University Hospitals of Leicester NHS
NHS Trust

Consent to Examination or Treatment UHL Policy (Includes consent for Photography)

Approved By:	POLICY & GUIDELINE COMMITTEE
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Trust Lead	Dr Colette Marshall – Deputy Medical Director UHL Consent Committee
Executive Lead	Medical Director
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Changes from V12	Incorporation of Digital consent Incorporation of current GMC guidance (Decision making and consent 2020) Updating contact details/telephone extension Gender neutral pronouns Miscellaneous minor and grammatical changes

CONTENTS:

1.0 BACKGROUND

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

1.2 Any treatment or investigation (and this can extend, in the extreme, to mere touching) carried out without consent may give rise to accusations of battery and/or negligence. This may result in an action for damages, or even criminal proceedings, and a finding of misconduct by the relevant professionalbody.

1.3 For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question. The informed person may either be the patient, someone with parental responsibility or a person who has authority under a Lasting Power of Attorney for Health and Welfare (see Advance Decisions and Lasting Powers of Attorney Policy – Trust Ref B20/2004 for further details).

1.4 Consent will not be legally valid if the patient has not been given adequate information or where they are under the undue influence of another. Acquiescence (agreement without understanding) is not "consent". Where there are doubts about a patient's capacity – refer to the Trust's Mental Capacity Act Policy. (MCA Policy - Trust Ref. B23/2007).

1.5 Since the case of *Montgomery v Lanarkshire Health Board* in 2015 a lawful consent process is no longer to be viewed from the perspective of the healthcare professional but is to be regarded as a Human Right of the patient.

2.0 SCOPE OF THIS POLICY

2.1 This Policy applies to all staff seeking consent to examination or treatment.

2.2 This policy sets out the standards and procedures in the University Hospitals of Leicester NHS Trust which aim to ensure that staff are able to comply with guidance issued by the Department of Health so far as it remains good practice to do so.

2.3 This Policy forms part of a suite of policies relating to Consent, including Delegated Consent Policy (Trust Ref. B10/2013) and the Mental Capacity Act Policy (Trust Ref. B23/2007).

3.0 DEFINITIONS

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

3.2 **'Material Risk'** means a risk which, in the circumstances of the case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

4.0 ROLES & RESPONSIBILITIES

4.1 The Medical Director shall have executive lead for this Policy and shall bring to the attention of the Trust Board any relevant matters relating to thisPolicy.

4.2 The CMG Directors shall have operational responsibility for this Policy and shall ensure that it is complied with within their CMG.

4.3 CMG Directors shall ensure that staff in their CMG's follow this Policy and that all staff within their CMG are appropriately trained, including the maintenance of appropriate records relating to training in consent CMG Directors will be responsible for ensuring appropriate action is taken as indicated by the audit results and appropriate action plans developed.

4.4 Each Head of Service, will be responsible for ensuring audits are carried out within their Service as required by the Consent Committee and for feeding back the results to the relevant clinical teams and managers.

4.5 Consultants shall have authority to delegate the taking of consent to a Health Care Professional who is capable of performing the procedure, or a clinician that is not capable of performing the procedure but has received appropriate training in delegated consent. The exception to this is general anaesthesia where information is given as part of the consenting process within the anaesthetic review.

4.6 Health Professionals carrying out the procedure are responsible for ensuring that the patient is genuinely consenting to what is being done and relevant process is followed.

5.0 POLICY PROCEDURES

5.1 VALID CONSENT

a) For the consent to be valid, the patient must:

- Be competent to take the particular decision;
- Have received sufficient information to take it; and
- Not be acting under duress

b) It must be noted that patients with learning disabilities and/or mental disorders are not sufficient grounds to determine that the patient is not competent to consent. A patient may be incompetent for some decisions but competent for others. Where doubt exists concerning the person's mental capacity to make

the decision then refer to the UHL MCA Policy.

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

d) Where an adult patient lacks capacity to give his or her consent to treatment, no one can give consent for that person unless they have authority under a Lasting Power of Attorney for Health and Welfare or have been authorised to make treatment decisions as a deputy appointed by the Court. In the absence of such a person then treatment may be given to a patient if it is in their best interests, as long as it has not been refused in a valid and applicable Advanced Decision to Refuse Treatment (ADRT).

Refer to the UHL Advance Decisions and Lasting Powers of Attorney Policy (Trust Ref B20/2004) and the MCA Policy (Trust Ref B23/2007) for further information.

e) For advice about Advance Decisions and Lasting Powers of Attorney please contact UHL Legal Services on ext. 27079.

5.2 THE CONSENTING PROCESS

a) When a patient formally gives their consent to a particular intervention, this is only the endpoint of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'.

b) 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.

c) Patients should be advised that they may have another person of their choosing present when receiving information about a diagnosis or procedure.

5.3 Is the Consent Given Voluntarily?

a) To be valid consent must be given voluntarily and freely, without pressure or undue influence being exerted on the patient either to accept or refuse treatment. Such pressure can come from partners or family members as well as health or care professionals. Professionals should be alert to this possibility, and where appropriate should arrange to see the patient on their own to establish that the decision is truly that of the patient.

When patients are seen and treated in environments where involuntary detention may be an issue, such as prisons and mental health hospitals, or treated in the Trust whilst under arrest, there is a potential for treatment offers to be perceived coercively, whether or not this is the case. Coercion invalidates consent and care must be taken to ensure that the patient makes a decision freely. Coercion should be distinguished from providing the patient with appropriate reassurances concerning their treatment, or pointing out the potential benefits of treatment for the patients' health. However, threats such as withdrawal of any privileges or loss or remission of sentence for refusing consent, or using such matters to induce the patient to give consent are not acceptable. Consent that has been obtained by fraud will not be valid.

5.4 Single Stage Process

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

b) If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

5.5 Two or More Stage Process

a) In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

b) It is incumbent on the practitioner carrying out the procedure to assure

themselves that valid consent has been obtained and where one is required to check the consent form prior to commencement of the treatment. The consent form (whether it is a paper form or digital form) must be checked against the operating list by the practitioner carrying out the procedure as part of the "Sign In" part of the Five Steps to Safer Surgery. This is to ensure that there are no discrepancies between the published list and the intended procedure.

c) Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure, and should have received a copy (which may be digital) of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish the treatment to go ahead, at any appropriate point before the procedure: in out-patients, at home (if a digital consent form is being used), at a pre-admission clinic, or when they arrive for treatment.

d) 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 reconfirmation of consent should be performed when the patient has signed the form more than 24 hours before the procedure and is particularly important where there has been a significant lapse of time between the form being signed and the procedure.

e) 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?"

f) While administrative arrangements will vary, it should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse or change their mind. It will rarely be appropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment (for example, by changing into a hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

5.6 PATIENT COMMUNICATION

a) The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need clear information in a format that they can understand. This includes information about:

- their condition
- possible treatments/investigations
- risks and benefits of proposed and any alternative treatments
- risks and benefits of no treatment
- the extent to which the treatment they are being offered is new innovative or experimental

b) In the case of *Montgomery v Lanarkshire Health Board (2015)* the court gave legal sanction to the approach of the GMC in Good Medical Practice and the Department of Health in "Consent: patients and doctors making decisions together". Thus, what in the view of the GMC amounted to good medical practice has now become necessary medical practice. The case reiterated that a signed consent form, by itself, does not constitute a lawful consent process.

c) Following *Montgomery* it is clear that the discharge of a doctor's duty in providing information to and taking consent from patients is not to be judged by reference to the Bolam test.

d) In the case of Montgomery it was made clear that in order to obtain informed consent it is important to ensure compliance with the following: -

- A doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any proposed treatment, and of any reasonable alternative treatments.

- A risk is material if, in the circumstances of the case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

- The assessment of whether or not a risk is material cannot be reduced to percentages: the significance of a risk will be affected by many patient-specific factors.

- The doctor's advisory role involves dialogue.

- A doctor can withhold from the patient information about a risk if they reasonably consider that its disclosure would be seriously detrimental to the patient's health. This "therapeutic exception" must not be abused.

