Name of Document:	Consent to Examination and Treatment Policy
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In Consultation with:	Medical Director, Director of Governance Clinical Governance Committee Divisional Board
Approved by:	PDRG
Associated Trust documents to be considered	Advance Directives to Refuse Treatment (ADRT) Procedure. Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS) Policy. Provision of Patient Information Policy.
Target Audience	Trust wide

DOCUMENT CONTROL

Document Reference Number:	TP - 23
Version Number:	9.3
Publication Date:	04/09/2020
Review date:	31/03/2021

AMENDMENT HISTORY

Version No.	Date of Issue	Page/Selection Changed	Description of Change	Review Date
9.1	7 August 2018	32	Insertion of Appendix F Notification of Competency to Take Delegated Consent Insertion para Consent Form 4	5 September 2020
9.2	15 January 2019	10/11	Information amended to read: The completion of Consent Form 4 must be supported by clearly documented best interest decision making process The best interest decision making must involve all interested parties, (including any members of the family, Lasting Power of Attorney holder, carers, IMCA if patient unfriended, the team looking after the patient, other health professionals involved in the proposed treatment decisions) The documented Best Interest decision will form the basis of evidential support of satisfactory completion of DOH Consent Form 4 Form 4 must be signed by the team looking after the patient (this does not have to be a consultant but should be a doctor who knows the patient and understands both the best interest decision and the need for the procedure). It is best practise that Form 4 should be countersigned by the clinician undertaking the procedure who should have had sight of the documented best interest decision.	5 September 2020
9.3	04/09/2020	All	Extension agreed, October 2020 PDRG. From No: 659	31/03/2021

- Principles of consent to examination & treatment
- The consent process, including provision of information and documentation
- Competence to take consent

Introduction
This policy is modelled upon the national (Department of Health) guidance for consent. The appendices provide further guidance in relation to the provision of documentation and where support and advice can be obtained when required.

Objective
To ensure that consent to treatment or examination is valid and that health professionals are able to comply with the guidance relating to taking consent as issued by the Department of Health.

TABLE OF CONTENTS:

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1 Scope

This document applies to all staff members and services within Lancashire Teaching Hospitals NHS Foundation Trust.

2 Introduction

This policy is modelled upon the national Department of Health guidance for consent. The appendices provide further guidance in relation to the provision of documentation and where support and advice can be obtained when required.

3 Statement of Intent/Purpose

The Department of Health has issued a range of guidance documents on consent and these should be consulted for details of the law and good practice requirements on consent. This policy sets out the standards and procedures at Lancashire Teaching Hospitals NHS Foundation Trust ("the Trust") which aims to ensure that health care professionals are able to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

4 Definition of Terms Used Within This Document

Term	Meaning
Audit	The formal examination of the organisation's records, financial situation or compliance with a set of standards.
Approval	The act of approving, or formal agreement.
Associated Trust Documents	Any document that relates to the procedural document by subject matter or where additional information may be useful
Chief Executive	The person who has delegated responsibility from the Trust Board of Directors for the management of governance arrangements within the Trust and is ultimately responsible for ensuring that the Trust meets its obligations with regards to the safe and effective delivery of services. This is delegated to responsible individuals within the Trust.
Clinical Audit	A process that has been defined as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change". The term 'clinical audit' will refer to both clinical and practice audits.
Clinician	A health professional whose practice is based on direct observation and treatment of a patient as

	distinguished from other types of health workers such as laboratory technicians
Safety and Quality Committee	The Trust committee authorised by and accountable to the Risk Management Committee
Consent	Agreement, approval or permission as to some act or purpose, given voluntarily by a competent person, legally effective.
Court Declaration	A formal statement by the Court of England and Wales. A proclamation or announcement usually embodied in an instrument or document of the court about a case's material facts.
Document	Something tangible on which words, symbols or marks are recorded. This may be in paper, electronic or any other legitimate form.
Examination	The act or state of being examined. To look at, inspect or scrutinise carefully or in detail. To investigate the patients state of health.
Equality Impact Assessment	An assessment to determine whether a proposed document or activity is likely to have a negative or adverse impact on sections of the community.
Health Care Professional	A person who by education, training, certification or licensure is qualified to, and is engaged in, providing health care.
Mental Capacity	The mental ability to understand the nature and effects of ones acts.
Patient	A person who is receiving medical care from the Trust.
Patient Record	The systematic documentation of a patient's individual medical history, treatment and care which may be in paper and/or electronic format
Procedure	A set of detailed step by step instructions that describe the appropriate method for carrying out tasks or activities to achieve the highest standards possible. They ensure efficiency, consistency and safety.
Proposal	Something offered for consideration or acceptance.
Tissue	A mass of cells or fibres forming one of the structures of which the body is composed.

Treatment	The application of medicines, surgery etc. to a patient, the care and management of a patient in order to combat, ameliorate or prevent a disease, disorder or injury.
The Trust	Lancashire Teaching Hospitals NHS Foundation Trust

5 Roles and Responsibilities

Policy Owner
The accountable Director is responsible for ensuring this procedural document is reviewed in a timely manner and is responsible for overseeing its development.

Policy Author
Will lead and co-ordinate the development or major review of the procedural document and is responsible for ensuring that the *Procedure for the Development and Management of Policies and Associated Documents* is followed.

Chief Executive
Ultimate responsibility for the effectiveness of this Policy in the Trust lies with the Chief Executive, but is devolved to the Medical Director.

