

Directorate of Governance & Assurance

POLICY FOR CONSENT TO EXAMINATION OR TREATMENT

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Northern Lincolnshire and Goole NHS Foundation Trust actively seeks to promote equality of opportunity. The Trust seeks to ensure that no employee, service user, or member of the public is unlawfully discriminated against for any reason, including the “protected characteristics” as defined in the Equality Act 2010. These principles will be expected to be upheld by all who act on behalf of the Trust, with respect to all aspects of Equality.

Contents

Section	Page
1.0 Introduction	4
2.0 Area	6
3.0 Duties.....	6
4.0 Documentation.....	7
5.0 When should consent be sought?.....	9
6.0 Provision of information	14
7.0 Who is responsible for seeking consent?.....	17
8.0 Refusal of treatment.....	19
9.0 Tissue	20
10.0 Clinical photography and conventional or digital video recordings.....	20
11.0 Training.....	22
12.0 Monitoring Compliance and Effectiveness	23
13.0 Associated Documents	24
14.0 References & Further Information.....	24
15.0 Definitions	24
16.0 Consultation	24
17.0 Dissemination	25
18.0 Implementation	25
19.0 Equality Act (2010).....	25
Appendices:	
Appendix A - 12 key points on consent: the law in England	26
Appendix B - Current forms in use in this organisation.....	28
Appendix C - Further information/advice – useful contacts.....	32
Appendix D - How to seek a court declaration.....	33
Appendix E - Seeking consent: remembering the patient’s perspective	35

Schedule 1 – Related Topics:

Parental Responsibility	36
When should written consent be obtained?	37
Training of Healthcare Professionals (e.g. Medical Students) & the Presence of Pharmaceutical or Other Sales Representatives During Patient Consultations.....	37
The Use of Chaperones for Intimate Examinations	37
Anaesthetised Patients:	38
Research and Innovative Treatment.....	38
Same Sex Partners.....	38
Advance Decisions (Living Wills)	38
Children and Consent to Treatment.....	40
Tissue - The Human Tissue Act 2004 (HTA 2004)	41
The Mental Capacity Act 2005.....	43
Making Decisions in Best Interests (under the Mental Capacity Act 2005).....	43

1.0 Introduction

1.1 Why consent is crucial

1.1.1 Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

1.2 This policy

1.2.1 The Department of Health has issued a range of guidance documents on consent (see overleaf), and these should be consulted for details of the law and good practice requirements on consent. DH Guidance 'Reference Guide to Consent for Examination and Treatment' has been amended to incorporate the changes to consent which have come into force since the Mental Capacity Act 2005. This policy sets out the standards and procedures within Northern Lincolnshire & Goole NHS Foundation Trust which aim to ensure that health professionals are able to comply with the law and guidance. Whilst 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.

1.3 What consent is – and isn't

1.3.1 "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:

- have the capacity to make the particular decision
- have received sufficient information to make it; and
- not be acting under duress

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

1.5 Every adult has the right to make their own decisions unless there is proof that they lack the capacity to make a particular decision. In the event that a person lacks capacity, a person appointed as an attorney under a registered Lasting Power of Attorney or appointed by the Court of Protection as a court deputy can consent or refuse consent to treatment where authorised to do so in a person's best interests. In all other circumstances treatment may be given if it is in a patient's best interests, as long as it has not been refused in advance in a valid and applicable Advance Decision. For further details on Advance Decisions – please refer to Schedule 1 of this document, the Trust's Policy on Advance Decisions (Living Wills) and see the Department of Health's Reference guide to consent for examination or treatment (chapter 1, paragraph 19). For further information on making decisions in 'best interests' please refer to Schedule 1 of this document.

1.6 Guidance on consent

1.6.1 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 Risk Management webpage under the 'consent' heading and may also be accessed on the internet at www.dh.gov.uk/consent.
- 12 key points on consent: the law in England has been distributed widely to health professionals working in England, although this pre-dates the MCA. This one-page document summarises those aspects of the law on consent which arise on a daily basis and is attached at Appendix A. Further copies are available from www.dh.gov.uk/consent.
- 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 these booklets have been issued to relevant wards and departments and are available on the Risk Management webpage under the 'consent' heading and on the internet at www.dh.gov.uk/consent.

1.7 The Mental Capacity Act 2005 and the accompanying Code of Practice came in to force in 2007 and set out the law and practice on decision making, including helping patients make their own personal welfare, including healthcare decisions, and what to do if a person lacks capacity to make a decision. Healthcare professionals must comply with the Act and "have regard" to the Code of Practice when assessing capacity to consent to treatment and when making decisions in best interests on behalf of incapacitated patients.

*On 1 July 2010, the General Medical Council (GMC) published new guidance for doctors, Treatment and Care Towards End of Life: Good Practice in Decision Making. This provides guidance on advance care planning for patients nearing the end of life, including how to manage advance requests and refusals of treatment. This guidance replaces the booklet Withholding and Withdrawing Life-Prolonging Treatments (2002) and expands on the guidance in Consent, Patients and Doctors Making Decisions Together.

1.8 Assessing Capacity

1.8.1 There is always an assumption that a person can make their own decisions. A person will be unable to make a decision if, after all appropriate help and support to make the decision has been given to them, they cannot:

- understand the information relevant to that decision
- retain that information
- use or weigh that information as part of the process of making the decision
- communicate their decision (whether by talking, using sign language or any other means - Section 3 of the MCA 2005 refers)

2.0 Area

This Policy applies to all employees of Northern Lincolnshire & Goole NHS Foundation Trust and who may be involved in the process of obtaining consent for treatment and to all Trust premises across Northern Lincolnshire & Goole NHS Foundation Trust.

3.0 Duties

3.1 Chief Executive

The Chief Executive has overall responsibility for ensuring that appropriate policies and procedures are in place for involving patients in their care and treatment.

3.2 Director of Governance & Assurance

The Director of Governance & Assurance is responsible for ensuring the development and implementation of this policy.

3.3 Directors / Clinical Leads / Managers

Directors/Clinical Leads/Managers are responsible for ensuring that this policy is implemented and available in all relevant areas and for ensuring that staff adhere to the guidance contain herein and attend or complete the relevant consent training.

3.4 Governance Leads

Governance Leads are responsible for ensuring, where the process of obtaining consent is delegated, the compilation of the local level registers of staff assessed as competent to take consent in these circumstances – see section 11.0 – Training.

3.5 Individual Healthcare Professionals

Any member of the healthcare team involved in the process of obtaining consent for treatment will be responsible for ensuring that they are familiar with and comply with the requirements outlined within this policy. Further, for ensuring that they attend or complete the required training.

4.0 Documentation

4.1 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 oral consent.

4.2 Written consent

4.2.1 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.

4.3 It is rarely a legal requirement to seek written consent¹, 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 Northern Lincolnshire & Goole NHS Foundation Trust

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

- 4.4** Completed consent forms should be kept with the patient's notes. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional. Where oral consent has been given and recorded in the patient's notes, any change must be clearly documented in the patient's notes.
- 4.5** 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 must be recorded in the patient's notes.
- 4.6 Procedures to follow when patients lack capacity to give or withhold consent**
- 4.6.1** Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented in form 4 (form for adults who lack the capacity to consent to investigation or treatment), along with the assessment of the patient's capacity, whether there is anyone authorised to make a decision on behalf of the patient under the MCA 2005, why the health professional believes the treatment to be in the patient's best interests, and the involvement of people engaged in the care or interested in the welfare of the patient when determining best interests. The standard consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient's notes.
- 4.7** There is an assumption of capacity that a person is able to make decisions themselves unless proved otherwise. An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. Under the MCA 2005 a person is not to be treated as unable to make a decision until all practicable steps to help the person to do so have been taken without success. You should involve appropriate colleagues in making such assessments of incapacity where appropriate, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient's situation prevents this. Where practicable, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate. Guidance is provided in the Code of Practice to the Mental Capacity Act 2005 on helping a person make their own decision (Chapter 3).
- 4.8** A patient (aged 18 or over) may have planned for incapacity by making an Advance Decision or appointing an attorney(s) under a registered Lasting Power of Attorney (LPA) to make personal welfare (including healthcare) decisions for them when they are unable to make a decision. You are referred to the Trust's policy on Advance Decisions if either an Advance Decision or LPA is in existence and to follow the guidance.
- 4.8.1** Otherwise, where a person lacks capacity to make a decision and the health professional is planning to make a decision in best interests, the decision maker has a duty under the Mental Capacity Act 2005 to follow best interests under the Act which includes taking into account, if it is practicable and appropriate to consult them, the views of others, which may include the views of an Independent Mental Capacity Advocate (IMCA) in circumstances where there is no-one else to consult (see Schedule 1: making decisions in best interests).

