CONTROLLED DOCUMENT

University Hospitals Birmingham NHS
NHS Foundation Trust

Consent to Examination or Treatment Policy

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1. Policy Statement

1.1 The purpose of this policy is to ensure that examination and/or treatment of patients only takes place with legal and valid consent or, in appropriate situations, when it is in the patient's best interests.

1.2 All patients have a fundamental legal right to make decisions about what happens to their own body, and it is the responsibility of those healthcare practitioners obtaining consent to ensure they disclose all appropriate information required for patients to make these decisions.

1.3 In many cases, 'obtaining 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.

1.4 Recent legal case law, in addition to longer-standing General Medical Council (GMC) guidance, has underlined both of these principles. A patient's right to bodily autonomy has reinforced the idea of consent as a two-way dialogue and process by which decisions are jointly made. The responsibility of the clinician is to provide guidance and recommendations tailored to the individual to allow them to make their own informed decisions regarding examination or treatment.

1.5 When a person is asked for their consent, information about the proposed care and treatment must be provided in a way that they can understand. This must include information about the risks, complications and any alternatives. A person with the necessary knowledge and understanding of the care and treatment should provide this information so that they can answer any questions about it to help the person consent to it. Patient Information Leaflets may form part of this information.

1.6 Discussions about consent must be held in a way that meets people's communication needs. This may include the use of different formats or languages and may involve others such as a speech language therapist or independent advocate. Consent may be implied and include non-verbal communication such as sign language or by someone rolling up their

sleeve to have their blood pressure taken or offering their hand when asked if they would like help to move.

1.7 Consent must be treated as a process that continues throughout the duration of care and treatment, recognising that it may be withheld and/or withdrawn at any time.

1.8 When a patient or a person acting lawfully on their behalf refuses to give consent or withdraws it, all people providing care and treatment must respect this.

1.9 Where a person lacks mental capacity to make an informed decision, or give consent, staff must act in accordance with the requirements of the Mental Capacity Act 2005 and associated code of practice.

1.10 Consent procedures must make sure that people are not pressured into giving consent and, where possible, plans must be made well in advance to allow time to respond to people's questions and provide adequate information.

1.11 This policy and the associated procedures set out the standards for staff at the Trust taking consent to ensure compliance with relevant guidance and law and meet Trust standards.

1.12 The Department of Health and other professional bodies, such as the GMC, have issued a range of guidance documents on consent, and these should be additionally consulted for details of the law and good practice requirements on consent.

1.13 While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

2. Scope

2.1 This policy applies to all clinical services of the Trust and all clinical staff employed by the Trust including contractors, volunteers, students, locum, bank and agency staff and staff employed on honorary contracts.

2.2 The policy does not cover taking consent for the following:

2.2.1 Consent for photographic images, as detailed in the Trust Photographic and Video Recording Consent and Confidentiality Policy;

2.2.2 Data protection or use of patient records, as detailed in the Trust Information Governance Policy; or

2.2.3 Clinical trials, as detailed in the Trust Research Governance Policy.

2.2.4 Post mortem examination (adult). Relevant only to cases where coronial referral is not indicated, and a medical certificate of the cause of death (MCCD) can be issued (there is an option on the MCCD to indicate information from post mortem may be available subsequently). If there are outstanding questions, either from the treating team or the family, the family can give consent for a post mortem examination (PM or autopsy). It is important to carefully define the questions/reasons for the PM, not all questions can be answered by PM or they may require specific consents. The consent process is governed by the Human Tissue Authority (HTA), post mortem examination can only be performed on HTA licensed premises and consent must be taken in collaboration with a specifically trained individual. Please offer the family the information leaflet ‘information about post mortem examination for relatives’ and contact the pathology department in your Hospital who will have an SOP for the consent process and can provide the post mortem request and consent form, the reasons for the PM/questions to address need to be listed on the first page.

2.3 For perinatal post-mortems, please refer to the Trust Procedure for the Consent to Perinatal Post-mortem Examination.

3. Framework

3.1 This section describes the broad framework for obtaining consent for examination or treatment. Detailed operational instructions and guidance for obtaining consent are contained in the associated Procedures and Guidance for Consent to Examination or Treatment (“the Procedures”). This policy is to be used in conjunction with those Procedures, the Procedure for Consent to Tissue Removal and Post-Mortem Examination,

and other relevant local and national guidance where appropriate.