Board of Directors
Implementation of the policy for Consent to Examination or Treatment is a priority for the Board of Directors and is part of its responsibilities.

Director of Nursing and Midwifery
The Director of Nursing and Midwifery will have shared responsibility for the implementation and administration of this policy and will identify the key stakeholders. These are groups or individuals, who may be affected by the document, or those not necessarily affected but who may have some specialist knowledge or can offer a necessary perspective to the development of the document, and hence may need to be included in the consultation process.

Medical Director
The Medical Director has overarching responsibility for ensuring that Consultants and other doctors working within the Trust follow the framework and standards of practice set out in this policy when undertaking examination or treatment.

Consultants
Consultants have shared responsibility for the implementation and administration of this policy.

Senior Managers
It is the responsibility of divisional Business Managers to ensure appropriate documents are available within the working environment. Managers are responsible for ensuring that service delivery is underpinned by this policy and that it forms part of continuing professional development.

Employees
Employees are responsible for adhering to all the aspects of this policy applicable to them, and for reporting any adverse experience to those responsible for the document.

Committees and Groups

The Clinical Governance Committee is responsible for the approval of this document and the ratification of this policy is by the Trust Patient Safety Group.

6 Details of the Operational and Procedural Requirements of This Document

Why Consent Is Crucial
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 care professionals and patients.

What Consent Is and Isn't
"Consent" is a patient's agreement for a health care 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:

- be competent to take the particular decision;
- have received sufficient information to take it; and
- not be acting under duress.

The context of consent can take many different forms, ranging from the active request by a patient of a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health care professional's advice.

In some cases, the health care 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 care 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 'Supported Decision-Making or Joint decision making'. The patient and health care professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health care professional's clinical knowledge.

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, only a person who has a special legal authorisation (e.g. Lasting Power of Attorney) may give or withhold consent on the patient's behalf. Treatment may be given if it is in the 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 see the *Department of Health's Reference guide to consent for examination or treatment* and *Advance Directives to Refuse Treatment (ADRT) Procedure*

Obtaining consent involves any clinical professional involved in treatment or other clinical procedures, including nursing, radiology and therapy staff. It is not limited to medical staff.

Consent is obtained to ensure that the patient has received, understood and determined the treatment or intervention which they believe to be the best for them as an individual. It is not simply to protect the Trust and staff from complaints and legal claims. The Trust seeks to help patients exchange information with their clinicians openly and constructively.

Consent must be completely voluntary – patients must have the time and opportunity to decline treatment; there must be no duress or coercion. The treatment given must not exceed that defined on the consent form or accepted verbally. Where there is a need to

perform additional procedures beyond the scope of the consent, these must only be carried out if there is an immediate and significant threat to the patient's life or well-being.

7 Guidance on Consent

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, for example the General Medical Council's publication (June 2008) *Consent: patients and doctors making decisions together*.

The Department of Health 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 may be accessed on the Internet at *Reference guide to consent for examination or treatment, second edition 2009: Department of Health - Publications*.

The Department of Health document '*12 key points on consent: the law in England'* has been distributed widely to health professionals working in England. This one-page document summarises those aspects of the law on consent which arise on a daily basis and is attached at Appendix A.

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 are available on the Department of Health website.

Process for Documenting Discussion and Provision of Information
For significant procedures, it is essential for health care professionals to document clearly both a patient's agreement to the intervention and the discussions and exchange of information which led up to that agreement. This may be done either through the use of the appropriate consent form (with further detail in the patient's record if necessary), or through documenting the discussion and information given in the patient's record and that they have given verbal consent.

A member of staff initiating treatment or undertaking any clinical procedure on a patient must always ensure that appropriate, informed consent has been received, whether or not a consent form has been signed.

Consent can be written, verbal or implied. In all circumstances patients have a right to receive sufficient information to reach a balanced judgement and come to an informed decision. They can expect to have an explanation of the proposed treatment and any alternative possible treatments, presented in a sensitive and understandable way. Written information should be available for patients to back up verbal explanations. All information provided must be clearly documented in the patient record.

If a consent form is used, relevant sections of the form must be completed (including ticking booklet boxes and entering free text as applicable). Consent forms should be clearly signed by the Consenting Clinician.

8 Process for Recording Consent

Verbal consent
During the course of an interaction with a patient, a health care professional may suggest an intervention they believe will be beneficial to the patient's treatment. Verbal consent to the intervention may be sought following full explanation of the intervention, its benefits, any risks or adverse effects and any alternatives to the intervention. If the patient verbally

consents, the intervention can then proceed. This verbal consent will subsequently be recorded in the patient's record.

Written consent
Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent, but is not proof of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature.

Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

It is rarely a legal requirement to seek written consent but it is good practice to do so, and therefore must be sought if any of the following circumstances apply;

- the treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications'),
- the procedure involves general/regional anaesthesia or sedation,
- providing clinical care is not the primary purpose of the procedure,
- there may be significant consequences for the patient's employment, social or personal life,
- the treatment is part of a project or programme of research approved by this Trust.

Completed forms must be kept with the patient's paper record. Any changes to a form, made after the form has been signed by the patient, must be initialled and dated by both patient and health care professional.

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 the health care professional has any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about similar care in the past), it would be appropriate to do so.