4.9 Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Wherever possible, disagreements about best interests should be resolved informally through local dispute resolution procedures. Chapter 15 of the Code of Practice to the Mental Capacity Act 2005 provides guidance on resolving disagreements and disputes. Where the consequences of having, or not having, the treatment is potentially serious, a court declaration may be sought - see Appendix D for details of how to do this.

4.10 Availability of forms

4.10.1 Standard consent forms and forms for adults who are unable to consent for themselves are reproduced at Appendix B and are available in all wards and departments. Further copies can be ordered from Stores.

4.10.2 There are three versions of the standard consent form:

- **form 1** is for adults or competent children
- **form 2** is for parental consent for a child or young person; and
- **form 3** is 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

4.10.3 Consent **form 4**: is for adults who lack capacity to consent to a particular treatment. A person may only be treated if that treatment is believed to be in their 'best interests'. This form requires health professionals to document both how they have come to the conclusion that the patient lacks the capacity to make this particular healthcare decision, and why the proposed treatment would be in the patient's best interests. It also allows the involvement of those engaged in the care or interested in the welfare of the patient in making this healthcare decision to be documented.

5.0 When should consent be sought?

5.1 When a patient formally gives their consent to a particular intervention, this is only the endpoint of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

5.2 Single stage process

5.2.1 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 orally.

5.3 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.

5.4 Two or more stage process

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

5.5 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?"

5.6 Whilst 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.

5.7 Seeking consent for anaesthesia

5.7.1 Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's notes or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

5.7.2 Within Northern Lincolnshire & Goole NHS Foundation Trust, the decision has been taken to implement a separate Anaesthetic Consent Form. The form will be utilised to obtain written anaesthetic consent where it is considered appropriate by the Anaesthetist concerned (e.g. where anaesthesia represents a significant risk to a particular patient). Where written consent is not considered appropriate, details of the discussion with and agreement of the patient (including details of the anaesthetic techniques, risks involved etc.) should be documented in the anaesthetic record.

5.8 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.

5.9 Emergencies

5.9.1 Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

5.10 Treatment of children who have capacity

(a) Children over the age of 16:

- A child who is aged 16 or 17 is assumed to have the same capacity as an adult to consent to treatment. If there is a reason to believe that such a child does not have capacity to provide consent, their capacity to make a decision about that particular treatment should be tested in accordance with the mental capacity test which is set out at Sections 2 and 3 of the Mental Capacity Act 2005 (See Schedule 1 "Children and Consent to Treatment")
- It is good practice to encourage children over the age of 16 to tell their families or someone with parental responsibility for them about their treatment. Given the duty of confidentiality to patients, information should not usually be provided to parents or a person with parental responsibility (see Schedule 1 for further information on "parental responsibility") for them without consent, but you should encourage the child to inform someone who would be able to offer assistance and support to them during and after treatment. If the child should refuse, their refusal should be respected unless you judge that:
 - the disclosure is in the best interests of the child
 - the child does not have the maturity or understanding to make a decision about the disclosure
 - there is an overriding public interest in the disclosure; or
 - disclosure is required by law
- If you are considering a disclosure on any of these grounds further guidance should be obtained before you take any action

(b) Children under the age of 16 who are able to consent ('Gillick competent' children)

- Children under the age of 16 are presumed to lack capacity to make decisions about treatment. However, they will be competent to give valid consent to a particular intervention if they have "sufficient understanding and intelligence to enable them to understand fully what is proposed" (known as 'Gillick competence'). Consideration therefore has to be given to whether the child has the maturity and intelligence to fully understand the nature of the treatment, the options, the risks involved and the benefits. (See Schedule 1 "Children and Consent to Treatment")
- Even if a child is Gillick competent to consent to a particular intervention, it is good practice to involve their family (someone with parental responsibility for that child) in the decision making process, if the child agrees. The rules relating to the disclosure of information without the child's express consent are the same for Gillick competent children as they are for competent children over the age of 16 (see (a) above)

(c) A competent child who refuses to consent to treatment

- A competent child's refusal of treatment may be overruled by someone with parental responsibility for them, if failing to carry out the treatment would lead to the child's death or severe permanent injury. In other circumstances you should seek legal advice since overruling a competent child's consent may constitute an interference with their fundamental human rights and may lead to a legal action being brought against the Trust under the Human Rights Act 1998

5.11 Treatment of children who lack capacity

5.11.1 Children under the age of 16 who are not 'Gillick competent' cannot lawfully give or withhold consent. A person with parental responsibility for a child must therefore provide their consent to the child's treatment (see Schedule 1).

(a) Where a person with parental responsibility accompanies the child

- If a person with parental responsibility is present to provide the necessary consent for the child's assessment or treatment consent should be obtained from that person
- You should note that in certain limited circumstances the courts have ruled that all those people with parental responsibility for a child should provide their consent to treatment, for example in cases involving non-therapeutic circumcision and cases involving immunisation. If you are in doubt you should seek legal advice

(b) Where a person with parental responsibility does not accompany the child

Advance Consent

- When children who lack capacity to consent are being cared for in a hospital, it will not usually seem practical to seek consent from someone with parental responsibility for them 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) someone who has parental responsibility for them what routine procedures will be necessary, and ensure that you have their valid consent for these interventions in advance. If a person with parental responsibility for a child specifies 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 of death or serious permanent injury

Consequential Treatment

- In circumstances where consequential treatment is required, for which you do not have valid consent, the treatment should be given where it is in the child's best interests to receive it there and then and there is not time to obtain valid consent. It would be lawful to carry out such treatment if delaying the treatment would put the child at significant risk of death or serious permanent injury
- Treatment without consent should be limited to what is reasonably required to deal with that particular emergency. In all cases, it is important to document fully what decisions were made, why and by whom

Delegated Consent

- You should note that in an emergency a person without parental responsibility (for example a child minder) may do what is reasonable, in all of the circumstances of the case, for the purpose of safeguarding or promoting the child's welfare, including giving consent for urgent medical treatment
- Those with parental responsibility may delegate authority to consent to a child's treatment to those in whose care the child has been placed but it would be prudent to only rely upon such consent where the child is being treated for a minor injury

6.0 Provision of information

- 6.1** The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where to go, how long they will be in hospital, how they will feel afterwards and so on.
- 6.2** Patients 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.
- 6.3** In considering the information to provide, health professionals should try to ensure that the patient is able to make an informed judgement on whether to give or withhold consent. Case law on this issue is evolving. It is therefore advisable to inform the patient of any 'material' or 'significant' risks or unavoidable risks, even if small, in the proposed treatment; any alternatives to it; and the risks incurred by doing nothing. It is advisable that healthcare professionals give information about all significant possible adverse outcomes and make a record of the information given. The 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. It advises that discussions should focus on the patient's 'individual situation and risk to them' and sets out the importance of providing the information about the procedure and associated risks in a balanced way and checking that patients have understood the information given.
- 6.4** The following sources of patient information are available within Northern Lincolnshire & Goole NHS Foundation Trust to support the consent process:
- In line with NHSLA and good practice requirements, patient information leaflets which contain information on particular procedures/treatments, including information on the risks/benefits and alternatives to treatment, are available within all specialties and will be provided to patients well before their proposed treatment
 - In order to ensure that only high quality, detailed and accurate information is provided, an 'Information for Patients' Group has been established to oversee the production of all patient information leaflets. Guidelines have also been produced which outline the various criteria to be met when producing leaflets. The guidelines, which cover such issues as content, font size and accessibility, are available on the Trust's intranet site. More detailed guidance on 'writing about risks, benefits and alternatives of treatment' is also available within these guidelines

- Other sources of patient information leaflets include the commercially available medical reference library 'Doctor on Line' which provides healthcare practitioners with access to hundreds of clearly written, clinically accurate and peer reviewed information leaflets for patients. 'Doctor on Line' can be accessed via the 'useful links/other healthcare links' section on the Trust's Intranet site.

