## TRUST CORPORATE POLICY
### CONSENT TO EXAMINATION AND TREATMENT

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<tr>
<th>APPROVAL</th>
<th>Trust Policies Committee and chairs action</th>
<th>Date approved: 19/03/15 and 20/05/16</th>
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<td>EFFECTIVE FROM</td>
<td>May 2016</td>
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<td>DISTRIBUTION</td>
<td>All Wards and Depts via Trust Bulletin</td>
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### RELATED DOCUMENTS
- Research & Development Policy (COR/POL/028/2016-001)
- Statutory and Mandatory Training Policy (COR/POL/026/2015-001)
- Safeguarding: Protecting Adults at risk of Harm (COR/POL/045/2015-001)
- Code of Responsible Practice for Medical Illustration
- Legacy Trust Policies
- BLT/WX/NUHT policies on Consent of Patients to Participate in Undergraduate Medical Education / Dental Education
- BLT/WX/NUHT policies on Management And Treatment Of Clients Refusing Blood Transfusion Including Jehovah’s Witnesses
- BLT/WX/NUHT policies on Advocacy and Communication Support Guidelines

### STANDARDS
- NHS General Consent requirements
- Mental Capacity Act
- Mental Health Act

### OWNER
- Chief Nurse

### AUTHOR/FURTHER INFORMATION
- Lead for MCA/MHA/DoLS/Prevent Safeguarding Adults Team

### SUPERSEDED DOCUMENTS
- Previous versions of the Policy for Consent to Examination and Treatment
- Previous versions of Consent Form 4, all legacy organisations

### REVIEW DUE
- Three years from approval

### KEYWORDS
- Consent, Mental Capacity

### INTRANET LOCATION(S)

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<th>Barts Health</th>
<th>Adult Safeguarding Team, Legal Services Team, CAG DoNS and Clinical Directors, Medical and Nursing Directors</th>
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<td></td>
<td>Clinical Policies Group, Quality and Safety Standards Board</td>
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<td>External Partner(s)</td>
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<td>Included in policy:</td>
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<tr>
<td>For the groups listed below, failure to comply with this policy may result in investigation and management action which may include formal action in line with the Trust's disciplinary or capability procedures for Trust employees, and other action in relation to organisations contracted to the Trust, which may result in the termination of a contract, assignment, placement, secondment or honorary arrangement.</td>
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<td>Other staff, students and contractors working within the Trust</td>
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CONSENT TO EXAMINATION AND TREATMENT

1 INTRODUCTION AND AIMS OF POLICY

1.1 This local policy incorporates the Department of Health model policy. It has been updated locally in line with Human Rights, Mental Capacity, Human Tissue, and Equality and Diversity legislation as well as changing national guidance. It also includes additional local procedures and requirements, additional to the requirements of the model policy.

Why consent is crucial

1.2 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 and high risk surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

What consent is – and isn’t

1.3 “Consent” is a patient’s agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:
   - be competent to take the particular decision;
   - have received sufficient information to take it; and
   - not be acting under duress.

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

2 PROCESS

2.1 The flowcharts below summarise the process of obtaining consent for examination or treatment. Detailed aspects of the procedure and the procedures in place for the other forms of consent are detailed within the policy.
Flowchart 1: Adult Patients (18 years and over) Capable of Giving Consent:

Note: If the patient is currently detained under the Mental Health Act, first work through Flowchart 4

Identify treatment proposed

Procedure treatment or care not requiring written consent (10)

Invasive procedure requiring written consent (10)

Clinician giving care: explains the care to be given and seeks informal consent

Consent indicated by patient – give and document care & summary of consent process

Elective procedure

Clinician doing procedure or approved delegate [appendix E] commences consent process by explaining the need for treatment and giving relevant information. Consent may be given or withheld at this point, or the decision may be deferred by the patient

Consent given. Complete Form 1 if procedure includes general anaesthetic, otherwise Form 3

Confirmed consent prior to procedure; document confirmation

Consent in place

Untake procedure

Emergency procedure

Seek written consent prior to procedure taking place (not on day of procedure unless at the endpoint of documented discussions)

Consent given. Complete Form 1 if procedure includes general anaesthetic, otherwise Form 3

Documented circumstances make it impossible to obtain consent pre-admission, or decision deferred by patient

Consent not given or consent withdrawn – do not continue; refer back to GP and seek immediate advice from Legal Team if proposed care/treatment is lifesaving
**Flowchart 2: Adult Patients (18 years and over) NOT Capable of Giving Consent**

This Flowchart is included for completeness, but issues relating to patients without capacity are included in the Safeguarding: Protection of Adults at Risk of Harm Policy, and not in this policy.

If the patient is currently detained under the Mental Health Act, first work through Flowchart 4.

**NOTE:** most patients without capacity should be subject to the Deprivation of Liberty Safeguards.

Treatig clinician must document the assessment which leads to the conclusion that patient is not capable. Wherever possible consult with relatives/carers before completing assessment.

Has the person appointed anyone to have lasting power of attorney in relation to health matters?

- **Yes**
  - Possibly – Consult with Legal Team asap; meanwhile give life saving treatment only.
  - Check validity with the Legal Services Team, then follow procedure for consent by capable adult, as if the Attorney were the person (patient) giving or refusing consent.

