Policy Document Control Sheet

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Table of Revisions

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March 2007	Full	Full revision to incorporate MCA advice and inclusion of delegate responsibility process	S Lonie
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July 2008	Full	Full revision to ensure policy meets the needs of the MCA 2005 and HTA 2004	S Lonie
June 2010	Full	Full review to ensure documents meet the requirements of DoH 'Reference guide to consent for examination or treatment' 2nd edition	S Lonie, P Moncur, A Mcculloch, L&D
December 2010	Partial	Monitoring section revised to include reporting framework	S Lonie
January 2011	Full	Policy harmonized and further details added to monitoring table	S Lonie
August 2011	Partial	Addition to monitoring table and process for sharing information with patients bullet pointed for clarity	D Kirkup
January 2012	Partial	Updated EIA and some minor formatting	D Kirkup
February 2012	Partial	Additional information added to sections 15/11/5.3/4.1/2.2	D Kirkup
October 2013	Full	Duties section and revised delegated consent	D Kirkup
September 2016	Full	Full review of content and new format	D Kirkup

Contents

1 Introduction

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is 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. English common law goes further and has established the principle that touching a patient without valid consent may constitute the civil and criminal offence of battery. In addition, legislation such as the Mental Capacity Act 2005, the Human Rights Act 1998, and the Human Tissues Act 2004 have all had an impact on the current consent process.

The standards expected of health professionals are high.

Failure to obtain proper consent, where a patient subsequently suffers harm, can lead to claim of negligence against both the individual and the organisation. It is therefore important that all staff involved in seeking consent from patients understand what is involved; who may seek consent, what 'informed consent' means, how to discuss consent with patients, and what needs to be recorded or written in patients notes.

Special rules apply in the case of young people and children, and for adults or children who lack capacity. These are discussed separately along with specialist areas such as organ donation, hospital post mortems and screening.

It is the responsibility of staff involved in seeking patient consent to ensure they understand the requirements of informed consent, and the patient has been given all assistance possible to help make his or her decision.

2 Purpose

The purpose of this policy is to set out the Trust's approach to seeking consent from the patient in connection with their health and care. This policy is based on guidance from the Department of Health and the Care Quality Commission.

The following guidance 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, eg the General Medical Council consent guidance "doctors and patients making decisions together" –
  see http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

- Reference guide to consent for examination or treatment provides a comprehensive summary of current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. This can be accessed on the Internet at http://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

- 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 law on consent which arise on a daily basis and is attached at Appendix 1.

- 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 via https://ethics.grad.ucl.ac.uk/forms/DH_GuideForChildrenAndYoungPeople.pdf

3 Scope

The guidance in this policy applies to all staff involved in care of patients who are involved in the consent process.

The guidance covers:

- Consent to examination and treatment
- Adults, young persons and children
- Patients who lack capacity
- What to do in the case of problems or disputes

Specialist areas such as organ donation, research and consent for blood product transfusions are covered in separate policies.

Duties

Health Professionals
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.

In practice the task of seeking consent may be delegated to another professional. They must be trained in the principles of consent and be familiar with the clinical procedure and any alternative treatments, including the risks and benefits of the various options. The consultant will ensure when delegating consent (e.g. nursing, allied healthcare professional and junior doctor) that the individual is fully conversant with the procedure for which the individual is authorised.

When 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.

Consultants and Associate Specialists

Consultants and Associate Specialists are responsible for the following.

- Ensuring that a patient has given valid consent before treatment begins.
- Ensuring that, on delegation of responsibility for consent to another healthcare professional, that the healthcare professional has received training and assessment in the consent process.
- Ensuring that following specific training the ‘Record of Competence to obtain Delegated Consent’ document is completed and signed, and that only staff with delegated responsibility take consent on their behalf.

- Ensuring that when local anaesthesia or sedation is being used that the patient has given consent to that form of anaesthetic before the procedure starts.
- Consultant Anaesthetists are responsible for ensuring that consent for anaesthesia is obtained from the patient having discussed the risks and benefits.
- It is a mandatory requirement to complete the BeINFOrMED consent training every three years. BeINFOrMED can be found on Staffnet – search for BeINFOrMED.
- The consent process should form part of the annual appraisal.

Trust Grade Doctors
May undertake independent practice, if this is the case, they will not be included in the delegation process and will receive a letter from their Care Group Clinical Director recording this exclusion. The consent process should form part of the annual appraisal.

Staff with Delegated Responsibility for Consent
Staff who can have delegated responsibility for consent include junior doctors, allied healthcare professionals and nursing staff.

Staff with delegated responsibility for consent must ensure that:

- They undergo training in the consent procedure by completing the e-learning package BeINFOrMED). For doctors in training an equivalent membership exam (e.g. MRCS/Anaesthetic Part 1) would be a suitable alternative.
- Undergo procedure specific training unless proof of competency can be provided.
- Registered nurses and allied healthcare professionals will be required to complete a competency assessment. In the event that the service does not have a procedure specific competency assessment, an example can be found at Appendix 6.
- The 'Record of Competence to obtain Delegated Consent' documentation should be completed and submitted to the Assurance, Risk and Compliance Team – cdda-tr.arc@nhs.net
- The consent process should form part of the annual appraisal.

Further details on the process can be found at Appendix 3 to 6.

It is a health professional's own responsibility to work within their own competency and not to agree to perform tasks which exceed their abilities.

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. They should have been assessed, be aware of their own knowledge limitations and registered locally to do this.

A health professional should not feel under pressure to obtain consent if they feel they are not competent to do so. If you feel under pressure to obtain consent, should contact your clinical supervisor/educational supervisor/line manager as appropriate.

