

Consent to Examination and Treatment for Children and Young People 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:	1
Date of Issue:	February 2019
Review Date:	February 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: (date)	20th February 2019
Distribution to:	All Trust staff via the Trust Intranet

Contents:

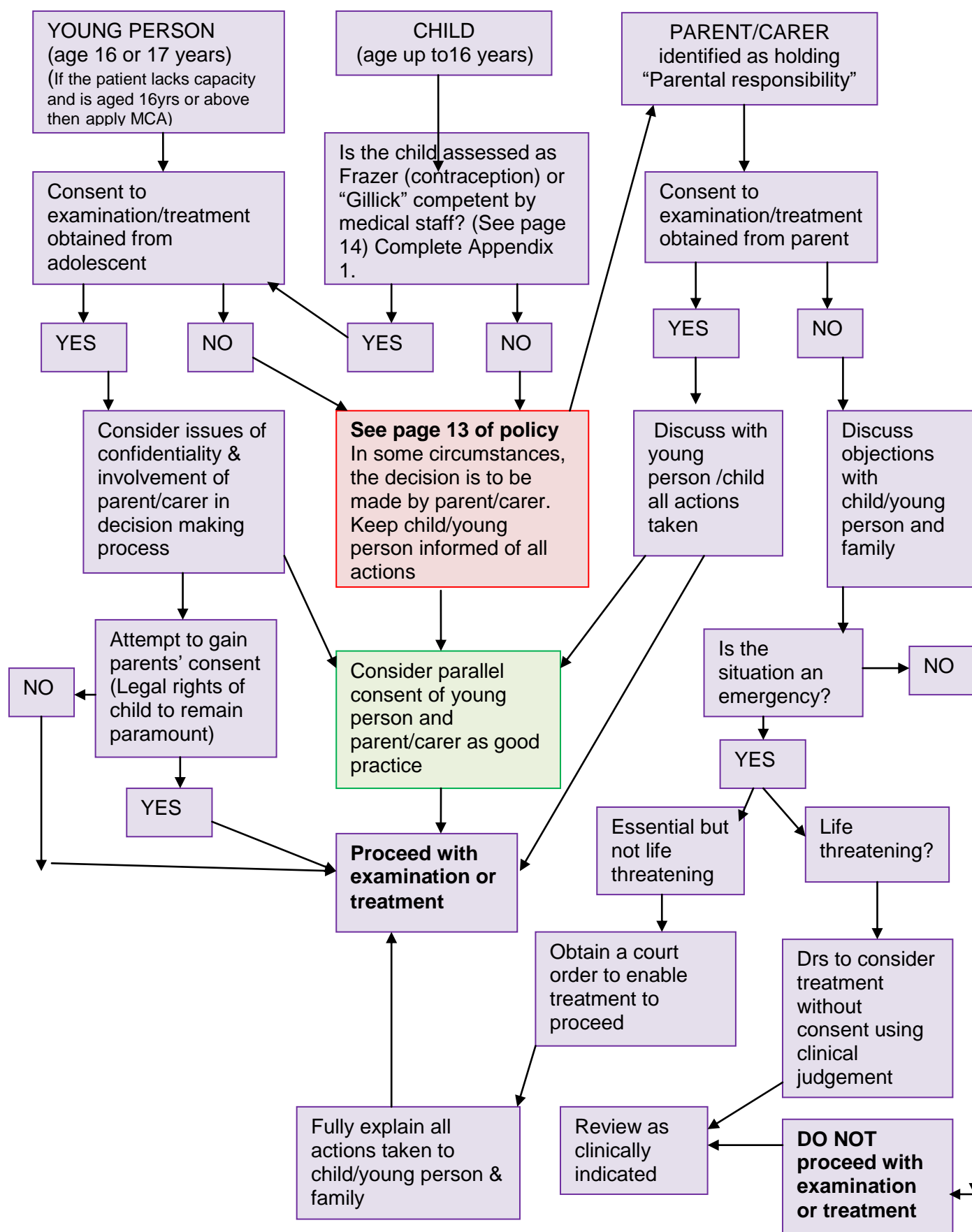
Heading Number	Consent to Examination and Treatment for Children and Young People Policy	Page Number
	Contents	2
	Key Points (of Policy)	3
	Consent Process Flowchart	4
	Delegation of Consent Flowchart	5
	12 Key Points – Law in England	6
1	Introduction / Purpose	7
2	Consent Policy	8
2.3	Process/Responsibility for obtaining consent	9
2.3.5	Consent for anaesthesia and sedation	11
2.4	Consent of Children and Young people	12
2.4.3	Fraser Guidelines / Gillick Competence	14
2.5.2	Delegation of Consent	17
2.7	Provision of Information	19
2.8	Refusal of Treatment	22
2.9	Consent for Tissue Samples	22
2.13	Consent for Hospital Post Mortem	23
2.14.1	Recording as part of patient care	23
5	Duties	25
6	Consultation	26
9	Monitoring and review	27
Appendix 1	Young Person's Competency Form	29

