Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Consent to Examination or Treatment Policy

This procedural document supersedes: Consent to Examination or Treatment Policy – PAT/PA 2 v.7

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Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 8	October 2021	• Update on new GMC guidance- guidance on decision making and consent. • Use of Procedure specific patient information leaflets. • Guidance for Consenting for radiological procedures. • Guidance for consenting patients on pooled lists. • Information on remote/electronic consenting.	Mr Olumuyiwa Olubowale
Version 7	October 2018	• More Update on guidance regarding the new rules of consent rules and editing of texts. • Corrections and word edit and formatting. • Update on guidance for patients whose first language is not English. • Update on contact information. • Update of references.	Mr Olumuyiwa Olubowale
Version 6	October 2015	• Update regarding new rules on consent. • Updates on Trust new Care Group structure. • Corrections and word edit. • Update on young people/children/emergencies. • New guidance on HTA on disposal of pregnancy following pregnancy loss or termination. • Update of references.	Mr Olumuyiwa Olubowale
Version 5 (amended)	August 2014	• Additional sub-section included at 6.4 - Nurse Consent in Endoscopy. • Addition of Appendix 6 – Guidelines for Registered Nurses Obtaining Written Informed Consent for Diagnostic Endoscopic Procedures.	Amendment written by Victoria Kenneth

Version 5	August 2012	• Monitoring compliance of policy is a new section. Each Clinical Director must note their responsibility with regard the monitoring of consent and ensure they have local arrangements via the clinical governance route for receiving assurance. • Section 6.2 now includes the use of "risk and benefit stickers". • Section 12, please read in full due to changes.	Mandy Dalton
Version 4	July 2010	• Update to section IV – provision of information for patients' whose first language is not English. • Update to section VII – Human Tissue – reference to updated consent form & information leaflet. • Update to section IX– availability of documented training and competency updates and addition of requirement of a documented training plan. • Update to named contacts in Appendix 2. • Update to Appendix 5 - clarification of consent requirements for post mortem. • Amended section III Seeking Consent to Interventional Radiological Procedures. • Included in section III Lung MDT for obtaining consent for procedures. • Appendix 3 – updated court decisions and declarations. • Updates throughout to reference Mental Capacity Act 2005.	H Lelew

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1 INTRODUCTION

1.1 Why consent is crucial

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

1.2 Scope of Policy

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

1.2.1 Principles of Decision Making and Consent

The General Medical Council (GMC) issued guidance on decision making and consent which came into effect on the 9th of November 2020 (Guidance on professional standards and ethics for doctors: Decision making and consent). This guidance sets a framework for doctors and interested clinicians on good practice for consent and decision making. This guidance should also be consulted on good practice. It sets out the principles to follow.

The Seven Principles of Decision Making and Consent

Principle One
All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.

Principle Two
Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.

Principle Three
All patients have the right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand it.

Principle Four
Doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.

Principle Five
Doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.

Principle Six
The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.

Principle Seven
Patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible.

1.3 What Consent is - and isn't

"Consent" is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:

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

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

1.4 Mental Capacity Act 2005

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves**, no-one else can give consent on their behalf.** However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance decision. For further details on advance decisions see the ***Mental Capacity Act 2005 Code of Practice*** (chapter 9 pages 158-176) available online and **PAT/PA 27 Advance Decision to Refuse Treatment (ADRT) Policy.**

2 PURPOSE

To enable staff to comply with the law and DoH guidance on obtaining valid consent to treatment, care and research, so that the process is properly focussed on the rights of the individual patient.

3 DUTIES AND RESPONSIBILITIES

3.1 Staff

Medical Director
The Medical Director will have executive responsibility and accountability for the implementation of this policy and associated training within the Trust.

Lead Nurse -Patient Safety and Quality
The Lead Nurse for Patient Safety and Quality is responsible for ensuring that this policy is reviewed every 3 years or whenever national policy or guideline changes are required to be considered (whichever occurs first).

Clinical Director (or delegated person)
The Clinical Director should delegate a named person for each Clinical Division to undertake the monitoring of compliance with policy.

Clinicians, Nursing and Allied Health Professionals.
It is the responsibility of staff providing treatment or care to a patient with capacity to ensure that valid consent has been obtained from the patient before providing that treatment or care.

Staff also have a legal duty to have regard to the provisions of the Mental Capacity Act 2005 and the code of practice when they have to take decisions on behalf of a person who lacks the mental capacity to take that decision for themselves.

3.2 Committees

Patient Safety Review Group (PSRG)
The PSRG will have the responsibility for the approval/ratification of this policy and will receive reports on any consent related issues or changes to the consent form.

4 PROCEDURE

4.1 Valid Consent

For consent to be valid, it must be given voluntarily by an appropriately informed person (the patient or someone with parental responsibility for a patient under the age of 16) who has the capacity to consent to the intervention in question.

Consent can be expressed (orally or in writing) or may be implied by conduct. Written consent merely serves as evidence of consent. A signature on a form will not make the consent valid if the elements of capacity and appropriate information have not been satisfied.

4.2 Does The Patient Have Capacity?

For a person to have capacity, he/she must be able to comprehend and retain information material to the decision, especially as to the consequences of having or not having the intervention in question, and must be able to use and weigh this information in the decision–making process. Patients also need to be able to communicate their decision.

The Mental Capacity Act 2005 defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary.

A person lacks capacity if:

- they have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works, and that impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made.

The assessment of capacity and the test for capacity are now set out in the Mental Capacity Act 2005. The Code of Practice to support the act is available where it is available eg on the intranet and staff working with people who lack capacity are required to have regard to the Code (MCA Code of Practice 2005).

PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the Extranet.

There is no single definition of Best Interest. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.*

4.3 Is The Consent Given Voluntarily?

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. Staff 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.

The Mental Capacity Act also requires that all practical and appropriate steps are taken to enable a person to make the decision themselves. These steps include the following:

- Providing relevant information. For example, if there is a choice, has information been given on the alternatives?
- Communicating in an appropriate way. For example, could the information be explained or presented in a way that is easier for the person to understand?
- Making the person feel at ease. For example, are there particular times of the day when a person's understanding is better?
- Supporting the person. For example, can anyone else help or support the person to understand information and to make a choice?

4.4.1 Patient information

The provision of information is central to the consent process. Before patients can come to a decision about a procedure/treatment, they need comprehensible information about their condition and about possible treatments/investigations/procedure and their risks and benefits (including the risks/benefits of doing nothing).

In 2015, the ruling of the UK Supreme Court in the case of Montgomery v Lanarkshire Health Board fundamentally changed the practice of consent, shifting the focus of the consent discussion to the specific needs of each individual patient.

The Royal College of Surgeons of England in 2016 developed guidance on consent that sets out the principles for working with patients through a process of supported decision-making. It includes the full implications of the new legal context, and provides guidance on the discussion with the patient, the role of the consent form and how to document the consent process.

This guidance is titled **Consent: Supported Decision- Making- a good practice guide** and the see link below:

(https://www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/consent-good-practice-guide/).

The key principles from this guidance are:

- The aim of the discussion about consent is to give the patient the information they need to make a decision about what treatment or procedure (if any) they want.

- The discussion has to be tailored to the individual patient. This requires time to get to know the patient well enough to understand their views and values.

- All reasonable treatment options, along with their implications, should be explained to the patient.

- Material risks for each option should be discussed with the patient. The test of materiality is twofold: *whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would likely attach significance to it*.

- Consent should be written and recorded. If the patient has made a decision, the consent form should be signed at the end of the discussion. The signed form is part of the evidence that the discussion has taken place, but provides no meaningful information about the quality of the discussion.

- In addition to the consent form, a record of the discussion (including contemporaneous documentation of the key points of the discussion, hard copies or web links of any further information provided to the patient, and the patient's decision) should be included in the patient's case notes. This is important even if the patient chooses not to undergo treatment.

Therapeutic exception

The Royal College of Surgeons Guidance also explains that the traditional concept of the therapeutic exception (sometimes referred to as therapeutic privilege) describes the situation in which a doctor may claim exemption from the duty to provide certain information to a patient if the doctor deems that this might cause the patient psychological harm to a degree which outweighs the benefits of informing them. The possibility of this exception presents significant legal difficulties for doctors. The Supreme Court in the Montgomery case made clear that the therapeutic exception should only be used in rare cases. Litigation is a likely consequence of the use of the therapeutic exception and surgeons should ensure that, if they use it at all, their reasons should be documented at the time. Where contentious issues are involved, legal advice should be sought. (Reference: Consent: Supported Decision- Making- a good practice guide, RCS England 2016).

Patients need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue, etc. The health care professional must enter into a dialogue with patient and be even more careful to give, and document, clear and accurate advice on the risks/benefits of a procedure and the alternatives.

The following questions should be asked by health professionals when obtaining consent:

- Does the patient know about the material risks of the treatment I am proposing? (What sort of risks would a reasonable person in the patients circumstances want to know and what sort of risk would this particular patient want to know).
- Does the patient know about reasonable alternatives?
- Have I taken reasonable care to ensure that the patient actually knows all this?
- Do any exceptions to my duty to disclose apply here? (e.g. if patient prefers not to know the risks, or if health professional might reasonably consider that telling the patient something would harm the patients' health and thirdly if no consent is required in circumstances of necessity, such as when a patient needing urgent treatment is unconscious or lacks capacity- see under section 4.2 above.

The General Medical Council also provides guidance under good medical practice and consent for doctors: Consent: Patient and doctors making decision together (2008) see links: http://www.gmc-uk.org/guidance/good_medical_practice.asp and http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp. The GMC begun a process in 2018 and is currently reviewing its Consent guidance because since the GMC guidance was last published in 2008, there have been shifts in the legal, policy and workplace environments. Doctors are concerned that increasing pressures and demands on their practice can make it difficult it to seek and record a patient's consent in line with our guidance and the law. The review will make sure the guidance remains clear, helpful, relevant to doctors' and patients' needs, and compatible with laws throughout the UK.