3.2 The Procedures may be amended by authority of the Chief Medical Officer, provided that such amendments are compliant with this policy.

3.3 If at any point, staff are not clear on the correct process to follow, the Clinical Governance and Patient Safety department can be contacted for advice. If a query is urgent and/or out of hours, the Executive on-call should be contacted for advice.

3.4 The Trust's framework for ensuring full participation in consent involves ensuring the following fundamental standards are always adhered to;

3.4.1 The patient must have capacity to make the decision.

3.4.2 Consent must be given freely, free of coercion or deceit.

3.4.3 The patient must be given sufficient information on which to base their decision to give consent or not.

3.5 In addition, the Trust will also ensure the following occurs:

3.5.1 All staff providing care or treatment to a patient with capacity will first ensure that the patient has freely consented to be examined, or to receive such care or treatment;

3.5.2 Patients who do not have capacity to make decisions are appropriately assessed and the correct processes are followed in accordance with the Mental Capacity Act 2005. See the Mental Capacity and Best Interests Policy for further details;

3.5.3 Only appropriately qualified staff obtain consent; and

3.5.4 The correct type (e.g. oral, written) of consent is obtained for the relevant treatment or procedure.

3.6 There may be exceptions or additional aspects to these standards in certain circumstances, for example, where the patient lacks capacity. These are set out below and additional information is set out in the Procedures.

3.7 The term 'risk' is used throughout this policy to refer to the likelihood of any adverse outcome, including those which some health professionals would describe as 'side-effects' or "complications".

3.8 References to patients' notes in this Policy and associated procedures cover both paper notes and electronic patient noting, as appropriate.

3.9 **Who can obtain consent?**

3.9.1 Any healthcare professional can obtain consent for interventions that they are qualified to do and intend to perform.

3.9.2 Consent refers to the entire process of consent, including confirmation of consent. Any staff confirming consent with a patient must either be capable of performing the procedure or have been formally authorised to obtain delegated consent.

3.9.3 In order to obtain formal written consent, a healthcare professional must either be able to perform that type of procedure themselves (and be able to provide all necessary information and answer any questions) or alternatively have formal delegated authority for obtaining consent. Details of the process for authorising staff to obtain delegated consent are set out in the Procedures.

3.9.4 Foundation Year 1 (FY1) Doctors must not obtain consent for the performance of a procedure or examination by another practitioner. If an FY1 Doctor is being supervised whilst performing a procedure the supervising practitioner must obtain consent. If FY1 Doctors are competent to perform a procedure unsupervised then the FY1 Doctor should obtain consent from the patient and where appropriate this must be evidenced by written consent.

3.10 Who can give consent?

3.10.1 It is important that consent is obtained from a person who is able to give valid consent. In the majority of circumstances, only the patient is able to consent to their own care and treatment. The only exceptions to this are if the patient lacks the capacity to do so, or where the patient is a child under the age of 16. There is a presumption of competence to consent to treatment for any person over the age of 16 (However a young adult (between 16 and 18) may not necessarily be able to refuse treatment).

Children under the age of 16

3.10.2 There is no presumption of competence to consent for treatment for any person under the age of 16.

3.10.3 However, if a child under the age of 16 is deemed competent, they may consent for their own treatment. This is known as Gillick consent or the Gillick test. A child under 16 may not necessarily be able to refuse treatment.

3.10.4 If a child is not Gillick competent, as described above, they cannot consent to their own treatment and the consent of an individual with parental responsibility, or the authority of the Court of Protection is required to proceed with treatment. Guidance regarding Gillick Competency and how to determine whether an

individual has parental responsibility are set out in the Procedures.

3.10.5 A child under the age of 16 who is not Gillick competent cannot refuse treatment if an individual with parental responsibility gives consent provided it is in the patient's interest. A child under the age of 16 who is Gillick competent but refusing to consent may have their refusal over-ruled by an individual with parental responsibility provided it is in the patient's interest.

3.10.6 It should be considered whether overriding the refusal to consent of a potentially distressed child is clinically necessary, and all staff should be encouraged to work with the parents in the child's best interests. However, where there is a dispute as to what is in the child's best interests, it may be appropriate to seek legal advice and refer to the court of protection.

3.10.7 A patient aged between 16 and 17 who refuses treatment can also be overruled in exceptional circumstances by an individual with parental responsibility and/or the court of protection, but advice must always be sought in this situation.

