Maidstone and Tunbridge Wells NHS Trust

Ref: FOI/GS/ID 4296

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03 November 2017

Freedom of Information Act 2000

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to consent.

1. In the past 5 years how many complaints have you had regarding communication with or supplying information to patients (written and oral)?
2. In the past 5 years how many complaints have you had regarding the inappropriate or incorrect taking of consent?
3. If the level of detail in questions 1 and 2 is unknown then please say how many complaints have you had in the past 5 years categorised as communication complaints?
4. In the past 5 years how many claims for compensation have you had involving the inappropriate or incorrect taking of consent?
5. If the level of detail in question 4 is unknown please say how many claims for compensation have you had categorised as communication claims?
6. How much did you pay the NHSLA for insurance last year?
7. Can I have a copy of your Consent to Examination or Treatment Policy?
8. If no Consent to Examination or Treatment Policy exists then can you supply me with your approved documented process for obtaining consent, as specified in the NHSLA Risk Management Standards 2013-14?
9. Can you tell me how information is provided to patients to support their decision making, including risks, benefits and alternatives where appropriate?
10. Can you tell me how the discussion and provision of information to patients is recorded?
11. Can you tell me the process for recording that consent has been given?
12. Can you tell me how your organisation monitors compliance with points 9 to 11?
13. Who has overall responsibility for your Consent to Examination or Treatment Policy? (There name would helpful)?
1. We do not have a specific sub-subject code entitled ‘communication with or supplying information to patients’ to allow the Trust to provide this information.
2. We have received 26 complaints relating to ‘formal consent to treat not being obtained’.
3.846 complaints were received between 1/10/12 and 30/9/17 where concerns were raised under our category of communication.

4. 8 claims solely relating to uninformed consent.
5. Please see response to Q4
6. The total paid to NHS litigation Authority (NHSR) for 17/18 is £20,864,926
7. Please note: The Trust Legal team have been reviewing the Policy that although has a date of review that has passed according to our Policy for Policies it still remains valid and applicable.

MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST

Policy and Procedure for Consent to Examination or Treatment

Requested/ Required by:	Quality and Safety Committee
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Directorate:	Corporate
Specialty:	Quality and Governance
Supersedes:	Policy and Procedure Document for Consent to Examination or Treatment (Version 4.0: November 2011) Policy and Procedure Document for Consent to Examination or Treatment (Version 4.1: February 2014)
Approved by:	Standards Committee, 14th February 2014 (agreed extension of review date to 1st June 2014)
Ratified by:	Policy Ratification Committee, 9th October 2014
Review date:	October 2016 (or sooner if new guidance issued)

Document history

Requirement for document:	• DH Guidance • GMC Guidance • Care Quality Commission Standards: Outcome 2

	• NICE Guidance • To reduce risks associated with consent which is either not sought or is sought inappropriately and the effect that this has on patients concerned and effects of litigation on staff and the Trust.
Cross references:	• DH model policy for Consent • DH reference guide to Consent for Examination or Treatment • The Human Tissue Act (2004). London: The Stationery Office • Human Tissue Authority (2014) *Codes of Practice. Code 1 – Consent.* www.hta.gov.uk Human Tissue & Embryology Authority (Oct 2013). *Code of Practice 8 – Infertility and Consent* . www.hfea.gov.uk/code • Every Child Matters: Change for Children in Health Services • *Mental Capacity Act* (2005) - Code of Practice (2013) • *Mental Health Act* (1983) – Code of Practice (2008) • *The Health and Social Care Act* (2008). London: The Stationery Office. • Department of Health. (2001). *Consent What You Have a Right to Expect - Children & Young People.* London: Department of Health. • Department of Health. (2001). *Consent: What You Have a Right to Expect - A Guide for Adults*. London: Department of Health. • Department of Health. (2001). *Consent: What You Have a Right to Expect - A Guide for Parents*. London: Department of Health. • Department of Health. (2001). *Consent: What You Have a Right to Expect - a guide for relatives and carers*. London: Department of Health. • Department of Health. (2001). *Good Practice in Consent Implementation Guide*. London: Department of Health. • Department of Health. (2001). *Reference Guide to Consent for Examination or Treatment*. London: Department of Health. • Department of Health. (2001). *Seeking Consent: Working with Children*. London: Department of Health. • Department of Health. (2001). *Seeking Consent: Working with Older People.* London: Department of Health. • Department of Health. (2002). *Consent: What You Have a Right to Expect - Taking Blood Specimens.* London: Department of Health. • Department of Health. (2003). *Toolkit for Producing Patient Information.* London: Department of Health. • Department of Health. (2004). *Better information, better choices, better health: Putting information at the centre of health.* London: Department of Health. • Department of Health. (2009). *Information to assist in amending consent forms*. London: Department of Health. • Department of Health. (2010). *The NHS Constitution: The NHS belongs to us all.* London: Department of Health. • General Medical Council. (2008). *Consent: Patients and Doctors Making Decisions Together.* London: General Medical Council. • NMC Regulation in Practice (2008) & Midwives Rules and Standards 2012