Once a decision to have a particular treatment/investigation/procedure has been made, patients need information about what will happen, where to go, how long they will be in hospital, how they will feel afterwards and so on.

Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options.

Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

All information given, whether verbally or in other format should be documented, either on the appropriate Trust Consent Form and in the event that a Consent Form is not used, within the patient health record.

Sources of patient information in the Trust include:

- Consultants
- Specialist Nurses
- Specialist Clinics
- Patient Information Leaflets

4.4.2 Patient Information Leaflets

To support the process of consent, it is good practice for clinicians to use validated procedure specific information leaflets that are regularly updated. The Trust now has a subscription with EIDO Healthcare's Inform Consent Suite (ICS). This provides a library of procedure specific patient information leaflets and is based on the best available evidence. It is endorsed by The Information Standard, RCS England, RCS Edinburgh, ASGBI, BAPS, The Preoperative Association, The Plain English Campaign, among others.

This is not a substitute for the discussion with patients but it is an aid to support the consent process. The leaflets can be handed out to patients during consultation/discussions about the procedure or treatment, on the ward, in clinics, at pre-assessment clinics etc, to allow patients to make an informed decision before the date of procedure or treatment.

CLINICIANS SHOULD DOCUMENT IN THE CASE NOTE AND OR CONSENT FROM THAT LEAFLETS HAVE BEEN GIVEN AND WHICH LEAFLETS.

The leaflets are available for download at: https://inform.eidosystems.com/rcs

Username: DON
Password: consent15.

The leaflets can be printed or can be sent to the patient by e mail. This will help the Trust and all clinicians meet its policy to support shared decision making, giving patients time to

consider the implications of having a medical procedure. They may need to share information with family or friends to help them decide whether to consent to a procedure.

Montgomery v Lanarkshire (2015) highlighted how vital the provision of procedure-specific information was to patients, alongside specific advice from clinicians, allowing patients to make informed decisions. The procedure specific information leaflets supports this legal obligation by ensuring that consistent, nationally recognised information is provided to all patients. The leaflets will be updated regularly to ensure that information is up to date.

To support patients with accessibility requirements, the EIDO Inform library is available in Large Print, Giant Print, a Screen Reader compliant and Easy Read format.

There are also new digital features which is being explored to allow clinicians to send information to patients electronically to support remote consultations and provide a clear audit trail to ensure this standard is upheld for every patient. This will be available soon.

4.5 Provision for Patients Whose First Language is not English

The Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. When a patient's first language is not English and they do not have a good understanding of the English language, the use of an interpreter/translation service should be offered, even where a family member or friend is able to translate for them. It must be recognised that they may feel unable to talk freely on personal and sensitive matters to family or friends and therefore a full clinical history may not be obtained or correct translation provided to the patient.

The Big Word should be used to provide all interpreter/translation services within the out patients department unless it is planned to deliver bad news or it is anticipated that the appointment will last for over 45 minutes, when a face to face translator may be the more appropriate and/or cost effective option. The contract to provide 'face to face' language service is with Doncaster Metropolitan Borough Council interpretation and translation services. If however, they are unable to provide the service, Sheffield Community Access Interpretation Service (SCAIS) or another interpretation service provider may be able to offer an interpreter/translator (although this should only be considered if all other options have been explored due to the high cost of the service). If this service is required, this is booked via the PALS Office at DRI.

Details and instruction on how to use 'The big word' and book face to face interpreters are available on the 'Interpretation and Translation Policy' (PAT/PA 34) which is on the Trust intranet.

In addition, to support patients whose first language is not English, they should be given information leaflets in their own language. The information leaflets in foreign language from the EIDO ICS library should be used as it has access to a foreign language library of over 400 documents.

4.6 Access to more detailed or specialist information

Patients may sometimes request more detailed information about their condition or about a proposed treatment or procedure that is not covered by the procedure specific information leaflets provided. This Trust has made the following arrangements to assist patients to obtain such information:

- The patient may in the first instance discuss the issue with their Consultant, a Senior doctor, Practitioner, Clinical Nurse Specialist, appropriate Clinician/Nurse in charge or involved in their care. A telephone or face to face appointment can be arranged for this discussion. This can be arranged by telephoning the patients identified contact number. Additional information or references may be provided if necessary. The discussion or additional information provided should be documented in the notes.
- The Patient Advice and Liaison Service on 01302642764/01302642765 or by visiting the PALS office at any DRI.
- NHS 111 online – https://digital.nhs.uk/about-nhs-digital/our-work/transforming-health-and-care-through-technology/urgent-and-emergency-care-domain-b/nhs-111-online.
- National Electronic Library for Health – http://www.library.nhs.uk
- Patients may also access advice on children's consent via the paediatric staff access to the Child Health Information centre at Doncaster Royal Infirmary children's outpatient department.

4.7 When Should Consent be Sought?

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

4.8 Single Stage Process

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

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 time 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.

For some patients, the choice may be easy - simply to agree to or to decline the operation. But **for many the choice will be a difficult one, requiring time to think, to take advice and to weigh up the alternatives.** The duty is owed as much to the patient who, if warned, would find the decision difficult as to the patient who would find it simple and could give a clear answer to the doctor one way or the other immediately.' (*Chester v Afshar* [2004] UKHL 41 [86] Lord Hope).

4.9.1 Two or More Stage Process

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

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

Patients who are placed on a pooled list to be operated by another surgeon should be consented in the outpatient clinic by the clinician discussing the treatment and the operating surgeon will then confirm the consent and update as necessary on the day of surgery.

When the consent is signed before patients arrive for treatment, the clinician or surgeon must check with the patient at this point whether they understand the procedure, have any further questions or concerns and if they understand all the risks and complications, and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?" There is a separate section on the consent form for the 'Confirmation of Consent'.

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.

4.9.2 Consent for Radiology Procedures

It is good practice and essential that patients do not arrive to Radiology department without prior information about their procedures. Our Interventional Radiologists do not have the opportunity to see the patients in advance of the procedure. The referring clinician should therefore have the initial conversation including the risks and do the initial consent if possible before the patient attends for the radiological procedure/test. This discussion should be aided by using and the giving of the related patient information leaflets to the patient about the radiological procedure or test. Interventional Radiologists can be involved throughout the process for the most complex of procedures. The ultimate responsibility to ensure that patient has all the relevant information lies with the Radiologists performing the procedure on the day who should complete the second part of the consent on day of procedure and ensure that consent is valid. The relevant information leaflets for radiological procedures are available in the EIDO library and the British Society of Interventional Radiology website (BSIR).

The BSIR website has a list of printable patient information leaflets for consent and information of any not covered in the EIDO library:
https://www.bsir.org/patients/patient-information-leaflets/#col_right

4.9.3 Consent for Pooled Operating Lists

Patients undergoing planned (elective) surgery should have the opportunity to reflect on risks, benefits and outcome of the procedure, and may need to ask further questions. This may be a particularly important consideration when there is a significant delay prior to surgery or when there is a need to clarify the surgical plan, or for example, when the patient is placed on a pooled list. Consent should be revisited at the time of the planned procedure as the patient may require additional information or their circumstances may have changed. The operating surgeon or clinician carrying out the procedure has the ultimate responsibility to ensure that patient understands the benefits, risks and any relevant specifics of the procedure or patient related circumstances. The operating surgeon or clinician on the day, should confirm the consent and document appropriately.

The use of agreed procedure specific consent information can be helpful to ensure that all relevant information have been discussed before the day of procedure.

If however, the operating surgeon has significant concern that there are significant risks/complications/information/circumstances that have not been discussed which require more time for patient to consider and reflect on, then the procedure can be delayed or postponed to give the patient more time especially if this will affect the outcome.

4.9.4 Consent After Significant Time Lapse

Consent is a process rather than a one-off decision. Where there has been a significant interval between a patient agreeing to a treatment and its start, or if new information has emerged, or the patient's condition has altered, consent should be reaffirmed.

4.9.5 Remote or Electronic Consenting

The Trust is currently exploring new digital features as part of the digital transformation that can bring close integration of current processes into a digital and remote or electronic consent process. This will be piloted in due course.

4.10 Seeking Consent for Anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks.

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

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.

Simply thrusting a leaflet into a patient's hands is no substitute to a face to face discussion with someone who can inform the patient and answer questions. The leaflet is a supplementary source of information, not an alternative.

5 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.

5.1 Written Consent

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is *evidence* that the patient has given consent, but is not *proof* of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

Although completion of a consent form is in most cases not a legal requirement it is however good practice to do so if any of the following circumstances apply:

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

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

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

5.2 Consent Forms

Standard consent forms and forms for adults who are unable to consent for themselves are available at ward and department level or by order from the supplies department.

There are three versions of the standard consent form and the fourth is only used for adults who lack capacity to consent for investigation and treatment:

- **Form 1** for adults or competent children whose treatment involves general and/or regional anaesthesia: local anaesthesia or sedation,
- **Form 2** for parental agreement to investigation or treatment for a child or young person,
- **Form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary; and
- **Form 4** for adults who are unable to consent to investigation or treatment.

It is recognised that there will be circumstances where individual departments will need to add further details to the standard consent form in order to meet specific criteria. In general terms it is acceptable to customise the forms in this way providing the existing information is not modified or removed. However, any changes and/or additions to the forms will have to be reviewed and approved by the Patient Safety Review Group.

Similarly the appropriate staff or groups must review any new consent forms developed within the Trust as requested by the Patient safety Review Group.