- **No**
  - Is planned care/treatment prohibited by a valid advance directive or advance decision?
    - **No**
      - Possibly – Consult with Legal Team asap; until situation clear, give life saving treatment only.
    - **Yes**
      - Possibly – Consult with Legal Team asap; meanwhile give life saving treatment only.

Does the proposed treatment amount to “Serious Medical Treatment”?

- **Yes**
  - Clinician proposing treatment consults an Independent Mental Capacity Advocate
  - Clinician proposing treatment consults with any involved carers/relatives
  - Document consultation(s), then take and carry out treatment decision in patient’s best interests taking account of consultation [Complete Form 4].

- **No**
  - Nature of treatment proposed
    - Simple procedure or care not requiring written authority
    - Invasive procedure requiring written authority

Clinician giving care: attempt to explain the care to be given. Give care in accordance with patient’s best interests. Document care given & summary of consent process.

- **Yes** – Confirm validity of directive with Legal Team, document confirmation. Do not proceed with treatment.
- **No** – Confirm validity of directive with Legal Team, document confirmation. Do not proceed with treatment.
Flowchart 3: Patients under 18

(See paragraph Error! Reference source not found. in relation to patients aged 16 or 17) Error! Reference source not found.

Note: If the patient is currently detained under the Mental Health Act, first work through Flowchart 4.
Flowchart 4: Adults or Children detained under the Mental Health Act

Note: This flowchart does not cover all aspects of the law that may apply to the patient, but will allow staff of Barts and the London to identify whether or not specialist Mental Health staff need to be involved in the consent process. Figures in brackets refer to paragraphs in this policy.

Is the proposed treatment solely for PHYSICAL disorder or injury?

Yes

- Is the treatment IMMEDIATELY ESSENTIAL to avoid IMMEDIATE AND SIGNIFICANT risk to patient or others?

Yes

- Give minimum essential treatment and discuss with patient's approved clinician or the Legal Team

No

- Is the patient being held under Section 4, Section 5(4), Section 5(2), Section 136 or Section 135?

Yes

- No or not sure

No

- Has the patient been subject to continuous detention under the MHA for the last 3 months or more? (include any immediately preceding treatment in another hospital and/or on a different section and/or any time "on leave" while subject to the Mental Health Act)

Yes

- Psychiatric treatment can be given under MHA, with or without patient's consent.

No

- Does the treatment involve any of the following?
  - Electro-Convulsive Therapy (ECT)
  - Surgery to treat mental disorder or manage behaviour
  - Hormonal treatment for sexual deviation

Yes or not sure

- No

- Is the proposed treatment medication for mental disorder?

Yes

- Has the patient been subject to continuous detention under the MHA for the last 3 months or more? (include any immediately preceding treatment in another hospital and/or on a different section and/or any time "on leave" while subject to the Mental Health Act)

Yes

- Psychiatric treatment can be given under MHA, with or without patient's consent.

No

- Consult Approved Clinician, document and follow advice, seeking new advice in relation to each new treatment type proposed
2.2 For significant procedures, it is essential for health professionals to document clearly both the patient’s agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient’s health record if necessary), or through documenting in the patient’s record that they have given verbal consent.

**Written consent**

2.3 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.

2.4 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 the potential for adverse outcomes, including those which some health professionals would describe as ‘side-effects’ or ‘complications’)
- the procedure involves general/regional anaesthesia or sedation
- providing clinical care is not the primary purpose of the procedure
- there may be significant consequences for the patient’s employment, social or personal life
- the treatment is part of a project or programme of research approved by this Trust

2.5 Completed forms include summary details of the information given to the patient and the discussion with the patient about the risks, benefits and any alternative to treatment as well as a record of the patient’s consent. Additional details may be included in the patient’s continuous healthcare record if required. A record must be kept in the healthcare records if the discussion leads to a refusal or withdrawal of consent. The consent 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.

**Consent where no form is used**

2.6 It will not usually be necessary to document a patient’s consent to routine and low-risk procedures, such as providing personal care, taking a blood sample, routine observations. However, if the health professional or care giver has any

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1 The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances
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 have become very distressed about receiving similar care in the past), it would be prudent and best practice to do so. A record of this and any discussions with the patient should be made in the health record.

Patients lacking capacity who are not capable of consent

NOTE: this issue is covered in more detail in the Policy Safeguarding: Protection of Adults at Risk of Harm.

2.7 Where an adult patient does not have the capacity to give or withhold consent to a significant or high risk procedure or intervention, this fact should be documented in Consent 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 must never be used for adult patients unable to consent for themselves.

2.8 For more minor interventions such as routine medical prescribing, nursing care, investigations, therapy etc information relating to this decision making and that the patient lacks capacity should be entered in the patient’s notes and if appropriate recorded on CRS. In these cases it should be recorded that care is being provided in the patients best interests. Wherever possible the patient’s carer and/or relative should be involved in the decision making discussion, and this should also be recorded along with any decisions or information discussed by the MDT.

2.9 (Further information about decision making in relation to patients not capable of consent, updated in relation to the implementation of the Mental Capacity Act 2005, is given in the Safeguarding: Protecting Adults at Risk of Harm Policy (COR/POL/045/2013-001)).