- A doctor need not confer with the patient in circumstances of necessity- such as where the patient needs urgent treatment, but is unconscious or otherwise unable to make a decision.

e) The patient must also be informed about any additional procedures which are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Refer to the UHL Procedure for Obtaining Informed written Consent for Blood Transfusion which is part of the Policy and Procedures for the Prescribing, Collection, Storage and Administration of Blood and Blood Components (Trust Ref B16/2003).

f) Any misrepresentation of these elements will invalidate consent. Where anaesthesia or sedation is, or is likely to be used, then information about anaesthesia/sedation should be given as well as information about the procedure itself.

g) Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where to go, how long they

will be in hospital, how they will feel afterwards and so on.

h) It is essential that patients are always given sufficient time to ask questions about what they are told, to seek further clarification, and to ask for more information.

i) It is expected that written information will be given or offered to patients well in advance of any planned procedure, this could be when attending a pre-assessment clinic, or sent with an appointment letter.

j) Patients should be encouraged to ask questions during the process of consent giving, and clinicians should use open questions to check understanding.

k) There will always be an element of clinical judgment in determining what information should be given. However, the *presumption* must be that the patient wishes to be well informed about the material risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

l) A patient will not be deemed to lack capacity merely because they have a limited ability to communicate. Care should be taken not to underestimate the ability of a patient to communicate, whatever their condition. In some cases, it may be because English is not the patient's first language. Health professionals should take all steps which are reasonable in the circumstances to facilitate communication with the patient, using interpreters or communication aids as appropriate and ensuring that the patient feels at ease. In particular careful consideration should be given to the way in which information is explained or presented to the patient. Refer to Interpreting and Translation Policy (Trust Ref B30/2015)

m) Staff should consider using an EasyRead version of written information where a patient has a communication need or might benefit from this.

n) Where appropriate, those who know the patient well, including their family, carers and staff from professional or voluntary support services, may be able to advise on the best ways to communicate with the person.

o) Where sign language is considered to be the most appropriate method of communication, arrangements should be made for a qualified British Sign Language (BSL) interpreter to be present. Family members should not be used to interpret. By using the services of a qualified BSL interpreter, health professionals will be more reassured that the patient has fully understood the procedures, potential risks and alternatives involved when giving their consent. It also ensures that the patient's wishes are properly communicated and removes the risk of undue influence by family or friends. If necessary, the UHL Equality Manager can be contacted for advice. Refer to Interpreting and Translation Policy (Trust Ref B30/2015)

5.7 Patient Information

a) Each patient information leaflet will be available on the Trust's website within the YourHealth online store (https://yourhealth.leicestershospitals.nhs.uk/). Service areas

are responsible for creating, updating and removing their leaflets in line with UHL policy for patient information. Each patient information leaflet has a unique identifier and this must be added to the patient's consent form. Please refer to Patient Information UHL Policy (Trust Ref. B18/2002) on the development of Information for patients, carers and the public

b) Advice on Patient Information leaflets can be sought from the Patient Information Librarian.

c) The Trust produces a number of printed information leaflets, which are to be made available to patients at specific points in their care, as an integral part of the consent process. All information produced by the Trust can be made available in Braille, large print or EasyRead formats on request. The Trust is also able to supply information in alternative languages if necessary and has a number of translated leaflets available to patients. For information on how to access translation and interpreting services and on local policies and guidance contact the Service Equality Manager (See Appendix C).

d) In this context, the use of patient information leaflets is considered to be an example of best practice. Additionally, a number of areas are developing other media to support the consent process e.g. videos which should be included wherever possible as part of the process to support delivery of patient information.

e) The obtaining of consent is a process, which involves effective communication and dialogue between the professional and the patient, and merely providing a patient with an information leaflet will not meet the practitioner's obligations. A patient's consent may be obtained remotely using a digital consent system or by post, and this gives the patient time to read and reflect on the consent form and information provided. However, any person carrying out a procedure on a patient must ensure that, immediately before the procedure, the patient has understood the information and that they still give their consent. If the patient has queries or concerns, he or she must be given time to consider any additional information.

f) Although informing patients of the nature and purpose of procedures may be sufficient for the purposes of giving valid consent as far as any claim of battery is concerned, this is **not** sufficient to fulfil the legal duty of care to the patient. Failure to provide other relevant information may render the professional liable to an action for negligence if a patient subsequently suffers harm as a result of the treatment received.

g) It is open to the courts to decide that information about a particular risk was so obviously necessary that it would be negligent not to provide it, even if a "responsible body" of medical opinion would not have done so (please refer to Section 5.16 Documentation).

h) It is now clear that the courts will be the final arbiter of what constitutes responsible practice, although the standards set by the health professions for

their members will still be influential.

i) It is now established that a health professional can be liable even in cases where it cannot be proved on the balance of probabilities that their negligence caused harm to the patient.

j) This decision has serious implications for health professionals. Failure to take adequate consent now over-rides any argument that such failure did not cause the adverse outcome, provided that the warning ought to have been given, and the condition or consequence which ought to have been mentioned actually develops.

k) The General Medical Council gives guidance on the type of information that patients may need to know before making a decision and has stated that doctors should do their best to find out about patients' *individual* needs and priorities when providing information about treatment options. The guidance also emphasises that if the patient asks specific questions about the procedure and associated risks these should be answered truthfully. In addition, if patients make clear they have particular concerns about certain kinds of risk, doctors should make sure they are informed about these risks, even if they are very small or rare.

l) When giving patients advice about proposed treatment, health professionals should:

- Inform the person about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about:
    - Risks of harm that you believe anyone in the patient's position would want to know
    - Risks of harm and potential benefits that the patient would consider significant for any reason
    - Any risk of serious harm, however unlikely it is to occur

- Ensure that warnings are <u>properly recorded in the notes;</u> (see below under Documentation).

- Invite the patient to sign the relevant form to confirm that he/she has been given the warning, has understood it, and accepts the risk.

- Make a full entry in the notes, preferably signed by the patient, if treatment is refused, including the reason when given.

- Use a pre-printed consent sticker or a digital consent system to ensure uniformity of basic information given but with any individual risks recorded in addition.

- Make use of other media to deliver information such as videos which may support the consenting process.

- Make a note on the consent form of the unique identifier and version number of the patient information leaflet given to the patient (or use the digital consent system and the associated links to patient information leaflets on YourHealth).

5.8 ACCESS TO HEALTH PROFESSIONALS BETWEEN FORMAL APPOINTMENTS

a) After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they take their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice)

b) Appropriate contact details should appear on patient information leaflets.

5.9 OPEN ACCESS CLINICS

a) Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment.

b) Health professionals examining the patient or delivering treatment should ensure that the patient has the information they need before proceeding with an investigation or treatment.

5.10 WITHHOLDING INFORMATION

a) Some patients may wish to know very little about the treatment which is being proposed and may ask that the health professional or other person should make decisions on their behalf. In such circumstances, the health professional should explain the importance of knowing about the treatment and try to encourage the patient to make the decisions for him or herself. However, if the patient still declines any information offered, it is essential to record this fact in the notes, and to ask the patient to sign the record to confirm their decision. It is possible that patients' wishes may change over time, and it is important to provide opportunities for them to express this.

b) The General Medical Council guidance 'Decision making and consent' (2020 London) requires doctors to give patients the information they want or need to make a decision.

c) In the very rare event that the healthcare professional believes that to follow the guidance in paragraphs above in full will cause the patient serious harm, the GMC guidance states that this view, and the reasons for it, should be recorded in the patient's notes. In this context "serious harm" means more than that the patient might become upset, decide to refuse treatment, or choose an

alternative.

d) When such concerns arise, it is advisable to discuss the issue within the team caring for the patient and consider taking legal advice. In individual cases the courts may accept such a justification but would examine it with great care.

e) In short, a doctor can withhold from the patient information about a risk if they reasonably consider that its disclosure would be seriously detrimental to the patient's health. This "therapeutic exception" must not be abused.

