CONSENT TO EXAMINATION OR TREATMENT POLICY

This policy mirrors the Department of Health Model Consent Policy and includes local additions specific to the Trust

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<tr>
<td><strong>Date:</strong> 29.12.2017</td>
<td><strong>Date:</strong> 13th February 2018</td>
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<tr>
<td><strong>Lead Director:</strong> Director of Nursing</td>
<td><strong>Review Date:</strong> 12th February 2021</td>
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<tr>
<td><strong>Effective Date:</strong> 13th February 2018</td>
<td><strong>Date Approved:</strong> 13th February 2018</td>
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DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format: Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

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<th>Director Responsible for Change</th>
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<td>29 Mar 12</td>
<td>5.0</td>
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<td>Executive Director of Finance</td>
<td>Logo &amp; Wording updated for new organisation</td>
<td>Approved</td>
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<td>Executive Director of Finance</td>
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<td>29 Dec 17</td>
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<td>Director of Nursing</td>
<td>Approved at Policy Management Sub-Committee</td>
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NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust
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1 EXECUTIVE SUMMARY

1.1 Introduction

Patients have a fundamental legal and ethical right to determine what happens to their own bodies.

Principle 1 of the Mental Capacity Act 2005 (section 1(2)) states ‘A person must be assumed to have capacity unless it is established that they lacks capacity’.

“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 consent to be valid, the patient must:

1. Understand information about the decision to be made (called ‘relevant information’);
2. Retain that information in their mind;
3. Use or weigh that information as part of the decision-making process; and
4. Communicate their decision (by talking, using sign language or any other means).

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no one else can give consent on their behalf.

1.2 Documentation

For significant procedures, it is essential for health professionals to document clearly both a patient’s agreement to the intervention and the discussions which led up to that agreement:

- either through the use of a consent form; or
- through documenting in the patient’s notes that they have given oral consent.

Written consent should be gained if any of the following circumstance 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;
- there may be significant consequences for the patient’s employment, social or personal life; or
- the treatment is part of a project or programme of research approved by this Trust through the Research and Development Committee.

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, 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.
You should involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability teams and speech and language therapists.

There are 4 standard consent forms

Form 1 Patient agreement to investigation or treatment (involving anaesthesia or sedation)

Form 2 Parental agreement to investigation or treatment for a child or young person (involving anaesthesia or sedation)

Form 3 Patient/parental agreement to investigation or treatment (where consciousness not impaired)

Form 4 Form for adults who are unable to consent to investigation or treatment.

The Trust also has some procedure specific consent forms.

1.3 When should consent be sought?

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 be offered a copy of the page documenting the decision making process. 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.

It will rarely be appropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment.

It is the responsibility of the anaesthetist to seek consent for anaesthesia, having discussed the benefits and risks with the patient. It is not acceptable to receive no information about anaesthesia until their pre-operative visit from the anaesthetist and patients should have the opportunity to discuss anaesthesia in a pre-assessment clinic.

Young people aged between 16 and 17 are entitled to consent to their own medical treatment and any ancillary procedure involved with the treatment, for example an anaesthetic.

Young people aged under 16 can consent for their own medical treatment providing they have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention. This is known as being ‘Gillick competent’.

The following ‘Fraser Guidelines’ are complimentary to ‘Gillick Competence’ but it accepted practice now to apply this to all under 16 year olds requesting all sexual health advice and care. The Fraser guidelines refer to the guidelines set out by Lord Fraser in his judgement of the Gillick case in the House of Lords (1985), which apply specifically to contraceptive advice. Lord Fraser stated that a doctor could proceed to give advice and treatment provided he/she are satisfied in the following criteria:

1. that the girl (although under the age of 16 years of age) will understand his/her advice;
2. that he/she cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice;

1 Gillick v West Norfolk and Wisbech AHA (1986)
3. that she is very likely to continue having sexual intercourse with or without contraceptive treatment;
4. that unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer;
5. that her best interests require him to give her contraceptive advice, treatment or both without the parental consent.

When babies or young children are admitted, you should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance.

Only people with ‘parental responsibility’ are entitled to give consent on behalf of their children, unmarried fathers do not automatically have such responsibility.

1.4 Provision of Information
The provision of information is central to the consent process. Patients need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing).

Presumption must be that the patient wishes to be well informed about the risks and benefits of the various options.

For visually impaired patients the Isle of Wight Society for the Blind are able to assist if necessary with provision of information. The Trust also has an interpreting service for hearing impaired patients: Island Support Services provide interpreting services for people with deafness and reduced hearing.

1.5 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.

1.6 Refusal of treatment
Refusal of consent must be one of the patient’s options including all treatment or a particular intervention.

Patients must realise that they are free to change their mind and accept treatment if they later wish to do so.

The possible consequences of their partial refusal must be explained. 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.

1.7 Clinical photography and conventional audio or digital video recordings
Health professionals must ensure that they make clear in advance if any photographic or video recording will result from a procedure.

Photographic and video recordings 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. 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.

Photographic and video recordings where there is not 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.
If 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.

If the patient is likely to be permanently unable to give or withhold consent, the agreement should be sought of someone close to the patient.

1.8 Informed consent post – Montgomery

Following the case of Montgomery the following practical measures should be considered

- Make full notes – it is more important than ever that these specifically document the consent process;
- Discuss reasonable alternatives – including the option of having no treatment at all;
- Focus on the individual patient – the records needs to show that you have taken steps to understand the concerns and wider circumstances of the individual patient;
- Engage in a genuine, two way dialogue – record both sides of the conversation;
- Do not simply focus on percentages – the scientific magnitude of risk is only a factor and should not determine what risks are discussed;
- Patient understanding – ensure that you are confident that the patient fully understood the advice given.

2 INTRODUCTION

This policy sets out the standards and procedures for gaining consent in the Isle of Wight NHS Trust.

