

Consent to Examination or Treatment

Date	Version
November 2016	9.1

Purpose

The purpose of this Policy is:

- to make sure that staff understand their responsibilities regarding consent; and
- to ensure that patients undergoing a procedure receive adequate information on which to base their decision making to ensure that they receive the best possible care.

Who should read this document?

All Trust staff.

Key messages

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients. Wherever possible procedure specific consent should be used as gold standard practice in the consenting process. 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 by documenting in the patient's notes that they have given verbal consent.

Accountabilities

Production	Assistant Medical Director for Quality
Review and approval	Clinical Effectiveness Group
Ratification	Medical Director
Dissemination	Assistant Medical Director for Quality
Compliance	Clinical Effectiveness Group

Links to other policies and procedures

South West Centre for Reproductive Medicine (SWCRM) protocol for consent
 Organ Donation Policy
 Disposal of Foetal Remains Policy
 Policy for the Use of Consent and the Surgical Safety Checklist in the Imaging Directorate.
 Translation and Interpretation Policy
 The Introduction of New Clinical Devices and Procedures Policy
 Research and Development Policy
 Trust Research Standard Operating Procedure G6 - Consent procedures for entry into a Research study
 Mandatory / Statutory Training Needs Analysis
 Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007) Policy.
 Resuscitation Policy
 Safeguarding Vulnerable Adults Policy
 End of Life (Standard Operating Procedure)
 Recording and Filing of Living Wills and Advance Directives Administrative Procedure Note
 The Hospital Transfusion policy

Version History

V2	October 2002	
V3	October 2005	Reviewed & approved CGSC, CRMG & CGC

V4	November 2007	Requirements of the Mental Capacity Act, Human Tissue Act and audit of the effectiveness of the policy included Reviewed CGSG Oct 2007.
V5	July 2009	Trust policy format. Considered against new CGC Regulations. Reviewed & approved CGSG Jul 2009
V5.3	October 2009	Updated Audit Process
V6	November 2010	Reviewed by GCSG & approved.
V7.1	September 2012	Reviewed by Effective Care & approved
V8	May 2013	Reviewed
V9	November 2016	Full planned review
V9.1	November 2022	Review date extended to April 2021
Last Approval		Due for Review
November 2016		April 2022

The Trust is committed to creating a fully inclusive and accessible service. By making equality and diversity an integral part of the business, it will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on the Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Section	Description	Page
1	Introduction	4
2	Purpose, Including Legal or Regulatory Background	4
3	Definitions	4
4	Duties	5
5	General Principles of Consent	5
6	When Should consent be Sought?	8
7	Provision of Information	14
8	Who is Responsible for Seeking Consent?	15
9	Completing consent form	17
10	Refusal of consent	18
11	Consent for Participation in Research Study	19
12	Consent for the use of human tissue and requesting autopsies	20
13	Consent for disposal of Foetal remains	21
14	Consent for Clinical Photography or Video Recordings	21
15	Training	22
16	Monitoring Compliance & Effectiveness	22
17	Overall Responsibility for the Document	22
18	Consultation and Ratification	22
19	Dissemination & Implementation	23
20	References	23
Appendix 1	How to seek Court Declaration	24
Appendix 2	Procedure for obtaining Consent for Adult Autopsy	25
Appendix 3	Consent to Visual Recording	27
Appendix 4	Montgomery v Lanarkshire Health Board (2015)	30
Appendix 5	Dissemination Plan	32
Appendix 6	Review and Approval Checklist	33
Appendix 7	Equality and Human Rights Impact Assessment	34

1 Introduction

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

2 Purpose, including legal or regulatory background

There are a range of guidance documents on consent (see section 20), and these should be consulted for details of the law and good practice requirements on consent. This policy sets out the standards and procedures in this Trust, which aim to ensure that health professionals are able to comply with the guidance. While this document is primarily concerned with healthcare, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

Relevant legislation includes:

- The Mental Capacity Act 2005 and associated Code of Practice outlines clinicians' responsibilities to assess the mental capacity of all adult patients as part of the consent process and taking appropriate steps to ensure valid consent is obtained. This may require the referral of patients to Independent Mental Capacity Advocates (IMCAs). For further information refer to the Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007) Policy.
- Mental Health Act 1983 – Treatment for mental disorders without consent
- Human Tissue Act 2004
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)
- Data Protection Act 1998
- Children Act 1989
- Human Fertilisation and Embryology Act 1990
- Human Rights Act 1998
- Video Recordings Act 1984
- Family Law Reform Act 1969
- Copyright Act 1988

Please refer to separate Trust policies for the requirements concerning gametes and organ donation.

3 Definitions

What consent is – and isn't

"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), verbally, or in writing. For the consent to be valid, the patient must:

- be competent to make the particular decision;
- have received sufficient information (which includes material risks involved in the treatment and any alternatives) within a sufficient timeframe to make 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 professional's advice. In some cases, the health professional will suggest

a particular form of treatment or investigation and after discussion the patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments (although these should not be provided unless deemed clinically appropriate in all the circumstances). 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.

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no one else can give consent on their behalf unless the decision is one which can be taken by an individual appointed under a valid and application Lasting Power of Attorney (LPA) (see Mental Capacity Act Policy) or somebody who has authority to make decisions as a Court Appointed Deputy. However, treatment may be given if it is in that person's best interests, as long as it has not been refused in advance by way of a valid and applicable Advance Directive. For further details on Advance Directives see the Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007) Policy.

Within this Trust, health professionals should seek advice on consent where necessary from their Clinical Director / Service Line Director, Medical Director, Assistant Medical Director for Quality, Director of Nursing or Director of Clinical Professions. In the situation where, after discussion with one of the professionals above, it appears that legal assistance is required, then this is obtained through the Legal Services Manager for the Trust. When legal assistance is required out of hours, the Trust's on call manager should be informed.

4 Duties

The **Medical Director** is responsible for ensuring that policy and practice related to consent comply with national guidance.

All **clinical staff** must ensure that patients are able to give informed consent. Specific duties related to the delegation of consent are detailed on page 16 of this Policy.

Service line management teams are responsible for ensuring that appropriate arrangements are in place for approving Procedure Specific Consent forms within their own area and for ensuring that audit of the consent process is incorporated within their audit plans.

The **Clinical Effectiveness Group** is responsible for review and approval of this Policy and seeking assurance that the outcomes of consent audits are addressed appropriately.

5 General Principles of Consent

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 by documenting in the patient's notes that they have given verbal 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.

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

Plymouth Hospitals NHS Trust requires written consent for all surgery/surgical procedures. In addition, the Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances. Patient consent in any form should be documented in a patient's records. It is good practice to seek written consent 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 possible 'side-effects' or 'complications'). In addition, the professional has a duty to ensure a patient is aware of material risks (see section 7 – 'Provision of Information' of this Policy).
- 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 and its Local Research and Ethics Committee (LREC).
- The treatment requires the transplantation of human tissue as defined by the Human Tissue Act 2004.

Completed forms should be kept with the patient's notes. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both the patient and the health 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 you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about similar care in the past), it would be helpful to do so.