5.11 ADDITIONAL PROCEDURES

a) During a procedure where the patient is under anaesthetic, it may become evident that the patient could benefit from an additional procedure. Health professionals should, so far as possible, try to anticipate additional procedures that may be necessary if certain circumstances arise and discuss these possibilities with the patient. They should consider the patient's views and that the patient may need time to think or discuss with family or friends. The views of the patient should be noted on the consent form.

b) If a patient expresses that they do not want a particular procedure to be carried out (for example that a mastectomy should not be carried out after a frozen section biopsy result) then their wishes must be respected.

c) However, if it is apparent that a procedure that has not been anticipated is necessary, and was not within the scope of the consent given by the patient but it would be unreasonable to delay the procedure until the patient regains consciousness (particularly if the procedure is to save the patient's life or prevent serious harm), it may be justified to perform the procedure on the grounds that it is in the patient's best interests.

d) The Health Professional should do no more than is reasonably required, in the best interests of the patient in accordance with the requirements of the Mental Capacity Act 2005 before he or she recoversconsciousness.

e) The patient should be informed if any additional procedure has been necessary as soon as he or she recovers consciousness.

f) A major procedure such as a hysterectomy should never be performed during an operation without explicit consent, unless it is necessary to save life.

5.12 EMERGENCIES

a) 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 itsquality.

b) When a patient presents unconscious because of injury or illness, then in the absence of a valid and applicable Advance Decision, or instructions from a validly appointed Attorney or Deputy, a clinician may undertake whatever treatment is necessary to ensure the patient's life or health, without waiting to obtain consent. A detailed record should be made in the patient's clinical records to explain the absence of formal consent.

c) It is good practice to involve relatives or other carers in decision making, but, in an emergency the desirability of this should not delay the clinician taking such actions as the best interests of the patient demand.

d) It is, however, important that the clinician confine himself to only providing essential treatment.

5.13 SEEKING CONSENT FOR ANAESTHESIA

a) Where an anaesthetist is involved in a patient's care, it is their responsibility to ensure that informed consent has been obtained for anaesthesia.

b) Information about anaesthesia, its benefits and any associated risks should be provided to patients as early as possible, this can be in the form of an evidence based online resource or leaflet that that patient can keep for future reference. Those undergoing elective surgery should be provided with information before admission, preferably at pre-assessment or at the time of booking, and should have the opportunity to discuss anaesthesia prior to admission.

c) If it is anticipated that there may be a higher risk associated with anaesthesia in a particular patient, a referral to the anaesthetic assessment clinic should be considered prior to the planned procedure.

d) Anaesthetists should document the elements of the discussion in the patient record, particularly the risks, benefits and alternatives (including no treatment) that were explained, as well as any questions that were asked by thepatient.

e) Anaesthetic procedures that are done to facilitate another treatment do not require a separate consent form.

f) 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.

g) In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility.

5.14 SEEKING CONSENT FOR INTERVENTIONAL RADIOLOGY

a) Where a patient requires an interventional radiology procedure, it is ultimately

the responsibility of the person undertaking the interventional radiological procedure to ensure that the patient has received enough time and appropriate information to be able to make an informed decision and has given their consent before anyinvestigation or procedure is started.

b) As it is not acceptable for the patient to receive no information about the interventional radiology procedure until their attendance in the department on the day of the procedure (at such a late stage the patient would not be in a position genuinely to make a decision about whether or not to undergo the procedure) and in order to start the consent process, patients should be provided with a patient information leaflet about the intended interventional radiology procedure at the time that the decision is made to refer the patient for the interventional procedure by the referring clinician.

c) This leaflet should outline what the procedure entails, the risks specific to the procedure and also the risk of sedation. However, it is the responsibility of the referring clinician to ensure that they have discussed with the patient the reasons for requesting the interventional procedure, the potential benefits and the alternatives to the interventional radiology procedure.

d) It is also permissible to delegate consent for interventional radiological procedures to named individuals who have received procedure specific consent training provided the delegation process fully complies with the Trust's Policy for Delegated Consent (Trust Ref B10/2013). However, it should be noted that as with all consent, the fundamental principle that ultimately the responsibility for ensuring that the patient has received enough time and appropriate information to be able to make an informed decision and has given their consent before any investigation or procedure is started remains with the person undertaking the interventional radiological procedure.

5.15 REFUSAL OF TREATMENT

a) **All competent adults** have the right to refuse treatment for physical illness even if refusal is not considered to be in the best interests of the patient or to be unwise.

b) If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the *Mental Health Act* 1983. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail.

c) **The following paragraphs apply primarily to adults**.

i) If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, the clinician (and where possible the patient) should note this on the form. If the patient has completed a digital consent form, this should be marked as "Revoked" on the Concentric digital consent application.

ii) Where a patient has refused a particular intervention, the clinician must ensure that the patient is provided with any other appropriate care to which they have consented.

iii) The clinician 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.

iv) If a patient consents to a particular procedure but refuses certain aspects of the intervention, the clinician must explain to the patient the possible consequences of their partial refusal. If the clinician believes that the procedure cannot be safely carried out under the patient's stipulated conditions, the clinician is not obliged to perform it.

v) The Clinician 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, the clinician must on request be prepared to transfer the patient's care to that Health Professional.

d) **Children under the age of 18** are unable to refuse to have life-saving treatment. In cases of dispute between parents, child and health care professional urgent legal guidance should be sought. See Section 5.24 for further detail.

5.16 DOCUMENTATION

a) Documenting 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 through documenting in the patient's notes that they have given oral consent.

b) Written Consent

i) 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.

Written consent shall be obtained in the following circumstances:-

- The treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications').

- The procedure involves general/regional anaesthesia or sedation.
- Providing clinical care is not the primary purpose of the procedure (e.g. for clinical photography).
- 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.
- Treatment involving fertility (i.e. gametes)

ii) For forms 1 to 3 the original signed completed consent form (the white copy) must be kept with the patient's notes. Any changes to a form, made after the form has been signed by the patient, must be initialled and dated by both patient and health professional. The patient must be offered the copy of the consent form (the yellow copy) together with the supporting patient information.

iii) 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.

iv) Where an adult patient does not have mental capacity to give or withhold consent to a significant intervention this fact should be documented on Consent Form 4. If the patient or court has appointed an attorney to make the decision, Consent Form 4 should also be used and this should be documented (in Section F of the paper Consent Form 4 or in the appropriate section of the digital Consent Form 4).

v) If it is necessary to use Form 4 then the clinician should note both the assessment of the patient's capacity and why the clinician believes the treatment to be in the patient's best interests together with details of discussions with people close to the patient.

vi) The standard Consent Form 1 or 3 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.

vii) 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.

c) Availability of Forms

i) Standard consent forms and forms for adults who are unable to consent for themselves are reproduced in Appendix B.

ii) There are three versions of the standard consent form:

- Consent Form 1 for adults or competent children and, where appropriate, their proxies,
- Consent Form 2 for parental consent for a child or young person
- Consent 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.

Iii) The use of Consent Form 3 is optional but may be thought more appropriate than Consent 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.

iv) For patients who lack consent and clinicians are providing treatment in the patient's best interests, Consent Form 4 must be used where required.

d) Completing Consent Forms

i) The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or they satisfy the requirements for the policy for delegated consent.

ii) If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered.

iii) 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 in order to confirm consent, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves.

e) Digital Consent Forms

i) Digital Consent Forms are being introduced throughout the trust, and it is envisaged that over time, digital consent will completely replace the use of paper based forms.

ii) The current supplier of Digital Consent to the trust is Concentric Health, although in the future this may change. This guidance applies to any digital

consent solution that has been procured by the trust.

iii) Digital Consent forms may be used in any situation where a paper consent form 1, 2, 3 or 4 is appropriate. Depending on the patient's age and mental capacity assessment, the correct form will automatically be used.

iv) The Digital Consent site can be accessed directly by a web browser on a desktop computer, laptop, tablet device or smartphone at https://app.concentric.health/. It will also be possible to access the Digital Consent site via a patient specific link in Nervecentre.

v) Digital consent forms can be completed on the day of the procedure, but completing them in advance of the procedure is preferred (see section 5.5 above). When completing a digital consent form in advance, this may be done during a consultation, in the presence of the patient (either in person or virtually with a video consultation), in which case the patient may wish to digitally sign the consent form at this point, or the consent form can be sent to the patient via a link to an email address or text message for the patient to read and think about before signing the form at their convenience. Alternatively, a link to the consent form can be sent to the patient after a clinic consultation or video/telephone call where the procedure and its alternatives have been discussed.