N.B. Care needs to be taken to ensure that commercially produced leaflets reflect actual local clinical practice and/or what the patient has been told verbally about his/her condition treatment, otherwise this can be confusing/misleading

- In respect of patients with sensory impairment, as outlined in the Trust's Sensory Impairment Policy, the Trust will endeavour to ensure that the environment of care is suitable and that any information made available will be in a format most acceptable to them. This will include Braille, large print, audit tape, sign support language etc.
- The Customer Services Function (which incorporates the Patient Advice & Liaison Service (PALS) Team) also have an extensive list of voluntary organisations offering support to patients and carers with specific disabilities/needs

6.5 Provision for patients whose first language is not English

6.5.1 The Northern Lincolnshire & Goole NHS Foundation 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 to interpret for family members who do not speak English:

- The Trust has in place a policy & procedure on the use and accessing of translation and interpreting services, which is available on the Trust's Intranet. This service is managed via the Customer Services Function. Where immediate assistance is needed the service of 'Big Word', a telephone interpreting service, can be accessed directly by staff members – details available from the Customer Services Function.
- Where the need for this is identified, translated versions/alternate formats of this policy and associated consent forms and patient information leaflets will be provided via the Customer Services Function

6.6 Access to more detailed or specialist information

6.6.1 Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. The Northern Lincolnshire & Goole NHS Foundation Trust has made the following arrangements to assist patients to obtain such information:

- For condition specific information, it will be the responsibility of the treating/caring healthcare professionals to ensure that patients receive adequate information about their condition/proposed treatment. However, where patients may require more detailed information, the PALS Team will also be a useful source of information. The PALS Team work with Directorates to identify all information given to patients and carers. This will include details of local and national voluntary support groups and organisations. It is anticipated however that the PALS Team will provide more of a 'signposting' role and will direct patients to sources of internally and externally available information rather than directly issuing information
- In developing information for patients, Directorates should bear in mind the need to ensure that information is provided in different formats and languages. This issue will be kept under review by the Trust's 'Information for Patients Group'
- As indicted under section 6.4 point 3 above, 'Doctor on Line' may also be a useful source of further information for healthcare professionals and their patients

6.7 Access to health professionals between formal appointments

- 6.7.1** 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 make 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). The Trust's 'Guidelines for Producing Patient Information' ask Directorates to ensure that all leaflets contain details of the appropriate person to call if the patients has concerns and/or further questions at any time and most leaflets in place include this information. This information can also be included on the consent form – a copy of which should be given to the patient. In addition, the PALS Team will deal with queries on any issue and this will often mean arranging for someone from the clinical team to talk to the patient within a few days and where necessary they may be able to arrange or rearrange out-patient appointments.

6.8 Open access clinics

- 6.8.1** Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. You should ensure that they have the information they need before proceeding with an investigation or treatment. The Trust will ensure that information is available for patients accessing open access clinics through the use of appropriate information leaflets and through work with the Commissioners.

6.9 Provision of Information to Third Parties

- 6.9.1** Under the Mental Capacity Act 2005 an attorney under an LPA or a court deputy may be authorised to consent to or refuse medical treatment where a patient is unable to make the decision for themselves. They will require necessary information to make the decision.

6.9.2 If the healthcare professional is making a decision in best interests then they have a duty to consult person(s) engaged in the care or interested in the welfare of the patient before making a decision in best interests. This will require the sharing of necessary information.

6.9.3 Chapter 16 of the Code of Practice to the Mental Capacity Act 2005 provides guidance to professionals on the sharing of information.

7.0 Who is responsible for seeking consent?

7.1 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, although the consultant responsible for the patient's care will remain ultimately responsible for the quality of medical care provided.

7.2 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 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.

7.3 Completing consent forms

7.3.1 The consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: 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.

7.4 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 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 questions they cannot handle themselves.

7.4.1 Where the task of obtaining consent is delegated:

- The Northern Lincolnshire & Goole NHS Foundation Trust supports the GMC's Guidance on Good Practice which states:

"If you are the doctor providing treatment or undertaking an investigation, it is your responsibility to discuss it with the patient and obtain consent, as you will have a comprehensive understanding of the procedure or treatment, how it is carried out, and the risks attached to it. Where this is not practicable, you may delegate these tasks provided you ensure that the person to whom you delegate:

- is suitably trained and qualified
- has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved

- You will remain responsible for ensuring that, before you start any treatment, the patient has been given sufficient time and information to make an informed decision, and has given consent to the procedure or investigation”
- Within the Northern Lincolnshire & Goole NHS Foundation Trust, where the process of obtaining consent is delegated to staff who are not capable of performing the procedure, it will be the responsibility of the relevant Consultant (in accordance with GMC guidance) or other senior healthcare professional to ensure that the person to whom this task is delegated (whether to a junior member of the medical staff, Nurse Practitioner or other healthcare professional) is appropriately trained and assessed as competent.
- In respect of medical staff in training, assessment of competence to obtain consent, for procedures they are not capable of performing, will form part of the review and assessment of the skills/competencies required to undertake their role within a particular specialty and will be recorded on the ‘Delegation of Consent: Assessment of Competency’ forms issued at induction.
- For non-medical staff, the Trust has developed a training/competency assessment package entitled ‘Obtaining Informed Consent by Healthcare Professionals to whom this task may be delegated’. This package can be obtained from the Risk Management webpage under both the ‘consent’ and ‘training’ headings
- In the event that a member of staff obtains consent for a procedure without being authorised to do so, it will be the responsibility of the relevant Consultant and/or Clinical Lead to ensure follow-up – including the provision of additional training/support as required. Dependent on the circumstances, an incident form should be generated
- Similarly, where the responsibility for ‘confirmation of consent’ is delegated, it will be the responsibility of the relevant Consultant/other healthcare professional to ensure that members of the healthcare team (including nursing staff) have access to appropriate colleagues where they are personally not able to answer any remaining questions

7.5 Responsibility of health professionals

7.5.1 Inappropriate delegation (for example where the clinician seeking consent has inadequate knowledge of the procedure) may mean that the ‘consent’ obtained is not valid.

7.5.2 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

7.5.3 If you feel that you are being pressurised to seek consent when you do not feel competent to do so please contact one of the following:

- your Directorate Governance Lead or Clinical Lead
- the Clinical Tutor
- the Trust's Medical Director
- the Director of Governance & Assurance
- the Chief Nurse
- the Head of Risk Management

8.0 Refusal of treatment

8.1 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 (aged 18 or over) is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983. The situation for children is more complex: see the Department of Health's Seeking consent: working with children for more detail. The following paragraphs apply primarily to adults.

8.2 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, you (and where possible the patient) should note this on the form.

8.3 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.

8.4 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.