3.10.8 In an emergency situation, where an individual with parental responsibility or equivalent is not available, it is appropriate to provide urgent medical care to a child without consent if it is in their best interests. For further guidance, please refer to the Mental Capacity and Best Interests Policy.

Young people over the age of 16

3.10.9 Any person aged 16 to 18 is presumed to have the capacity to consent or refuse for themselves unless proven otherwise, as is the case with any adult.

3.10.10 If, for any reason, a person aged 16 or 17 lacks the capacity to consent for themselves, an individual with parental responsibility may consent on their behalf, or treatment decisions may be made on the basis of a best interest process and decision. The patient should be involved in the decision-making process as much as possible.

Adults Lacking Capacity and best interests

3.10.11 Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves; no one is able to give consent on their behalf, unless they have been authorised to do so as a done under a registered Lasting Power of Attorney for Health and Welfare (entitled Welfare

Power of Attorney if registered in Scotland)1 or they have the authority to make treatment decisions as a Court appointed deputy. All treatment decisions in the absence of any such authorised individual must therefore be made on the basis of a best interest process and decision. Further information can be found in the Mental Capacity and Best Interests Policy.

3.10.12 If a patient makes a decision about their care that is considered unwise this does not mean that they lack capacity. However, if the decision raises questions about their capacity a formal assessment must be carried out as described above.

3.10.13 Lack of capacity may be due to a temporary condition, such as in patients who are intoxicated, suffering from a head injury, or have been sedated. It is possible for capacity to fluctuate. In such cases, it is good practice to establish, while the person has capacity, their views about any clinical intervention that may be necessary during a period of anticipated incapacity, and to record these views.

Advance decisions

3.10.14 The Mental Capacity Act forms the legal basis for advance decisions, which is a document that can be written by a person who has capacity at the time of writing it and allows for the refusal of certain treatments. A valid Advance Decision must be followed by Health Care Professionals and is legally binding. Further information can be found in the Mental Capacity and Best Interests Policy.

3.11 Consent in practice

3.11.1 Patients can give consent orally or in writing or may imply consent by complying with the proposed examination or treatment, e.g. by offering their arm to have an injection.

3.11.2 For low risk, minor and routine aspects of healthcare, such as taking observations, bloods and performing an abdominal examination, oral or implied consent will usually be sufficient. Healthcare practitioners must still explain what they propose to do to the patient beforehand, including the purpose and any associated risks, and ensure the patient understands and consents. In such cases, it will often be appropriate for a health practitioner to initiate a procedure immediately after discussing it with the patient and consent will normally be obtained through a

[1] In England, an older form of Power of Attorney (an Enduring Power of Attorney) may still be valid if made and signed before October 1, 2007 and registered. For further information, please see the Mental Capacity and Best Interests Policy.

one stage process.

3.11.3 In cases that involve higher risk, written consent should be obtained, so that it is clear that everyone involved understands what was explained and agreed. Written consent **must** be obtained:

a. Where written consent is required by law (i.e. under the Mental Capacity Act 2005 and the Human Fertilisation and Embryology Act 1990);

b. For all elective and, where possible, emergency surgical interventions;

c. For high risk medical interventions such as chemotherapy;

d. Where the investigation or treatment is complex and/or involves significant or material risks;

e. Where providing clinical care is not the primary purpose of the procedure;

f. Where there may be significant consequences for the patient's employment, social or personal life;

g. If the treatment is part of a project or programme of research approved by this Trust; or

h. If tissue samples are to be taken for any purpose, i.e. diagnostic or research.

3.11.4 Consent should be considered a two-stage+ process for any interventions that meet the criteria for formal written consent. The first stage involves the discussion of treatment options and provision of information, and an initial decision regarding a treatment option. This will usually occur in clinic but may happen over more than one visit. The second stage involves discussing any further questions from the patient and confirmation of the decision. This would happen within 24 hours of the procedure.

3.11.5 Patients must be given sufficient and accurate information about their treatment options to make an informed decision. If a patient does not have all the information regarding their options, their consent may not be considered valid. This must include alternative available treatments, including the option not to treat the condition, and any procedures/treatments that, although not planned, may, foreseeably, become necessary as part of their proposed procedure/treatment must be discussed with the patient.

3.11.6 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.

3.11.7 For elective treatment, patients must be given information about anaesthesia prior to 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 must 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 must 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.

3.11.8 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.

3.11.9 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.