vi) The documented risks for each procedure recorded on the consent form are standardised, but the form can be tailored on an individual patient basis - by adding or removing risks and by altering the standard likelihood of any of the documented risks. There is the opportunity for the clinician to add notes to any section of the digital consent form.

vii) Links to further information for the patient about the proposed procedure are available to the patient from their digital consent form. These may be links to UHL produced patient information which is hosted on the YourHealth website, or they may be links to externally produced information hosted on external websites. It is recorded (on the Concentric audit trail) if a patient accesses any of this information by clicking on the links.

viii) If the consent form is signed by the patient more than 24 hours before the procedure, consent should be confirmed on the day of the procedure

ix) Once the patient has signed the consent form, a digital copy of the consent form is sent to the patient's medical record in the electronic document system (currently CITO). On the day of the procedure, the consent form can be accessed electronically on CITO or on the Concentric site to perform the pre-procedure checks. This may be necessary in the ward/theatre admission area/theatre reception and in the operating theatre or procedure room. This could be done using a mobile device or computer, depending on the availability and location of these devises locally. Alternatively, it is possible to print a copy of the consent form from the Concentric site to enable pre procedure checks to take place if there are no means to complete these checks digitally.

x) Delegated consent may be taken digitally by health care professionals who satisfy the requirements of the Policy for Delegated Consent (see section 5.17

below)

5.17 DELEGATED CONSENT

a) The taking of written consent is only delegated to health care professionals who satisfy the requirements of the Policy for Delegated Consent (Trust ref. B10/2013).

b) The Trust recognises two mechanisms for taking valid informed consent, they are:

- Standard Consent - Consent for the procedure is taken by the healthcare professional who is competent to perform the procedure.

- Delegated Consent - Consent is taken by a healthcare professional who is not competent to perform the procedure, but has been trained to take consent for this procedure.

5.18 TRAINING

a) To enhance the quality of the consent process within the Trust, it is mandated that all staff who are involved in the written consent process as a requirement of their job role must access and familiarise themselves with a copy of the Trust consent policy and successfully complete the UHL e-learning training. This training must be refreshed every three years or sooner if there is a significant revision of the UHL Consent policy.

b) Various forms of consent training are available across the Trust for healthcare professionals involved in the process. Individualised courses may be designed to meet specific needs, and these will be recorded on the electronic skills passport (ESP).

c) The e-learning module titled 'Mental Capacity Act and Deprivation of Liberty Safeguards' available on HELM must be completed by all front line staff who have direct clinical contact with patients.

d) Specific UHL Consent training modules must also be completed by all Doctors within UHL. There are four standard consent modules on HELM to complete.

e) This training must be completed as a minimum once every three years (or sooner if there are material changes to the consent policy).

f) Additional training opportunities;

- Principles of consent must also be included in CMG speciality induction packages focusing on any CMG specific issues.
- All foundation doctors (FY1 and FY2) will access the foundation school consent training.

g) Core Module

i) The core module will teach the healthcare professional:

- the legal aspects of taking delegated consent in accordance with Trust policy;
- the skills necessary to ensure the patient makes an informed decision.

ii) Gaining consent is also an integral part of the education on all clinical skills training (for example cannulation and venepuncture) and assessed using the Leicester Clinical Assessment Tool (LCAT). This tool is used by both the Clinical Skills Unit and Education Teams within CMG's to assess competence in practice.

iii) Successful completion of the training must be recorded on the electronic skills passport

5.19 ADULTS WITHOUT CAPACITY – Refer to the Mental Capacity Act Policy

a) **A healthcare professional's legal duty is to care for a patient and to take reasonable steps to prolong their life.** Although there is a strong presumption in favour of providing life-sustaining treatment, there are circumstances when continuing or providing life-sustaining treatment stops providing a benefit to a patient and is not clinically indicated.

b) **There is no legal distinction between 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. If a person lacks capacity, this decision must be taken in their best interests and in a way that reflects their wishes (if these are known).

c) The legal principles around consent are the same for all medical interventions, including decisions to withdraw or withhold life-sustaining treatment, but the issues surrounding seriously ill or dying patients are necessarily more grave and sensitive. Persons with the capacity to do so can make such decisions for themselves. If the person is an adult who lacks capacity to make such decisions then the provisions of the Mental Capacity Act 2005 will apply to these, as to other decisions.

d) **When making a best-interests decision in relation to life-sustaining treatment**, healthcare professionals should be aware that the Mental Capacity Act requires that the healthcare professional must not be motivated by a desire to bring about the person's death.

e) Sometimes decisions will need to be made immediately – for example whether it is appropriate to attempt resuscitation after severe trauma. In an emergency situation, where there is doubt as to the appropriateness of treatment, there should be a presumption in favour of providing life-sustaining treatment. When more time is available and the patient is an adult or child without capacity, all those concerned with the care of the patient – relatives, partners, friends, carers and the multidisciplinary team – can potentially make a contribution to the assessment. The discussions and the basis for decisions should be recorded in the notes.

f) Legally, the use of artificial nutrition and hydration (ANH) constitutes medical treatment. Thus the legal principles that apply to the use of ANH are the same as those that apply to all other medical treatments, such as medication or ventilation. Where the provisions of the MCA 2005 are followed and the relevant guidance observed, and if there is agreement upon what is in the best interests of the patient, life-sustaining treatment (whether ANH or another form of such treatment) can be withdrawn (or withheld) without needing to make an application to the court. If at the end of the process of decision-making the way forward is finely balanced, or there is a difference of medical opinion, or a lack of agreement to a proposed course of action from those with an interest in the patient's welfare, a court application must be made.

g) **There is an important distinction between withdrawing or withholding treatment that is of no clinical benefit to the patient or is not in the patient's best interests, and taking a deliberate action to end the patient's life**. A deliberate action that is intended to cause death is unlawful. Although there is a strong presumption in favour of providing life- sustaining treatment, there are circumstances when continuing or providing life- sustaining treatment stops providing a benefit to a patient and is not clinically indicated. Healthcare professionals should discuss the situation with a patient with capacity and agree if and when the patient no longer wishes treatment to continue. If the patient lacks capacity, this decision must be taken in their best interests and in a way that reflects their wishes, beliefs and values (if these are known). Suitable care should be provided to ensure that both the comfort and dignity of the patient are maintained.

h) Concerns about Mental Capacity

i) The Mental Capacity Act 2005 now applies in relation to determining whether a patient has capacity to give their consent to care or treatment. It is a principle of the Act that a person is presumed to have capacity to make decisions for themselves unless it is established on the balance of probability that they do not. A person lacks capacity if they are unable to make a decision for themselves in relation to a specific matter because they have an impairment of, or a disturbance in their mind or brain. This impairment or disturbance can either be temporary or permanent. In ascertaining a patient's capacity, the health professional must not make a judgement on the basis of the patient's appearance or on any other aspects of his or her behaviour. Where there is any doubt about a person's capacity, a formal two stage mental capacity assessment must be completed.

ii) If a formal assessment is inconclusive an application for determination of person's capacity may be made to the Court of Protection, in exceptional circumstances.

iii) Further information about how to assess decision specific mental capacity can be found in the Trust's Mental Capacity Act Policy (Trust Ref. B23/2007) and the Mental Capacity Act 2005 Code of Practice (https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice).