Procedures to follow when patients lack capacity to give or withhold consent

For the purposes of consent the adult patient must be assessed as to their capacity to give consent under the Mental Capacity Act 2005 (see Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007) Policy. All adult patients must be assumed to be competent until assessed as otherwise.

Capacity is defined as the ability to understand, retain and weigh up information and communicate the decision reached.

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 specialist learning disability teams and speech and language therapists, 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.

Where an adult patient has been assessed as lacking capacity to give or withhold consent to a significant intervention, this fact should be documented using **form 4** (form for adults who are unable to consent to investigation or treatment). Along with the consent form there should be documentation of the mental capacity assessment and best interest principles (a template can be found in Appendix A of the Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007) Policy):

- The assessment of the patient's capacity.
- A record of why the health professional believes the treatment to be in the patient's best interests.
- A record of the involvement of people close to the patient including IMCA's where they have been involved – details about IMCA's and application form can be found on StaffNet Safeguarding Adults Mental Capacity Act page.

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.

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. A court declaration must be sought for cases concerning "Serious Medical Treatment" Appendix 1). See also the section in this Policy "Withdrawing and withholding life-sustaining treatment" on page 19.

Any potentially life-threatening circumstances where consent is refused or unavailable must be brought to the attention of the relevant Clinical Director / Service Line Director (or Medical Director, Assistant Medical Director for Quality, Director of Nursing or Director of Clinical Professions). In the situation where, after discussion with one of the professionals above, it appears that legal assistance is required, then this is obtained through the Legal Services Manager for the Trust. When legal assistance is required out of hours, the Trust's on call manager should be informed.

Self-harm

Cases of self-harm present a difficulty for healthcare professionals. Where the person is able to communicate, an assessment of their mental capacity should be made as a matter of urgency. If the person is judged not to have capacity, then they may be treated on the basis of their best interests. Similarly patients who have attempted suicide and are unconscious should be given emergency treatment unless there is a valid Advance Decision specifically preventing the proposed treatment. If a patient has attempted suicide you may also wish to consider whether the person requires assessment under the Mental Health Act.

However patients with capacity **do** have the right to refuse life-sustaining treatment both at the time it is offered and in the future. The MHA 1983 is used for treatment of mental disorders and, in limited circumstances, related physical health needs. However, if a patient has capacity and is not subject to MHA or require physical health care not covered by MHA, their decision to accept or refuse treatment should be respected. Any such refusal should be clearly and fully documented in the patient's records. If the person is clearly suicidal, this may raise questions about their capacity to make the decision. If a patient with capacity has harmed themselves, a prompt psychosocial assessment of their needs should be offered and consideration given to referring them for a MHA assessment.

Availability of forms

Standard consent forms and forms for adults who are unable to consent for themselves are available by ordering the pads from EPROC. There are three versions of the standard consent

form: **form 1** for adults or competent children, **form 2** for parental consent for a child or young person and **form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary. .

Where possible **procedure specific consent (PSC)** should be used as gold standard practice in the consenting process. Procedure specific consent forms provide patients with procedure specific information to improve the process of consent. They provide written information that may be read away from the pressure of the clinical environment and at a pace that suits the patient. They facilitate patients and their loved ones to understand more completely the procedure they are about to embark on. They provide the patient with standardised risks as agreed by consensus and allow infrequent risks to be documented. Risks that are very rare or unpredictable would not normally be listed and therefore patients and clinicians should recognise this in the consent process. The use of procedure specific consent should not diminish the need for clinicians to take an individualised approach.

PSC forms are widely produced by speciality branches of the Royal Colleges as well as some commercial companies. They are available for most routine, elective procedures. Service lines will be responsible for approving PSCs within their own area once the PSP programme has been rolled out across the hospital. The content of the forms should mirror the standard defined in section 9 of this policy.

These forms should be used in conjunction with Patient Information Leaflets and both should be presented to the patient as early in the consent process as possible – ideally in outpatients. The forms should be reviewed and signed on the day of the procedure.

The evidential value of pro forma consent forms and information leaflets will be limited unless accompanied by a discussion with the patient to discuss the issues which are specifically relevant to the patient, in particular around material risks, and this is then documented.

6 When should consent be sought?

When a patient formally gives their consent to a particular intervention, this represents the *endpoint* of the consent process. It is helpful to regard the whole process of assessment, 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.

Single stage process.

In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given verbally.

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.

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 outpatient 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.

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.

They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in outpatients, 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; in this instance it is recommended that the patient re-signs the consent form. 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?"

When a patient gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, the clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent repeated on the basis of this information. Similarly, if the patient's condition has changed significantly in the intervening time it may be necessary to seek consent again, on the basis that the likely benefits and/or material risks of the intervention may also have changed.

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 or taking routine pre-operative medication), unless this is unavoidable because of the urgency of the patient's condition.

Medication that is required as part of the procedure should not be administered until after consent has been given. This is particularly important for any medication that could lead to an altered state of consciousness in which case any consent taken after administration of the medication would be invalid.

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 material risks of that treatment as well as any potential alternatives (i.e. sedation). 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 or any alternatives in outpatients, or have the opportunity to discuss the benefits and material risks with the anaesthetist prior to surgery, in a pre-assessment

clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's notes or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

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. In life threatening situations consent may not be possible and treatment may need to be provided without consent in the best interests of the patient (see the Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007) Policy).

Children and Young People.

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position of adults. For the purpose of this policy, 'children' refers to people aged below 16 and 'young people' refers to people aged 16 or 17.

Young people aged 16 or 17

People aged 16 or 17 are presumed to have capacity to and capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic as if they were an adult. The Mental Capacity Act 2005 applies to anyone aged 16 or over. Whether an individual aged 16 or over is therefore able to consent to treatment will be dependent on whether they are deemed to have capacity to take that decision. As with adults, consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention.

Young people aged 16 and 17 may sometimes not have capacity to consent to treatment or take particular decisions. This could be for a variety of reasons – they are unconscious, suffering from the effects of medication and so on. You should consider whether that young adult may have fluctuating capacity, and it would be possible to wait to take any decision until that young person has regained capacity. Where a young adult does not have capacity to consent, any treatment or decision would need to be taken forward in their best interests.

Where a young person has capacity, their decision should be respected and you can rely on that young person's consent even if those with parental responsibility disagree. Equally a young person with capacity is entitled to refuse treatment. If the young person does not have capacity, and there is a disagreement between the clinician and those with parental responsibility with regard to decisions relating to serious medical treatment, and this is unable to be resolved, then the matter should be referred to the Court of Protection.

Where a young person of 16 or 17 who could consent to treatment in accordance with section 8 of the Family Law Reform Act 1969 refuses treatment, it is possible that such a refusal could be overruled if it would in all probability lead to the death of the young person or to severe permanent injury. However this power to override a competent young person's decision should be used rarely, particularly given the difficulties of forcing treatment on that child.