3.11.10 All of the relevant risks and benefits of each treatment option, including the option of no treatment, must be fully disclosed and explained. The relative risks of the different treatment options may affect the decision the patient makes. The patient cannot make an informed decision if they do not know the benefits and risks of each of the available treatment options.

3.11.11 Appropriate patient information leaflets should be used where available, but additional information specific to the patient should be provided where appropriate. All such documents given to the patient must be recorded on the consent form, including the version number, which may become essential for identifying the exact information provided to the patient. **Patient Information leaflets must be reviewed in accordance with the Patient Information Procedure to ensure they remain up to date.** For further advice on available patient information, or developing patient information, please contact the Trust's Medical Illustration Department.

3.11.12 Patients should also be advised who will be performing their procedures.

3.11.13 Healthcare practitioners must communicate with the patient in a way that is accessible and understandable. The patient must be able to ask questions, and healthcare practitioners must understand that simply bombarding the patient with technical

information does not fulfil this obligation.

3.11.14 Consideration must be given to provision of information for patients who do not speak English as their first language or have other requirements. The Trust's interpreting services can provide spoken and sign language interpretation. They should be contacted, where possible with 24 hours' notice, for all discussions regarding treatment options and consent.

3.11.15 Use of adult relatives as translators should only be used as a last resort where there is no available interpreter or member of staff able to interpret, and a clinical need for the consultation to occur before these can be made available.

Patients must be given sufficient time to come to an informed decision.

3.11.16 Patients must have time to weigh up the options and information about risks given to them and come to the right decision for them. Where they do not have time to do so, consent may be considered to be not freely given. For elective procedures, consent may not be considered to be freely given if the first-time risks are disclosed or options are discussed is on the day of examination or treatment.

3.11.17 The consent process must be commenced in advance of the patient's admission for examination or treatment. Unless there is a clinical requirement for the procedure to happen urgently, a patient should not be asked to review and sign the consent form for the first time on the day of the procedure.

Consent must be freely given.

3.11.18 Where a patient feels they have already committed to the decision, such as already having attended the hospital for their procedure, or already being in their theatre gown, then consent taken at this stage may not be considered to be valid.

3.11.19 The patient must have been given an opportunity to change their mind.

3.11.20 Healthcare professionals may recommend a particular option for the patient but must not pressurise the patient into choosing any particular option.

Further considerations and exceptions

3.11.21 There are some limited exceptions from disclosing full information or risks to patients, or undergoing the full consent process, as follows:

a. in an emergency situation (see below);

b. where a patient explicitly states that they do not wish to be informed of the risks. In this situation, this must be clearly documented in their medical records; or

c. where it is reasonably considered that disclosing the full risks associated with a procedure would cause a serious threat to the patient's health. This must be more significant than simply causing the patient distress. (If it is considered that this is the case, contact the Clinical Governance and Patient Safety department for advice. If urgent and/or out of hours then the Chief Medical Officer, or Executive on-call should be contacted).

3.11.22 During an operation, it may become evident that the person could benefit from an additional procedure that was not within the scope of the original consent. (Care should be taken when obtaining consent from a patient to ensure possible additional procedures that may be potentially expected are considered during the consenting process to avoid being in this position). A decision may be taken to carry out the procedure on a best interests basis if, for example, the risks of delay and/or another anaesthetic merit it. However, the procedure must not be performed merely because it is convenient. Where possible, consultation with independent senior clinicians should occur before proceeding with any significant change in procedure to confirm that proceeding is in the patient's best interests.

Urgent and Emergency Situations

3.11.23 In an emergency, what would normally require a standard two stage+ process of formal written consent may not be appropriate or practicable and the two stages of consent will follow straight on from each other.

3.11.24 The nature of the situation may limit the quantity of information the patient is given, but should not affect the quality of the information or interaction. Patients must still be told of their options and provide consent to the procedure freely.

3.11.25 In an urgent situation, whenever possible, time should still be provided to the patient to consider the information being given to them prior to being asked to make a decision on consent.

3.12 Refusal of treatment and withdrawal of consent

3.12.1 A patient can choose to withdraw consent at any time, provided they have the mental capacity to do so at the time. Withdrawal of consent may be communicated verbally or by implication i.e. by

pulling away from a needle etc. The patient must be made aware of the implications of a procedure not being carried out as part of the consent process.

