# Obtaining Consent to Examination and Treatment

<table>
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<tr>
<th>Reference Number:</th>
<th>728</th>
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| Review Date:            | 21\textsuperscript{st} November 2023 |
| Ratified by:            | Dr Bernie Marden, Medical Director |
| Date Ratified:          | 21\textsuperscript{st} November 2019 |
| Version:                | 7.0                          |

### Related Policies and Guidelines
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- Compliance with the Human Tissue Act 2004 (791)
- Writing and producing information for patients (209)
- Resuscitation policy (774)
- Care of adult patients sectioned under mental health act (729)
- Blood component transfusion (702)
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<th>Authorised</th>
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<tr>
<td>4</td>
<td>Approved</td>
<td>10 February 2010</td>
<td>Planned Review</td>
<td>Operational Governance Committee</td>
</tr>
<tr>
<td>5</td>
<td>Approved</td>
<td>4 February 2013</td>
<td>Planned Review</td>
<td>Tim Craft Medical Director</td>
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<tr>
<td>6.0</td>
<td>Approved</td>
<td>March 2016</td>
<td>Planned Review</td>
<td>Tim Craft - Medical Director</td>
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<tr>
<td>7.0</td>
<td>Approved</td>
<td>November 2019</td>
<td>Planned Review</td>
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1. Policy Summary

The purpose of this policy is to provide guidance for staff within the Royal United Hospitals Bath NHS Foundation Trust about the requirements and processes for obtaining informed consent.

This policy applies to all individuals in the employ of the Royal United Hospitals Bath NHS Foundation Trust.

It is based on the Department of Health’s model consent policy and has been updated following recent legislative changes, namely the Mental Capacity Act (2005) and Human Tissue Act (2004).

Updates have been made locally pending the anticipated revision of the Department of Health’s Model policy to include the implications of the Human Tissue Act and the Mental Capacity Act.

1.1. 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. Without respecting these principles, healthcare staff (and the organisation) may make themselves liable to legal action as well as action by their professional body.

1.2. This policy

The Department of Health has issued a range of guidance documents on consent (see section 1.4), and these should be consulted for details of the law and good practice requirements on consent. This policy sets out the standards and procedures in this Trust which aim to ensure that health professionals are able to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

1.3. What consent is – 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.
Consent is not valid if obtained by fraudulent means.

The context of consent can take many different forms, ranging from the active request by a patient for a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional’s advice. In some cases, the 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, in general, no-one else can give consent on someone else’s behalf. However treatment may be given if it is in their best interests, as long as the requirements of the Mental Capacity Act 2005 are adhered to and it has not been refused in advance in a valid and applicable advance directive or advance decision (please see section 6.1 and 7 for more information).

1.4. Guidance on consent

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

Reference guide to consent for examination or treatment provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies are available on the Trust’s intranet, through the Head of Risk & Assurance on extension 5927, and may also be accessed on the internet at https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition.

2. Policy statements

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 the
health professional carrying out the procedure who will be held responsible in law if this is challenged later. 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.

Following a Supreme Court judgement, doctors must now ensure that patients are aware of any “material risks” involved in a proposed treatment and of reasonable alternatives following the judgement in the case Montgomery vs Lanarkshire Health Board. This a marked change to the previous Bolam test which asks whether a doctor’s conduct would be supported by a responsible body of medical opinion. This test will no longer apply to the issue of consent, although it will continue to be used more widely in cases involving other alleged acts of negligence.

Patient information leaflets/fact sheets are a useful means of providing information on the procedure and the risks, benefits, alternatives and sources of information. All patient information leaflets used must be developed as per the process for writing and producing information for patients.

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’). Healthcare professionals must follow an advance decision if it is valid and applicable, even if it may result in the person’s death. If they do not, they could face criminal prosecution or civil liability. Clinicians should seek legal advice where an advance directive is in place.

Each consultant and specialty wishing to delegate the responsibility for obtaining informed consent for specific procedures must:

- identify the procedures for which delegated consent is undertaken.
- develop a procedure specific training package for undertaking delegated consent for that particular procedure. The procedure specific fact sheets may form the basis of this competency-training package.
- identify the individual clinicians (including Specialist Nurses and AHPs) who are trained to obtain delegated consent.

A record of those staff that are not capable of performing the procedure but are authorised to take consent will be maintained by each speciality using Appendix 4.

### 3. Definition of terms used

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<tr>
<td>DH</td>
<td>Department of Health</td>
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<td>PDF</td>
<td>Portable Document Format</td>
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<td>AHP</td>
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4. Duties and Responsibilities

All staff have a responsibility for ensuring that the principles outlined within this document are universally applied. This policy applies to all members of staff who are involved in taking consent.

Key duties are identified as follows:

- Line managers and Speciality leads should ensure that all members of staff involved in taking consent are fully conversant with the contents of the policy.
- Divisional governance committees are responsible for monitoring compliance and developing any necessary action plans.
- Divisional Boards are responsible for implementing any necessary changes required to achieve compliance with the policy.

5. 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.

5.1. Single stage process

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 ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient’s condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given orally.

If a proposed procedure carries significant 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.
5.2. **Two or more stage process**

In most cases where *written* consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages.

**The first** being the provision of information, discussion of options and initial (oral) 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.

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**Figure 1. Seeking consent: remembering the patient’s perspective**

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: in out-patients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patients arrive for treatment, however, 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 alright?”

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.

5.3. Seeking consent for anaesthesia and sedation

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

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.
5.4. **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.

5.5. **Treatment of young children**

Where a child is admitted, you should discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. When babies or young children are being cared for in hospital, it may not seem practicable to seek their parents’ consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, you should remember that, in law, such consent is required. If parents specify that they wish to be asked before particular procedures are initiated, you must do so, unless the delay involved in contacting them would put the child’s health at risk.