Children under 16 – the concept of Gillick competence

In the case of *Gillick*, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention, what the material risks and benefits are, what alternative treatment options there are (including the consequences of no treatment) as well as the material risks and benefits of those alternative treatments; will also have the capacity to consent to that treatment or intervention. This is sometimes described as being 'Gillick competent'. A child under 16 may be Gillick competent to consent to medical treatment, research, donation or any other activity that requires consent.

The concept of Gillick competence is said to reflect a child's increasing development to maturity. The understanding required for different interventions will vary considerably and may also vary as between children. Thus a child under 16 may have the capacity to consent to some interventions but not to others. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made.

If the child is Gillick competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child's family in the decision-making process, if the child consents to their information being shared. However clinicians must respect any request from an under 16 year old to keep their treatment confidential, unless disclosure to a particular individual or organisation is justified on the basis that you have reasonable cause to suspect that the child is suffering or is likely to suffer significant harm.

The requirement of voluntariness & a child with capacity providing consent

Although a child or young person may have the capacity to give consent, this is only valid if it is given voluntarily. This requirement must be considered carefully. Children and young people may be subject to undue influence by their parent(s), other carers or a sexual partner (current or potential), and it is important to establish that the decision is that of the individual him or herself.

Those with parental responsibility cannot override the consent of a competent child who agrees to treatment, although if this concerns serious medical treatment and cannot be resolved through discussion and mediation, very real consideration will need to be given about how best to proceed, and whether this matter should be referred to the Local Authority or to the Court.

Child with capacity refusing treatment

Where a child under 16 but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled by those with parental responsibility if it would in all probability lead to the death of the child or to severe or permanent injury. However this power to override a competent child's decision should be used rarely, particularly given the difficulties of forcing treatment on that child.

Where the treatment involved is for mental disorder, consideration should be given to using mental health legislation.

A life-threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the person with parental responsibility refuses consent despite such emergency treatment appearing to be in the best interests of the child. In such cases the courts have stated that doubt should be resolved in favour of the preservation of life, and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health whilst the wider issues are resolved.

Children lacking capacity

Where a child under the age of 16 lacks capacity to consent (i.e. is not Gillick competent), consent

can be given on their behalf by any one person with parental responsibility or by the court. In the face of parental disagreement, you can rely on one parent's consent provided they have parental responsibility. As is the case where patients are giving consent for themselves, those giving consent on behalf of child patients must have the capacity to consent to the intervention in question, be acting voluntarily and be appropriately informed. The power to consent must be exercised according to the 'welfare principle': that the child's 'welfare' or 'best interests' must be paramount. Even where a child lacks capacity to consent on their own behalf, it is good practice to involve the child as much as possible in the decision-making process.

If parents refuse treatment for their child, then treatment should not go ahead. If health professionals believe that the treatment is crucial, then the Courts can be asked to determine what is in the child's best interests. Where necessary, the courts can overrule a refusal by a person with parental responsibility. It is recommended that certain important decisions, such as sterilisation for contraceptive purposes, should be referred to the courts for guidance, even if those with parental responsibility consent to the operation going ahead. Similarly, parents cannot require professionals to provide treatment which they do not believe to be clinically appropriate, although it may be helpful to request a second opinion and attempt mediation.

Parental Responsibility

The Children Act 1989 sets out persons who may have parental responsibility. These include:

- The child's mother.
- The child's father, if he was married to the mother at the time of birth.
- Unmarried fathers, can acquire parental responsibility in several different ways:
For children born before 1 December 2003, unmarried fathers will have parental responsibility if they:
 - Obtain a parental responsibility order from the court.
 - Register a parental responsibility agreement with the court or by an application to court.For children born after 1 December 2003, unmarried fathers will have parental responsibility if they:
 - Register the child's birth jointly with the mother at the time of birth (you will want to see a copy of the birth certificate to ensure that the father's name appears on it).
 - Obtain a parental responsibility order from the court.
 - Register with the court for parental responsibility.
- The child's legally appointed guardian.
- A person in whose favour the court has made a residence order concerning the child.
- A local authority designated in a care order in respect of the child.
- A local authority or other authorised person who holds an emergency protection order in respect of the child. Section 2(9) of the Children Act 1989 states that a person who has parental responsibility for a child 'may arrange for some or all of it to be met by one or more persons acting on his or her behalf'. Such a person might choose to do this, for example, if a childminder or the staff of a boarding school have regular care of their child. As only a person exercising parental responsibility can give valid consent, in the event of any doubt then specific enquiry should be made. Foster parents do not automatically have parental responsibility.

If you are in any doubt about whether the person with the child has parental responsibility for that child, you must seek assurance in writing.

Where a child is subject to a "legal order" the local authority will assume parental responsibility. In these circumstances where a child is admitted to a hospital for treatment the local authority should give consent for treatment although it is expected that they should normally do this in consultation

with the parents of that child. If the child is admitted for a routine surgical procedure then the social work team leader, where the child is placed, should sign the consent form or someone else with relevant authority. The Trust should not accept faxes for planned operations unless there are exceptional circumstances. The preferred method of obtaining consent should be a meeting between the social worker, the parent(s) and the relevant doctor in order to gain consent.

Consent given by one person with parental responsibility is valid, even if another person with parental responsibility withholds consent. However, the courts have stated that a 'small group of important decisions' should not be taken by one person with parental responsibility against the wishes of another, citing in particular non-therapeutic male circumcision and immunisation. Where persons with parental responsibility disagree as to whether these procedures are in the child's best interests, it is advisable to refer the decision to the courts. It is possible that major experimental treatment, where opinion is divided as to the benefits it may bring the child, might also fall into this category of important decisions.

Where there is doubt about whether a parent is acting in the interest of the child then the healthcare practitioner would be unwise to rely on the parent's consent. Consideration should be given as to whether a referral should be made to the Local Safeguarding Children Board (via the Local Authority), or even to Court. You are also referred to Government Guidance: 'Working Together to Safeguard Children' dated March 2015 where abuse or neglect is suspected.

In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity. Where the person with parental responsibility for a child is themselves under 18, they will only be able to give valid consent for the child's treatment if they themselves are aged under 16 but Gillick competent, or if aged 16-17, meet the test of capacity within the Mental Capacity Act 2005. Whether or not they have capacity may vary, depending on the seriousness of the decision to be taken.

Where a child is a ward of court, no important step may be taken in the life of the child without the prior consent of the court. This is likely to include more significant medical interventions but not treatment for minor injuries or common diseases of childhood.

In an emergency, it is justifiable to treat a child who lacks capacity without the consent of a person with parental responsibility, if it is impossible to obtain consent in time and if the treatment is vital to the survival or to prevent a serious deterioration to the health of the child.

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.

If emergency treatment is required then the senior clinician should act in the best interest of the child.

Use of Unlicensed Medicines

Written informed patient consent must be sought and obtained on each occasion that a patient is treated with a high risk unlicensed medicine (see Pharmacy website for list of unlicensed medicines and their associated risk classification). Although not essential, clinicians are also advised to seek written patient consent for use of low risk unlicensed medicines. A patient consent proforma is available in the Unlicensed Medicines Policy and on the Pharmacy website.