Where a doctor obtains consent without the authorisation to do so, on discovery it will be reported to the Care Group Clinical Director for investigation.

Clinical and Educational Supervisors
- Will be responsible for ensuring that their junior doctors are assessed for delegated consent and the 'Record of Competence to obtain Delegated Consent' is completed and forwarded to Assurance, Risk and Compliance Team - cdda-tr.arc@nhs.net

- The 'Record of Competence to obtain Delegated Consent' should be reviewed according to the junior doctor's educational attainment during their time with the Trust.
- At the end of the junior doctor's employment, the Clinical/Education Supervisor will be responsible for ensuring a final copy of the 'Record of Competence to obtain Delegated Consent 'is retained for the Trust. This should be submitted to the Departmental Secretary for the relevant Care Group.

Care Groups Nominated Lead for Consent
Each Care Group will:

- Nominate a Lead for Consent to ensure clear lines of communication to the Medical Director or his nominee.
- Ensure that a Care Group Consent Register is updated and associated documents 'Record of Competence to obtain Delegated Consent' are retained on behalf of the Trust.
- Ensure storage of documents on the consent site on the intranet
- Nominate a departmental secretary to support the administration process.

Care Group Clinical Directors
The Care Group Clinical Directors:

- Will investigate incidents where a doctor, nurse or allied healthcare professional obtains consent without the authorisation to do so and will provide the Medical Director with any consent related performance issues for consideration. The Medical Director will be responsible for reporting any such concerns to the General Medical Council. Any other consent related incidents will be managed through the Trust's Incident Management Policy.
  In the instances involving a nurse or allied healthcare professional the Executive Director of Nursing will consider any consent related performance issue and will be responsible for reporting any such concerns to the relevant statutory body.
- Ensure audit of the consent process is considered at consultant and doctors appraisal.
- Nominate a Lead for Consent to ensure clear lines of communication to the Medical Director or his nominee.
- Ensure at least 2 consent audits per year are completed by the care group (this is dependent on the amount of procedures requiring written consent).

The Medical Director
The Medical Director has responsibility for developing the policy in relation to consent and ensuring implementation. Compliance with this policy will be part of the doctor's revalidation.

Audit information on the application of the policy will be fed into doctor's appraisal by the Care Group Clinical Directors.

The Medical Director will be responsible for considering any consent related performance issues prior to reporting to the General Medical Council.

The Medical Director will nominate Associate Medical Directors to work with the Head of Assurance and Compliance on monitoring the consent policy.

Executive Director of Nursing
The Executive Director of Nursing will be responsible for considering any consent related performance issues prior to reporting to the relevant registration body.

Head of Assurance and Compliance
The manager will:

- Support the Medical Director or his nominee with the updating of this policy
- Will receive information regarding the investigation into any incidents reported where a doctor, nurse or allied healthcare professional has taken consent without being authorised to do so.
- Will receive consent audits against the policy from the Care Groups.
- Maintain the Consent intranet site.
- Liaise with the Care Group Consent Leads regarding the delegation of consent registers and associated documents.

Locums
A check of the procedures for which the locum can consent should be carried out by the inducting Consultant when a locum is appointed and arrangements for supervision should be made. The 'Record of Competency to Obtain Consent' should be completed and a copy sent to the nominated departmental secretary.

People and Organisational Development
People and Organisational Development (P&OD) will:

- Attendance at essential training is recorded by P&OD and entered onto the Trust training management system, OLM. Monitoring of non-attendance will be carried out in line with the Training Needs Analysis, Monitoring and Evaluation Policy. Please refer to this policy for detailed information.
- Ensure access the e-learning package BeINFOrMED.

Integrated Quality Assurance Committee (IQAC)
The IQAC Committee will approve the policy

The Clinical Standards and Therapeutics Committee (CSTC)
The CSTC will review the policy and receive information on compliance with this policy, this may be in the form of audit information or for onward escalation to IQAC.

Care Group Governance Meetings
Receive consent audits against the policy from their services and should request action plans for areas where there are concerns about the quality of consent documentation.

4 Definitions

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:

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

The context for consent can take many different form, 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 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. 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.

5 Management

5.1 Process for Obtaining Consent

When a patient formally gives their consent to a particular intervention, this is only the end point 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.

Who is responsible for seeking consent?
The accountable healthcare professional is responsible for seeking consent. If this responsibility has been delegated to another see section 4 for further details.

Single stage
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 on-going 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 and the procedure will be carried out. The oral consent should be recorded in the patient health record.

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. A copy of the written consent should be stored in the patient's health record.

Two or More Stage Process
In most cases where *written* consent is being sought, treatment options will 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. A copy of the consent form should be retained in the patient's health record.

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?"

While 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.

Seeking Consent for Anaesthesia

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 on the anaesthetic record.

There is a section on the consent form, if information on the type of anaesthetic is known at the point of completing a consent form, this should be recorded.

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 be responsible for ensuring that the patient has given consent to that form of anaesthesia and the anaesthetic consent form completed.

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.

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.

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, you should remember that, in law, such consent is

required. Where a child is admitted, you should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. If parents specify 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.

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children. If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check. Further information is available at https://www.gov.uk/parental-rights-responsibilities/who-has-parental-responsibility

Recommendations from the Victoria Climbe Enquiry
Children at Risk from Carer (Recommendation 65, Para 9.39 from the Victoria Climbie Inquiry).