5.20 PATIENTS ON LIFE SUPPORT

a) Withdrawing and Withholding Life-prolonging Treatment

i) The courts have confirmed that it is for the clinician to decide what treatment options are clinically indicated, and they will discuss with the patient the benefits and risks of each treatment. It is for the patient to decide whether they wish to accept any of those treatments and a competent patient has an absolute right to refuse any treatment. However, if a patient refuses all treatment options offered to them and decide they want an alternative form of treatment but the clinician considers that the treatment is not clinically indicated, then the clinician has no duty to provide that treatment. The clinician must however offer the patient a second opinion.

ii) There is an important distinction between withdrawing or withholding treatment which is of no clinical benefit to the patient or is not in the patient's best interests, and taking a deliberate action to end the patient's life. A deliberate action which is intended to cause death is unlawful. Equally, there is no lawful justification for continuing treatment which is not in a patient's best interests.

b) Persistent Vegetative State

i) Where in consultation with colleagues it is the considered opinion that treatment to sustain life would be futile in a patient with a persistent vegetative state and no longer in the patient's best interests then the decision as to whether or not to withdraw CANH comes down to a best interests decision on the facts. The relevant GMC/BMA Guidance can be found on the BMA website https://www.bma.org.uk/advice/employment/ethics/mental-capacity/clinically-assisted-nutrition-and-hydration/decision-making-process

ii) Where there is a dispute between clinical staff and the family or the IMCA then legal advice must be sought.

c) Do Not Attempt Cardio-Pulmonary resuscitation)

Failure to undertake appropriate consultation is an extremely serious matter and the strong expectation of UHL is that consultation will occur. **Please refer to the Trust Resuscitation Policy (Trust ref. E4/2015).**

d) Other Types of Advance Statements

i) If an advance statement has been made that is not valid and applicable under the Mental Capacity Act 2005, this does not mean that the statement can be ignored. It should at least be noted as an expression of the patient's feelings and wishes about what should happen to them if they lack capacity to decide for themselves, and should be taken into account in deciding what is in their best interests.

ii) As well as an advance statement to refuse treatment, some statements will express the patient's wishes that a particular course of action should be taken or that they should receive a particular type of treatment in the event that they

no longer have capacity. Whilst a health professional may have a legal duty to their patient, they are not under a legal obligation to provide treatment because the patient demands it. The decision to treat is ultimately a matter for the health professional's clinical and professional judgment. It follows that advance decisions may be binding upon doctors when they express a refusal of treatment in circumstances anticipated by the patient. An advance decision can never be used as a method of demanding treatment.

iii) The Trust recognises that unless they are illegal (e.g. euthanasia) the wishes of the patient shall be followed when establishing whether treatment should be withdrawn, providing always that the patient has reached the age of 18 years at the time the wishes are expressed. Below the age of 18, further advice shall be sought from Trust legal services on ext. 27079

iv) Details of advance decisions should be fully documented in the patient's records.

v) Wherever any doubt exists further advice shall be sought (see – Useful contact details in Appendix B).

vi) Advance decisions to refuse treatment – Statutory rules with clear safeguards confirm that people may make a decision in advance to refuse treatment if they should lose capacity in the future. An advance decision will have no application to any treatment which a doctor considers necessary to sustain life unless strict formalities have been complied with. These formalities are that the decision must be in writing, signed and witnessed. In addition, there must be an express statement that the decision stands "even if life is at risk".

5.21 YOUNG PEOPLE AGED 16–17

a) For the purposes of this Policy 'children' refers to people aged below 16 and 'young people' refers to people aged 16–17(young people are generally referred to age 14-18 rather than 16-17).

b) By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16–17 may in certain circumstances be overridden by either a person with parental responsibility or a court.

c) Section 8 of the Family Law Reform Act 1969 applies only to the young person's own treatment. It does not apply to an intervention that is not potentially of direct health benefit to the young person, such as blood donation or non-therapeutic research on the causes of a disorder. However, a young

person may be able to consent to such an intervention under the standard of Gillick competence, considered below.

d) In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used. If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of, the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over. If however they are unable to make the decision for some other reason, for example because they are overwhelmed by the implications of the decision, then the Act will not apply to them and the legality of any treatment should be assessed under common law principles. It may be unclear whether a young person lacks capacity within the meaning of the Act. In those circumstances, it would be prudent to seek a declaration from the court. More information on how the Act applies to young people is given in chapter 12 of the Mental Capacity Act (2005) Code of Practice.

e) If the 16/17-year-old is capable of giving valid consent then it is not legally necessary to obtain consent from a person with parental responsibility for the young person in addition to the consent of the young person. It is, however, good practice to involve the young person's family in the decision-making process if the young person consents to their information being shared, unless the young person specifically wishes to exclude them.

5.22 CHILDREN – UNDER 16

a) The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults. For the purposes of this Policy 'children' refers to people aged below 16

b) The Concept of Gillick Competence

i) 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 will also have the capacity to consent to that 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 their consent.

ii) 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. 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.

iii) In some cases, for example because of a mental disorder, a child's mental state may fluctuate significantly, so that on some occasions the child appears Gillick

competent in respect of a particular decision and on other occasions does not. In cases such as these, careful consideration should be given as to whether the child is truly Gillick competent at the time that they need to take a relevant decision.

iv) 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.

v) Where advice or treatment relates to contraception, or the child's sexual or reproductive health, the healthcare professional should try to persuade the child to inform his or her parent(s), or allow the medical professional to do so. If however the child cannot be persuaded, advice and/or treatment should still be given if the healthcare professional considers that the child is very likely to begin or continue to have sexual intercourse with or without advice or treatment, and that unless they receive the advice or treatment then the child's physical or mental health is likely to suffer.

vi) If the child seeks advice or treatment in relation to abortion and cannot be persuaded to inform her parent(s), every effort should be made to help the child find another adult (such as another family member or a specialist youth worker) to provide support to the child.

5.23 The Requirement of Voluntariness – Children and Young People

a) 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.

b) 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.

5.24 Child or Young Person with Capacity Refusing Treatment

a) 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, or a child under 16 but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child/young person or to severe permanent injury.

b) The court has stated that it has jurisdiction to override a refusal of a child/young person, at least where they seek to refuse treatment in circumstances that will, in all probability, lead to the death of the child/young person or to severe permanent injury; or where there is a serious and imminent risk that the child/young person will suffer grave and irreversible mental or physical harm.

c) The courts have, in the past, also found that parents can consent to their competent child being treated even where the child/young person is refusing treatment. However, there is no post-Human Rights Act 1998 authority for this proposition, and it would therefore be prudent to obtain a court declaration or decision if faced with a competent child or young person who is refusing to consent to treatment, to determine whether it is lawful to treat the child.

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

e) The changes made to section 131 of the Mental Health Act 1983 by section 43 of the Mental Health Act 2007 mean that when a young person of 16 or 17 has capacity (as defined in the Mental Capacity Act 2005) and does not consent to admission for treatment for mental disorder (either because they are overwhelmed, do not want to consent or refuse to consent), they cannot then be admitted informally on the basis of the consent of a person with parental responsibility.

f) 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.

g) See Section 5.26 i) and j) for further information

5.25 Child Lacking Capacity

a) 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 (if the matter is within the ‘zone of parental control’) or by the court.

b) 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.

c) 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.

d) The European Court of Human Rights has made clear that the failure to refer such cases to the court is not only a breach of professional guidance but also potentially a breach of the European Convention on Human Rights. In situations where there is continuing disagreement or conflict between those with parental responsibility and doctors, and where the child is not competent to provide consent, the court should be involved to clarify whether a proposed treatment, or withholding of treatment, is in the child's best interests. Parental refusal can only be overridden in an emergency.