Additional Procedures

It is good practice to seek the views of the patient on possible additional procedures when seeking consent for the original intervention. If a patient has refused certain additional procedures before the anaesthetic, then this must be respected if the refusal is applicable to the circumstances.

During an operation it may become evident that the patient could benefit from an additional procedure that was not within the scope of the original consent. If it would be unreasonable to delay the procedure until the patient regains consciousness (for example in order to save the patient's life) it may be justified to perform the procedure on the grounds that it is in the patient's best interests. The patient or carers/family involved in the consent process must be informed of any additional procedures undertaken at the earliest opportunity. However, the procedure should not be performed just because it is convenient. If the procedure is not essential then the patient should be recovered and the additional procedure consented for and undertaken at a later date. Where additional procedures are frequently required then it may be wise to consider adding these to the consent process to avoid patients unnecessarily undergoing further sedation.

7 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 material risks and benefits (including the risks/benefits of doing nothing and any variant treatments). This needs to be written in plain English and in a format that they can understand. 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, possible side effects and so on.

The professional seeking consent has a legal duty to ensure that the patient is aware of any material risks included in any recommended treatment and of any reasonable alternative or variant treatments. What constitutes a material risk depends on the circumstances of the particular case and whether 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. For further information on the legal test for provision of information as set out in the case of *Montgomery v Lanarkshire Health Board* (2015) see Appendix 4. It is imperative to ensure good contemporaneous record keeping of the discussions and issues of risk discussed with the patient either on the consent form or in the patient's records. This record keeping should include documentation of the name of the information sheet provided together with the version number and, if possible, date of publication. The Trust Policy for Producing and Managing Patient Information is available within the Trust Documents folder on StaffNET. This gives advice on all aspects of designing, writing and registering patient information as well as considerations and controls to be applied to the use of externally produced information. For more information contact the Patient Services Team who will be able to take you through the registration and approval process.

Provision for patients whose first language is not English or visual/auditory impairment

This Trust is committed to ensuring that patients whose first language is not English or who have visual or auditory impairment receive the information they need and are able to communicate appropriately and effectively with healthcare staff. It is not appropriate to use family members or children to interpret for family members who do not speak English, see Trust Interpreting and Translation Policy and Procedure.

The Patient Services Department will be able to organise translation or transcription of a document / patient information into other languages / formats. Please contact them for advice on Ext 39743 or out of hours contact the on-call manager.

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. This Trust has made the following arrangements to assist patients to obtain such information:

- Leaflets about conditions or treatments will, where appropriate, list external sources of information e.g. How to contact local self-help groups and national bodies.
- Leaflets will also include who to contact within the Trust for further information e.g. specialist nurse, ward, or consultant's secretary.

Access to health professionals between formal appointments

After an appointment with a health professional, patients will often think of further questions, which they would like answered before taking a 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). Please ensure you give patients contact numbers for the relevant local healthcare teams for further information or queries.

Open access clinics

Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to a particular treatment. You should ensure that they have the information they need before proceeding with an investigation or treatment. Please ensure that you give patients contact numbers for the relevant local healthcare teams for further information or queries.

8 Who is responsible for seeking consent?

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.

The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, teamwork 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.

Delegation of consent

Where it is not practical for the health professional undertaking the procedure to obtain consent, it can be delegated to a competent individual. Except in exceptional circumstances they should be competent to carry out the procedure. The health professional performing the procedure is responsible for:

- Ensuring that the person delegated to is suitably trained and qualified with regards to the procedure **and** the consent taking process (and that this training is documented). Through this

process the healthcare professional performing the procedure is responsible for identifying individuals who are not capable of performing the procedure but in exceptional circumstances are authorised to obtain consent for that procedure.

- Ensuring that the person delegated to has been assessed as competent to undertake consent for that procedure by the health professional performing the procedure.
- Ensuring that the person delegated to has sufficient knowledge of the proposed investigation or treatment and understands the risks involved.
- Ensuring that the person delegated to is comfortable and confident to obtain consent on the behalf of the health professional performing the procedure.
- Ensuring that the person delegated to is either:
 - present for the procedure; or
 - provides a competent handover of consent to the health professional prior to performing the procedure.

If you are the health professional performing the procedure and you delegate the consent to another individual, you are still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before you start any investigation or treatment.

In circumstances where it is deemed that the individual that has taken consent did not have the authorisation to do so, it is the responsibility of the health professional performing the procedure to report this as an incident using the Trust incident reporting system (Datix). This will then be investigated in line with the Trust's Incident Management Standard Operating Procedure at a level appropriate to the severity of the incident. Should escalation to the GMC be appropriate, this will be mediated through the Medical Director.

Doctors in training taking consent

Foundation trainees taking consent must:

- Have attended a course or session on consent as part of their induction or training as a foundation doctor.
- Have received specific training in taking consent for the particular procedures required by the department.
- Not take consent for an invasive procedure unless observed by the doctor responsible for undertaking the procedure, and been deemed competent to do so.

Note: F1 doctors should not take written consent for any procedure. This does not exclude F1s taking verbal consent for practical procedures that they are themselves undertaking where they have been appropriately trained in both the procedure and the taking of consent.

F1 doctors should only take consent for a procedure that they are not undertaking themselves as part of a structured training opportunity and with direct supervision. This does not exclude F1s taking consent for practical procedures that they are themselves undertaking where they have been appropriately trained in both the procedure and the taking of consent.

The F2 year should be seen as a transitional year. F2 doctors can take consent when the steps detailed above have been completed and the doctor has been deemed competent to undertake the task. There are core competences relating to Valid Consent in the Foundation curriculum¹.

Foundation trainees should not be asked to provide a second signature on Form 4 (Incapacity to Consent Form).

Post foundation (Core and Specialist trainees): Core and specialist trainees must:

¹ The Foundation Curriculum: <http://www.foundationprogramme.nhs.uk/pages/home/training-and-assessment>

- Be encouraged to be involved with the consenting process.
- Have been delegated with the responsibility of taking consent by the senior operator for the procedure.
- Have demonstrated competence to take consent by having completed the tasks and experience in points 1, 2 and 3 for foundation trainees, and be sufficiently familiar with the operative procedure and its potential complications.

Specialty grades should have a clearly defined step by step approach for training in taking consent. This should be performed as a Direct Observation of Procedural Skills (DOPS) whereby the early stages are formative and build incrementally to result in a combined assessment of the entire process.

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

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
- work within their own competence and not to agree to perform tasks which exceed that competence.

If you feel that you are being pressurised to seek consent when you do not feel competent to do so contact, your Clinical Director / Service Line Director, Matron, Head of Service or the Assistant Medical Director for Quality.

9 Completing consent forms

The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. It is good practice for the patient to receive a copy of the consent form.