Only people with ‘parental responsibility’ are entitled to give consent on behalf of their children. Parental responsibility is defined in the Children Act (1989) as:

“All the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to a child and his property” (Children Act 1989, section 3 (1)).

You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers will have such responsibility if jointly registered with the mother on the birth certificate (for births registered after 1st December 2003), but not otherwise). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.

5.6. **Duration of consent**

When a person gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, the General Medical Council (GMC) guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent.

The clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent repeated on the basis of this information.
Similarly, if the patient’s condition has changed significantly in the intervening time it may be necessary to seek consent again, on the basis that the likely benefits and/or risks of the intervention may also have changed.

If consent has been obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent (assuming that they retain capacity) still wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

Further information on the law and consent can be found at Appendix 1.

6. Documentation

For clinical intervention 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.

6.1. Written consent

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

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

It is rarely a legal requirement to seek written consent (The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances), but it is good practice to do so if any of the following circumstances apply:

- the treatment or procedure is complex, or involves significant risks (the term ‘risk’ is used throughout to refer to any adverse outcome, including those which some health professionals would describe as ‘side-effects’ or ‘complications’)
- the procedure involves general/regional anaesthesia or sedation
- providing clinical care is not the primary purpose of the procedure, *e.g. research trials, student observation*
• there may be significant consequences for the patient’s employment, social or personal life, e.g. HIV and Hepatitis B testing, pregnancy testing, stress testing
• the treatment is part of a project or programme of research approved by this Trust

Attending for a procedure and proffering an arm or removing clothing implies consent for the majority of the population. However, there are times when people may be directed or instructed what to do, without fully understanding why, or what is happening.

In the case of people with a learning disability, who present as inpatients, at out-patient clinics, the Emergency Department, community clinics and surgeries, they may not always arrive fully understanding why or what they are there for.

In these cases it is important to establish a person’s preference regarding treatment and their capacity to consent. This should include their level of understanding, their ability to retain the information and their ability to express their choice. This is important even in the most common procedures, (such as the taking of blood pressure, an injection, taking of blood and cytology).

Completed consent forms should be stored securely either in the patient notes or electronically once the e-consent mechanism is established. 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.

### 6.2. Availability of forms

Standard consent forms and forms for adults who are unable to consent for themselves are available from the Supplies Department. There are three versions of the standard consent form:

- **Form 1:** for adults or competent children,
- **Form 2:** for parental consent for a child or young person and
- **Form 3:** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures.
because they will be in a position to make any such decisions at the time if necessary.

**Form 4:** is provided for adults who are unable to consent to investigation or treatment.

# 7. 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. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented in their health record. If a hazard that should have been mentioned is not mentioned, the law will impose an obligation to compensate if that hazard occurs. Recent court judgements (Chester vs Afshar, also Montgomery vs Lanarkshire) have reinforced the importance of identifying serious risk to the patient, even if that risk is relatively rare. Any risk to which a reasonable person in the patient's position would attach significance, must be disclosed. This applies especially if the patient may choose an alternative treatment or no treatment at all if made aware of the risk.

## 7.1 Accessible information standard

As of July 2016, the Trust has adopted the Accessible Information Standard which requires that information is provided to people with sensory loss/impairment or a learning disability in a format that they can understand, and any communication support they might need is also provided. More detail can be found in the Trust’s Accessible Information Standard policy or on the Accessible Information Standard intranet page.

Patient information leaflets/fact sheets are a useful means of providing information on the procedure and the risks, benefits, alternatives and sources of information. All patient information leaflets used must be developed as per the process for writing and producing information for patients. Research based patient information should be reviewed by the local Research and Development department. The Health Research Authority (HRA’s) oversees the research ethics service and is one of...
the HRA’s core functions. Guidance on the preparation of NHS Litigation Authority compliant information leaflets is available at Appendix 2 and 3.

When providing patient information as part of the consent process, the use and provision of the relevant leaflet must be clearly documented in the patient’s health record.

7.2 Information leaflets (general and research)

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

Patients will be asked whether they would like to have a friend or relative present for the discussion regarding their consent and whether they would like a taped recording of the discussion.

Once a patient information leaflet has been approved, the PDF version will be given a unique code number which will appear on the rear of the leaflet. This PDF document will be returned to the author and a version placed on the shared drive and stored according to year and month. Information regarding the title, author, department and period of validity will be added to the spread sheet which forms the electronic library. The author will be asked to ensure the PDF is sent to the web team for uploading on the relevant public facing pages for their department.

Within three months of the end of the period of validity, normally assumed to be one year unless stated otherwise, the author will be reminded to review the document. The updated document will then be re-listed. Authors will also be reminded to ensure that any printed copies of the previous version are destroyed.

7.3 Provision for patients whose first language is not English

This Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English.

Interpreter service arrangements at the RUH are available on the intranet under Consent. The Trust has a contractual arrangement with Language Empire Ltd and the use of an interpreter must be recorded by their statement on the Consent Form. Any specific queries can be referred to the Head of Communication & External Relations.
7.4 **Provision for patients with hearing or sight loss**

This Trust is committed to ensuring that patients with hearing or sight loss receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to rely on children or family members to interpret or communicate to patients.

Interpreter service arrangements at the RUH are available on the intranet under Consent. The Trust has a contractual arrangement with British Sign Language (BSL) for Deaf patients. The use of an interpreter must be recorded by their statement on the Consent Form.

The production of procedure specific information must take into account the need for provision of that information in “easy read”, Braille or in large print.

Any specific queries can be referred to the Head of Communication & External Relations.

7.5 **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 treating clinician should be prepared to provide more detailed information on request. Specific information sources are outlined in section 4.4.

The Trust wide and locally produced fact sheets include information for both the patient and clinician regarding sources for further information. These include the Patient Advice & Liaison Service (PALS) (extension 5656), NHS Choices contact numbers, phone numbers of relevant local self-help groups and various internet resources.

