrimental to the patient`s health. The clinician is also excused from conferring with the patient in circumstances of necessity, e.g. where the patient required urgent treatment but is unconscious or otherwise unable to make a decision.

Three further points need to be considered:

1. The assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides it magnitude: e.g. the nature of the risk, the effect which its occurrence would have on the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risk involved in these alternatives. The assessment is therefore fact-sensitive and sensitive to the characteristics of the patient.

2. The clinician`s advisory role includes dialogue, the aim of which is to ensure that the patient understands the seriousness of their condition and the anticipated benefits and risk of the proposed treatment, and any reasonable alternatives, so that they are in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The clinician`s duty is not to be fulfilled by bombarding the patient with technical information and statistics which they cannot reasonably be expected to understand, let alone by routinely requesting their signature on a consent form.

3. It is important that the therapeutic exception is not abused. It is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the clinician to prevent the patient from making an informed choice where they are liable to make a choice which the clinician/doctor considers to be contrary to their best interests.

2.6.1 Failure to Warn / Montgomery Test

If patients convince a Court that they were not warned of known complications and/or side effects and that if they had been warned they would not have gone ahead with treatment, then this will be considered as negligence on behalf of the organisation. It is not enough to be simply ready to answer a patient's questions. Risks should be openly explained as far as is reasonable for the particular patient, indicating the probability of each arising and the likely seriousness. All discussions must be documented in the patient's health records.

The Montgomery test should be considered in two stages:

- Firstly, the patient must be told about any material risks, which are risks which would be considered significant by an objective person
- Secondly, the patient must also be told about any risks which, although they might not be considered as significant by an objective standard, would be considered significant in the particular circumstances of the individual patient. This will include personal, social and medical circumstances.

Risks need to be discussed and understood in the context of the relative benefits of the proposed treatment. Finally, patients must be made aware of any alternative treatments, which may include treatments only available outside the Trust.

2.6.2 Patient Information Leaflets

Patient information leaflets / fact sheets are a useful means of providing information on the procedure and the risks, benefits, alternatives and sources of information, as patients can take them away with them and consider the implications of the required treatment.

Information leaflets / fact sheets do not negate the clinician's responsibility to provide a verbal explanation of much of the same information. For example, the clinician will clearly need to explain why one procedure has been suggested over the alternatives in a specific patient's case.

When providing patient information as part of the consent process, the use and provision of the relevant leaflet must be clearly documented in the patient's health record along with the EIDO reference number.

Patients may require more detailed information about their condition or about a proposed treatment than that provided in general leaflets. If further information is required this should be obtained from the Consultant responsible for the patient's care.

2.6.3 Provision of Information for Patients 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 staff.

Translation Services are available through the Big Word, for telephone or face-to-face translation, details of which are available in the Trusts "Interpreting and Translation Policy". A staff contact list for accessing the Big Word is available via the Trust Intranet.

If a translator is required to obtain valid consent from a patient the *Interpreting and Translating Policy* should be followed. For elective cases the need for an interpreter should be identified by the Consultant/practitioner on the listing sheet which is sent to the scheduler who will notify the designated contact person for the division / sub-speciality, who will book an interpreter for the required time.

Translation of Consent Forms 1, 2 and 3 are also available from the Department of Health's Website via the following link:
http://www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Consent/Consentgeneralinformation/DH_4001986

It is not appropriate to use children or other family members to interpret for patients who do not speak English other than in emergencies or exceptional circumstances.

2.6.4 Provision of Information for Patients with Other Communication or Learning Difficulties / Disabilities

A patient with communication or learning difficulties will need extra time to comprehend the information provided and reach a decision. A record should be kept in the health records, and by the patient, of the information given during the discussion, which may be in the form of key written words, pictures etc. The patient can use this to refer back to and ask further questions, and use as a basis to make or change a decision.

If possible, the patient should be assisted to make and communicate their own decision, by providing information in non-verbal ways where appropriate. Examples include pointing to their choice of your written words or pictures, writing, drawing or using gestures (e.g. nodding or shaking his/her head). In these circumstances, the healthcare professional must document how the patient has agreed.