When the deliberate harm of a child from a carer is identified as a possibility, the examining healthcare professional should consider whether taking a history directly from the child is in that child's best interests. When that is so, the history should be taken when the consent of the carer has not been obtained, with the reason for dispensing with consent recorded by the examining healthcare professional. In those cases in which English is not the first language of the child concerned, the use of an interpreter should be considered.

Children at Risk from Hospital Staff (Recommendation 75, Para 10.73 from the Victoria Climbie Inquiry).

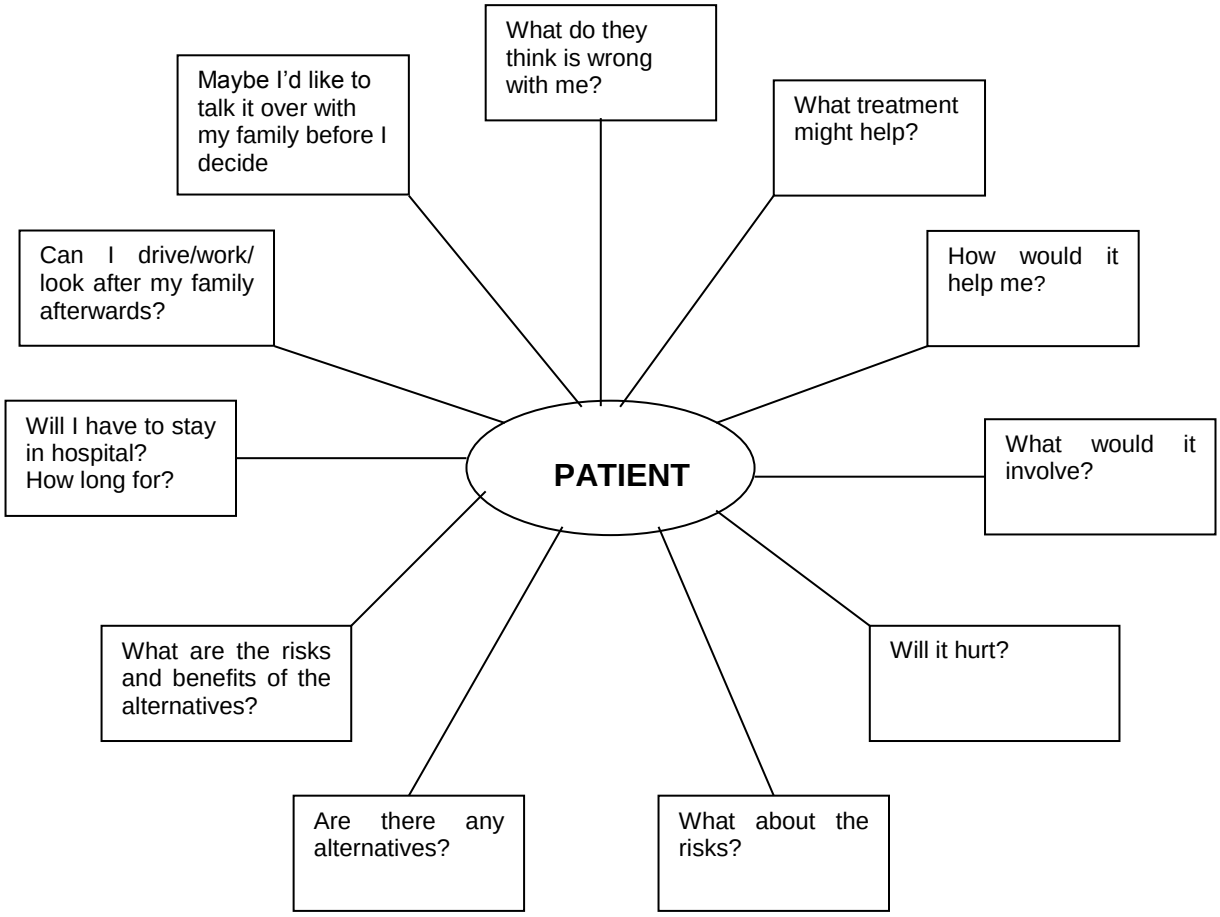
When the deliberate harm of a child from a health care professional is identified as a possibility and permission is required from the child's carer for the investigation of such possible deliberate harm, or for the treatment of the child's injuries, the permission must be sought by a doctor above the grade of Foundation Year 2 doctor.

5.2 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 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.

Patients and their relatives or carers, 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.

Remember the patient's perspective:



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 in the patient's notes.

The following sources of patient information are available in this Trust:

- Patient Information Leaflets are available from specific ward, clinics and departments.
- The Patient Experience Team have developed a number of resources and support mechanisms for patient information provision.
- EIDO Healthcare information leaflets are available on the Trust Intranet.

Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. This Trust has made the following arrangements to assist patients to obtain such information:

- Detailed information about patients' conditions and their treatment is available on an individual speciality basis from nurse specialists and medical staff.
- Alternatively, additional information can be gained from www.aboutmyhealth.org

All versions of the consent form include a section for the clinician taking consent to summarise the risks and benefits of the proposed treatment which they have discussed with the patient, and to record what written information has been provided to the patient as part of the consent process. Where patient information is available, it should be noted on the consent form.

Key recent legal judgement on material risks

The legal duty on health professionals with regard to informed consent has been express in the recent case of Montgomery v Lanarkshire Health Board [2015] which was heard by the Supreme Court. This judgment requires a health professional to ensure that a patient is made aware of all material risks.

In a move away from the 'reasonable doctor' to the 'reasonable patient', the Supreme Court's ruling outlined the new test: **"The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."**

Therefore providing information by reference to the standards of a reasonable medical practitioner is no longer adequate. The relevant standard is whether the patient would attach significance to the risk. It is a standard that explicitly recognises the patient as an individual and not a homogenous entity.