In addition, the Head of Patient Experience may be contacted to provide more detailed information, having access to a wide variety of information sources.

7.6 **Production of patient information**

Please refer to the Trust process for Writing and producing information for patients, which is available on the intranet. This outlines the content requirements for the any locally produced procedure specific information leaflets/fact sheets targeted at enabling patients to give informed consent.

7.7 **Access to health professionals between formal appointments**

After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they take 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). To ensure patients
can easily follow up any queries, there is a section on the Form 1 and
Form 2 consent forms for the health professional to fill in their contact
details.

PALS may also be able to assist with more general enquiries.

In compliance with cancer treatment guidelines, all patients are given
contact details, including the number of the appropriate health
professional, prior to treatment.

7.8 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.

7.9 Provision for patients with a learning disability
For patients with a diagnosed learning disability, a referral to the
patient's specialist learning disabilities team in the community may be
needed to ensure information is adequate and appropriate.

8. Who is responsible for 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 health
professional carrying out the procedure 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.

8.1. Delegated consent
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. This is known as
delegated consent; the clinician has been given delegated authority to
obtain consent.
Each consultant and specialty wishing to delegate the responsibility for obtaining informed consent for specific procedures must:

- identify the procedures for which delegated consent is undertaken (Appendix 4);
- develop a procedure specific training package for undertaking delegated consent for that particular procedure. The procedure specific fact sheets may form the basis of this competency-training package.
- identify the individual clinicians (including Specialist Nurses and AHPs) who are trained to obtain delegated consent (Appendix 4).

A record of those staff that are not capable of performing the procedure but are authorised to take consent will be maintained by each speciality using Appendix 4.

Each Directorate must complete the Trust standardised documentation for recording:

a. the process by which consent is delegated and
b. Completion of the specialty specific training package for those who are delegated to consent for particular procedures, but are not capable of performing that particular procedure.

The delegating clinician must remember that they retain accountability for the information provided to the patient at all times, even if they have not personally provided it.

All Consultants, or responsible senior clinicians, will be accessible via Switchboard (first and second system for contact, for example mobile phone or landline) if the responsible Consultant is not available an appropriate second Consultant should be contacted. It is recommended that a second Consultant is identified in advance and may be called upon to give advice on behalf of the nominally responsible Consultant.

Where the healthcare professional 'confirming' consent does not feel competent to do so the clinical, Divisional or Governance Lead should be contacted.

8.2. 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 and trained to do so; and
- work within their own competence and not to agree to perform tasks which exceed that competence.

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.

If you feel that you are being pressurised to seek consent when you do not feel competent to do so contact the Medical Director or the Head of Risk & Assurance, who will carry out an independent investigation.

If you are taking consent for research please contact the Research and Development Manager.

9. Refusal of Treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient’s options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983. The situation for children is more complex: see https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition The following paragraphs apply primarily to adults. For the young patient who is not deemed to be Gillick competent, refer to the parent/carer. For further information on issues of refusal in a child, please refer to the document: Guidance on Clinical Ethics.

9.1. Advance decisions to refuse treatment

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. This is a well-established rule of common law, and the Mental Capacity Act 2005 now puts advance decisions on a statutory basis. The Act sets out the requirements that such a decision must meet to be valid and applicable. Further details are available in chapter 9 of the Mental Capacity Act (2005) Code of Practice.

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

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

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

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

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

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

This is a non-standard addendum to the DoH Model Consent Policy, developed locally to guide clinical staff considering the implications of the Mental Capacity Act.

A capable (or competent) person may not be given medical treatment to which he does not consent. The treating of an incapable person is governed by the Mental Capacity Act 2005. In some cases the Act permits medical treatment to be given without the patient’s consent, as long as it is in their best interests and has not been refused in a valid and applicable advance directive (living will) or advance decision. Different rules apply in the case of children and in the case of patients detained under the Mental Health Act 1983, which take precedent.

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

The patient is unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.

It does not matter if the impairment or disturbance is permanent or temporary. A person is unable to make a decision for himself if he is unable:

- to understand the information relevant to the decision
- to retain that information
- to use or weigh the information as part of the process of making the decision
- to communicate the decision

The assessment of capacity should be made by the practitioner in charge of the patient’s medical treatment. Although a psychiatric opinion may be helpful, it should not in itself be regarded as conclusive. Guidance is provided at appendix 4, 5 and 6.

Restraint will only be lawful to compel an incapable patient to receive treatment when the person using it reasonably believes that it is necessary in order to prevent harm to the patient and the restraint is proportionate to the likelihood and potential severity of that harm.

10.1. Third party consent and advanced decisions

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

- Lasting Power of Attorney (LPA): the person is instructed under an LPA, validly made by the patient while they were still capable and which relates to their health and social care.
- Court of Protection: the person is a Deputy appointed to make decisions on behalf of the patient.
An advance decision (AD) is a refusal of healthcare treatment made when the person is capable. It will only apply when the person lacks capacity. If it is valid and applicable (i.e. it mentions the proposed treatment and circumstances), it will take precedence over consent given by an LPA appointed prior to the AD or Court of Protection Appointed Deputy. It need not be in writing unless it is refusing life-sustaining treatment, in which case it must be signed and witnessed.

An AD that otherwise would be valid and applicable will not be so if:

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

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

10.2. Advocacy – Independent Mental Capacity Advocacy (IMCA)

In some circumstances, an advocate will have to be appointed for a patient who lacks capacity:

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

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

- a single treatment is proposed and there is a fine balance between its benefits and burdens (and risks);
- there is a choice of treatments but a decision as to which one to use is finely balanced; or
- what is proposed would be likely to involve serious consequences for the patient.

10.3. Procedures to follow when patients lack capacity to give or withhold consent

Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented in form 4 (form for adults who are unable to consent to investigation or treatment), along with the assessment of the patient’s capacity, why the health professional believes the treatment to be in the patient’s best...
interests, and the involvement of people close to the patient. The 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 are potentially serious, a court declaration may be sought. See Appendix 7 for further information on how to do this.