9 Procedure When Patients Lack Capacity to Give or Withhold Consent

Consent Form 4 (for adults who are unable to consent to investigation or treatment) must be used when an adult patient does not have the capacity to give or withhold consent to a significant intervention. Their incapacity must be documented on the form, together with the reason the health professional believes the treatment to be in the patient's best interests, and the involvement of people close to the patient. The standard consent forms (forms 1-3) must never be used for adult patients unable to consent for themselves. For more minor interventions, this information must be entered in the patient's notes.

The completion of Consent Form 4 must be supported by clearly documented best interest decision making process
The best interest decision making must involve all interested parties, (including any members of the family, Lasting Power of Attorney holder, carers, IMCA if patient unfriended, the team looking after the patient, other health professionals involved in the proposed treatment decisions) The documented Best Interest decision will form the basis of evidential support of satisfactory completion of DOH Consent Form 4

Form 4 must be signed by the team looking after the patient (this does not have to be a consultant but should be a doctor who knows the patient and understands both the best

interest decision and the need for the procedure). It is best practise that Form 4 should be countersigned by the clinician undertaking the procedure who should have had sight of the documented best interest decision.

The *Mental Capacity Act 2005* sets out a clear test for assessing whether a person lacks capacity to take a particular decision at a particular time. It is a decision specific and time specific test.

For further guidance on capacity and the standard proforma to use for *Assessment of Capacity & Best Interest Decisions*, refer to the Trust document entitled: Capacity Assessment and Best Interests Form

An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. The clinician should involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability services, speech and language therapists, unless the urgency of the patient's situation prevents this. If at all possible, the patient must be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate. Policy for the Care of Patients with Learning Disabilities within Lancashire Teaching Hospitals NHS Foundation Trust

The health professional caring for a patient who lacks capacity must verify whether the patient has discharged Lasting Powers of Attorney (LPAs) for an appointed person (it need not be a lawyer) to make health and welfare decisions on their behalf. In order for LPAs to be permissible and effective they have to be registered with the Office of the Public Guardian.

The Court of Protection can appoint deputies who may be responsible for making decisions on the welfare, healthcare and/or financial matters of an individual without capacity. The decision making powers given to a deputy by the Court will vary from case to case and it will be important to confirm this with the Deputy. Deputies however will not be able to refuse consent to life sustaining treatment.

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Where the consequences of having, or not having, the treatment are potentially serious, a court declaration may be sought from the Court of Protection. The Court of Protection will make declarations, decisions and orders affecting people who lack capacity; and make decisions for, or appoint deputies to make decisions on behalf of, people lacking capacity as to what is in their best interests.

The health care professional caring for a patient who lacks capacity and has no one to speak for them e.g. family or friends, can invoke the services of an Independent Mental Capacity Advocate (IMCA). If the decision relates to serious medical treatment and/or a change in long term residence of a patient without capacity, clinicians must involve an IMCA if there is no one else to advocate for the patient.

10 Consent Forms

Standard consent forms and forms for adults who are unable to consent for themselves are listed on the Intranet under Managed Stationary and are available in the Wards/Departments.

There are 3 versions of the standard consent form;

- **Form 1**: For adults or competent children able to consent themselves but where consciousness will be impaired;

- **Form 2**: For parental consent for a child or young person;
- **Form 3**: For patients able to consent themselves but where it is envisaged that the patient will remain conscious and alert throughout the procedure and no anaesthetic 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.

As explained above, **Form 4** is available for adults who lack capacity and are unable to consent for themselves.

Blank versions of these four forms are available, and can be ordered from Managed Stationary through the Oracle System.

Should individual department wish to develop a new or amend an existing procedure specific consent form the process to follow-please see Appendix D

11 When Should Consent Be Sought?

When a patient formally gives their consent to a particular intervention, this is only the endpoint of the consent process. It is necessary 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.

12 Process for Obtaining Consent

Single Stage Process
In many cases, it will be appropriate for a health care 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 material 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 and it is good practice to document this within the patients' records.

If a proposed procedure carries material risks, it will be appropriate to seek written consent, and health care 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.

Two or More Stage Process
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 care 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 must be used as a means of documenting the information stage(s), as well as the confirmation stage.

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?"

The 'confirmation of consent' section of the consent form must be completed by the health care professional when the patient arrives for treatment if 24 hours or more has elapsed since they signed the form.

While administrative arrangements will vary, it must 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.

13 Seeking Consent for Anaesthesia

Where an anaesthetist is involved in a patient's care, the signed consent form provided by Lancashire Teaching NHS Foundation Trust and undertaken by the surgeon does include consent for anaesthesia. However, it does remain the responsibility of the anaesthetist involved in the case to seek verbal consent for anaesthesia. A separate consent form, signed by the patient, is not required for anaesthetic procedures that are done to facilitate another treatment.

In elective treatment patients must receive information about anaesthesia at their preoperative clinic appointment. Providing, the options available to the patient, along with risks and benefits, can be done in a number of ways, for instance by providing a general leaflet about anaesthesia in out-patients/preoperative assessment and/or discussion in a pre-assessment clinic. This information and the method of delivery (i.e. verbal or leaflet) must be recorded in the medical records. Having this information gives patients the opportunity to reflect on their anaesthetic and raise questions should they wish. Only receiving this information immediately prior to surgery does not provide patients with time to genuinely make a decision about whether or not to undergo anaesthesia.

In addition, patients are reviewed by an anaesthetist on the day of their surgery at which time confirmation of the anaesthetic and the associated risks can be discussed and questions posed if not previously answered.