9.0 Tissue

- 9.1** The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues and has recently been extensively reviewed. 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, the Northern Lincolnshire & Goole NHS Foundation Trust recognises 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. Details of such refusals should be recorded on the Consent Form and relevant pathology forms and the laboratory informed.
- 9.2** Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply. Any express request received from a patient for their tissue not to be used will be recorded and dealt with in line with the Public Health policy governing this.
- 9.3** Tissue samples from living persons may be used for quality assurance purposes without requiring specific patient consent (although tissue from a deceased person to be used for quality assurance purposes requires specific consent from an appropriate person) 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. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised. Those health professionals seeking consent are responsible for ensuring that patients fully understand the reasons for taking tissue samples and the purposes for which they may be used. Where patients refuse permission for tissue taken from them during surgery to be used in this way, this should be recorded in the patient's medical records and the laboratory informed. Please see Schedule 1 of this policy for further information in light of the Human Tissue Act 2004.

10.0 Clinical photography and conventional or digital video recordings

- 10.1** Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.
- 10.2** Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

- 10.3** Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.
- 10.4** If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.
- 10.5** The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.
- 10.6** If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of some-one close to the patient. 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.
- 10.7** * General Medical Council (GMC) guidance for doctors, Making and Using Visual and Audio Recordings of Patients, came in to effect on 9 May 2011 and replaced previous versions of the guidance which was issued in 2002. The guidance provides detailed guidance on situations where doctors make recordings of patients, which may be used for a variety of purposes. The guidance can be view on the GMC's website at www.gmc-uk.org/recordings

11.0 Training

11.1 The following training on consent is provided within the Northern Lincolnshire and Goole NHS Foundation Trust:

- **Generic Training on the Consent Process**
 - Annual legal/consent update training/awareness sessions provided by the Trust's Legal Advisors. These sessions are available to all staff involved in the process of obtaining consent and are used to update on recent developments and changes in the law affecting the law on consent. Details are available on the Risk Management webpage under 'Training' and will be notified to all relevant staff as they are arranged. Attendance at these sessions will be recorded on the OLM training database. Further information on consent – including useful links – is available on the risk management webpage on the Trust's Intranet
 - As part of the wider Risk Management Training Programme, training on consent is provided on an on-ongoing basis through the use of the EIDO e-learning consent training package which is available to all staff involved in the process of obtaining consent. This system can be accessed via the Risk Management webpage under 'Training'
 - Ad hoc training sessions are provided, as required, by staff within the Risk Management Department. More in-depth sessions are provided for junior medical staff as part of the Post Graduate Medical Education Centre programmes.
- **Procedure Specific Consent Training**
 - Training/assessment of competence to obtain consent for specific procedures, for example where this task is delegated to staff not capable of performing the procedure themselves, will continue to be undertaken within individual Directorates/Specialties. Where the process of obtaining consent is delegated, it is the responsibility of the relevant Consultant to ensure that the staff to whom the task is delegated are appropriately trained and their competence to do so has been assessed and is recorded.
 - Before confirming competency, the relevant Consultant should be satisfied that the delegate:
 - has sufficient knowledge of the proposed procedure or treatment and understands the risks, benefits and alternatives and can explain them in a way the patient understands
 - is aware of the information sources available
 - is aware of his or her own knowledge limitations and knows when to defer to more experienced colleagues
 - Assessment of competency to take consent for medical staff in training is recorded on the 'Delegation of Consent: Assessment of Competency' forms issued at induction

- Non-Medical staff: the Trust has developed a training/competency assessment package entitled 'Obtaining Informed Consent by Healthcare Professionals to whom this task may be delegated'. This package can be obtained from the Risk Management webpage under both the 'consent' and 'training' headings
- In the event that a member of staff obtains consent for a procedure without being authorised to do so, it will be the responsibility of the relevant Consultant and/or Clinical Director to ensure follow-up – including the provision of additional training/support as required. Dependent on the circumstances, an incident form should be generated

N.B. Training sessions will include education on communicating with and obtaining consent from those patients whose first language is not English and/or where race/culture/religion has implications for the consent process.

12.0 Monitoring Compliance and Effectiveness

12.1 The Trust will monitor compliance with the requirements outlined within this policy via the following mechanisms:

- **Obtaining & Documenting Consent (including the provision of information)**
 - incident forms in respect of any failures in the consent process will be reviewed and action taken within the relevant area and will also be reviewed by the Trust Governance & Assurance Committee as part of consideration of the quarterly incident analysis reports and any further actions/awareness will be agreed as part of that process
- **Consent Training**
 - completion of the generic consent training including the monitoring of the numbers of staff who have completed the on-line consent to treatment package will be monitored by Directorate Governance Groups and Governance Liaison Group
 - in respect of procedure specific consent to treatment and the competence of staff to take consent, this will be monitored within the respective Directorate/specialities. In the event that a member of staff obtains consent for a procedure without being authorised to do so, it will be the responsibility of the relevant Consultant and/or Clinical Lead to ensure follow-up – including the provision of additional training/support as required. Dependent on the circumstances, an incident form should be generated
 - incident forms in respect of any failures in the consent process will be reviewed and action taken within the relevant area and will also be reviewed by the Trust Governance & Assurance Committee as part of consideration of the quarterly incident analysis reports and any further actions/awareness will be agreed as part of that process

13.0 Associated Documents

It is recommended that this policy is read in conjunction with the following Trust policies and procedures:

- Policy for Advance Decisions (Living Wills)
- Mental Capacity Act (MCA) 2005 & MCA Deprivation of Liberty (DOLS) Policy
- Restraint Policy
- Guidance on Producing Information for Patients
- Interpreting and Translation Policy

14.0 References & Further Information

- 14.1 Good Practice in Consent Implementation Guide, DOH (2001).
- 14.2 Reference Guide to Consent for Examination or Treatment (Second Edition), DOH (2009).
- 14.3 Seeking Consent: Working with Children, DOH (2001).
- 14.4 Mental Capacity Act (2005) & Mental Capacity Act Code of Practice.
- 14.5 Mental Capacity Act Deprivation of Liberty Safeguards & Mental Capacity Act Deprivation of Liberty Safeguards.
- 14.6 Human Tissue Act (2004) & Human Tissue Act Code of Practice on Consent (2006).
- 14.7 Consent Guidance: Patients and Doctors Making Decisions Together, GMC (2008).
- 14.8 NHSLA Risk Management Standards for Acute Trusts, NHSLA
- 14.9 The DOH website provides a number of documents and information relating to consent and can be accessed via the following link:
www.dh.gov.uk

15.0 Definitions

None.

16.0 Consultation

Trust Governance & Assurance Committee

17.0 Dissemination

The Trust's Consent to Treatment Policy will be disseminated to all clinical staff in wards/departments in hard copy and via email and on the Trust's Intranet. Amendments to the policy will be communicated to these staff as and when they occur.

18.0 Implementation

Awareness and training in support of the implementation of this policy will be provided in accordance with the arrangements outlined in section 11.0 above.

19.0 Equality Act (2010)

19.1 In accordance with the Equality Act (2010), the Trust will make reasonable adjustments to the workplace so that an employee with a disability, as covered under the Act, should not be at any substantial disadvantage. The Trust will endeavour to develop an environment within which individuals feel able to disclose any disability or condition which may have a long term and substantial effect on their ability to carry out their normal day to day activities.

19.2 The Trust will wherever practical make adjustments as deemed reasonable in light of an employee's specific circumstances and the Trust's available resources paying particular attention to the Disability Discrimination requirements and the Equality Act (2010).

**The electronic master copy of this document is held by Document Control,
Directorate of Governance & Assurance, NL&G NHS Foundation Trust.**

Appendix A

12 key points on consent: the law in England

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.
2. Adults are always assumed to be competent unless proven otherwise. If you have doubts about their competence, the question to ask is can this patient:
3.
 - a) understand the information relevant to that decision;
 - b) retain that information;
 - c) use or weigh that information as part of the process of making the;
 - d) communicate their decision (whether by talking, using sign language or any other means).

Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.