11. The Human Tissue Act (HTA)

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.

The healthcare professional taking a tissue sample from the living is responsible for making the patient aware that their sample will be analysed, removed, and retained, and may be used for quality assurance purposes.

A post mortem examination (or autopsy) may take place because the Coroner considers it necessary or because it has been agreed upon by the deceased person or relative.

Before the post-mortem the person obtaining the consent should, in collaboration with the Pathologist, check that the post mortem examination and any removal, storage and use has been properly authorised.

This authorisation will either come from a completed consent form or from the Coroner.

Consent to the post mortem must be separate from consent to the subsequent removal, storage and use of tissue and organs (including blocks and slides) i.e. relatives must be clear that these are two separate decisions.

Specific consent must be obtained to store and/or use tissue, including blocks and slides, for any of the scheduled purposes listed in the Act.
11.1. **Coroner’s post mortem**

Although the consent of the deceased person or relatives is not required for the post mortem the reasons for the post mortem and the procedures to be followed should be explained to them. They should be given information of when and where the post mortem will take place and told of their right to be represented at the post mortem by a doctor, if they so wish.

The Coroner has a duty to inform relatives or representatives of the deceased person about the retention of organs or tissue for examination. This should include the material being kept, the period for which it will be kept and the options for subsequent disposal.

There is a service level agreement between the RUH and the Coroner’s office regarding compliance with the HTA, including protocols to ensure proper communication with the deceased person’s relatives.

11.2. **Hospital post mortem**

A hospital post mortem is carried out with the prior consent of the deceased person, or with the consent of their nominated representative or a person in a qualifying relationship as detailed in section 6. The consent should cover the removal and storage of organs and tissues for purposes scheduled in the HTA.

Consent is also required for post-mortems undertaken for research purposes. Consent is required from the individual prior to death or from an identified individual post death.

There are further restrictions under the HTA, therefore all research programmes should be referred to the Research and Development Department prior to undertaking research activities.

In order to allow tissue to be removed and stored for future, unspecified research, there will be an option on the consent forms for the patient to agree/ disagree for their samples to be used for this purpose. All samples will be used on an anonymised basis.

Where a patient is unable to consent prior to a procedure, specific consent **must** be obtained afterwards in order for the tissue to be stored for future research.

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply. This will be included in the patient declaration on the consent form.

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.

Use of tissue for audit will be included in the patient declaration on the consent form. If you are in any doubt as to whether you are conducting an audit or research please contact the Research and Development Department or the National Research Ethics Service prior to taking any tissue.

12. Clinical Visual and Audio 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.

Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient’s care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in the next paragraph. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

Documented consent for visual or audio recordings should be recorded in the electronic notes and on the consent form if appropriate. This is advisable even if the patient is not recognisable. Use of this for publication should be managed differently with formal expressed consent.

Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.

If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.
The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of some-one close to the patient. You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

13. Training

13.1. Generic consent training

Doctors in training receive specific training on consent as part of their induction. Successful completion of this training is monitored via the Post Graduate Medical Centre.

The principles of informed consent must be included as part of the best practice guidance of any clinical skills training.

All mental capacity training will discuss issues of consent.

13.2. Procedure specific consent training

Clinicians seeking to delegate the role of procuring consent to junior staff have a responsibility to ensure that those to whom they wish to delegate are competent in the general principles of consent and in the specific details of the proposed procedure. The proforma in Appendix 4 is to be completed by the clinician seeking accreditation of competency and returned to the Head of Risk & Assurance as directed.

Each consultant or specialty wishing to devolve the responsibility for obtaining informed consent for specific procedures must develop a procedure specific training package for consent to that particular procedure. The delegating clinician must remember that they retain accountability for the information provided to the patient at all times, even if they have not personally provided it. Procedure specific fact sheets may form the basis of this competency training package.

The primary responsibility for ensuring that knowledge of consent principles and law is possessed by an individual clinician lies with the clinician themselves.
Managers are responsible for ensuring that all their staff receive the appropriate training commensurate with their role.

13.3. Consent for Research
Research in the NHS involving patients, carers, staff and normal volunteers requires written informed consent. This is a legal requirement and is an integral part of gaining ethical approval for research to take place.

Informed consent in the context of clinical research may be regarded as: the voluntary confirmation of a subject’s willingness to participate in a particular trial and the documentation of the process and decision.

All potential participants should be given the up to date, approved participant information sheet about the study, prior to inclusion in the study.

Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the participant ample time (sometimes a specific time period is specified in the study protocol) and opportunity to inquire about details of the study and to decide whether or not to participate in the research.

All questions about the research should be answered to the satisfaction of the participant.

When describing the study the person seeking consent should explain the risks, benefits and alternatives to participation. This process and a copy of the study patient information sheet and signed consent form should be added to the medical records with evidence of the discussion that has taken place.

If a potential research participant for a study lacks capacity there is provision under the Mental Capacity act (2005) to involve a nominated individual in the decision making process for an observational study. For research involving an investigational medicinal product the Medicines for Human use clinical trials Regulations (2004) make provision for inclusion of these participants, again, by involving a nominated individual in the decision making process.

All staff taking an active role in research within the Trust are required to undertake Good Clinical Practice Training (GCP).
13.4. **Training records**

As identified within the mandatory training policy, the Learning Management System will maintain training records detailing which members of staff attend generic consent training.

Records of training packages and competency assessments will be maintained locally by each speciality in each Division, as identified in Appendix 4.

Where training has taken place across specialities, as in the case of providing out of hours cover, the record will be held by the Surgical Division Clinical Governance and Complaints Co-ordinator.

Staff must keep a record of all training in their portfolio.

14. **Monitoring Compliance**

An annual audit of effectiveness and compliance with the consent process forms part of the clinical audit programme. The audit, Appendix 10, will include:

- Whether the correct consent forms are being used;
- Whether the forms are being used correctly;
- Whether the appropriate person obtained consent;
- Whether training on delegated consent was undertaken.