Consent Policy

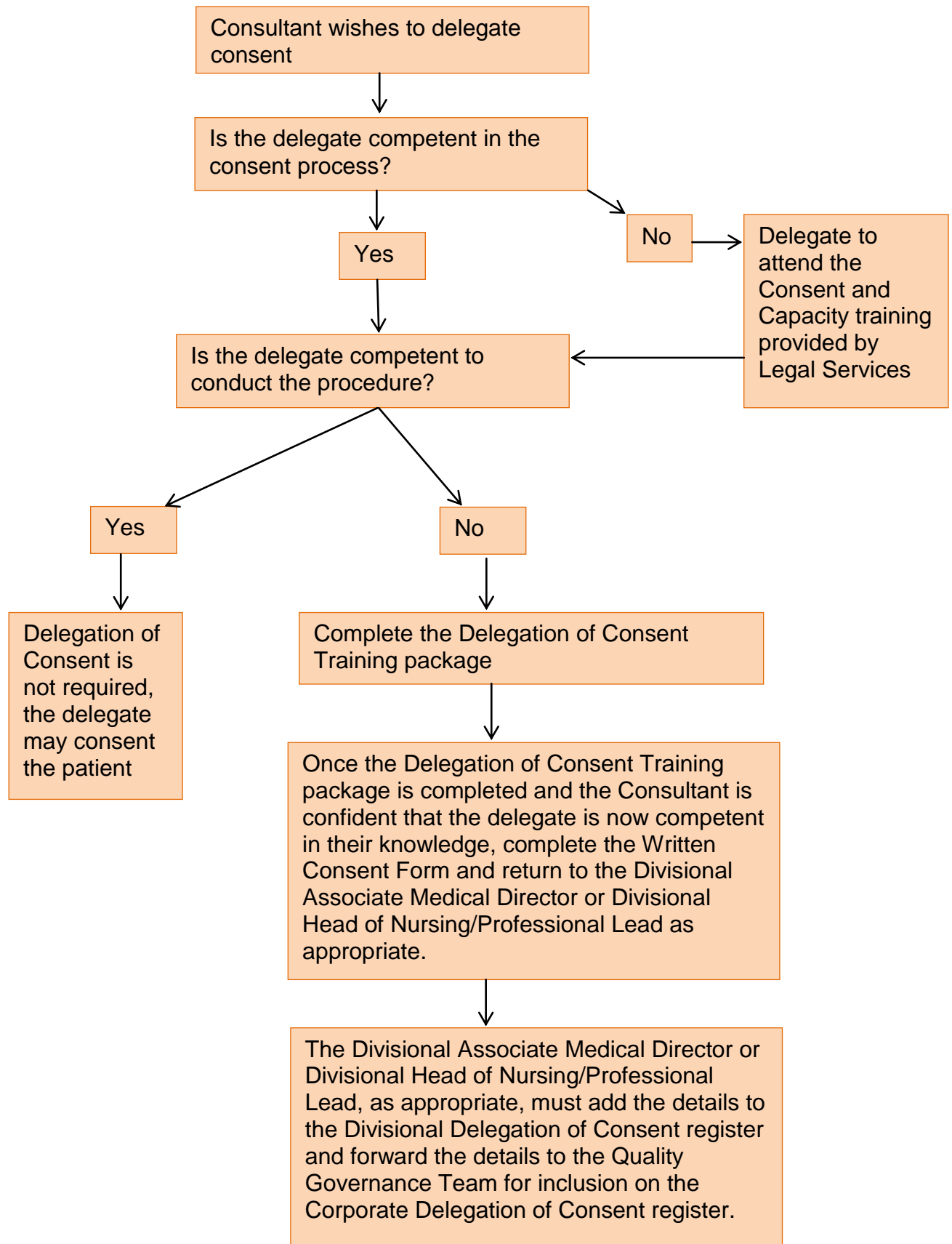
KEY POINTS

- ❖ 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 nurse led preoperative clinic. Patients that are identified as high risk will be discussed with a consultant anaesthetist and will normally be referred to a tertiary centre for their surgery. 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
- ❖ 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 mobile telephone cameras is prohibited under any circumstances (unless supplied by the Trust for use in community settings e.g. CCICP). Any clinician who does use a 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 to Examination & Treatment for Children and Young People



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** override 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.

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

This policy has been developed to give guidance to staff on consent to examination, treatment and autopsy. 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

The issue of consent is more complicated in those under 18, as the Children's Act (1989) defines childhood as under 18, but the Family Law Reform Act (1969) defines children as under 16.