3 DEFINITIONS: refer to main text

4 SCOPE

This policy applies to all patients undergoing examinations and treatments within the Isle of Wight NHS Trust.

The policy relates to both clinical and administrative staff involved in the consent process.

5 PURPOSE

This policy sets out the process for obtaining valid and informed consent for examination and treatment within the Trust.
6 ROLES AND RESPONSIBILITIES

The responsible Consultant/Health Professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done. The Consultant is also responsible for ensuring that any members of their clinical staff who are not capable of performing the procedure but who are authorised to obtain consent are appropriately trained.

Any member of the clinical team who is not capable of performing the procedure but who obtains consent from any patient must ensure that they have gone through the Trust process for delegated consent with their Consultant and completed the appropriate documentation.

The Clinical Risk & Claims Manager is responsible for writing and reviewing this policy.

7 POLICY DETAIL/COURSE OF ACTION

7.1 Introduction

7.1.1 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.

7.1.2 This policy

The Department of Health has issued a range of guidance documents on consent (see overleaf), and these should be consulted for details of the law and good practice requirements on consent. This policy sets out the standards and procedures at the 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.

Guidance on consent for post mortems is now included in the separate document - Consent policy for removal, storage and use of human organs and tissue for scheduled purposes including post mortem.

7.1.3 Mental Capacity Act 2005

Following the introduction of the Mental Capacity Act 2005 (the Act) legal practices regarding capacity that were previously based on common law have now been given legal meaning under the Act. An accompanying Code of Practice has been issued and this gives practical advice to all people involved in this process.

The Act only applies to adults (aged 16 years or over). The previous common law still stands for children aged under 16.

The Act provides a legal framework for acting and making decisions on behalf of individuals who lack the mental capacity to make particular decisions for themselves. Everyone working with and/or caring for an adult who may lack capacity to make a particular decision must comply with this Act when making decisions or acting for that person, when the person lacks capacity to make a particular decision for themselves. The same rules apply whether the decisions are life changing events or everyday matters.
The Act has five statutory principles which underpin the legal requirements of the Act. These have been incorporated into the relevant sections of this document.

7.1.4 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.

7.1.5 Assessing Capacity

7.1.5.1 Principle 1: ‘A person must be assumed to have capacity unless it is established that they lacks capacity’ (section 1(2)).

This principle states that every adult has the right to make their own decisions – unless there is proof that they lack the capacity to make a particular decision when it needs to be made. This has been a fundamental principle of the common law for many years and is now set out in the Act.

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.

To help determine if a person lacks capacity to make particular decisions, the Act sets out a two-stage test of capacity:

Stage 1: Does the person have an impairment of, or a disturbance on the functioning of, their mind or brain?

This stage required proof that the person has an impairment of the mind or brain, or some sort of disturbance that affects the way their mind or brain works. If a person does not have such an impairment or disturbance of the mind or brain, they will not lack capacity under the Act.

Examples of an impairment or disturbance on the functioning of the mind or brain may include the following:

- Conditions associated with some forms of mental illness;
- Dementia;
- Significant learning disabilities;
- The long-term effects of brain damage;
- Physical or medical conditions that cause confusion, drowsiness or loss of consciousness;
- Delirium;
- Concussion following a head injury; and
- The symptoms of alcohol or drug use.

This principle states that every adult has the right to make their own decisions – unless there is proof that they lack the capacity to make a particular decision when it needs to
be made. This has been a fundamental principle of the common law for many years and is now set out in the Act.

**Stage 2:** Does the impairment or disturbance mean that the person is unable to make a specific decision when they need to?

7.1.5.2 **Principle 2:** ‘A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success’ 1(3)).

For a person to lack capacity to make a decision, the Act says their impairment or disturbance must affect their ability to make the specific decisions when they need to. But first people must be given all practical and appropriate support to help them make the decision for themselves. Stage 2 can only apply if all practical and appropriate support to help the person make the decision has failed.

The standard of proof that any individuals lack capacity is that they should be able to show on the balance of probabilities that the individual lacks capacity to make a particular decision, at the time it needs to be made.

7.1.6 Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, **no one else can give consent on their behalf.** However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance directive. For further details on advance directives see the Department of Health’s *Reference guide to consent for examination or treatment* (chapter 1, paragraph 19), or the Advance Decisions to Refuse Treatment (ADRT) Policy on Advance Directives/Living Wills.

7.1.7 **Best Interests**

**Principle 4** of the Act states: ‘An act done, or decision made, under the Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests’ (session 1(5)).

There are 2 exceptions to this statement; firstly where someone has made an advance decision (see paragraph 8); and secondly in certain circumstances when research involved. Please refer to the Act.

7.1.8 **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* (second edition) 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 from the Quality Governance Team, St Mary’s Hospital and may also be accessed on the internet at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1_.pdf

• **12 key points on consent: the law in England** has been distributed widely to health professionals working in England. This one-page document summarises those aspects of the law on consent which arise on a daily basis and is attached at Appendix A.

• **Mental Capacity Act 2005** – Guidance to staff has been produced locally in accordance with the Isle of Wight Council and provides further information on best

- Specific guidance, incorporating both the law and good practice advice, is available for health professionals working with children, with people with learning disabilities, with older people and people in prison. Copies of these booklets are available from the Quality Governance Team, St Mary’s Hospital.

7.2 Documentation

7.2.1 Following the case of Montegomery it is now vital that for significant procedures, it is essential for health professionals to document clearly both a patient’s agreement to the intervention, the information given 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 directly in the patient's healthcare record where verbal/oral consent has been given. Where written patient information leaflets are given during the consent process, i.e. either at clinic or during pre-assessment this should be documented either on the consent form or within the healthcare record.