Availability of forms

2.10 There is one form which must be completed to document the status of any patient admitted as an in-patient, or admitted as a day patient where no other consent form is being used. This is the Capacity to Consent to Admission for Medical Care Form, and is completed on admission by any member of the clinical team. It identifies whether the patient has capacity and is consenting to admission or lacks capacity and is being admitted in their best interests. (An escalation procedure, included on the form, covers any situation which is neither of the above).

2.11 This form relates only to the patient’s general consent to being in hospital for purposes of clinical care and treatment, and does not cover any specific procedure which may require separate written consent. In some cases a patient may be noted on this form as having capacity to consent to admission, even though they do not have capacity to consent to more complex issues, such as specific clinical treatments.

2.12 Where it is proposed that a patient undergoes procedure for which written consent is required, one of the four standard consent forms must be used. There
are three versions of the standard consent form and one for recording assessment of lack of capacity.

- **Form 1**: for adults or competent children
- **Form 2**: for parental consent for a child or young person
- **Form 3**: for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care
- **Form 4**: for adults who lack capacity (this form has been updated in compliance with the Mental Capacity Act)

2.13 The use of Form 3 is optional but may be thought more appropriate than Form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary.

2.14 Standard consent forms and are ordered as stationary stock items.

**Local provision for the use of customised or pre printed consent forms**

2.15 Only consent forms containing all the wording of the forms approved and listed in Appendix A of this policy may be used within the Trust.

2.16 In some cases it may be appropriate for departments to develop standard information relating to specific, frequently conducted procedures, which can be pre-printed as a consent form whose wording is in all other respects the same as one or other of the standard consent forms. (The format of the form may differ from the standard form, but the Trust logo and all of the existing wording must be included, in the order in which it appears in the standard form).

2.17 Any such development must be approved by the relevant CAG Committee, on a case by case basis, so that details may be included in Appendix A of this policy.

2.18 Any other proposal to develop a new Consent Form, (differing in any other respect from the standard forms listed at Appendix A) must be referred to Safeguarding Adults team, who will consult with the legal services team about the acceptability of the wording before proposing inclusion in the policy.

2.19 Approval of any such consent form, not match the wording in any of the currently approved consent forms (Appendix A), may only be given by the Trust Policies Committee, after which the new form would be included in Appendix A as an update to this policy.

**When should consent be sought?**

2.20 Consent should be obtained prior to any intervention involving contact with the patient.

2.21 When a patient consents to admission to hospital, or a decision is made to admit a patient not capable of consenting to this, in their best interests, this should be recorded on the **Capacity to Consent to Admission for Medical Care Form**.
When a patient gives their consent to a particular intervention, formal written consent is often required. Usually, the completion of a consent form 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. Services providing treatment to children in the school setting should refer to the procedural document Obtaining Consent in the School Setting for guidance on the process for involving parents and children in the consent process.

**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. Similarly, a nurse will seek consent prior to carrying out a wound dressing or a urinary catheter insertion. 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 most such cases, verbal consent is provided.

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.

**Two or more stage process**

In most cases where written consent is being sought, treatment options will generally be discussed in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital outpatient or preadmission 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.

Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure, and should have received a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment.

If a form is signed before patients arrive for treatment, however, a member of the healthcare team must check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient’s consent and understanding, it is advisable to use a form of words which requires more than a
yes/no answer from the patient: for example beginning with “tell me what you’re expecting to happen”, rather than “is everything all right?”

2.28 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. Therefore it is not best practice and will in most cases be inappropriate to ask a patient to sign the consent form on the morning of surgery or 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.

### Seeking consent for anaesthesia

2.29 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.

2.30 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. Responsibility for giving this information will rest with the dentist, along with the anaesthetist if an anaesthetist is involved in the treatment.

### Changes to the proposed treatment

2.31 During operative procedures it sometimes becomes evident that the patient requires treatment other than the one for which consent has been obtained and which has not been anticipated nor discussed during the consent taking process.

2.32 In such cases, the policy of Barts Health NHS Trust is that if the revised treatment can be undertaken on an elective, non-emergency basis, the patient must be given the opportunity and time to make the decision about the additional treatment. This may include waking and returning the patient to the ward and re-consenting them for the revised treatment plan, consistent with best practice guidance. If the treatment need is urgent then treatment should be given in the patient’s best interests, providing this is not prohibited by any advance decision that the patient may have taken (see Section VII below).

### Emergencies

2.33 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.

Treatment of children

2.34 Consent for minors (under 18) may be given either by the person with parental responsibility for the child or, where the child has capacity to give consent, by the child. Generally, a parent makes the decision for their child. However, where the child has sufficient maturity and understanding of the proposed procedure (often referred to as meeting the Frazer guidelines or being “Gillick competent”), then the child is legally able to consent to treatment (but may not be able to refuse treatment). In the event of a conflict between a parent and a child, healthcare professionals should discuss this with the Legal Team.

2.35 It is the responsibility of the clinician responsible for the treatment to assess and document the child’s capacity if the child may be asked to give consent or indicates a wish to be involved in the consent process. A checklist of issues which must be considered in all cases when assessing and documenting capacity is included in Appendix D. In any case which involves complex issues, including potential conflict between adult and child choices, treatment of a child without parental knowledge etc, staff are expected to use the form ‘Gillick Competency Assessment for under 16s including Fraser Guidelines’ to document the process of obtaining consent.