6 WHO CAN OBTAIN CONSENT?

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later. Consent should not be taken by doctors who are not registered with the General Medical Council (GMC).

Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, teamwork is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

The Clinician must not take consent for procedures he/she has not received training for without supervision and if they are unable to inform the patient of the procedure, risks, benefits and alternatives including not having the procedure.

6.1 Clinicians obtaining consent must be suitably trained and qualified

The clinician discussing treatment with the patient should be suitably trained and qualified to provide the treatment in question and have sufficient knowledge of the associated risks and complications, as well as any alternative treatments available for the patient's condition (RCSEng).

Each Clinician/nurse specialist will agree consent taking with the relevant Consultants.

The Consultants will train the Nurse Specialist/Clinician and will then observe and assess their consent taking prior to taking on the role. The Nurse Specialist/Clinician will be subject to an assessment using a competency framework that reflects the following requirements:

- The Health Professional must be educated in the Department of Health Principles of Consent.
- The Health Professional must have sufficient knowledge of the investigations or procedures have an understanding of the risks involved (including material risks) and qualified to provide the treatment.
- The Health Professional must provide patients with the information they ask for or need about their condition, its treatment and prognosis including effects on the patient's lifestyle.
- The Health Professional must know alternatives to the proposed treatment, frequency of adverse effects and the seriousness and permanence of such effects.
- The Health Professional must be able to communicate satisfactorily to patients in a way the patient understands.
- The Health Professional must ensure that the patient is satisfied and has understood what is proposed and consents to it.
- The Health Professional's competence will be assessed.

  Each Division within the Trust has a responsibility to keep a record of who can take (or delegated) consent for any procedures relevant to that specialty, and also ensure that professionals are adequately trained and aware of the guidance on Consent. Only a Consultant can delegate this responsibility and must ensure that this competency is maintained.

  A record of competence will be held by those practitioners who are unable to perform the procedure themselves, but who have been assessed and signed off as competent by the relevant consultant to take consent.

6.2 Completing consent forms

The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this

procedure, risks, benefits and alternatives and have been assessed, are aware of their own knowledge limitations.

The clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins, although the consultant responsible for the patient's care will remain ultimately responsible for the quality of medical care provided.

The task of seeking consent may be delegated to another health professional, so long as the health professional is suitably trained and qualified in providing the treatment and obtaining consent for that procedure. They must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require. The use of "risk and benefit stickers" is approved by the Trust, but their development must be in line with the Developing Information for Service Users Policy and Guidelines - CORP/COMM 5. They must "mirror" the risks and benefits detailed on the information leaflet and be placed on the top and carbonated copy of the consent form.

Inappropriate delegation (for example where the clinician seeking consent has inadequate knowledge of the procedure) may mean that the "consent" obtained is not valid. Clinicians are responsible for knowing the limits of their own competence and should seek the advice of appropriate colleagues when necessary.

If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), they should be given a copy of the consent form to take away with the relevant information before the procedure. A health professional/clinician 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. The healthcare professional, clinician or Doctor undertaking the procedure is responsible for ensuring that consent has been taken and should confirm this with the patient.

All Consultants are responsible for ensuring that any procedures, where consent is taken by another health professional, that health professional has knowledge of the procedure, including risks, benefits and alternatives.

6.3 Actions to be taken when consent is obtained without authorisation

The clinical Director/Matron of the appropriate Clinical Division will meet with the health care professional and undertake a formal investigatory meeting.

Where managerial action is concluded this may lead to disciplinary action and their appropriate professional body (e.g. GMC, NMC, HPC) being informed.

The form to use to notify the GMC of any individual who has obtained consent without the authorisation to do so is available at http://www.gmc-uk.org/education

6.4 Nurse Consent in Endoscopy

Registered nurses of Band 5 or above working in endoscopy who have been trained and assessed are able to take consent from a patient. Consent can only be taken for *DIAGNOSTIC* Gastroscopy, therapeutic flexible Sigmoidoscopy and Colonoscopy procedures, including polypectomy where the polyps do not fit the criteria for the large polyp protocol, argon coagulation and banding of haemorrhoids.

A minimum of 6 months endoscopy experience is essential before participating in this process if the Nurse is not newly qualified.

The Nurse will be educated in the consent process by the Colorectal Nurse Endoscopy training Lead, and then thoroughly assessed using Trust Consent package.
Consent will be gained by the nurse during the admissions process prior to the procedure.

The consent form is counter signed by the Endoscopist performing the procedure.

Supported by the Joint Advisory Group (JAG) and GRS standards for endoscopy.

Please see Appendix 6 for the endoscopy nurse consent package.

7 MENTAL CAPACITY

Also see: Mental Capacity Act 2005 Policy and Guidance including Deprivation of Liberty Safeguards (DoLS) - PAT/PA 19

The Mental Capacity Act 2005 (MCA), which came into force on 1st October 2007, sets out a statutory framework for making treatment decisions for people who lack the capacity to make such decisions themselves. The Act establishes overarching statutory principles governing these decisions, setting out who can make them and when. It sets out the legal requirements for assessing whether or not a person lacks the capacity to make a decision.

Where a person lacks the capacity to make a decision for themselves, any decision must be made in that person's best interests. The Mental Capacity Act introduced a duty on NHS bodies to instruct an independent mental capacity advocate (IMCA) in serious medical treatment decisions when a person who lacks the capacity to make a decision has no one who can speak for them, other than paid staff. The Act allows people to plan ahead for a time when they may not have the capacity to make their own decisions: it allows them to appoint a personal welfare attorney to make health and social care decisions, including medical treatment, on their behalf or to make an advance decision to refuse medical treatment.

7.1 Assessing Capacity

Staff should always start from the assumption that the person has capacity to make the decision in question. Under the Act staff will be required to make an assessment of capacity before carrying out any care or treatment. The more serious the decision, the more formal the assessment of capacity will need to be.

7.2 When Should Capacity be Assessed?

It is important to remember that lack of capacity may not be a permanent condition.

Assessments of capacity therefore should be time and decision specific, which means that:

- the assessment of capacity must be about the particular decision that has to be made at a particular time and is not about a range of decisions
- if someone cannot make complex decisions this does not mean that they cannot make simple decisions. For example, it is possible that someone with learning disabilities could make decisions about what to wear or eat but not about whether or not they need to live in a care home.

Staff cannot decide that someone lacks capacity based upon their age, appearance, condition or behaviour alone.

Staff must involve family, friends and/or carers or an Independent Mental Capacity Advocate (IMCA) if one has been appointed in making an assessment of capacity. This will depend on the situation and the decision that needs to be made.

7.3 Who Should Assess Capacity?

The person who wishes to make a decision on behalf of an incapacitated person is responsible for assessing his or her capacity. Where consent to medical treatment is required, the health professional proposing the treatment needs to decide whether the patient has the capacity to consent. The reasons why capacity is in doubt should be recorded in the medical record, as should details of the assessment process and its findings.

7.4 How do you access capacity?

Although the Act contains a single clear test for assessing whether a person lacks capacity to take a particular decision at a particular time, the reality of clinical practice is always likely to be slightly more complex. The Act nevertheless makes use of a ‘functional’ test of capacity, adapted from the common law, which focuses on the decision-making process itself. Under the Act, a person is regarded as being unable to make a decision if, at the time the decision needs to be made, he or she fails:

- To understand the information relevant to the decision
- To retain the information relevant to the decision
- To use or weigh the information, or
- To communicate the decision (by any means)

Where an individual fails one or more parts of this test, then they do not have the relevant capacity and the entire test is failed. Clearly difficult judgements will still need to be made, particularly where there is fluctuating capacity or where some capacity is demonstrable but its extent is uncertain.

This four stage test is nevertheless well established, and more detailed advice on practical procedures for assessing capacity is available from other sources. The Act requires that any decision that a person lacks capacity must be based on a 'reasonable belief' backed by objective reasons. Where there are disputes about whether a person lacks capacity that cannot be resolved using more informal methods, the Court of Protection can be asked for a judgement.

An Assessment of Capacity Form and prompt sheet is available in the Policy on Mental Capacity.

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 assessments of capacity, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient's situation prevents this.

A patient's capacity to understand may be temporarily affected by factors such as confusion, panic, shock, fatigue, pain or medication. However the existence of such factors should not be assumed automatically to render the patient incapable of consenting.

Staff should be able to show in the records why they have come to the conclusion that the person lacks capacity to make the particular decision.

7.5 Best interests

If a person has been assessed as lacking capacity then any action taken, or any decision made for, or on behalf of that person, must be made in his or her best interests.

The person who has to make the decision is known as the 'decision-maker' and normally will be the carer responsible for the day to day care, or a professional such as a doctor, nurse or social worker where decisions about treatment, care arrangements or accommodation have to be made.

A best interest decision must be recorded on the Best Interest Form (available in the Policy on Mental Capacity).

7.6 Form 4

Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented in Form 4 (form for adults who are unable to consent to investigation or treatment), along with the assessment of the patient's capacity, why the health professional believes the treatment to be in the patient's best interests, and the involvement of people close to the patient. For more minor interventions, this information should be entered in the patient's notes.

7.7 The Independent Mental Capacity Advocate

In cases where the patient lacks capacity and requires serious medical treatment the Trust is under a duty to appoint an Independent Mental Capacity Advocate (IMCA). The IMCA will be responsible for bringing to the attention of the professional any relevant information, challenge any decision previously made in the best interests of the patient.

7.8 Lasting Powers of Attorney / Advance Decisions / Advanced Directives

The Mental Capacity Act introduced a new form of power of attorney (from October 2007), which will allow people over the age of 18 to formally appoint one or more people to look after their health, welfare and/or financial decisions, if at some time in the future they lack the capacity to make these decisions for themselves.