Patients should be asked whether they have any questions; any such questions should be addressed fully and details recorded. Anaesthetists should record in the anaesthetic record or in the patient's notes, details of the information provided and the elements of discussion, noting the risks, benefits and alternatives (including no treatment) that were explained.

Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then they will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

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.

14 Emergencies

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.

15 Treatment of Young Children

When babies or young children are being cared for in hospital, it will not usually seem practicable to seek their parents' consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, it must be remembered that, in law, such consent is required. Where a child is admitted, the clinician must therefore discuss with their parent(s) what routine procedures will be necessary and ensure that they have obtained their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, the clinician must do so, unless the delay involved in contacting them would put the child's health at risk.

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. Health care professionals must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If the health care professional is in any doubt about whether the person with the child has parental responsibility for that child, they must check.

16 Older Children

Clinicians seeking consent for children must refer to the Department of Health document Seeking Consent: working with children.

Children of 16 and 17 are presumed to be capable of consenting to their own medical treatment. However, in limited circumstances, this consent (or refusal) can be overridden by someone with parental responsibility or the Court.

Children of 16 years or younger with understanding can give consent on their own behalf. The term 'Gillick Competence' is used in medical law to determine whether a child under 16 is able to consent to his/her own medical treatment without the need for parental permission or knowledge. This is where the child is deemed to have sufficient understanding and intelligence to enable him/her to fully understand what is being proposed.

If a child is capable of giving consent for themselves, it is not a legal requirement to obtain consent also from someone with parental responsibility. However, it is good practice to involve the parents in the decision making unless the child has expressed a wish to exclude them. Clinicians must ensure the child's rights in such circumstances.

17 Provision of Information

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, their risks and benefits (including the risks/benefits of doing nothing) and alternatives to the proposed treatment. 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.

18 Process for Providing Patients with Information

Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those that only need and want minimal information to make a decision on the treatment being proposed. 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.

The details of information provided to the patient must be recorded on the consent form or in the patient record. If a booklet/video/other format is provided then this must be clearly identified and the title of the information documented. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this must be documented.

It is crucial that information is provided to the patient in ways that he/she can understand. Clinicians must be prepared/ willing to provide information in accessible formats. Communication of information must be made accessible for patients with specific needs e.g. patients with a learning disability (such as Down's syndrome), patients with learning difficulty (such as Dyspraxia), deaf patients, blind patients and patients with mental health conditions. Patients with learning disability, for example, may require written information in 'easy-read' format with simple language and pictures.

An extensive range of patient information leaflets are available on the intranet and most of the surgical procedures have accompanying patient information. See Provision of Information for Patients Policy (under review)

It must be emphasised again that a signature on the consent form by the health professional and patient is not sufficient in itself to constitute consent – it must be demonstrated in the documentation that sufficient information has been given to enable the patient to make a balanced judgement.

20 Provision for Patients Whose First Language Is Not English

The 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. The professional translating and interpreting service is available and recommended for all patients whose first language is not English, including those who use British Sign Language.

The use of relatives or friends as interpreters in consent situations should be avoided, and under no circumstances should children under the age of 16 be used as the main source of continuous language support for relatives.

More information is available on the trust intranet under Interpretation and Translation Policy and Procedure

21 Access to More Detailed or Specialist Information

Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. The following arrangements are in place to assist patients to obtain such information:

- Patient Advice and Liaison Service.
- Additional consultation or second opinion if required.

22 Access to Health Professionals between Formal Appointments

After an appointment with a health care 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.

23 Open Access Clinics

Where patients access clinics directly, it must not be assumed that their presence at the clinic implies consent to particular treatment. The health care professional must ensure that they have the information they need before proceeding with an investigation or treatment.

24 Who Is Responsible For Seeking Consent?

The health care 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.

If this person delegates the responsibility of taking consent to another health care professional, then they must assure themselves that the healthcare professional is competent to undertake this task. The process for assessing competence to take consent is detailed below.

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 care 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.

25 Completing Consent Forms

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

If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a health care professional involved in their care on the day must sign the form ('confirmation of consent' section) 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 this second signature, as long as they have access to appropriate colleagues (such

as their consultant or other members of the disease group) to answer questions they cannot handle themselves.

26 Responsibility of Health Professionals

It is a health professional's own responsibility:

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

If the health care professional feels that they are being pressurised to seek consent when they do not feel competent to do so they must raise the difficulty with their clinical supervisor, Medical Director, or the Director of Nursing and Midwifery.

27 Refusal of Treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in certain 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.

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

- Where a patient has refused a particular intervention, the health care professional must ensure that they continue to provide any other appropriate care to which the patient has consented. The health care professional must 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 must be advised accordingly.

- If a patient consents to a particular procedure but refuses certain aspects of the intervention, the health care professional must explain to the patient the possible consequences of their partial refusal. If the health care professional genuinely believes that the procedure cannot be safely carried out under the patient's stipulated conditions, they are not obliged to perform it. The health care professional 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 there must, on request, be preparedness to transfer the patient's care to that health professional.

- When a patient refuses to consent, the health professional must see the patient with a witness (a relative where possible) and give a clear explanation of the consequences of not being treated.

- A contemporaneous record must be made in the patient's notes of the proposed treatment and the explanation given of the consequences of rejecting it. It must be stated explicitly that the patient understands this and continues to withhold consent.

This must be dated, timed, and signed by the health professional, the patient and the witness.

- .
- All members of the clinical team must be told of the patient's decision.

