Consent to Assessment Examination and/or Treatment Policy (including Mental Capacity Act)

<table>
<thead>
<tr>
<th>Policy Number</th>
<th>CL/Pol/001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Audience</td>
<td>All Clinical Staff including Bank, Agency and Students</td>
</tr>
<tr>
<td>Approving Committee</td>
<td>Clinical Document Approval Group</td>
</tr>
<tr>
<td>Date Approved</td>
<td>January 2012</td>
</tr>
<tr>
<td>Last Review Date</td>
<td>July 2017</td>
</tr>
<tr>
<td>Next Review Date</td>
<td>July 2019</td>
</tr>
<tr>
<td>Policy Author</td>
<td>Head of Clinical Governance, Quality and Effectiveness</td>
</tr>
<tr>
<td>Version Number</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Applicable Statutory, Legal or National Best Practice Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Law Reform Act 1969 (Section 8)</td>
</tr>
<tr>
<td>Human Rights Act 1998</td>
</tr>
<tr>
<td>Reference guide to consent for examination or treatment (DoH 2009)</td>
</tr>
<tr>
<td>Human Tissue Act 2004</td>
</tr>
<tr>
<td>CQC Registration Regulations – Regulation 11</td>
</tr>
<tr>
<td>NHSLA Risk Management Standards 2012/13</td>
</tr>
<tr>
<td>Code of Practice to the Mental Health Act 2008</td>
</tr>
<tr>
<td>Mental Capacity Act 2005</td>
</tr>
<tr>
<td>NHS Constitution (DH, 2009)</td>
</tr>
<tr>
<td>NHS General Dental Services Regulations</td>
</tr>
<tr>
<td>NHS Dental Patient Charge Regulations</td>
</tr>
<tr>
<td>Montgomery v. Lanarkshire Health Board [2015] UKSC 11, 11</td>
</tr>
<tr>
<td>March 2015</td>
</tr>
<tr>
<td>Children Act 1989</td>
</tr>
</tbody>
</table>

The Trust is committed to an environment that promotes equality, embraces diversity and respects human rights both within our workforce and in service delivery. This document should be implemented with due regard to this commitment.

This document can only be considered valid when viewed via the Trust’s intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one online.
## Version Control Sheet

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Reviewed By</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>Nov 2011</td>
<td>A. Melbourne</td>
<td>Bridgewater policy drafted</td>
</tr>
<tr>
<td>0.2</td>
<td>Dec 2011</td>
<td>D. Williams</td>
<td>Additional Consent forms added</td>
</tr>
<tr>
<td>0.3</td>
<td>Jan 2012</td>
<td>L. Holden</td>
<td>Addition of information relating to NHS General Dental Services Regulations and NHS Dental Patient Charge Regulations</td>
</tr>
<tr>
<td>0.4</td>
<td>Jan 2012</td>
<td>L. Spooner</td>
<td>General comments</td>
</tr>
<tr>
<td>1.0</td>
<td>Jan 2012</td>
<td>SMT</td>
<td>Policy Approved</td>
</tr>
<tr>
<td>1.0</td>
<td>Jan 2012</td>
<td>IGC</td>
<td>Policy Ratified</td>
</tr>
<tr>
<td>1.1</td>
<td>Feb 2012</td>
<td>M. Smith</td>
<td>Amendment requested re use of FP17</td>
</tr>
<tr>
<td>1.1</td>
<td>Feb 2012</td>
<td>D. Williams</td>
<td>Amendment approved</td>
</tr>
<tr>
<td>1.2</td>
<td>March 2012</td>
<td>A. Aspinall</td>
<td>Consent form for non-clinical photographs revised</td>
</tr>
<tr>
<td>1.2</td>
<td>March 2012</td>
<td>D. Williams</td>
<td>Amendment Approved</td>
</tr>
<tr>
<td>1.3</td>
<td>Jan 2013</td>
<td>A. Melbourne</td>
<td>Policy reviewed. Additional information added but overall requirements of the policy unchanged</td>
</tr>
<tr>
<td>2.0</td>
<td>March 2013</td>
<td>Clinical Policy Sub-Group</td>
<td>Revised policy approved</td>
</tr>
<tr>
<td>2.1</td>
<td>July 2013</td>
<td>A. Melbourne</td>
<td>Link to consent page on the intranet added to policy</td>
</tr>
<tr>
<td>2.1</td>
<td>July 2013</td>
<td>D. Williams</td>
<td>Amendment approved</td>
</tr>
<tr>
<td>2.2</td>
<td>Oct 2013</td>
<td>A. Melbourne</td>
<td>Guidelines for Staff undertaking Mental Capacity Assessments added</td>
</tr>
<tr>
<td>2.2</td>
<td>Oct 2013</td>
<td>D. Williams</td>
<td>Amendment approved</td>
</tr>
<tr>
<td>2.3</td>
<td>June 2015</td>
<td>A. Melbourne</td>
<td>Policy reviewed. Updated regarding the new decision from a Justice Supreme Court March 2015 (Montgomery v. Lanarkshire Health Board) re provision of information regarding risk but overall requirements of the policy unchanged. Amendments to Research, Medicines and Information Sharing sections.</td>
</tr>
<tr>
<td>2.4</td>
<td>July 2015</td>
<td>CDAG</td>
<td>Approved subject to amendments</td>
</tr>
<tr>
<td>3.0</td>
<td>July 2015</td>
<td>Andrea Melbourne</td>
<td>Amendments completed, section 20, appendix I and consultation box updated</td>
</tr>
<tr>
<td></td>
<td>Issue Date</td>
<td>Author</td>
<td>Notes</td>
</tr>
<tr>
<td>---</td>
<td>------------</td>
<td>--------</td>
<td>-------</td>
</tr>
<tr>
<td>3.1</td>
<td>Oct 2015</td>
<td>A. Melbourne</td>
<td>Appendix H re Service Areas where Formal Written Consent for Treatment is required has been amended</td>
</tr>
<tr>
<td>3.2</td>
<td>July 2017</td>
<td>A. Melbourne</td>
<td>Policy reviewed. The main changes are to sections 7, 10.6 and the appendices. Info relating to sharing information has been removed as this is covered in a separate policy</td>
</tr>
<tr>
<td>3.3</td>
<td>July 2017</td>
<td>Lisa McLaren</td>
<td>References updated</td>
</tr>
<tr>
<td>3.4</td>
<td>July 2017</td>
<td>Clinical Document Approval Group</td>
<td>Approved subject to minor amendments</td>
</tr>
<tr>
<td>4</td>
<td>July 2017</td>
<td>S. Arkwright</td>
<td>Amendments approved by chair action</td>
</tr>
</tbody>
</table>

Equality Impact Assessment Form
By: Andrea Melbourne
Date: June 2017
## Contents

1. **Introduction**  
   1.1 **Objective**  
   1.2 **Scope**  
2. **Definitions**  
3. **Abbreviations**  
4. **Other Relevant Procedural Documents**  
5. **Roles and Responsibilities**  
6. **General Principles**  
   6.1 **Why Consent is Crucial**  
   6.2 **What is consent – and isn’t**  
   6.3 **The Necessity for Consent**  
   6.4 **The Nature of Consent**  
   6.5 **Guidance on Consent**  
7. **Mental Capacity**  
   7.1 **Mental Capacity Act 2005 (MCA)**  
   7.2 **Assessing Capacity**  
   7.3 **Best Interests**  
   7.4 **Procedure to Follow when Patients Lack Capacity to Give or Withhold Consent**  
   7.5 **Independent Mental Capacity Advocates (IMCA)**  
   7.8 **Limited Consent**  
8. **Documentation**  
9. **Type of Consent**  
   9.1 **Expressed Consent**  
   9.2 **Written Consent**  
   9.3 **Verbal Consent**  
   9.4 **Implied Consent**  
   9.5 **Voluntary Consent**  
10. **When should Consent be sought?**  
   10.1 **Single Stage Process (Verbal)**  
   10.2 **Two or More Stage Process (Written)**  
   10.3 **Seeking Consent for Anaesthesia**  
   10.4 **Emergencies**  
   10.5 **Treatment of Children and Young People**
19 Childhood Immunisation
20 Consultation
21 Dissemination and Implementation
21.1 Dissemination
21.2 Implementation
22 Process for Monitoring Compliance and Effectiveness
24 References

Appendix A Key points of this policy
Appendix B Seeking Consent: Remembering the Patient’s Perspective
Appendix C 12 Key Points on Consent: The Law in England
Appendix D Mental Capacity Act Assessment Decision making Process and Best Interest Process Chart
Appendix E Assessing Fraser Competence Checklist
Appendix G Service Areas where Formal Written Consent for Treatment is required
1 Introduction

1.1 Objective

It is the objective of Bridgewater Community Healthcare NHS Foundation Trust, hereafter referred to as the organisation, to encourage the active participation of individual patients in decisions relating to their treatment, and to promote patient education regarding the risks and benefits of clinical procedures. Misunderstandings and disagreements about consent lead increasingly to complaints and litigation.