The Mental Capacity Act 2005 brought in a new system of Lasting Powers of Attorney (Replacing Enduring Powers of Attorney). A Lasting Power of Attorney (LPA) will give one or more people the power to make decisions about a patient's personal welfare, including medical treatment, if the patient does not have the mental capacity to make the decision.

The Mental Capacity Act 2005 gives patients in England and Wales a statutory right to refuse treatment through the use of an Advance Decision. An Advance Decision allows a patient with capacity of at least 18 years of age, to refuse specified medical treatment at some future time when they may lack capacity.

8 CHILDREN AND YOUNG PEOPLE

8.1 Children Under 16 – the concept of "Gillick competence"

Following the case of *Gillick v West Norfolk and Wisbech AHA* [1986], the courts have held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will have the capacity to consent to that intervention. This is sometimes described as being "*Gillick* competent" and may apply to consent for treatment, research or tissue donation. As the understanding required for different interventions will vary considerably, child under 16 may therefore

have the capacity to consent to some interventions but not others. Children under 16 can consent to medical treatment if they understand what is being proposed. It is up to the doctor to decide whether the child has the maturity and intelligence to fully understand the nature of the treatment, the options, the risks involved and the benefits.

As with adults, assumptions that a child with a learning disability may not be able to understand the issues should never be made automatically.

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. However where the decision will have on-going implications, such as long-term use of contraception, it is good practice to encourage the child to inform his or her parents unless it would clearly not be in the child's best interests to do so.

8.2 Young People Aged 16 – 17

Young people aged 16 or 17 are entitled to consent 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 patient capable of consenting to the particular intervention.

However, unlike adults, the refusal of a competent person aged 16-17 may in certain circumstances be over-ridden by either a person with parental responsibility or a court.

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 the requirements for valid consent are met, it is not legally necessary to obtain consent from a person with parental responsibility for the young person in addition to that of the young person. It is, however, good practice to involve the young person's family in the decision making process, unless the young person specifically wishes to exclude them.

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

- the child's mother
- the child's father, if he was married to the mother at the time of birth
- unmarried fathers, can acquire parental responsibility in several different ways:

For children born **before 1 December 2003**, unmarried fathers will have parental responsibility if they: marry the mother of their child or obtain a parental responsibility order from the court, register a parental responsibility agreement with the court or by an application to court

For children born **after 1 December 2003**, unmarried fathers will have parental responsibility if they:

register the child's birth jointly with the mother at the time of birth, re-register the birth if they are the natural father, marry the mother of their child or obtain a parental responsibility order from the court , register with the court for parental responsibility

- the child's legally appointed guardian
- a person in whose favour the court has made a residence order concerning the child
- a Local Authority (LA) designated in a care order in respect of the child
- a Local Authority (LA) or other authorised person who holds an emergency protection order in respect of the child.

8.3 Child or young person with capacity refusing treatment

Where a competent child or young person of 16 or 17 refuses treatment, such a refusal can be over-ruled either by a person with parental responsibility for the child or by the court.

If more than one person has parental responsibility for the young person, consent by any one such person is sufficient, irrespective of the refusal of any other individual. This power to over-rule must be exercised on the basis that the welfare of the child/young person is paramount.

9 EMERGENCIES

In emergencies, it will often be in a person's best interests for urgent treatment to be provided without delay. The two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Where the consequences of having, or not having, the treatments are potentially serious, a court declaration may be sought.

In the case of children, an emergency protection order (EPO), can be applied for otherwise a care order should be sought. Although an EPO gives the Local Authority parental responsibility it can only be exercised as is reasonably required to safeguard the welfare of the child.

If a life threatening emergency arise when consultation with either a person with parental responsibility or the court is impossible, or the persons with parental responsibility refuse 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.

10 REFUSAL/WITHDRAWAL OF TREATMENT

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

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

Where a patient has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

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

If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment (whether contemporaneously or in advance), this decision **must** be respected, except in certain circumstances as defined by the Mental Health Act.

This is the case even where this may result in the death of the person (and/or the death of an unborn child, whatever the stage of the pregnancy)

A person with capacity is entitled to withdraw consent at any time, including during the performance of a procedure. Where a person does object during treatment, it is good practice for the practitioner, if at all possible, to stop the procedure, establish the person's concerns and explain the consequences of not completing the procedure. At times, an apparent objection may in fact be a cry of pain rather than withdrawal of consent, and appropriate reassurance may enable the practitioner to continue with the person's consent. If stopping the procedure at that point would genuinely put the life of the person at risk, the practitioner may be entitled to continue until that risk no longer applies. Assessing capacity during a procedure may be difficult and, as noted above, factors such as pain, panic and shock may diminish capacity to consent. The practitioner should try to establish whether at that time the person has capacity to withdraw a previously given consent. If capacity is lacking, it may sometimes be justified to continue in the person's best interests but this should not be used as an excuse to ignore distress.

11 ADVANCE DECISIONS

A person may have made an advance decision to refuse particular treatment in anticipation of future incapacity (sometimes previously referred to as a 'living will' or 'advance directive'). A valid and applicable advance decision to refuse treatment has the same force as a contemporaneous decision to refuse treatment. This is a well-established rule of common law, and the Mental Capacity Act 2005 now puts advance decisions on a statutory basis. The Act sets out the requirements that such a decision must meet to be valid and applicable. Further details are available in chapter 9 of the Mental Capacity Act (2005) Code of Practice, but in summary these are:

- the person must be 18 or over
- the person must have the capacity to make such a decision
- the person must make clear which treatments they are refusing
- if the advance decision refuses life-sustaining treatment, it must be in writing (it can be written by someone else or recorded in healthcare notes), it must be signed and witnessed and it must state clearly that the decision applies even if life is at risk
- a person with capacity can withdraw their advance decision at any time.

Healthcare professionals **must follow** an advance decision if it is valid and applicable, even if it may result in the person's death. If they do not, they could face criminal prosecution or civil liability. The Mental Capacity Act 2005 protects a health professional from liability for treating or continuing to treat a person in the person's best interests if they are not satisfied that an advance decision exists which is valid and applicable. The Act also protects healthcare professionals from liability for the consequences of withholding or withdrawing a treatment if at the time they reasonably believe that there is a valid and applicable advance decision. If there is genuine doubt or disagreement about an advance decision's existence, validity or applicability, the case should be referred to the Court of Protection.

While a decision is awaited from the courts, healthcare professionals can provide life sustaining treatment or treatment to stop a serious deterioration in the patient's condition.

12 HUMAN TISSUE ACT (HTA)

The Human Tissue Act 2004 sets out a legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead. The Act also established the Human Tissue Authority (HTA) as a regulatory body for all matters concerning the removal, storage, use and disposal of human tissue for scheduled purposes. The Human Tissue Authority has issued codes of practice which are available on the HTA website:
https://www.hta.gov.uk/guidance-professionals/codes-practice

The statutory requirements for consent are as follows:

12.1 Tissue from the living

Consent for treatment and examination including removal is a common-law matter dealt with in the Department of Health's *Reference Guide to Consent for Examination and Treatment.* Organs, tissues and bodily fluids from living patients (including surgical biopsy and resection specimens) do not fall under the terms of the Human Tissue Act 2004 if the primary purpose for removing and storing the material is for diagnosis.

Consent from the living **is needed** for storage and use of tissue for obtaining scientific or medical information which may be relevant to any other person now or in the future, research (but see exceptions below), public display and transplantation.

Consent from the living **is not needed** for storage and use of tissue for: Clinical audit, educational training, performance assessment, public health monitoring and research where.

i) the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come; and
ii) the material is used for a specific research project with ethical approval.

Data about the tissue does not have to be permanently or irrevocably unlinked, and may be pseudonymised where, for example, a system of coding is used.

There may be occasions when a clinician involved in research may also have access to a secure database that would permit identification of a sample used in research and the identity of the patient whose material is being used. Providing the research material is not identifiable to the researcher (e.g. coded by a laboratory accession number) and the researcher does not seek to link the sample to the patient, it will still be regarded as non-identifiable and the research will be permissible without consent if it is given ethical approval by a recognised research ethics committee.

At present, this Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedures to be used for educational or research purposes. If the patient expresses a wish for samples ***not*** to be available for use then **the clinician must inform the laboratory direct** for pathology to action. Further guidance on the use of clinical samples retained in the pathology laboratory can be obtained from the Royal College of Pathologists.

12.2 Post mortem samples (adults)

Obtaining consent for a hospital (voluntary) autopsy should involve a team approach. The team should comprise a member of the bereavement staff, a member (preferably senior) of the clinical team involved in the care of the deceased and the pathologist who will be carrying out the examination.

The clinician and pathologist should preferably meet prior to seeing the relatives and discuss what the requirements of the autopsy are from the clinician's viewpoint, that is, what questions do they want answered. The pathologist can then give advice on what autopsy procedures would be ideally required to achieve this.

There can then be an informed discussion with the relatives and bereavement staff in attendance, as to what type of examination is envisaged and what specimens may be required. They can then be guided through the consent process to make their decisions having been fully informed of all the options.