Young People aged 16-17

2.36 Under Section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are entitled to consent to their own treatment, and any ancillary procedures involved in their treatment, such as an anaesthetic. As for 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 16-17 may in certain circumstances be overridden by either a person with parental responsibility or a court. Like adults, young people (aged 16 or 17) are presumed to have sufficient capacity to decide on their own medical treatment, unless there is significant evidence to suggest otherwise. In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used.

2.37 If a young person refuses treatment, and by doing so this may lead to their death or a severe permanent injury, their decision can be overruled by the Court of Protection. This is the legal body that oversees the operation of the Mental Capacity Act (2005). The parents of a young person who has refused treatment may consent for them, but it is usually thought best to go through the courts in such situations, so the trust Legal Services Team should always be contacted to discuss this issue..

Babies and young children

2.38 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.

“Parental responsibility”

2.39 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, following amendment of the Children Act 1989 by the Adoption & Children Act 2002, an unmarried father has parental responsibility if his name is registered on the birth certificate of a child born after 1st December 2003, but may not always do so where the birth occurred before that). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check, involving the Legal Services Managers if necessary.

2.40 For further information and local guidance on consenting children and young people, please refer to the also refer to the DoH’s guidance Seeking consent: working with children, November 2001

Provision of information

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

2.42 Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

2.43 Wherever possible, information should be given both verbally and in writing, eg through a patient information leaflet given during a consultation with a relevant clinician. Approved information leaflets are available through the Trust intranet.

2.44 Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. Other sources of information; details of additional information sources are given in Appendix B. The Patient Advice and Liaison Service and Patient Information leads in Clinical Academic Groups and Directorates can also support patients in locating sources of specialist information.

2.45 The Patient Communications Manager (based in the Communications Department) can assist and advise on how to access, order, and develop new patient information in accordance with the Trust Guidelines for developing Patient
Provision for patients whose first language is not English

2.46 Barts Health has access to bilingual advocates, independent advocacy and other patient support services that might be required during the consent process, such as interpreters or signers. This includes an out of hours advocacy and interpreter service. (See appendix B for contact details).

Access to health professionals between formal appointments

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

2.48 The person seeking written consent should provide contact details of where further sources of information and advice can be accessed should patients wish to discuss their proposed treatment between formal appointments or admission. Contact details must be written in the designate space provided on the consent form.

Open access clinics

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

Who is responsible for seeking consent?

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

2.51 Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible.

2.52 Accountability for obtaining written consent normally rests with the clinician delivering the care or carrying out the procedure. That person may, however, delegate responsibility for taking consent to another clinician who is also competent to carry out the procedure and who is aware of any special factors relating to the patient and the procedure which may need to be included in the discussion leading to consent.

2.53 In certain circumstances, responsibility for taking consent may be delegated to a clinician who is not competent to undertake the procedure. This may only be done as set out at Appendix C.

2.54 The taking of written consent may not be delegated to nursing, medical or midwifery students. However, it may be appropriate for other members of the
team to observe or participate under direct supervision, as part of their education and training.

Completing consent forms

2.55 The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so. They should also be able to demonstrate that they are aware of their own knowledge limitations and be subject to periodic supervision and audit.

2.56 If the patient signs the form in advance of the procedure (for example in outpatients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered.

Refusal of treatment

2.57 If the process of seeking consent is to be a meaningful one, refusal must be one of the patient’s options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983. The situation for children is more complex: see the Department of Health’s Seeking consent: working with children for more detail. The following paragraphs apply primarily to adults.

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

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

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

2.61 If a patient is refusing treatment that is essential for their welfare and you have any concerns about their mental state at the time of this refusal, you should discuss the case with a member of the Legal Team. Contact details are provided in Appendix B.

Withdrawal of consent

2.62 A patient with capacity is entitled to withdraw consent at any time, including during the performance of a procedure. Where a patient does object during treatment, it is good practice for the practitioner, if at all possible, to stop the
procedure, establish the patient’s concerns and explain the consequences of not completing the procedure. If stopping the procedure at that point would genuinely put the life of the patient at risk, the practitioner may be entitled to continue until the risk no longer applies.

2.63 Assessing capacity during a procedure may be difficult but the practitioner should try to establish whether at that time the patient has the capacity to withdraw a previously given consent. If capacity is lacking, it may sometimes be justified to continue in the patient’s best interests, although this should not be used as an excuse to ignore distress.

3 PATIENTS WHO LACK CAPACITY TO GIVE OR WITHHOLD CONSENT

3.1 Arrangements for this issue have significantly changed since the publication of 2001 NHS Model Consent Policy, as a result of the implementation of the Mental Capacity Act 2005.

3.2 Routine management of this issue is no longer included in this policy, but is covered in the Safeguarding: Protecting Adults at Risk of Harm Policy (COR/POL/045/2013-001).

4 ADVANCE REFUSAL OF TREATMENT

4.1 Competent adults may wish to make arrangements for treatment that they wish to refuse in the future, in the event that they have lost capacity when that treatment is proposed.

Residual powers still in force from before the Mental Capacity Act 2005

4.2 Prior to the implementation of the Mental Capacity Act, competent adults could indicate their wishes in relation to future treatment through an Advance Directive. An Advance Directives made prior to the implementation of the Mental Capacity Act continues to carry the same weight as previously, provided that it meets particular conditions. These are that there is a reasonable belief that the advance decision was made before 1 October 2007, a reasonable belief that the person has lacked capacity to amend their advance decision since 1 October 2007 and the advance decision is in writing (Article 5 of the Mental Capacity Act (Transitional and Consequential Provisions) Order 2007.