4. Patients may be competent to make some health care decisions, even if they are not competent to make others.
5. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

6. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent **cannot** over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare. Additional information regarding the ability of children to give consent is set out in the main body of this policy, at paragraphs 3.10 and 3.11. The Mental Capacity Act 2005 has limited application to children. Chapter 12 of the Code of Practice to the Act provides guidance on how it applies.

Who is the right person to seek consent?

7. It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.

What information should be provided?

8. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.
9. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

10. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusal of treatment

11. Competent adult patients are entitled to refuse treatment, even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the fetus.

Adults who are not competent to give consent

12. **No-one** can give consent on behalf of an incompetent adult. (From 1 October 2007 a person appointed as an attorney under a registered Lasting Power of Attorney (LPA) or appointed by the Court of Protection as a court deputy will be able to consent or refuse consent to treatment in a patient's best interests where authorised to do so).

Where there is no person(s) authorised to consent or refuse treatment then you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People engaged in care or interested in the welfare of the patient who are close to the patient may be able to give you information on some of these factors. Relatives, carers and friends may be best placed to advise on the patient's needs and preferences. See Appendix F for Making Decisions in Best Interests and the duty to consult with others when determining best interests.

13. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'Advance Decision'), and the Advance Decision is valid and applicable then you must abide by that refusal - best interests will not be a factor – see Schedule 1 'Advance Decisions/Living Wills' for further information.

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment*, available from the NHS Response Line 08701 555 455 and at www.dh.gov.uk/consent.

Appendix B

Current forms in use in this organisation

Standard consent forms and forms for adults who are unable to consent for themselves are available in all wards and departments. Further copies can be ordered from Stores.

There are three versions of the standard consent form:

- **form 1:** for adults or competent children able to consent for themselves;
- **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 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.

Consent **form 4:** is for adults who lack capacity to consent to a particular treatment. A person may only be treated if that treatment is believed to be in their 'best interests'. This form requires health professionals to document both how they have come to the conclusion that the patient lacks the capacity to make this particular healthcare decision, and why the proposed treatment would be in the patient's best interests. It also allows the involvement of those engaged in the care or interested in the welfare of the patient in making this healthcare decision to be documented.

Within Northern Lincolnshire and Goole NHS Foundation Trust the decision has been taken to implement a separate **Anaesthetic Consent Form**. This form will be utilised to obtain written anaesthetic consent where it is considered appropriate by the Anaesthetist concerned (e.g. where anaesthesia represents a significant risk to a particular patient). Where written consent is not considered appropriate, details of the discussion with and agreement of the patient (including details of the anaesthetic techniques, risks involved etc) should be documented in the anaesthetic record.

The above consent forms are available in A3 'no carbon required' format, allowing a copy to be offered to the patient/person with parental responsibility. .

The information leaflet entitled 'About the Consent Form' should be made available to patients in advance of their being asked to sign a consent form. Copies of these leaflets, in versions for adults, children, parents, carers/relatives and people with learning difficulties, are available in all wards and departments where consent forms are used.

Customisation of Consent Forms

The DoH's 'Good Practice in Consent Implementation Guide' states that:

“Relevant sections of the forms (such as those dealing with benefits and risks) may be pre-printed where high through-put specialties make this feasible and desirable. If this is done, it will, of course, always be necessary for health professionals to consider whether additional risk/benefit information should be added by hand, to reflect the particular needs of the individual patient. It is essential, however, to ensure that this does not lead to a ‘conveyor belt’ approach to consent in these circumstances”.

There are a number of customised consent forms in place within Northern Lincolnshire and Goole NHS Foundation Trust these are available on the Trust's Intranet.

Where individual specialties/departments wish to customise consent forms as outlined above, this should be co-ordinated in the first instance via the Trust's Document Controller who can be contacted on (DPoWH) Ext: 2579.

Consent for Hospital Post Mortem

Hospital consent/request autopsies are performed under the guidelines within the Human Tissue Act 2004 and are performed for the purpose of medical education, research and clinical audit.

These autopsies can only be performed with the written consent from a person in a qualifying relationship (see below), a nominated person or the deceased patient before death. The death certificate **must** have been issued and the requesting clinician must complete the hospital post-mortem examination request form.

The extent of the examination may be limited by consent and such limitations **must** be respected to comply with the Human Tissues Act 2004.

Definition of a Qualifying Relationship

Those in a qualifying relationship to the deceased person are (highest first):

- a) Spouse or partner (including civil or same sex partner)
- b) Parent or child (in this context a 'child' can be any age)
- c) Brother or sister
- d) Grandparent or grandchild
- e) Niece or nephew
- f) Stepfather or stepmother
- g) Half-brother or half-sister
- h) Friend of long standing.

Requests for a Hospital Post-Mortem

If a Hospital Post Mortem is requested, the doctor will contact the mortuary to make the request. They will be given two options.

Option 1 – they will be asked to attend the mortuary department to collect the necessary consent and request forms. It will be explained that when they attend the mortuary to collect the forms they will not be permitted to take them away until they have received the necessary instruction to enable them to take a full and informed consent.

Option 2 – If they cannot attend the mortuary as above, they will be given the option for a trained person to accompany them when they take consent for the post-mortem. This will ensure the person giving consent has been fully informed about and understands the processes that they are consenting to.

Consent form

To enable a hospital post-mortem examination to go ahead the consent to a hospital post-mortem examination form must be completed and signed by a person in a qualifying relationship, nominated person or the patient before death. All sections and sub-sections **must** be completed, even in the negative, to enable proper informed consent. These include:

- Part 1 – Consent For Post-Mortem Examination of an Adult
- Part 2 – Post Mortem Examination
- Part 3 – Retention and future use of tissue samples
- Part 4 – Retention of organs for more detailed examination
- Part 5 – Other requirements of the post-mortem examination
- Part 6 – Signatory Section
- Part 7 – Staff Support and Witness
- Part 8 – Withdrawal of Consent

If any section or sub-section is not completed, the form will be returned to the ward for completion.

Two copies of the form should be made. One copy should be offered to the person giving consent and one copy filed with the patient's notes.

Hospital post-mortem examination request form

As well as the consent form, the requesting doctor must complete a hospital post-mortem examination request form. This form will have the following details:

- Patient's identification details (name, address, ward, date and time of death etc.)
- The cause of death as given on the death certificate (if the doctor does not know the cause of death they should report it to the Coroner)

- Clinical summary
- Specific questions to be answered by post-mortem
- Any hazards likely to be presented to mortuary staff

Paediatric Referral

In the case of the death of a child, (under 16 years of age), the autopsy examination can only be performed by a Paediatric Pathologist, which will require the deceased to be transferred to a centre that deals with Paediatric autopsies.

Referrals from Grimsby and Scunthorpe will be taken via local Funeral Directors to the Sheffield Children's Hospital. (Contact – Mortuary 01142 717246)

Appendix C

Further information/advice – useful contacts

Where problems/queries arise in respect of the application of this policy or if further information/advice is required, staff should in the first instance contact a member of the Governance / Risk Management Team (details below). Other useful contact details within Northern Lincolnshire & Goole NHS Foundation Trust are also outlined below:

Wendy Booth, Director of Governance & Assurance	Ext: 304549
Tara Filby, Chief Nurse	Ext: 304382
Kelly Burcham, Head of Risk & Clinical Audit	Ext: 302302
Mr Lawrence Roberts, Medical Director	Ext: 302508

Further information

For further information on consent / related documents, please refer to the Risk Management webpage.

Appendix D

How to seek a court declaration

The information contained within this policy is not intended to be exhaustive and will not cover all treatment issues/situations which will arise for all healthcare professionals. Where it is not possible to resolve a disagreement or dispute about capacity to consent, best interests, the legality of an Advance Decisions etc or in very serious cases it may sometimes be necessary to consult with senior colleagues, and where appropriate seek legal advice from the Trust's Legal Advisers as to whether it is necessary to apply to the court for a declaration.