5.26 PARENTAL RESPONSIBLITY

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

a) Who has parental responsibility (PR)?

i) The biological mother will always have PR; this will only be removed if the child is adopted.

ii) The father will automatically have PR if:

- he is married to the mother or
- marries the mother after the child's birth or
- he is registered on the birth certificate and that registration took place after 1 December 2003

b) How can a father obtain parental responsibility?

i) PR can be obtained in a number of ways:

- By entering into a PR agreement with the child's mother. This must be a formal agreement recorded on a special form.
- By obtaining a PR order from the court

- By obtaining a Residence Order (court orders that the child lives with him) then at the same time the court will make a PR order.
- On the death of the mother if she has appointed him as guardian in her will.

c) Can anyone else obtain parental responsibility?

i) A range of other people may acquire PR by a court order, e.g. step-parents, grandparents. A 'second parent' in a same-sex relationship will have PR where she/he is named on the birth certificate.

ii) There is no limit on the number of people who can have PR at the same time and nobody loses it just because another person gains it.

d) Same-sex Parents

i) Civil Partners

Same-sex partners will both have parental responsibility if they were civil partners at the time of the treatment, eg donor insemination or fertility treatment.

ii) Non-civil Partners

For same-sex partners who aren't civil partners, the 2nd parent can get parental responsibility by either:

- applying for parental responsibility if a parental agreement was made
- becoming a civil partner of the other parent and making a parental responsibility agreement or jointly registering the birth
- Female Civil Partners will both automatically acquire PR if they are in a civil partnership at the point of conception which must be by donor insemination.

e) A Local Authority will acquire PR where it obtains either an Emergency Protection Order or a Care Order in respect of a Child until the Order is terminated at which point PR ceases.

f) Can parental responsibility be terminated?

i) PR ceases altogether once a child reaches 18.

ii) PR is lost if a child is adopted. This is the only way mothers lose PR.

iii) Fathers who have PR due to marriage to the mother do not lose PR on separation or divorce.

iv) PR obtained by fathers through agreement or court order can only be terminated by a court order.

v) PR obtained by people other than the father can be terminated by the court.

vi) In addition 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.

vii) As only a person exercising parental responsibility can give valid consent, in the event of any doubt then the healthcare professional should confirm their relationship to the child and that they have parental responsibility.

viii) Foster parents do not automatically have parental responsibility. However medical treatment can be provided using the 'best interests test' if delay in obtaining consent would introduce unacceptable risk for the child.

ix) 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.

x) 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, although such a case has not yet been considered in the English courts.

xi) Where there is doubt about whether a parent is acting in the interest of the child or young person, then the healthcare practitioner would be unwise to rely on the parent's consent, for example if a child alleges abuse and the parent supports psychiatric treatment for the child. The Government's guidance *Working Together to Safeguard Children* covers situations involving parental consent where abuse or neglect is suspected.

xii) 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 themself under 18, they will only be able to give valid consent for the child's treatment if they themselves are Gillick competent. Whether or not they have capacity may vary, depending on the seriousness of the decision to be taken and complexity of information to be processed.

xiii) 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.

xiv) 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 health of the child.

g) Research involving children

i) 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. It may also be compatible with the welfare principle for a person with parental responsibility to give consent to a research intervention that is not strictly in the best interests of the child,but is not against the interests of the child either. Such an intervention must involve only minimal burden to the child.

ii) Decisions about experimental treatment must be made in the child's best interests.

h) Using Children as Bone Marrow Donors

i) This is covered by the Human Tissue Authority's code of practice on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation, and healthcare professionals should consult this for detailed information on the legal requirements and how toproceed.

ii) When babies or 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 a blood or urine test or x-rays. However, it should be remembered that, in law, such consent is required.

iii) 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.

i) Parental Consent

i) Parents have a parental responsibility for their children and the emphasis as far as rights of control are concerned is that they should be exercised responsibly. The right to control is neither absolute nor capable of precise definition and is less robust as the child grows up.

ii) It is good medical practice, in the case of older children, to seek the child's agreement as well as the consent and authority of the parent.

ii) If a child under 16, having capacity, refuses treatment that refusal may (but not necessarily) be over-ridden by the child's parents. Further advice should be sought for individual cases.

iii) If a child lacks capacity it may be unlawful to continue with treatment against the wishes of the child's parent/guardian.

iv) Particular care must be taken when a child presents for examination without an accompanying adult or when accompanied by an adult who does not have parental responsibility.

j) Parental Refusal to Consent

i) Parental refusal may be contrary to the best interests of the child and conflict with accepted and reasonable medical practice. In these circumstances a second opinion from a suitably qualified professional should always be sought and an application to the court may be necessary.

ii) Normally any life-saving procedure in an emergency may proceed without parental consent. However, due regard must be given to all significant factors including the appropriateness and availability of alternative measures.

5.27 USE OF HUMAN TISSUE

a) Principles

i) The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all.

ii) At present, this Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes. For further guidance, contact the Research and Innovation Department.

iii) Except where a sample is taken only for the purposes of research the Human Tissue Act 2005 does not deal directly with the removal of tissue from the living. Although the process of seeking consent for the storage and use of tissue from patients will often be undertaken at the same time as consent to investigation or treatment, the consent for removal itself in these circumstances remains a matter of common law.

iv) The Department of Health believes that tissue samples may be used for quality assurance purposes without requiring specific patient consent provided there is an active policy of informing patients of such use. This is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised.

b) Requirements Concerning Gametes

i) It is a legal requirement under the *Human Fertilisation and Embryology Act 1990* that consent to the storage and use of gametes must be given in writing after the person has received such relevant information as is proper and had an opportunity to receive counselling. Where these requirements are not satisfied, it is unlawful to store or use the person's gametes. Health professionals should ensure that written consent to storage exists before retrieving gametes.

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

c) Living Donor Transplantation

i) Any transplantation of an organ from one living person to another must be carried out in accordance with the requirements of the Human Tissues Act 2004. All such transplants require the prior approval of the Human Tissue Authority.

ii) Where it is proposed that transplantation is to be undertaken where the individuals are genetically related, the potential donor may feel under considerable emotional pressure to help their sick relative.

iii) Before taking any steps, it is important that the health professional ensures that the potential donor is giving consent freely and not because they feel under undue pressure to do so.

d) Subsequent use of Removed Tissue

i) The Human Tissue Act 2004 regulates the removal, storage and use of human tissue.

ii) Where human tissue which is defined as material which has come from a human body and consists of, or includes, human cells (but does not include cell lines or hair and nails from living people) is removed, the Act provides that

certain specified activities (including research) require the consent of the patient.

iii) Consent must be given by an appropriate person and penalties of up to three years imprisonment or a fine, or both, can be imposed for failure to obtain or misuse of consent. Live gametes and embryos are excluded as they are regulated under the Human Fertilisation and Embryology Act 1990

iv) Full details about these activities and when consent is required can be found in Codes of Practice published by the Human Tissue Authority

5.28 RESEARCH

a) Where capacity lacking

i) Whenever research is proposed on a person who lacks capacity to consent, careful consideration should be given to the ethical and legal requirements of such research.

ii) Such requirements are now underpinned by the Mental Capacity Act 2005, which introduces new statutory safeguards for carrying out research on persons who are 16 years and above and lack capacity.

b) Intrusive Research

i) Any intrusive research will be unlawful unless it is carried out as part of a research project that has been approved by a recognised independent Research Ethics Committee (REC). All RECs established in England and Wales under the Governance Arrangements for NHS Research Ethics Committees (GAfREC) are recognised for this purpose by both the Secretary of State for Health and Welsh Ministers, and are therefore appropriate bodies for the purposes of approving research under the Act.

ii) "Intrusive research" means any research that would normally require the consent of a person with capacity in order to be lawful.

v) Before approving a research project, the REC must be satisfied that certain conditions are satisfied. These are:

- that the research is connected with an impairing condition, i.e. a condition which is, or may be attributable to, or which does or may cause or contribute to, disturbance in the functioning of the mind or brain;
- research of comparable effectiveness cannot be carried out using people who have capacity to consent; and
- that it has the potential to benefit the patient without imposing a

disproportionate burden on him or her.

v**i**) If the research does not satisfy the last of these conditions then approval may still be given providing there are reasonable grounds for believing:

- that the risk to the patient from taking part in the project is likely to be negligible; and that anything done to, or in relation to, the patient will not: interfere with the patient's freedom of action or privacy in a significant way; or be unduly invasive or restrictive.

vi) In determining whether the patient should participate in the research, the best interests test will apply. The Mental Capacity Act also requires that carers or other persons who have an interest in the patient's welfare must be consulted. If there is no one who can be consulted, then a person who is unconnected with the research project must be appointed to advise on whether the patient should take part in the research. If at any time during the research it appears that the patient is upset or unhappy, it should cease immediately.

v**i**) A clinical trial is not research for the purposes of the Mental Capacity Act and in such cases the trial should be carried out in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, and other regulations relating to clinical trial that may from time to time be in effect.

5.29 CONSENT FOR CLINICAL PHOTOGRAPHY OR VIDEO RECORDINGS

a) Guidance on procedures for seeking consent in respect of clinical photography or video recordings is given in Appendix A.