Powers in force as a result of the Mental Capacity Act 2005

4.3 Since the implementation of the Mental Capacity Act, competent adults (aged 18 and over) can make decisions about what treatment they may not wish to receive in the event that they subsequently become incapable, by means of an Advance Decision to refuse treatment. This decision may be expressed verbally or in writing.

4.4 If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an ‘advance decision to refuse treatment’), and those circumstances arise, then the health professional(s) must abide by that refusal. However, if the refusal is in relation to treatment essential to preserve life, this advance decision must have been made in writing.
and included a clear statement that it applied even in the case of treatment essential to preserve life.

4.5 Further information about Advance Decisions, see the Lord Chancellor’s Mental Capacity Act 2005 Code of Practice.

5 LASTING POWER OF ATTORNEY

5.1 Prior to the implementation of the Mental Capacity Act, there was provision for a competent adult to appoint another adult “Enduring Power of Attorney”, which would allow that attorney to make decisions about the person’s affairs should they lose capacity at some point in the future. Where an Enduring Power of Attorney arrangement was in place before the implementation of the Mental Capacity Act, this continues to have effect. However, this power does not include decision making in relation to health matters or consent to treatment.

5.2 The Mental Capacity Act introduces the “Lasting Power of Attorney” (LPA) which allows an adult who has capacity to appoint an attorney to make a wider range of decisions on their behalf, including health and welfare decisions, should they lose capacity at some point in the future. Before a LPA can be used it must be registered with the new Office of Public Guardian.

5.3 If treatment is to be given to an incapable person who has previously established a LPA covering health and welfare, the consent of their Attorney must be obtained for the patient, and the same considerations apply in relation to the Attorney as would apply to a competent adult making decisions on their own behalf. www.publicguardian.gov.uk.

5.4 There are certain limited restrictions on the right of Attorney’s to make decisions relating to the persons concerned. In any case where there is concern about a decision being taken by an attorney, advice should be sought from the Legal Services Team.

6 TISSUE

6.1 The text in this section replaces the material previously included in the 2001 NHS Model Consent Policy, to reflect the requirements of the Human Tissue Act 2004 which became law on 1 September 2006. From the Act the Human Tissue Authority has issued a Code of Practice on consent. This requires Trusts to provide patients with information regarding the use of tissue for research purposes.

6.2 The Code also states that once tissue is taken from patients, for whatever purpose, it can be shared and used without consent for a number of purposes, on the basis that they are integral to the general provision of clinical and diagnostic services.

6.3 Consent from the living is needed for storage and use of tissue for:

- obtaining scientific or medical information which may be relevant to any other person, now or in the future (i.e. where the purpose is storage or use, in relation to another person, rather than where it might, incidentally, be of future relevance to another person).
research in connection with disorders, or the functioning, of the human body

- public display, and
- transplantation.

6.4 Consent from the living is not needed for storage and use of tissue for:

- clinical audit
- education or training relating to human health (including training for research into disorders, or the functioning, of the human body)
- performance assessment
- public health monitoring
- quality assurance.


6.5 This section relates to Barts Hospital, Royal London, Mile end and The London Chest Hospital as Whipps Cross and Newham do not currently retain surplus tissue for research.

6.6 Barts and the London NHS Trust promoted good practice by ensuring that written consent is obtained for the use of tissue in research. The pre merge Trust Consent Forms 1, 2 and 3 have a section included on research, relating to the use of surplus diagnostic tissue for research. This tissue refers to tissue taken during operations, diagnosis and treatments, which would normally be discarded.

6.7 Information on the potential use of tissue and samples for research purposes is contained in the BLT Tissue Use Information leaflet, reference: BLT/PTINFO/064, which is available for patients to read on the wards and also in Pre-admission Clinics. The contents of this leaflet should be discussed with the patient prior to them being asked to sign the consent form.

6.8 Patients must indicate on the consent form whether they agree or do not agree to their tissue being used for research and sign to confirm their consent to this issue, separately from their consent to treatment. Patients must also indicate whether or not they agree to authorised staff, who are not directly involved in their clinical care, accessing their health records to obtain relevant personal information. There is also space on the consent form for the patient to list their preference for tissue use and any exclusions.

6.9 Research involving reproductive cloning or testing for inherited diseases is not covered by the consent for research taken as part of operations / treatment. Explicit consent for this must be obtained from the patient.

6.10 The completed triplicate consent form will be distributed as follows:

- Gold Copy – to be filed in the patient’s health records
- White Copy* – to be placed in the health records

* If tissue specimens are taken, this copy will then be sent to Pathology by the theatre, clinic, or unit staff with the specimens and then it will be forwarded to the
Human Tissue Resource Centre. If no specimens are taken, the form should remain filed in the health record.

- Blue Copy – to be given to the patient.

For further information and advice on any aspects of the Human Tissue Act, consent and research, please access the Trusts Human Tissue Resource Centre via the link below:

www.bartsandthelondon.nhs.uk/research/human_tissue_resource_centre.asp

7 CLINICAL PHOTOGRAPHY AND CONVENTIONAL OR DIGITAL VIDEO RECORDINGS

7.1 Photographic and video recordings made for clinical purposes form part of a patient’s record. Although consent to certain recordings, such as X-rays, is implicit in the patient’s consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

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

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

7.4 If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

7.5 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.
7.6 If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of some-one close to the patient. Please refer to the Code of Responsible Practice for Medical Illustration referenced below for clarity. 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.