	• NHS Executive. (2003). *Good Practice in Consent - Achieving the NHS Plan Commitment to Patient-centred Consent Practice*. London: Department of Health. • Department of Health (2009). *Reference Guide to Consent for examination or treatment: Second edition.* Department of Health • Nice Guidelines: CG3; 55; 132; 135 • NICE *Consent- Procedures for which the benefits and risks are uncertain(2003)*
Associated documents:	• Maidstone and Tunbridge Wells NHS Trust. *Patient Information Policy and Procedure, Development & Production of Written* [RWF-OPPPCS-NC-CG28] • Maidstone and Tunbridge Wells NHS Trust. *Mental Capacity Act and Deprivation of Liberty Safeguards Policy and Procedure* [RWF-OPPPCS-C-NUR1] • Maidstone and Tunbridge Wells NHS Trust: *Blood Transfusion Policy and Procedure* [RWF-OPPPCSS-C-PATH1] • Maidstone and Tunbridge Wells NHS Trust. *Supervision Policy and Procedure, Medical Staff Clinical* [RWF-OPPPCS-NC-WF21] • Maidstone and Tunbridge Wells NHS Trust. *Patient Photographic and Video Recording Policy and Procedure* [RWF-OPPPCS-NC-CG8] and [RWF-OPPPCS-NC-CG9]

Version Control:		
Issue:	**Description of changes:**	**Date:**
1.0	Policy and procedure documents	November 2005
2.0	Policy and procedure split process for assessing competency to take consent strengthened	April 2007
3.0	April 2007 policy updated to incorporate subsequent changes to MCA 2005 following MHA 2007 and new guidance from HTA and to incorporate DH revision guidance.	November 2009
3.1	Clarification on training for specific procedures.	December 2009
4.0	Inclusion of consent process relating to Children and young persons and new consent form for chemotherapy	November 2011
4.1	Standards Committee (14th February 2014) agreed to extend review date to 1st June 2014	February 2014
5.0	Reviewed following advice from Trust solicitors; key changes include update of source references, inclusion of reference to Cheshire West (2014), amendment to Consent 4 for people lacking capacity to consent to treatment, amendment to consent form 7 for people refusing treatment with blood or blood products (previously known as Jehovah's Witnesses), updating of monitoring process	September 2014
5.1	Appendix 5I added (consent form 9)	October 2014

Policy statement for

Consent to Examination or Treatment

Consent is an essential element in all aspects of care and treatment and ensuring high standards of practice remains a key aim. The Department of Health is reviewing the consenting process to identify and evaluate the NHS approach and practice of gaining consent and how quality for consent may be best developed, enhanced and embedded across the NHS. This policy is based on current practice, will be reviewed and amended as guidance and recommendations are released.

Principles of consent

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

The following additional policy statements are related to written consent and must be followed at all times:

1. Initiating the written consent process

- Where possible, the consent process should be started at the point in time that a patient is listed or offered a procedure. Consent must be sought at the earliest opportunity in order to give patients time to make their decision. The consent process for planned procedures should be started at least two weeks before the procedure. For particular circumstances where this is difficult see point 4 below:
- Patients should be provided with information about the procedure and given a copy of the consent form signed by the clinician. This consent form must outline on the form or in the written information provided (and noted as being given on the consent form) the risks, benefits and alternative options of the procedure.
- Consideration should be given to where and how patients can seek further advice or information if they have questions, particularly if they will not be attending a pre assessment clinic. Information on how to access further information should be on all written information leaflets given to the patient.

4. Consent for specific processes

- Consent should be sought for **hospital post mortems** from the relatives/next of kin of the patient by the patient's consultant or equivalent grade, using specific forms available from the mortuary service.
- Consent for all **photography and digital recording** of patients must be recorded using the photography consent form following the *Patient Photographic and Video Recording Policy and Procedure*
- Consent for patients involved in research projects must comply with this policy and procedure and be compliant with research protocols.

Procedure for Consent to Examination or Treatment

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1.0 Introduction and scope

What consent is – and isn't

1.1 "Consent" is a patient's agreement for a health professional to provide care. Consent may be implied (for example by presenting their arm for their pulse to be taken), given verbally or in writing. For the consent to be valid, the patient must:

- be competent to take the particular decision (*have capacity*)
- have received sufficient information to take the decision, (*fully informed*) and
- be free from external duress

1.2 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 make a choice. 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.