The patient may already be using a communication aid. Under these circumstances appropriate advice should be sought from a Speech and Language Therapist.

Carers of patients with learning or communication difficulties should be provided with the appropriate written information and contact details. The Privacy and Dignity Matron may be contacted to assist with accessing more detailed information.

2.7 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*. The situation for children is more complex (see the Department of Health's *Seeking consent: working with children* for more detail) and refer to the trust's *"Consent to Examination and Treatment for Children and Young People (over 16 years) Policy*.

The following paragraphs apply primarily to adults.

2.7.1 Advance Decisions to Refuse Treatment

A person may have made an advance decision to refuse a particular treatment in anticipation of future incapacity (sometimes previously referred to as a 'living will' or 'advance directive/decision'). A valid and applicable advance decision to refuse treatment has the same effect as if that person has capacity and is refusing consent to treatment. This is a well-recognised rule of common law, and the Mental Capacity Act 2005 now puts advance decisions on a statutory basis. The Act clearly sets out the requirements that such a decision must meet to be valid and applicable. These are:

- The person must be 18 years of age or over
- The person must have the capacity to make such a decision
- The person must make clear which specific treatments they are refusing

- If the advance decision includes the refusal of life-sustaining treatment, it must be in writing (it can be written by somebody else or recorded in the health records), it must be signed and witnessed and it must state that the decision applies even if life is at risk

- A person with capacity has the right to withdraw their advance decision at any time.

Healthcare professionals **must follow** an advance decision if it is valid and applicable, even if it may result in the person's death. If they do not, they could face criminal prosecution or civil liability. The Mental Capacity Act 2005 protects a health professional from liability for treating or continuing to treat a person in the person's best interests if they are not satisfied that an advance decision exists which is valid and applicable. The Act also protects healthcare professionals from liability for the consequences of withholding or withdrawing a treatment if at the time they reasonably believe that there is a valid and applicable advance decision. If there is genuine doubt or disagreement about an advance decision's existence, validity or applicability, the case should be referred to the Court of Protection. The Court does not have the power to overturn a valid and applicable advance decision. While a decision is awaited from the Court, healthcare professionals can provide life-sustaining treatment or treatment to stop a serious deterioration in the patient's condition.

If an advance decision is not valid or applicable to current circumstances, healthcare professionals must consider the advance decision as part of their assessment of the person's best interests. Advance decisions made before the Mental Capacity Act came into force may still be valid if they meet the provisions of the Act. There are transitional arrangements for advance decisions to refuse life-sustaining treatment made before 1 October 2007. Further information is available on the Department of Health website.

Some healthcare professionals may disagree in principle with a person's right to refuse life-sustaining treatment. The Mental Capacity Act does not change the current legal position. Healthcare professionals do not have to act in a way that goes against their beliefs. However, they must not simply abandon patients or cause their care to suffer. A patient should have the option of transferring their care to another healthcare professional or, if the patient lacks capacity, arrangements should be made for the management of the patient's care to be transferred to another healthcare professional.

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

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

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

In the event of any doubt about the validity of an Advance Decision, staff should contact Legal Services for advice in the first instance.

2.8 Mental Capacity

NOTE: Please refer to the Trust's "Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy".

The Mental Capacity Act 2005 defines a person who lacks capacity as a person who is unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain. It does not matter if the impairment or disturbance is permanent or temporary.

A person is unable to make a decision for themselves if they are unable to:

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

The assessment of capacity should be made by the practitioner in charge of the patient's medical treatment. Although a psychiatric opinion may be helpful, it should not in itself be regarded as conclusive. Guidance is provided in chapter 4 of the Mental Capacity Act (2005) Code of Practice.

NOTE: Every adult is assumed to be capable. The default position, therefore, is that all adults have capacity until they are proven otherwise.