The role of the Court of Protection (and the role of the court deputy) which is the relevant court to resolve disputes relating to adults is set out in Chapter 8 of the Code of Practice to the Mental Capacity Act 2005.

A court declaration is a ruling from the Court that it is legal to perform a medical intervention on a patient whose capacity to consent is in doubt, where there is dispute or uncertainty as to the validity and/or applicability of an Advance Decision, or where differences of opinion exist about the patient's best interests which cannot be resolved satisfactorily. A court declaration is also required where the patient lacks capacity to consent to a medical intervention which is non-therapeutic or controversial – e.g. contraceptive sterilisation, withdrawal of Artificial Nutrition and Hydration (ANH) from a patient in a persistent vegetative state (PVS) or cases involving organ, bone marrow or peripheral blood stem cell donation.

The Consultant who has overall responsibility for the patient (or in their absence, their deputy or the most senior clinician involved) should be responsible for ensuring that further advice or legal intervention is sought as appropriate. He/she must ensure that they have access to all the relevant information about the patient when seeking legal advice, including medical/nursing records, and any documented past/present wishes or beliefs of the patient, their carers, family and friends. They will need to be able to explain to the Trust's Legal Advisers:

- The patient's diagnosis and the reasons for the proposed medical intervention/withdrawal of treatment
- The risks and benefits of the proposed intervention, and any alternative options available
- The evidence as to the patient's capacity (e.g. who has carried out a formal assessment of capacity, when was this, is there a dispute as to capacity, has an independent assessment been sought? etc)
- All the factors and views which have been considered in reaching a conclusion as to what is in the patient's best interests
- Any issues/dispute surrounding the validity or applicability of an Advance Decision

If it is deemed appropriate to seek a court declaration for the medical intervention, the patient's family should be informed immediately – it will usually be more appropriate for the treating Consultant or other senior healthcare professionals to talk to the family (rather than the Trust Legal Advisers). If the patient is unable to instruct solicitors, or is believed to be incapable of doing so, the Trust's Legal Advisers will notify the Official Solicitor in the case of adults and CAFCASS in the case of children to represent the patient's views.

Where legal advice or a court declaration needs to be sought, healthcare professionals can act in the patient's best interests to provide the medical treatment necessary to sustain life or prevent a serious deterioration in their condition until the legal advice is obtained or the court makes a ruling, UNLESS they are aware of that the patient has a valid and applicable Advance Decision, in which case the Advance Decision must be followed.

If further advice/assistance is required or should legal intervention (for example a court declaration) be necessary, during office hours one of the following should be contacted in the first instance:

Dawn Ojadi, Clinical Advisor - Complaints	Ext: 306089
Wendy Booth, Director of Governance & Assurance	Ext: 304549

Advice will then be sought, as necessary, from the Trust's Legal Advisers.

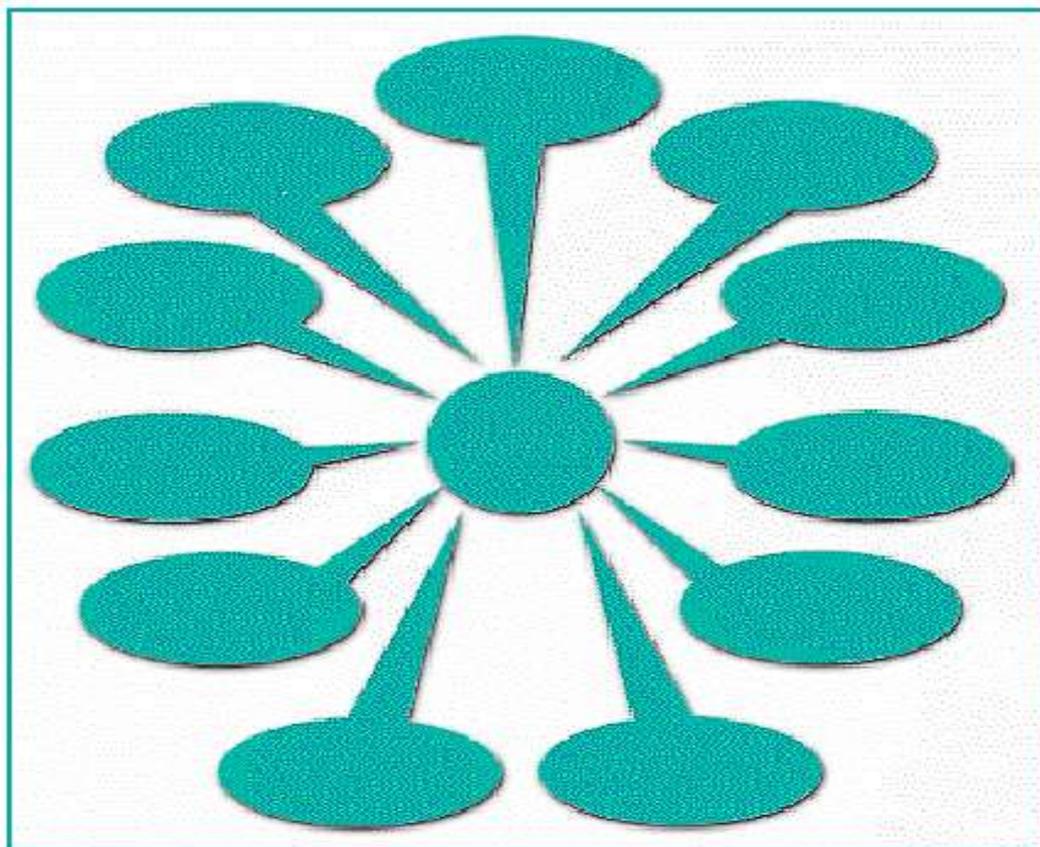
Out of hours, the advice of the Trust's Legal Advisers can be sought via the Site Manager(s) or by contacting switchboard.

Where advice is sought out of hours, the Head of Risk Management must be informed at the earliest opportunity the following working day.

For further information on Advance Decisions, please see Schedule 1 of this policy, and the Trust's Policy on Advance Decisions (Living Wills) - this can be accessed via the Trust's intranet, and copies are also available on all wards and departments.

Appendix E

Seeking consent: remembering the patient's perspective



Schedule 1 – Related Topics

This additional schedule to the Trust's Policy for Consent to Examination of Treatment provides information on related topics not covered in the main body of the policy:

Parental Responsibility

This term refers to all the rights, duties, powers, responsibilities and authority which, by law, a parent has in relation to a child and the child's property.

People with parental responsibility (PR) include:

- the mother;
- the father if he was married to the child's mother at the child's birth (even if the parents have since separated or divorced);
- the father if he was not married to the child's mother when the child was born but:
 - the child was born after 1 December 2003 and the parents jointly register or re-register the birth together and put the father's name on the birth certificate;
 - he now has a Residence Order in respect of the child;
 - he now has a Court Order which gives him parental responsibility;
 - he now has a formal 'Parental Responsibility Agreement' with the mother – this is only valid if it is in the prescribed form as required by the Court;
 - he has since married the mother;
- a guardian of the child appointed by the court or appointed by a parent with PR or another guardian (but only takes effect after the parent's death);
- someone who holds a Residence Order
- a local authority which has a care order (NB. if the child is placed in care voluntarily, parental responsibility remains with the mother/parents/guardian);
- someone who holds an emergency protection order;
- any man or woman who has adopted the child. (Step-parents and/or civil partners do not have automatic parental responsibility – this must be gained by court order or adoption, or by entering into a formal Parental Responsibility Agreement with the parent(s).)
- anyone granted a Special Guardianship Order by the court has parental responsibility whilst it is in force.

When should written consent be obtained?

Within Northern Lincolnshire & Goole NHS Foundation Trust, it is recommended that written consent should be obtained for surgery, endoscopy procedures, certain forms of drug therapy e.g. cytotoxic therapy and therapy involving the use of ionising radiation regulations.