7.7 Barts and The London NHS Trust has a Code of Responsible Practice for Medical Illustration which outlines local arrangements and standards in relation to consent for medical photography and illustration for both therapeutic and non-therapeutic uses such as publication, education, poster production.

7.8 For further guidance please see the Department of Health’s Supplementary guidance: ‘Making and Using Visual and Audio Recordings of Patients’ [link](http://www.gmc-uk.org/guidance/ethical_guidance/making_audiovisual.asp).

7.9 For guidance in relation to clinical recordings for academic settings please see [link](http://www.cherri.mvm.ed.ac.uk/cherri.pdf).

8 TRAINING AND COMPETENCY ASSESSMENT

Generic teaching and education on Consent

8.1 Barts Health NHS Trust is a teaching organisation and is committed to ensuring that all staff receive appropriate training, education and supervision to enable them to carry out their duties safely and competently and this applies to the patient consent process and policy.

8.2 Trust requirements in relation to consent training are set out in each pre-mergered Trust’s Training Needs Analysis and monitored as set out in Statutory and Mandatory Training Policy.

8.3 Outside of the routine programme of consent training, additional sessions relating to Consent and Capacity, including consent practice, accountability and the law, can be provided by the Legal Services Managers (contact details in Appendix B). The Trust recognises that training on consent issues may be included in relevant training courses for example record keeping training and immunisation training.

Training for delegated consent taking

8.4 Consent may under some circumstances be delegated by the clinician who will be undertaking the procedure to a clinician who is not personally capable of undertaking the procedure for which consent is sought. Such delegates must have received both theoretical and procedure specific training to equip them to take consent for this procedure. Responsibility for providing or arranging the procedure specific training, and logging it on the Trust’s Consent Training and Delegation Database, rests with the clinicians planning to delegate consent.

8.5 The procedure that must be followed in this circumstance is detailed at Appendix C.
### DUTIES

| Managers | Ensure that all clinical staff undertake training in consent where required under the Trust’s Training Needs Analysis.  
|          | Ensure the effectiveness of the consent procedures are monitored and changes to practice implemented as required.  
|          | Maintain and update the Trust’s Consent Training and Delegation Database.  
| All staff working with patients | Protect patient’s rights, including the right to refuse treatment.  
|          | Ensure that patients are given necessary information and opportunities to ask questions about treatment before giving consent.  
|          | Identify those patients who may lack the capacity and to ensure that they are assessed under the Mental Capacity Act procedures.  
|          | Be aware of any patient being treated under the Mental Health Act and that special consent requirements may apply.  
|          | Ensure that the process of seeking and obtaining consent to treatment is appropriately documented in each case.  
|          | Work within own competence and not to agree to perform tasks which exceed their competence.  
|          | Escalate any concerns about consent to a senior clinician, manager or member of the Legal Team.  
| Staff undertaking procedures for which written consent is required | As above, plus the following:  
|          | Document consent using the appropriate form.  
|          | Work to ensure that consent is taken at the appropriate time.  
|          | Ensure that consent is not delegated to staff not capable of performing the procedure except as set out in Appendix C of this policy.  
| Healthcare Governance staff | To provide advice as required and to support the monitoring process.  
| Legal Services Team | To respond to queries relating to consent, and facilitate access to legal advice as needed. |
required.
To monitor the consent process and follow up any cases where this policy has not been followed.
To monitor changes in law or precedent, and arrange for this policy to be updated when necessary.
To liaise with the Safeguarding team over any issues which relate to the Mental Capacity Act, the Mental Health Act, Deprivation of Liberty Standards.

Medical Director
To review any requests for customisation of consent forms, and approve any changes where relevant, in consultation with the Legal Services Team.

10 **BREACHES OF POLICY**

10.1 Any breach of the arrangements set out in this policy which is identified during clinical practice must be reported as an incident and followed up in line with the Trust’s incident reporting policy, escalating as a serious incident if the circumstances make this appropriate.

10.2 Any breach of the arrangements set out in this policy which is identified as a result of audit will be noted in the audit report and actions required to avoid further breaches will be included in the resulting action plan.

10.3 In addition to the above, in any case where it appears that consent has been taken by a person who is neither capable of doing the procedure nor authorised as set out in Appendix C, the Legal Team must be notified. The Legal Team will follow up such each case with the clinician concerned and their supervisor and will agree and document any action that is taken in relation to the breach.