Regardless of age, emergency treatment to save life or prevent deterioration can be given without consent.

NOTE: This Policy must be read in conjunction with the Trust's Consent to Examination, Treatment or Autopsy (Adults) and Clinical Photography / Images Policies for further guidance.

2.1 Treatment of children

When young babies/children or young people are being cared for in hospital, it will not usually seem practicable to seek their consent from those with parental responsibility on every occasion for every routine intervention such as blood, urine tests, x-rays etc. However, the healthcare professional should remember that, in law, such consent **is** required.

Where a baby/child or young person is admitted to the hospital the healthcare professional should discuss with the parent(s) or carers and the patient which routine procedures will be necessary and ensure that they have parental consent for these interventions in advance. This discussion should be documented in the health records. If parents specify that they wish to be asked before particular procedures are initiated, the healthcare professional must do so, unless the delay involved in contacting them would put the child's health at risk.

Feedback should be discussed at the end of each treatment session with the parents / carers /patient and other options available and the advantages/disadvantages of each option if symptoms are not improving.

2.2 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 the risks and benefits.

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

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.

There are two categories of formal consent:

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)

2.3 Process for Obtaining Consent

2.3.1 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 nor the healthcare professional conducting the procedure) 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).

2.3.2 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/parent 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/parent has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient/parent 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.

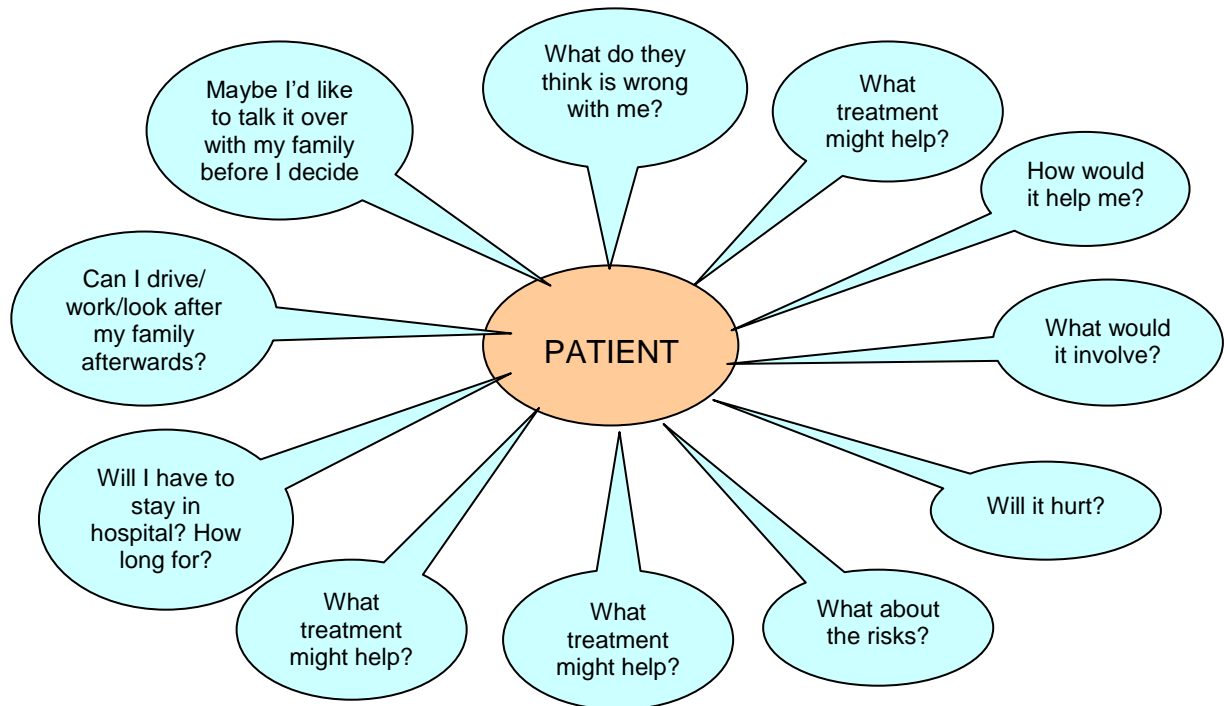
- The first is the provision of information, discussion of options, risks, benefits and alternatives (if relevant) and a signature confirming that the patient/parent wishes to go ahead with the procedure
- The second is the confirmation that the patient/parent still wants to go ahead. If a form is signed before the patient arrives for treatment a member of the healthcare team **must** check at this point if they have any concerns or whether their condition has changed. When confirming the patients/parents' consent and understanding it is advisable to use a form of words which requires more than a yes/no answer e.g. "tell me what you're expecting to happen".

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

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.

2.3.3

Gaining Consent: Remembering the Patient's Perspective



2.3.4 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 notes 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.