1.3 In situations where an adult's capacity has been assessed following the Mental Capacity Act 2007 Code of Practice guidance and deemed to lack the ability to consent to the specific treatment/care being offered (either temporarily or permanently), no other person can consent on their behalf unless appointed under a Lasting Power of Attorney for health and welfare - (see the Mental Capacity Act Code of Practice (MCA Code of Practice)**. This must be evidenced to the treating clinician by way of a signed and registered document from the Office of the Public Guardian.**

In emergency (life-threatening) situations however, treatment may be given if it is in the patient's best interests, as long as it has not been refused in advance in the form of a valid and applicable Advance Decision to Refuse Treatment (ADRT-

MCA Code of Practice) (formerly known as an Advance Directive/Living Will).

Patients lacking capacity may also be in a situation where they cannot "consent" to remaining in hospital in order to receive care and treatment. It is possible in these circumstances that the Deprivation of Liberty Safeguards (DoLS) under the Mental Capacity Act can apply. Consideration should be given following the Supreme Court judgement 2014 (Cheshire West), which could include any patient over whom the health care professional has BOTH continuous supervision and complete control, and they would be stopped from leaving hospital Advice should be sought from the Safeguarding Adults Matron and/or the Legal Team:- You must follow the MCA and DoLS Code of Practice and make relevant applications where patients need to have their liberty taken away in their own best interests to protect them from harm. See Trust guidance available on the Q-Pulse via the Trust intranet.

Guidance on consent

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

- **Reference guide to consent for examination or treatment** provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies are available on the Internet.
- **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 4**.
- Specific guidance, incorporating both the law and good practice advice, is available for health professionals working with children, with people with learning disabilities and with older people. Copies of this are available on the Internet.
- Where there is any element of doubt, advice must be sought from the Legal Services team or from the on-call manager if out of hours

2.0 Definitions

- **Advance Decision to Refuse Treatment:** (ADRT) a decision to refuse specified treatment made in advance by a person who has

the capacity to do so. This decision will then apply at a future time when the person lacks the capacity to consent to or refuse, the specified treatment (*Section 24(1) Mental Capacity Act 2005 Code of Practice*) Specific rules apply to decisions made in relation to life-sustaining treatment.

- **Best Interest:** Any decision made or anything done for a person who lacks capacity to make specific decisions, must be in the person's best interest. There are standard minimum steps to follow when working out someone's best interest. These are set out in Section 4 of the Mental Capacity Act and in the non-exhaustive checklist section 5.13**.Capacity:** the ability to make a decision about a specific matter at the time the decision needs to be made. The legal definition of a person who lacks capacity can be found in Section 2 of the Mental Capacity Act.
- **Consent:** an affirmation or agreement to proceed (in healthcare relating to treatment)
- **Decision-maker:** A person who may be required to make decisions or act on behalf of someone who lacks capacity.
- **Deprivation of Liberty Safeguards (DoLS):** Term used in the European Convention on Human Rights about the circumstances when a person's freedom is taken away and the Safeguards that need to be put into place when this occurs
- **Donor:** A person who makes a Lasting Power of Attorney
- **Lasting Power of Attorney for (health and welfare or property and financial Affairs):** Two types of Power of Attorney created under the Mental Capacity Act 2005 *(section 9(1))* appointing person or persons known as attorneys to make decisions about the donor's personal welfare (including healthcare) and/or deal with the donor's property and financial affairs
- **IMCA:** Independent Mental Capacity Advocate. An individual who provides support and representation for a person who lacks capacity to make specific decisions, where the person has no-one else to support them – *(section 35 Mental Capacity Act 2005)*
- **Office of the Public Guardian:** The Public Guardian is an officer established under section 57 of the Mental Capacity Act. The Public Guardian is supported by the Office of the Public Guardian which will supervise deputies, keep a register of deputies, lasting powers of attorney, enduring powers of attorney, and check on what attorneys are doing and investigate complaints about attorneys or deputies. This replaces the public guardianship office previously in existence.
- **Risk:** 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'.
- **Unbefriended:** a person who has no-one else to support them and who lacks the capacity to make specific decisions.

3.0 Duties

Who is responsible for seeking consent?

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

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

3.3 Competency of staff taking consent, who are unable to carry out the procedure (delegated consent) must be assessed by the relevant consultant or clinical lead and will be specific to the type of procedures and regularly audited.

Medical staff competency should be assessed in line with the Trust *Medical Staff Clinical Supervision Policy and Procedure*. A record of medical staff competency for consent for specific procedures will be maintained by the directorate and will be subject to regular audit.

Nursing staff competency must be recorded on the *Consent Competency Assessment form* **(Appendix 9).**

3.4 Clinical teams should ensure that they have arranged their working practices so that the staff taking consent either undertake the procedure, or are trained to take procedure specific consent and have been appropriately assessed as competent.