11 **MONITORING THE EFFECTIVENESS OF THIS POLICY**

<table>
<thead>
<tr>
<th>Monitoring method</th>
<th>Lead</th>
<th>Frequency</th>
<th>Scope</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent documentation (including evidence of consent process, information given and documentation of discussion), included in Medical Records Audit</td>
<td>Audit Department</td>
<td>At least biennially</td>
<td>Sample of records from all specialties</td>
<td>Summary to Q&amp;SC; detailed report to CAGs</td>
</tr>
<tr>
<td>Rolling audit of consent documents and compliance with delegation arrangements set out in this policy</td>
<td>Legal Services Managers</td>
<td>Annually</td>
<td>Sample of records from all surgical specialties</td>
<td>Annual Report to Q&amp;SC</td>
</tr>
<tr>
<td>Monitoring method</td>
<td>Lead</td>
<td>Frequency</td>
<td>Scope</td>
<td>Report</td>
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<tr>
<td>Any breaches of consent delegation arrangements identified through the above will be reported to the GMC in line with GMC/NHSLA recommendations</td>
<td>Legal Services Managers/Audit</td>
<td>Ongoing</td>
<td>Sample of medical records from all specialties</td>
<td>Annual Report to Q&amp;SC</td>
</tr>
<tr>
<td>Annual review of Consent Training and Delegation Database, giving numbers of clinicians and procedures included, by CAG</td>
<td>Legal Services Team</td>
<td>Annually</td>
<td>All records in consent database</td>
<td>Included in above report</td>
</tr>
<tr>
<td>Review of breaches of policy (including delegation arrangements) and action taken</td>
<td>Legal Services Managers</td>
<td>Annually</td>
<td>All relevant Datix records and cases identified through audit</td>
<td>Included in above report</td>
</tr>
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</table>
APPENDIX A: CURRENT FORMS FOR CONSENTING TO TREATMENT AND CARE IN USE IN THIS ORGANISATION

Local form: Capacity to Consent to Admission for Medical Care Form.

Department of Health (as amended by Barts Health NHS Trust)
Consent Form 1
Consent Form 2
Consent Form 3

The above general consent forms previously published by Legacy Trusts are no longer approved for use in Barts Health

Consent Form 4 (Trust specific version, updated in line with Mental Capacity Act)

Previous versions of form 4 previously published by Legacy Trusts or Barts Health are no longer approved for use in Barts Health
APPENDIX B: CONTACTS, INFORMATION RESOURCES AND REFERENCES

Sources of Patient Information

Patient information leaflets are available on the Trust’s intranet at http://bartshealthintranet/About-Us/The-Trust/Publications-and-patient-information/Patient-information.aspx

The following additional sources of patient information are available:

- BACUP Cancer Information Center at Barts Hospital
- Patient Advice & Liaison Services (PALS) see http://bartshealthintranet/About-Us/Corporate-Directorates/Nursing-and-Governance/Patient-experience-and-engagement/PALS.aspx
- NHS Net Doctor Online patient information service www.doctoronline.nhs.uk
- NHS Direct www.nhsdirect.nhs.uk

How to Access Legal Advice

The Legal Services Team
3rd floor Prescot Street
18 4802 and 18 4850

Beachcroft Solicitors: For Legal Emergencies & Out of Hours, contact with the Trust’s Legal firm Kennedy’s is only via the Site Managers

Court declarations:

Should the need arise to obtain a court declaration, the following steps need to be taken:

Between 9:00 and 17:00 Monday to Friday please contact the legal services team as above

Out of Hours and Weekends

Ask a Site Manager to contact the Trust Emergency Legal Representatives and liaise with them in obtaining the Court Declaration

Health Advocates:

<table>
<thead>
<tr>
<th>Site</th>
<th>Advocacy</th>
<th>Interpreting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royal London Hospital, St Barts Hospital, Mile End Hospital, London Chest Hospital</td>
<td>0207 377 7000 ext 7280, (14 – 7280) or by on-line Health Advocacy booking service available via the Trust intranet. To register for the online booking service staff must email _Health Advocacy to arrange registration and training. Health advocates can be booked in advance The Health Advocacy Service is located at:</td>
<td>Interpreting services Interpreting services can be arranged through Health Advocates, as above. The Trust’s Bengali/Sylheti speaking health advocates provide an extended service to patients in the evenings and at weekends in the Royal London Hospital A&amp;E Department and Maternity Services, as well as on weekdays. The Trust’s designate</td>
</tr>
</tbody>
</table>
Health Advocate Service  
3rd floor John Harrison House 
Royal London Hospital 
E 1 1BB  
Details in Legacy Policy  
Advocacy and communication support - Barts and The London

Health Advocate Service  
3rd floor John Harrison House 
Royal London Hospital 
E 1 1BB  
Details in Legacy Policy  
Advocacy and communication support - Barts and The London

Online Resources:  
Current legal issues are included on Kennedy’s internet site, http://www.Kennedys-law.com  

Department of Health and Statutory References

  Mental Capacity Act 2005 Code of Practice  
  Model consent policy, Department of Health.

Consent - what you have a right to expect, July 2001 (leaflet for patients, with versions for adults, children/young, people with learning difficulties, parents and relatives and carers)

Seeking consent: working with children, November 2001

Seeking consent: working with older people, November 2001

Seeking consent; working with people with learning difficulties, November 2001.

General Medical Council guidance - “Seeking Patients’ Consent the Ethical Considerations”

12 key points on consent law in England


http://www.cherri.mvm.ed.ac.uk/cherri.pdf

http://www.gmc-uk.org/guidance/ethical_guidance/making_audiovisual.asp
APPENDIX C: DELEGATION OF CONSENT TAKING

Note 1: This Appendix relates only to primary consent taking. Subsequent confirmation of consent prior to the procedure can be undertaken by any appropriate healthcare professional without recourse to this procedure.