The doctor is however, entitled to withhold from the patient information as to a risk if it is reasonably considered that its disclosure would be seriously detrimental to the patient's health – the therapeutic exception.

The Montgomery case makes three further points;

1. The assessment of whether a risk is material cannot be reduced to percentages. It is in fact sensitive and sensitive also to the characteristics of the individual patient.
2. The clinician's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of the condition, the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, including doing nothing, so that the patient is then in a position to make an informed decision. This role will only be performed effectively if the information is provided is comprehensible. The duty is not therefore fulfilled by bombarding the patient with technical information which the patient cannot reasonably be expected to grasp, let alone by routinely demanding a signature on a consent form.
3. It is important that the therapeutic exception should not be abused. It is a limited exception to the general rule that the patient should make the decision.

Provision for patients whose first language is not English

This 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 nor staff who are not fluent with medical terminology in the language required.

For assistance with translators/interpreters, staff can access 'Language Line'/'Everyday Language Solutions', which provides interpretation service.

- The Trust has made available basic hospital information in other languages for non-English speaking patients.

Specific information and consent forms are available in other languages for non-English speaking patients and are available via the Intranet.

Access to Health Professionals between formal appointments
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 take 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).

Where the service is available, patients will be provided with appropriate contact details. If patient information leaflet is available within the service, contact details will be included.

Open Access Clinics
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.

Archiving arrangements for information to patients
Archiving is essential to ensure on-going access to all previous versions of patient information leaflets. Archived patient information may be required as evidence in clinical negligence cases. For details of Trust produced patient information leaflet, please see the Policy for production of clinical patient information.

In the case of leaflets produced by EIDO Healthcare, EIDO retain their own archive and are able to provide previous versions of leaflets on request.

5.3 Documentation

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

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 (The Mental Health Act 1983, the Human Fertilisation and Embryology Act 1990 and the Mental Capacity Act 2005 require written consent in certain circumstances) 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 this trust.

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

There are four main versions of the consent form which are outlined below.

- **Consent Form 1** for adults or competent children;

- **Consent Form 2** for parental consent for a child or young person.

- **Consent Form 3** both for patients able to consent for themselves and, for those with parental responsibility consenting on behalf of a child/young person, where the procedure does not involve impairment of consciousness. NB: If there is a possibility that during the procedure conversion to a general anaesthetic may be required, consent form 1 should be used.

- **Consent Form 4** is available for decision where a "best interest" decision is made due to capacity related issues.

In addition, there are a number of procedure specific consent forms. A list of procedure specific consent forms can be found at Appendix 8.

All versions of the consent form include a section for the clinician taking consent to summarise the risks and benefits of the proposed treatment which they have discussed with the patient, and to record what written information has been provided to the patient as part of the consent process. Where patient information is available, it should be noted on the consent form.

The consent form should be completed early in the patient journey (see section 6.2 'two or more stage process'); extra procedures may not have been identified at this stage. However if extra procedures are required this should be recorded on the consent form.

Verbal or Implied Consent

It will not usually be necessary to document a patient's consent for routine and low-risk procedures, such as providing personal care or taking blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of a particular concern to the patient (for example if they have declined, or become very distressed about, similar care in the past), it would be helpful to do so.

Confirming Consent

If the patient signs the form in advance of the procedure (for example in out-patients or at 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 respond themselves and feel competent to do so.

5.4 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 circumstances governed by the Mental Health Act 1983 and the Mental Capacity Act 2005. The situation for children is more complex: see the Department of Health's Seeking consent: working with children for more details https://ethics.grad.ucl.ac.uk/forms/DH_GuideForChildrenAndYoungPeople.pdf. The following paragraphs apply primarily to adults.

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.

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 realizes 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.

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 the health professional.

5.5 Procedures to Follow when Patients Lack Capacity to Give or Withhold Consent

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 (from for adults who are unable to consent to investigate or treatment), along with the assessment of the patient's capacity, why 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 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.

An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. You should involve appropriate colleagues in making such assessments of incapacity, such as the Safeguarding team, unless the urgency of the patient's situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

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. See Appendix 7 for details of how to do this.

When Patients Lack Capacity to Gove or Withhold Consent

Core Principles of the Mental Capacity Act

The Mental Capacity Act applies in England and the key points identified in this legislation are:

- A person (18 years old and over) is assumed to have capacity; a lack of capacity has to be clearly demonstrated
- No one should be treated as unable to make a decision unless all reasonable steps to help them have been exhausted and shown not to work
- A person can make an unwise decision, this does not necessarily mean they lack capacity
- If it is decided a person lacks capacity then any decisions taken on their behalf must be in their best interests.

Any decision taken on the behalf of a person who lacks capacity must take into account their rights and freedom of action. Any decision should show that the least restrictive option or intervention is achieved.

Consent Form 4 should only be used where it would be usual to seek written consent from an adult patient (18 or over) who lacks capacity to give or withholds consent to treatment. If an adult has capacity to accept or refuse treatment, you should use the standard consent form (Consent Form 1) and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to complete a form at the time, but the healthcare professional should document their clinical decisions appropriately afterwards including a mental capacity assessment and best interest decision.

If treatment is being provided under the authority of Part IV of the Mental Health Act 1983 ("how does the act define capacity to make a decision and how should capacity be assessed"), different legal provisions apply and the healthcare professionals are required to complete more specialised forms (although in some circumstances the healthcare professional may find it helpful to use consent form 4 as well).

For further information see the Mental Capacity Act which can be found on Staff Net on the Nursing and Quality site.