The following practical measures should be considered:

- Make full notes – it is more important than ever that these specifically document the consent process;
- Discuss reasonable alternatives – including the option of having no treatment at all;
- Focus on the individual patient – the records needs to show that you have taken steps to understand the concerns and wider circumstances of the individual patient;
- Engage in a genuine, two way dialogue – record both sides of the conversation;
- Do not simply focus on percentages – the scientific magnitude of risk is only a factor and should not determine what risks are discussed;
- Patient understanding – ensure that you are confident that the patient fully understood the advice given.

7.2.2 Written consent

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

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

- the treatment or procedure is complex, or involves significant 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 Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances:
• the procedure involves general/regional anaesthesia or sedation;
• providing clinical care is not the primary purpose of the procedure;
• there may be significant consequences for the patient’s employment, social or personal life; or
• the treatment is part of a project or programme of research approved by the Trust’s Research and Development Committee.

7.2.4 Completed forms should be kept with the patient’s notes. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional. A copy of the consent form should be given to the patient on their request.

7.2.5 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.

7.2.6 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.

In light of the decision in the case of HL v UK (the “Bournewood” Case) any patient that lacks capacity to consent or objects to medical treatment must not be detained under the common law doctrine of necessity in conditions that amount to a deprivation of liberty. If treatment is essential an assessment of detention under the Mental Health Act 1983 (for treatment of mental disorders) or under the Deprivation of Liberty safeguards (for treatment of physical disorders) should be considered and if this is not possible, treatment will need to be given in a less restrictive manner. The full text can be found at http://www.mentalhealthlaw.co.uk/HL_v_UK_45508/99_(2004)_ECHR_471 (application number 45508/99).

7.2.7 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.

7.2.8 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 D for details of how to do this.

7.2.9 Availability of forms

Standard consent forms and forms for adults who are unable to consent for themselves are reproduced in Appendix B and are available from the Print Room, St Mary’s Hospital. There are four standard consent forms: 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, form 4 for adults who are unable to consent to investigation or treatment. 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.

7.3 When should consent be sought?

7.3.1 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.

7.3.2 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.

7.3.3 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.

7.3.4 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.

7.3.5 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 be offered 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 all right?”

7.3.6 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.

7.3.7 Seeking consent for anaesthesia

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

The following procedure takes place locally - all elective surgery patients having a general anaesthetic or sedation are assessed for suitability prior to the planned procedure.

All elective surgical patients having general anaesthesia or sedation are assessed for fitness before their operation.

This is undertaken in pre-assessment, initially by a nurse using a standardised questionnaire. If the information taken by the nursing staff highlights any potential anaesthetic problems the patient is reviewed by a Consultant Anaesthetist. This may be in person or by examining the medical records. Examples of this include patients with abnormal ECGs or cardiac problems or a family member having anaesthetic problems.

At the pre-assessment appointment all patients are given the leaflet “your operation and anaesthetic”. Patients are advised to contact the Pre-assessment Unit should they have any further questions or queries. Patients are then seen by the Anaesthetist on the day of surgery.

All elective surgery patients having a local anaesthetic are not currently included in the pre-assessment process and are given the ‘local anaesthetic information sheet and are seen by the Surgeon on the day of surgery.

7.3.8 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.

7.3.9 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.
7.3.10 Treatment of young children

When babies or young children are being cared for in hospital, it will not usually seem practicable to seek their parents’ consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, you should remember that, in law, such consent is required. Where a child is admitted, you should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. 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.

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

The Children Act 1989 sets out persons who may have parental responsibility. These include:

- The child’s parents if married to each other at the time of conception or birth;
- The child’s mother, but not father if they were not married, unless the father has acquired parental responsibility via a Court Order or Parental Responsibility Agreement or the couple subsequently marry. From 1 December 2003 the law changed to make it easier for unmarried fathers to get equal parental responsibility for their children. This can be achieved by both parents being present and registering the birth of the baby together;
- The child’s legally appointed guardian;
- A person in whose favour the Court has made a Residence Order concerning the child;
- A Local Authority designated in a Care Order in respect of the child; or
- A Local Authority or other authorised person who holds an emergency protection order in respect of the child.

7.3.12 Treatment of young people

Young people aged between 16 and 17 are entitled to consent to their own medical treatment and any ancillary procedure involved with the treatment, for example an anaesthetic. As with adults, consent will be valid only if it is given voluntarily by an appropriately informed patient capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16 and 17 may in some circumstances be over-ridden by either a person with parental responsibility or the Court.

7.3.13 Young people under 16 can consent for their own medical treatment providing they have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention. This is known as being ‘Gillick competence’. If a child is Gillick competent and is able to give voluntary consent after receiving appropriate information, the consent will be valid and additional consent by a person with parental responsibility will not be required. It is however good practice to encourage the child to inform his or her parents unless it would clearly not be in the child’s best interest to do so.

8. CONSULTATION

This policy will be disseminated via e-bulletin for comment and amendment prior to its final ratification at the Policy Management Group.
9. TRAINING

This model policy for consent to examination or treatment has a mandatory training requirement which is detailed in the Trusts mandatory training matrix and is reviewed on a yearly basis. This is necessary for the following clinical staff:

- All Consultants, Associate Specialists and Speciality Doctors – Consent training is covered in their basic training, with any additional training being via CPD which will be checked at annual appraisal;
- All Registrar’s ST3s – Consent training is covered in their basic training, with any additional training being via CPD;
- All Junior Staff FY2s and FY1s – this is a mandatory part of their relevant curricular which is usually delivered by the Consultants and is monitored by the Deanery; and
- Nurse Specialists – please see Procedure Specific Training below.