Further information on helping patients to understand treatment options is available at the following link: https://www.nice.org.uk/guidance/gs15/chapter/Quality-statement-5-Understanding-treatment-options

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is absolutely central to healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

Please note this policy relates to consent to assessment, examination or treatment. Please refer to the Confidentiality and Information Sharing Policy for advice regarding consent to share information.

Please see appendix A for Key Points of this policy and appendix B Seeking Consent: Remembering the Patient’s Perspective.

1.2 Scope

This policy applies to all employed clinical staff, registered and unregistered, bank and sessional staff who are required to work in clinical areas in the organisation. This includes but is not limited to doctors, nurses, health care assistants and allied health professionals.

2 Definitions

The definitions applicable to this policy are as follows:

Consent - A patient’s agreement for a health professional to provide care.

Treatment - Is taken to include assessment, examination, investigation and treatment.

Lasting Power of Attorney - A Lasting Power of Attorney is a legal document that lets a person appoint someone to make decisions about their welfare, money or property. It can be used at any time when or if a person is not able to make their own decisions.
**Advance Decision** - A person may have made an advance decision to refuse particular treatment in anticipation of future incapacity (sometimes previously referred to as a ‘living will’ or ‘advance directive’). A valid and applicable advance decision to refuse treatment has the same force as a contemporaneous decision to refuse treatment.

**Bolam Principle** - In the mid-1980s a majority of the House of Lords in the Sidaway case decided that it was on the whole a matter for doctors to decide how much to tell patients about the risks of treatment, and that therefore you could not sue your doctor in negligence for failing to inform you of a risk if other reasonable doctors would not have informed you of the risk. Thus the principle that the standard of medical care is to be determined by medical evidence (known as the Bolam principle) was extended to the quality of information to be provided to a patient about a given treatment.

The Supreme Court has now unequivocally said that Sidaway and Bolam should not be followed with respect to the quality of information provided e.g. regarding risks. Bolam still applies in relation to the principle that the standard of medical care is to be determined by medical evidence.

The move is away from a model of medical paternalism. Social and legal developments point towards an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors (and then being prone to sue their doctors in the event of a disappointing outcome), treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.

**Risk** - Is used throughout to refer to any adverse outcome, including those which some health professionals would describe as ‘side-effects’ or ‘complications’.

**Best Interest principle** - Best interests’ is a method for making decisions which aims to be more objective than that of substituted judgement. It requires the decision maker to think what the ‘best course of action’ is for the person. It should not be the personal views of the decision-maker. Instead it considers both the current and future interests of the person who lacks capacity, weighs them up and decides which course of action is, on balance, the best course of action for them.

### 3 Abbreviations

The abbreviations applicable to this policy are as follows:

- LPA – Lasting Power of Attorney
- MCA – Mental Capacity Act
- HCP – Healthcare Professionals
- IMCA – Independent Mental Capacity Advocates
4 Other Relevant Procedural Documents

This policy should be read in conjunction with the following documents:

- Language Interpretation and Translation Policy
- Medicines Policy
- Procedure for the Management and Storage of Clinical Photographs and Digital Images
- Confidentiality and Information Sharing Policy
- Immunisations Policy
- Safeguarding Adults Policy
- Safeguarding Children Policy
- Health Records Management Policy
- Research & Development Policy
- Advance Decisions to Refuse Treatment Policy
- Clinical Audit Policy.

5 Roles and Responsibilities

5.1 Chief Executive

The Chief Executive has ultimate accountability for ensuring the provision of high quality, safe and effective services within the organisation and for ensuring that resources are available to ensure effective implementation.

5.2 Clinical Managers / Line Managers

To ensure that all relevant staff are aware of and adhere to this policy.

5.3 All Staff involved in the Clinical Care of Patients

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.
Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, team work is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

All staff involved in gaining consent have a responsibility to familiarise themselves with this policy.

6 General Principles

In general, each patient has the right to accept or refuse treatment, and in this policy the term ‘treatment’ is taken to include assessment, examination, investigation and treatment. This is not only a right under common law, but is recognised as a basic tenet of ethical health care.

The organisation seeks to ensure that relevant information is provided to all patients, in ways that each patient can understand, about proposed treatments, including non-medical interventions such as personal care and therapy and including any alternatives. This information should contain an estimate of the relative risks and benefits of proposed treatments, and should be sufficiently detailed to enable patients to arrive at a balanced judgment, having had the opportunity to put their own value on the relative risks and benefits described.

The organisation recognises that patients may withdraw consent after it has been given, and may refuse treatment at any time.

6.1 Why Consent is Crucial

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 health professionals and patients.

6.2 What is consent – and isn’t

“Consent” is a patient’s agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing.

For the consent to be valid, the patient must:

- Be competent to take the particular decision;
- Have received sufficient information to take it; and
- Not be acting under duress.
The context of consent can take many different forms, ranging from the active request by a patient of a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional’s advice. In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. In many cases, ‘seeking consent’ is better described as ‘joint decision-making’: the patient and health professional need to come to an agreement on the best way forward, based on the patient’s values and preferences and the health professional’s clinical knowledge.

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no-one else can give consent on their behalf. However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance decision or where a Lasting Power of Attorney has been appointed. For further details see section 7 of this policy.

Specific attention should be given to the requirements of the Mental Capacity Act when dealing with situations where patients do not have the capacity to make decisions about their treatment. For further information see section 7 of this policy.

6.3 The Necessity for Consent

Consent is necessary for two reasons:

- Obtaining of informed consent, with discussion of risks, benefits and side effects associated with any treatment, is part of the process of developing trust and cooperation between patient and healthcare professionals
- It provides practitioners with a defence to subsequent charges under criminal law, or of trespass to the person under the law of tort.

It is relevant also to the law of negligence, which requires all healthcare professionals to counsel their patients in a way recognised by their peers as appropriate. It is necessary to answer patients’ questions truthfully and fully.

6.4 The Nature of Consent

For consent to be valid, three elements must be satisfied:

- The act of consenting must be wholly voluntary
- The person consenting must be capable of understanding the nature of the treatment
- The person consenting must be provided with sufficient information about the treatment to know what he/she is accepting.
It is the responsibility of the practitioner to ensure that communication with the patient is effective. Any issues in understanding caused by language, understanding, and/or special requirements must be addressed. Extra time will be needed; explanations should be in plain language, without the use of jargon. A communication assessment including the use of communication aids may be needed. Assistance may be necessary in the form of an accompanying family member, friend or advocate. However, this should only be arranged with the consent of the individual and consideration of the likely impartiality of the family member. Where English is a second language an interpreting or translation service should be used rather than a family member. The use of children as interpreters for parents is not always advisable for example if discussing an appointment time it would be acceptable but not if the child was being asked to interpret during a sexual health appointment. It is critical to check understanding by asking the patient to describe what they understand the information means. Only then is it possible to ensure that informed consent to any assessment, care or treatment is being given. Please refer to the organisations Language Interpretation and Translation Policy for further information.

6.5 **Guidance on Consent**

- 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.

  It can be accessed on the internet at:


- General Medical Council guidance re consent: patients and doctors making decisions together.


- 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 and is attached at Appendix C.

- Health professionals must also be aware of any guidance on consent issued by their own regulatory bodies.
7 **Mental Capacity**

7.1 **Mental Capacity Act 2005 (MCA)**

The legal requirements in the Mental Capacity Act are supported by five statutory principles. These five statutory principles of capacity include:

- A person must be assumed to have capacity unless it is established that he lacks capacity
- A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success
- A person is not to be treated as unable to make a decision merely because he makes an unwise decision
- An act done or decision made, under the Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests
- Before the act is done, or the decision is made, regard must be had to whether the purpose of which it is needed can be effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.


A patient detained under the Mental Health Act (1983) may be treated without consent for the mental disorder. For any border-line case where a physical disorder may in fact be part of the mental disorder, advice should be sought from the consultant who is responsible for the patient’s overall care.

7.2 **Assessing Capacity**

A person lacks capacity if they are unable to make a decision for themselves in relation to a matter because they have an impairment, or disturbance, of the mind or brain. This can be either permanent or temporary. The health professional should not make a judgement of the patient’s capacity on the basis of the patient’s behaviour or other aspects of their behaviour. Where there is any doubt with regard to the patient’s capacity, a formal assessment must be made.

