CORPORATE POLICY - Consent Policy

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Consent Policy

Document Control / History	
Revision No	**Reason for change**
Updated	Alteration to reflect changes to legislation – Mental Capacity Act (2005) and Human Tissue Act (2004) and Department of Health: Reference guide to consent for examination or treatment 2nd Edition 2009
1	Amendment – change of contact details for IMCA – see 1.3.8.
2	Changes to Case Law and Legislation; inclusion of Monitoring Table and Equality Impact Assessment
3	Inclusion of consent for post mortems
4	To accommodate revisions to NHSLA risk management standards
5	Scheduled update – no changes to guidance
6	Policy updated and split into individual SOPs
7	Reviewed – remove Form 8 no longer required
8	Reviewed with no major changes – added reference to 2.14

Consultation
Brachers Solicitors

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Consent Policy

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To be read in conjunction with any policies listed in Trust Associated Documents.

Introduction

1.1 This policy sets out the standards and procedures in this Trust, which aim to ensure that health professionals are able to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

1.2 Responsibility for ensuring the application of this policy lies with the Director of Clinical Operations for each Directorate. Adherence to this policy will be monitored by the Medical Director via the Clinical Effectiveness and Research Group.

Purpose / Aim and Objective

2.1 This Policy sets out the Trust arrangements for Consent and associated governance to ensure compliance with the regulatory framework.

2.1.1 Health professionals must all be aware of guidance on consent issued by their own regulatory bodies, e.g. the General Medical Council consent guidance "doctors and patients making decisions together" - see http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

2.1.2 The Department of Health (DoH) updated its guidance in 2009 after the Mental Capacity Act and Code of Practice came into effect in its Reference Guide to Consent for Examination or Treatment (2nd Edition). See https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

2.1.3 The Human Tissue Authority Code of Practice 1, Consent (July 2014) at https://www.hta.gov.uk/guidance-professionals/codes-practice/code-practice-1-consent gives practical guidance and establishes standards on how consent should be sought and what information should be given in relation to the retention, storage and use of human tissue for various specified purposes, and concerning the removal of tissue from the deceased.

2.1.4 Royal College of Surgeons: Consent: Supported Decision Making – a good practice guide (November 2016) https://www.rcseng.ac.uk/library-and-publications/college-publications/docs/consent-good-practice-guide/. The Trust Policy is that the consent process must be underpinned by the key principles set out in this good practice guide:

- The aim of the discussion about consent is to give the patient the information they need to make a decision about what treatment or procedure (if any) they want.

- The discussion has to be tailored to the individual patient. This requires time to get to know the patient well enough to understand their views and values.

- All reasonable treatment options, along with their implications, should be explained to the patient.

- Material risks for each option should be discussed with the patient. The test of materiality is twofold: *whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would likely attach significance to it*.

  See Montgomery v Lanarkshire Health Board (2015) UK Supreme Court.

- Consent should be written and recorded. If the patient has made a decision, the consent form should be signed at the end of the discussion. The signed form is part of the evidence that the discussion has taken place, but provides no meaningful information about the quality of the discussion.

- **In addition to the consent form, a record of the discussion (including contemporaneous documentation of the key points of the discussion, hard copies or web links of any further information provided to the patient, and the patient's decision) should be included in the patient's case notes**. This is important even if the patient chooses not to undergo treatment.

2.2 The principles set out in this Policy apply to treatment in an elective situation when the patient has time to consider their options. In an urgent or emergency situation where it is imperative to save life or limb, or prevent serious deterioration, the surgeon will have to proceed with limited discussion or even without consent (see Appendix 1 of the Royal College of Surgeons good practice guide referred to in 2.1.4 above) on acting in the patient's best interests).

Definitions

3.1 **Capacity**

3.1.1 The ability to carry out the processes involved to make and communicate a specific decision at a specific time (as set out in the Mental Capacity Act)

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

3.1.3 have capacity to take the particular decision;

3.1.4 have received sufficient information to take it; and

3.1.5 not be acting under duress.

3.2 A signature on a form is not consent; it is part of the consent process. It can be evidence of understanding and acceptance of information given during the consent process. Patients with capacity may withdraw consent at any time before or during an investigation or treatment taking place.

3.3 **Independent Medical Capacity Advocate (IMCA)**

3.3.1 This service helps the Trust to make decisions in the best interests of people who lack the capacity and who have no family or friends that it would be appropriate to consult about these decisions.

3.4 **Risk**

3.4.1 Any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications'

(Duties) Roles and Responsibilities

4.1 The health professional actually carrying out any procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is this health professional that will be held responsible in law if there is a challenge later.

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

4.3 Completing consent forms

4.3.1 The standard consent form provides space for a health professional to specify key information provided to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

4.3.2 The consent form will normally also be signed by the patient. However, if a patient is unable to do so (e.g. because of blindness, amputation, locked in syndrome), verbal consent can be witnessed and documented by a second member of staff after the whole form has been read out to the patient. If a patient completes the form in advance of a procedure (e.g. in out-patients or

at a pre-assessment clinic), a health professional involved in their care on the day of the procedure should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer any questions they cannot handle themselves.

4.4 Delegation of Consent

4.4.1 Any specialty that wishes to develop training for health professionals to enable them to seek informed consent for one or more specified procedures (which they are not able to perform themselves) must produce documentation specifying the knowledge and practical skills required before this is undertaken. They must also produce details of the competency assessment that will be undertaken before such a practitioner seeks consent for the procedure, specifying how often this will be reviewed or the person will be reassessed. This training and documentation must be approved by the specialty lead consultant (who must confirm in writing that it meets the requirements of the consent policy), and by the Clinical Management Board, before it is implemented.