Where doubt exists as to whether written consent is required for a particular treatment/procedure, advice can be sought from staff within Risk Management.

Training of Healthcare Professionals (e.g. Medical Students) & the Presence of Pharmaceutical or Other Sales Representatives During Patient Consultations

Care should be taken to respect the patient's wishes, particularly when he/she may be involved in the training of professionals in various disciplines. An explanation should be given of the need for practical experience to be obtained by healthcare professionals, and agreement obtained before proceeding. It should be made clear that a patient may refuse to agree without this adversely affecting his or her care in any way.

Similarly, staff are reminded that the patient's explicit consent must be obtained before allowing Pharmaceutical, Equipment or Other Sales Representatives to be present during a patient consultation.

The Use of Chaperones for Intimate Examinations

Intimate examinations (examinations of the breasts, genitalia or rectum) can be stressful and embarrassing for patients. The use of chaperones not only provides comfort and support for the patient but protection for the doctor or healthcare professional. Whenever possible, where patients (particularly women) are undergoing intimate examination a chaperone should be offered. There may however be occasions where the patient declines a chaperone. Provided that the clinician feels comfortable in this situation he/she should proceed. It would, however, be prudent to document in the patient's healthcare record the offer of a chaperone, and the patient's decision for an unchaperoned examination.

The following information, taken from the GMC's 'Guidance on Intimate Examinations' provides a useful checklist for any member of staff who may be involved in conducting intimate examinations:

When conducting intimate examinations you should:

- explain to the patient why an examination is necessary and give the patient an opportunity to ask questions;
- explain what the examination will involve, in a way the patient can understand, so that the patient has a clear idea of what to expect, including any potential pain or discomfort;
- obtain the patient's permission before the examination and be prepared to discontinue the examination if the patient asks you to. You should record that permission has been obtained;
- keep discussion relevant and avoid unnecessary personal comments;

- offer a chaperone or invite the patient (in advance if possible) to have a relative or friend present. If the patient does not want a chaperone, you should record that the offer was made and declined. If a chaperone is present, you should record that fact and make a note of the chaperone's identity. If for justifiable practical reasons you cannot offer a chaperone, you should explain that to the patient and, if possible, offer to delay the examination to a later date;
- give the patient privacy to undress and dress, and use drapes to maintain the patient's dignity. Do not assist the patient in removing clothing unless you have clarified with them that your assistance is required;

Anaesthetised Patients:

You must obtain consent prior to anaesthetisation, usually in writing for the intimate examination of anaesthetised patients. If you are supervising students you should ensure that valid consent has been obtained before they carry out any intimate examination under anaesthesia. See also section on 'training of healthcare professional' above.

Research and Innovative Treatment

The same legal principles apply when seeking consent from patients for research purposes as when seeking consent for investigations or treatment. However, in acknowledgement of the fact that research may not have direct benefits for the patients involved, the GMC states that 'particular care' should be taken to ensure that possible research subjects have the fullest possible information about the proposed study and sufficient time to absorb it. *Further detailed guidance on this issue is provided in the DOH's 'Reference Guide to Consent for Examination or Treatment' which is available from www.doh.gov.uk/consent or via the link on the risk management webpage (see 'useful links')*. The Mental Capacity Act 2005 and the Code of Practice to the Act provide the legal framework for research involving mentally incapacitated adults (excluding research under the Clinical Trials Regulations) and should be followed. Chapter 11 of the Code of Practice provides guidance concerning research

Same Sex Partners

Healthcare professionals should bear in mind that 'same sex' partners have the same right to be recognised as the patient's point of contact as anyone else. The concept of 'next of kin' is in fact not a legally recognised position but is used as a convenient description of a person's nearest relative. Where this policy refers to relatives and others engaged in the care or interested in the welfare of the patient this should also therefore include 'same sex' partners.

Advance Decisions (Living Wills)

An Advance Decision /'Living Will' can be defined as an 'advance refusal of treatment'. An advance refusal is valid if made voluntarily by an appropriately informed adult person of 18 years and over with capacity. Capacity is the ability to make a decision, and it must always be assumed that someone has capacity unless it is established that he lacks capacity. Difficulty communicating a decision is not the same as a lack of capacity to make a decision. The test for capacity is laid out in the Mental Capacity Act 2005 – please refer to the Trust's policy on Advance Decisions/Living Wills for further information.

Where an adult patient, who is no longer in a condition to give or withhold consent to medical treatment but has previously expressed the wish not to receive a specific treatment in circumstances where that treatment would otherwise be given (by way of an Advance Decision/'Living Will'), his/her wishes must be respected. An Advance Decision cannot be used to demand certain medical treatments if this goes against the clinical judgment of the doctor, it can only state what treatments a person would refuse. Further, it cannot refuse 'basic care' (i.e. procedures essential to keep an individual comfortable) but can refuse Artificial Nutrition and Hydration (ANH) which is considered to be medical treatment. Similarly, an Advance Decision cannot ask for a person's life to be ended – any actions whose primary purpose is to hasten or bring about death are illegal in this country.

Generally, advance refusals of medical treatment can be in written form, or made orally, and both will be legally binding as long as the patient is competent to make the decision at the time of doing so. Advance Decisions to refuse life sustaining treatment however must be in a particular format if they are to be valid and applicable, including being in writing, signed and witnessed (either by the patient or a nominated witness), and clearly stating that the decision is still to apply even if life is at risk.

A healthcare professional may not over-ride a valid and applicable advance refusal on the grounds of the professional's personal conscientious objection to such a refusal, and is under a duty to ensure that the management of the patient's care is transferred to another healthcare professional who is willing to carry out the terms of the Advance Decision. Failure to respect such an advance refusal can result in legal action against the Trust and disciplinary action by the healthcare professional's regulatory body...

Problems can arise:

- if the Advance Decision/'Living Will' does not specifically apply to the patient's current condition; or
- if the patient's instructions are vague and open to interpretation; or
- if there is doubt as to the patient's state of mind at the time he/she made the Advance Decision; or
- if there is a good reason to believe that the patient's wishes have changed since making the Advance Decision

If there is any doubt or concern about the reliability of an Advance Decision/'Living Will', legal advice should be sought via Risk Management. If necessary the Court of Protection can make a ruling concerning the validity and applicability of an Advance Decision. Whilst this ruling is sought, healthcare professionals can provide life sustaining treatment or treatment to prevent a serious deterioration in the patient's condition without incurring liability.

Where a patient requires urgent life saving treatment, and there is doubt as to the existence, validity or applicability of an Advance Decision, treatment should always begin without delay. If the Advance Decision is later found to be in existence, valid and applicable, treatment must be discontinued if the clinical conditions match those specified in the Advance Decision – the best interests' principle is no longer applicable.

For further information on Advance Decisions, please refer to the Trust's Policy on Advance Decisions (Living Wills), which is available on the Risk Management webpage under 'Documents'. Copies of the Mental Capacity Act 2005 and Chapter 9 of the Code of Practice can be accessed via www.opsi.gov.uk or via the Trust's Intranet. Further advice can be obtained from the Risk Management department.

Children and Consent to Treatment

Assessing capacity – Children over 16

The test for capacity is set out in the Mental Capacity Act 2005, at Sections 2 and 3, which states as follows:

Section 2 – People who lack capacity

(1) For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.

(2) It does not matter whether the impairment or disturbance is permanent or temporary.

(3) A lack of capacity cannot be established merely by reference to:

(a) a person's age or appearance, or

(b) a condition of his, or an aspect of his behaviour, which might lead others to make unjustified assumptions about his capacity.

(4) In proceedings under this Act or any other enactment, any question whether a person lacks capacity within the meaning of this Act must be decided on the balance of probabilities.

Section 3 – Inability to make decisions

(1) For the purposes of section 2, a person is unable to make a decision for himself if he is unable:

(a) to understand the information relevant to the decision;

(b) to retain that information;

(c) to use or weigh that information as part of the process of making the decision; or

(d) to communicate his decision (whether by talking, using sign language or any other means).