Documentation – recording consent:

3.5 The standard consent form includes space for a health professional to provide information to patients and to sign confirming that they have done so.

3.6 The health care professional obtaining consent must document in the health care records, any discussions had relating to consent, including the risks and benefits and alternatives discussed. This should also include the response to any questions the patient has asked.

3.7 The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit. Any additional conversations with the patient/and relatives should be documented in the medical records.

3.8 If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead, that their

circumstances have not changed and that any further questions have been answered. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves

3.9 In cases where verbal or implied consent is taken, all possible measures must be undertaken to ensure that this is documented within the medical records to include conversations regarding risks. Evidence of patient information leaflets can be added to the healthcare records or the consent form itself (see section 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.

3.10 Responsibility of health professionals

It is a health professional's own responsibility:

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

If you feel that you are being pressurised to seek consent when you do not feel competent to do so you should contact the relevant Clinical Director in the first instance.

4.0 Training / competency requirements

- Generic training on consent will be given to all doctors in training as part of their induction process.
- Generic Training in relation to consent is mandatory for all staff responsible for obtaining consent or involved in the process. This is delivered by way of e-learning (part of the safeguarding adults level 2 e-learning package) and should be undertaken every three years. This information will be held on the Learning and Development data base.
- Health professionals with delegated authority to consent to specific procedures will undergo individual training via the lead clinician/delegated directorate trainer. Assurance must be obtained in relation to competency (see **Appendix 9**). This must be regularly audited to ensure compliance.

5.0 Process for obtaining consent

Process for documenting

For significant procedures, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient's healthcare records if necessary), or through documenting in the patient's healthcare records that they have given verbal or implied consent. Those patients deemed to lack capacity through appropriate and documented assessment of capacity may require the intervention of an IMCA (advocate) or inclusion of a relative. It is important to remember to discuss Lasting Power of Attorneys and Advance Decisions to Refuse Treatment. This should also be documented within the medical records.

5.1 Written consent

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

5.2 It is rarely a legal requirement to seek written consent,[1] but it is good practice to do so if any of the following circumstances apply:

- the treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications')
- the procedure involves general/regional anaesthesia or sedation
- providing clinical care is not the primary purpose of the procedure
- 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

5.3 Completed forms should be kept with the patient's healthcare records. 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 form should be handed to the patient.

[1.] The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances.

Table 1: Examples of procedures where written consent is required

	Circumstances where any of the following occur, consent must be sought	Indicative examples
1.	the treatment or procedure is complex, or involves significant risks	Angioplasty Spinal Analgesia/ Pain control
2.	the procedure involves general/regional anaesthesia or sedation	Endoscopy Manipulation Under Anaesthesia Hip Replacement
3.	providing clinical care is not the primary purpose of the procedure	Bone marrow donation
4.	there may be significant consequences for the patient's employment, social or personal life and well-being	Vasectomy
5.	the treatment is part of a project or programme of research approved by this Trust	Any invasive procedure or treatment where risks and benefits are under review. Consent is specific to the trial. Please refer to the Research Policy for further guidance or the Clinical Audit and Research Team.

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

5.4 Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented on **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 Mental Capacity Act 2005 (MCA) procedural code will apply in relation to the test for capacity and steps to be taken in making best interest decisions (see MCA Code of Practice). The other Trust approved consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, MCA assessment and relevant information should be entered in the patient's healthcare records.

5.5 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. The patient's wishes should be taken into account and close friends, relatives or advocates consulted.

5.6 Occasionally, having followed the steps set out under the MCA, there may not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. If after undertaking a best interest meeting with the patient/patient's representatives and all relevant healthcare professionals, a consensus is not reached and the treatment is potentially serious, a court declaration may be sought. If a serious deterioration in condition or loss of life is imminent it is lawful to take appropriate steps to sustain life pending a Court decision. In urgent situations legal guidance can be obtained through the Patient Safety /Legal Department or out of hours through the Trust's solicitors by contacting the Executive on Call. Further advice can also be gained from the Matron for Safeguarding Adults

Availability of forms

5.7 Standard consent forms and forms for adults who are unable to consent for themselves are reproduced as examples in this Procedure. Carbonated forms for use are available through stationery purchase – non-carbonated forms for photography or removal of products of conception can be downloaded from the intranet. There are four versions of the DH standard consent form:

5.8 **Form 1** for adults or competent children

5.9 **Form 2** for parental consent for a child or young person

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

5.11 **Form 4** as described above for patients lacking capacity. (this now includes the assessment of mental capacity as Consent Form 4 should not be used without the required assessment being documented) All forms are available via the Trust Policies and Procedures database (Q-Pulse)

WHEN SHOULD CONSENT BE SOUGHT?