2.3.5 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) to seek consent for anaesthesia, having discussed the benefits and risks. A patient for an elective procedure should be seen in the Paediatric preoperative clinic where they are seen by the Paediatric POAC and Day Case Nurse and a Play therapist. The anaesthetist is contacted if any concerns/queries around anaesthesia are raised at this time e.g.

- Previous anaesthetic problems
- Existing medical conditions ie epilepsy, diabetes etc
- Family history ,especially Sick Cell disease, Malignant Hypothermia etc
- Medication that may affect anaesthesia and vice versa.
- Particular anxieties surrounding anaesthetics or the operation in general such that a pre-med may be required.

Most consultants obtain consent at outpatient's clinic but some do not obtain written consent until the day of surgery itself. Any outstanding consent forms are identified and flagged at POAC.

If the patient is deemed to be high risk then these patients are discussed with a consultant anaesthetist and normally referred to a tertiary centre. 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.

Children may require anaesthesia for diagnostic procedures such as MRI scans. Anaesthetists should ensure that parents and legal guardians have been informed about the associated risks and common side effects of the anaesthetic.

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 they will also be responsible for ensuring that the patient has given consent to that procedure.

2.3.6 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.

2.3.7 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 performing 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.

2.4 Consent of Children and Young people

In UK law, a person's 18th birthday draws the line between childhood and adulthood (Children Act 1989 s105), so in health care matters, an 18 year old enjoys as much autonomy as any other adult.

To a more limited extent, 16 and 17 year-olds can also take medical decisions independently of their parents. The right of younger children to provide independent consent is proportionate to their competence, a child's age alone is clearly an unreliable predictor of his or her competence to make decisions.

Young people aged 16 or 17 are presumed in UK law, like adults, to have the capacity to consent to medical treatment. However, unlike adults, their refusal of treatment can, in some circumstances be overridden by a parent, someone with parental responsibility or a court. This is because we have an overriding duty to act in the best interests of a child. This would include circumstances where refusal would likely lead to death, severe permanent injury or irreversible mental or physical harm.

If there are reasons to believe a child aged 16 or over lacks capacity, an assessment of capacity to consent should be conducted and recorded in their notes.

The legal position concerning consent and refusal of treatment by those under the age of 18 is different to that of adults. The consent of a young person with capacity is sufficient even in the face of a refusal from a person with parental responsibility.

Parental consent is always required in cases where a child does not have sufficient understanding of the entire purpose and risks of the proposed treatment.

Practitioners should satisfy themselves that the person offering consent on behalf of the child has parental responsibility for that child.

Only people with "parental responsibility" are entitled to give consent on behalf of their children e.g. those who have an adoption order, a residential order, special guardianship and shared parental responsibility with the local authority if the child is on an interim care order, care order or a voluntary care order section 20. Those who do not have parental responsibility e.g. foster parents and the local authority. There must also be awareness that not all parents have parental responsibility for their children e.g. unmarried fathers do not automatically have such responsibility although they can acquire it. If there is any doubt about whether the person with the child has parental responsibility for that child, **checks must be undertaken** before consent is gained. Seek advice for the Safeguarding team.

For planned procedures parental responsibility should be established in advance of admission, and appropriate consent procedures followed, involving the court and/or social services as appropriate. If there is doubt about parental responsibility, advice should be sought from the Legal Services Manager and the Safeguarding Team. If emergency procedures are required out-of-hours then the anaesthetist defence organisations may be consulted (RCoA 2018). These conversations/decisions must be documented in the patients' health records.

Fathers who are not married to his child's mother may acquire parental responsibility via three routes:

- For children born after December 2003, by jointly registering the birth of the baby with the mother

- By a parental responsibility agreement with the mother
- By parental responsibility order, made by a court.

2.4.1 Civil / Non-civil partnerships

Civil partners: - Same-sex partners will both have parental responsibility if they were civil partners at the time of treatment, e.g. donor insemination or fertility treatment.

Non-civil partners: - For same-sex partners who are not civil partners, the 2nd parent can get parental responsibility by either:

- Applying for parental responsibility if a parental agreement was made
- Becoming a civil partner of the other parents and making a parental responsibility agreement or jointly registering the birth

Further information can be obtained via the following website:
Parental rights and responsibilities: Directgov-Parents.

Where it is not a scheduled appointment, or it is the first appointment, and a child is accompanied by someone else who does not have parental responsibility, the clinician should check directly with the person who has parental responsibility, to establish whether they consent to the treatment/have authorised this other person to give consent. The only exception to that would be where a child is brought for emergency/urgent treatment by someone who has “care of” the child at that particular time.