- If a patient refuses a specific aspect of treatment, e.g. the use of blood on a Jehovah's Witness, an additional record of this must be made on the consent form.

- Patients may decide to state in advance on the consent form that a particular procedure must not be performed under any circumstance, however urgent, e.g. the removal of a woman's ovaries if disease was discovered during an operation for a different purpose.

28 Withdrawal of Consent

A competent adult has the right to reject all, or a part of, the recommended treatment and also to withdraw consent after having signed a consent form. The issue is always whether the patient consents to treatment at the time of treatment. Even in life threatening situations the competent patient's right to decide remains even if the reasons given seem irrational or no reason is given.

29 Sedated patients and withdrawal of consent

Sedation is described as:

'a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation should carry a margin of safety wide enough to render loss of consciousness unlikely' [Safety and sedation during endoscopic procedures: British Society of Gastroenterolgy (BSC) Guidelines 2003]

When a patient is sedated it is a reasonable assumption that the patient has impaired ability to give consent. The anticipated effect of sedation is that the patient will be able to communicate, but is in a relaxed state. However, sedation is unpredictable and patients react differently.

Assessing capacity during a procedure can be difficult, therefore the decision to stop the procedure is a matter of clinical judgement. There needs to be a balance between the level of distress being experienced by the patient and the need to complete the procedure at the time and alternatives available to achieve the same result or conclusion.

'The clinician should try to establish whether the patient has capacity to withdraw a previously given consent. If consent is lacking, it may be justified to continue in the patient's best interest'. Reference Guide to Consent to Examination or Treatment: DOH 2009

For guidelines on consent withdrawal during endoscopy, please refer to appendix B.

30 Advance Decisions

There can also be referred to as Advance Directives, Advance Refusals or Living Wills.

For detailed information related to these, staff must refer to the *Advance Directives to Refuse Treatment (ADRT) Procedure*

Under the *Mental Capacity Act 2005* adult patients with capacity may prepare an 'Advance Decision'. This is designed to clarify their long-term wishes with regard to treatment that may become necessary at a time in the future when they have lost the capacity to decide. The directive must meet the following criteria;

- The patient had capacity to give or withhold consent at the time of making the directive;
- Refusal of the specified treatment was intended to apply to the current circumstances (i.e. the specific circumstances were anticipated);
- The patient was aware of the likely consequence of the directive;
- If at any time after making the directive a patient (who still has capacity) indicates that they have changed their mind, the Advance Decision is over-written;
- There is no subsequent Lasting Power of Attorney appointed with the authority to consent or refuse consent to the treatment.

N.B. The Advance Decision must be filed in the patient notes.

It is crucial to remember that an Advance Decision is only applicable in a life-threatening situation if it includes an explicit statement that it stands 'even if life is at risk'. This clause must also be in writing, signed and witnessed.

If a clinician becomes aware of an Advance Decision but suspects that the patient may have changed their mind, this must be documented carefully and the patient encouraged to confirm this in writing. It must be in writing if it applies to a decision refusing lifesaving treatment.

If treatment is refused within the terms of the Advance Decision signed by the patient, then this fact must be documented in the patient's notes. If a patient's Advance Decision specifies that a certain procedure must not be performed as part of a treatment to which they do consent (for example, a blood transfusion for a Jehovah's Witness during a surgical operation involving general anaesthetic), then this must also be noted on the form.

31 Tissue

Consent for the removal, storage and use of human tissue from the deceased and storage and use of human tissue from the living is governed under The Human Tissue Act 2004.

General purposes requiring consent under the Human Tissue Act 2004 are:

- Anatomical examination
- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to him
- Obtaining scientific or medical information about a living or diseased person, which may be relevant to any other person (including future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Transplantation

Under the Human Tissue Act, consent from the living is not required for:

- Storage and use of tissue
- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

Please see appendix C for the Human Tissue Act Consent Requirements.

Exceptions to the consent requirements under The Human Tissue Act 2004 include:

- Samples collected from the living or the deceased before September 1st 2006, referred to as “existing holdings”. While such samples are technically exempt from the consent requirements, efforts should still be made to get consent where practical. For further information about how to deal with “existing holdings” please see the code of practice on disposal of human tissue, available on the HTA website.
- Research in connection with disorders, or the functioning, of the human body where the material has come from the body of a living person and the research is ethically approved and the samples are anonymised. However, please note that gaining consent is always best practice and will assist with the ethical approval process.
- Carrying out an investigation into the cause of death under the authority of a Coroner.
- Keeping material after a post mortem under the authority of a coroner, for no longer than the coroner requires it to discharge their statutory functions.
- Keeping material in connection with a criminal investigation or following a criminal conviction.

Removal of tissue from the living during the course of examination or treatment must be performed with the informed consent of the donor. Exceptions to this may occur if, for example, a patient is undergoing an operation and as a life-saving procedure requires removal of some tissue or an organ which is not covered under the original consent taken for the procedure. This may only be justified if it is in the best interests of the patient and it would be life-threatening to wait until after the operation to ask for further consent to remove the tissue/organ. It is important to note that organs or tissue must never be removed merely for convenience, without the explicit consent of the patient.

For further information about consent relating to human tissue, the *Human Tissue Authority Code of Practice on Consent* should be consulted in line with the *Deceased Organ and Tissue Donation for Transplant and Research Policy*.

32 Clinical Photography and Conventional or Digital Video Recordings

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 care professionals must always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

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.