2.8.1 Third Party Consent and Advanced Decisions

As a general rule, one adult may not provide consent for the medical treatment of another adult. There are two exceptions under the Mental Capacity Act 2005:

- Lasting Power of Attorney (LPA) for Health & Welfare: the person is instructed under an LPA, validly made by the patient while they were still capable and which relates to their health and social care

- Court of Protection: the person is a deputy appointed to make decisions on behalf of the patient

An advance decision (AD) is a refusal of healthcare treatment made when the person has capacity and is over 18 years of age. It will only apply when the person lacks capacity. If it is valid and applicable (i.e. it mentions the proposed treatment and circumstances), it will take precedence over consent given by an LPA appointed prior to the AD or Court of Protection appointed deputy. It need not be in writing unless it is refusing life-sustaining treatment, in which case it must be signed and witnessed. An AD is no longer valid or applicable if:

- The patient has withdrawn the AD
- There are reasonable grounds for believing that circumstances exist that the person did not anticipate when the AD was made and that would have affected the decision
- A LPA for Health & Welfare has been appointed since the AD
- Since making the AD, the patient has done something inconsistent with it

Existing ADs (from before the Mental Capacity Act 2005 came into force) are still valid unless they have subsequently been withdrawn.

2.8.2 Advocacy – Independent Mental Capacity Advocacy (IMCA)

NOTE: Please refer to the Trust's "Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy".
For decisions regarding serious medical treatment, where there is no appropriate person available except for paid staff, professionals involved in the care of the individual that lacks capacity must instruct an IMCA. An IMCA is not a decision-maker for the person who lacks capacity, but is involved in ensuring that the decision making is done appropriately and in accordance with the Mental Capacity Act 2005.

An advocate/IMCA will have to be appointed for a patient who lacks capacity under the following circumstances:

- The patient is to have 'serious medical treatment' (see below)
- The patient is to be in hospital for more than 28 days or in a care home for more than 8 weeks
- The local authority is to arrange for the patient to be accommodated for more than 8 weeks

A 'serious medical treatment' will involve providing, withdrawing, or withholding treatment in circumstances where:

- A single treatment is proposed and there is a fine balance between its risks and benefits
- There is a choice of treatments but a decision as to which one to use is finely balanced
- What is proposed is likely to involve serious consequences for the patient

2.9 Consent for Tissue Samples

2.9.1 Consent is required when tissue is taken from a living patient. This may be:

- in the course of a diagnostic procedure (e.g. tissue biopsy, cervical screening)
- in the course of treatment (removing organs and/or tumours during surgery)
- for the purpose of research

In the first two cases, the usual 'consent to treatment' process will naturally include discussion about the tissue that will be removed, and should include any 'material' or 'significant' risks inherent in the way the sample will be obtained. This is recorded on the main consent form. If tissue is being taken specifically for research, then consent will be obtained and recorded by the researcher, or a trained and competent delegate.

2.9.2 Provision of Information

To give consent patients, or their parent or person with parental responsibility, must understand the nature and purpose of what is proposed and be able to make a balanced judgment. They should be told of any 'material' or 'significant' risks inherent in the way the sample will be obtained, how the tissue will be used and any possible implications of its use (e.g. genetic testing).

If identifiable tissue is to be used for research or audit purposes, patients should be told about any implications this may have. For example they may be contacted by researchers or auditors, given feedback, or be asked for access to their medical records.

Patients should be told whether the consent is generic (i.e. for use in any future research project approved by a Research Ethics Committee) or specific.

2.9.3 Form of Consent

The validity of consent does not depend on the form in which it was given. The information required, and the manner in which consent is taken and recorded, can vary depending on the particular circumstances. Consent may be expressed verbally or non-verbally.

When consent is obtained for future storage or use of samples, but the consent itself is not in writing, an appropriate note should be kept of the fact that consent has been given, and for what purpose(s). This must be entered in the patient's health record, the laboratory records, or both.