The following training is available at the Trust for staff

- An e-learning package (an overview of the consent process) available on Training Tracker. Staff may contact the Training and Development department for help in accessing the e-learning module;
- The MPS Consent training package is available as a resource; and
- Other training is available or by specific request to the Clinical Risk & Claims Manager

9.1 Procedure Specific Training

Those staff who have been delegated to take consent but do not carry out the procedure themselves, e.g. Junior Medical Staff, or Nurse Specialists etc must be sufficiently informed about the procedure so that they can relay relevant information to patients. Therefore, all staff who are required to obtain consent for a procedure they have not carried out will receive procedure specific training, including the risks, benefits, alternative and information needs of the procedure. This will be delivered from the relevant Consultant.

Any individual who is found to be taking consent without the necessary authority to do so will be identified to their Consultant and must stop obtaining consent for the specific procedure with immediate effect. An incident form should be completed in accordance with the Incident Management Policy and appropriate action taken by Consultant/Associate Director of Medical Education. In accordance with the Trust’s Being Open policy any patient who has been the subject of inappropriately gained consent will be informed by their Consultant/responsible clinician. If deemed necessary this matter will be managed in accordance with the Conduct, Capacity, Ill Health and Performance for Medical Staff policy.
10. **MONITORING COMPLIANCE AND EFFECTIVENESS**

10.1 Process for obtaining consent – an annual Trustwide consent audit forms part of the Directorates audit programmes.

10.2 Process for recording consent – similarly this criteria can be reviewed as part of the annual Trustwide audit, see a) above.

10.3 Staff who are not capable of performing the procedure but are authorised to obtain consent will be covered by Procedure specific training on consent.

10.4 Generic training on the consent process – this element is not included in the mandatory training programme within the Trust. An e-learning package (An introduction to the Consent Process) is available for staff on the Training tracker system. Consent is part of the FY1 doctors training and is included as a formal talk in the junior doctor induction programme. Junior doctors who come out of sequence must provide the Clinical Tutor with evidence that that have had previous training in the consent process. Registrars also attend the induction programme, with those coming at different time again being asked to evidence proof of training. Consultants should complete the e-learning package every three years. Responsibility for this lies with the Quality Governance Department who will update the package accordingly and monitored uptake electronically.

10.5 Results will be shared with Clinical Business Units.

11. **LINKS TO OTHER ORGANISATIONAL DOCUMENTS**

- Incident Management Policy
- Protocol for Last Officers (Adults)
- Transfusion of Blood and Blood Components Policy
- Mental Capacity Act 2005 – Guidance for staff in Health and social care
- Consent policy for removal, storage and use of human organs and tissue for scheduled purposes including post mortem
- Treatment Under Part 4 And Part 4a Of The Mental Health Act 1983 (Sections 56 – 64) policy

12 **REFERENCES**

- Consent and Marking of an Operating Site policy – Wessex Deanery
- Consent and Induction Form – General Medical Council
- Gillick Guidelines (1986)
- Fraser Guidelines (1985)

13 **APPENDICES**

A. 12 Key Points on Consent: the Law in England
B. Current Consent forms in use at the Isle of Wight NHS Trust
C. Useful contact details
D. How to seek a Court Declaration
E. Seeking Consent: Remembering the Patient’s Perspective
F. Financial and Resourcing Impact Assessment on Policy Implementation
G. EIA Screening Tool
12 key points on consent: the law in England

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.

2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: “can this patient understand and weigh up the information needed to make this decision?” Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.

3. Patients may be competent to make some health care decisions, even if they are not competent to make others.

4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child’s behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent cannot over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent?

6. It is always best for the person actually treating the patient to seek the patient’s consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.
Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusal of treatment

10. Competent adult patients are entitled to refuse treatment, even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the foetus.

Adults who are not competent to give consent

11. No-one can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

12. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'advance refusal'), and those circumstances arise, you must abide by that refusal.

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 https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition
Current forms in use in the Trust are:

- Consent Form 1  Patient agreement to investigation or treatment (involving anaesthesia and sedation)
- Consent Form 2  Patient agreement to investigation or treatment for a child or young person
- Consent Form 3  Patient/parental agreement to investigation or treatment (where consciousness is not impaired)
- Consent Form 4  Form for adults who are unable to consent to investigation or treatment

Procedure specific consent forms

Orthopaedic consent forms
- Partial fasciectomy dupuytrens Contracture
- Trapeziectomy hand
- Carpal tunnel release
- Cubital tunnel release
- Total shoulder replacement
- Arthroscopic subacromial decompression shoulder
- Shoulder Stabilisation Bankart Procedure
- Open Decompression of the Shoulder
- Replacement of the Shoulder Joint
- Knee Arthroscopy
- Revision Total Hip Replacement
- Delta3 Shoulder Replacement of the Shoulder
- Excision of Lateral End of Clavicle
- Revision Total Knee Replacement
- Rotator Cuff Tendon Repair
- Shoulder Arthroscopy
- Total Hip Replacement
- Total Knee Replacement
- Weaver-Dunn Procedure of the Shoulder

Anaesthetic consent forms
- Epidural blood patch

Maternity consent forms
- Lower segment caesarean section sterilisation
- Lower segment caesarean section

Urology consent forms
- Flexible cystoscopy
- Cystoscopy & Urethral Dilation in Men
- Transurethral Resection of Bladder Tumour
- Transurethral Incision or Resection of the Prostate
- Suprapubic Catheter Insertion - Cystostomy
- Simple Nephrectomy
- Radical Nephrectomy
- Cystoscopy & Urethral Dilation in Women
- Cystoscopy & Stent Procedure
- Cystoscopy & Retrograde Pyelogram
- Cystoscopy & Optical Internal Urethrotomy

**Gynaecology consent forms**
- Abdominal Hysterectomy
- Diagnostic Cystoscopy
- Diagnostic Hysteroscopy
- Diagnostic Laparoscopy
- Laparoscopic Bilateral Oophorectomy
- Laparoscopic Salpingectomy or Salpingotomy after Confirmation of Tubal Ectopic Pregnancy
- Laparoscopic Tubal Occlusion Female Sterilisation
- Tension Free Vaginal Tape
- Vaginal Sacrospinal Fixation
- Vaginal Surgery for Prolapse

The above listed forms are all available from the Print Room, St Mary’s Hospital or via the Trust intranet site.
ISLE OF WIGHT NHS TRUST

Consent Form 1

Patient agreement to investigation or treatment (involving anaesthesia or sedation)

Patient details (or pre-printed label)

Patient’s surname/family name .................................................................
Patient’s first names ..................................................................................
Date of birth .............................................................................................
Responsible health professional ................................................................
Job title of health professional ................................................................
NHS number (or IW Number) .................................................................