1. INTRODUCTION

The most appropriate person to take written consent for treatment is normally the clinician undertaking the procedure, or another clinician who is also competent to undertake the procedure and aware of any clinical or other factors which may be relevant to that patient.

Under certain circumstances, the role of consent taker can also be delegated to other clinical staff who are not themselves competent to undertake the procedure. This appendix sets out the training and assessment that must take place before any such delegation may take place.

It is the responsibility of the consultant delegating consent to satisfy himself/herself that the necessary criteria have all been met, before delegating consent to a healthcare professional who is not personally competent to undertake the procedure.

2. PROCESS

Authority to take consent may be delegated to a clinician not capable of performing the procedure as follows.

a) A Consultant capable of performing the procedure identifies the clinician(s) to whom consent taking for the procedure might be delegated.

b) The Consultant assures him/herself that the clinician(s) concerned have received the necessary generic and procedure specific training to take consent for the procedure identified. This assurance may be gained from review of individual training records (generic consent training is delivered at Induction and procedure-specific training is sometimes delivered as part of local induction programmes) or by personally delivering or arranging the training.

c) The Consultant assures him/herself that the clinician(s) concerned have the necessary skills to undertake the consent taking for the identified procedure. This assurance may be gained by direct supervision of the clinicians concerned or by referral to other supervising clinicians.

d) The Consultant confirms the above, by recording on the Trust consent database the names of the clinicians concerned and the procedure for which they have been delegated to take consent. (The database forms part of the Trust Governance Warehouse. Contact the Legal Services Managers for further details).

e) On completion of all the above, any clinician who is undertaking the procedure may delegate the clinicians concerned to take consent for that procedure. It is the responsibility of the delegating clinician to assure him/herself that the authority to delegate to that clinician for that procedure, is recorded on the Trust database.
APPENDIX D: QUESTIONS FOR THE CLINICIAN TO CONSIDER WHEN ASSESSING CAPACITY AND SEEKING CONSENT

(a note of the discussion leading to a conclusion on these matters should be recorded in the patient’s healthcare record. Staff are encouraged to use the form ‘Gillick Competency Assessment for under 16s including Fraser Guidelines’ to document this process in any case which involves sensitive issues.)

All patients
In your professional judgement, does the patient:

- **understand** adequately what the treatment and any examination will involve?
- **understand** adequately the risks and benefits of the treatment?
- **understand** adequately the implications of not having the treatment?
- **appreciate and give consideration** to any available alternatives?
- **understand** the practical effects of having, or not having, the treatment?
- Can they **retain** the information provided for long enough to reach a decision?
- Can they **communicate** their decision and the reasons for it?
- Can they **weigh up** one aspect of the situation against another?
- Can they **explain** their understanding of the implications?
- Is this a **rational** decision based on their own religious belief or value system?
- Is their decision made based on a perception of reality?

Additional considerations in relation to safeguarding adults and children
Note: safeguarding concerns may arise whether or not the patient has capacity. Safeguarding issues are particularly likely to arise during the consent process where:

**Adult patients**
- An adult patient lacks capacity and has no involved carers/family or there are concerns about the carers
- A vulnerable adult is refusing consent to necessary treatment

**Child patients**
- Consent relates to a sexually active child (eg abortion, contraception)
- A child is seeking to exclude parents from the consent process
- The parent is seeking to exclude a possibly capable child from the consent process
- The child or the parent is withholding consent to a necessary procedure
- There appears to be significant disagreement between the child and the parents about whether consent should be given.

Additional considerations in relation to patients under 18

**Age**
- Children aged 16 and over are normally presumed to be capable, unless special circumstances indicate otherwise.
- Younger children may have capacity, but more detailed assessment and documentation may be required to establish this.

**Independence**
Does the child express a clear personal view, as distinct from repeating what someone else thinks they should do?

Are they consistent in their views, rather than constantly changing their mind?

Are you confident they are not being coerced or pressured by someone else?

**Parental involvement**

Does the child refuse to involve their parents or refuse to allow you to do so?

If so, why do they not want parents involved?

If so, is it in their best interest to have treatment without parental consent?

If the child or the parent is refusing consent, is the child’s physical or mental health likely to suffer without treatment?
APPENDIX E: CHANGE LOG

This should be included for all updated policies, summarising the changes between the current and previous version. (Earlier changes should be deleted from the list when the policy is updated.)

Do not list minor and stylistic changes or changes which do not alter the processes described.

If the update includes a significant reorganisation of the material, indicate this and list the main areas where the process itself has changed.

<table>
<thead>
<tr>
<th>Change Log – Policy Name</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Substantive changes since previous version</strong></td>
</tr>
<tr>
<td>June 2014 Removal of detailed material relating to patients who lack capacity to consent</td>
</tr>
<tr>
<td>June 2014 Update of contacts and structures</td>
</tr>
<tr>
<td>January 2016 Update in relation to patients without capacity – material now included in Safeguarding Adults Policy</td>
</tr>
<tr>
<td>January 2016 Update to include revision of Form 4</td>
</tr>
<tr>
<td>Clarification of arrangements for pre-printed procedure specific forms, and transfer of responsibility, under some circumstances, to CAGs.</td>
</tr>
</tbody>
</table>

APPENDIX F: IMPACT ASSESSMENTS

Equalities impact checklist - must be completed for all new policies

Organisational impact checklist - must be completed for all new policies