Please note that qualifying relationships for consent as described in the Human Tissue Act (2004) – is as follows (highest first).

a) Spouse or partner (including civil or same sex partner). The HT act states that for these purposes, a person is another person's partner if the two of them live as partners in an enduring family relationship.
b) Parent or child (child may be of any age but must be competent if under the age of 18 and means a biological or adopted child)
c) Brother or sister
d) Grandparent or grandchild
e) Niece or nephew
f) Stepfather or stepmother
g) Half-brother or half sister
h) Friend of long standing

The Trust currently uses the following Trust documents: WPR32771 Consent for Voluntary Post Mortem examination on an adult (the consent form) and the explanatory leaflet - WPR32780 A simple guide to the post mortem examination procedure. Health professionals taking consent will need to have undertaken a short teaching session on the possible uses of surplus pathological tissue/samples. Information/paperwork containing details of the relative's consent or objection should on all occasions be filed in the patients clinical records, with copies sent to Pathology/Medical Photography/X-ray department as is relevant. A copy of the form is also provided to the relatives and there is a 24 hour period during which they have the right to change their mind.

It is the responsibility of the bereavement staff to ensure that all copies of the consent form are forwarded to the relevant people.

Consent **is required** for removal, storage and use of tissue for the following scheduled purposes:

a) After a Coroner's post mortem, for material no longer required to be kept for the Coroner's purposes.
b) Anatomical examination, to determine the cause of death, and establishing after a person's death the effects of any drug or other treatments administered to them.

c) To obtain scientific or medical information, public display, research, transplantation, clinical audit, educational training, performance assessment, public health monitoring and quality assurance.

Families should be made aware that scanning Post Mortem (digital autopsy) procedure is available privately offered by iGENE Sheffield. http://digitalautopsy.co.uk/contact/

Consent **is not** needed for:

a) Carrying out investigation into the cause of death under the authority of the Coroner.

b) Keeping material after post mortem under the authority of a Coroner for as long as the Coroner requires it.

c) Keeping material in connection with a criminal investigation or following a criminal conviction.

See **Appendix 5** for more details.

12.3 Pregnancy loss samples

The Trust has a separate policy for the sensitive disposal of non-viable foetus/products of conception and stillbirths. This policy adheres to the following national guidelines: The Royal College of Obstetricians and Gynaecologists Good Practice Guideline 5 *Disposal following pregnancy loss before 24 weeks gestation* January 2005 and also The Stillbirth and Neonatal Death Society (SANDS) G*uidelines for Professionals – Pregnancy Loss and the Death of a Baby* 2007. At this time, it was recommended that all identifiable bodies of foetuses should be respectfully disposed of by cremation or burial. Foetal tissues and products of conception without an identifiable foetus could be incinerated, provided the parents are aware of all options available to them.

In 2015 the HTA issued *Guidance on the disposal of pregnancy remains following pregnancy loss or termination*. This states that all pregnancy loss under 24 weeks gestation should be respectfully disposed by burial or cremation regardless if discernible fetal remains are present or not.

An information leaflet, *Information for Parents Following a Pregnancy Loss under 24 Weeks Gestation* should be given to parents, which explains what disposal options are available to them.

The Trust has a single consent form for disposal of a pregnancy loss less than 24 weeks gestation. Completion of this consent form is required for all products of conception (including miscarriages, ectopic pregnancies, termination of pregnancies and evacuation of retained products only where no live birth has occurred) and should accompany the specimen to the laboratory/mortuary.

In addition a Maternity certificate from the doctor or registered midwife should be completed to confirm that no visible signs of life were present after birth. This should also accompany the specimen to the laboratory/mortuary.

All staff requesting consent for burial or cremation should access training on these issues, which is available from the Bereavement Support Midwife at a dedicated multi-disciplinary study day or on the wards as an individual short training session. A Trust Bereavement Support Midwife is available to:

- Support staff obtaining consent
- Provide information and support to patients
- To discuss the service offered in a greater depth on an individual basis.
- Provide information, support and practical assistance to patients arranging a private funeral service.

12.4 Post Mortem Samples (Paediatric/neonatal)

A separate paediatric consent form has been introduced by Sheffield Children's Hospitals who currently perform all paediatric post mortems and are available from the PALS office.

12.5 Research

The Pathology department has a policy of not releasing tissue to outside laboratories for research use unless a signed copy of informed consent is provided. The consent forms are kept on file in the department.

12.6 Public Health Surveillance

Explicit consent is not necessary for public health surveillance using an unlinked anonymous method. Any patient considered for a prospective public health surveillance survey, even if the unlinked anonymous method is used, must be given full information about the survey and must be given the choice of refusing to participate and their refusal must be registered on the pathology request form. For any retrospective public health surveillance study, each patient should be contacted, given information and their consent or objection noted in their hospital medical records and in the Pathology department.

12.7 Quality Assurance

Tissue samples may be used for quality assurance purposes without requiring specific patient consent *provided* we actively document in the patients records the information provided to 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. The Trust in most instances anonymises tissue

samples used for quality assurance. If pseudonymised, the tissue will be given a code, which is known to one senior member of laboratory staff only. It is preferred that patient's do not opt-out of this tissue use as it is essential to maintain reliable and reproducible results.

12.8 HTA Codes of Practice

The HTA has issued a Code of Practice Code : Guiding principles and the fundamental principle of consent published April 2017, which sets out the statutory requirements for consent, and related matters and these can be accessed online www.hta.gov.uk. In addition, guidance on consent to post mortem examination has been produced by the pathology department for doctors in training and is incorporated within the junior doctor's handbook. See Appendix 5. This is also covered in a lecture to each new intake of trainees.

The repercussions of organ retention from post mortem examination without the consent and knowledge of families have been considerable. The Post Mortem examination Code of Practice & Standards (published April 2017) supersedes the Department of Health Guidance *Families and Post Mortems – a Code of Practice* (and related information leaflets and forms). The HTA code sets out recommended practice of all those who communicate with relatives of children and adults who may undergo or have undergone a post mortem examination (whether or not ordered by the Coroner). This also includes communication after pregnancy loss.

The Human Tissue Authority has issued other codes of practice which are available on the HTA website: http://www.hta.gov.uk/guidance/codes_of_practice.cfm

13 CLINICAL PHOTOGRAPHY AND CONVENTIONAL OR DIGITAL VIDEO RECORDINGS

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

- It is essential that when considering the issue of Clinical photography and conventional or digital video recordings, that detailed consideration is given to the Trust's policy PAT/PA 14 **"Photography and Video Policy: to Govern Clinical and Non-clinical Recordings"** and that the taking of any video, pictures, etc, comply in full with this policy.

- Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 4 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the

possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

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

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

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

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

14 TRAINING

Please note: The training requirements of staff will be identified through a learning needs analysis (LNA). Role specific education will be co-ordinated/ delivered by the topic lead. Alternatively, training may be accessed via an approved e-learning platform where available.

See The Trust's Statutory and Essential Training (SET) Policy - CORP/EMP 29 training needs analysis minimum data set gives details of the levels of training required and available for particular groups of staff.

The responsibility for training on consent, in terms of the law, specific consent issues and specific procedures used in the Trust will rest with each individual Clinical Division. The Clinical Governance Lead for each Clinical Division will be accountable to ensure that appropriate training on consent in all areas is disseminated to all relevant staff.

15 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

The Clinical Director (or delegated person e.g. Clinical governance lead) of each Clinical Division will monitor compliance with this policy on a 6 monthly basis as per the chart below. The results will be noted at the local clinical governance group and noted in the minutes. Any non-compliance will be addressed with the individual immediately by the Clinical Director of the Clinical Division.

The Head of Patient Safety and Experience will monitor adverse incident reports and concerns relating to consent issues and these will be reported at the Clinical Governance Standards Committee, and all Dat0ix incidences about consent will be directed to the Head of Patient safety and Experience. Individuals taking consent without the authority to do so will be investigated by their immediate manager and disciplinary action will be taken as indicated.

A minimum of 10 consent forms to be reviewed 6 monthly (April and September) against the following criteria				
Criteria	**Who**	**How**	**Frequency**	**Where**
Process of obtaining consent	Clinical Director (or delegated other)	Review of completed consent form	6 monthly	Local clinical governance group
Provision of information	Clinical Director (or delegated other)	Review of completed consent form	6 monthly	Local clinical governance group
Documentation of information given	Clinical Director (or delegated other)	Review of completed consent form	6 monthly	Local clinical governance group
Documentation of consent	Clinical Director (or delegated other)	Review of completed consent form	6 monthly	Local clinical governance group
Archiving of patient information	Clinical Director (or delegated other)	Review of completed consent form and archiving of patient info system	6 monthly	Local clinical governance group

16 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. **(See Appendix 7).**

17 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Mental Capacity Act 2005 Policy and Procedure, including Deprivation of Liberty Safeguards (DoLS) - PAT/PA 19 and the Privacy and Dignity Policy - PAT/PA 28.

Advance Decision to Refuse Treatment (ADRT) Policy – PAT/PA 27

Photography and Video Policy: to Govern Clinical and Non-clinical Recordings - PAT/PA 14

Developing Information for Service Users Policy and Guidelines - CORP/COMM 5

Unlicensed Medicines Policy - PAT/MM 4

Approved Procedural Documents (APDs) – Development and Management Policy – CORP/COMM 1

Fair Treatment for All Policy – CORP/EMP 4

Equality Analysis Policy – CORP/EMP 27

Statutory and Essential Training (SET) Policy - CORP/EMP 29

Interpretation and Translation Servces Policy - PAT/PA 34

18 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

19 REFERENCES

Consent: Supported Decision-Making - a good practice guide https://www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/consent-good-practice-guide/

Daniel K Sokol: Update on the UK law on consent. *BMJ* 2015; 350:h1481

HTA guidance on the disposal of pregnancy remains following pregnancy loss or termination (March 2015) https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf

Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) (March 2015) https://www.supremecourt.uk/decided-cases/docs/UKSC_2013_0136_Judgment.pdf

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Department of Health., (2001) *Seeking consent: working with children* Available from http://dera.ioe.ac.uk/9286/

Guidance on the use of clinical samples retained in the pathology laboratory. The Royal College of Pathologists. 2007. www.rcpath.org

The Royal College of Obstetricians and Gynaecologists Good Practice Guideline 5 *Disposal following pregnancy loss before 24 weeks gestation* January 2005

The Stillbirth and Neonatal Death Society (SANDS) G*uidelines for Professionals – Pregnancy Loss and the Death of a Baby* 2007.