5.12 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.

Single stage process

5.13 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 verbally. An example would be if a patient attends an outpatient clinic and requires an intimate examination or blood test, verbal consent should be obtained and documented.

5.14 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. In all cases the individual's circumstances should be taken into account.

Two or more stage process

5.15 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 have at least two stages: the first being the provision of information, discussion of options and initial (verbal) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

5.16 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?"

5.17 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.

Seeking consent for anaesthesia

5.18 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 to genuinely 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 healthcare record 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.

5.19 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.

Emergencies

5.20 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 healthcare records to document any discussion and the patient's consent, rather than using a form. The urgency of

the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

5.21 In an emergency if a patient is unconscious or unable to give consent for other reasons and because of the urgency of the situation the procedure needs to be undertaken speedily the clinician can proceed in the 'best interests' of the patient. Remember that if the patient has written a valid Advanced Decision to Refuse Treatment or appointed a Lasting Power of Attorney for Personal Welfare then these must be taken into consideration if they are relevant to the circumstances (e.g. a Jehovah's Witnesses might have a valid Advanced Decision regarding advanced blood transfusion refusal).

Treatment of children and young people

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults. For the purposes of this guidance 'children' refers to people aged below 16 and 'young people' refers to people aged 16–17.

Young people aged 16–17

5.22 By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent will be valid only if it is given voluntarily by an appropriately informed young person 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

5.23 Section 8 of the Family Law Reform Act 1969 applies only to the young person's own treatment. It does not apply to an intervention that is not potentially of direct health benefit to the young person, such as blood donation or non-therapeutic research on the causes of a disorder. However, a young person may be able to consent to such an intervention under the standard of Gillick competence, considered below.

5.24 In order to establish whether a young person aged 16 or 17 has the capacity to consent to the proposed intervention, the same criteria as for adults should be used). If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of, the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over. If however they are unable to make the decision for some other reason, for example because they are overwhelmed by the implications of the decision, then the Act will not apply to them and the legality of any treatment should be assessed under common law principles. It may be unclear whether a young person lacks capacity within the meaning of the Act. In those

circumstances, it would be prudent to seek a declaration from the court.

5.25 If the 16/17year-old is capable of giving valid consent then it is not legally necessary to obtain consent from a person with parental responsibility for the young person in addition to the consent of the young person. It is, however, good practice to involve the young person's family in the decision-making process – unless the young person specifically wishes to exclude them – if the young person consents to their information being shared.

Children under 16 – the concept of Gillick competence

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

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

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

5.29 If the child is Gillick competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child's family in the decision-making process, if the child consents to their information being shared.

5.30 Where advice or treatment relates to contraception, or the child's sexual or reproductive health, the healthcare professional should try to persuade the child to inform his or her parent(s), or allow the medical professional to do so. If however the child cannot be persuaded, advice and/or treatment should still be given if the healthcare professional considers that the child is very likely to begin or continue to have sexual intercourse with or without advice or treatment, and that unless they receive the advice or treatment then the child's physical or mental health is likely to suffer.

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

5.32 Although a child or young person may have the capacity to give consent, this is only valid if it is given voluntarily. This requirement must be considered carefully. Children and young people may be subject to undue influence by their parent(s), other carers or a sexual partner (current or potential), and it is important to establish that the decision is that of the individual him or herself.

Child or young person with capacity refusing treatment

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

5.34 In the case of *Re W (a minor) (medical treatment),* the court stated that it has jurisdiction to override a refusal of a child/young person, at least where they seek to refuse treatment in circumstances that will, in all probability, lead to the death of the child/young person or to severe permanent injury; or where there is a serious and imminent risk that the child/young person will suffer grave and irreversible mental or physical harm.

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

Where the treatment involved is for mental disorder, consideration should be given to using mental health legislation.

5.36 The changes made to section 131 of the Mental Health Act 1983 by section 43 of the Mental Health Act 2007 mean that when a young person of 16 or 17 has capacity (as defined in the Mental Capacity Act 2005) and does not consent to admission for treatment for mental disorder (either because they are overwhelmed, do not want to consent or refuse to consent), they cannot then be admitted informally on the basis of the consent of a person with parental responsibility (see chapter 36 of the Code of Practice to the Mental Health Act 1983, as amended 2008).

5.37 A life-threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the person with parental responsibility refuses consent despite such emergency treatment appearing to be in the

best interests of the child. In such cases the courts have stated that doubt should be resolved in favour of the preservation of life, and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health.

5.38 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. This should be documented in the medical records for all health care professionals to be made aware.