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

- To understand the information relevant to the decision
- To retain that information
- To use or weigh that information as part of the process of making the decision
➢ To communicate their decision, whether by talking, using sign language or any other means.

If they fail to meet one or more of the above, they will be deemed to lack capacity to make a decision

7.3 Best Interests

Where a person lacks capacity to make decisions for themselves, any decision must be made in that person’s best interests. The Mental Capacity Act provides healthcare professionals (HCP) with protection from civil and criminal liability for acts or decisions made in the best interests of the person who lacks capacity. The Act emphasises that when determining what is in an individual’s best interests a HCP must not make assumptions about someone’s best interests solely on the basis of the person’s age or appearance, condition or any other aspect of their behaviour.

The Act requires that the Professional must consider all the appropriate circumstances relating to the decision in question. These are expressed as factors that the Professional is aware of and which are reasonable to take into account. When considering the relevant circumstances, the Act deems that the Professional must consider whether the person is likely to regain capacity and if so whether the decision can wait. In addition, the Professional should involve the individual as much as possible in the decision that is being made on their behalf. As much as possible, the Professional must consider the persons past and present wishes and feelings (especially if they are recorded in writing), any particular beliefs or values the person may have that could influence the decision in question, and any other factors that the individual may consider if they were able to do so.

Professionals should demonstrate in their record-keeping that the decision has been based on all available evidence and has taken in any conflicting views. As far as possible, and if it is appropriate to do so, the Professional should take into account the views of any of the following individuals:

➢ A person previously named by the person lacking capacity as someone who should be consulted

➢ The patient’s carers or anyone who is interested in his or her welfare

➢ Any attorney appointed under a Lasting Power of Attorney

➢ Any deputy appointed by the Court of Protection to make decisions for the person who lacks capacity

7.4 Procedure to Follow when Patients Lack Capacity to Give or Withhold Consent

Where an adult patient has been assessed and found not to have the capacity to give or withhold consent to a significant intervention, this fact should be documented on consent form 4 (form for adults who are unable to consent to
investigation or treatment), along with the formal assessment of the patient’s capacity, why the health professional believes the treatment to be in the patient’s best interests, and the involvement of people close to the patient. The standard consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient’s notes.

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

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult’s best interests. Where the consequences of having, or not having, the treatment is potentially serious, a court declaration may be sought. Please contact the safeguarding adults team if this arises.

7.5 Independent Mental Capacity Advocates (IMCA)

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. If the decision relates to the provision or withdrawal of life-sustaining treatment, the person making the best interests decision must not be motivated by a desire to bring about the person’s death.

An IMCA is not a decision-maker for the person who lacks capacity, but is involved in ensuring that the decision-making for the person who lacks capacity is done appropriately and in accordance with the Mental Capacity Act.

An Independent Mental Capacity Advocate must be consulted for decisions about major medical treatment and where there is no-one who fits into the categories:

- Previously named person, by the patient, who might be consulted in such an event
- Close relatives or others who take an interest in the persons welfare
- An attorney appointed under a Lasting Power of Attorney made by the person
- Anyone engaged in the caring for the person
- Any deputy.
The duties of an IMCA include supporting the person who lacks capacity and demonstrating their views and interests to the decision maker, obtaining and evaluating information through interviewing the person and reviewing relevant records and documents, obtaining the views of professionals that are providing the treatment for that person, identifying alternative courses of action, obtaining further medical opinions if required, and preparing a report that the decision maker must consider.

In cases where a patient, when previously competent, has already withheld consent for the proposed treatment this refusal should be respected. This is so even where the patient is no longer competent to make a decision, provided that the patient anticipated or intended his/her decision to apply to the situation in which he/she now finds themself. See section 7 for further information.

Any practitioner involved in the care of a person who lacks capacity should make sure that a record is kept of the process of working out the best interests of that person for each relevant decision, setting out:

- How the decision about the persons best interests was reached
- What the reasons for reaching the decision were
- Who was consulted to help work out the best interests, and
- What particular factors were taken into account.

Please see the Mental Capacity Policy and the HUB for further details on IMCAs.

### 7.6 Advance Decisions to Refuse Treatment

A person with capacity may have made an advance decision to refuse treatment in anticipation of any future incapacity (previously referred to as a ‘living will’ or ‘advance directive’). 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 summarised below:

- The person must be over 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 healthcare notes), 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 indeed valid and applicable, even if it may result in the person’s death. If they do not comply with this, they could ultimately face criminal prosecution or civil liability. The Mental Capacity Act does however protect a healthcare 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. Likewise, the Act also protects healthcare professionals from liability for the results of withholding or withdrawing a treatment if at the time they reasonably believe that there is a valid and applicable advance decision. If however there is genuine doubt or disagreement regarding whether an advance decision exists, or is valid and applicable, the case should be referred to the Court of Protection. Although the Court does not have the power to override an advance decision, healthcare professionals can provide life sustaining treatment or treatment to prevent the patient’s condition deteriorating further, whilst awaiting a decision from the court.

If an advance decision is not valid or applicable to current circumstances, the healthcare professional involved must consider the advance decision as part of their assessment of the person’s best interests. Some healthcare professionals may disagree with a person’s right to refuse life sustaining treatments, however the Mental Capacity Act does not change the current legal position. Although healthcare professionals do not have to act in such a way that goes against their beliefs, they must not abandon patients or cause their care to suffer. If this is the case, patients should have the option of transferring their care to another healthcare professional or, if they lack capacity, arrangements should be made for the management of the patients care to be transferred to another healthcare professional.

Patients should always be offered measures that are essential to keeping them comfortable. This is sometimes referred to as ‘basic’ or ‘essential’ care, and includes warmth, shelter, actions to keep a person clean and free from distress and the offer of food and water by mouth. The BMA’s guidance advises that basic care should always be provided unless it is actively resisted by a patient, and that ‘refusals of basic care by patients with capacity should be respected, although it should be continued to be offered’. Advance decisions made under the Mental Capacity Act cannot refuse actions that are needed to keep a person comfortable. The Act allows healthcare professionals to carry out these actions in the best interests of a person who lacks capacity. An advance decision can refuse artificial nutrition and hydration. However, although basic/essential care would include the offer of oral nutrition and hydration, it would not cover force feeding an individual or the use of artificial nutrition and hydration. The courts have recognised that an individual with capacity has the right to choose to refuse food and drink, although this may be qualified if the person has a mental disorder. Towards the end of such a period an individual is likely to lose capacity, and the courts have stated that if the individual has, while they have capacity, expressed the desire to refuse food until death supervenes, the person cannot be force fed or fed artificially when they lack capacity. If the person is refusing food as a result of mental disorder, then detention and treatment without consent may be a possibility under the Mental Health Act.
1983, different considerations may apply and more specialist guidance should be consulted.

7.7 Lasting Power of Attorney (LPA)

The Mental Capacity Act enables a person aged 18 or over to appoint an attorney to look after their health and welfare decisions if they should lack the capacity to make such decisions in the future. Under a personal welfare LPA, the attorney – if they have the authority to do so – can make decisions that are as valid as those made by the person themselves. The LPA must be made in the form, and meet the criteria, set out in the regulations, and it must be registered with the Office of the Public Guardian before it can be used.

The LPA may specify limits to the attorney’s authority, and the LPA must specify whether or not the attorney has the authority to make decisions about life-sustaining treatment. Healthcare practitioners directly involved in the care or treatment of a person who lacks capacity should not agree to act as that person’s attorney other than in exceptional circumstances (for example if they are the only close relative of the person). If the person lacks capacity and has created a personal welfare LPA, the attorney will have the authority to make decisions and consent to or refuse treatment as set out in the LPA. Healthcare practitioners should read the LPA if it is available, in order to understand the extent of the attorney’s power.

The attorney must follow the statutory principles under the Mental Capacity Act and make decisions in the best interests of the person lacking capacity. If the decision is about life-sustaining treatment, the attorney must not be motivated by a desire to bring about the person’s death. Attorneys also have a legal duty to have regard to the guidance in the Mental Capacity Act (2005) Code of Practice. If there is a dispute that cannot be resolved, e.g. between the attorney and a doctor, it may have to be referred to the Court of Protection. More information about LPAs is given in chapter 7 of the Code of Practice.

7.8 Limited Consent

In certain circumstances a patient may provide only limited consent. Practitioners agreeing to proceed under such restrictions must respect the patient’s wishes. Practitioners should not take any action without obtaining the patient’s consent beforehand except for measures that are both unforeseen and necessary to save life or prevent irreversible damage.