☐ Male    ☐ Female

Special requirements ................................................................................ (e.g. other language/other communication method)

To be retained in patient’s notes
Patient identifier/label

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

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Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits ........................................................................................................................
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Serious or frequently occurring risks ................................................................................................
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Any extra procedures which may become necessary during the procedure
☐ blood transfusion............................................................................................................................
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Patient identifier/label

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

Patient’s signature …………………………………… Date ………………………
Name (PRINT) ……………………………………………

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signature …………………………………………… Date ………………………
Name (PRINT) ……………………………………………

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed: ………………………………………………… Date ………………………
Name (PRINT) …………………………… Job title ………………………

Important notes: (tick if applicable)

☐ See also advance directive/living will (e.g. Jehovah’s Witness form)
…………………………………………………………………………………………...

☐ Patient has withdrawn consent (ask patient to sign /date here) ………………………
Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for
This form documents the patient’s agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoire to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has “sufficient understanding and intelligence to enable him or her to understand fully what is proposed”, then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally ‘competent’ younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child’s care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form
If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:
- they are unable to comprehend and retain information material to the decision and/or
- they are unable to weigh and use this information in coming to a decision.
You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so.
Relatives cannot be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information
Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about ‘significant risks which would affect the judgement of a reasonable patient’. ‘Significant’ has not been legally defined, but the GMC requires doctors to tell patients about ‘serious or frequently occurring’ risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 2 of the form or in the patient’s notes.
Consent Form 2

Parental agreement to investigation or Treatment for a child or young person (involving anaesthesia or sedation)

Patient details (or pre-printed label)

Patient’s surname/family name ..................................................................................

Patient’s first names .................................................................................................

Date of birth ...............................................................................................................

Responsible health professional .................................................................................

Job title of health professional ..................................................................................

NHS number (or IW Number) ..................................................................................

☐ Male ☐ Female

Special requirements .................................................................................................

(e.g. other language/other communication method)

To be retained in patient’s notes
Patient identifier/label

Name of proposed procedure or course of treatment
(include brief explanation if medical term not clear)
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Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits .......................................................................................................................... 
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Serious or frequently occurring risks ........................................................................................................
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Any extra procedures which may become necessary during the procedure
☐ blood transfusion ..............................................................................................................................
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☐ other procedure (please specify) ........................................................................................................
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I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

☐ The following leaflet/tape has been provided ..............................................................................

This procedure will involve:
☐ general and/or regional anaesthesia  ☐ local anaesthesia  ☐ sedation

Signed: ............................................................................ Date: .................................
Name (PRINT) ...................................................... Job title ..................................................

Contact details (if patient wishes to discuss options later) .............................................................

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed ................................................................. Date .............................................
Name (PRINT) .........................................................................................................................

Top copy accepted by patient: yes/no (please ring)
Patient identifier/label

Statement of patient

Please read this form carefully. If the procedure has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form and I confirm that I have ‘parental responsibility’ for this child.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that my child and I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of the situation prevents this. (This only applies to children having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save the life of my child or to prevent serious harm to his or her health.

I have been told about additional procedures which may become necessary during my child’s treatment. I have listed below any procedures which I do not wish to be carried out without further discussion. ………………………………………………………
…………………………………………………………………………………………………………
……………………………………………………………………………………………………
Signature …………………………… Date…………………………………………
Name (PRINT) ……………………… Relationship to child…………………………

Child’s agreement to treatment (if child wishes to sign)

I agree to have the treatment I have been told about.

Name ……………………………………… Signature ……………………………
Date …………………………………………………………………………………

Confirmation of consent (to be completed by a health professional when the child is admitted for the procedure, if the parent/child have signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the child and his or her parent(s) that they have no further questions and wish the procedure to go ahead.

Signed:…………………………………… Date ……………………………
Name (PRINT) ……………………………………… Job title …………………..

Important notes: (tick if applicable)

☐ See also advance directive/living will (e.g. Jehovah’s Witness form)
☐ Parent has withdrawn consent (ask parent to sign /date here) …………………
Guidance to health professionals (to be read in conjunction with consent policy)

This form
This form should be used to document consent to a child’s treatment, where that consent is being given by a person with parental responsibility for the child. The term ‘parent’ has been used in this form as a shorthand for ‘person with parental responsibility’. Where children are legally competent to consent for themselves (see below), they may sign the standard ‘adult’ consent form (form 1). There is space on that form for a parent to countersign if a competent child wishes them to do so.

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. The courts have stated that if a child under the age of 16 has “sufficient understanding and intelligence to enable him or her to understand fully what is proposed”, then he or she will be competent to give consent for himself or herself. If children are not able to give consent for themselves, someone with parental responsibility may do so on their behalf.

Although children acquire rights to give consent for themselves as they grow older, people with ‘parental responsibility’ for a child retain the right to give consent on the child’s behalf until the child reaches the age of 18. Therefore, for a number of years, both the child and a person with parental responsibility have the right to give consent to the child’s treatment. In law, health professionals only need the consent of one appropriate person before providing treatment. This means that in theory it is lawful to provide treatment to a child under 18 which a person with parental responsibility has authorised, even if the child refuses. As a matter of good practice, however, you should always seek a competent child’s consent before providing treatment unless any delay involved in doing so would put the child’s life or health at risk. Younger children should also be as involved as possible in decisions about their healthcare. Further advice is given in the Department’s guidance Seeking consent: working with children. Any differences of opinion between the child and their parents, or between parents, should be clearly documented in the patient’s notes.