When treatment can be given to a patient who is unable to consent

Capacity

Capacity is 'decision-specific': a patient may lack capacity to take a particular complex decision, but be quite able to take other more straightforward decisions or parts of decisions. For a treatment to be given to a patient who is unable to consent it must be considered whether the patient has an impairment of or disturbance in the function of the mind or brain.

If this is the case further consideration must be given regarding the patient's ability to understand the information relevant to the decision, retain the information and use or weigh up that information as part of the process for making the decision.

Also consideration must be given as to whether it is possible for the patient to communicate their decision by talking, using sign language or any other means.

Before making judgment that a patient lacks capacity a healthcare professional must take all steps reasonably in the circumstances to assist the patient in taking their own decisions (this will clearly not apply if the patient is unconscious).

This may involve explaining what is involved in very simple language, using pictures and communication and decision-aids as appropriate. People close to the patient (spouse/ partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists, independent advocates or supporters.

Best Interests
A person's best interests are not limited to their best medical interests. Other factors which form part of the best interests decision including:

- The wishes and beliefs of the person when competent
- Their current wishes
- Their general well-being
- Their spiritual and religious welfare

Two incapacitated persons, whose physical condition is identical, may therefore have different best interests.

Unless a patient has clearly indicated that particular individuals should not be involved in their care, or unless the urgency of their situation prevents its, healthcare professionals should attempt to involve people close to the patient (spouse/partner, family and friends, carer, supporter or advocate) in the decision-making process and document the names of those spoken to.

Those close to the person cannot require the healthcare professional to provide particular treatment, which they do not believe to be clinically appropriate.

The friends and relatives will know the person much better than the healthcare professional and therefore are likely to be able to provide valuable information about the person's wishes and values.

In considering what is in the patient's best interests the 7 "Statutory Checklist Points" should be considered (MCA Code of Practice):

- Do not make assumptions about a person's best interests
- All relevant circumstances must be considered
- Is the person likely to regain capacity, if so, can the decision wait?
- Involve the person as much as possible
- Decisions concerning the provision or withdrawal of like sustaining treatment must not be motivated by a desire to bring about a person's death
- Consider the person's past and present wishes, their feelings together with any relevant beliefs or values. These may be written in and advance decision (refusal of treatment) and/or an advance statement (advance care planning) or a Lasting Power of Attorney Health and Welfare (LPAHW)
- Both advance decisions and LPAHW are applicable to all health care treatment decisions. If the treatment is life sustaining or the consequences of not having the treatment cause death then the document must contain words specifically detailing 'even if my life is put at risk'.

The healthcare professional must consult other people if appropriate and take account of views, especially anyone previously named by the person as someone to be consulted, including any attorney appointed under a LPAHW and any deputy appointed by the Court of Protection to make decisions for the person.

The "Decision Maker" weighs up all the information in order to determine what decision is in the person's best interests. Clear record keeping of the above is crucial.

For decisions about serious medical treatment up to life sustaining treatments and where there is no one who fits into any of the previously described categories, healthcare professionals may

need to instruct an Independent Mental Capacity Advocate (IMCA). For patients in Durham area, referrals are made to Skills for People on 0191 2818737 or email information@skillsforpeople.org.uk

For patients in the Darlington area, referrals are made to Darlington Association on Disability (DAD) on 01325 360524 or email advocacy@darlingtondisability.org

A referral form is available for the DAD service here:

DAD Referral Form.doc

Delaying Decisions

Careful consideration needs to be given whether a patient is likely to regain capacity within the time limits required for a decision. Also, consideration should be given to whether the person's understanding is better at different times of the day or in particular contexts, whether they are able to make decisions when they are in a comfortable environment, perhaps with loved ones in attendance or if medications have different effects over the course of a day and the patient would have capacity if a decision is delayed until later in the day.

Second Opinions and Court Involvement

Where treatment is complex and/or people close to the person express doubts about the proposed treatment, a second opinion should be sought, unless the urgency of the patient's condition prevents this.

Donations of regenerative tissue such as bone marrow, sterilization for contraceptive purposes and withdrawal of artificial nutrition or hydration from a person in persistent vegetable state must never be undertaken without prior Court of Protection approval. Court of Protection approval can also be sought wither there are doubts about the person's capacity or best interests.

5.6 Mental Health Act

Patients with mental health needs have the right be involved in their care planning, their views should be taken into consideration and their consent for treatment obtained. The patient's care and consent should be recorded in their health record.

Patients detained under the Mental Health Act have a legal right to an Independent Mental Health Advocate (IMHA). Assess to the IMHA is provided by a Service Level Agreement with Tees, Esk and Wear Valley Trust. Contact details can be located on Staff Net: Nursing and Quality site / Mental Health Act.

5.7 Tissue

The Act, which extends to England, Wales and Northern Ireland only, sets out new legal framework for the storage and use of tissues from the living and for the removal, storage and use of tissue and organs from the dead. This includes 'residual' tissue following clinical and diagnostic procedures.

The 2004 Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display. It also covers the removal of such material from the deceased. (It

does not cover removal of such material from living patients – this continues to be dealt with under the common law and the Mental Capacity Act 2005.)

The 2004 Act regulates removal, storage and use of human tissue. This is referred to in the Act as 'relevant material' and is defined as material that has come from a human body and consists of, or includes, human cells. Cell lines are excluded, as is hair and nail from living people. Live gametes and embryos are excluded as they are already regulated under the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008.

The Human Tissue Act 2004 lists the purposes for which consent is required in Schedule 1, and they are referred to as 'scheduled purposes'. The consent required under the Act is called 'appropriate consent', which means consent from the appropriate person, as identified in the Act. Where there has been a failure to obtain or misuse of consent, penalties of up to three years imprisonment or a fine, or both, are provided for in the Act.