It is incumbent upon practitioners to discuss fully with patient’s the consequences of limited consent, preferably in the presence of a medical, nursing or AHP colleague. It is particularly important that such discussions are fully and contemporaneously documented in the clinical records.

If practitioners feel unable to proceed without unlimited consent, attempts should be made to identify a colleague who would be prepared to continue treatment within the limits specified by the patient.
The most frequent example of limited consent is found when patients who are Jehovah’s Witness refuse transfusion of blood and blood products on religious grounds - see appendix F for further information regarding Jehovah’s Witnesses.

8 **Documentation**

For significant procedures, it is essential for health 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 notes if necessary), or through documenting in the patient’s notes that they have given oral consent.

Consent Forms:

- 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 anaesthetic will be involved in their care
- Form 4 must be completed in appropriate situations for adults who are unable to consent. Unless it is a life threatening emergency you must complete a formal Mental Capacity assessment and best interest documentation prior to completing a consent form 4

The Business Services Authority forms (FP17, FP17DC, and FP17PR) are to be used where appropriate within the Dental services as required by the General Dental Service and Personal Dental Service Regulations. For dental patients undergoing a general anaesthetic, oral surgery, sedation, complex or other high risk procedures or for patients where capacity is an issue then both a Business Services Authority and a Department of Health consent form should be completed.

Completed consent forms should be kept with the patients notes for retention in accordance with the Health Records Management Policy.

9 **Type of Consent**

Consent may be written, oral or implied. Implied consent occurs for example when a patient proffers an arm for the taking of a blood sample. In order to defend an allegation of assault or negligence at a later date, it is helpful to have fully documented consent to treatment by the patient. For procedures with significant, unavoidable or frequently occurring risk, it is essential for practitioners to document clearly both a patient’s agreement to the intervention and the discussion, which led up to that agreement.

In all circumstances, patients have a right to receive sufficient information to reach a balanced judgment and come to an informed decision. This is known as ‘valid consent’. They can expect to have an explanation, presented in a sensitive and
understandable way, of the benefits, significant, unavoidable or frequently occurring risks, alternatives, known complications and side effects.

Written advice (i.e. information leaflets) should be prepared whenever possible and given to patients to back up verbal explanations.

9.1 Expressed Consent

Expressed consent is given when a patient confirms their agreement to a procedure or treatment in clear and explicit forms whether orally or in writing.

9.2 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: the signature is evidence of the process of consent-giving, not a binding contract.

It is rarely a legal requirement to seek written consent but it is good practice to do so if any of the following circumstances apply:

- The treatment or procedure is complex, or involves significant, unavoidable or frequently occurring 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
- There may be significant consequences for the patient’s employment, social or personal life
- The treatment is part of a project or programme of research approved by the organisation.

Completed forms should be kept with the patient’s notes. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional.

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 to do so.
See appendix G for service areas where formal consent for treatments is required.

9.3 Verbal Consent

Verbal consent should be limited to those procedures where there is minimal risk, and the agreement for the procedure to take place must always be recorded in the patient’s health care records by the professional administering the procedure.

9.4 Implied Consent

Implied consent applies where it is reasonable to assume the patient’s consent by their actions, e.g. undressing and lying on a couch for a physical examination. Although such circumstances normally present no problems, consideration must always be given to the need to explain and obtain written consent for any procedure where an adverse consequence could arise about which the patient might not be aware or where particular difficulties in explaining the procedure or doubts as to the patient’s understanding occur. In those circumstances a full entry should be made in the health records, which the patient should be asked to counter-sign. In a circumstance where a patient declines to sign and has the capacity to do so, the procedure must not proceed. However, if a patient lacks capacity refer to section 7.

There is no legal requirement that consent for treatment should be given in a particular way. Consent in writing is by far the best form of evidence and is the preferred method if any risk is contemplated.

9.5 Voluntary Consent

Consent must be obtained in the absence of coercion or duress. A patient’s apparent consent to, or refusal of, treatment may be rendered invalid by undue influence of a third party, if it can be shown that the patient’s will has been overridden. In this respect practitioners have an obligation to satisfy themselves that the decision reached is really that of the patient. Important points to consider are the effect of the patient’s condition on his/her ability to withstand third party influence, and the proximity of this relationship to the third party in question. This point is particularly important in situations where the patient is refusing consent. Where the patient is agreeing to clinically justified treatment recommended by clinical practitioner, there is a presumption in favour of an adult patient’s competence.

A mentally competent patient may refuse treatment for any reason, rational or otherwise, even if such a decision is fatal for the patient. In principle this remains the case where the consequences are fatal for a patient’s unborn child. However, when faced with a case where an apparently irrational decision has fatal consequences, the possibility of temporary incapacity must be considered. (Please refer to Section 7).
10 When should Consent be sought?

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

10.1 Single Stage Process (Verbal)

In many cases, it will be appropriate for a health 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, unavoidable or frequently occurring 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. Discussions related to the consent process e.g. provision of patient information leaflets, any questions asked etc must be annotated in the patients’ notes.

If a proposed procedure carries significant, unavoidable or frequently occurring risk risks, it will be appropriate to seek written consent, and health 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 health professional may then proceed.

10.2 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 or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (verbal) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure, and should have received a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure. If a form is signed before patients arrive for treatment, a member of the healthcare team must check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient’s consent and understanding, it is advisable to use a form of words which requires more than a
yes/no answer from the patient: for example beginning with “tell me what you’re expecting to happen”, rather than “is everything all right?”

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

10.3 Seeking Consent for Anaesthesia

Where an anaesthetist is involved in a patient’s care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient’s notes 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 form of anaesthesia.

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

10.4 Emergencies

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

10.5 Treatment of Children and Young People

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from 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 a child has parental responsibility for that child.

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

Where it is not a scheduled appointment, or it is the first appointment, and a child is brought by someone 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 urgent/emergency treatment e.g. dental and podiatry by someone who has “care of” the child at that particular time.

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

- For children born after 1st 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.

Further information can be obtained on this subject via the following link:

Parental rights and responsibilities: Directgov - Parents

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 sufficiently broad understanding of the hazards involved in any proposed treatment, and of any available alternatives
- That there is full documentation in the clinical 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 not considered competent (see next section) to be fully responsible for consent, healthcare professionals may involve them in the process. Children even of a young age should be encouraged to take part in the giving of consent, for example by adding their signature to the parental consent. See appendix E for Assessing Fraser Competence Checklist.
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 Fraser 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 or the Safeguarding Children Team.

For National Screening Programmes (e.g. childhood measurement programme) the organisation operates in accordance with National Guidance relating to letters requesting consent from parents). Also, specific measures under the Children Act 1989 allow teachers to give consent under specific circumstances to safeguard children’s welfare in schools (e.g. for immunisation in absence of parents in boarding schools).

10.6 Fraser Guidelines/Gillick Competence

Gillick competence is concerned with determining a child’s capacity to consent. Fraser guidelines, on the other hand, are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment. By confusing them, we lose crucial details necessary for obtaining consent.

Age of consent

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.

Victoria Gillick challenged Department of Health guidance which enabled doctors to provide contraceptive advice and treatment to girls under 16 without their parents knowing. In 1983 the judgement from the case laid out criteria for establishing whether a child under 16 has the capacity to provide consent to treatment; the so-called ‘Gillick test’. It was determined that children under 16 can consent if they have sufficient understanding and intelligence to fully understand what is involved in a proposed treatment, including its purpose, nature, likely effects and risks, chances of success and the availability of other options.

If a child passes the Gillick test, he or she is considered ‘Gillick competent’ to consent to that medical treatment or intervention. However, as with adults, this consent is only valid if given voluntarily and not under undue influence or pressure by anyone else. Additionally, a child may have the capacity to consent to some treatments but not others. The understanding required for different interventions will vary, and capacity can also fluctuate such as in certain mental health conditions. Therefore each individual decision requires assessment of Gillick competence.
If a child does not pass the Gillick test, then the consent of a person with parental responsibility (or sometimes the courts) is needed in order to proceed with treatment.

The ‘Fraser guidelines’ specifically relate only to contraception and sexual health. They are named after one of the Lords responsible for the Gillick judgement but who went on to address the specific issue of giving contraceptive advice and treatment to those under 16 without parental consent. The House of Lords concluded that advice can be given in this situation as long as:

1. He/she has sufficient maturity and intelligence to understand the nature and implications of the proposed treatment

2. He/she cannot be persuaded to tell her parents or to allow the doctor to tell them

3. He/she is very likely to begin or continue having sexual intercourse with or without contraceptive treatment

4. His/her physical or mental health is likely to suffer unless he/she received the advice or treatment

5. The advice or treatment is in the young person’s best interests.

Health professionals should still encourage the young person to inform his or her parent(s) or get permission to do so on their behalf, but if this permission is not given they can still give the child advice and treatment. If the conditions are not all met, however, or there is reason to believe that the child is under pressure to give consent or is being exploited, there would be grounds to break confidentiality.