Parental responsibility
The person(s) with parental responsibility will usually, but not invariably, be the child’s birth parents. People with parental responsibility for a child include: the child’s mother; the child’s father if married to the mother at the child’s conception, birth or later; a legally appointed guardian; the local authority if the child is on a care order; or a person named in a residence order in respect of the child. Fathers who have never been married to the child’s mother will only have parental responsibility if they have acquired it through a court order or parental responsibility agreement (although this may change in the future).

Information
Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for children and their parents when making up their minds about treatment. The courts have stated that patients should be told about ‘significant risks which would affect the judgement of a reasonable patient’. ‘Significant’ has not been legally defined, but the GMC requires doctors to tell patients about ‘serious or frequently occurring’ risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly.

Guidance on the law on consent
Patient/parental agreement to investigation or treatment (where consciousness not impaired)

Patient details (or pre-printed label)

Patient's surname/family name .................................................................
Patient's first names .................................................................
Date of birth ........................................................................
Responsible health professional ..............................................................
Job title of health professional ..............................................................
NHS number (or IW Number) ..............................................................

☐ Male  ☐ Female

Special requirements ..............................................................................
(e.g. other language/other communication method)

To be retained in patient's notes
Patient identifier/label

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

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:
The intended benefits

Serious or frequently occurring risks

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

☐ The following leaflet/tape has been provided

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed ........................................ Date ............................Name (PRINT) .........................

I agree to the procedure described above

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that the procedure will/will not involve local anaesthetic

Signature ........................................ Date ..........................................................

Name (PRINT) .................................. Relationship to child ........................................

Confirmation of consent (to be completed by a health professional when the child is admitted for the procedure, if the parent/child have signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the child and his or her parent(s) that they have no further questions and wish the procedure to go ahead.

Signed: ........................................ Date ........................................

Name (PRINT) ................................. Job title ..................................................

Top copy accepted by patient: yes/no (please ring)
Guidance to health professionals (to be read in conjunction with consent policy)

This form
This form documents the patient’s agreement (or that of a person with parental responsibility for the patient) to go ahead with the investigation or treatment you have proposed. It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care: for example for drug therapy where written consent is deemed appropriate. In other circumstances you should use either form 1 (for adults/competent children) or form 2 (parental consent for children/young people) as appropriate.

Consent forms are not legal waivers – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients also have every right to change their mind after signing the form.

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally ‘competent’ younger children, may therefore sign this form for themselves, if they wish. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child’s care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form (see also ‘This form’ above)
If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:
they are unable to comprehend and retain information material to the decision and/or
they are unable to weigh and use this information in coming to a decision.
You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information
Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds about treatment. The courts have stated that patients should be told about ‘significant risks which would affect the judgement of a reasonable patient’. ‘Significant’ has not been legally defined, but the GMC requires doctors to tell patients about ‘serious or frequently occurring’ risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this overleaf or in the patient’s notes.

The law on consent
Consent Form 4

Form for adults who are unable to consent to investigation or treatment

Patient details (or pre-printed label)

Patient's surname/family name ………………………………………………………………………
Patient’s first names …………………………………………………………………………………
Date of birth …………………………………………………………………………………………
Responsible health professional …………………………………………………………………
Job title of health professional ……………………………………………………………………
NHS number (or IW Number) ………………………………………………………………………

☐ Male ☐ Female

Special requirements …………………………………………………………………………………
(e.g. other language/other communication method)

To be retained in patient's notes
All sections to be completed by health professional proposing the procedure

A Details of procedure or course of treatment proposed

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

(NB see guidance to health professionals overleaf for details of situations where court approval must first be sought)

B Assessment of patient’s capacity

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

☐ the patient is unable to comprehend and retain information material to the decision; and/or

☐ the patient is unable to use and weigh this information in the decision-making process; or

☐ the patient is unconscious

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

C Assessment of patient’s best interests

To the best of my knowledge, the patient has not refused this procedure in a valid advance directive. Where possible and appropriate, I have consulted with colleagues and those close to the patient, and I believe the procedure to be in the patient’s best interests because:

(Where incapacity is likely to be temporary, for example if patient unconscious, or where patient has fluctuating capacity)

The treatment cannot wait until the patient recovers capacity because:

……………………………………………………………………………………
……………………………………………………………………………………
D  Involvement of the patient’s family and others close to the patient

The final responsibility for determining whether a procedure is in an incapacitated patient’s best interests lies with the health professional performing the procedure. However, it is good practice to consult with those close to the patient (e.g. spouse/partner, family and friends, carer, supporter or advocate) unless you have good reason to believe that the patient would not have wished particular individuals to be consulted, or unless the urgency of their situation prevents this. “Best interests” go far wider than “best medical interests”, and include factors such as the patient’s wishes and beliefs when competent, their current wishes, their general well-being and their spiritual and religious welfare.

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

Any other comments (including any concerns about decision)

Name ……………………………………Relationship to patient…………………………
Address (if not the same as patient…………………………………………………………
………………………………………………………………………………………………….
Signature ………………………………………… Date………………………………

If a person close to the patient was not available in person, has this matter been discussed in any other way (e.g. over the telephone?)
☐ Yes ☐ No Details:

Signature of health professional proposing treatment
The above procedure is, in my clinical judgement, in the best interests of the patient, who lacks capacity to consent for himself or herself. Where possible and appropriate I have discussed the patient’s condition with those close to him or her, and taken their knowledge of the patient’s views and beliefs into account in determining his or her best interests.

I have/have not sought a second opinion.