Explicit consent must be sought for all photography and audio recordings for all uses including clinical purposes, teaching/research and publication.

The medical practitioner requiring the image must ensure that;

- There are no alterations to a patient’s image in any way to achieve anonymity and avoid the need for consent;
- The patient is given an explanation of the consent procedure;
- The patient receives specific details of the imagery and its use as part of treatment, medical teaching, research or publication;
- If a patient refuses to give consent it must be clear that this will not affect their treatment in any way;

- A patient has a right to withdraw consent at any time;
- The patient's consent is in writing for the original imagery or photography and is in the patient's record.

Consent must be sought in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular if applicable, the person must be made aware that the health care professional 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, it must not be used, even if a person with parental responsibility consents.

If the photographic or video recording of a patient is being made specifically for education, publication or research purposes, patients must know that they are free to stop the recording at any time. The patient must also be made aware that they are entitled to view the recording if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for the 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 or restrict it once it is in the public domain.

The situation may sometimes arise where there is a 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, such a recording may be made, but consent must be sought as soon as the patient regains capacity. The recording must not be used until consent has been received for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, an agreement may be sought with someone close to the patient. Use of the recording must not be made which might be against the interests of the patient. Such recording must not be made or used if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

The principles and processes outlined in the *Policy and Procedure Photography and Video Recordings of Patients (Confidentiality, Consent, Copyright and Storage)* should be adhered to.

33 Post Mortems

A coroner's post-mortem is undertaken to establish the cause of death (this is a legal requirement and consent is not needed).

A hospital post-mortem is undertaken to understand the process of disease; to establish, after a person's death, the efficacy of any drug or other treatment; implications for medical education and research; implications for other members of the family (this requires consent). Respectful and sensitive communication with bereaved families is essential to help them make important decisions at a difficult time.

A hospital post mortem examination is carried out, with the prior consent of the deceased person, the consent of their nominated representative or the consent of a person in a 'qualifying relationship' (see *HTA Code of Practice - Post Mortem Examination*). NHS 'Consent to a hospital post-mortem examination on a baby or child' forms are available from the Pathology Department.

Where the death of a patient is referred to H.M. Coroner, the Coroner's office will keep the family fully informed of the progress of the investigation. Consent is not required for a

coroner's post mortem; however the reasons for the post mortem and the procedures to be followed must be explained sensitively to the relatives.

Refusal of post mortem must be documented in the patient's medical records.

Who can give consent?
Competent adults are asked to nominate their next-of-kin/ contact person formally on admission to the hospital – this nominated representative need not be a blood relative.

Where a person who has died has no immediate and obvious next of kin/nominated representative, all reasonably practical steps must be taken to trace one.

Withdrawal of consent
Next of kin may change their minds following consideration. It is important that the bereavement service is informed directly of this and that it is clearly documented

Who may seek consent?
It is important that the person who obtains the consent has sufficient knowledge about the procedure, including risks – this is usually the senior doctor (consultant or specialist registrar). Help is also available from a bereavement officer.

Consent must be taken in conjunction with bereavement services staff. It is important to ensure that all documentation of the consent process is complete.

Provision of Information
Written information should be given to the next of kin with contact numbers for further information about the procedure. Bereavement services can provide this information.

34 Research

The same principles apply when seeking consent from a person for research purposes.

Patients must be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties (GMC, 2008).

Clinical trials involving medicinal products are covered by the *Medicines for Human Use (Clinical Trial Regulations) 2004* and all other research projects should adhere to the principles of *Good Clinical Practice as described in the Research Governance Framework for Health and Social Care 2005*. Consent to research processes, compliance measures & monitoring arrangements, are captured in the Centre for Health Research and Innovation documentation.

35 Training

Consent training is part of the Trust mandatory/essential training process as described in the Trusts Training Needs Analysis. This describes how the training will be delivered and to whom.

Consent awareness training (essential for all staff taking consent and recommended for all staff involved in clinical care where consent (written, verbal or implied) is required) covers:

- Policy awareness
- Principles of consent
- The current consent process

- Key requirements of the consent process (including patient information, consent forms, assessment of competence to take consent, refusal of treatment, withdrawal of consent).

Procedure-specific consent-taking competence training & assessment (essential for staff delegated to take consent) covers:

- Principles of consent
- Knowledge & understanding of the patient's condition, its treatment & prognosis
- Understanding of the treatment/procedure for which the consent is to be taken (including benefits, adverse effects, alternatives to the treatment)
- Communication and provision of information
- Trust process and practice related to consent
- Re-affirmation of competence

Training covering the legal aspects of consent will be provided by the Legal Team. These sessions are open to all Trust staff and will be advertised on the intranet.

Maintaining an up to date understanding of the issues surrounding consent remains the responsibility of the health professional carrying out the procedure and/or taking consent for the procedure.

36 Competence to Take Consent: Principles and Process

The following principles and process will apply which are essential to the overall consent process. The Research & Innovation standard operating procedures must also be adhered to where consent to research is required.

All staff seeking consent must be educated in the principles and process of consent.
The consultant (as treatment provider) will agree with the health care professional the procedure(s) for which consent taking is to be delegated. This will depend on the level of experience of the health professional and their role.