Full details on the requirements of the Human Tissue Act 2004 and the HTA's codes of practice are on the HTA's website at www.hta.gov.uk these should be consulted to ensure compliance.

Requirements Concerning Gametes

It is a legal requirement under the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008 that consent must be obtained in writing before a person's gametes can be used for the treatment of others, or to create an embryo in vitro. Consent in writing is also required for the storage of gametes. Information and an opportunity to receive counselling must be provided before the consent is given. Where these requirements are not satisfied, it is unlawful to store or use the person's gametes for these purposes. Clinicians should ensure that written consent to storage exists before retrieving gametes.

Outside specialist infertility practice, these requirements may be relevant to health practitioners whose patients are about to undergo treatment that might render them sterile (such as chemotherapy or radiotherapy), where a patient may wish to have gametes, or ovarian or testicular tissue, stored prior to the procedure. Healthcare practitioners may also receive requests to remove gametes from a person who is unable to give consent.

Requirements for Living Donation

The HTA is responsible for the regulation, through a system of approvals, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. Information on the legal requirements and how to proceed is available from the HTA.

5.8 Consent to Visual and Audio Recordings

Consent should be obtained for any visual or audio recording, including photographs or other visual images. The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made. If it is to be used for teaching, audit or research, people must be aware that they can refuse without their care being compromised and that when required or appropriate it can be anonymised. GMC guidance gives more detailed advice, including situations when permission is not required and about obtaining consent to use recordings as part of the assessment or treatment of patients and for training or research.

See Consent to Clinical Photography and Illustration of Patients Policy for details.

5.9 Research

The same legal principles apply when seeking consent from a person for research purposes as when seeking consent for investigations or treatment. GMC guidance advises that patients 'should 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'. Clinical trials are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004.

Please see Research Consent Policy for further information.

5.10 Training

Generic Consent

The Trust has an online consent training package (BeINFOrMED). This is once only training and requires a pass mark of 60%. This is mandatory for all medical/dental staff and should be undertaken every 3 years.

Delegated Consent

See section 5 (and Appendix 3 - 6) for details, a 'Record of Competence to Obtain Delegated Consent form' must be completed.

Nursing and Allied Healthcare Professionals must complete the Nursing/Allied Healthcare Professionals Competency Assessment in addition to the 'Record of Competence to Obtain Delegated Consent Form' which must be returned to the relevant Departmental Secretary.

6 Monitoring

6.1 Compliance and Effectiveness Monitoring

Performance will be measured on a regular basis as shown below.

6.2 Compliance and Effectiveness Monitoring Table

Monitoring Criterion	Response
Who will perform the monitoring?	Assurance, Risk & Compliance
What are you monitoring?	The process for providing patients with information and process for documenting the discussion.
When will the monitoring be performed?	Clinical audit of consent forms and patient notes carried out by the clinical services (twice a year for those care groups with procedures requiring a written consent form)
How are you going to monitor?	Monitoring via the clinical audit forward plan
What will happen if any	Shortfalls will be reported to the Care Group Governance meetings.

shortfalls are identified?	
Where will the results of the monitoring be reported?	Care Group Governance meetings. If there are any risks associated with the audit findings it will be reported to the Clinical Standards and Therapeutics Committee.
How will the resulting action plan be progressed and monitored?	Where the audits identifies areas of poor compliance with the policy, the action plan will be monitored by the Care Group Governance meetings
How will learning take place?	Development of action plans, Care Groups to implement, dissemination of reports and minutes via e-mail and intranet

7 Glossary of Terms

- P&OD – People and Organisational Development
- CSTC – Clinical Standards & Therapeutics Committee
- IQAC – Integrated Quality Assurance Committee

8 Associated Documentation

8.1 References

- Department of Health (2009), Reference guide to consent for examination or treatment, 2nd Edition, Department of Health, [Online] Available at http://www.doh.gov.uk/consent.
- Department of Health 12 key points on consent: the law in England www.doh.gov.uk/consent.
- Department of Constitutional affairs (2007), Metal Capacity Act Code of Practice, [Online] Available at http://www.dca.gov.uk/legal-policy/mental-capacity/mca-cp.pdf
- Department on Constitutional Affairs (2007), Making decisions, A guide for people who work in health and social care, Department of Constitutional affairs, [Online] Available at http://www.publicguardian.gov.uk/docs/making-decisions-book3-2nd-edition.pdf
- Department of Health (2001), Good practice in consent implementation guide: consent to examination or treatment, Department of Health, [Online] Available at http://www.doh.gov.uk
- Care Quality Commission, Monitoring the Mental Health Act in 2011/12
- General Medical Council “Doctors and patients making decisions together” [Online resources] Available at http://www.gmc uk.org/guidance/ethical_guidance/consent_guidance_index.asp
- 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 via https://ethics.grad.ucl.ac.uk/forms/DH_GuideForChildrenAndYoungPeople.pdf

- Medical Protection (2015), New judgment on patient consent. Medical Protection [Online] Available at http://www.medicalprotection.org/uk/for-members/news/news/2015/03/20/new-judgment-on-patient-consent

- With thanks for Wirral University Teaching Hospitals NHS Foundation Trust for sharing their policy format, and Brighton and Sussex University Hospital.