The findings of the audit will be provided to the clinical Divisional Chairs, for submission to the Divisional Governance group. Each Division is responsible for addressing areas of non-compliance by the creation, monitoring and completion of an action plan to address the identified areas of risk.

If the audit identifies an individual taking consent who has not been trained to do so the circumstances will be reviewed by the speciality lead clinician and governance lead. It is recognised that exceptional circumstances, such as emergency situations, can occur. In cases where the taking of consent was deemed inappropriate this will be discussed with the Medical Director prior to notification to the GMC.

Clinical audit exception reports are submitted to the Operational Governance Committee. The committee will monitor progress against the completion of recommendations identified within the report. Analysis of any reported incidents, complaints or claims regarding the consent process will be included in the monthly incident reports submitted to the Specialties, for local analysis and identification of non-compliance.

Training attendance is monitored as identified within the mandatory training policy, to identify whether all relevant staff are receiving the required training.
15. Review

This policy will be in effect for three years, unless otherwise stated. Prior to the third anniversary of the policy, the author will be asked to review it and make any necessary changes prior to further ratification.

16. References


Re B (adult: refusal of medical treatment) [2002] EWHC 429 (Fam) at paragraph 100(viii); paragraph 9.61 of the Mental Capacity Act (2005) Code of Practice


Chester v Afshar [2004] UKHL 41
Appendix 1: 12 Key Points on Consent: The Law

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. Legal aspects – Capacity and Consent (2,3)

   A. From the age of 16 years the individual is presumed to have capacity. Background: Although in English Law a minor is a person less than 18 years old, the Family Law Reform Act 1969 states: "The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, should be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian".

   B. The 16 to 17 year old is therefore assumed to have capacity to give consent. The RUH consent guidelines have detailed advice about assessing capacity.

   C. If a 16 or 17 year old who has capacity refuses medical treatment, in particular where there is a threat to their life or risk of serious harm in refusing, then under certain circumstances that decision can be overruled if it passes a best interests test. This is different to the competent adult (18 and over) who can refuse treatment even if it seems unwise to do so for any reason, or indeed no reason. Specific legal advice is likely to be required in such situations.

   D. If a competent 16 or 17 year old gives consent for treatment which is in their best interests for them to receive, that decision cannot be overruled by
somebody who has parental responsibility.

E. Children under the age of 16 can consent to medical treatment if they have sufficient maturity and judgement to enable them fully to understand what is proposed. This is sometimes referred to as ‘Gillick Competence’.

F. GMC advice regarding assessing ability to give consent is:
‘You must decide whether a young person is able to understand the nature, purpose and possible consequences of investigations or treatments you propose, as well as the consequences of not having treatment. Only if they are able to understand, retain, use and weigh this information, and communicate their decision to others can they consent to that investigation or treatment. It is important that you assess maturity and understanding on an individual basis and with regard to the complexity and importance of the decision to be made. You should remember that a young person who has the capacity to consent to straightforward, relatively risk-free treatment may not necessarily have the capacity to consent to complex treatment involving high risks or serious consequences. The capacity to consent can also be affected by their physical and emotional development and by changes in their health and treatment. That means you must make sure that all relevant information has been provided and thoroughly discussed before deciding whether or not a child or young person has the capacity to consent’.

For further information see the GMC webpages: http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp

G. ‘Gillick competence’ refers to the assessment in regards to whether a child under 16 has the capacity to consent to treatment without parental or guardian consent. It initially came from a ruling in the case of Gillick v West Norfolk, 1984 and subsequent ruling in the House of Lords:
"...whether or not a child is capable of giving the necessary consent will depend on the child’s maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent."

H. ‘The Fraser guidelines’ are in reference to Lord Fraser's involvement with the Gillick case. He commented on the responsibility of doctors to ensure adequate capacity of children specifically on receiving contraceptive prescription and advice.
• the young person will understand the professional's advice
• the young person cannot be persuaded to inform their parents
• the young person is likely to begin, or to continue having, sexual intercourse with or without contraceptive treatment
• unless the young person receives contraceptive treatment, their physical or mental health, or both, are likely to suffer
• the young person's best interests require them to receive contraceptive advice or treatment with or without parental consent

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. A capable (or competent) person may not be given medical treatment to which he does not consent. The treating of an incapable person is governed by the Mental Capacity Act 2005. In some cases the Act permits medical treatment to be given without the patient’s consent, as long as it is in their best interests and has not been refused in a valid and applicable advance directive (living will) or advance decision. In some cases appointed advocates can make a decision on the patient’s behalf.

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.
This summary cannot cover all situations. For more detail, consult the Reference guide to consent for examination or treatment, available from the NHS Response Line 08701 555 455 and at www.dh.gov.uk/consent.
Appendix 2: Improving the Achievement of Informed Consent for our Patients

The following information provides a template for the development of information leaflets/fact sheets on any procedures that require informed consent to be gained from the patient or their guardian. The intention is to hold them on the intranet for immediate access by clinicians gaining consent.

Such procedures may include:

- non-invasive investigations
- invasive examinations, with or without sedation
- surgical procedures
- medical photography
- organ retention
- inclusion in research

The list is not exhaustive.

The consent forms require any clinician attempting to gain informed consent to explain the risks and benefits of the procedure to the patient and to record that interaction for medico legal reasons. It is anticipate that this information will be time consuming to deliver and document before every procedure, without some pre-planned information leaflet. The provision of a leaflet will also achieve consistency between clinicians.

It is assumed that about 80% of the procedures currently undertaken in the trust are undertaken with enough frequency to warrant the development of such information leaflet, leaving the remaining procedures, less frequently encountered, to be documented in the usual way.

It is anticipated that each Directorate/specialty area will undertake a review to discuss the procedures deemed to be most commonly undertaken and delegate the responsibility for producing the particular information leaflets required.