In the case of trainee grade doctors, the consent competence process will begin at first induction meeting with the Educational Supervisor, who will ensure that existing consent competencies of the trainee are centrally recorded with Trust Training Department. New competencies acquired during the trainee's time in the Trust will be centrally recorded promptly on an on-going basis

Procedure specific training will be provided by the consultant so that the health care professional taking consent understands the procedure, its benefits, risks and alternatives; and is able to provide accurate information and answer any questions the patient may ask
All non-consultant grade staff who takes formal written consent must be recorded on Trust Consent database

Health Care professionals must not take consent for any treatments or procedure other than those recorded against their name on the consent database.

The consent database will be available in the Trust Training Department

Where staff have obtained consent for a procedure without authority to do so, i.e. lack of evidence of competence/non-compliance with this aspect of policy, this will be reported as an incident via the Trust Datix reporting system.

37 Monitoring Compliance with this Document

The table below confirms the Trust's current monitoring arrangements to ensure compliance with the requirements of this document.

Aspect of compliance or effectiveness being monitored	Monitoring method	Individual responsible for the monitoring	Frequency of the monitoring activity	Group / committee which will receive the findings / monitoring report and act on findings.	Group / committee / individual responsible for ensuring that the actions are completed
Annual Consent Policy audit	Review of consent records	Clinical Audit Team	12months	Local clinical Audit Committee. With action plans	Clinical Governance Committee
Legal aspect of consent and delegated consent Training	Attendance record and consent database	Training Department	12months	Local Clinical Audit Committee	Clinical Governance Committee

38 References/ Bibliography

- Reference Guide to Consent for Examination or Treatment 2nd edition (DoH 2009)
- Good Practice in Consent – Implementation Guide (DoH 2001)
- Model Consent Forms (DoH 2002)
- Consent: patients and doctors making decisions together (GMC, 2008)
- Royal College of Surgeons: Supported Decision Making. (November 2016)
- 12 Key Points on Consent: the Law in England (DoH 2001)
- Department of Health document Seeking Consent: Working with Children
- Safety and sedation during endoscopic procedures: British Society of Gastroenterology (BSC Guidelines 2003)
- The Medicines for Human Use (Clinical Trial Regulations 2004)
- Research Governance Framework for Health and Social Care (2005)
- Mental Health Act (1983)
- Mental Capacity Act (2005 – effective from 1st October 2007)
- Human Tissue Act (2004)
- HTA Code of Practice 1 – Consent (2014)
- Standard Operating Procedure for Taking Consent for a Hospital Post Mortem
- Consent for anaesthesia 2017:Association of Anaesthetists of Great Britain and Ireland (Anaesthesia 2017, 72, 93–105)

39 Equality Impact Assessment: The Equality Act 2010

Lancashire Teaching Hospitals NHS Trust is committed to ensuring that the organisation plays its part in promoting a fairer society by addressing discrimination and providing equality for all.

Public bodies have a duty to consider the needs of all individuals in shaping policy, delivering services and in relation to our own employees. This is termed "Equality Duty" and is set out in Section 149 of *The Equality Act 2010.*

Prior to the development of this document and the processes of decision making involved, the author confirms that due regard has been given to ensure the document and its application has been developed to facilitate the following:

- Eliminate unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Act.
- Advance equality of opportunity between people who share a protected characteristic and people who do not share it, and
- Foster good relations between people who share a protected characteristic and people who do not share it.
- Regard for the aims of the Equality Duty is a continuing duty and the Trust regularly reviews its position and approach in line with The Equality Act 2010.

The author of this document has given due regard to the Equality Duty in terms of this document, which is summarised in the Equality Impact Assessment overleaf.

Lancashire Teaching Hospitals NHS Foundation Trust Impact Assessment Screening
Policy Title: Click here to enter text. Policy Author: Click here to enter text.

1.	Does the policy/strategy affect one group more or less favourably than another on the basis of:	Yes/No	Evidence in support of either positive or negative impacts, including references to research and national documents must be provided for the sections below
	Race	No	These are Protected Characteristics and therefore Protected by virtue of Equality Act 2010
	Disability	No	
	Gender	No	
	Sexual Orientation	No	
	Religion or Belief	No	
	Age	No	
	Marriage and Civil Partnership	No	
	Gender reassignment	No	
	Pregnancy and Maternity	No	
2.	Is there any evidence some groups will be affected differently?	Yes	Patient who lack capacity to consent
3.	If potential discrimination has been identified is this justifiable (you must explain why)?	Yes	Protected by Mental Capacity Act
4.	What methods of consultation have you used and with whom please describe?		Clinical Governance Committee Mental Capacity Act and Code of Practice Policy
5(a)	Is the impact identified likely to have a negative impact on the Policy/Strategy?	No	Choose an item.
5(b)	Can the impact be avoided?	No	Click here to enter text.
5(c)	Are there alternative ways of achieving the aims of the Policy/Strategy to remove the impact?	No	Click here to enter text.
5(d)	Can measure be put in place to reduce the impact?	Yes	Statutory protection in place as detailed above.

If anyone reading this form identifies any potential discriminatory impact that has not been identified on this form, please contact the Policy Author named above, along with suggestions how the impact can be eliminated or reduced. Further advice can be sought from the Trust's Equality Lead.

40 Appendices

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 demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.

3. Patients may be competent to make some health care decisions, even if they are not competent to make others.

4. 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?

5. 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, someone 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** override 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.

Who is the right person to seek consent?

6. 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?

7. 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.

8. 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?

9. 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

10. 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 foetus.

