

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Consent for Examination or Treatment (with reference to the Mental Capacity Act 2005)

Date: September 2009

Review: September 2012

1. Introduction

1.1 Valid Consent

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

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question. This will be the patient or someone with parental responsibility for a patient under the age of 18, ¹ someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has the authority to make treatment decisions as a court appointed deputy ². Agreement where the person does not know what the intervention entails is not 'consent'.

1.2 This policy

This policy ensures that all NuTH staff who are involved in undertaking the consent procedure comply with the following policy.

Where application of this policy can not be achieved an Incident/Accident/Near Miss reporting form should be completed with a full explanation and methods of remedial action.

1.3 Relevant Policies

The policy should be read in conjunction with the relevant national and Trust policies where appropriate:

Department of Health guidance ³

The Mental Capacity Act (MCA) 2005 ²

Mental Health Act 1983 Code of Practice ⁷

[Medical photography service guidance within working hours](#)

[Clinical Recoding of Patients](#)

[Organ Tissue Donation](#)

2. Roles and Responsibilities

Responsibility for ensuring the application of this policy lies with the Clinical Director of each Directorate, supported by the Directorate Manager.

3. Capacity

3.1 Assessing capacity

The MCA 2005² states *'A person must be assumed to have capacity unless it is established that he lacks capacity.'* The MCA 2005² defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain (either temporary or permanent). The decision of whether or not the patient has capacity is 'decision specific' and must relate to the procedure being proposed. An optimal time for the patient during the day must be chosen when the assessment of capacity takes place. An appropriate location, respect and dignity for the patient should be maintained at all times and support from other people or professionals should be offered as required.

Capacity should not be confused with a healthcare professional's assessment of the reasonableness of the person's decision. A person is entitled to make a decision which may be perceived by others to be unwise or irrational as long as they have the capacity to do so.

3.2 Lack Capacity

The MCA 2005² applies in England and Wales to everyone who works in health and social care and is involved in the care, treatment or support of people over 16 years of age who may lack capacity to make decisions for themselves.

No one is able to give consent to the examination or treatment of an adult who lacks capacity to give consent for themselves, unless they have been authorised to do so under a LPA or they have the authority to make treatment decisions as a court appoint deputy³.

In most cases, parents, relatives or members of the healthcare team cannot consent on behalf of such an adult. The MCA 2005² sets out the circumstances in which it will be lawful to carry out such examinations or treatment.

A record of all communications should be documented in the patients' clinical records.

4. Form of Consent

4.1 Written Consent

The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent: if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make the consent valid.

Although completion of a consent form is in most cases not a legal requirement (exceptions include certain requirements of the Mental Health Act 1983 and of the

Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008) the use of such forms is good practice where an intervention such as surgery is to be undertaken. Where there is any doubt about the person's capacity, it is important, before the person is asked to sign the form, to establish both that they have the capacity to consent to the intervention and that they have received enough information to enable valid consent to be given. Details of the assessment of capacity, and the conclusion reached, should be recorded in the case notes.

4.2 Capacity but limited literacy

If the person has capacity, but is unable to read or write, they may be able to make their mark on the form to indicate consent. It would be good practice for the mark to be witnessed by a person other than the clinician seeking consent, and for the fact that the person has chosen to make their mark in this way to be recorded in the case notes. If the person has capacity, and wishes to give consent, but is physically unable to mark the form, this fact should be recorded in the notes. Or, the person can direct someone to sign the form on their behalf, but there is no legal requirement for them to do so. If consent has been given validly, the lack of a completed form is no bar to treatment, but a form can be important evidence of such consent.

4.3 Capacity given verbally/non-verbally

Consent may be expressed verbally or non-verbally: an example of non-verbal consent would be where a person, after receiving appropriate information, holds out an arm for their blood pressure to be taken. However, the person must have understood what examination or treatment is intended, and why, for such consent to be valid. It is good practice to obtain written consent for any significant procedure, such as a surgical operation or when the person participates in a research project or a video recording (even if only minor procedures are involved).

5. Seeking and obtaining consent

Consent must be given voluntarily and freely without pressure or undue influence being exerted on the person either to accept or refuse treatment. To validate the consent the person needs to understand the nature and purpose of the procedure. Health professionals should discuss 'significant, unavoidable or frequently occurring risks' with the patient rather than simply recording 'serious or frequently occurring risk'. If a proposed procedure carries significant risks or adverse events it is necessary to seek written consent and make a record of the information given. Where relevant, information, risks and benefits about the anaesthesia is the responsibility of the anaesthetist (not the surgeon) alongside information about the procedure itself.

If consent is given over a two stage process (for example: in an outpatient department for an elective procedure and the patient is admitted at a later date) the healthcare team should confirm that the patient would like to proceed with their decision, if they have any

further concerns or would like to reconsider their decision. Any misrepresentation of the decision will invalidate consent.