2.9.4 Refusal of Consent for Sampling

If a competent adult refuses consent for samples to be taken in respect of their treatment, the risks and implications for their treatment must be explained to them, and the discussion documented clearly in the patient's health record. Notwithstanding this, patients should be informed that other treatments will continue as far as is possible without the desired information. As with any part of their treatment, a patient can change his / her mind at a later date.

If a competent person (as assessed by a doctor) refuses to consent for samples to be taken as part of a police investigation of a suspected alcohol or drug-related driving offence, then the samples may not be taken (but the patient is guilty of an offence in refusing).

2.9.5 Consent for Tissue Samples from Adults who Lack Capacity

NOTE: Please refer to the Trust's "Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy".

2.9.6 Consent for Tissue / Organ Transplantation

In respect of Tissue / Organs for transplantation, it is important to ensure that this is performed in line with the Human Tissue Act (2004). The process for such procedures is documented in the Trusts "Operational Policy for Organ Donation and Required Referral"

2.9.7 Consent Requirements Concerning Gametes

It is a legal requirement under the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) that consent must be obtained in writing before a person's gametes can be used for the treatment of others, or to create an embryo in vitro. Consent in writing is also required for the storage of gametes. Information, and an opportunity to receive counselling, must be provided before the consent is given. Where these requirements are not satisfied it is unlawful to store, or use, the person's gametes for these purposes. Clinicians should ensure that written consent to storage exists before retrieving gametes.

Outside specialist infertility practice, these requirements may be relevant to healthcare practitioners whose patients are about to undergo treatment that might render them sterile (such as chemotherapy or radiotherapy). Under these circumstances a patient may wish to have gametes, or ovarian or testicular tissue, stored prior to the procedure. Healthcare practitioners may also receive requests to remove gametes from a person who is unable to give consent.

2.9.8 Consent for the Storage and Use of Tissue

Once tissue has been obtained from patients, for whatever purpose, it can be stored and used for a number of purposes.

Consent is required for the storage and use of tissue for:

- obtaining scientific or medical information about a person specifically because it may be relevant to any other person, now or in the future (e.g. paternity testing)

- research (on samples initially taken for diagnosis or treatment) in connection with disorders, or the functioning, of the human body
- public display (i.e. display not confined to teaching rooms)
- transplantation

Although consent is NOT required for storage and use of tissue under the following circumstances, it is considered good practice to make patients aware of them when consenting for the original procedure:

- clinical audit
- education or training (e.g. teaching medical students or trainees in pathology)
- for performance assessment (i.e. in external quality assurance schemes to test pathologists' competence in reporting)
- internal quality control
- anonymised cases sent to teaching sets for external quality assurance
- public health monitoring
- 'anonymous' research on samples originally taken for diagnosis or treatment (i.e. the researcher cannot identify the person from the sample)

2.9.9 Disposal of Organs and Tissue

During the consent process for obtaining tissue and organs, patients should be informed of the procedures for their disposal. These are complex, but in summary it is lawful to treat as 'waste' any tissue or organ which has come from a person who was:

- in the course of receiving medical treatment
- undergoing diagnostic testing
- participating in research

The organs or tissue must be disposed of by incineration in accordance with the current guidelines (Human Tissue Act 2004).

Furthermore it is lawful to dispose of 'waste' any material defined as surplus material. This includes:

- tissue fragments trimmed from the tissue sample before it is processed for histology
- tissue in sections trimmed from a wax-embedded block before the useable sections are cut
- unrecoverable bodily material that is washed out of the tissue during its processing into a wax block

For further information, see Human Tissue Act - code of practice: The removal, storage and disposal of human organs and tissue.
http://www.hta.gov.uk/guidance/codes_of_practice.cfm

2.9.10 Consent in Relation to Deceased Patients

Attitudes towards post mortem examination, in particular the removal of organs and tissue and the use of tissue after death, differ greatly. When death has occurred unexpectedly or as a potential consequence of procedures / interventions undertaken, referral should be made to the Coroner who has responsibility for deciding whether a post mortem should be performed.