NPSA Incident decision Tree (2004) Available from http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900

Department of Constitutional Affairs Mental Capacity Act (2005): Code of Practice, 2007 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf

APPENDIX 1 – 12 KEY POINTS ON CONSENT: THE LAW IN ENGLAND

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.

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

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

4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent **cannot** over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent?

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

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much

information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

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

Refusal of treatment

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

Adults who are not competent to give consent

11. **No-one** can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

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

APPENDIX 2 – USEFUL CONTACT DETAILS

Contact	Extension Number
Medical Director	642150
Lead Nurse – Patient Safety & Quality	642277/642274
Legal Team	642272
Clinical Governance Coordinator	644072

Contact details for Clinical Governance Leads: Available on Trust intranet.

APPENDIX 3 – COURT DECISIONS AND DECLARATIONS

Court decisions and declarations – when are they required, and how can they be obtained?

Circumstances occasionally arise when it is either necessary or desirable to seek an order from the Court about a proposed course of treatment, or a decision to withhold treatment.

An adult patient with sufficient mental capacity can consent to treatment, or refuse it, even if this will lead to injury or death. However, they cannot insist on a treatment that the clinician feels is inappropriate. In most circumstances, when an adult patient lacks capacity nobody else can consent on their behalf, and they must be treated in accordance with their best interests **(see section 10 of the Mental Capacity Act 2005 – Policy and Guidance, including Deprivation of Liberty Safeguards (DoLS) - PAT/PA 19 and Chapter 5 pages 64-88 of the MCA Code of Practice.**

However the Mental Capacity Act (MCA) allows patients to use a Lasting Power of Attorney (LPA) to appoint a proxy to make specified welfare decisions for them should they subsequently lose capacity. There must be rigorous compliance with formalities including registering the documents with the Office of the Public Guardian, who keep a register that can be accessed by health care professionals. The proxy must act in the best interests of the patient. Further information can be found in chapter 7 of the MCA Code of Practice.

When a patient lacks sufficient mental capacity to reach a particular decision, in order to assist the treating clinician in determining what course of action is in their best interests, appropriate family or friends must be consulted. Where a patient lacking capacity has no friends or family to consult, and time allows, an Independent Mental Capacity Advocate (IMCA) must be appointed to ensure that the patient's interests are fully considered. For further information about the IMCA service or to make a referral contact the IMCA hotline 0845 650 0081.

Those with parental responsibility can consent to or refuse treatment on behalf of a child under 18, although they too must act in the best interests of the child.

Adult cases are now dealt with by the Court of Protection which has the power to make declarations as to a patient's capacity and best interests, appoint somebody (known as a deputy) to make welfare decisions, or declare that a past or proposed course of treatment is lawful. The Official Solicitor may become involved to look after the patient's interests at the hearing. For children, applications are made to the Family Division of the High Court.

In addition to declaring that proposed treatment is lawful, the child can be made a ward of court, which allows the court itself to take treatment decisions. The Children and Family Court Advisory and Support Service (CAFCASS) often become involved on the child's behalf.

There are few hard and fast rules to guide when a court declaration should be sought. The most common circumstances are where there are uncertainties as to whether a patient has sufficient mental capacity to refuse treatment that the treating clinicians believe it is clearly in his best interests; or where there is an irresolvable disagreement between the clinicians and those close to an incapacitated patient, about whether a proposed treatment or its withdrawal is in the patient's best interests.

The withholding or withdrawal of artificial hydration and nutrition can be a particularly difficult area. The situation is complicated for pregnant women as under English law an unborn baby has no legal rights, so it is the mother's mental capacity and best interests that must be considered – legal advice should always be sought in these circumstances. The possibility of making an application should be considered in the following circumstances, although this list is not exhaustive:

- There is a real doubt as to the patient's capacity to consent/refuse and a significant decision must be taken.

- The patient lacks capacity but will not cooperate with treatment that is in his best interests.

- The patient lacks capacity and there is real doubt, or conflict within the therapeutic team, as to what treatment is in his best interests.

- The patient lacks capacity, treatment or its withholding is felt to be in his best interests, but those closest to him disagree.

- There is conflict between those with parental responsibility, and the therapeutic team, over what is in a child's best interest (e.g. Jehovah's Witnesses refusing to allow their child to receive an essential blood transfusion).

- There is conflict between a child and those with parental responsibility as to best interests.

- The proposed treatment will render a patient who lacks capacity infertile, or result in a termination of pregnancy.

An application to court **must** be made if:

- The primary purpose of the treatment is to sterilize an incapacitated patient.

- It is proposed that artificial hydration/nutrition is withdrawn from a patient in a permanent vegetative state.

Most cases turn on their peculiar facts, and legal advice should be sought on each occasion. Often it will ultimately be concluded that an application to court is not necessary. In many circumstances a court declaration merely gives advanced clearance, by confirming the lawfulness of a proposed course of action. The court will never direct a clinician to undertake an unconscionable act.

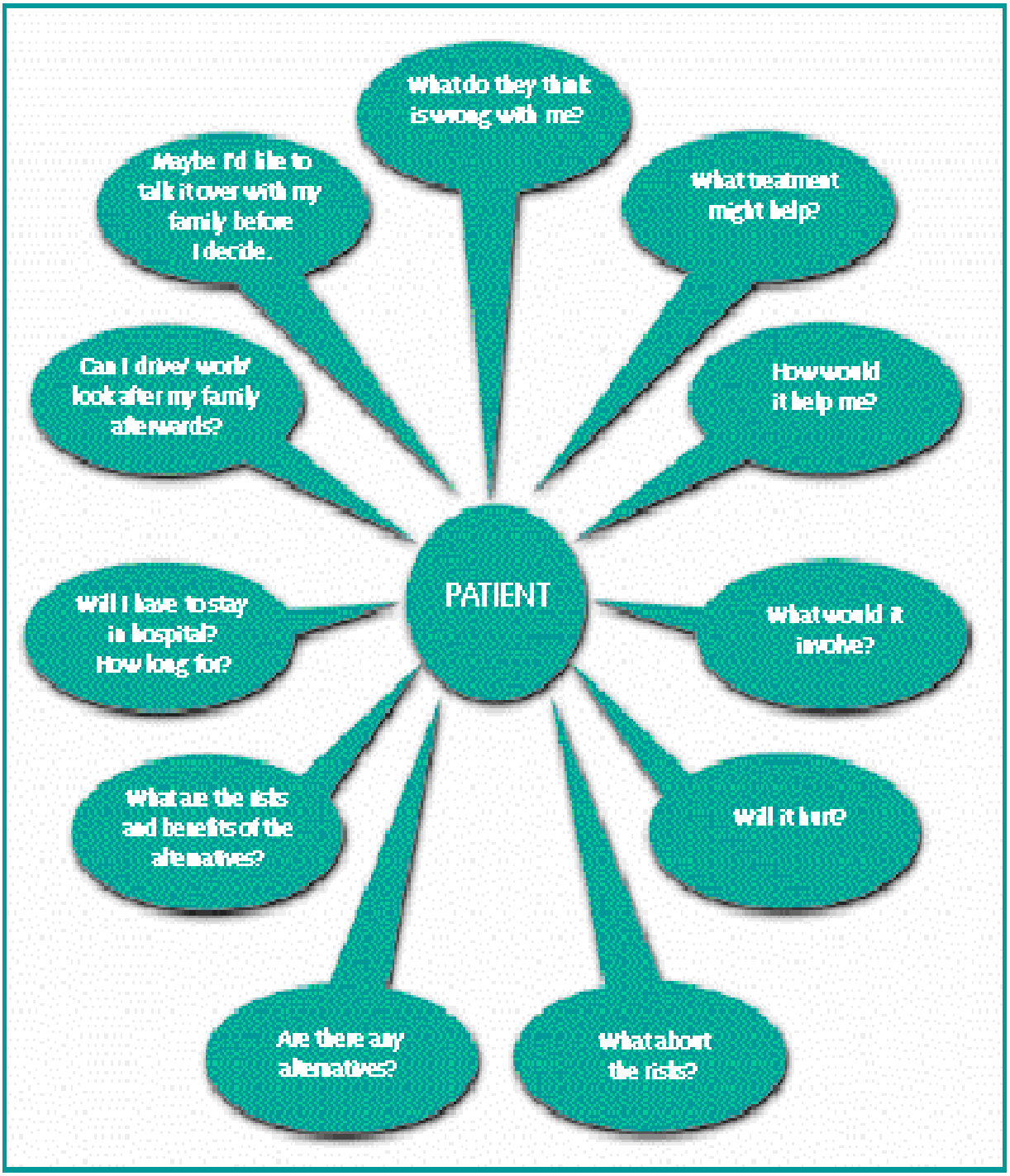
Whilst in an emergency it is possible to obtain a court declaration within a few hours, potential problems should be anticipated and legal advice obtained at an early stage. Where the primary problem is a difference of opinion between carers and relatives, rather than real doubt as to the patient's mental capacity or what is in their best interests, it is often possible to resolve the situation through discussion, the obtaining of second (or more) opinions, or mediation. Obviously this has a greater prospect of success if embarked upon early. Senior clinicians should be involved.