5.39 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, 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.(advice can be sought from Legal Services Department)

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

- the child's mother
- the child's father, if he was married to the mother at the time of birth
- unmarried fathers, who can acquire parental responsibility in several different ways:
  - for children born **before** 1 December 2003, unmarried fathers will have parental responsibility if they: marry the mother of their child or obtain a parental responsibility order from the court; register a parental responsibility agreement with the court or by an application to court
  - for children born after 1 December 2003, unmarried fathers will have parental responsibility if they: { register the child's birth jointly with the mother at the time of birth; re-register the birth if they are the natural father; marry the mother of their child or obtain a parental responsibility order from the court ; register with the court for parental responsibility.
- 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

In order for the person with parental responsibility to be able to consent, they must have capacity themselves.

PROVISION AND ARCHIVING OF INFORMATION

5.41 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, benefits and alternative options (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.

5.42 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.

5.43 Wherever possible, and for all high volume or high risk procedures, Healthcare Professionals should ensure that they have available Trust approved patient information leaflets. Trust patient information leaflets are developed following a template and procedure set out in the Trust's **Patient Information Policy and Procedure, Development & Production of Written**, published on the Trust Intranet (Q-Pulse). This template and procedure ensures that all Trust patient information leaflets contain information regarding risks, benefits and alternatives options where appropriate, and also information about what will happen, where to go, how long they will be in hospital, how they will feel afterwards and so on.

Trust leaflets will enable the clinician to provide high quality information. Available approved leaflets are published on the Trust intranet – Guidelines / Information; these can be downloaded and printed as required and some are available from central stock. Please contact the Clinical Governance Assistant if you are unsure how to obtain stock. A note of which patient information leaflet is given should be written on the consent form or documented in the medical records. Version control is maintained electronically. See the Trust's **Patient Information Policy and Procedure, Development & Production of Written**, published on the Trust Intranet (Q-Pulse).

5.44 **Archiving of patient information leaflets:** When a new version of a patient information leaflet is published on the Trust intranet document publishing software the Clinical Governance Assistant will archive any existing copy. The dates of publication and archiving are recorded on a **Leaflet Progress Sheet**, as is the location of the leaflet on the Trust intranet, and in the archive. Please also **Patient Information Policy and Procedure, Development & Production of Written.**

Provision for patients whose first language is not English

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

- The Trust has a language bank of staff with foreign languages, including sign language. For details contact your department head, PALS or the HR department. An interpreter service may also be used.

Access to health professionals between formal appointments

5.46 After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they take their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice). A contact and contact number should be inserted in the consent form. Please check with your head of department for details.

Open access clinics/One Stop Clinic

5.47 Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. Trust healthcare professionals treating patients under a direct access scheme should ensure that all referring clinicians such as GPs are aware of the need to inform and prepare patients for the appointment. Hospital staff should support referring healthcare professionals to do this by providing information leaflets for them to give or by providing patients with information prior to their appointment. It is the responsibility of the Healthcare Professional undertaking the procedure to ensure and document that patients have had sufficient time and information to give informed consent.

REFUSAL OF TREATMENT

5.48 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*. A patient who is sectioned or detained under the MHA may still have capacity to consent to treatment or to refuse treatment for physical illness and will need to be assessed and managed under the provisions of the MCA 2005. Chapter 13 of the MCA Code of Practice contains further guidance. 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.

5.49 If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their healthcare records. 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.

5.50 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.

5.51 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.

If you have concerns for the patient's wellbeing as a result of refusal of care, you should escalate this. Legal advice may be required in certain circumstances (e.g. anorexia and refusal of nutrition).

USE OF TISSUE

5.52 The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all. At present, this Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes. Patient can object to particular uses or the removal of particular tissues in writing on this form. If they choose to object, a copy of the consent for should be sent with the request form and

specimen to the laboratory to ensure compliance with the patient's wishes. A register of such patients and their specimens will be kept in the pathology department and computer records and reports will record the objection. (*Also see Human Tissue Authority requirements under HTA licence see 5.68)*

5.53 Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but the opt-out policy above applies.

5.54 Tissue samples may be used for quality assurance purposes without requiring specific patient consent *provided* there is an active policy of informing patients of such use. This is essential to ensure the high quality of service, which all patients have the right to expect. Samples of tissue used in this way are always anonymised.

CLINICAL PHOTOGRAPHY AND CONVENTIONAL OR DIGITAL VIDEO RECORDINGS

5.55 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.

5.56 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 5.57** 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.

5.57 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.

5.58 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. You may use **Form 5**, in addition to the relevant standard consent for to do so. 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.

5.59 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.

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

5.61 For further details consult the Trust policy on Patient Photographic and Video Recording.

5.62 In some circumstances such as when safeguarding concerns are raised photographic evidence of injuries, and /or bodily condition may be required to assist in a safeguarding investigation. Where this is the case if the patient has mental capacity and can consent to this, their consent should be gained and documented. If they do not have mental capacity to consent for photographs to be taken it will need to be decided what is in their best interest. You must document your rationale for this. (Seek advice from the Legal Services Department or the Matron for Safeguarding Adults, or Head of Information Governance.)