Signature:…………………………………… Date. ………………………
Name (PRINT) ……………………………………… Job title ………………………

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

Signature:…………………………………… Date ………………………
Name (PRINT) ……………………………………… Job title ………………………
Guidance to health professionals (to be read in conjunction with consent policy)

This form should only be used where it would be usual to seek written consent but an adult patient (18 or over) lacks capacity to give or withhold consent to treatment. If an adult has capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If treatment is being provided under the authority of Part IV of the Mental Health Act 1983, different legal provisions apply and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form as well). If the adult now lacks capacity, but has clearly refused particular treatment in advance of their loss of capacity (for example in an advance directive or ‘living will’), then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the law on consent, see the Department of Health’s Reference guide to consent for examination or treatment (www.doh.gov.uk/consent).

When treatment can be given to a patient who is unable to consent

For treatment to be given to a patient who is unable to consent, the following must apply:
• the patient must lack the capacity (‘competence’) to give or withhold consent to this procedure; AND
• the procedure must be in the patient’s best interests.

Capacity

A patient will lack capacity to consent to a particular intervention if he or she is:
• unable to comprehend and retain information material to the decision, especially as to the consequences of having, or not having, the intervention in question; and/or
• unable to use and weigh this information in the decision-making process.
Before making a judgement that a patient lacks capacity you must take all steps reasonable in the circumstances to assist the patient in taking their own decisions (this will clearly not apply if the patient is unconscious). This may involve explaining what is involved in very simple language, using pictures and communication and decision-aids as appropriate. People close to the patient (spouse/partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates or supporters.
Capacity is ‘decision-specific’: a patient may lack capacity to take a particular complex decision, but be quite able to take other more straight-forward decisions or parts of decisions.

Best interests

A patient’s best interests are not limited to their best medical interests. Other factors which form part of the best interests decision include:
• the wishes and beliefs of the patient when competent
• their current wishes
• their general well-being
• their spiritual and religious welfare
Two incapacitated patients, whose physical condition is identical, may therefore have different best interests.
Unless the patient has clearly indicated that particular individuals should not be involved in their care, or unless the urgency of their situation prevents it, you should attempt to involve people close to the patient (spouse/partner, family and friends, carer, supporter or advocate) in the decision-making process. Those close to the patient cannot require you to provide particular treatment which you do not believe to be clinically appropriate. However they will know the patient much better than you do, and therefore are likely to be able to provide valuable information about the patient’s wishes and values.
Second opinions and court involvement
Where treatment is complex and/or people close to the patient express doubts about the proposed treatment, a second opinion should be sought, unless the urgency of the patient’s condition prevents this. Donation of regenerative tissue such as bone marrow, sterilisation for contraceptive purposes and withdrawal of artificial nutrition or hydration from a patient in PVS must never be undertaken without prior High Court approval. High Court approval can also be sought where there are doubts about the patient’s capacity or best interests.
CONSENT FORM FOR PHOTOGRAPHY/VIDEO/AUDIO/DIGITAL IMAGE

Photographs, audios and videos

As part of your treatment some kind of record may be made – clinical photographs or sometimes a recording. You will always be told if this is going to happen. The photograph or recording will be kept with your notes and will be held in confidence as part of your medical records. This means that it will normally be seen only by those involved in providing you with care or those who need to check the quality of care you have received. The use of photographs and recordings is also extremely important for other NHS work, such as teaching or medical research. However, we will not use yours in a way that might allow you to be identified or recognised without your express permission.

I (Print name) ............................................................... give consent for the Isle of Wight NHS Trust to make a video, audio, digital image and print of me/or the child (if not deemed Gillick competent)

Named ............................................................... 

Date of birth ............................................................... 

I understand that the above will form part of my/their confidential medical records. I also understand that the illustrations may be useful for the purpose of medical teaching and research and agree that they may be shown to appropriate professional staff. If any illustration revealing the face or identity is required for reproduction in a medical or scientific journal or textbook I understand that consent for this will be specifically sought.

Signed: .................................................................* Date: ........................................

Address: ............................................................................................................................... 

Name: .................................................................. Ward: ............................................................... 

Date of Birth: ............................................................... 

IW number: ............................................................... Consultant: ............................................................... 

Area(s) to be photographed: ............................................................................................................ 

Requested by Consultant, Registrar or Named Nurse:

Signed: ............................................................... Date: ............................................................... 

Print Name: ............................................................... Position: ............................................................... 

* May be a doctor if the patient is unable to give informed consent and the photograph is for valid clinical or legal purposes

THIS FORM MUST BE FILED IN THE PATIENT’S NOTES  (1 of 2 pages)
GUIDANCE FOR HEALTHCARE PROFESSIONALS

1. Photographic and recordings made for clinical purposes form part of a patient’s record and must be stored to Trust guidelines. 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 recording will result from that procedure.

2. Photographic and 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 paragraph 3 below. 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 use of the material. In particular, the person must be 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.

3. Photographic and 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.

4. If you wish to make a photographic or 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 hear or 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.

5. 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.

6. 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. No third party may give consent except in the case of a child who is not Gillick Competent when a person with parental responsibility may do so.

Good practice in consent implementation guide Department of Health November 2001

(2 of 2 pages)
APPENDIX C

Useful contact details

Advice in consent issues can be obtained from

- Clinical Risk & Claims Manager 53(4099) during working hours
- Senior Manager on-call (out of hours)
- Bevan Brittan Solicitors – through either of the above.
APPENDIX D

How to seek a court declaration

This should be undertaken by the Trust’s solicitors Bevan Brittan. During office hours contact the Clinical Risk and Claims Manager, out of hours contact the Senior Manager on Call.
APPENDIX E

Seeking consent: remembering the patient’s perspective

Diagram indicating various questions a patient might ask, such as:
- What do they think is wrong with me?
- What treatment might help?
- Can I have work/look after my family afterwards?
- How would it help me?
- Will I have to stay in hospital? How long for?
- What are the risks and benefits of the alternatives?
- What about the risks?
- Will it hurt?
- What will it involve?
- Are there any alternatives?