4.4.2 Each specialty is responsible for keeping a list of those staff approved to obtain delegated consent, together with the date of this approval, and a note of each procedure for which the member of staff is now competent to obtain delegated consent.

4.4.3 The annual consent audit will include a process for checking that consent is being sought by staff who are competent to perform the procedure concerned, or who are documented as having successfully completed the relevant training showing they are competent to undertake this process.

4.4.4 Any member of staff who is asked a supplementary question by a patient, which is outside their immediate professional expertise to be able to answer, should not countersign the form unless or until they are satisfied that

- an appropriate professional has addressed any outstanding concerns of the patient; and
- the patient has received full information to enable him/her to make a decision on whether or not they wish the proposed procedure to go ahead.

4.5 Responsibility of health professionals

4.5.1 It is a health professional's own responsibility:

- to ensure that if a colleague seeks 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.

4.5.2 If a health professional feels that they are being pressurised to seek consent when they do not feel competent to do so, they should contact one of the following for advice and support:

- a member of the Directorate management team,
- the specialty lead or principal lead consultant,
- the Medical Director

4.5.3 If the Trust has reason to believe (e.g. following an audit / investigation) that any trainee doctor has inappropriately sought consent for a medical procedure, or obtained consent without the authorisation to do so, this should be reported to the Medical Director, who will take it up if appropriate with the General Medical Council (GMC)

Monitoring and Review

What will be monitored	How/Method/ Frequency	Lead	Reporting to	Deficiencies/ gaps Recommendations and actions
Policy review	First review in one year and then every three years	Author	Clinical Effectiveness and Research Group	Policy will be updated and made available to staff.
Elective Surgical Consent process to include: Process for obtaining consent Process for recording consent Process for identifying staff authorised to take consent Process for delivery of procedure specific training on consent for those staff to whom consent training is delegated Generic training on consent	Annual audit of patient records, delegated consent directories, procedure specific and generic training records as required.	Medical Directors' Assistant	Medical Director	Where gaps are recognised action plans will be put into place

What will be monitored	How/Method/ Frequency	Lead	Reporting to	Deficiencies/ gaps Recommendations and actions
Trust – wide Consent Forms	Annual audit	Medical Directors' Assistant	Medical Director	Where gaps are recognised action plans will be put into place

Training and Implementation

6.1 Training on generic consent issues is available for all staff via the Trust e-learning programme. In addition, ad hoc training services are available at Directorate/departmental levels as required. Staff requiring general training on the Consent policy, procedure or best practice in obtaining consent in specific clinical settings should contact the Head of Legal Services, Corporate Compliance and Resilience on ext 3881.

6.2 Training and assessment for nurses or junior doctors obtaining consent, who do not themselves undertake the procedure(s) being consented for, should be developed locally by the senior clinicians. The Trust requires that each Directorate should identify which individual nurses or junior doctors are deemed competent to obtain consent for specific procedures (which are serious enough to usually warrant written consent) either by virtue of their existing skill base, or by virtue of having undertaken specific training in obtaining consent for that procedure. This procedure specific training should be provided by a person trained to perform the procedure or by a person with the required medico-legal skills. Training should relate to a specific procedure or groups of procedures and cover the knowledge and skills required to enable the nurse to advise the patients and respond to specific questions, especially in relation to the risks and benefits of the procedure in question and the risks and benefits of the alternatives to that procedure. Competence to perform the consent process for nurses or junior doctors not undertaking the clinical procedure must be documented on the individuals' training record and a note should be added to the procedure Directory held by the relevant Directorate. Directorates must also ensure that where nurses and junior doctors are involved in assessing continuance of consent, that ready access is available to appropriate colleagues where they are unable to answer personally any questions raised by the patient.

6.3 Any incident about the process of gaining consent or giving patients sufficient information on which to make a decision will be reported via the incident reporting system. In the event that a patient's consent is obtained by Trust personnel not considered appropriate to obtain such consent, the matter will be reported using the Trust's incident reporting system.

6.4 The effectiveness of the implementation of this policy will be subject to annual audit which will be led by the Medical Director's Assistant and the results of which will be considered at Directorate governance group meetings.

References

Document	Ref No
References:	
Care Quality Commission Fundamental Standard	Regulation 11
Human Tissue Act 2004	
Mental Capacity Act 2005	
Consent: Supported Decision Making – a good practice guide (Royal College of Surgeons November 2016)	
Good practice in consent implementation guide (Department of Health 2002)	
Trust Associated Documents:	
Consent Procedure	SOP0131
Consent - Tissue	SOP0134
Consent - Clinical photography and conventional or digital video recordings	SOP0135
Consent - Medway Elective Surgical Consent Pathway	OTCGR161
Consent - Consent Flow Chart for Children Under 16 Years of Age	OTCGR162
Consent - ICU Photographs Guideline	GULGR003
Consent - Form 1 - Patient agreement to investigation or treatment	OTCGR165
Consent - Form 2 - Parental agreement to investigation or treatment	OTCGR166
Consent - Form 3 - Patient-parental agreement to investigation or treatment -procedures where consciousness not impaired	OTCGR167
Consent - Form 4 - Form for adults who are unable to consent to investigation or treatment	OTCGR168
Consent - Form 6 - Supplementary Consent for Gifting of Tissue	OTCGR158
Consent - Form 7 - Consent to photography and conventional or digital video recordings	OTCGR159
Consent - Form 9 - Post Mortem Consent Form - Baby	OTCGR163
Consent - Patient Diary Acceptance Form	OTLGR0023
Management and Publication of Written Patient Information Policy and Procedure	POLCGR019
Interpreter/Translator Policy	POLCGR023
Use of Unlicensed Products	POLCPCM034

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