Fraser guidelines originally just related to contraceptive advice and treatment but, following a case in 2006, they now apply to decisions about treatment for sexually transmitted infections and termination of pregnancy.

Although this ruling was around sexual health advice it has now been accepted that it can be applied to any situation requiring consent.

The healthcare professional must be able to justify that the young person has sufficient maturity to understand the nature, purpose, hazards and benefits of the treatment in order to give a valid consent. A young person may have the capacity to consent to an uncomplicated procedure but not to a more complex one, e.g. request for emergency hormonal contraception as opposed to termination of pregnancy.

A child’s request for confidentiality must be respected even when this includes refusing permission to discuss the treatment with his/her parents. However, the healthcare professional should seek to persuade a young person to tell his/her parents or allow the healthcare professional to do so. If the healthcare professional is to proceed with the treatment without parental involvement he/she must be able to justify that the best interest of the child are being served. When such situations arise, it may be helpful to obtain advice from senior colleagues or the Safeguarding Children Team.
In the majority of cases where there are no issues between child and parent, it is advisable to obtain both the child’s and the parental consent.

Problems may arise if assessment of competence is disputed by parents/guardians. Some parents believe that children under the age of 16 should not have the right to consent to any treatment on their own behalf. This is not a correct statement of law. The test is not one a parent can make. Where such a disagreement arises, the health professional should explain the legal position to the parent.

10.7 Young Person (16-17 years)

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 a child. This would include circumstances where refusal would likely lead to death, severe permanent injury or irreversible mental or physical harm.

Where young persons 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 patients 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 Team.

If the young person with capacity is refusing treatment, but the Healthcare Professional still believes that it is their interests to have the treatment then they should discuss with their line manager or the Safeguarding Children Team. It is not considered good practice, in line with the human rights legislation, to rely upon the consent of a person with parental responsibility to overrule the refusal of a young person with capacity in all the circumstances.

For further guidance on the Mental Capacity Act and 16 and 17 year olds please refer to Safeguarding Children Guideline 26 – Mental Capacity and the Mental Capacity Act (2005).

10.8 Adults

Every adult has the right to make his or her own decisions, including the right to consent to assessment, examination and /or treatment and must be assumed to have capacity to do so unless it is proved otherwise (See section 7). This means that you cannot assume that someone cannot make a decision for themselves just because they have a particular medical condition or disability. The five principles of the MCA must be applied.
Consent can only be obtained from the patient. No adult, next of kin or other third party can consent to treatment on behalf of another adult and must never be asked to sign the Consent Form.

NB – See section 7.7 (Lasting Power of Attorney) for adults who lack the capacity to make decisions.
It is good clinical practice for near relatives to be involved and it is helpful to receive their cooperation but there are no circumstances in which they can consent on the patient’s behalf.

If the patient is unconscious or otherwise unable to communicate their wishes, relatives may be in a good position to shed light on what the patient would wish in these circumstances. The role of relatives is not to impose their own views on what they would like to see happen and this should be recorded in the records.

11 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 and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where to go, how long they will be in hospital, how they will feel afterwards and so on.

Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them.

The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in Sidaway by Lord Scarman, and by Lord Woolf MR in Pearce, subject to the refinement made by the High Court of Australia in Rogers v Whitaker. An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and their consent must be obtained before treatment interfering with their bodily integrity is undertaken. The clinician/doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the clinician/doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

The clinician/doctor is however 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/doctor is also excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision. It is
unnecessary for the purposes of this case to consider in detail the scope of those exceptions.

Three further points should be made. First, it follows from this approach that 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: for example, the nature of the risk, the effect which its occurrence would have upon 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 risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.

Secondly, the clinicians/doctor’s advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of their condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that they are then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The clinician’s/doctor’s duty is not therefore fulfilled by bombarding the patient with technical information which they cannot reasonably be expected to grasp, let alone by routinely demanding their signature on a consent form.

Thirdly, it is important that the therapeutic exception should not be 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/doctor 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.

There are, of course, arguments which can be advanced against this approach: for example, that some patients would rather trust their clinicians/doctors than be informed of all the ways in which their treatment might go wrong; that it is impossible to discuss the risks associated with a medical procedure within the time typically available for a healthcare consultation; that the requirements imposed are liable to result in defensive practices and an increase in litigation; and that the outcome of such litigation may be less predictable.

11.1 Provision for Patients whose First Language is Not English

The organisation is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English. Please refer to the organisation’s Language Interpretation and Translation Policy for further information.

11.2 Access to more Detailed or Specialist Information

Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets.
The following arrangements are available to assist patients to obtain such information:

- Patient Services Team
  Telephone: 0800 587 0562
- NHS Choices

11.3 **Access to Health Professionals between Formal Appointments**

After an appointment with a health professional, patients will often think of further questions which they would like answered before they make their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient’s choice).

Following a consultation, it is the responsibility of the health professional seeing the patient to give specific contact details should the patient have further queries between consultations. This information should be clearly outlined to the patient and shown in the space on the Consent Form for contact details.

11.4 **Open Access Clinics**

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

11.5 **Failure to Warn**

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 the 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 would need to be appropriately documented.

A risk is material if, in the circumstances of a particular case where a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it: or, where the practitioner is aware, or should reasonably be aware to attach significance to it. There may be particular characteristics about a patient, e.g. age, occupation or lifestyle, which may make certain medical information more relevant to them than it would be to other patients. If so, they must be informed of this.
11.6 Written Patient Information

Where appropriate patients should be provided with written patient information to supplement and reinforce verbal discussions.

12 Responsibilities of Staff Seeking Consent

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

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

12.1 Completing Consent Forms

The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because 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.

It is the responsibility of local managers, as part of local induction, to ensure that staff that do not carry out specific procedures but could provide patient information understands how to seek access to appropriate colleagues to answer any additional queries.

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

- It is a requirement that staff taking consent are trained in the risks relating to specific procedures where they do not themselves carry out the specific procedure, but could potentially provide the information patients need in coming to a decision. When staff are trained and competent it is a requirement that they access clinical supervision

- Health professionals confirming the patient’s consent must have access to appropriate colleagues where they are not able to answer any remaining questions
Should access to appropriate colleagues not be available, consent cannot be obtained.

Procedure specific training and general consent training is available in each service. This will form part of the induction to service training and as new procedures are developed further training will be provided.

12.2 Responsibility of Health Professionals

It is a health professional's own responsibility to:

- Ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so; and
- Work within their own competence and not to agree to perform tasks which exceed that competence.

If you feel that you are being pressurised to seek consent when you do not feel competent to do so contact the relevant Assistant Director of Operations or Associate Chief Nurse.

12.3 Who Gains Consent?

Consent should be gained by a practitioner, who is both capable of performing the procedure and is able to explain the risks and benefits. Where this is not practicable, the task may be delegated (although responsibility remains with this practitioner). Where the process is delegated the following must be clearly demonstrated:

- The person giving the information is conversant with the procedure, understands the benefits and risks involved, and has been trained and assessed and is aware of his or her own knowledge limitations
- The patient is made aware of the implications of the treatment including pre, peri and post-procedure effects and consequences
- The person explaining the procedure is subject to an audit process
- Adequate literature describing the procedure, its benefits and risks and any alternative is always given to the patient
- The patient has proper access to the delegating practitioner so that any problems or queries, which cannot be answered by the person explaining the treatment, can be easily and speedily addressed.
12.4 Assessing the Patient’s Understanding

In assessing the patient’s understanding, note should be taken of the possible limiting factors, e.g.:

- Poor hearing or sight
- Language barriers (if necessary an interpreter should be used)
- Patient’s level of literacy
- Mental disabilities, e.g. memory, neurological disability/impairment.

These restrictions to communication should be acted upon and use of communication aids, advocacy (formal or informal) translation, interpreting and/or British Sign Language interpreters should be used. To increase the potential for a full level of understanding, patients may wish to have relative or friend or nurse with them so that they can discuss what is said, then and later, more effectively. There must always be a reasonable opportunity to ask questions.

12.5 Blanket Consent

Blanket consent must not be used and the Consent Form must always state specific assessment, examinations and/or treatments. These must be described in words that patients will understand and abbreviations should not be used. More than one procedure may be recorded on the form as long as it is linked and undertaken within an appropriate time-scale. It is important always to record the date of consent and the site of an operation must always be adequately specified, e.g. left hand.

12.6 Prior to Treatment

Before any procedure takes place, checks should be made to ensure that it matches what has been written on the Consent Form.