8.2 Associated Documents

- Policy for the production of clinical patient information
- Consent to Clinical Photography and Illustration of Patients Policy
- Research Consent Policy
- Mental Capacity Act 2005, Policy and Guidance notes for staff, CDDFT 2010
- Mental Health Act
- TNA and TNA Policy
- Incident Management Policy

9 Appendices

Appendix 1 – 12 Key Points on Consent: The Law in England

Appendix 2 – Locum Competency Check at Induction Flow Chart

Appendix 3 – Delegated Consent – Doctors (F2 and above)

Appendix 4 – Delegated Consent – Registered Nurses & Allied Healthcare Professional Staff

Appendix 5 – Record of Competence to Obtain Delegated Consent

Appendix 6 – Registered Nurses/Allied Healthcare Professional Delegated Consent Competency Record

Appendix 7 – Points to Consider Before Seeking a Court Declaration

Appendix 8 – List of Current Forms in use within the Organisation

Appendix 9 – Equality Analysis/Impact Assessment

Appendix 1 – 12 Key Points on Consent

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** 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.

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 specifically 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. 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 2 – Locum Competency Check at Induction

Locum Competency Check at Induction

As part of the induction process - the Consultant meets with Locum.

The Consultant will be responsible for ensuring that the Locum is suitably supervised and that the arrangements for obtaining consent are documented on the 'Record of Competence to obtain Delegated Consent' form.

The 'Record of Competence to obtain Delegated Consent' form will be submitted to the Department Secretary and the Department Register* updated with the Locums details.

***Although delegated consent is not required, the details of the Locum and their competence should be recorded on the department database and updated when the Locum next commences working with the Trust.**

Appendix 3 – Delegated Consent – Doctors

DELEGATED CONSENT - DOCTORS (F2 and above)

No Delegated Consent

At the induction meeting the Clinical Supervisor will review the doctor's portfolio for evidence of obtaining consent

If no evidence is available and delegation is not appropriate, no further action is required.

Note

The 'Record of Competence to obtain Delegated Consent' form once completed will be returned to the relevant department secretary for archiving and recording on the Care Group Delegated Consent Register.

Competency Check

Discussion held between the doctor and Clinical Supervisor regarding delegated consent

Evidence of operating delegated consent in previous Trust is available in the doctor's portfolio

The 'Record of Competence to obtain Delegated Consent' form (Appendix E) is completed listing the procedures where consent will be delegated.

Delegated Consent

Clinical Supervisor reviews portfolio and no evidence of delegated consent available.

The Clinical Supervisor discussed with the doctor potential development opportunities and procedure specific training provided.

Clinical Supervisor directly observes the doctor obtaining consent

The 'Record of Competence to obtain Delegated Consent' form (Appendix E) will be completed by the Clinical Supervisor listing the procedures where delegated consent applies.

Appendix 4 – Delgated Consent – Registered Nurses & Allied Healthcare Professional Staff

DELEGATED CONSENT - REGISTERED NURSES AND ALLIED HEALTHCARE PROFESSIONAL STAFF

All registered nursing and allied healthcare professionals must undertake a competency assessment prior to operating delegated consent. This process will not be restricted to particular grades but based on assessment of individual's competence.

The Consultant will discuss with the nurse/allied healthcare professional potential development opportunities.

The nurse/allied healthcare professional will complete the e-learning package BeINFOrMED.

Procedure specific training will be provided by the Consultant and a competency assessment, either the example provided at Appendix F or service specific competency assessment will be competed.

Consultant directly observes the nurse obtaining consent.

'Record of Competence to Obtain Delegated Consent' form (Appendix E) will be competed and signed by the Consultant and the nurse/allied healthcare professional.

A copy of the 'Record of Competency to Obtain Delegated Consent' will be returned to the relevant department secretary for archiving and recording on the Care Group Delegated Consent Database.

Appendix 5 – Record of Competence to Obtain Delegated Consent

County Durham and Darlington NHS
NHS Foundation Trust

Record of Competence to Obtain Delegated Consent
(Demonstrating competency to gain procedure specific consent)

This document reflects the training received and systems in place to support medical/ nursing and Allied Healthcare Professional staff prior to obtaining written delegated consent.

Name of healthcare professional	
Status:	
Directorate:	
Department:	

Statement of delegate (please tick appropriate statement)

☐ I confirm that I completed generic consent training (BeINFOrMED) on ……(date) and achieved …… % pass (above 60%)

☐ OR I have the equivalent eg MRCS/Anaesthetic Part 1

☐ I confirm that I understand the risks and benefits of the above procedures, any alternatives to the procedures (and the risk and benefits of these alternatives), where to go to seek further information, knowledge of any procedure specific consent forms, and options when consent is withheld or withdrawn.

Signed…….... (delegate) ……..(date)

Statement of responsible consultant

I confirm that ……has been trained in the risks and benefits of the above procedures, any alternatives to the procedures (and the risk and benefits of this alternatives), where to go to seek further information, knowledge of any procedure specific consent forms, and options when consent is withheld or withdrawn.

☐ Evidence is available with the delegate's portfolio.

☐ I confirm I have directly observed the delegate taking consent on one occasion

☐ I confirm that the delegate can obtain consent for the indicated procedures upon mine and my consultant colleagues' behalf

Signed…… (Consultant)

Print Name ……..... Date……

A copy of the completed form is to be sent to your nominated Care Group Departmental Secretary.

Demonstrating competency to gain procedure specific consent
Name of healthcare professional: - (Print)

List of Procedures	**Signature of Assessor & GMC Number**	**Date**

Appendix 6 – Registered Nurses/Allied Healthcare Professional Delegated Consent Competency Record

County Durham and Darlington NHS
NHS Foundation Trust

Registered Nurses/Allied Healthcare Professional Delegated Consent Competency Record

Template competency assessment (other procedural specific document can be used as an alternative).