2.4.2 Young People Aged 16 to 17

Young people aged 16 or 17 are presumed in UK law, like adults, to have the capacity to consent to medical treatment. However, unlike adults, their refusal of treatment can in some circumstances be overridden by a parent, someone with parental responsibility or a court. This is because there is an overriding duty to act in the best interests of the child. This would include circumstances where refusal would likely lead to death, severe permanent injury or irreversible mental or physical harm.

Where young people aged between 16 and 17 years give consent to treatment, this consent is as effective as that of an adult. In these cases any additional consent from a parent or legal guardian with parental responsibilities is unnecessary. However, it is good practice to ask the permission of such parents to discuss any major or potentially hazardous procedure with parents or guardians. In this age group, such discussion with parents or legal guardian with parental responsibilities in the absence of the patient's permission is likely to constitute a breach of confidentiality. However, if there is a safeguarding concern this confidentiality may be breached. In such circumstances the health professional **must** seek advice from the Safeguarding Children's Team.

If the young person with capacity is refusing treatment, but the healthcare professional still believes that it is in their best interests to have the treatment then they should discuss with their line manager and the Safeguarding Children's Team.

In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used. If a young person lacks capacity to consent because of impairment, or a disturbance in the functioning, of the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over. If the young person is unable to make the

decision for some other reason, for example because they are overwhelmed by the implications of the decision, then the Act will not apply to him / her and the legality of any treatment should be assessed under common law principles. It may be unclear whether a young person lacks capacity within the meaning of the Act. In those circumstances, it would be prudent to seek a declaration from a court.

2.4.3 Fraser Guidelines / Gillick Competence

Gillick competence is concerned with determining a child's capacity to consent.

Fraser guidelines are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment.

In some cases, where a child has sufficient understanding of the proposed treatment, it may be appropriate for the child to give valid consent. In these cases the practitioner should ensure:

- The child has a sufficient broad understanding of the hazards involved in the proposed treatment and of any suitable alternatives
- That there is full documentation in the health records of those factors considered in deciding that the child is competent to give valid consent
- That the child is positively encouraged to inform his/her parent of any proposed treatment unless it is not in his/her interests to do so.

Where children are deemed to be Gillick competent, and they are able to give consent to treatment, healthcare professionals may involve them in the process. In this instance it is good practice to provide parents /carers with information and document in the clinical record. Children even at a young age should be encouraged to take part in the giving of consent, e.g. by adding their signature to the parental consent. **When assessing whether a child or Young Person is competent the “Young Persons Competency Assessment Document” should be completed and filed in the health records.**

Where a child is deemed not Gillick competent and a parent(s) is consenting to treatment on their behalf, parent(s) must be given information about the nature and purpose of treatment and this must be documented in the clinical record.

Where children or young people who have not yet reached their 18th birthday purport to refuse treatment, whether they have been assessed as competent or not under the Gillick guidelines, their refusal may be countermanded by parents, or if necessary by the Courts. Practitioners should take into consideration the importance of the proposed treatment and the degree of comprehension of the child. In difficult cases further advice should be sought via the line manager and the Safeguarding Children Team.

Children Under 16 – the Concept of Gillick Competence/ Fraser Guidelines

In the case of Gillick, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention. This is sometimes described as being “Gillick competent”. A child under 16 years of age may be Gillick competent to consent to medical treatment, research, donation, or any other activity that requires their consent.

The concept of Gillick competence is said to reflect a child's increasing development to maturity. The understanding required for different interventions will vary considerably. Thus a child under 16 years of age may have the capacity to consent to some interventions, but not to others. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made.

In some cases a child's mental state may fluctuate significantly, for example because of a mental disorder, so that on some occasions the child appears Gillick competent in respect of a particular decision and on other occasions does not. In cases such as these, careful consideration should be given as to whether the child is truly Gillick competent at the time that they need to take a relevant decision.

Gillick competency tends to be used in reference to wider areas of consent whereas the Fraser Guidelines are specific to the provision of contraceptive services.

Where advice or treatment relates to contraception, or the child's sexual or reproductive health, the healthcare professional should try to support the child to inform his or her parent(s) or to allow the medical professional to do so. If however the child cannot be convinced, advice and / or treatment should still be given if the healthcare professional considers that the child is very likely to begin, or continue to have, sexual intercourse with or without advice or treatment and that unless they receive the advice or treatment then the child's physical or mental health is likely to suffer. If during such consultations safeguarding concerns emerge, these should be acted upon as per the Trust Safeguarding Children Policy, ideally with the knowledge and agreement of the child. However, if the child does not agree safeguarding concerns must still be acted upon appropriately.

If the child seeks advice or treatment in relation to abortion and cannot be persuaded to inform her parent(s) every effort should be made to help the child find another adult (such as another family member or a specialist youth worker) to provide support to the child.