CONSENT FOR POST MORTEM EXAMINATION

5.63 The Trust endorses both the Department of Health code of practice ‘Families and post mortems’ (DH 2003): http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_4080449

(for further information or guidance related to post mortems this document should be consulted), and the Human Tissue Authority “Code of Practice – Consent July 2009 (Directive 002/2009)”

5.64 No hospital post mortem examination should be undertaken without valid consent of the family or those close to the deceased. Consent forms for post mortem are available from the Mortuary. (See additional guidance **Appendix 11**.)

5.65 Consultants should have a thorough knowledge of the purpose and procedure for post mortem examination, and the management of bereavement, before seeking consent. Specific training and guidance is available through an e-learning package and should be identified as part of Consultant appraisal.

5.66 Consent for post mortem should usually be sought by the consultant responsible for the care of the patient, who knows the medical problems and unresolved aspects that merit investigation. Consultants with limited experience of the post mortem procedure should seek the support of a Consultant with greater knowledge. The Designated Individual (HTA) for the Trust may also be contacted.

5.67 Careful judgement is needed as to the most appropriate person to give consent. The HTA Code of Practice – Consent gives details of appropriate persons able to give consent. Identifying who is most appropriate to give consent is not straightforward and staff should not make assumptions.

5.68 Consent to post mortem is separate to consent for retention of tissues or organs and relatives should be supported to make individual decisions about both issues.

5.69 In the unusual event that tissue is required to be stored or used for anatomical examination or public display, recommendations of the Human Tissue Act Codes of Practice must be followed at all times. www.hta.gov.uk/guidance/codes_of_practice.cfm

6.0 Monitoring and audit

6.1 Monitoring

- An annual clinical audit of this policy, across all specialties will take place, with a 6 monthly spot check of patient notes to scrutinise compliance with this policy in more depth will be undertaken.
- The Clinical Audit Team (working in conjunction with the Trust legal department and the clinical lead for consent) will co-ordinate the annual and spot check audits.
- **Archiving arrangements for information given to patients**

  The dates of publication and archiving are recorded on the **Leaflet Progress Sheet**, as is the location of the leaflet on the Trust intranet, and in the archive. Please also see bullet point B for details of reporting to committee and **Patient Information Policy and Procedure, Development & Production of Written.**

A 6 monthly report, based on the findings of the audits, will be compiled by the Policy lead in conjunction with the Patient Safety and Legal Manager and submitted to the Standards Committee. The report will include any shortfalls or deficiencies and will make recommendations with necessary actions plans to address them. Good practice will also be shared across the organisation.

APPENDIX ONE

Process requirements

1.0 Implementation and awareness

Electronic circulation – September 2014

- Once approved the document lead or author will submit this policy/procedural document to the Clinical Governance Assistant who will activate it on the Trust approved document management database on the intranet, under 'Trust polices, procedures and leaflets'.
- A monthly publications table is produced by the Clinical Governance Assistant which is published on the Trust intranet under "Policies"; notification of the posting is included on the intranet "News Feed" and in the Chief Executive's newsletter.
- On reading of the news feed notification all managers should ensure that their staff members are aware of the new publications.

In addition:

- The approved document should be cascaded through the Directorates to all staff by the Clinical Directors, ADN's and matrons.
- The policy and procedures should be discussed at the junior doctors' induction programme to raise awareness.
- Directorate will identify any additional training needs and request appropriate training.
- Generic training to be delivered to all nurses and doctors on induction.

2.0 Review

The policy and procedure will be reviewed informally following each annual audit to ensure that the process is being followed. Appropriate actions plans will dictate future change prior to the formal review after two years. Should any changes in legislation arise or be implemented at any time, immediate review of the policy should be undertaken.

3.0 Archiving

The Trust intranet (Q-Pulse) retains all superseded files in an archive directory in order to maintain document history.

APPENDIX TWO

CONSULTATION ON: Policy and Procedure for Consent to Examination or Treatment

Consultation process – Use this form to ensure your consultation has been adequate for the purpose.