Consent **is NOT required** in respect of post mortem examinations for:

- carrying out an investigation into the cause of death under the authority of a Coroner
- keeping material after a post mortem for as long as the Coroner requires
- keeping material in connection with a criminal investigation or conviction

Consent is required for the storage and use of material from a Coroner's post mortem that is no longer required to be kept for the Coroner's purposes

2.9.11 Consent for Post Mortem

Hospital Post Mortems are no longer offered by the Trust. Post Mortems will only be performed under the authority of the Coroner.

Two related Consent Forms are available:

- Alder Hey Post Mortem Consent Form "Your wishes about the post mortem examination of your baby" - for use when consent is sought from the parent for a hospital post mortem on a child, baby or foetus and (if applicable) for the retention and use of tissue and / organs afterwards.

- Form 2 - Consent form for the Examination of tissue following a miscarriage.

These are available on Trust Intranet, Frequently Used Forms, Legal Services. Further advice is available from the Bereavement Manager and the Legal Services Manager.

2.10 Consent for Research and Innovative Treatment

The same legal principles apply when seeking consent from a person for research purposes as when seeking consent for investigations or treatment. GMC guidance advises that patients should be told how the proposed treatment differs from the usual methods, why it is being offered and if there are any additional risks or uncertainties. Clinical trials are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004.

If the treatment being offered is of an experimental nature, but not actually part of a research trial, this fact must be clearly explained to a person with capacity before their consent is sought, along with information about standard alternatives. It is good practice to give the person information about the evidence to date on the effectiveness of the new treatment, including information about known possible side effects.

Where the person is an adult who lacks capacity or a child, then the experimental treatment cannot be given unless it would be in their best interests. Where there is no alternative treatment available and the disease is progressive and fatal, it will be reasonable to consider experimental treatment with unknown benefits and risks but without significant risks of increased suffering to the patient, if there is some chance of benefit to the patient

2.11 Consent for Photography, Video and Audio Recordings

Please refer to the "Clinical Photography / Images Policy"

2.11.1 Recordings made as part of patients care

The GMC identifies six categories of recordings for which consent to make the recordings is implicit in the consent given to the investigation or treatment, and does not need to be obtained separately:

- Images of internal organs or structures
- Images of pathology slides
- Laparoscopic and endoscopic images
- Recordings or organ functions
- Ultrasound images
- X-rays

The making of other recordings and images which contribute to patient care, and which fall outside the list above, generally require express patient consent. The GMC advises that, where practicable, doctors should explain any possible secondary uses of the recording in an anonymised form when seeking consent to make the recording. This discussion should be recorded in the patient's medical record.

3 Definitions

Written Consent: A patient's signed agreement for the healthcare professional to provide care.

Oral and Non Verbal (Implied) Consent: A patient's verbal or non-verbal agreement for a healthcare professional to provide care

Delegated Consent: Obtaining consent can be delegated to other healthcare professionals, not necessarily doctors, providing that they are suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment and understand the risks involved, and otherwise act in accordance with the guidance set out by the GMC and the Department of Health.

Doctrine of Necessity: Medical staff can treat an unconscious patient in the absence of consent under the "Doctrine of necessity". This means that as long as the clinician can justify their actions as being in the best interests of the patient then they will be protected against any subsequent legal action.

Advance Decision: The term advance decision (previously known as advanced directive) means a statement explaining what medical treatment the individual would not want in the future, should that individual 'lack capacity' as defined by the Mental Capacity Act 2005. An advance decision is legally binding in England and Wales. Except in the case where the individual decides to refuse life-saving treatment, it does not have to be written down, although most are and a written document is less likely to be challenged. Whilst the patient has capacity their word overrides anything contained in their advance decision or anything their legal representative may say.

The Bolam Principle: In the mid-1980s a majority in the House of Lords (Sidaway vs Bethlem Royal Hospital, 1985) decided that it was on the whole a matter for doctors to decide how much to tell patients about the risks of treatment, thus ensuring that doctors could not be sued for negligence in failing to inform you of a risk if other reasonable doctors would not have informed you of the risk. This was known as the ***Bolam*** principle.