3.12.2 If a patient who lacks capacity, including those whose capacity is impaired temporarily (e.g. because of the effect of anaesthetics, sedation or drugs used as part of the procedure), appears to indicate that they wish the procedure to stop or is showing signs of discomfort or distress, consideration must be given to the following:

a. A procedure must be stopped if the patient is becoming so distressed that it is dangerous to continue;

b. the healthcare professional should decide whether to continue with the treatment on a best interests basis, taking into account the potential impact of the distress on the patient and balancing that against the potential impact of not providing/completing the treatment;

c. If the patient has given their written consent to a treatment or intervention which is likely to cause pain or discomfort and the patient has been sedated, deciding whether the patient lacks capacity or not can be difficult.

3.12.3 However, this decision is always going to require a clinical judgement of each individual case and a clinician must always act in what they believe to be the patient's best interests.

3.12.4 Withdrawal of consent whilst sedated during a procedure is of particular relevance to Endoscopy and further guidance is available in Guidance for Obtaining a Valid Consent for Elective Endoscopic Procedures April 2008. This guidance has been produced by the British Society of Gastroenterology and is available on their website at www.bsg.org.uk.

3.13 Recording consent

3.13.1 All procedures that require formal written consent, except where the clinical urgency of the situation prevents it, must use a Trust approved consent form. In urgent situations, it may be appropriate to use the patient's notes to document consent rather than using a consent form.

3.13.2 Procedure specific consent forms are encouraged to be produced and used within the Trust. Such forms should include pre-populated information regarding intended purpose, risks and benefits of procedures and as such can aid in the consent process.

3.13.3 The Head of Operational Support for Corporate Affairs will keep a record of all such consent forms in use and can help facilitate the production of new forms, so should be contact for advice.

3.13.4 The use of a consent form does not in itself prove valid consent, and it is important to not equate the process of consent with a signature on a consent form. However, if used properly, a consent form provides a structured means for recording the key aspects of the consent process.

3.13.5 Where verbal consent is taken, it must still be recorded in the patient's notes. This differs from formal written consent as it is not co-signed by the patient and is often recorded retrospectively.

3.13.6 Capacity assessments and the rationale for best interests decisions must be fully documented in the patient's notes, using the appropriate checklists.

4. Duties

4.1 Chief Medical Officer

The Chief Medical Officer is responsible for ensuring that:

4.1.1 there is a framework for reviewing compliance with this Trust policy and associated procedures; and

4.1.2 the policy remains fit for purpose and is reviewed as required and at least every three years.

4.2 Clinical Delivery Group (CDG) Medical Directors

CDG Medical Directors are responsible for ensuring that appropriate measures/SOPs are in place in all specialties/services within their CDG so as to ensure compliance with this policy and its associated procedures including ensuring timely reviews of patient information leaflets are carried out according to the Patient Information Procedure;

4.3 Clinical Service Leads/Senior Nurses/Clinical Managers (Senior Nurse refers to Matron or Sister/Charge Nurse)

Clinical Service Leads or Senior Nurses are responsible for ensuring that:

4.3.1 Appropriate measures/SOPs are in place in their area of responsibility so as to ensure compliance with this policy and its associated procedures;

4.3.2 Delegated consent is only taken by staff who have been

authorised to do so in accordance with the procedure;

4.3.3 A local procedure specific training programme is in place for staff who are to be delegated authority to obtain consent;

4.3.4 Any staff who are identified, through the annual consent audit or otherwise, as having obtained consent for a procedure without being authorised to do so are immediately informed that they must not undertake such consent processes until they have been assessed as competent to do so;

4.3.5 Action plans are produced within their specialty, when necessary, as a result of the annual consent audit.

4.3.6 Review appropriate Patient Information Leaflets within their specialties according to the Patient Information Procedure.

4.4 Head of Operational Support for Corporate Affairs

The Head of Operational Support for Corporate Affairs is responsible for:

4.4.1 maintaining accurate and up to date records of:

a. those specialties that have delegated authority for consent;

b. individuals authorised to obtain delegated consent, as identified by specialties; and

c. competency statements supplied by specialties, and

4.4.2 monitoring compliance with this policy and the associated procedures by conducting an annual consent audit, which will include checking that the consent process is being undertaken only by the appropriate staff in accordance with records of competency statements.