2.4.4 Accompanying a Child or Young Person to Theatre

When a child is transferred to theatre they must be accompanied by the person granting consent unless that person has assigned this duty to a legally acceptable representative and both are present at the time (e.g. mother granting consent can assign to father or in the event of a social worker this can be assigned to another named social worker who is familiar with the case).

2.4.5 Child or Young Person with Capacity Refusing Treatment

When a young person of 16 or 17 who could consent to treatment in accordance with section 8 of the Family Law Reform Act 1969 or a child under 16 but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child / young person or to severe or permanent injury.

The courts have, in the past, also found that parents can consent to their competent child being treated even where the child / young person is refusing treatment. However there is no post Human Rights Act 1998 authority for this proposition and it would therefore be prudent to obtain a court declaration or decision if faced with a competent child or young person who is refusing to consent to treatment, to determine whether it is lawful to treat the child.

A life threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the person with parental responsibility refuses consent, despite such emergency treatment appearing to be in the best interests of the child. In such cases the courts have stated that doubt should be resolved in favour of the preservation of life or to prevent serious damage to health.

2.4.6 Child Lacking Capacity

Where a child under the age of 16 lacks capacity to consent (i.e. is not Gillick competent) consent can be given on their behalf by any one person with parental responsibility (if the matter is within the zone of parental control) or by the courts. As in the case where patients are giving consent for themselves, those giving consent on behalf of child patients must have the capacity to consent to the intervention in question, be acting

voluntarily and be appropriately informed. The power to consent must be exercised according to the “welfare principle” i.e. that the child’s “welfare” or “best interests” must be paramount. Even where a child lacks capacity to consent on their own behalf, it is good practice to involve the child as much as possible in the decision making process.

Where necessary, the courts can overrule a refusal with parental responsibility. It is recommended that certain important decisions, such as sterilisation for contraceptive purposes, should be referred to the courts for guidance, even if those with parental responsibility consent to the operation going ahead.

If a child is treated contrary to their parent(s) wishes without a court order, this will be considered breach of professional guidance and potentially a breach of the European Convention on Human Rights. In situations where there is a continuing disagreement or conflict between those with parental responsibility and doctors, and where the child is not competent to provide consent, the court should be involved to clarify whether a proposed treatment or withholding of treatment is in the child’s best interests. Parental refusal can only be overridden in an emergency (e.g. giving blood to a child of a Jehovah’s Witness if it were deemed to be lifesaving).

If there are reasons to believe a child aged 16 or over lacks capacity, an assessment of capacity to consent should be conducted and recorded in their notes applying the principles of the MCA (2005). If the child is deemed to lack capacity a best interests meeting should take place in relation to the decision being made – please refer to the “*Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy*”.

2.5 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.

2.5.1 Written Consent

Patients/parents 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.

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/parent, **must** be initialled and dated by both patient/parent and healthcare professional.

Completed consent forms **must** be checked before the patient/parent 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

2.5.2 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*
- c) understands the risks involved*
- d) 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 he or she does not 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 Quality Governance Team 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 Team must be informed of any additions to ensure that they are added to the Corporate 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), this must be reported via the Ulysses reporting system 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 General Medical Council (GMC).

2.6 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/parent and reconfirm their consent.

The clinician should consider whether the new information should be drawn to the attention of the patient/parent 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 still wishes the intervention to proceed, and sign the consent form even if no new information needs to be provided or further questions answered.

2.7 Provision of Information

To be able to give valid consent, the child / patient / parent need to understand the nature and purpose of the investigation or treatment. The information needs to be given in a way that will help the patient / parent understand the specific decision to be made and its implications, risks and benefits. This could include pictures, simple words, clear terminology and where required the use of interpreters, including British Sign Language (BSL). Staff must record the information given to the patient, either on the consent form or in the patient's health records.

Where children are deemed to be Gillick competent, and they are able to give consent to treatment, it is good practice to provide parents /carers with information and document in the clinical record.

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 its 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.

2.7.1 Information sharing

Parents generally need to be provided with information about their child's problems and treatment in order to adequately support and care for them. Check the clinical records to see whether there is evidence of a discussion with the child, and where appropriate their parent(s), about information sharing and confidentiality and the limits of confidentiality.

The extent and nature of the discussion will vary according to the age of the child and

the nature of treatment as some treatments, for example family therapy, directly involve the parents, whereas others such as medication or individual counselling involve the child. Where information is shared with parents about the problems or treatment of a competent child, the child's agreement to share the information should be obtained and evidence recorded in the notes. The agreement should be absolutely clear and should cover the specific detail of what will be shared, the reason the information is being shared, as well as any special aspects of the processing that may affect the individual. It should also be freely given, for example without undue influence from the parents.