Risk: Is used throughout to refer to any adverse outcome, including those which some health professional would describe as "side-effects" or "complications".

4 Associated Documents

- Royal College of Surgeons - Consent: Supported decision-making (2016)
- Department of Health Reference Guide to Consent for examination or treatment 2009 – Second edition
- Family Law Reform Act 1969
- Department of Health Seeking Consent – working with Children
- The NHS Constitution
- Ms.B v An NHS Hospital Trust (2002) 2 All ER 449
- Glass v United Kingdom (61827/00)(2004)1 FLR 1019 European Court of Human Rights
- Chester v Afshar 2004
- Burke v the General Medical Council (2005) 3 WLR 1132
- Freeman v the Home Office (No 2) (1984)
- Sidaway v Board of Governs of the Bethlem Royal Hospital (1985)
- Bolam v Friern Hospital Management Committee (1957) 2 All ER 118
- Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) (2005) UKSC 11
- MCHFT Incident Investigation, Learning, Reporting and Improving
- MCHFT Clinical Record Keeping Standards
- MCHFT Confidentiality and Data Protection

- MCHFT Being Open Including the Duty of Candour Policy
- MCHFT Whistleblowing Policy
- MCHFT Advance Decisions and Advance Statement Policy
- MCHFT Standard Operating Procedures – Pathology (Post Mortem & Consent**)**
- MCHFT Interpreting and Translation Policy

5 Duties

5.1 Duties within the Organisation

Medical Director

The Medical Director is the designated Executive Lead for maintaining the professional standards of medical staff.

Director of Nursing and Quality

The Director of Nursing and Quality is the designated Executive Lead for maintaining the professional standards of all healthcare professionals with the exception of medical staff

Associate Director of Quality Governance

The Associate Director of Quality Governance is responsible for:

- Reviewing the Consent Policy every three years or sooner if legislation dictates

Legal Services Manager

The Legal Services Manager is responsible for:

- Providing legal advice where consent issues are giving cause for concern
- Providing training on consent and all aspects of the Mental Capacity Act 2005
- Providing training for the process of taking consent under the Human Tissue Act, including Mental Capacity Act, Best Interests, Advance decisions, Lasting Power of Attorney.

Quality Governance Department

This Department is responsible for:

- Monitoring of the implementation of this policy on at least an annual basis
- Ensuring that all incident report forms received with respect to consent are analysed with actions to address the incident and requesting further investigation should it be required
- Maintaining a Delegation of Consent Register of staff not capable of performing a procedure but trained and authorised to take consent.

Divisional General Managers

Divisional General Managers are responsible for:

- Ensuring that this policy is disseminated through the divisional management system
- The co-ordination of the completed Delegation of Written Consent Form and for investigating any potential omissions in the Delegation of Consent process.

Divisional Associate Medical Director / Divisional Head of Nursing / Professional Lead

These individuals are responsible for:

- Ensuring that the Divisional Delegated Consent Register is updated and maintained
- Inform the Quality Governance Team of additions to or removal from the Delegated Consent Register

Consultants / Medical Practitioners

- Individual Consultants must ensure that their patients are appropriately consented in line with the Trust Consent Policy and the Department of Health's Guidance on Consent (DH 2009)
- Ensuring breaches of this policy are reported through the Trust's Incident Reporting Procedure
- Ensuring all medical and non-medical practitioners who are required to undertake the role of obtaining consent are competent and authorised to do so. The Delegated Consent Proforma must be completed for these individuals
- Ensuring that when they require a medical or non-medical colleague to seek consent on their behalf they are confident that the colleague is competent to do so
- Ensuring that they act as supervisors to medical and non-medical personal undertaking delegated consent training
- Ensuring that where the patient lacks the capacity to give or withhold consent in an emergency situation the "Doctrine of Necessity" is clearly documented in the patient healthcare record and the MCHFT Consent Form completed
- Ensuring that the patient is given the duplicate Patient's Copy of the Consent Form on completion
- Ensuring that the Consent Form is filed with the Case Notes on completion.