Name of Individual Being Trained:	
Job Title:	
Area or Work:	
List of Procedures (where consent will be obtained by the delegate):	
Consultant Responsible:	

THEORY CHECK

	DATE AND COMMENTS
Received and read Trust Consent Policy:	
Knowledge of anatomy and physiology relevant to Consent scope:	
Law on Consent and awareness of correct Consent Form to be used (BeINFOrMED Training):	

PRACTICAL APPLICATION
The Consultant should discuss the following areas to confirm that the individual being trained has the knowledge and ability to obtain consent.

	DATE AND COMMENTS
Introduce self to patient:	
Confirm patient identity and intended procedure:	
Explain of intended procedure including: • Type of procedure. • Reason for procedure. • Type of anaesthetic. • Hospital stay arrangements and after care.	

Ability to answer the following: • Is this the best option for me? • Will the treatment help me? • How will it help me? • What will happen during the procedure? • Will it hurt?	
Ability to explain the risks and benefits for each individual patient:	
Identification of alternative treatment or no treatment for each individual patient:	
Has access to Senior Staff as required:	
Ability to gain additional information as required by patient:	
Ability to complete Consent Form correctly:	

PRACTICAL
The Consultant should complete the following sections to confirm that the individual being trained has been observed taking consent. This forms part of the competency assessment.

Observation of Consent episodes by Consultant: _____	**DATE AND COMMENTS**

SIGN OFF
Once the Consultant has deemed the individual being trained is competent the assessment should be signed.

I,_____ Consultant (delegating professional) _____, state that the named person has been fully trained and is competent to obtain valid consent for the procedure(s) listed on the front sheet.	Signed: _____ Date:_____
I,_____ accept responsibility for obtaining Consent for the procedure(s) listed on the front sheet.	Signed: _____ Date:_____

A copy of the completed form is to be sent to your nominated Care Group Departmental Secretary.

Appendix 7 – Points to Consider Before Seeking a Court Declaration

Points to Consider Before Seeking a Court Declaration

1. Obtain the patient's consent before examining, treating or caring for the patient.

2. You must always assume that an adult is competent unless there is evidence to suggest otherwise.

   If you have any doubts about their competence, then you need to consider whether the patient can 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. Does the patient have capacity?

   - Does the patient have an impairment of or a disturbance in the functioning of the mind or brain?
   - To understand the information relevant to the decision
   - To retain the information
   - To use or weight that information as part of the process of making the decision
   - Is the patient able to communicate their decision, whether by talking, using sign language or any other means

4. If yes, a competent adult is entitled to refuse treatment even when it would be of benefit to their health.

5. If no, if the patient's capacity is in question, then the opinion of the treating consultant and another experienced healthcare professional must be sought as to the extent of their capacity and whether they understand the repercussions of their decision. If it is considered that the patient does not have capacity, then you may still treat such a patient if the treatment is necessary and would be in their best interests as stated in accordance with the case of F v West Berkshire Health Authority (1989).

6. If there is a dispute as to what the wishes of the patient may have been or a dispute as to the wishes of the family and with what is in the patient's best interest, then a Declaration from the Court must be sought.

7. In doing so, it is important to contact the Legal Team, with the following information:

   a. patient's name
   b. patient's date of birth
   c. whether the patient has got capacity
   d. supporting statement from the treating consultant and another experienced healthcare professional as to the extent of the patient's capacity
   e. information regarding the dispute and evidence to support that it is in the patient's best interest and it is necessary.

Appendix 8 – List of Current Forms in Use within the Organisation

LIST OF CURRENT FORMS IN USE WITHIN THE ORGANISATION

Speciality	Form No	Procedure / Title
N/A Trustwide	1	Patient Agreement to investigation or treatment
N/A Trustwide	2	Patient agreement to investigation or treatment for a child or young person
N/A Trustwide	3	Procedures where consciousness is not impaired
N/A Trustwide	4	Form for adults who are unable to consent to investigation or treatment
Ophthalmology	5	Pre-Printed Consent Form for Course of Lucentis Treatment
Ophthalmology	6	Cataract Implant Surgery Consent Form
Dermatology Department	7	Consent to Ultra-Violet B (UVB) phototherapy
Obstetrics and Gynaecology	8	Caesarean Section
Obstetrics and Gynaecology	9	Laparoscopy
Obstetrics and Gynaecology	10	Vaginal Prolapse Surgery
Ophthalmology	11	Cataract Extraction
Cardiac Cathlab	12	Cardiac Catheterisation
Cardiac Cathlab	13	Generator Box Change
Cardiac Cathlab	14	Loop Recorder Insertion
Cardiac Cathlab	15	Permanent Pacemaker Insertion
Cardiac Cathlab	16	Transoesophageal Echocardiogram
Cardiac Cathlab	17	Cardiac Resynchronization Therapy Pacemaker
Cardiac Cathlab	18	Implantable Cardiac Defibrillator
Cardiac Cathlab	19	Cardiac Resynchronization Therapy with Cardioverter Defibrillator
Bariatric Service	20	Gastroscopy & Gastric balloon insertion
Bariatric Service	21	Laparoscopic Adjustable Gastric Band
Bariatric Service	22	Laparoscopic Gastric Bypass
Bariatric Service	23	Laparoscopic Sleeve Gastrectomy
Dermatology	24	Narrowband UVB Phototherapy
Chemotherapy	26	Range of forms for the differing types of chemotherapy delivered as part of patient care.

Appendix 9 – Equality Analysis / Impact Assessment

EIA - Consent Policy.docx