12.7 Influence of Medication and Alcohol

Occasionally some substances such as medication and alcohol may affect the patient’s ability to give consent. It is important to remember that consent must not be obtained from a patient after pre-medication. Patients who are sufficiently affected may not have the capacity to consent, which means that any consent obtained in these circumstances will not be valid and should not be relied upon. Treatment should not be commenced until the patient is deemed to have regained sufficient capacity to make an informed decision and give consent, unless the patient’s life is endangered or their health would be significantly compromised without immediate treatment.
13 Refusal of Treatment

The organisation recognises the rights of patients to vary or withdraw consent after it has been given, without prejudice to their care. Advice on significant risks and further discussion concerning difficult and exceptional cases may be found in section 15 and appendix F (Jehovah’s Witness Patients).

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 2005. The situation for children is more complex: see the General Medical Councils Website for further information:


The following paragraphs apply primarily to adults:

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

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

If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient’s stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care.

Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient’s care to that health professional.

13.1 Treating without Consent

Patients have an absolute right to give or to withhold consent to any intervention as long as they have the mental capacity to do so. Patients are deemed competent unless otherwise proven. In the event of a patient refusing to consent the practitioner should make every effort to obtain a signature declining treatment. In these instances taking the opinion of a Psychiatrist is necessary, and therefore they cannot be coerced, however necessary the treatment may be.
The circumstances where treatment can be given without consent are limited to:

- Life threatening situations where the patient is unconscious and cannot express a wish. In such cases it would be appropriate for the practitioners to speak to the patient’s relatives (if available) outlining the treatment to be given and the reasons for its necessity.

- The treatment of a mental disorder, if sufficiently connected to the mental disorder for which the patient has been sectioned, may be treated under the Mental Health Act.

- Where a minor is a ward of Court and the Court rules that the treatment is in the child’s best interests.

- In accordance with statutory powers, e.g. Public Health Act 1984.

In cases, where additional treatment is considered necessary during a procedure under general anaesthetic it must not take place without the patient’s consent. The need must be discussed after the patient has recovered and a further intervention scheduled if the patient gives the appropriate consent.

In the circumstances where treatment can be given without the consent of the patient the Consent Form must not be signed by another party on behalf of the patient. No person, however closely related, can give consent for the treatment of another adult, regardless of whether or not that person is deemed competent or not. Instead, contemporaneous notes must be made in the health record explaining the situation and the decision to proceed without patient consent. In addition, the Consent Form for assessment, examination and/or treatment of a ‘Patient Who Lacks Capacity’ (consent form 4) must be completed and signed by the practitioner undertaking the procedure or treatment.

In an emergency and where the patient lacks competence, the practitioner must act in the patient’s best interests and must provide such treatment as is necessary to save the patient’s life or to preserve health. Ideally, the most experienced practitioner available should make this decision.

In all circumstances, once a patient has been assessed as lacking competence they must be treated as swiftly and with as much skill and care as a competent patient. The duty of care is exactly the same for those lacking competence as competent patients.

If there is any doubt over whether the proposed treatment is in the best interests of the patient, or there is a dispute within the clinical team or between the team and relatives as to what is in the patient’s best interests, then advice must be sought from the Directorate Management Team, the relevant Assistant Director of Operations or the Medical Director straight away.

A patient’s capacity to consent may vary day by day. Valid consent given when the patient was competent remains valid if the patient subsequently becomes incompetent whether temporarily or permanently. Wherever possible the relatives
should be involved in the discussions about the treatment plan as they may be able to shed light on what the patient would have chosen to do. However, the final decision lies with the decision-maker.

14 Consent to Treatment with Medicines

14.1 Information on Medicine(s)

Informed consent must be obtained and documented for all medicine use, having discussed the benefits and risks of that treatment.

In order to obtain consent, health professionals must ensure that all decisions around medicines are properly informed. It is important that patients have access to reliable, factual and balanced information over choices of healthcare involving medicines.

Health professionals should have ready access to accurate up to date information on any medicine they prescribe, dispense or administer. Health professionals must give patients and/or their representatives’ sufficient information about the proposed medicine(s) and satisfy themselves that the patient has understood what is proposed according to the relevant NICE guidelines on medicines adherence and medicines optimisation, so that the patient is able to give informed consent to the treatment, for example:

- What the medicine is
- How the medicine is likely to affect their condition (that is, its benefits)
- Likely or significant adverse effects and what to do if they think they are experiencing them
- How to use the medicine
- What to do if they miss a dose
- Whether further courses of the medicine will be needed after the first prescription
- How to get further supplies.

It is important to discuss treatment options carefully with the patient to ensure that the patient is content to take the medicine as prescribed, (also termed adherence) In particular the patient should be helped to distinguish the side-effects of prescribed medicines from the effects of the medical disorder. Where the beneficial effects of the medicine are likely to be delayed the patient should be advised of this. The information given to patients, carers, children and other Health Professionals must be given in a way they can understand, and be accurate and consistent. Please refer to the relevant NICE Clinical Guidelines on Medicines adherence – involving patients in decisions about prescribed medicines and supporting
adherence and Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes, for further information.

https://www.nice.org.uk/guidance/ng5 and http://www.nice.org.uk/guidance/cg76

When administering medicines, the healthcare professional must ensure that appropriate consent has been obtained and that the patient is still content to take the medicine as prescribed. In addition, refer to the Medicines Policy and Standard Operating Procedure for Administration of Medicines.

It is the responsibility of the person administering to ensure that a medicine supplied for a particular patient is only administered to that patient. If supplied as a stock item, the person administering should ensure that where possible the batch number and expiry date are recorded on the patient’s health record, that the medicine is of a suitable quality, and the integrity of the product has been maintained.

**14.2 Unlicensed Medicines or Medicines used Off-Licence / ‘off label’**

Informed consent must be obtained and documented for all medicine use, having discussed the benefits and risks of that medicine treatment. This is equally true when using unlicensed medicines or for medicines used off-licence/off label. The prescriber must take account of the safety of the medicine, how well established it is in practice, the treatment options of not giving the medicine etc.

Prescribers must be fully aware of the current information about the use and contraindications of the medicine that they propose to prescribe. In particular, unlicensed or off-licence/off label medicines are less likely to be approved formulary choices and every alternative formulary choice must be explored prior to consideration of the use of an unlicensed or off licence / off label medicine. For unlicensed or off-licence/off label use, the manufacturers information may be of limited help and the necessary information where available must be sought from elsewhere.

Many medicines are not licensed for use in children. The use of some unlicensed medicines or licensed medicines for off-licence/off label use is often necessary in paediatric practice. See also the Trust Medicines Policy available on the intranet.

If there is no alternative other than to prescribe an unlicensed or off-licence/off label medicine, the prescriber must inform the patient (or the patient’s carer where appropriate) of the medicines licence status, what this means and where appropriate explain that its effects will be less understood than those of a licensed product. The results of the discussion must be documented in the patient’s notes.

**14.3 Patient Group Directions (PGDs)**

PGDs provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber. A PGD is a specific written instruction for the supply or administration of named medicines, in an identified clinical situation, by a named Health Professional.
Health Professionals working under a PGD must obtain consent from the patient to be treated, and follow the same processes as above in section 14.1, and refer to the Trust Medicines policy

14.4 Covert Administration of Medicines - see also Medicines Policy

The Nursing and Midwifery Council (NMC) recognises that this is a complex issue that has provoked widespread concern. It involves the fundamental principles of patient and client autonomy and consent to treatment, which are set out in common law and statute and underpinned by the Human Rights Act 1998.

Disguising medicine(s) in the absence of informed consent may be regarded as deception. However, a clear distinction should always be made between those patients/clients who have the capacity to refuse medicine(s) and whose refusal should be respected, and those who lack capacity. Among those who lack this capacity, a further distinction should be made between those for whom no disguising is necessary because they are unaware that they are receiving medicine(s) and others who would be aware if they were not deceived into thinking otherwise.

The covert administration of medicines is only likely to be necessary or appropriate in the case of patients or clients who actively refuse medicine(s) but who are assessed not to have capacity to understand the consequences of their refusal.

The NMC recognises that there may be certain exceptional circumstances in which covert administration may be considered to prevent a patient or client from missing out on essential treatment. In such circumstances and in the absence of informed consent, the following considerations may apply:

- The best interests of the patient or client must be considered at all times
- The medicine(s) must be considered essential for the patient’s or client’s health and wellbeing, or for the safety of others
- The decision to administer medicine(s) covertly should not be considered routine, and should be a contingency measure. Any decision to do so must be reached after assessing the care needs of the patient or client individually. It must be patient, or client specific, in order to avoid the ritualised administration of medicine in this way
- There should be broad and open discussion among the multi-professional clinical team and the supporters of the patient or client, and agreement that this approach is required in the circumstances. Those involved should include carers, relatives, advocates, and the multi-disciplinary team (especially the Pharmacist). Family involvement in the care process should be positively encouraged
- The method of administration of the medicines should be agreed with the General Practitioner and Pharmacist
The decision and action taken, including the names of all parties concerned, should be documented in the care plan and reviewed at appropriate intervals.