Adults who are not competent to give consent

11. **No-one** can give consent on behalf of an incompetent adult, unless they have a social legal authorisation to do so (e.g. Lasting Power of Attorney). However, 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 close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

12. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'advance refusal'), and those circumstances arise, you must abide by that refusal.

Appendix B: Guidelines for withdrawal of consent during endoscopy

The endoscopist and the most senior nurse in the endoscopy room have a joint responsibility for the patient's well-being and care during the endoscopy procedure

If the patient shows signs of distress and discomfort during the endoscopy procedure the senior nurse, as the patient's advocate, has a duty of care to raise her/his concerns with the endoscopist and ask if the patient can be permitted a short rest to recover.

The endoscopist must consider a pause for explanation and discussion with the patient and the senior nurse how best to proceed. If clinically indicated, further sedation/opiates can be administered. The decision on how best to proceed should represent a joint consensus from both the endoscopist and the senior nurse. Alternatively the procedure can be performed at a later date under a general anaesthetic, or a less invasive procedure may be considered.

If the decision is to proceed with the procedure and the patient continues to struggle and verbally withdraws consent with more than a few minutes remaining, it is then prudent to abandon the procedure.

If at any time the patient is struggling violently and likely to injure themselves or the nursing staff, then the procedure must be abandoned.

Once the patient has recovered he/she must be informed that they found the procedure quite traumatic and that the decision was made to abandon the procedure in their best interests, and discuss alternatives.

Failure to comply with withdrawal of consent guidelines will be registered as a clinical incident to allow the event to be investigated.

A detailed description of the rational to abandon the procedure, the discussion with the patient and future plans must be clearly documented in the patient's records.

Appendix C: Human Tissue Act Consent Requirements for Scheduled Purposes

Appendix A

Table setting out consent requirements under the HT Act for scheduled purposes.

Scheduled purpose	Consent required for human tissue from the living			Consent required for human tissue from the deceased		
	Removal	Storage	Use	Removal	Storage	Use
Anatomical examination	N/A	N/A	N/A	✓	✓	✓
Determining the cause of death**	N/A	N/A	N/A	✓	✓	✓
Establishing after a person's death the efficacy of any drug or other treatment administered to them	N/A	N/A	N/A	✓	✓	✓
Obtainingscientific or medical information about a living or deceased person which may be relevant to any person (including a future person)	N/A	N/A	N/A	✓	✓	✓
Public display	X*	✓	✓	✓	✓	✓
Research in connection with disorders, or the functioning of the human body	X*	✓	✓	✓	✓	✓
Transplantation	X*	✓	✓	✓	✓	✓
Clinical audit	X*	X	X	✓	✓	✓
Education or training	X*	X	X	✓	✓	✓
Performance assessment	X*	X	X	✓	✓	✓
Public health monitoring	X*	X	X	✓	✓	✓
Quality assurance	X*	X	X	✓	✓	✓

✓ Consent is required under the HT Act
X Consent is not required under the HT Act
* Consent is required under the common law of removal of tissue from the living
** Consent is not needed for investigating cause of death under the authority of the coroner

35

Appendix D: **Process for amendment and development of new procedure specific consent forms**

Development Process

When health professionals wish to develop a new procedure specific consent form, the process to follow is:

Using a general consent form, make suggested amendments (**NB detail cannot be taken out of the standard consent form, additions only can be made)**

The Lead Consultant must ensure the following:

1. They are supported by the Trust's Library and Knowledge Services Department with literature searches relevant to this document.
2. A Peer Review takes place
3. There is compliance with the National and Professional/Regulatory Guidance.
4. Plain English review.
5. Appropriate patient information leaflet is available.

Approval and Printing Process

Approved at Clinical Business Unit/Audit/Governance meeting.

The Approved Consent Form must be sent to the Printers for proofing.

The Printers will return the Proof for final approval by the author.

A Managed Stationery (MS) number will be assigned and the Consent Form will be uploaded to the Trust's Intranet and catalogue.

Completion of Quality Assurance Checklist:

- Is the Consent Form:
- The subject of wider peer review?
- Supported by a literature search?
- Compliant with NICE/National Guidance/Professional/Regulatory Guidelines
- Reviewed by the Plain English Group?
- Approved by the relevant Committee?
- Logged on the register of Procedure Specific Consent Forms *(Heritage/Intranet?)*
- Is this an updated form? If Yes:
- Remove old forms from the register and archive for future reference. Old forms must be rescued from Clinical practice.

If previous version is in stock, the department must decide if obsolete stock will be destroyed and paid for OR stock used up before changes introduced.

Appendix E Useful Contacts

Medical Director	01772 528344
Company Secretary	01772 522010
Divisional Director of Governance	01772 522123
Divisional Clinical Directors	TBC
Claims & Legal Services Manager	01772 522790

Click here **for Notification of Competency to take Delegated Consent Form for completion** ……Appendix F

Notification of Competency to take Delegated Consent

Lancashire Teaching Hospitals NHS
NHS Foundation Trust

Re entries marked with an '*' please print the information

***Name of Procedure/s**

1

2

3

4

5

***Name of person deemed competent to take delegated consent** _____

***Job title or position** _____

***Department** _____

Signature _____

Date _____

***Name of Person verifying competency** _____

***Job title or Position** _____

***Department** _____

Signature _____

Date _____

Once completed hard copies can be mailed to: Mandatory Education Administration, Education Offices, Block G, Royal Preston Hospital. Alternatively scanned copies can be emailed to: training.booking@lthtr.nhs.uk