How to obtain legal advice
Trust's Legal Team Extension: 642272

Emergencies
In an **emergency situation**, when there is a real prospect of death or injury resulting from the delay whilst legal advice is obtained, in the first instance clinicians should act in accordance with their own judgement as to mental capacity and best interests. Unless it is unequivocally clear that the patient is an adult with full mental capacity who is refusing treatment, clinicians should act in the patient's best interests and **do what is necessary to save life, or avoid serious injury.**

APPENDIX 4 – SEEKING CONSENT

Seeking Consent: Rembering the Patient's Perspetive



APPENDIX 5 – CONSENT TO A POST MORTEM EXAMINATION (ADULTS)

Post mortem examination is important for informing relatives, clinicians and legal authorities about the cause of death. It can also inform bereaved relatives about possible acquired or genetic diseases which may need treatment and care. Post mortem examination may lead to improvements in clinical care, maintenance of clinical standards, increase our understanding of disease and prevent the spread of infectious diseases and may contribute to research and training.

The Trust currently uses the following Trust documents: WPR32271 Consent for Voluntary Post Mortem examination on an adult (the consent form) and the explanatory leaflet - WPR32780 - A simple guide to the post mortem examination procedure. Health professionals taking consent will need to have undertaken a short teaching session on the possible uses of surplus pathological tissue/ samples. Information/ paperwork containing details of the relative's consent or objection should on all occasions be filed in the patients clinical records, with copies sent to Pathology/ Medical Photography/ X-ray department as is relevant. A copy of the form is also provided to the relatives and there is a 24 hour period during which they have the right to change their mind.

It is the responsibility of the bereavement staff to ensure that all copies of the consent form are forwarded to the relevant people.

Bereaved people should be treated with respect and sensitivity at all times, both to help them take important decisions at a difficult time and to ensure continuing improvements in care.

A post mortem examination may take place either because the Coroner (medical/legal autopsy) considers it necessary or because it has been agreed upon by the deceased person or their relatives (voluntary/consent autopsy).

Consent is not required for the carrying out of a Coroner's post mortem. Consent is however required for the removal, storage and use of human tissue or organs (see below). Voluntary post mortems require informed consent.

The Human Tissue Act 2004 sets out a legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead. The Act also established the Human Tissue Authority (HTA) as a regulatory body for all matters concerning the removal, storage, use and disposal of human tissue for scheduled purposes. The Human Tissue Authority has issued codes of practice which are available on the HTA website: https://www.hta.gov.uk/guidance-professionals/codes-practice

Consent **is required** for removal, storage and use of tissue for the following scheduled purposes:

a) After a Coroner's post mortem, for material no longer required to be kept for the Coroner's purposes.

b) Anatomical examination, to determine the cause of death, and establishing after a person's death the effects of any drug or other treatments administered to them.

c) To obtain scientific or medical information, public display, research, transplantation, clinical audit, educational training, performance assessment, public health monitoring and quality assurance.

Consent **is not** needed for:

a) Carrying out investigation into the cause of death under the authority of the Coroner.

b) Keeping material after post mortem under the authority of a Coroner for as long as the Coroner requires it.

c) Keeping material in connection with a criminal investigation or following a criminal conviction.

Discussing the post mortem with the family: who may seek consent?

The way in which a post mortem examination is discussed with the deceased person's relatives or close friends is extremely important. They need to be given honest, clear, objective information; the opportunity to talk to someone they can trust and whom they feel able to ask questions; reasonable time to reach decisions (about a hospital post mortem and about any donation of organs or tissue); privacy for discussion between family members if applicable and support if they need and want it. Only once relatives have had time to reach a decision should they be invited to sign the consent form.

Obtaining consent for a hospital (voluntary) autopsy should involve a team approach. The team should comprise a member of the bereavement staff, a member (preferably senior) of the clinical team involved in the care of the deceased and the pathologist who will be carrying out the examination. Those seeking consent for hospital post mortem examination should be sufficiently senior and well informed, with a firm knowledge of the procedure. They should have been trained in the management of bereavement and know the purpose and procedures of post mortem examinations.

Wherever possible, before the discussion with relatives, the responsible clinician should contact the Pathologist who will perform the post mortem examination. They can give accurate guidance on which if any tissue or organs are likely to be retained, for how long and for what purpose. There can then be an informed discussion with the relatives and bereavement staff in attendance, as to what type of examination is envisaged and what specimens may be required. They can then be guided through the consent process to make their decisions having been fully informed of all the options.

The current Trust consent forms (WPR 322771) should be used as a basis for obtaining informed consent. There are accompanying explanatory leaflets (WPR32780). A simple guide to a hospital post mortem) which should be made available to the relatives. The various options such as limiting the post mortem examination and the consequence of this should be explained to the relatives.

The discussion with the relatives should include a basic explanation of what happens in a post mortem examination; the benefits of a post mortem examination and the questions to be addressed in any particular case. Possible alternatives to a full post mortem examination and any limitations of these alternatives should be explained. Information about tests needed and whether these might cause delays in the process (eg retention of the whole brain) should be explained. Options for what will happen to the body or remains and any organs or tissue removed including tissue blocks and slides should be discussed. The timing of burial or cremation should be established and discussions take place about the uniting of any material with the body for burial or cremation if the relatives so wish. Religious factors, such as the need for quick funerals in the Jewish, Muslim and Hindu faiths should be taken into account. Relatives should be given a copy of the signed consent form and there should be a cooling off period during which relatives may change their mind.

APPENDIX 6 – GUIDELINES FOR REGISTERD NURSES OBTAINING WRITTEN INFORMED CONSENT FOR DIAGNOSTIC ENDOSCOPIC PROCEDURES

Author	Karen Smith Colorectal Nurse Consultant Victoria Kenneth Sister, Endoscopy Unit
First Issue Date	June 2014 Reviewed May 2015
Agreed by	Endoscopy Users Group Endoscopy Sisters Patient Safety Review Group
Target Audience	Endoscopy Staff Nurses

1. Introduction
2. Criteria for nurse led consent in endoscopy
3. Appropriate procedures
4. Situations in which the policy does not apply
5. Required actions for the registered nurse prior to obtaining consent for endoscopic procedures
6. Information to be given to patients prior to consent for endoscopic procedures
7. Risks/complications specific to procedure
8. Training programme for the registered nurse obtaining written consent for endoscopic procedures

    - TRAINING RECORD FOR DIAGNOSTIC GASTROSCOPY
    - ASSESSMENT OF COMPETENCE NURSE CONSENT DIAGNOSTIC GASTROSCOPY
    - TRAINING RECORD FOR FLEXIBLE SIGMOIDOSCOPY AND BASIC THERAPEUTIC PROCEDURES E.G. BANDING OF HAEMORRHOIDS, SIMPLE POLYPECTOMY THAT DOES NOT FIT THE CRITERIA FOR THE LARGE POLYP PROTCOL
    - ASSESSMENT OF COMPETENCE NURSE CONSENT FLEXIBLE SIGMOIDOSCOPY
    - TRAINING RECORD FOR COLONOSCOPY AND BASIC THERAPEUTIC PROCEDURES E.G. BANDING OF HAEMORRHOIDS, SIMPLE POLYPECTOMY THAT DOES NOT FIT THE CRITERIA FOR THE LARGE POLYP PROTCOL
    - ASSESSMENT OF COMPETENCE NURSE CONSENT COLONOSCOPY

1. INTRODUCTION

Consent should be a continuous process, which begins when a patient is informed that they require a procedure prior to their appointment, and should continue throughout the admission process when questions or concerns can be addressed. If the Registered Nurse obtains written consent for endoscopic procedures as an integral part of the admission process within the Endoscopy unit, this helps to ensure that the patient is able to give fully informed written consent for the procedure.

The Registered Nurse will increase the patients understanding of the procedure, using an interpreter if necessary and/or visual or hearing aids. This approach will ensure less confusion, duplication or fragmentation of information as the information can be given by one practitioner who is a permanent member of the Endoscopy team. This facilitates the patients' journey through the unit in a seamless, well-co-ordinated and individualised manner.

The Registered Nurse assesses the patient and provides all the relevant care, information, advice and support in the pre-procedure phase of the process, including ascertaining if the patient has received, read and understood information about the procedure beforehand and if they have any questions in order for them to give written consent. In this manner, the Registered Nurse is involved throughout the patient journey and is able to build a relationship with the individual patient. Consent can then be obtained outside of the procedure room, as required by the Global Rating Scale.

2. CRITERIA FOR NURSE LED CONSENT IN ENDOSCOPY

a) The Registered Nurse will be Band 5 or above with Endoscopy knowledge and clinical experience of the procedures involved.

b) The Registered Nurse will have completed the training and assessment programme for Registered Nurses obtaining consent for endoscopic procedures.

c) The Registered Nurse will have been assessed as competent to obtain consent by a consultant endoscopist or a nurse Endoscopist.

d) The Registered Nurse will adhere to the policy for obtaining consent as laid down by Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust.

e) The Registered Nurse will work within the boundaries of his/her job description, practice under the legal and professional guidelines identified by the Nursing and Midwifery Council and practice in the best interests of patients at all times.

f) The Endoscopist performing the procedure will always counter-sign the consent form prior to performing the procedure.

3. APPROPRIATE PROCEDURES

Registered Nurses obtaining written consent to treatment, are applicable to adult patients being admitted to Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust for:

- Diagnostic Gastroscopy, Flexible Sigmoidoscopy and Colonoscopy.

4. SITUATIONS IN WHICH THE POLICY DOES NOT APPLY:

a) Children under the age of 16 years.

b) Adults without the capacity to retain or recall the information given to them.

c) Patients who do not agree to the Registered Nurse obtaining their written consent.