Regular attempts should be made to encourage the patient or client to take their medicine(s). This might best be achieved by giving regular information, explanation and encouragement, preferably by the team member who has the best rapport with the individual.

15 Special Situations

15.1 Withholding or Withdrawing Life Sustaining Treatment

15.1.1 General

A healthcare professional's legal duty is to care for a patient and to take reasonable steps to prolong their life. Although there is a strong presumption in favour of providing life-sustaining treatment, there are circumstances when continuing or providing life-sustaining treatment stops providing a benefit to a patient and is not clinically indicated. There is no legal distinction between withdrawing and withholding life-sustaining treatment. A person with capacity may decide either contemporaneously or by a valid and applicable advance decision that they have reached a stage where they no longer wish treatment to continue. If a person lacks capacity, this decision must be taken in their best interests and in a way that reflects their wishes (if these are known).

15.1.2 The Dying Patient

The aim of medical and nursing practitioners in this situation is to ease suffering without attempting to prolong life artificially. In those rare situations where disagreement arises between patients or their parents/relatives a Court may authorise the withholding or withdrawing of such treatment as is appropriate to the individual case.

In the case of children, staff are referred to detailed advice issued by the Royal College of Paediatrics and Child Health. In these cases health professionals should seek advice from the Safeguarding Children Team.

15.2 HIV Testing

For consent to be real and valid, it is not sufficient for a patient to consent to blood testing in general terms without being told the nature and purpose of the proposed test. Consent for HIV testing should be expressly sought, and the possible consequences of the testing explained.

These should include the fact that by testing a baby for HIV, the mother is also being tested. Practitioners are advised to consult the Local Sexual Health Clinic regarding the protocol on testing for HIV.
16 **Tissue**

The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all. At present, this organisation requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes.

Blood samples are obtained during investigation of a disorder or to monitor treatment. Patients are able to consent verbally to the procedure as the blood samples are not obtained under anaesthetic.

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply. The right to opt out will be documented on consent information and in the patient record. Any enhanced health surveillance undertaken in the organisation is at the direction of the Health Protection Agency and in accordance with national guidance. Notifiable diseases are reported in line with statutory requirements and are exempt from the Data Protection Act.

Pending the outcome of the review of the law governing the use of human organs and tissue, the Department of Health believes that tissue samples may be used for quality assurance purposes without requiring specific patient consent provided there is an active policy of informing patients of such use. This is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised.

The organisation does not undertake any research on tissue samples and only takes tissue samples for testing purposes. The organisation would expect that those institutions used for testing of tissue samples to abide by the governing laws of England at the time.

In specific situations where clinical governance considerations require it, staff will ensure that as part of obtaining consent, they will advise patients that samples may be kept for quality control and future diagnostic reasons;

For example: When consent is obtained from patients for cervical smears to be taken, it will be explained that slides will be kept for an adequate period of time, for future reference if any future slide shows a developing abnormality, or the slides are required to be re-checked within the parameters of a Quality Assured service.

16.1 **Human Tissue**

The Human Tissue Act 2004 makes consent a fundamental principle in the lawful retention and use of body parts, organs and tissue from living or the deceased.
17 **Clinical Photography and Conventional or Digital Video Recordings**

Photographic and video recordings made for clinical purposes form part of a patient’s record. Although consent to certain recordings, such as X-rays, is implicit in the patient’s consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure. This is especially pertinent if photographic and video recordings are made for research purposes. Please see Management and Storage of Clinical Photographs and Digital Images Procedure for further information and associated consent form.

18 **Research and Clinical Audit**

18.1 **Research**

No research may be carried out on patients, including access for research purposes to their medical records, without the prior approval of the Trust, an appropriate Research Ethics Committee (if required) and the patient’s prior consent being obtained. In certain cases the Research Ethics Committee may waive the need for the patient’s consent to be obtained.

The Health Research Authority is responsible for producing guidelines for the securing of a patient’s consent for research projects.

Research involving children is covered by additional regulations and guidance.

18.2 **Clinical Audit**

All clinical audit activity must be registered with the Clinical Audit Manager before it commences.

“Section 251 of the NHS Act allows patient information to be used for clinical audit without explicit patient consent if data are anonymised”. “Although explicit consent is not required patients should be informed about how their information could be used in the NHS including the potential use of their information for clinical audit.”

In order to assist with this, the Trust distributes a patient information leaflet entitled “Protecting your Privacy”.

Anyone wishing to undertake a research project or clinical audit must contact either the Head of Research or the Clinical Audit Manager.

Please refer to the Trust’s Research & Development and Clinical Audit Policies for further information.
19 Childhood Immunisation

It is good practice to gain written consent for childhood immunisations. However, there is no requirement for the national model consent forms to be used for a school routine immunisation programme, if a simpler form is more appropriate. The main concern is that:

- The consent given is valid, i.e. is given voluntarily by an appropriately informed person (either the patient or someone with parental responsibility for a patient under the age of 18)

- The process of consent is recorded, with this record accessible to both the patient and the medical professionals concerned.

Please refer to the Immunisations Policy for further information.

20 Consultation

Key individuals/groups involved in the development of the document to ensure it is fit for purpose once approved.

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bernie Connell</td>
<td>Associate Chief Nurse</td>
</tr>
<tr>
<td>Jeanette Hogan</td>
<td>Associate Chief Nurse</td>
</tr>
<tr>
<td>Sharan Arkwright</td>
<td>Associate Director: Quality Governance</td>
</tr>
<tr>
<td>Kristine Brayford-West</td>
<td>Associate Director for Safeguarding</td>
</tr>
<tr>
<td>Bernie Hardman</td>
<td>Associate Director End of Life</td>
</tr>
<tr>
<td>Karen Slade</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Caroline Williams</td>
<td>Area Director</td>
</tr>
<tr>
<td>Michelle Bradshaw, Anne Doyle, Karen Plant, Barry Hutton, David Mills</td>
<td>Assistant Directors of Operations</td>
</tr>
<tr>
<td>Sarah Quinn</td>
<td>Head of Medicines Management</td>
</tr>
<tr>
<td>Jan McCartney</td>
<td>Head of Information Governance</td>
</tr>
<tr>
<td>Rachel Hall</td>
<td>Head of Research</td>
</tr>
<tr>
<td>Lisa McLaren</td>
<td>Head of Knowledge and Library Services</td>
</tr>
</tbody>
</table>
Dissemination and Implementation

21.1 Dissemination

The Head of Clinical Governance, Quality and Effectiveness is responsible for disseminating this policy via the Trust the intranet and staff bulletin.

21.2 Implementation

Training on consent issues relating to treatments or procedures carried out in specific service areas should be carried out by the line manager as part of clinical supervision or when a member of staff starts work.

The Local induction programmes will cover issues relating to consent issues and processes specific to each service area. It is the service manager’s responsibility to ensure that local induction includes discussion and familiarisation of staff with consent issues pertinent to the activities of their service.

Training on Consent and the Mental Capacity Act can be accessed via e-Learning. Staff must attend the e-Learning introductory session prior to undertaking any of the e-learning courses. Relevant courses should be identified as part of individual development plans.

Health professionals should be aware of any guidance on consent issued by their own regulatory bodies.

Further Information and all the approved consent forms are available on the organisations intranet via the following link:

http://nww.bridgewater.nhs.uk/corporate/Pages/Consent.aspx

22 Process for Monitoring Compliance and Effectiveness

Compliance with this policy will be monitored through the assessment of incidents, complaints and claims that are related to this policy. Any identified trends that relate to a failure to comply with this policy will be addressed appropriately.

Compliance with the policy will also be monitored through the record keeping audit within service areas and action plans developed where appropriate.

23 Standards/Key Performance Indicators

None applicable.

24 References

Data Protection Act 1998, c.29 [online]. Available at:

National Institute for Health and Care Excellence (2009) Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence [online]. Available at: https://www.nice.org.uk/guidance/cg76


Appendix A  

Key points of this policy

1. Everyone has a fundamental legal and ethical right to determine what happens to their own body.

2. Valid consent underpins healthcare delivery whether basic care or major surgery.

3. For the consent to be valid, the patient must:
   - Have capacity to make the particular decision
   - Have received sufficient information to make it
   - Not be acting under duress.