Failure to provide relevant information may render the practitioner liable to an action for negligence if a person subsequently suffers harm of the treatment received.

If a student or trainee is carrying out the procedure to further their own education (for example: physical examination) verbal consent if the patient is conscious is required for this to take place.

The General Medical Council (GMC) provides guidance on the type of information that patients may need to know before making a decision, and recommends that doctors should do their best to find out about patients' individual needs and priorities when providing information about treatment options. Clear, accurate information should be given to the patient about the risks of any proposed investigation or treatment, presented in a way the patient can understand to help them make informed decisions.

In order to have effective discussions with patients about risk, the adverse outcomes that may result from the proposed options must be identified. This includes the potential outcome of taking no action. Risks can take a number of forms, but will usually be side effects, complications or failure of an intervention to achieve the desired aim. Risks can vary from common but minor side effects, to rare but serious adverse outcomes possibly resulting in permanent disability or death ⁴.

In cases that involve higher risk, it is important that you get the patient's written consent. This is so that everyone involved understands what was explained and agreed. By law you must get written consent for certain treatments, such as fertility treatment and organ donation. You must follow the laws and codes of practice that govern these situations ⁴.

5.1 Additional procedures

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. If it would be unreasonable to delay the procedure until the person regains consciousness (for example because there is a threat to the person's life) it may be justified to perform the procedure on the grounds that it is in the person's best interests. However, the procedure should not be performed merely because it is convenient. For example, a hysterectomy should never be performed during an operation without explicit consent, unless it is necessary to do so to save life.

If a person has refused certain additional procedures before the anaesthetic (for example, specifying that a mastectomy should not be carried out after a frozen section biopsy result), then this must be respected if the refusal is applicable to the circumstances. The GMC guidance states that it is good practice to seek the views of the patient on possible additional procedures when seeking consent for the original intervention.

5.2 Children/Young People

5.2.1 Parental Responsibility

Only people who have 'parental responsibility' are entitled to give consent on behalf of their children. Not all parents have parental responsibility for their children (for example: unmarried fathers do not automatically have such responsibility although they can acquire it).

5.3.2 Young people aged 16-17

By virtue of the Family Law Reform Act 1969⁵ young people who are aged 16-17 are presumed to be capable of consenting to their own medical treatment. Consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention.

In order to establish whether a young person aged 16-17 has the requisite capacity to consent to the proposed intervention, the same criteria as for an adult should be used (see paragraph 3.1).

If the 16-17 year-old is capable of giving valid consent then it is not legally necessary to obtain consent from a person with parental responsibility, however it is good practice to involve the young persons' family in the decision-making process.

5.3.3 Children under 16 – the concept of Gillick competence

The concept of 'Gillick' competent is when a child is deemed to have the understanding and intelligence to enable them to understand fully what is involved in a proposed intervention and have the capacity to consent to that proposed intervention. Additional consent by a person with parental responsibility is not required however it is good practice to involve the child's family in the decision-making process.

In some cases a child's mental state may fluctuate significantly, hence careful consideration should be taken in the decision whether the child is truly Gillick competent and has the capacity to consent at the time they need to make a relevant decision.

5.3 Emergencies

During an emergency situation the two stage process where discussion of options and confirmation that the patient wishes to go ahead with the procedure will follow straight on from each other. Document of the discussion and patient's consent should be clearly recorded. The urgency of the patient's situation may limit the quantity of information that they can be given but should not affect the quality.

5.4 Removed tissue

The Human Tissue Act 2004⁶ makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display. It also covers the removal of such material from the deceased. This Trust requires that patients should be given the opportunity to refuse permission for tissue to be taken from them during surgery or other procedures to be used for education or research purposes (Appendix 1). Further information on can be accessed through the Clinical Governance website at: [Organ Tissue Donation](#)

5.5 Clinical Photography and audio recordings

Consent should be obtained for any visual or audio recording, including photographs or other visual images. The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made. If it is to be used for teaching, audit or research, people must be aware that they can refuse without their care being compromised and that when required or appropriate it can be anonymised. Further information can be accessed through the Clinical Governance website at: [Medical photography service guidance within working hours](#)

5.6 Requirements concerning gametes

It is a legal requirement under the Human Fertilisation and Embryology Act 2008 that consent must be obtained in writing before a person's gametes can be used for the treatment of others, or to create an embryo *in vitro*. Consent in writing is also required for the storage of gametes. Information and an opportunity to receive counselling must be provided before the consent is given. Where these requirements are not satisfied, it is unlawful to store or use the person's gametes for these purposes. Clinicians should ensure that written consent to storage exists before retrieving gametes.