All information leaflets must be created in line with the procedure for writing and producing information for patients before they can be utilised.
Appendix 3: Patient Information Leaflet Development Template

To assist you in making an informed decision to undergo xxxx procedure.

(Fact sheet number)

The Procedure’s Name: …………….. Technical (and common name where it exists) for the procedure, preceded by the Trust Reference Number allocated to this fact sheet by the Information Team. The number relates to the list of trust-wide procedures found in the grid on the intranet and begins with PPFS, followed by the number 001 or thereafter

Normal function of the Organ involved:
Provide a description of the procedure that is framed in terms that will be easily understood by a layman.
This will normally involve describing the organs involved and their function.
(Provide illustrative diagrams wherever you believe that these will assist the patient in understanding anatomy, physiology or the disease in general.)

Reason for the procedure:
Describe, in lay terms, the most common reasons why this procedure is performed. These may include diagnostic or corrective or palliative etc. Include all the conditions that you may be looking for or confirming.

Preparation:
A brief explanation of preparations that may be required, e.g. enema, laxatives, nil by mouth, autologous blood collection cease warfarin, etc. This section need not be detailed if there is a separate patient information leaflet covering these issues. Also include any individual preparations that can be taken before the procedure to lower individual risk, like losing weight, smoking cessation

The Equipment
Describe the equipment used to achieve the procedure, in layman's terms, and in as much detail as you feel the average patient would wish to know.
(Provide illustrative diagrams wherever you believe that these will assist the patient in understanding anatomy, physiology or the disease in general.)

The Procedure:
Include information on steps in procedure of which the patient will be aware and not aware. Detail will vary but should cover what you know to be of common concern to patients. Include steps that may be taken leading up to the procedure, such as weighing, removal of false teeth, pre-medication, shower, etc as well as the anticipated duration of the procedure and the recovery phase.
Results:
Explain the need for retention of any pathology specimens for diagnostic purposes and quality assurance purposes, stating clearly that they can opt out from the latter. Explain when the results will be available or when feedback on the success of the operative procedure should be available.

Alternatives:
Explain the options that are available to this proposed procedure, and explain the limitations of those procedures.

Benefits:
Explain the benefits of this procedure over the alternatives, in general terms.

Side effects and Risks:
Describe the side effects and risks associated with this procedure. Please provide actuarial tables outlining the likelihood of each possible complication or side effect, where they are available on either national or local data. Where such detail is not possible, usually in more complicated/multi-systems disease processes just provide a general level of risk as High, Medium, Low, or by using terms like often, seldom, rarely, occasionally.

Increased risk factors:
Provide information here related to reasons why this procedure’s inherent risks may be elevated by any particular factor in individual patients, like obesity, smoking, pregnancy.

Post-Procedural care:
Provide information here about the customary post-operative recovery period from the procedure and signs to watch out for and report to the medical or nursing staff.

Summary:
Provide a brief summary of the fact sheet for patients who do not wish to have as much detail as the main text provides.

Internal Sources for more information: Names and phone numbers.
External Sources for more information: Provide accredited sources such as doctoronline.com, NHS Direct, your specialties professional organisations and any appropriate "self help" groups in the local area (along with contact details). Also include reference sources from which your material was taken.
If you have difficulty reading this fact sheet, please call the PALS line and ask for a tape copy, or ask the person who provided you with the sheet to print it off in a larger font.

Last review date: ______________

Next review date due: _____________

Responsible Directorate: ____________________

Fact sheet RUH reference number: _________

Notes for authors of fact sheets:

- Don't copy printed material without the permission of the author. If for example there are national pamphlets from specialty organisations, like the BHF, their permission should be sought before transcribing them into a fact sheet for IT use.
- Be prepared to review the details on the fact sheet for accuracy at least once a year and update on an ongoing basis.
- All fact sheets should comply with the Trust branding requirements.
- When providing a list of external sources for further information, use only the accredited list of sources obtainable through the Head of Communication & External Relations, or check with them for any you wish to use that are not listed.
- Remember to whom you are writing and avoid jargon.
- Have someone else read your fact sheet for spelling, meaning errors.
- Be prepared to modify your masterpiece following any consultation feedback.
- Maintain back-copies of all documents after any changes or review. These may be required to defend the trust in any future litigation cases involving informed consent.
Appendix 4: Record of Delegated Consent

Delegation of Informed Consent for Interventional Procedures

It is the policy of the Trust to conform to NHSLA Risk Management standards for training, assessment and audit of practice for any professional to whom obtaining consent is delegated. This form should only be completed after familiarisation with the Trust consent policy.

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.

**Directorate:** ___________________________

**Speciality:** ___________________________

**Name of Lead Clinician authorising delegation of consent:** ___________________________

I hereby certify that the following named practitioner has received training in obtaining fully informed consent in line with the Trust consent policy, and is subject to regular audit of practice:

**Name of Practitioner:** ____________________________  **Role:** ____________________________

Procedures for which the above practitioner is authorised to take consent:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Date of training</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>

**Date of signing:** __________  **Review date:** __________

**Signature of lead clinician:** ____________________________

**Signature of Divisional Chair:** ____________________________

*Complete all fields and return to the Head of Risk & Assurance*
Appendix 5: Algorithm to Determine Capacity

Treatment for a person’s mental disorder under the Mental Health Act 1983 falls outside the remit of the Mental Capacity Act.

Is there an impairment of, or disturbance in the functioning of the mind or brain?

Yes

Is this of a nature or degree which might be sufficient to affect their capacity for this decision?

Yes

Does the patient have sufficient information to make a decision?

Yes

Has the information been presented in ways which can enhance the patient’s likelihood of understanding and retaining the information?

Yes

Does the person understand the information?

Yes

Can the person retain the information for long enough to reach a decision?

Yes

Can the person use or weigh the information as part of the process of reaching a decision?