5. REQUIRED ACTIONS FOR THE REGISTERED NURSE PRIOR TO OBTAINING CONSENT FOR ENDOSCOPIC PROCEDURES

To make sure the Endoscopist has reviewed the patient's notes in order to:

a) Be fully aware of the patient's past medical and surgical history, including previous Endoscopy results where indicated.

b) Ensure that referral for the planned endoscopic procedure is available.

c) Ensure that no contra-indications to the planned procedure are evident.

6. INFORMATION TO BE GIVEN TO PATIENTS PRIOR TO CONSENT FOR ENDOSCOPIC PROCEDURES

a) Ensure the patient received information about the proposed procedure and consent with their appointment, and that they have read and understood that information.

b) Ensure that the patient has had time to read the consent form and understands it's implications.

c) Ensure that the proposed endoscopic procedure is entered on the consent form legibly.

d) Outline the reason for the proposed procedure, in order to diagnose and/or treat.

e) Outline the main risks of endoscopic procedures together with the course of action/treatment that may become necessary due to bleeding and/or perforation, including the possibility of the procedure failing to identify a significant finding.

7. RISKS/COMPLICATIONS SPECIFIC TO PROCEDURE

Gastroscopy

a) Adverse reaction to sedation and topical local anaesthesia

b) Perforation – rare, less than 1:10,000

c) Bleeding – increased risk with those taking anticoagulation therapy

d) Sore throat.

e) Damage to teeth, crowns, and loose teeth.

f) Possibility that the endoscopist fails to identify a significant diagnosis.

Sigmoidoscopy/Colonoscopy

a) Adverse reaction to sedation and/or analgesia.

b) Perforation – 1:1000 or less.

c) Bleeding following biopsy – less than 1:150.

d) Possibility that the endoscopist fails to identify a significant diagnosis.

Other risks and complications are dependent on other co-existing morbidity and therapeutic intervention.

8. TRAINING PROGRAMME FOR THE REGISTERED NURSE OBTAINING WRITTEN CONSENT FOR ENDOSCOPIC PROCEDURES

Prior to participating in the training programme, nurses will be registered and Band 5 or above with Endoscopy knowledge and clinical experience of the procedures involved.

In order for the Registered Nurse to obtain the patients written consent for endoscopic procedures, the nurse must be assessed as being competent in all of the following areas:

a) Must be able to articulate the types of medications used prior to, during and after endoscopic procedures.

b) Must be able to discuss the advantages/disadvantages of having the procedure with/without sedation to enable patient choice.

c) Must have the ability to identify and discuss potential risks and problems with regards to endoscopic procedures.

d) Must be able to describe alternative methods of investigation to emphasise why the procedure is deemed more appropriate.

e) Must be able to assess the patient's ability to comprehend and comply with instructions and information.

f) Must be able to recognise signs of patient anxiety and have to skills to relieve anxiety.

g) Must be able to give clear and unambiguous pre and post procedure instructions.

h) Must be able to support and guide the patient through the process of the procedure.

i) Must be able to adopt information and instructions to cover perceived deficits in patient knowledge.

j) Must be able to ensure that each patient gives fully informed consent.

k) Must be able to document accurately on the consent form.

The Training programme will include:

a) Training on the fundamentals of consent.

b) Training specific to obtaining consent for gastroscopy, sigmoidoscopy, colonoscopy and capsule endoscopy.

c) Reading and understanding of:

i) Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust Policy for Obtaining Consent to Treatment.
ii) Department of Health Guide to Consent for Examination for Treatment (DOH, 2003).
iii) The 12 Key Points for obtaining consent (DOH, 2003).
iv) Nursing and Midwifery Council Code of Professional Conduct (NMC, 2002).

The Assessment process with include:

a) Observation and understanding of the practice of patient sedation.

b) Observation of communication skills.

c) Observation of knowledge and information giving in relation to specific endoscopic procedures i.e. gastroscopy, flexible sigmoidoscopy and colonoscopy.

d) Observation of accurate documentation on the consent form.

NURSE CONSENT TRAINING RECORD
DIAGNOSTIC GASTROSCOPY

Name ……

Assessor ……..

Supervised Practice	Date	Comments	Signature of Observer
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Staff Nurse …….. (Signature) Assessor …….. (Signature)

Staff Nurse …….. (Print Name) Assessor …….. (Signature)

ASSESSMENT OF COMPETENCE
NURSE CONSENT DIAGNOSTIC GASTROSCOPY

Assessment Criteria	Competence Achieved
Identifies the components of valid consent	
Identifies correctly the procedure(s) for which consent is delegated	
Demonstrates the process of obtaining valid consent: • Describes the procedure(s) clearly to the patient • Discuss risks, benefits, alternatives with the patient and ensure they fully understand • Assess the patient's ability to comprehend and comply with the information • Answers any queries or concerns the patient may have • Uses the correct consent form • Legible documentation in black ink • Nursing documentation accurately completed • Overall communication with the patient is in a manner that is appropriate to their level of understanding • Raises any concerns to the consultant or Endoscopist	
Correctly identifies their professional responsibility regarding: • Consent from a patient who has not got capacity • Consent for procedures other than those detailed above • Refusal of consent • Confirm consent • Advice/Support regarding consent problems	
Competence Achieved: I have assessed the participant as competent to obtain consent for the procedure(s) identified. Assessor Signature: Participant Signature: Print Name: Print Name: Designation: Designation: Date of assessment in practice: Date of theory session:	
Competence has not been achieved, and the following action is advised: Assessor Signature: Print Name: Designation: Date:	

On successful completion of the assessment, a copy must be filed in the participants individual file and a copy sent to the Patient Safety Team.

NURSE CONSENT TRAINING RECORD
DIAGNOSTIC FLEXIBLE SIGMOIDOSCOPY

Name ……

Assessor ……..

Supervised Practice	Date	Comments	Signature of Observer
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Staff Nurse …….. (Signature) Assessor …….. (Signature)

Staff Nurse …….. (Print Name) Assessor …….. (Signature)

ASSESSMENT OF COMPETENCE
NURSE CONSENT DIAGNOSTIC FLEXIBLE SIGMOIDOSCOPY

Assessment Criteria	**Competence Achieved**
Identifies the components of valid consent	
Identifies correctly the procedure(s) for which consent is delegated	
Demonstrates the process of obtaining valid consent: • Describes the procedure(s) clearly to the patient • Discuss risks, benefits, alternatives with the patient and ensure they fully understand • Assess the patient's ability to comprehend and comply with the information • Answers any queries or concerns the patient may have • Uses the correct consent form • Legible documentation in black ink • Nursing documentation accurately completed • Overall communication with the patient is in a manner that is appropriate to their level of understanding • Raises any concerns to the consultant or Endoscopist	
Correctly identifies their professional responsibility regarding: • Consent from a patient who has not got capacity • Consent for procedures other than those detailed above • Refusal of consent • Confirm consent • Advice/Support regarding consent problems	
Competence Achieved: I have assessed the participant as competent to obtain consent for the procedure(s) identified. Assessor Signature: Participant Signature: Print Name: Print Name: Designation: Designation: Date of assessment in practice: Date of theory session:	
Competence has not been achieved, and the following action is advised: Assessor Signature: Print Name: Designation: Date:	

On successful completion of the assessment, a copy must be filed in the participants' individual file and a copy sent to the Patient Safety Team.

NURSE CONSENT TRAINING RECORD
DIAGNOSTIC COLONOSCOPY

Name ……

Assessor ……..

Supervised Practice	Date	Comments	Signature of Observer
1			
2			
3			
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7			
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Staff Nurse …….. (Signature) Assessor …….. (Signature)

Staff Nurse …….. (Print Name) Assessor …….. (Signature)

ASSESSMENT OF COMPETENCE
NURSE CONSENT DIAGNOSTIC COLONOSCOPY

Assessment Criteria	**Competence Achieved**
Identifies the components of valid consent	
Identifies correctly the procedure(s) for which consent is delegated	
Demonstrates the process of obtaining valid consent: • Describes the procedure(s) clearly to the patient • Discuss risks, benefits, alternatives with the patient and ensure they fully understand • Assess the patient's ability to comprehend and comply with the information • Answers any queries or concerns the patient may have • Uses the correct consent form • Legible documentation in black ink • Nursing documentation accurately completed • Overall communication with the patient is in a manner that is appropriate to their level of understanding • Raises any concerns to the consultant or Endoscopist	
Correctly identifies their professional responsibility regarding: • Consent from a patient who has not got capacity • Consent for procedures other than those detailed above • Refusal of consent • Confirm consent • Advice/Support regarding consent problems	
Competence Achieved: I have assessed the participant as competent to obtain consent for the procedure(s) identified. Assessor Signature: Participant Signature: Print Name: Print Name: Designation: Designation: Date of assessment in practice: Date of theory session:	
Competence has not been achieved, and the following action is advised: Assessor Signature: Print Name: Designation: Date:	

On successful completion of the assessment, a copy must be filed in the participants' individual file and a copy sent to the Patient Safety Team.

APPENDIX 7 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
PAT/PA 2 v.7 – Consent to Examination or Treatment Policy	Patient Safety	Mr O Olubowale	Existing policy	06/06/2018

1) Who is responsible for this policy? Name of Division/Directorate: **Mr O Olubowale (Specialty Care Group) for Patient Safety Group**

2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes? **Guidance for health professionals consenting patients for procedures and treatment. Patient Safety**

3) Are there any associated objectives? Legislation, targets national expectation, standards: **Update and New rules on consent**

4) What factors contribute or detract from achieving intended outcomes? Non compliance

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] - **No**

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? [any actions to be taken]

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	N	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.

Date for next review:

Checked by: **Ray Cusheri** **Date:**

APPENDIX 8 – GMC UPDATED DECISION MAKING AND CONSENT GUIDANCE - NOVEMBER 2020

https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf

GMC
updated-decision-mal