6. Post Mortem consent

The staff member who seeks consent for a hospital post mortem examination should be sufficiently senior and well informed with a thorough knowledge of the procedure. They should have been trained in the management of bereavement and in the purpose of post mortem examination and this responsibility for obtaining consent should not be delegated to untrained or inexperienced staff.

7. Delegated consent

The clinician providing the treatment or investigation is responsible for ensuring that the person has given valid consent before treatment begins, although the consultant responsible for the person's care will remain ultimately responsible for the quality of medical care provided.

The GMC guidance states that the task of seeking consent may be delegated to another person, as long as they are suitably trained and qualified and are competent to do so, to work within their own competence and not to agree to perform tasks which exceed that

competence They must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require.

Competence records should be held by each Directorate. It is the Directorates responsibility to keep a record (Appendix 3) of all the staff who are competent to undertake delegated consent and for which procedures and treatments.

8. Documentation

For significant procedures, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient's notes if necessary), or through documenting in the patient's notes that they have given verbal consent. Further information can be accessed through the Clinical Governance website at:

[Clinical Recoding of Patients](#)

Standard consent forms and forms for adults who are unable to consent for themselves are available through the normal supply service and should be available wherever a relevant procedure will be undertaken. There are three versions of the standard consent form:

form 1 for adults or competent children

form 2 for parental consent for a child or young person and

form 3 for cases where it is envisaged that the patient will remain alert throughout the procedure and does not involve any impairment in consciousness

form 4 should be used when considering consent issues for patients who lack mental capacity.

Completed consent forms should be kept with the patient's notes. Any changes/modifications to the consent form after it has been signed by the patient should be signed and dated by both the patient and healthcare professional involved in the procedure.

9. Provision of Information

Provision of information is central to the consent process. The Trust provides a range of information leaflets in normal and large print, on the intranet, by tape and in Braille. The Patient Advice and Liaison Service (PALS) provide advice and support for patients. The Trust offers an interpreter service to assist translation of information for patients who do not speak or read English.

10. Refusal of Treatment

An adult with capacity is entitled to refuse any treatment (whether at the time or in advance), this decision must be respected, except in circumstances governed by the Mental Health Act 1983 ⁷ (part 4 sets out circumstances in which persons liable to be detained under the Act may be treated without consent for their mental disorder).

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

If a LPA has been appointed and they have the authority to do so – they can make decisions and consent to or refuse treatment as valid as those made by the person themselves. If there is no LPA and the adult does not have capacity then the Court of Protection can make an order making a decision on their behalf or appoint a deputy to make a decision on behalf of the person who lacks capacity.

If a child aged 16 -17 or under 16 and deemed Gillick competent refuses treatment, it is possible in certain circumstances that the decision is overridden by either a person with parental responsibility or a court (for example: if treatment is refused and the outcome will probably lead to death or severe permanent injury to the child/young person or where there is a serious and imminent risk that the child/young person will suffer grave and irreversible mental or physical harm). Power to over-rule may be given to any one parent or person who has 'parental responsibility' or the court if need be. In cases where the child's best interest is disputed a court decision may be required.

11. Withdrawal of Consent

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

12. Training

12.1 Generic consent training

Training on Generic consent related issues is available for all staff via an annual training programme, which includes sessions delivered by Trust personnel or by contracted solicitors.

A training needs analysis should be undertaken by the Directorate Management Teams to identify the training needs of all staff in relation to consent. Consideration must be given to ensure competencies set meet individual staff needs.

In the event of the appropriate training being unavailable from any source, and or where the risk assessment has identified the requirement for urgent training and competency assessment, the departmental manager must raise this with their Directorate Manager/ Clinical Director.

12.2 Post mortem consent training

Training for all health professionals involved in seeking consent for post mortem examinations is currently through an on-line training package.

A copy of the training records for seeking post mortem consent should be kept at departmental level.

12.3 Delegated Consent Training

Training and assessment for health professionals involved in the consent process, who do not themselves carry out the specific procedure (delegated consent), should be developed within the relevant Clinical Directorates.

This training and assessment should be provided by a person competent to undertake the procedure. Training should relate to a specific procedure or groups of procedures and cover the knowledge and skills required to enable the practitioner to advise the patient and respond to specific queries in relation to all issues.

A copy of the training records for delegated consent and for which procedures should be kept at departmental level (Appendix 3) and a copy of the delegated consent form should be sent to the Nurse Specialist Patient Safety.

13. Monitoring and Review

Compliance with this policy will be monitored by the Nurse Specialist Patient Safety who will review incident reports relating to consent issues will provide a quarterly report to the Clinical Governance and Quality Committee.

An annual audit will also be undertaken to review the process of identifying staff to whom obtaining consent is delegated and to ensure that those staff have received procedure specific training as required.

The reports will be presented to the Clinical Governance and Quality Committee which will identify any areas for improvement, devise an action plan and monitor these until all actions are completed.