The standard consent form must include the following information as a minimum:

- Name of proposed procedure or course of treatment (including brief explanation if medical term not clear).
- Special requirements e.g. other language or communication method.
- Name of responsible health professional.
- Statement of health professional obtaining consent confirming necessary knowledge and training to take this consent under the following circumstances:
 - competent to perform the procedure.
 - not competent to perform the procedure but in receipt of appropriate training from a competent health professional to enable them to obtain consent for the procedure; this training must include knowledge of the procedure and knowledge of the consent process.
- What the procedure involves.
- Intended benefits.
- Alternatives.
- Consequences of not going ahead with procedure.
- Serious or frequently occurring risks.

- Material risks
- Any extra procedures that may become necessary.
- Patient information that has been provided.
- The level of sedation e.g. local anaesthetic, general anaesthetic.
- Details of the individual obtaining consent (name, signature, job title and date).
- Contact details (for patient to discuss options at a later date).
- Statement of interpreter if appropriate to include name, signature and date.

The current version of the standard consent forms can be ordered from EPROC.

10 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 (even where this may result in the death of the patient and / or the death of an unborn child), except in circumstances governed by the *Mental Health Act 1983*. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail.

The following paragraphs apply primarily to adults:

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 realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

Any potentially life threatening circumstances or cases that might lead to significant disability must be brought to the attention of the Clinical Director / Service Line Director, Medical Director, Director of Nursing, Director of Clinical Professions or the Legal Services Manager.

Refer to The Hospital Transfusion policy for a brief overview of the treatment of patients who refuse transfusion.

Withdrawing and withholding life-sustaining treatment

A person with capacity may decide either contemporaneously or by a valid and applicable Advance Decision that they have reached a stage where they no longer wish treatment to continue. Except in circumstances governed by the *Mental Health Act 1983*, if an adult with the capacity to make the decision refuses treatment, be it life-sustaining treatment or otherwise, or requests that it be withdrawn, practitioners **must** comply with the person's decision, even if it may result in the person's death. If a refusal is ignored, they will be treating the person unlawfully.

If an adult lacks capacity, and has not made a valid and applicable Advance Decision to refuse life-

sustaining treatment, the provisions of the Mental Capacity Act will apply and the decision must be based on the best interests of the adult, again involving the person as far as this is possible.

If a child with capacity makes such a request or refusal it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child or to severe permanent injury. Moreover, the courts consider that to take a decision which may result in the individual's death requires a very high level of understanding, so that many children or young people who would have the capacity to take other decisions about their medical care may lack the capacity to make such a serious decision.

If a child lacks capacity, it is still good practice to involve the child as far as is possible and appropriate in the decision. The decision to withdraw or withhold life-sustaining treatment must be made in the best interests of the child. A person with parental responsibility for a child or young person is legally entitled to give or withhold consent to treatment. A person with parental responsibility cannot demand a particular treatment to be continued where the burdens of the treatment clearly outweigh the benefits for the child. If agreement cannot be reached between the parent(s) and the healthcare professionals, a court should be asked to make a declaration about whether the provision of life-sustaining treatment would benefit the child.

As with all decisions made under the Mental Capacity Act, before deciding to withdraw or withhold life-sustaining treatment, the healthcare professional must consider the range of treatment options available in order to work out what would be in the person's best interests (see Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007) Policy). All of the factors set out in the Mental Capacity Act (2005) Code of Practice should be considered, and in particular the healthcare professional should consider any statements that the person has previously made about their wishes and feelings about life-sustaining treatment as well as consulting with key family and relevant professionals who can offer an opinion as to what may be in this individual's best interests in all the circumstances. If agreement cannot be reached between healthcare professionals and family members as to what may be in an individual's best interests, the Court should be asked to make this determination in the context of serious medical treatment. Some matters such as the withdrawal of treatment for somebody in either a minimally conscious state or who is in a permanently vegetative state requires the Order of the Court before treatment is withdrawn.

Staff should refer to the Trust's Advance Decision Guidance for further information.

11 Consent for Participation in Research Study

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 as amended by the 2008 Regulations.

Informed consent in the context of a research study is a process of information exchange, which involves the giving of information, the discussion and clarification of the information and in the majority of research studies the taking of the subject's verbal and written consent advising of any material risks involved in the experimental treatment for the patient which are known. Subjects must have given their informed consent prior to participating in any study procedures. The process of obtaining informed consent should be documented in the subject's medical records and a copy of the signed consent form inserted.

Approval for delegation of consent need not be sought from the Assistant Medical Director for Quality, where the task of receiving of written consent is to be delegated by the Chief or Principal

Investigator of a research study to another member of the research team. In line with the PHNT R&D policy and the Trust Research Standard Operating Procedure (SOP), *G6 - Consent procedures for entry into a Research study*, the delegation of the task of receiving consent must be recorded on the studies 'Delegation of Responsibilities Log' and stored in the Study Site File. It is important to remember that the delegation of the task of receiving consent is not a delegation of responsibility. The responsibility of ensuring the consenting process is carried out correctly always remains with the Chief or Principal Investigator of a research study. Therefore it is imperative that the delegated members of the research team are appropriately trained and willing to participate in the consenting process.

Where children lack capacity to consent for themselves, parents may give consent for their child to be entered into a trial where the evidence is that the trial therapy may be at least as beneficial to the patient as the standard therapy. Where there is perhaps no alternative treatment available and the disease is progressive and fatal, it will be reasonable to consider experimental treatment with unknown benefits and (material) risks but without significant risks of increased suffering to the patient, and where there is some chance of benefit to the patient. However in discussing this with relevant relatives, the doctor should ensure that there is a clear understanding of the potential consequences of the recommended experimental treatment, and any alternatives, including providing no treatment at all as an option for example. Decisions about experimental treatment must be made in the child's best interests. Consent should also be obtained from a child who is able to understand, whereby the purpose of the study, the involved risks and benefits should be explained. In addition to providing the information sheet to the parent or legal guardian, an information sheet should be developed for the appropriate age range of the child for his or her easier comprehension.

12 Consent for the use of human tissue and requesting autopsies

The legal position regarding the use of human tissue has been clarified by the Human Tissue Act (2004) which regulates the removal, storage and use of human tissue (including blood and other bodily fluids). Breach of the act is a criminal offence. Full details on the requirements of the Human Tissue Act and the HTA's Codes of Practice are on the website <http://www.hta.gov.uk/>. These should be consulted to ensure full compliance with the legislation

Patient consent is required for the use of tissues removed at surgical procedures for research (with certain exceptions), transplantation or obtaining medical information relevant to another person e.g. genetic information. Consent is not required for the use of tissue from living patients for the following purposes; clinical audit, quality control, public health monitoring, education or training in relation to human health, although it is good practice to inform patients that their tissues may be used for these purposes via patient information literature, and should any patient specify that they do not want their samples to be kept or used for such purposes, these should be respected. These latter uses of tissue are essential to ensure the high quality of service, which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised. It is important that the Department of Cellular and Anatomical Pathology is informed of the patient's wishes in respect to the use of tissues for research in all cases where tissue samples are removed at surgery (using the tick box on the pathology request form) so that this information can be stored on the laboratory computer system, linked to the sample.