(2) A person is not to be regarded as unable to understand the information relevant to a decision if he is able to understand an explanation of it given to him in a way that is appropriate to his circumstances (using simple language, visual aids or any other means).

(3) The fact that a person is able to retain the information relevant to a decision for a short period only does not prevent him from being regarded as able to make the decision.

(4) The information relevant to a decision includes information about the reasonably foreseeable consequences of:-

(a) deciding one way or another, or

(b) failing to make the decision.

‘Gillick Competency’ – Children under 16

Children under 16 years of age may be competent to give consent if they have sufficient understanding and intelligence to enable them to understand fully what treatment is proposed, the risks and benefits of proceeding with that treatment, and the consequences of not doing so. The age of maturity is known as Gillick competency. The test is whether a child has sufficient maturity, understanding and intelligence to consent to what is proposed. It is ultimately a fact finding mission, with the child being asked specific questions about their illness and proposed treatment, in order to assess their competence and whether they are able to consent to treatment themselves. Some decisions require a very high level of understanding and intelligence whereas others may require much less developed intellectual maturity. It is therefore consistent that the same child may be assessed for one procedure as not being competent but being competent to consent to another treatment.

Tissue - The Human Tissue Act 2004 (HTA 2004)

The HTA 2004 came into force on 1 September 2006, and regulates the storage and use of human organs and tissue from living individuals, and the removal, storage and use of human tissues and organs from the deceased. It also established the Human Tissue Authority (HTA) to issue guidance about the HTA 2004, ensure best practice and act as the regulator for those areas subject to licensing requirements, such as post mortem activities, anatomical examinations of human bodies, and storage of human tissue for other purposes (e.g. human tissue banking for transplant purposes or research).

The HTA 2004 does not cover the removal, storage and use of tissues from living individuals as part of their diagnosis or treatment, and this remains covered by the usual ethical rules on consent to treatment.

The Act does however give a list of 12 activities or ‘scheduled purposes’ for which consent is required, and also outlines who is an appropriate person to give this consent. The consent requirements vary depending upon whether the individual to whom the tissue relates is alive or dead.

The following ‘scheduled purposes’ always require consent, whether the tissue is from a living or deceased person:

- Anatomical examination
- Determining the cause of death (EXCEPT where the Coroner orders a Post Mortem)
- Establishing after death the efficacy of any drug or other treatment administered to that person (e.g. hospital Post Mortem)

- Obtaining scientific or medical information about a person (living or deceased) which may be relevant to any other person, including a future person (e.g. genetic information)
- Public display
- Research in connection with disorders, or the functioning of the human body
- Transplantation

The following 'scheduled purposes' require consent only if the tissue is from a deceased person, but not if taken from a living person:

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

There are certain exceptions within the Act to the general rules listed above, and healthcare professionals should be aware that consent is NOT required to store or use human tissue where:

- The Coroner orders an investigation into the cause of death and orders a PM
- The tissue was already in storage for a scheduled purpose (including for research and obtaining medical information) when the Act came into force
- Residual tissue from living individuals is used anonymously for research that has approval from a research ethics authority, or approval is pending – this allows for linking with medical records, provided patient-identifying information is not obtained.

The Act provides penalties of up to 3 years imprisonment, or a fine, or both, if consent is not appropriately obtained or if it is misused in any way. There are specific rules relating to adults who lack capacity and are therefore unable to give consent for their tissue to be lawfully stored and used, and further information can be obtained from the Risk Management department, or by accessing the Department of Health guidance at www.doh.gov.uk

The Mental Capacity Act 2005

The Mental Capacity Act 2005 came in to force in 2007.

Making Decisions in Best Interests (under the Mental Capacity Act 2005)

It is the responsibility of clinicians proposing treatment in the patient's best interests to ensure that they comply with the Mental Capacity Act in reaching that decision and have regard to the Code of Practice. Chapter 5 of the Code of Practice provides guidance on best interests. All decisions must be made in the best interests of the person who lacks capacity. This means the decision maker:

- must involve the person who lacks capacity
- have regard for past and present wishes and feelings
- must involve the person who lacks capacity
- must consult with others who are involved in the care of the person

Can include:

- anyone nominated by the person
- family/friends
- an attorney under an LPA
- a court deputy
- an independent mental capacity advocate (IMCA)
- if necessary - the Court of Protection

Independent Mental Capacity Advocates (IMCA's)

In most situations, people who lack capacity will have a network of support from family members or friends who are engaged in their care or interested in their welfare, or there may be a court appointed deputy or an attorney appointed under a Lasting Power of Attorney who can be consulted about best interests. However, some people who lack capacity may have no one who can be consulted so the Mental Capacity Act 2005 creates an Independent Mental Capacity Advocate (IMCA) to represent and support them in their best interests. An IMCA is a specific type of advocate that will only have to be involved if there is no-one other than a person engaged in care or treatment in a professional capacity e.g. family or friends who can be consulted or where it is not appropriate to consult e.g. the person is abroad and uncontactable or vulnerable adult protection procedures have been instigated. An IMCA will not make the decision in the patient's best interests, but the person who will make that decision must take into account any the information given or submissions made by the IMCA.

An IMCA will only be involved if the decision is about:

- serious medical treatment provided by the NHS
- the provision of or any change in accommodation in hospital or care home which is likely to last more than 28 days in a hospital or 8 weeks in a care home

Serious medical treatment is defined as: Providing, withdrawing or withholding treatment:

- In a case where a single treatment is being proposed there is a fine balance between its benefits to the patient and the burdens and risks it is likely to entail for him;
- In a case where there is a choice of treatments, a decision as to which one is to use is finely balanced; **or**
- What is proposed would be likely to involve serious consequences for the patient.

The duties of an IMCA are to:

- support the person who lacks capacity and represent their views and interests to the decision-maker
- obtain and evaluate information

- as far as possible, ascertain the person's wishes and feelings, beliefs and values
- ascertain alternative courses of action
- obtain a further medical opinion, if necessary
- act in the person's best interests.

There are two further types of decisions where the decision maker has the power to instruct an IMCA for a person who lacks capacity. These are decisions relating to care reviews and adult protection cases. In such cases, the decision maker must decide in each individual case whether it would be of particular benefit to the person who lacks capacity to have an IMCA to support them. Chapter 10 of the Code of Practice provides guidance on the IMCA service.

If you think a patient without capacity requires the services of an IMCA please refer to the information on the Trust's MCA Intranet site for further details on contacting the IMCA service.

Lasting Power of Attorney

Where an adult patient does not have the capacity to give or withhold consent to treatment clinicians should consider whether the patient had appointed an attorney under a Lasting Power of Attorney (LPA) to consent or refuse the proposed treatment on their behalf (or whether anyone else is appointed to make treatment decisions on their behalf such as a court deputy).

Any decision has to be made in best interests and the attorney or court deputy must follow the best interests' requirements of the Act and have regard to the Code of Practice.

A person with capacity can appoint another person(s) to make healthcare decisions for them when they are unable to do so through a personal welfare LPA (from 1 October 2007).

The LPA applies only when a person cannot make the decision for themselves. To be effective the LPA must be registered with the Office of the Public Guardian.

Providing there are no limits on the attorney's authority (which will be evident from the Form) the attorney can consent to and refuse medical treatment. Any authority to consent to or refuse life sustaining treatment must be expressly granted. You should check any limits on the attorney's authority. Also there may be more than one attorney who may be jointly and severally appointed to make decisions. The Code of Practice gives guidance on LPAs in Chapter 7.

Where an LPA is made after an Advance Decision is made then the authority of the attorney will "trump" any previous advance decision unless the attorney's powers are limited to exclude decision making in circumstances where the Advance Decision is valid and applicable.

For further information on the MCA, please refer to the MCA section on the Trust Intranet.