References

¹Department of Health (2001) *Consent – What you have a right to expect A guide for children and young people*. London: DH

²Mental Capacity Act 2005 (2007) Code of practice London: TSO

<http://www.publicguardian.gov.uk/docs/mca-code-practice-0509.pdf>

³Department of Health (2009) *Reference guide to consent for examination or treatment*. 2nd Edition. London: DH

⁴GMC (2008) *Consent: patients and doctors making decisions together*. London: GMC

⁵ Family Law Reform Act 1969

www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1969/cukpga_19690046_en_2#ptH1q8

⁶ The Human Tissue Act 2004

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4103686.pdf

⁷ Mental Health Act 1983 Code of Practice (2008)

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087073.pdf

Author: Nurse Specialist Patient Safety

The Newcastle upon Tyne Hospitals NHS Trust

Supplementary Consent for Gifting of Tissue

You will shortly be undergoing biopsy (tissue sampling) or surgery to remove diseased tissue. The major purposes of this procedure are to confirm your diagnosis and contribute to your treatment.

Once your diagnosis has been made, remaining tissue is very valuable to this Trust for use in education, research and quality assurance. We therefore request your consent to use any remaining tissue for these purposes, by making a gift of the material to this Trust. An information leaflet (reference) is available containing more information about the Trust's use of such tissues and describing our policy for the safe keeping of tissue gifted in this way.

Your diagnosis and treatment will not be compromised in any way by giving consent. Any research studies in which your tissue is used will have been approved by our local research ethics committee or an equivalent organisation, to ensure that the research is valid and meets current ethical standards. Research will be conducted anonymously; tissue samples will be identified by a code and your personal details will not be accessible by researchers. Your confidentiality will be respected at all times.

We may use the tissue in association with commercial partners but human tissue is never sold (this is illegal) and our partnerships are organised on a not-for-profit basis, with any resulting benefits being used directly to improve patient care within the Trust. Use of your tissue for education, research or quality control in this way will not influence your treatment directly. Withholding consent will not harm your diagnosis or treatment in any way. If you do not wish to give consent, we guarantee that any tissue surplus to needs for diagnosis is disposed of appropriately, following national guidelines.

Statement to be signed by patient:

I agree to the use of my tissue after diagnosis for education, research and quality assurance

YES NO

I understand that by agreeing to this I am making a gift of the tissue to Newcastle upon Tyne Hospitals NHS Trust and that subsequent use of the material will be entirely at the discretion of the Trust.

Signed:

Name (please print):

Witnessed by: (signature)

..... (name)

..... (position)

Date:

**Consent form for non-proceeding living kidney donation
 for intended recipient**

Tel: 0191 233
 6161

Fax: 0191 213 1968

Donor details

Name:

Address:

.....

.....

DOB:

Hospital Number:

.....

NHS Number:

.....

Recipient details

.....

.....

.....

.....

Hospital Number:

.....

NHS Number:

.....

My name is:

and I am the donor of a kidney which is intended for recipient name:

.....

I understand that there is a very small risk that it may not be possible for the surgeon to transplant my kidney into the patient named above once surgery has begun (only two cases of this nature have been identified in the last ten years). In this situation, I wish the following to take place:

Please select only **one** option

1. I wish for my kidney to be transplanted into an alternative recipient

Please circle: Yes No

2. I wish for my kidney to be re-implanted.

Please circle: Yes No

3. I wish for my kidney to be used for research

Please circle: Yes No

4. I wish for my kidney to be disposed of

Please circle: Yes No

I also confirm that the surgeon has discussed what the risks and benefits associated with each option are; and that I have had the opportunity to ask any questions and have them answered to my satisfaction.

Name of donor (Print):

Signature: **Date:**.....

Medical Practitioner / Living Donor Coordinator (Print):

Name:

Designation: **Hospital:**

Signature: **Date:**.....

THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
IMPACT ASSESSMENT – SCREENING FORM A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	Consent to Examination or Treatment (with reference to the MCA 2005)	Policy Author:	Nurse Specialist Patient Safety
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		This policy does not discriminate against any individual on the basis of race, ethnicity, nationality, gender, culture, religion, sexuality, age or disability.
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems.	No	
2.	Is there any evidence that some groups are affected differently?		
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4(a).	Is the impact of the policy/guidance likely to be negative? (If “yes”, please answer sections 4(b) to 4(d)).	NA	
4(b).	If so can the impact be avoided?		
4(c).	What alternatives are there to achieving the policy/guidance without the impact?		
4(d).	Can we reduce the impact by taking different action?		

Comments:	Action Plan due (or Not Applicable):
	NA

Name and Designation of Person responsible for completion of this form: Jo Coward Nurse Specialist Patient Safety Date: 11/09/2009

Names & Designations of those involved in the impact assessment screening process: Clinical Governance and Quality Committee

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)