4. Where an adult patient lacks capacity no-one else can give consent on their behalf unless they are a personal welfare lasting power of attorney or a deputy appointed by the Court of Protection.

5. Only people who have parental responsibility for the child can give consent on their behalf and it is important to check this with the adult who accompanies the child.

6. A young person aged 16 or 17 has an explicit right to provide consent to surgical, medical or dental treatment.

7. An adult patient with capacity is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act.

8. Identifiable photographic and video recordings made for treating or assessing a patient must not be used for any purpose other than the patient’s care without the consent of the patient or a person with parental responsibility.

9. There are four forms available on the intranet via the following link: http://nww.bridgewater.nhs.uk/SubPage.aspx?iPageID=14762
   - 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
   - Form 4 must be completed in appropriate situations for adults who are unable to consent.
Appendix B  Seeking Consent: Remembering the Patient's Perspective

- What treatment might help?
- Are there any alternatives?
- What are the risks and benefits of the alternatives?
- What about the risks?
- Can I drive/work/look after my family afterwards?
- What do they think is wrong with me?
- How would it involve & would it help me?
- Will it hurt?
- Will I have to stay in hospital?
- Maybe I'd like to discuss it with my family before I decide
Appendix C  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, some-one 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. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.
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. 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 (an ‘advance refusal’), and those circumstances arise, you must abide by that refusal.
Mental Capacity Act 2005 process for person 16 years and older

Does the person have the capacity to make the decision in question?

No/unsure

Point to consider: Is it time and decision specific?

Assess the person’s capacity using the Trusts capacity assessment form

Patient lacks capacity to make decisions for the following:
- Serious medical treatment
- NHS arranges hospital stay for 28 days or more
- An accommodation move for 8 weeks or more is arranged
- Person (over 18) requires restrictions which amount to a Deprivation of Liberty (including meeting the Acid test criteria)

Yes

Point to consider: Offer the person further help and support to make a decision. Engage the help of people the person trusts. Present the relevant information to the person in a way they will best understand, retain, weigh up and communicate the decision. Consider using pictures and diagrams, interpreter or other specialist help?

No family or friends

Refer to an Independent Mental Capacity Advocate (IMCA) and complete an IR1

Best Interest discussion or meeting

Outcome of decision documented on the Best Interest Decision form and kept in persons records. Complete a consent form 4 if required for consent

Point to consider: Can the decision be delayed until person regains capacity?

Respect the person’s wishes and views even if you think it is an unwise choice. Document the person’s wishes and views and support offered in their patient record

Remember to document fully in persons records and include a copy of the Capacity and Best interest forms

Point to consider: Always consider the least restrictive options. If person aged over 18 Consider if a Deprivation of Liberty Safeguard is required (seek further advice from safeguarding team if unsure)

Family or friends involved in the person’s life

Disagreement regarding the decision or a safeguarding allegation (seek further advice from safeguarding team if unsure)

Is there an Advanced Directive/LPA or Court Appointed Deputy

Yes

Seek further advice from the Safeguarding or legal team

No

Point to consider: Always consider the least restrictive options. If person aged over 18 Consider if a Deprivation of Liberty Safeguard is required (seek further advice from safeguarding team if unsure)
Appendix E  
Assessing Fraser Competence Checklist

This form is to be used by Health Professionals assessing young persons (ages 11-16) consent to treatment or refusal to consent in the absence of a person with responsibility.

Name of Child/Young Person…………………… Venue/ School ........................................
D.O.B…………………………………… Yes No

- Parent/Guardian has provided consent □ □
- Parent/Guardian has refused consent to this treatment/procedure □ □
- Has the young person refused to tell the Parent/Guardian or to allow the health professional to discuss it with their parents? □ □

If answered “yes” to any of the above points, what actions have been taken and what evidence do you have to support this? (Please write all relevant evidence in the space provided).

……………………………………………………………………………………………………………
……………………………………………………………………………………………………………

The Young Person:

- Understands the benefits of proposed treatment □ □
- Understands the risks of proposed treatment □ □
- Understands what the treatment involves □ □
- Understands the implications of not having the treatment □ □
- Understands the alternatives available □ □
- Understands what effects on their lives of having or not having the treatment will be □ □
- Understands the language and clinical terms □ □
- Understands the procedure to be carried out □ □
- Demonstrates the ability to communicate a choice □ □

Name of Professional Completing this form .................................................................
Signature……………………………… Designation……………………………………
Date……………………………………………….
Appendix F  Jehovah’s Witness Patients: Consent and Treatment Background

Some patients referred for treatment are Jehovah’s Witness. Their religious convictions prevent them from accepting blood or blood products, even when these are necessary to sustain life. In common with all patients the wishes of Jehovah’s Witness patients should be respected throughout any care and treatment.

It is the responsibility of the practitioner in charge of the patient’s care to ensure that the position regarding the administration of blood or blood products is clarified before the patient is admitted for the procedure in question. The responsible practitioner should discuss with every Jehovah’s Witness patient the implications of any refusal to accept blood or blood products. This should be at the earliest opportunity, and always before a decision is taken to recommend a procedure, which might, in normal circumstances, require the use of blood products.

If a patient on a waiting list or scheduled treatment is discovered to be a Jehovah’s Witness, then he/she should be contacted at the earliest opportunity to discuss the administration of blood and blood products.

Procedures

If the patient’s refusal of blood and blood products is absolute, the practitioner must decide whether he is able to treat the patient while fully complying with the patient’s wishes. If he feels unable to comply with the wishes of the patient, then he should refer him/her to a colleague who does feel able to.

If the practitioner is willing to proceed with treatment in accordance with the patient’s wishes, he should use the standard Consent Form produced for this situation. Occasionally, it will emerge during discussions, that the patient is willing to subordinate religious conviction to survival and allow the practitioner to use blood or blood products if this is necessary to save the patient’s life. In these situations, the amended Consent Form should be used.

If a patient is unconscious and found to be carrying a card stating that as a Jehovah’s Witness a transfusion must not be given in any circumstances, even if necessary to save life, the practitioner must respect the patient’s wishes. Decisions should always be documented.

Children of Jehovah’s Witness Patients

Parents who are Jehovah’s Witness may not prohibit practitioners from administering blood or blood products to their children, but consent should be obtained for procedure, usually from the Court.
Where a parent or parents are Jehovah’s Witness and purport to refuse transfusion of blood or blood products in the course of treatment of their child, practitioners must always seek legal advice. In emergency situations, practitioners may rely on the support of Courts to endorse decisions that are taken in good faith and in the best interests of the child concerned.

If the patient is the child of a Jehovah’s Witness and the child is under the age of 16 the practitioner must assess whether the child is ‘Fraser Guidelines’ competent. If he/she is and consents to treatment, the procedure should go ahead even if the parents object. Where time allows, legal advice should be sought.
## Appendix G Service Areas where Formal Written Consent for Treatment is required

<table>
<thead>
<tr>
<th>Service Area</th>
<th>Forms Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Services</td>
<td>Photography</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>Acupuncture, Steroid Injections</td>
</tr>
<tr>
<td>Dental Services</td>
<td>Extractions, Surgical Procedures, All treatment performed in sedation, All treatments performed under general anaesthetic</td>
</tr>
<tr>
<td>Podiatry</td>
<td>Nail surgery</td>
</tr>
<tr>
<td>Children’s Services</td>
<td>Newborn Screening, National Childhood Measurement Programme</td>
</tr>
<tr>
<td>Sexual Health</td>
<td>Utilise FFPRHC &amp; RCOG Service Standards on Obtaining Consent in Sexual Health Services</td>
</tr>
<tr>
<td>Dermatology</td>
<td>Excisions</td>
</tr>
</tbody>
</table>

### Guidance for procedures which need a written consent form

It would not be practicable to identify all procedures which require a written consent, nor anticipate all new areas of service development. Therefore, each clinical service must refer to guidance from their professional bodies and keep updated on best practice.

The following statement is key to the decision making:

The treatment or procedure is complex, or involves significant, unavoidable or frequently occurring 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’

Evidence in the patient’s notes and consent forms will demonstrate how the health professional obtained consent which needs to be both informed and understood by the patient.

### Types of Forms to be used:

**DoH Form One** - only if anaesthesia is to be used

**DoH Form Two** - for parental agreement to investigation or treatment for a child or young person. Only people with parental responsibility are entitled to give consent on behalf of their treatment
**DoH Form Three** – for patient / parental agreement to investigation or treatment where consciousness is not impaired. *This would be the most commonly used in Community Services and General Practice*

**DoH Form Four** is for adults who are unable to consent to investigation or treatment.