The central node is labeled "PATIENT."
**APPENDIX F**

**Financial and Resourcing Impact Assessment on Policy Implementation**

NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.

<table>
<thead>
<tr>
<th>Document title</th>
<th>CONSENT TO EXAMINATION OR TREATMENT POLICY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Totals</td>
<td>WTE</td>
</tr>
<tr>
<td>Manpower Costs</td>
<td>0</td>
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<tr>
<td>Training Staff</td>
<td>0</td>
</tr>
<tr>
<td>Equipment &amp; Provision of resources</td>
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</table>

**Summary of Impact:**

**Risk Management Issues:**

**Benefits / Savings to the organisation:**

**Equality Impact Assessment**

- Has this been appropriately carried out? YES/NO
- Are there any reported equality issues? YES/NO

If “YES” please specify:

**Use additional sheets if necessary.**

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

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<thead>
<tr>
<th>Manpower</th>
<th>WTE</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
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</thead>
<tbody>
<tr>
<td>Operational running costs</td>
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Totals:

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<th>Staff Training Impact</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
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</table>

Totals:

<table>
<thead>
<tr>
<th>Equipment and Provision of Resources</th>
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<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accommodation / facilities needed</td>
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<td></td>
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</table>

Consent to Examination or Treatment Policy
Version No 7.3
<table>
<thead>
<tr>
<th>Item</th>
<th>Costs</th>
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<tbody>
<tr>
<td>Building alterations (extensions/new)</td>
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</tr>
<tr>
<td>IT Hardware / software / licences</td>
<td></td>
</tr>
<tr>
<td>Medical equipment</td>
<td></td>
</tr>
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<td>Stationery / publicity</td>
<td></td>
</tr>
<tr>
<td>Travel costs</td>
<td></td>
</tr>
<tr>
<td>Utilities e.g. telephones</td>
<td></td>
</tr>
<tr>
<td>Process change</td>
<td></td>
</tr>
<tr>
<td>Rolling replacement of equipment</td>
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</tr>
<tr>
<td>Equipment maintenance</td>
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</tr>
<tr>
<td>Marketing – booklets/posters/handouts, etc</td>
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**Totals:**

- Capital implications £5,000 with life expectancy of more than one year.

<table>
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<tr>
<th>Funding /costs checked &amp; agreed by finance:</th>
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<tbody>
<tr>
<td>Signature &amp; date of financial accountant:</td>
<td></td>
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<tr>
<td>Funding / costs have been agreed and are in place:</td>
<td></td>
</tr>
<tr>
<td>Signature of appropriate Executive or Associate Director:</td>
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APPENDIX G

Equality Impact Assessment (EIA) Screening Tool

<table>
<thead>
<tr>
<th>Document Title:</th>
<th>Consent to Examination or Treatment Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of document</td>
<td>To set out a process for obtaining consent to examination or treatment within the Trust</td>
</tr>
<tr>
<td>Target Audience</td>
<td>All Trust staff</td>
</tr>
<tr>
<td>Person or Committee undertaken the Equality Impact Assessment</td>
<td>Claire Willis, Clinical Risk &amp; Claims Manager</td>
</tr>
</tbody>
</table>

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below?

   If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

   If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

<table>
<thead>
<tr>
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<th>Negative Impact</th>
<th>Reasons</th>
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<tbody>
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<td>Consent process is accessible to all</td>
</tr>
<tr>
<td>Women</td>
<td>X</td>
<td></td>
<td>Consent process is accessible to all</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian or Asian British People</td>
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<td></td>
</tr>
<tr>
<td>Chinese people</td>
<td>X</td>
<td>Consent process is accessible to all</td>
<td></td>
</tr>
<tr>
<td>People of Mixed Race</td>
<td>X</td>
<td>Consent process is accessible to all</td>
<td></td>
</tr>
<tr>
<td>White people (including Irish people)</td>
<td>X</td>
<td>Consent process is accessible to all</td>
<td></td>
</tr>
<tr>
<td>People with Physical Disabilities, Learning Disabilities or Mental Health</td>
<td>X</td>
<td>Consent process is accessible to all</td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td>Transgender</td>
<td></td>
<td>Consent process is accessible to all</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------</td>
<td>---</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Lesbian, Gay men and bisexual</td>
<td></td>
<td>Consent process is accessible to all</td>
</tr>
<tr>
<td>Age</td>
<td>Children</td>
<td>X</td>
<td>Consent process is accessible to all</td>
</tr>
<tr>
<td></td>
<td>Older People (60+)</td>
<td></td>
<td>Consent process is accessible to all</td>
</tr>
<tr>
<td></td>
<td>Younger People (17 to 25 yrs)</td>
<td>X</td>
<td>Consent process is accessible to all</td>
</tr>
<tr>
<td>Faith Group</td>
<td>X</td>
<td></td>
<td>Consent process is accessible to all</td>
</tr>
<tr>
<td>Pregnancy &amp; Maternity</td>
<td>X</td>
<td>Consent process is accessible to all</td>
<td></td>
</tr>
<tr>
<td>Equal Opportunities and/or improved relations</td>
<td>X</td>
<td>Consent process is accessible to all</td>
<td></td>
</tr>
<tr>
<td>Issues</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes:
Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

3. Level of Impact

If you have indicated that there is a negative impact, is that impact:

<table>
<thead>
<tr>
<th>Legal (it is not discriminatory under anti-discriminatory law)</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:

3.2 Could you improve the strategy, function or policy positive impact? Explain how below:

3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?

Scheduled for Full Impact Assessment | Date:  
Name of persons/group completing the full assessment | Claire Willis  
Date Initial Screening completed | 16.01.2018