Non-Medical Practitioners

- Ensuring that they have completed the MCHFT delegated consent training programme
- Ensuring that their patients are appropriately consented in line with the Trust Consent Policy and the Department of Health's Guidance on Consent (DH 2009)
- Ensuring that when they require a medical or non-medical colleague to seek consent on their behalf they are confident that the colleague is competent to do so
- Ensuring breaches of this policy are reported through the Trust's Incident Reporting Procedure.

All MCHFT Staff

- Ensuring that their patients are appropriately consented in line with the Trust Consent Policy and the Department of Health's Guidance on Consent (DH 2009)

Bereavement Manager and Mortuary Manager

- HM Coroner has the authority to order a post mortem examination in cases where the cause of death is unknown or unnatural. In such cases, the consent of the family is not required. However it is good practice to keep the family informed and this responsibility will rest with the Bereavement Manager.

6 Consultation and Communication with Stakeholders

- Medical Director and Executive Lead for Governance
- Associate Director of Quality Governance
- Divisional General Managers
- Associate Medical Directors
- Clinical Leads
- Divisional Heads of Nursing / Lead Professionals
- Practice Development Co-ordinator for the Treatment Centre
- Specialist Nurse Endoscopists
- Divisional Quality Governance Managers
- Legal Services Manager
- Dignity Matron
- Named Nurse for Safeguarding Children
- Governance.policies@mcht.nhs.uk

7 Implementation

Integrated Governance will issue a Policy flyer to all Associate Medical Directors, Divisional General Managers, Divisional Heads of Nursing /Lead Professionals, Divisional Matrons, Divisional Quality Governance Managers and Ward Managers. The policy will be launched through MCHFT Trust News and a copy of the policy will also be placed on the MCHFT intranet site.

8 Education and Training

Training will take place as part of the Trust's induction process for all clinical staff.

The training will cover the background to the current consent process and will review the key requirements of this policy including patient information, consent forms and assessment of competence to take consent.

More detailed training covering the legal aspects of consent will be covered in the bi annual mandatory update. Specialised training on the Mental Capacity Act and consent is available from Legal Services.

9 Monitoring and Review

Standard/process/issue required to be monitored	Monitoring and Audit			
	Process for monitoring e.g. audit	**Responsible individual /group**	**Frequency of monitoring**	**Responsible committee**
Duties	Policy review	Associate Director of Quality Governance /Legal Services Manager	3 yearly	Executive Quality Governance Group (EQGG)
Delegation of Consent: - Process for identifying staff that are not capable of performing the procedure but are authorised to obtain consent. - Process for the delivery of procedure specific training on consent for staff to whom the consent process is delegated, and who are not capable of performing the procedure	Audit	Associate Director of Quality Governance	Annual	EQGG
Process for obtaining consent -process for providing patients with information to support their decision making, including risks, benefits and, where appropriate, alternatives	Audit	Patient Access and Health Records Service Manager/Legal Services Manager	Annual	EQGG

-process for documenting the discussion and provision of information to patients -process for recording consent				

10 References / Bibliography

Department of Health Reference Guide to Consent for examination or treatment 2009 – Second edition
Department of Health Seeking Consent – working with Children
Family Law Reform Act 1969
Mental Capacity Act 2005
Mental Capacity Act Code of Practice
The Human Rights Act 1998
The Human Tissue Act 2004
The NHS Constitution
Royal College of Surgeons - Consent: Supported decision-making (2016)
Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) (2005) UKSC 11

11 Appendices

All Appendices must be in numerical order 1, 2, 3 etc and positioned before the mandatory appendices below.

A Version Control Document
B Communication / Training plan
C Equality Impact and Assessment Tool

APPENIDX A - Control Sheet

This must be completed and form part of the document appendices each time the document is updated and approved.