Where a competent child refuses to allow information to be shared with their parent(s), there should be evidence that the risks of not sharing the information have been considered. Where it is thought to be in the child's best interests to share information, there should be evidence of attempts to seek a compromise. It is sometimes possible to provide parent(s) with general information about the treatment or condition as a compromise, rather than the specific details of the child's case. Where it is the clinician's opinion that it is necessary to share information in the best interests of the competent child, against their wishes, the Caldicott Guardian should be consulted and the safeguarding team informed.

2.7.2 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:

- 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.

2.7.2 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/parents can take them away with them and consider the implications of the required treatment. Child friendly information leaflets about different treatments and what they involve should be available.

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.

2.7.3 Provision of Information for Patients Whose First Language is not English

This Trust is committed to ensuring that patients/parents 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, 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.

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.

2.7.4 Provision of Information for Patients with Other Communication or Learning Difficulties

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.

2.8 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). The following paragraphs apply primarily to adults. For the young patient who is not deemed to be Gillick (Fraser) competent, refer to the person with parental responsibility.

Where the child/parent refuses treatment, there should be evidence in the records that risks have been considered and explored. This includes whether refusal may result in significant harm to the child and that safeguarding concerns have been considered. The case records should document fully what decisions were made and why, including when the decision relates to hospital admission and whether the use of the Mental Health Act

would have been appropriate or not. The safeguarding team should be informed of these cases.

Complex cases: wherever possible for more complex cases, such as those involving disagreements about treatment, there should be evidence of discussion with colleagues and the offer of a second opinion (this should be proportionate to the circumstances of the case).

2.9 Consent for Tissue Samples from Children (In this context a child is under 18 years of age).

Children may consent to a proposed medical procedure, or the storage and use of their tissue, if they are competent to do so.

A child's parent or person who has parental responsibility can consent on their behalf only if the child:

- is not competent to do so
- chooses not to make that decision

However, it is good practice to consult the child's parents and to involve them in the process of the child making a decision.

2.10 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"

2.11 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)

2.12 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

2.13 Consent for Hospital Post Mortem

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

The related Consent Form available is:

- 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.

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

2.14 Consent for photography and/or video

Please refer to Clinical Photography / Images Policy

2.14.1 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 of 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 patients/parents 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.

The Bolam Principle: In the mid-1980`s 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 Governors 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 Policy
- MCHFT Clinical Record Keeping Standards Policy
- MCHFT Confidentiality and Data Protection Policy
- 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 Mental Capacity Assessment Process and Deprivation of Liberty Safeguards (DoLS) Policy
- CQC Brief guide: capacity and competence in under 18s (BG004)

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

Head of Nursing for Paediatrics

The Head of Nursing for Paediatrics 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. This is included in the Mandatory Training BEMU sessions for all staff.

Quality Governance Department

This Department is responsible for:

- 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.

Anaesthetists

- Anaesthetists should be aware of legislation and good-practice guidance relevant to children and according to the location in the UK. These documents refer to the rights of the child, child protection processes, and consent (RCoA 2018)
- Although separate written consent for anaesthesia is not mandatory in the UK, there should be a written record of all discussions with the child and/or parent/carers about methods of induction, and provision of postoperative pain relief (including the use of suppositories). (RCoA 2018)
- Children may require anaesthesia for diagnostic procedures such as MRI scans. Anaesthetists should ensure that parents and legal guardians have been informed about the associated risks and common side effects of the anaesthetic.

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

Are responsible for:

- Ensuring that the Divisional Delegated Consent Register is updated and maintained
- Inform the Integrated 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 Risk and 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	Head of Nursing for Paediatrics /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 -process for documenting the discussion and provision of information to patients -process for recording consent	Audit	Patient Access and Health Records Service Manager/Legal Services Manager	Annual	EQGG

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.

- 1 Young person's Competency Form**
- A Version Control Document**
- B Communication / Training plan**
- C Equality Impact and Assessment Tool**

Appendix 1

YOUNG PERSON'S COMPETENCY ASSESSMENT FORM

COMPLETE FOR ALL PATIENTS UNDER 16 YEARS OF AGE WHEN REQUIRED TO DEMONSTRATE COMPETENCE TO CONSENT TO INVESTIGATION AND/OR TREATMENT

GENERAL PRINCIPLES

- Obtaining valid consent is just as important when treating children as it is with adults.
- A competent child can consent to medical treatment on his/her own behalf.
- A refusal of treatment, however, may be overridden by a person with Parental Responsibility, if treatment is considered to be in the best interests of the child.
- If the child is deemed not competent to consent to treatment, consent will need to be obtained from a person with Parental Responsibility, unless it is an emergency.
- There is detailed guidance on the child safeguarding intranet page about who has, or may not have, Parental Responsibility.
- In an emergency, treatment can be provided without consent to save the life of, or prevent serious deterioration in the health of, a child or young person.

AGE AND CAPACITY

The law distinguishes between children aged 16 and 17 years old (young persons), and children under 16, in respect of the capacity to consent.