Please return comments to: Patient Safety and Legal Manager/Deputy Director of Nursing

By date: 6 October 2014

Name: Name:	Date sent	Date reply received	Modification suggested? Y/N	Modification made? Y/N
Chief Executive and Directors	30/9/14	3/9/14	Y	Y
Divisional Directors	30/9/14			
Clinical Leads	30/9/14			
ADO's	30/9/14			
ADNO	30/9/14			
Matrons	30/9/14			
Directorate Risk Lead	30/9/14			
Standards Committee	30/9/14			
Quality and Safety Committee	30/9/14			
Clinical Governance Assistant	30/9/14			
Risk & Compliance Manager	30/9/14			
Ethics Committee	30/9/14			
Head of Quality and Governance	30/9/14	3/9/14	N	N
Head of Learning and Development	30/9/14			
Safeguarding Children Lead	30/9/14			
Matron for Safeguarding Vulnerable Adults	30/9/14	3/9/14	Y	Y
The role of those staff being consulted upon as above is to ensure that they have shared the policy for comments with all staff within their sphere of responsibility who would be able to contribute to the development of the policy.				

APPENDIX THREE

Equality Impact Assessment

In line with race, disability and gender equalities legislation, public bodies like MTW are required to assess and consult on how their policies and practices affect different groups, and to monitor any possible negative impact on equality. The completion of the following Equality Impact Assessment grid is therefore mandatory and should be undertaken as part of the policy development and approval process. Please consult the Equality and Human Rights Policy on the Trust intranet, for details on how to complete the grid. **Please note that completion is mandatory for all policy development exercises. A copy of each Equality Impact Assessment must also be placed on the Trust's intranet.**

Title of Policy or Practice	Policy and Procedure for Consent to Examination or Treatment
What are the aims of the policy or practice?	This policy issues guidance on the process of taking consent, who should undertake it and when. This ensures that patients and relatives are fully informed regarding the risks, benefits and alternative options

	involved in their treatment.
Identify the data and research used to assist the analysis and assessment	Department of Health guidance on Consent for Treatment 2009, GMC guidance on Consent 2008
Analyse and assess the likely impact on equality or potential discrimination with each of the following groups.	Is there an adverse impact or potential discrimination (yes/no). No
Males or Females	No
People of different ages	No
People of different ethnic groups	No
People of different religious beliefs	No
People who do not speak english as a first language	No – interpreters and translations available on request
People who have a physical disability	No
People who have a mental disability	No see Mental Capacity Act
Women who are pregnant or on maternity leave	No
Single parent families	No
People with different sexual orientations	No
People with different work patterns (part time, full time, job share, short term contractors, employed, unemployed)	No
People in deprived areas and people from different socio-economic groups	No
Asylum seekers and refugees	No
Prisoners and people confined to closed institutions, community offenders	No
Carers	No
If you identified potential discrimination is it minimal and justifiable and therefore does not require a stage 2 assessment?	n/a
When will you monitor and review your EqIA?	With the policy and procedure, every two years, or sooner as changes in law or practice dictate.
Where do you plan to publish the results of your Equality Impact Assessment?	As Appendix Three of this policy on the Trust Intranet (Policies and Guidelines).

FURTHER APPENDICES

The following appendices are published as related links to the main policy /procedure on the Trust approved document management database on the intranet (Trust policies, procedures and leaflets):

No.	Title	Unique ID
4	12 key points on consent: the law in England	RWF-OWP-APP32
5	Consent forms in use at Maidstone & Tunbridge Wells NHS Trust	RWF-OWP-APP33
5A	Consent Form 1	RWF-OWP-APP34
5B	Consent Form 2	RWF-OWP-APP35
5C	Consent Form 3	RWF-OWP-APP36
5D	Consent Form 4	RWF-OWP-APP37
5E	Consent Form 5	RWF-OWP-APP38
5F	Consent Form 6	RWF-OWP-APP39
5G	Consent Form 7	RWF-OWP-APP40
5H	Consent Form 8	RWF-OWP-APP41
5I	Consent Form 9 (knee replacement / knee arthroplasty)	RWF-OPF-CS-C-CG3
6	How to seek a court declaration	RWF-OWP-APP42
7	Seeking consent: remembering the patient's perspective	RWF-OWP-APP43
8	Seeking consent: remembering the healthcare professional's perspective	RWF-OWP-APP44
9	Consent competency framework and record sheet	RWF-OWP-APP45
10	Referral to an Independent Mental Capacity Advocacy service (IMCA)	RWF-OWP-APP46
11	Laboratory instructions for obtaining consent forms for a hospital post mortem	RWF-CP-MOR-LI26

8. Please see the response to Q7.
9. Information in a variety of forms. Verbally during consultation and in patient information leaflets. Some consent forms contain specifics relating to the procedure such as chemotherapy and radiotherapy
10. This should be written in the patient's clinical notes at the time of discussion.
11. It is anticipated that initial consultations will detail the nature of condition, potential treatments options. If an intervention/operation is required a consent form will be signed either at pre assessment or prior to the procedure with again the details of risks, benefits and alternatives noted on the form. A copy is placed in the medical records and the patient will be offered a copy as well.
12. This is audited as per the policy by the audit team on an annual basis
13. Trust Medical Director – further details can be found on the Trust website.