4.5 Trust Practice Development Team

The Practice Development Team are responsible for ensuring that:

4.5.1 Any delegation of responsibility for consent protocol or local guideline includes details of how staff are identified for taking delegated consent in the specialty, the arrangements for training and competency assessment, and the monitoring and auditing arrangements to ensure that all staff who obtain consent are authorised to do so; and

4.5.2 Approved delegation of responsibility for consent protocols or local guidelines are published on the Intranet.

4.6 Consultant Staff

All consultants:

4.6.1 Have an overall responsibility for the care of the patient and this will also extend to ensuring consent is appropriately obtained.

4.6.2 Are to ensure that when the consent process has been delegated the staff obtaining consent are fully trained and competent to obtain consent for the procedure in accordance with the Procedures.

4.7 Clinical Staff

All healthcare practitioners are responsible for ensuring that:

4.7.1 They are only taking consent for procedures they can perform, or where they have been formally authorised to take delegated consent;

4.7.2 Valid and effective consent has been freely given by the patient and, where written consent is required, all Trust documentation has been completed as appropriate;

4.7.3 They will, where they are making decisions on behalf of a patient who lacks capacity, follow the Best Interests Checklist, consult with the patient's family and or carers and will ensure, based on all evidence available, that the care provided is in the patient's best interests;

4.7.4 They respect a patient's refusal of treatment when the patient is considered to have capacity to consent;

4.7.5 They complete an incident form in line with the Policy for the Prevention and Management of Incidents including Serious Incidents Requiring Investigation if there is any breach of this policy; and

4.7.6 They record evidence of the consent process, to include use of the appropriate Trust approved consent form.

5. Implementation and Monitoring

5.1 Implementation

5.1.1 The Policy and Procedures will be published on the Trust intranet site.

5.1.2 Regular taught sessions will be made available via the Trust's education department and e-learning resources will be made available via the Trust intranet.

5.1.3 Generic training on good practice in consent is provided as part of the Trust Postgraduate Doctor Induction at which it is reinforced that FY1 must not take written consent except as specified above.

5.1.4 There is an electronic learning module on consent available via the Trust intranet, and there will be quarterly/six monthly sessions open to all staff to provide general advice and training on consent which can be booked via the Clinical Governance and Patient Safety Department.

5.1.5 In addition, the Clinical Governance and Patient Safety Department can be contacted for advice on any other minor queries.

5.1.6 Procedure specific training on consent for staff to whom the consent process is delegated, and who are not capable of performing the procedure, must be delivered within specialties.

5.2 Monitoring

Appendix A provides full details on how the policy will be monitored by the Trust

6. References

Department of Health (2009) - Reference guide to consent for examination or treatment, 2nd Ed. (online)

UK Parliament (2004) - Human Tissue Act

General Medical Council (2008) - Consent: patients and doctors making decisions together, (online) available from: www.gmc-uk.org

Nursing & Midwifery Council (2008) - Consent, (online) available from: www.nmc-uk.org

Human Tissue Authority (2009) - Code of Practice A: Consent, (online) available from: https://www.hta.gov.uk/guidance-professionals/licensing/licensing-under-human-tissue-quality-and-safety-human-application

NHSLA (2012/13) - NHSLA Risk Management Standards

7. Associated Policy and Procedural Documentation

Procedures and Guidance for Consent to Examination or Treatment

Procedure for the Consent to Perinatal Post-mortem Examination

Mental Capacity and Best Interests Policy

Trust Photographic and Video Recording Consent and Confidentiality Policy

Policy on Research Governance

Policy for the Prevention and Management of Incidents Including Serious Incidents Requiring Investigation

Patient Information Procedure

APPENDIX A Monitoring Matrix

MONITORING OF COMPLIANCE	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Adherence to this policy will be monitored by the Clinical Governance and Patient Safety Department via an annual Trust wide audit of consent (part of the Trust documentation audit).	Head of Clinical Governance and Patient Safety	Group Care Quality Meeting GCQM	This will involve auditing a random sample of consent forms from those taking written consent in the Trust to ensure that documentation is being completed and that consent is being taken only by the appropriate staff. The audit will include the review status of patient leaflets which form part of the consent process.	Annually
The results of the audit will be disseminated to specialty level where an action plan to improve the completion of the consent forms will be generated,	Head of Clinical Governance and Patient Safety	Group Care Quality Meeting GCQM	The responsibility of producing and implementing this action plan will be that of the Clinical Service Leads or Senior Nurses depending on the group of staff involved. The implementation of these action plans will be monitored by the Clinical Governance and Patient Safety Department and exceptions reported to Site Quality and Safety Group and the Group Care Quality Meeting GCQM	Annually