The Human Tissue (Quality and Safety for Human Application) Regulations were fully implemented into UK law on 5 July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). The HTA's remit was extended by the Q&S Regulations to include the regulation of: Procurement, testing, Processing, Storage, Distribution and Import / export of tissues and cells for human application.

The removal and use of tissues (including blood) for any purposes after death requires appropriate consent with the exception of autopsies carried out on behalf of the Coroner. Consent should be

obtained by the most senior clinician involved in the care of the patient (who should have training in obtaining consent and have a full understanding of the autopsy procedure), and from the highest ranking qualifying relative. The procedure outlined in Appendix 2 should be followed for obtaining consent. Consent forms and the information leaflet, 'Information for relatives explaining post-mortem examinations' are available from the Bereavement Service, part of Patient Services Department on level 7 (Ext 39743). Please note that paediatric autopsies are not carried out at Derriford, but consent forms for referral of such cases to Oxford are available in the maternity department.

Any research carried out on patients and/or their tissue samples requires approval from the Local Research Ethics Committee and the Research and Development Committee.

13 Consent for disposal of Foetal remains

Disposal of foetal remains should be discussed and consent obtained as per the Foetal Remains Policy.

14 Consent for clinical photography or 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 professionals should 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. The one exception to this principle is set out in paragraph 3 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be identified, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised.

If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed and documented in the patient's records. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of the parents/family/IMCA. You must not make any use of the recording, which might be against the best interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by assessing patients who are able to give or withhold consent

Please refer to the Trust's specific policy and photographic consent form for the taking and use of photographic material or contact the Medical Photography Department for further information (see appendix 3).

15 Training.

Staff are reminded of their responsibilities regarding consent at their induction training and in the statutory & mandatory update training. For any advice relating to consent training please contact the Learning and development team on plh-pr.wodadminteam@nhs.net

Part of the junior doctor induction process includes a session on the consent process. Please contact the Director of Medical Education for more information.

In addition consent is covered within service line or department teaching sessions. Please contact your specific tutor or clinical trainer for further information.

16 Monitoring Compliance and Effectiveness.

Service lines should audit the consent process annually. Recommendations and actions arising from the consent audits will be assigned to an appropriate lead with a specified timescale for delivery. The results of the audits and delivery of arising actions will be reported and monitored within the Service Line and Care Group governance framework and will also be reported to the Audit, Assurance and Effectiveness Team for inclusion in routine reporting to Clinical Effectiveness Group.

17 Overall Responsibility for the Document

Medical Director and Assistant Medical Director for Quality (Vice Chair of Clinical Effectiveness Group).

18 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the Clinical Effectiveness Group and ratified by the Medical Director.

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated author. These must be ratified by the Medical Director and should be reported, retrospectively, to the Clinical Effectiveness Group.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

19 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the named Executive Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

20 References

The Department of Health has issued a number of guidance documents on consent, and these should be consulted for advice on the current law and good practice requirements in seeking consent. Health professionals must also be aware of any guidance on consent issued by their own regulatory bodies.

Reference guide to consent for examination or treatment 2nd edition 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.

General Medical Council (GMC) - Making and using visual and audio recordings of patients.

Institute of Medical Illustrators (IMI) - Consent to Clinical Photography.

Contact Legal Services Manager for the Trust or during out of office hours contact the On-call Duty Manager. If necessary, contact Bevan Brittan through the Legal Services Manager.

The following will be required:-

1. The consultant in charge of treatment will provide, either in a written form or verbally, sufficient details to Bevan Brittan in order that the latter can reach a decision as to whether such an application is necessary and/or will be successful.
2. Statements from:
 - The consultant in charge of treatment.
 - Immediate treating doctors.
 - Any other member of the treating team who may have a valuable input.

These statements should set out the witness's position, qualifications, involvement with the patient, the clinical background, efforts being made to obtain consent to treatment, the patient's views (and the views of the parents if the patient is a child).

If there is no time to produce such statements, then these witnesses may need either to attend court or to provide details on the telephone to the judge.

3. A clinician may need to be available, either in person or on the telephone, to guide the judge as to whether the patient has capacity; this will probably be a psychiatrist or at least somebody who is well versed in ascertaining the capacity of patients.
4. It may be necessary to obtain a second opinion from either within or outside the Trust, in respect of the capacity issue and/or the overall issue as to whether to treat or not.
5. These witnesses will need to provide their contact details in case they are required to attend Court in an emergency.
6. The original medical records must be available for the Court along with copies for the lawyers to review and refer to in Court.
7. Attend Court, either in person, via video link or on the telephone. In some circumstances, in particular if there is a need to appear before a certain judge during the summer recess, attendance in London may be necessary.
8. Once the Court Declaration is obtained, then it will be lawful to proceed or decline to proceed, depending upon what declaration was obtained.

This guidance should be read by anyone seeking to obtain consent for an autopsy at Derriford Hospital. It has been written to ensure compliance with the Human Tissue Act 2004. Under the Act consent is required in order to undertake an autopsy, for the retention and any subsequent use of the tissues retained, including for education, audit and research. Consent must be obtained from someone in the hierarchy of qualifying relationships as defined by the Act (see below).

A consented autopsy should not be requested unless the medical certificate of the cause of death has been issued and that the case does not require referral to the Coroner.

Before approaching the family, the consent seeker should ensure they are familiar with the autopsy consent form and information leaflet for family.

If you are unclear about any aspects of the procedure, please ask a member of the bereavement team or a Pathologist for further advice.

Forms to be completed before an autopsy can occur:

- 1) Medical certificate of the cause of death.
- 2) Autopsy request form.
- 3) Consent for post mortem examination form.

Who should seek consent?

Ideally the most senior clinician involved in the care of the deceased should seek consent. However, other doctors involved in the care of the deceased or healthcare professionals, particularly if they have built up a relationship with the family, may seek consent if the senior doctor is unavailable.

Anyone seeking consent should have a thorough knowledge of the autopsy procedure and have had training in bereavement. Ideally they should have witnessed a post mortem examination. It may be helpful to have a member of the bereavement team present whilst seeking consent.

Obtaining Consent

Consent should be obtained in a quiet and private room, which may be a side room of the main ward or the family meeting room used by the bereavement team on level 7.

When discussing the post mortem examination with the relatives, it is important that the family understand the information provided (if they require a translator or information in another format please contact the general office). They should be given a reasonable amount of time to reach a decision and including an opportunity to change their minds (usually at least 24 hours).

The following basic information must be given to the family prior to obtaining consent, including the following:

- What happens during an autopsy examination, including the removal and examination of organs and tissue samples.
- What is meant by tissue (i.e. organs and parts of organs, from which small samples will be made for examination under a microscope).
- The benefits of the autopsy examination and questions to be addressed in the case.
- Alternatives to the full autopsy examination, making clear the limitations.
- Information about tests that may be needed (e.g. histology and genetic testing) which may cause delays in determining the cause of death.
- Options of what may happen to tissue and organ samples which may be removed from the body after post mortem information.