6.0 MONITORING AND REVIEW

Implementation of the policy will be audited across the Trust on an annual basis and will be co-ordinated by the Clinical Audit team as part of the Trust's Clinical Audit Programme. Individual CMGs or Specialities within CMG's may choose to do audit more frequently for specific purposes and this would form part of their local audit programme.

Element to be monitored	Lead	Method	Frequency	Reporting
The completion of a range of consent forms across CMG's, specifically reviewing the completion of the section regarding risks and benefits of investigation/treatment and that supporting information given to patient is listed and grade of staff taking consent. Review of selection of patients medical records to ensure documentation of discussions linked to consent for investigation/procedure. Also to ensure that the 'patients copy' is not present in the notes.	Deputy Director of Quality Assurance (DDQA)/ Clinical Audit Manager	Clinical Audit	Annual ly	Reports to Consent Committee
Review of completion at consent training, including follow up of staff who have not maintained the 3 year renewal of knowledge via the e-learning package.	Deputy Medical Director	Review of training records	Quarterly	Reports to Consent Committee
Review the process for reviewing and archiving patient information and ensure, through spot-checks, that this process is robust to allow retrieval of information.	Clinical Directors	Audit		CMG Quality & Safety Meetings
Monitor on an annual basis the records identifying where consent has been delegated and compliance with the associated training required.	DDQA/ Clinical Audit Manager	Clinical Audit	Annually	CMG Quality & Safety Meetings
Monitor Datix reports for any instances of consent being taken without the authority to do so.	DDQA	Regular Reports	Quarterly	CMG Quality & Safety Meetings

APPENDIX A

CONSENT FOR CLINICAL PHOTOGRAPHY OR VIDEO RECORDINGS

1.0 Purposes

1.1 Recordings, whether originated in Medical Illustration or by using cameras owned by other Trust departments or by individuals, which illustrate a patient's condition, form a part of that patient's medical records and are protected in the same way as any other medical record.

1.2 Photographic and video recordings which are made for treatment 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.

1.3 The one exception to this principle is set out in section 4.1, Anonymous records.

1.4 If such a recording is required for education, publication or research purposes, consent must be sought 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 future use of the material once it has been placed in the public domain may not be able to be controlled.

2.0 Consent Principles

2.1 Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as x-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

2.2 Further guidance on the limited situations where it may be acceptable to proceed without explicit consent are available from the General Medical Council available at: www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/making-and-using-visual-and-audio-recordings-of-patients
Even in these circumstances, consent should be sought unless it is impractical to do so.

2.3 If the need for photographic or video recordings arises during anaesthesia, the patient should be advised retrospectively; if the patient declines to consent the records must be destroyed. If retrospective consent has not been received within four weeks, Medical Illustration will destroy the records.

2.4 Patients have the right to withdraw consent for the use of their recordings at any time. If a patient decides to withdraw consent, the records must be destroyed subject to ongoing legal and/or coroners considerations.

2.5 A Patient's image may not be altered in any way to achieve anonymity and so avoid the need for consent. Blacking out of the eyes in a facial photograph is not an effective way of anonymising the image.

2.6 Generally speaking, because it is impossible, with certainty, to guarantee that an image of an external part of the body will be inherently anonymous, it is recommended that recordings are never taken without specific consent (see also 4.1, Anonymous records, and 4.7, post mortems).

2.7 For some recordings (e.g. radiographs, photomicrographs) it is more reasonable to assume that the absence of identifying marks will make the image anonymous. However, caution should be exercised. If an image believed to be anonymous is subsequently shown to be identifiable, its use without appropriate consent will be contrary to the provisions of the Data Protection Act 1998.

2.8 Recordings of both children and adults should only be taken if there are specific features that need recording for clinical (e.g. assessing the progression of a skin lesion) or teaching purposes (e.g. an important clinical sign that might onlybe seen rarely.

3.0 Staff taking Consent

3.1 Medical Illustration Staff

a) Clinical staff will record consent on the Clinical Photography Consent form when patients are referred to the Medical Illustration Team.

b) The Clinical Photography Consent form allows for two levels of consent:

I. for medical record use.

II. for printed or online teaching and publication purposes.

The photographs may be conveyed electronically within the healthcare network and also in medical textbooks, medical posters, and scientific papers. They could be viewed by other patients to assess possible treatment plans and help to understand what treatments or surgeries are available.

3.2 Healthcare Professionals

a) Healthcare Professionals (e.g. Doctors, Nurses, AHP's) taking recordings must only do so after proper informed consent has been obtained, in accordance with the Consent policy on the relevant standard consent form 1, 2, 3 and 4 (see Appendix B of this policy). Consent may also be obtained using the Trust's Digital Consent Form.

b) A Clinical Special Photography Request Card can be used by Healthcare professionals to gain consent for the recording of images in specific cases. Permission must be given by Medical Illustration and the card developed and agreed with Medical Illustration before use:

c) A Clinical Special Photography Request Card is available for:

- Photography of Stillborn Babies by Midwives

- Photography of Skin Damage Suspected to be due to Pressure by Nurses / Midwives / ODP's

3.3 Freelance professional photographers are sometimes employed to make recordings. They may only be introduced to Trust premises by arrangement with Communications Team who will also be responsible for ensuring consent is obtained.

3.4 Governance principles for Recordings Taken by Non Medical IllustrationStaff

a) Copyright of all recordings is vested in the University Hospitals of Leicester NHS Trust.

b) It is important that in any contract for publication the copyright in the recording remains with the Trust and does not pass automatically to the publishers on first publication.

c) Original digital camera files and digital video must be securely stored, filed and logically catalogued.

d) Since any medical record has to be available for disclosure, if required, it is essential that every identifiable recording is properly logged in the casenotes (this must include the date and name of person who took the photographs).

e) Digitally originated recordings are easy to copy in electronic form and are, therefore at risk of image manipulation and inappropriate distribution. Particular care must be taken to protect the image and maintain its integrity. Digital manipulation which is applied uniformly to the whole image is likely to be acceptable, but any manipulation which might mislead or in any way alter the meaning of the image is not acceptable.

f) All recordings of patients must be stored on Trust premises.

g) See Mobile Device Management Policy (Trust Ref B7/2007) for further information

4.0 Clinical Photography and Video Recordings in specific circumstances

4.1 Anonymous Records

a) Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient.

b) However, express consent must be sought for any form of publication [see also 2.5 above].

4.2 Education, Publication and Research

a) 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.

b) Guidance on the few situations where consent may not be required for use of recordings in education, publication and research is available from the General Medical Council available at;
https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/making-and-using-visual-and-audio-recordings-of-patients
Even in these situations it is good practice to obtain and record consent wherever practical.

c) 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.

d) If the patient decides that they are not happy for any recording to be used, it must be destroyed.

e) As with recordings made with therapeutic intent, patients must receive full information on the possible futures uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

f) In the case of electronic publication, it should be made clear to the patient that, once a recording is in the public domain, there is no opportunity for effective withdrawal of consent.

g) In cases where it is proposed to use recordings in publications it is the author's responsibility to obtain permission to publish from the patient.

h) This must be filed in the patient's case notes and a copy given to thepatient.
A copy must also be given to the Medical Illustration Department, if they have to produce additional copies of the recording.

4.3 Unconscious Patient

a) 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.

b) In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity.

c) 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 (see also 4.6, deceased patients).

d) If a patient, who is temporarily unable to give or withhold consent, does not recover

the material can only be used with the written consent of the next of kin.

4.4 Permanent Inability to Give Consent

a) If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of some-one close to the patient.

b) You must not make any use of the recording which might be against the interests of the patient.

c) You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

4.5 Incapacity to Give Consent (for further guidance please refer to the main Consent Policy)

a) In seeking consent for recordings there is an issue of the patient's ability to give consent, i.e. whether they understand what is being asked and the way the recordings will be used.

b) Judgment of their ability to understand is solely that of the psychiatrist, psychologist or other appropriate clinician caring for the patient.

c) It is not the case that all mentally ill patients necessarily have diminished responsibility in this respect, though they may be disturbed in otherways.

d) Even those who are 'sectioned' i.e. held under the provisions of the Mental Health Act (1983), do not, as a consequence of this fact, have diminished responsibility of that kind. Persons detailed for treatment under the Mental Health Act should not be assumed to have sacrificed their rights in respect of clinical illustration if they are still capable of making a judgment in which case they have the right to have the recording erased or destroyed at a subsequent time, should they wish it.

e) For those patients who lack the competency to give consent, the decision to take recordings must rest with the treating clinician based on the principle of 'patients best interest'.