- **Children aged 16 and 17** are presumed in law to have the same capacity as an adult to consent to treatment. They do not therefore require parental consent for medical treatment or interventions, unless there is reason to believe that they lack capacity.
- **Children under 16** can only consent to medical treatment if they are assessed as having the maturity and intelligence to fully understand the nature of the treatment, the options, the risks involved and the benefits. A child who has such understanding is considered to be Gillick competent
- Children under 16 who are not Gillick competent and very young children cannot give or withhold consent to medical treatment. A person with Parental Responsibility will need to consent on their behalf.

The checklist below is designed to assist staff in assessing the competency of **children under 16** to consent to medical treatment. A copy of the completed checklist should be included in the child's medical records.

ASSESSING COMPETENCE TO CONSENT

- *"...whether or not a child is capable of giving the necessary consent will depend on the child's maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent."* (Gillick v West Norfolk & Wisbech AHA, 1986)
- The clinician/nurse/health advisor who is going to be providing the treatment should be the person who assesses the capacity of the child and takes consent if the child is deemed to be competent.

- The clinician/nurse/health advisor must decide whether the child is able to understand the nature, purpose and possible consequences of investigations or treatments proposed, as well as the consequences of not having treatment. All relevant information must be provided and discussed before deciding whether or not a child has the capacity to consent.
- The child must be able to understand, retain, use and weigh this information, and communicate his/her decision to others.
- A child may have the capacity to consent to straightforward, relatively risk-free treatment but may not necessarily have the capacity to consent to complex treatment carrying high risks or serious consequences
- The capacity to consent can also be affected by the child's physical and emotional development and by changes in their health and treatment.
- If a child is deemed not competent to consent to medical treatment, consent will need to be obtained from a person with Parental Responsibility for the child.

REFUSAL OF TREATMENT

- Children under 16 who are Gillick competent may refuse treatment but their refusal can be overridden by a person with Parental Responsibility who can consent to the treatment if it is deemed to be in the child's best interests.
- If a Gillick competent child refuses treatment and the person with Parental Responsibility also withholds consent, a Court Order may be necessary prior to proceeding with treatment which is believed to be in the best interests of the child.

CONFIDENTIALITY

- If the child is Gillick competent, it follows that he/she also has a right to confidentiality.
- Staff should always encourage children to involve their parents/carers in decisions about their care and treatment. Government guidance advocates that persons with Parental Responsibility should be involved in decisions about the child's care, unless there is a very good reason for not doing so.
- If however, a competent child under the age of 16 is insistent that his/her family should not be involved; their right to confidentiality must be respected, unless such an approach would put them at serious risk of harm.
- If a decision is made to disclose information to a Gillick competent child's parents/carers against his/her wishes, the child should be informed before the information is disclosed to the parents/carers.
- Any decision to disclose must be in the child's best interests. The clinician must document the decision and the reasons for it in the medical record, and be prepared to justify it.
- Sexual activity with a child aged under 13 years of age is statutory rape, irrespective of apparent consent and there is a legal obligation to inform Social Services, who should in turn contact the police. Staff should seek advice promptly from the consultant, senior nurse or Named professional for child safeguarding. In addition, any other safeguarding concerns should be acted upon as per the Trust Safeguarding Children Policy.

DOCUMENTATION

It is vital to document carefully in the notes all the factors contributing to an assessment of competence. This should include what information was provided to the child and the parents/carers and how the decision was reached.

ORGAN DONATION

In the case of a child, who was competent to reach a decision before he/she died and consented to organ donation taking place after their death, the position is legally no different from that of an adult. The child's consent is sufficient to make the removal, storage or use of their organs for transplantation lawful.

COMPETENCY CHECKLIST:

1. Understands nature of treatment offered i.e. **WHAT IT INVOLVES** [YES/NO]
2. Understands purpose of treatment offered i.e. **WHAT IT IS FOR** [YES/NO]
3. Understands possible risks of taking treatment i.e. **SIDE EFFECTS** [YES/NO]
4. Understands consequences of not taking treatment [YES/NO]
5. Patient understands the clinician's advice [YES/NO]
6. Patient encouraged to inform parent/guardian of consultation [YES/NO]
7. Patient's physical/mental health would suffer if s/he does not receive advice/treatment [YES/NO]
8. It is in the patient's best interests for the clinician to give advice/treatment without Parental consent [YES/NO/NA]
9. Patient assessed as competent based on understanding, retaining, reflecting and deciding on the treatment information provided [YES/NO]

Doctor /Nurse/Health Advisor

Signature: _____

Please PRINT: _____

Date: _____

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
August 2018	1	Corporate Quality Governance Manager	Extracted from Trust Consent policy. Addition of Montgomery test.

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	February 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 MCHT 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 2018Name: ...K Wynn

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

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

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