Yes

Can the person communicate their decision?

Yes

Patient has capacity to make this decision— their consent or dissent must be respected. The only exception would be for a treatment decision related to a mental illness when the patient is detained under the Mental Health Act 1983.

NO

Has capacity

NO

Give adequate information

NO

Try other methods of presentation E.g., written, pictures

POSSIBLE

Patient lacks capacity for this decision

This decision must be made in the patient’s “best interests” as defined by the Mental Capacity Act 2005

Does an LPA for Health & Welfare Decisions exist, has a deputy been appointed, is there a relevant advance directive?
## Mental Capacity Assessment

<table>
<thead>
<tr>
<th>Date completed:</th>
<th>Time:</th>
<th>Assessor:</th>
<th>Role:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient label:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Part one of two stage test of Capacity

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>Details</th>
</tr>
</thead>
</table>

- Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works? (It doesn't matter whether the impairment or disturbance is temporary or permanent.)
- If so, does that impairment or disturbance mean that the person is unable to make the decision described below at the time it needs to be made?

**What is the decision that has to be made? (each decision needs a separate assessment)**

### Part two of two stage test

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>Details</th>
</tr>
</thead>
</table>

- Does the person understand the information about the decision to be made?
- Can the person retain the information?
- Does the person use or weigh up that info as part of the decision making process?
- Can the person communicate their decision (by any means)?

**Evidence what practical steps were taken to support the assessment**
<table>
<thead>
<tr>
<th>Outcome of assessment</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the person have capacity in relation to this decision at the time of the assessment?</td>
<td></td>
</tr>
<tr>
<td>If no does a best interest meeting need to be convened?</td>
<td></td>
</tr>
</tbody>
</table>

File in patient’s records V3

This is only a checklist, an aide-memoire. Full details, as appropriate to the gravity of the decision to be made, must be entered in the patient’s record using this form.
# Appendix 7: Checklist for Best Interests

<table>
<thead>
<tr>
<th>Patient label:</th>
<th>Date:</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

This form should only be used where a Mental Capacity Assessment has been recorded to show that the patient lacks capacity in relation to the specific decision below.

### Specific decision to be made?

<table>
<thead>
<tr>
<th>Mental Capacity Assessment Completed?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>By who:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date completed:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If No – **STOP.** The patient must have a capacity assessment completed to continue.

### Medical treatment decisions:

Does the person have a valid advance decision that relates to the above decision?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If Yes – **STOP.** Seek advice from the Trust lead for claims, inquests and clinical risk.

### Is there a Lasting Power of Attorney, Deputy or Court of Protection Order for Personal Welfare in place relating to the above decision?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If Yes – **STOP.** The best interest decision will be made by these people or stated within the court order.

### Serious healthcare and treatment decisions:

Cases involving any of the following decisions should always be brought to the Court of Protection:

- Cases involving organ or bone marrow donation by a person who lacks capacity to consent
- Cases involving the proposed non-therapeutic sterilisation of a person who lacks capacity to consent to this (eg for contraceptive purposes)
- All other cases where there is doubt or dispute about whether a particular treatment will be in the persons best interests

Mental Capacity Code of Practice, (Chapter 8, Sections 8.18-8.24)
Seek advice from the Trust lead for claims, inquests and clinical risk

The statutory checklist (MCA 2005 Section 4) requires that the following issues are taken into account (as far as is reasonably ascertainable), in deciding best interests:

<table>
<thead>
<tr>
<th>Issues to be considered</th>
<th>Tick</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could the person regain capacity in the future and if so, can the decision be delayed until then?</td>
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<tr>
<td>The person’s past and present wishes and feelings (verbal or written):</td>
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<tr>
<td>The person’s beliefs and values that would likely influence the decision?</td>
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<tr>
<td>Consultation with and views recorded of:</td>
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<tr>
<td>Anyone previously named by the person to consult with:</td>
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<td></td>
</tr>
<tr>
<td>Anyone involved in caring for the person:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anyone involved in their welfare (family, close friends, advocates etc):</td>
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<td></td>
</tr>
<tr>
<td>An Independent Mental Capacity Advocate (IMCA). An IMCA MUST be appointed if there is no-one else to support the person other than paid staff.</td>
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<tr>
<td>Further considerations:</td>
<td></td>
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<tr>
<td>So far as is reasonably practicable, have you encouraged and permitted the person to participate in the decision?</td>
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<tr>
<td>Have you considered less restrictive options that may be available, in terms of the person’s rights?</td>
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<tr>
<td>Confirm that the decision is non-discriminatory and has not been made based solely on age, appearance,</td>
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<tr>
<td>behaviour or condition:</td>
<td>Completed by:</td>
<td>Signature</td>
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</table>

File in Patient's records V3
Appendix 8: How to seek a Court Declaration

DECLARATORY PROCEEDINGS

Adults with and without capacity to consent to medical treatment.

The advice of the patient's Consultant must be sought before any other avenues are pursued.

Legal advisors for the trust are Bevan Britton – authorised contact through the Complaints and Litigation Manager or the Director on Call out of hours.

If a clinician believes that it is necessary to obtain legal advice in regard to consent they must contact the Medical Director or Deputy Medical Director, Head of Patient Safety, Complaints and Litigation Manager in office hours or the Duty Manager out of hours. The responsible manager will decide whether the legal advisor needs to be contacted.

Initial advice may also be sought from the chair of the Clinical Ethics Committee where the requesting clinician and the above managers believe that it could be helpful and is obtainable.

The legal advisor will probably ask for:
- Patient’s details,
- A factual summary of case
- The specific issues you are facing.
- Next of Kin wishes.

Copies of patient records may be requested and psychiatric reports may be required where relevant, however, these will be specifically requested at the time.

Process

Applications for a declaration that proposed medical treatment for a patient can lawfully be carried out should be by originating summons in the Family Division of the High Court.