- Potential benefits of storage of tissue and organ samples such as research and teaching. If the relatives wish the tissue samples to be reunited with the body prior to burial or cremation then some idea of the timing of the burial or cremation should be obtained so that this information can be provided to the pathologist.
- They should be informed that medical students, doctors and other health care professionals may witness the examination for educational purposes and develop their professional skills.

It is normal practice to retain small samples for histological assessment and this should be explained. In some circumstances, retention of a whole organ may be desired in order to allow detailed examination following fixation (e.g. brain or heart). Often discussion with the pathologist in cases of complex neurological or cardiac conditions is helpful prior to meeting with the family so that accurate information about the value of organ retention can be given to the family. If organ retention is likely to be desirable, then the organ(s) to be retained should be listed on the consent form. Brain retention and examination is likely to cause a delay in issuing the final report (it may take 6-8 weeks) and this should be explained to the family.

Families should be given the booklet 'Information for relatives: explaining Post-Mortem Examinations', and time to read it. Any questions resulting from this should be answered.

At the end of the meeting the relatives should be provided with a copy of the autopsy consent form and an indication of when the autopsy is likely to be undertaken. They should be offered the opportunity of meeting to discuss the autopsy findings with the clinicians involved in the deceased patient's care.

From whom should consent be obtained?

In line with the Human Tissue Act 2004, consent should be obtained from the following in this order:

- 1) The deceased - where an adult has while alive given valid consent for a post mortem examination to take place after death then this consent is sufficient.
- 2) If the deceased adult nominated a representative during life to provide consent then this person is the appropriate person.
- 3) If the deceased has not indicated their consent (or refusal) to post mortem examination, or appointed a nominated representative, then the appropriate consent should be obtained by somebody in the qualifying relationship with the deceased.

Those in a qualifying relationship are ranked in the following order:

- Spouse or partner (including civil or same sex partner)
- Parent or child (in this context, child may be of any age)
- Brother or sister
- Grandparent or grandchild
- Niece or nephew
- Stepfather or stepmother
- Half brother or half sister
- Friend of longstanding

Consent is needed from only one person in the hierarchy of relationships and should be obtained from the person ranked highest. If the highest ranked person is not available then consent should be obtained from the next person down. In situations where relationships are listed together, it is sufficient to obtain consent from just one person. However, the person giving consent should be encouraged to discuss the decision with other family members.

This sets out a procedure for obtaining consent to visual recording by all health care professionals in Plymouth Hospitals (NHS) Trust. For the purposes of simplicity, Plymouth Hospitals (NHS) Trust will hereafter be referred to as PHNT and visual recording defined as conventional photography, video recording, digital recording, or an illustration in any other form of pictorial representation. This policy applies to visual recordings in which any person appears, whether patients, staff, visitors or any other person having business with PHNT, with the exception of images recorded by security CCTV.

Aim

- a) treat those appearing in a visual recording with consideration and respect in honouring their wishes, opinions and rights whether socially, morally or in law.
- b) make clear the uses to which a visual recording may be applied in order to avoid misunderstanding.
- c) protect PHNT from the possibility of litigation or adverse publicity.

Application

The Medical Photography Department will classify consent into 3 levels –

Medical Records (no consent required)

Medical Record and / or Education in a clinical setting (i.e. educating any NHS staff including students where the patient cannot be recognised but only where the policy is well publicised)

Teaching or Lecturing (written consent required)

Teaching NHS Staff or the general public on where the patient may be recorded

Publication (Written consent required)

Publication (e.g. textbooks, journals, broadcast, internet, poster for scientific meeting, public display/exhibition)

- a) Applies to any situation where a person appears in any visual recording made by a PHNT health care professional.
- b) Applies to all visual recordings whatever the intended use, for example;
 - i) medical case notes
 - ii) teaching of all health care professionals
 - iii) public health care information by any health care staff
 - iv) medico-legal
 - v) publication e.g. textbooks, journals, general publications and all forms of electronic publication, including the internet.
 - vi) broadcasting

N.B. This list may not be comprehensive.
- c) Minors: If a child is under 16 years of age a parent / guardian must sign the form. If the child is judged to be Gillick competent then they should be allowed to sign the form.
- d) Situations where the normal consent procedure cannot be followed when making a visual recording of a patient.
 - i) Where the patient is temporarily incapacitated e.g. Operating theatre, A&E, ICU. Consent should be obtained as soon as the patient is capable. Visual recordings requiring level two or level three consent will not be released from the Medical Photography Department without written consent.
 - ii) Where the patient does not have capacity to make the decision for themselves the requesting person should sign the consent form with a short explanation as to why the form is incomplete. In such a situation visual recordings will only be made at level One where consent is not required.
 - iii) Stillbirth – to avoid undue stress to parents we advise the midwives to obtain consent verbally at their discretion.

- iv) Post Mortem consent includes making visual recordings for notes, research and teaching. Publication requires additional consent from the next of kin, should the visual recording be identifiable.
- v) Where parental consent is refused for the visual recording of a minor e.g. NAI. This decision can be overridden in the best interests of the child. An incomplete consent form will be accepted with a consultant signature and should include a short explanation for lack of parental consent. Visual recordings will only be made for the patient record.
- e) The subject of a visual recording may withdraw their consent in writing at any time. However where a visual recording is made by PHNT and used by the media, then PHNT although owners of the visual recording are not bound or necessarily able to accept withdrawal of consent once a recording has been released to the media.
Visual recordings made by organisations independent of PHNT must obtain their own agreement for which PHNT will not be responsible.

Consent Procedure

- 1) It is **not** the responsibility of the Medical Photographer to obtain consent.
It is the responsibility of the person requesting a visual recording to explain why it is required and at the same time obtain a fully completed consent form from each of those who will appear in the visual recording. Those required to appear in the visual recording must be:-
 - a) Given a comprehensive explanation of the purpose of the visual recording, e.g. for case notes, teaching or publication.
 - b) Clearly informed that they may be identifiable in the visual recording even in a non-facial image if it includes a distinctive topographical features.
 - c) Encouraged to feel at ease about declining to be photographed without feeling unhelpful or that refusal may give rise to an awkward situation. People have a right to refuse for whatever reason without prejudice to their treatment.
 - d) Given the opportunity to ask questions.
- 2) Consent must be obtained prior to a visual recording being made. If a completed consent form is not presented to the Medical Photography Department they will not be able to carry out the request. (For exceptions see Section d in the Application section above).
- 3) A new consent form must be completed for each occasion that visual recordings are made.
- 4) If a different use for the visual recording is required to that for which agreement was originally sought then under The Data Protection Act 1998, a new consent form must be completed.
- 5) Visual recording & Consent Forms are available on Staffnet under HRSG Documents (see link below) - these must not be photocopied.
- 6) The Visual Recording Request & Consent Form contains a section for details to be given of the person responsible for making the recording and where those images are stored. The copy of the form should be placed in the patient's notes along with the photographs.

Please note, that all requests for Medical Photography must be on a Trust revised 'visual recording request and consent form' which can be downloaded/printed from staffnet.