4.6 Deceased Patients

a) If a patient dies before consent is obtained (see also 4.3, unconscious patients), recordings shall be retained until the next of kin have been approached. If they decline, the material shall be destroyed.

b) If a consenting patient subsequently dies, permission should be sought from the next of kin for any new use outside the terms of the existing consent.

4.7 Post-Mortems

a) Confidentiality, and the requirement for consent to take recordings from which a

patient may be identified, applies to post-mortem cases in the same way as it does to living patients.

b) Therefore, written consent is required from the next of kin in Hospital Post Mortems, or as per the coroner's requirements for their Post Mortems, before any images are taken of an external part of the body at post-mortem [see also consent principles section 2.5.

c) Internal organs are inherently anonymous, even when specific and rare pathologies are present, and specific consent is not required to take images, provided they are stored in an anonymous form.

4.8 Serial Recording

a) Where frequent serial recording is concerned, single consent is adequate for a whole course of treatment e.g. orthodontics.

b) Therefore, it is not necessary to obtain written consent on each occasion, providing the nature of the illustration/recording does not change.

c) It is suggested that 'frequent' means more than 3 times a year.

4.9 Non-Clinical Recordings

a) In cases where the patient is incidental to the recording, e.g. where the picture is to illustrate a particular equipment set-up etc, consent to appear in the recording is still required from any patient or member of the public.

b) Where staff may be included in any non-clinical photography, written consent is not required. However, it is the responsibility of the photographer to make it clear to the staff member the purpose and use of the photographs.

c) Should the staff member not wish to be included, they shall be given an opportunity to withdraw and not participate.

d) This is covered by the Non-Clinical Photography Consent form, which is available from the Medical illustration Department (ext. 6369), if consent has to be arranged in advance.

4.10 Additional Requirements for Recordings of Children

a) Records should only include the specific area of interest. Whole body shots should only be taken if completely necessary (see also section 2.7).

b) Records of genital areas, or of the chest in peri or post-pubescent females, should only be taken in exceptional circumstances. It is strongly recommended that a clear indication is recorded in the notes justifying the record (see also section 2.7).

4.11 Non-accidental Injury (NAI)

a) In the case of suspected NAI, where it is likely that the clinical photograph will be required for legal purposes, it is justifiable to proceed without consent from the parent, although this should always be sought (Consultant level authority is required in such cases – this must be clearly indicated on the consentform).

b) Such records may only be used for record and legal purposes. There is a clear duty towards the child and the recording of injuries is demonstrably to the patient's benefit. Therefore, it is important to act swiftly before extent of superficial injury fades.

4.12 Grieving Procedure

a) Recordings of neonates on the point of death should be covered by the normal consent procedure for minors.

b) Photography of stillborn babies is covered by a separate consent procedure, as is cot death (see 3.2 c) i)).

4.13 Persons Obtaining Treatment Under False Pretences

a) There is justification in obtaining identifying records of persons attempting to deceive hospital staff into providing treatment e.g. fabricated induced illness.

b) Recordings can be made without consent as part of the case notes and the person's co-operation is not required, as the material would have no teaching value. Care should be taken to protect the photographer from violence in such cases.

c) N.B. Self-inflicted injury may be a different matter, one where a patient may need psychiatric treatment and is, therefore, not intentionally deceiving the Trust.

4.14 Photography of Pressure Ulcers

The 'Guideline for the photography of skin / tissue damage suspected to be due to pressure' (Trust Ref B6/2013) is to be used by healthcare professionals and Medical Illustration staff in all instances where an image of a pressure ulcer or wound suspected to be a pressure ulcer is requested.

APPENDIX B

CURRENT CONSENT FORMS IN USE IN UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

These documents are available throughout the Trust and samples for illustration purposes only are available separately on the SharePoint System

Consent Form 1

Patient Agreement to Investigation or Treatment

Consent Form 2

Parental Agreement to Investigation or Treatment for a Child or Young Person

Consent Form 3

Patient/Parental Agreement to Investigation or Treatment

Consent Form 4

Form for Adults Who Are Unable to Consent to Investigation or Treatment.

APPENDIX C

USEFUL CONTACT DETAILS

Legal Services
Assistant Director of Corporate and Legal Affairs
Ext: 27079 or via switchboard outside of normal working hours

Coroners Inquests
Claims and Litigation Department
Ext: 27082

Patient Information and Liaison Service/Complaints
Senior Patient Safety Manager
Ext: 18901

Research and Innovation
Director of R&I
Ext: 18043

Service Equality
Service Equality Manager
Ext: 14382

Data Protection Issues
Head of Privacy
Ext: 18537

Patient Information
Patient Information Librarian
Ext: 18355

Acute Liaison Team for Learning Disabilities
Ext. 12809

APPENDIX D

Frequently Asked Questions: Consent

How long is a consent form valid for?

There is no definite period of validity for a consent form. A common sense approach should be adopted by checking with the patient that they still wish to go ahead with the operation; and by the clinician signing the confirmation of consent box if there has been a significant delay since the first part of the consent form was signed.

Can a consent form be altered once it has been signed?

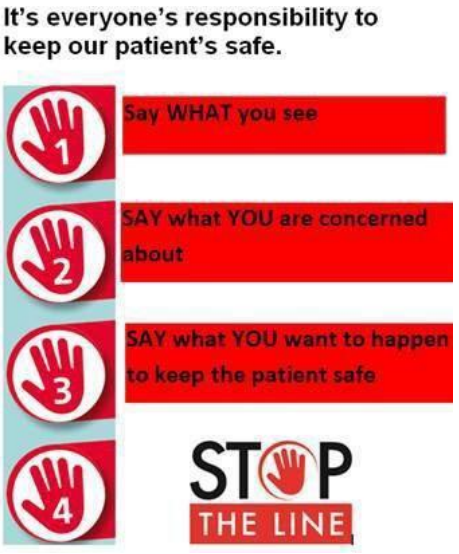
Yes – if the alteration is small and does not involve re-writing large portions of the form this is acceptable. Any errors should be crossed out; and new insertions initialled by the person taking consent and countersigned by the patient. Alterations must involve the two carbon copies of the form. If they are not together a new form should be filled in. Again a common sense approach should be used here.

What should you do when the signatory to the consent form is not available in theatre at the sign in?

This may occur in the case of children where consent may have been taken from their parents some time before the operation – e.g. the day before. In such circumstances it is recommended that the parents are contacted by phone to confirm consent in conjunction with the health care professional that took consent.

What should I do if I am not happy with a consent form, but the team wish to proceed?

Under these circumstances "STOP THE LINE" by saying what you see, what you are concerned about and what you want to happen next. For instance: "I see that this patient is consented for a right side operation, but I am concerned that the theatre list states we need to operate on the left side. Let's pause for a moment to check with the patient and surgeon which is the correct side."
If a resolution cannot be found, issues can be escalated to floor control if necessary.



I am looking after a 17 year old young person who is refusing to have life-saving surgery. Her parents have signed the consent form but she does not want to go ahead. What should I do?

The law states that young people up to the age of 18 cannot refuse life-saving treatment. In such a dispute it would be wise to seek legal advice as soon as possible.

Written Consent:

Best practice		Sub-optimal practice	
Take written consent in the OPD	☑	Consent process left until day of surgery	☒
Procedure and side written out in full	☑	Abbreviations used	☒
Give a copy to the patient	☑	Patient copy retained in notes	☒
Use pre-printed stickers to record risks and benefits	☑	Variation in risks and benefits explained, important risks not mentioned	☒
All sections of Consent form 4 filled in if the patient lacks capacity	☑	Inadequate assessment of capacity	☒
Stickers used to record risks of blood transfusion	☑	Need for transfusion not anticipated, risks not explained fully	☒
Consent taken by person competent to do the procedure or who has been trained to take delegated consent	☑	Consent taken by untrained individual	☒
Interpreter used for translation	☑	Family member used for translation	☒