The Application is made by those responsible for the care of the patient. The Patient must be a party to the proceedings. In cases in which the patient is a respondent, the patient’s guardian ad item or next friend should normally be the respondent. In some circumstances, this may be the Official Solicitor. Where the Official Solicitor is not a party, the Court would usually wish to join him as ex officio defendant.

It is preferable that applications are made 8 weeks in advance of any proposed treatment being required or necessary. Applications can be made on an urgent basis.
In order to protect confidentiality, the hearing of the issues takes place in Chambers (i.e. at a private hearing before the Judge). The Decision, is made in open Court, with reasons.

**Adults with Capacity: refusal to consent to medical treatment.**

A capable adult cannot be subjected to treatment without their consent. Any application for declaratory proceedings in those circumstances are unlikely to succeed.

The only available grounds for such application is that the treatment is essential and in the best interests of the patient.

**Adults without Capacity**

An adult who has been assessed as lacking decision making capacity, and who refuses medical treatment of a physical disorder, may be treated provided there is a serious justifiable issue requiring a decision from the Court.

**In considering lawfulness of medical or surgical treatment**, the treatment must be necessary to preserve the life, health or well-being of the patient.

The standard of care required of the doctor concerned in all cases is that the doctor should act in accordance with a responsible body of relevant professional opinion (Bolam v Frien Hospital Management Committee [1957] 1 WLR 582).

It is good practice to consult with relatives and others who are concerned with the care of the patient, other specialists or the inter-disciplinary team. Decisions should be documented in the clinical notes. It should be clearly stated that in the opinion of the treating doctor, the treatment should be given and that it is in the best interests of the patient.

Where the treatment is urgent and necessary, the Court process should not delay the treatment being commenced if no other option is available. As a last resort, the declaration can be made at the same time that treatment is given, or retrospectively.

**The Court will expect the Applicant in Declaratory Proceedings to evidence the decision to treat the patient.** The Court will also expect the Applicant to state what efforts have been made to take into account the views of relatives or other specialists and to refer to this in its own application.
A checklist of evidence is set out below.
The Completed checklist, a copy of the medical records and a full report from the treating consultant should be sent to the Trust's legal advisor (who is contactable via an Executive) and who will advise and make the Application.

**DECLARATORY PROCEEDINGS: EVIDENCE CHECK LIST.**

<table>
<thead>
<tr>
<th>General information</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Details of patient:</strong></td>
<td></td>
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<tr>
<td>Details of patients next of kin, guardian etc.</td>
<td></td>
</tr>
<tr>
<td><strong>Name of Consultant(s)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Members of multi-disciplinary team.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Details of Hospital:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Type of case</strong></td>
<td></td>
</tr>
<tr>
<td>Sterilisation of an adult patient</td>
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<tr>
<td>Discontinuance of artificial nutrition and hydration for a patient in a vegetative state.</td>
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</tbody>
</table>

(Note: There is no longer need to go to court if all are in agreement that it is in the patient's best interests to withdraw)
<table>
<thead>
<tr>
<th>Difference of opinion on 'best interests' test</th>
<th>Other (please explain)</th>
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<table>
<thead>
<tr>
<th>Outline of Treatment to date:</th>
<th></th>
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</table>

<table>
<thead>
<tr>
<th>Explanation of medical opinion:</th>
<th></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>State whether treatment is / or is not in best interests of patient.</th>
<th>Please note the following: The Applicant must adduce evidence from a responsible medical practitioner of: 1. that performing the treatment/procedure would not be negligent, and 2. it is necessary in the best interests of the patient. The advantages and disadvantages of the treatment should be stated so that the court can assess in percentage terms the likelihood of them occurring. The Court will take into account the broader social, ethical moral and welfare considerations and any emotional, psychological and social benefit to the patient.</th>
</tr>
</thead>
</table>

<table>
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<tr>
<th>Explanation of lack of capacity:</th>
<th>Please note the following: 1. Evidence from a psychiatrist or psychologist is generally required. 2. Does the assessment address the patient's capacity to make personal decisions about the matter in issue in the future?</th>
</tr>
</thead>
</table>

| Grounds for refusal. | |
| Are relatives, guardians, or other medical specialists opposed to the treatment plan? | 
|---|---|
| Is there a valid Advance Refusal Statement? | If applicable, provide full details. |
## Appendix 9: Consent Audit – Patient List

**Speciality**

**Week Commencing**

**Details of patients audited:**

<table>
<thead>
<tr>
<th>ID</th>
<th>Name of patient</th>
<th>Hospital Number</th>
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<tbody>
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</table>
## Appendix 10: Consent Audit

**Speciality:**

**Week Commencing:**

Please complete the table below for patients requiring written consent (1/3 of patients selected for the audit should be emergencies)

<table>
<thead>
<tr>
<th>ID</th>
<th>State name of procedure</th>
<th>Emergency or elective?</th>
<th>Info leaflet given?</th>
<th>Were listed complications appropriate? <em>(If No, please state omissions)</em></th>
<th>State name of person who obtained consent</th>
<th>Grade of person obtaining consent documented?</th>
<th>Name of person obtaining consent legible?</th>
<th>Were they adequately trained?</th>
<th>Standard consent form used?</th>
<th>Consent form completed fully?</th>
<th>Discussion of consent documented in notes?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Emergency</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td>9</td>
<td>Emergency</td>
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<td>Yes</td>
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<tr>
<td>ID</td>
<td>State name of procedure</td>
<td>Emergency or elective?</td>
<td>Info leaflet given?</td>
<td>Were listed complications appropriate? (If No, please state omissions)</td>
<td>State name of person who obtained consent</td>
<td>Grade of person obtaining consent documented?</td>
<td>Name of person obtaining consent legible?</td>
<td>Were they adequately trained?</td>
<td>Standard consent form used?</td>
<td>Consent form completed fully?</td>
<td>Discussion of consent documented in notes?</td>
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</table>

Any other comments? (please state the id of the patient that the comments relate to)