VERSION CONTROL SHEET			
Date dd/mm/yy	**Version**	**Author**	**Reason for changes**
May 2008	7	Patient Safety Manager	Policy due for Review
February 2010	8	Deputy Legal Services Manager	Review following change in law and new GMC guidance.
November 2010	8.1	Deputy Legal Services Manager	Updated following withdrawing of Consent Form 4.
August 2015	9	Governance Lead	Policy review and update
September 2015	9.1	Governance Lead	Minor amendments to incorporate changed documents.
August 2018	10	Corporate Quality Governance Manager	Policy review and update Addition of Montgomery test. Splitting “Consent for Children and Young people”.

APPENDIX B - Training needs analysis

Communication/Training Plan (for all new / reviewed documents)	
Goal/purpose of the communication/training plan	Ensure that all staff involved in obtaining and recording consent are aware of the revised policy
Target groups for the communication/training plan	Any staff member involved in the consent process
Target numbers	Relevant to all staff members involved in the consent process
Methodology – how will the communication or training be carried out?	Written communication via the trust intranet and launch flier as per Trust Policy and Team Brief
Communication/training delivery	"In house" and External experts – Legal Surgeries
Funding	None required
Measurement of success. Learning outcomes and/or objectives	Ensure compliance with the Trust policy Audit of consent training and incidents
Review effectiveness – learning outputs	Via monitoring process as defined in the consent policy
Issue date of Document	January 2019
Start and completion date of communication/training plan	From issue of document
Support from Learning & Development Services	None, other than possibly Laptop and Projector on occasions

For assistance in completing the Communication / Training Plan please contact the MCHFT Learning and Development Services

APPENDIX C - Form 1

Equality Impact Screening Assessment

Please read the Guide to Equality Impact Assessment before completing this form. To be completed and form part of the policy or other document appendices when submitted to governance-policies@mcht.nhs.uk for consideration and approval or to be completed and form part of the appendices for proposals/business cases to amend, introduce or discontinue services.

POLICY/DOCUMENT/SERVICE: Consent Policy

		Yes/ No	Justification and Data Sources
A	**Does the document, proposal or service affect one group less or more favourably than another on the basis of:**		
1	Race, ethnic origins (including gypsies and travellers) or nationality	**N**	Whilst the publication of the document is in English via the internet and it may disadvantage some groups the Trust ensures that Interpreters are available to explain consent for all patients whose first language is not English and who request the service.
2	Sex	**N**	No issue identified as of yet
3	Transgender	**N**	No issue identified as of yet
4	Pregnancy or maternity	**N**	No issue identified as of yet
5	Marriage or civil partnership	**N**	No issue identified as of yet
6	Sexual orientation including lesbian, gay and bisexual people	**N**	No issue identified as of yet
7	Religion or belief	**N**	No issue identified as of yet
8	Age	**Y**	Publication of documents primarily via the internet may disadvantage some groups. The Trust will consider arrangements to minimise this impact whenever requested. Risk accepted
9	Disability - learning disabilities, physical disability, sensory impairment and mental health problems	**Y**	Publication of documents primary in written form and via the internet may disadvantage some groups. The Trust will consider arrangements to minimise this impact. Risk accepted
10	Economic/social background	**Y**	Publication of documents primarily via the internet may disadvantage some groups. The Trust will consider arrangements to minimise this impact. Risk accepted.
B	**Human Rights – are there any issues which may affect human rights**		
1	Right to Life	**N**	No issue identified as of yet

2	Freedom from Degrading Treatment	**N**	No issue identified as of yet
3	Right to Privacy or Family Life	**N**	No issue identified as of yet
4	Other Human Rights (see guidance note)	**N**	No issue identified as of yet

NOTES

If you have identified a potential discriminatory impact of this document, proposal or service, please complete form 2 or 3 as appropriate.

Date: …November 2018 ……Name: …K Wynn……..

Signature: …… Job Title: Associate Director of Quality Governance (Acting)..

Date: ……November 2018…….. Name: ……E Davies……..

Signature: ……Job Title: Corporate .Quality Governance Manager……