<http://staffnet.plymouth.nhs.uk/Portals/1/Documents/HRSG%20documents/Medical%20Photography/0120-5,%20Imaging,%202016,%20Medical%20Photography%20Consent%20Form.pdf?timestamp=1469191472565>

This document forms part of the patients' clinical records and should not be photocopied in any way. Any photocopied or incomplete forms will not be actioned and may result in a DATIX form being submitted.

Additional information relating to Medical Photography can be obtained through the "Consent to Medical Photography" information leaflet and "The Department of Medical Photography" information for patients booklet.

http://staffnet.plymouth.nhs.uk/Portals/1/Documents/HRSG%20documents/Medical%20Photography/Medphoto-patientinformation_2016v1.pdf?timestamp=1469191698253

<http://staffnet.plymouth.nhs.uk/Portals/1/Documents/HRSG%20documents/Medical%20Photography/consent%20leaflet.pdf?timestamp=1469191747177>

All relevant documentation is also available to order through the print room which is now based at Bush Park, contact number 31272 or via e-mail plh-tr.PrintRoom@nhs.net. It would be advisable to order a supply of these to be used in conjunction with the 'visual recording request and consent form'.

Relevant Legislation

- Data Protection Act 1998
- Video Recordings Act 1984
- Children Act 1989
- Copyright Act 1988

Montgomery v Lanarkshire Health Board: The Impact on the Law of Consent

On 11 March 2015, the Supreme Court handed down a unanimous judgement on appeal from the Scottish Courts in *Montgomery v Lanarkshire Health Board (2015) UKSC 11*. This is a binding decision on the law of consent for England and Wales as well as Scotland, and has potential ramifications for all clinicians and health bodies.

In the context of a diabetic patient of small stature expecting a large baby in January 1999, who had expressed concern about her ability to deliver vaginally, it was held that the duty to warn about risks would no longer be governed by a doctor sensitive test (i.e. what a responsible body of medical opinion would conclude are the risks that should be disclosed to a patient) [Bolam v Friem Hospital Management Committee, 1957, or Sidaway v Board of Governors of Bethlem Royal Hospital, 1985] as this no longer reflects a modern doctor-patient relationship, and a shift towards self-determination and autonomy.

The New Test: Material Risk

The new test is patient-sensitive and is based upon materiality of risk:

- A doctor is under a legal duty to take reasonable care to ensure that the patient is aware of any material risk involved in the recommended treatment, and of any reasonable alternative or variant treatments.

Limited Exceptions:

- I. A doctor is entitled to withhold information if he or she reasonably considers that its disclosure would be seriously detrimental to the patient's health;
- II. A doctor is also excused from conferring with the patient in situations of necessity: where emergency treatment is required for a patient who is unconscious for example.

It is of note that if subsequently challenged, a doctor would need to be able to justify that his or her application of those exemptions was reasonable in all the circumstances.

The Montgomery test of material risk asks, whether, in the circumstances of the individual case, either:

- 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.

Additional

- Members of the medical profession have a duty of care to advise and inform patients of anything which the ordinary sensible patient would be justifiably aggrieved not to have been told when fully appraised of its significance.
- Medical practitioners do not need to warn of risks which are theoretical and are not material. A patient cannot simply rely on Montgomery to state that they have an absolute right to know all risks, and in particular where actions suggest that the risk would not in fact, have been material to them.
- How the patient has communicated with clinicians and decisions taken during treatment are also relevant.

Compliance and Impact

To ensure compliance with the new Montgomery test for consent, a doctor will need to:

- Engage in a dialogue with the patient about: (i) the nature of the risks, (ii) the effect which the occurrence of the risk would have on the particular patient, (iii) the importance to the patient of the benefits of the proposed treatment, (iv) any alternatives or variants available and the risks versus benefits involved in those alternatives.
- It is imperative to ensure good contemporaneous record keeping of the discussions and issues of risk discussed with the individual patient.
- The evidential value of pro forma consent forms and information leaflets will be limited unless accompanied by a discussion with the patient to discuss these issues, and this is then documented.
- It is possible that a different outcome could be achieved by applying the Montgomery test to two different patients undergoing the same treatment, and therefore it is imperative that an appropriate discussion is undertaken and documented.

Bevan Brittan LLP

Core Information

Document Title	Consent to Examination or Treatment
Date Finalised	November 2016
Dissemination Lead	Clinical Effectiveness Group

Previous Documents

Previous document in use?	Consent Policy
Action to retrieve old copies.	Document controller

Dissemination Plan

Recipient(s)	When	How	Responsibility	Progress update
All staff	10 th September 2012	Email	Document Control	
All staff	14 th September 2012	Vital Signs	Patient Safety & Effectiveness Manager	
All staff	14 th September 2012	Email	Assistant Medical Director	
Key Stakeholder/ Consultation	24 th August 2016	Email	Assistant Medical Director	
All staff	By December 2016	Email	Assistant Medical Director	

Review		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Yes
	Does the document identify which Executive Director will ratify it?	Yes
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes
	Is there a plan to review or audit compliance with the document?	Yes
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Core Information

Manager	Clinical effectiveness group
Directorate	Trustwide
Date	24/08/2016
Title	Clinical Effectiveness group
What are the aims, objectives & projected outcomes?	<p>To provide staff with standards and procedures to ensure they are able to comply with the guidance when seeking and receiving consent</p> <p>Ensure staff seek valid consent to treatment, enabling patients to be in control of the decision taken for treatment and are fully informed</p> <p>All patients have completed a fully considered consent form before examination or treatment</p>

Scope of the assessment

The Equality Impact Assessment (EIA) has been undertaken ensure that the publication of this policy is compliant with the Equalities Act 2010.

Collecting data

Race	This is mitigated as the policy can be made available in alternative languages.
Religion	The document has no impact in this area.
Disability	This is mitigated as the policy can be made available in alternative formats.
Sex	The document has no impact in this area.
Gender Identity	The document has no impact in this area.
Sexual Orientation	The document has no impact in this area.
Age	The document has no impact in this area.
Socio-Economic	The document has no impact in this area.
Human Rights	The document has no impact in this area.
What are the overall trends/patterns in the above data?	There are no trends/patterns in this data. External consideration has been given t 2011/12 NHS Litigation Authority Risk Management Standards for NHS Trusts.
Specific issues and data gaps that may need to be addressed through consultation or further research	Trust wide documents can be made available in a number of different formats and languages if requested. No further research is required as there are no further equality issues.

Involving and consulting stakeholders

Internal involvement and consultation	Clinical Governance Leads, Clinical Directors / Service Line Directors inclusive of a Patient representative.
--	---

External involvement and consultation				
Impact Assessment				
Overall assessment and analysis of the evidence	<p>This assessment has shown that there could be an impact on race or disability groups. However, this document can be made available in other formats and languages if requested.</p> <p>The document does not have the potential to cause unlawful discrimination. The document does not have the any negative impact.</p>			
Action Plan				
Action	Owner	Risks	Completion Date	Progress update
Provide document in alternative formats and languages if requested.			Ongoing	The action will be addressed as and when the need occurs.