NHS
Maidstone and Tunbridge Wells
NHS Trust

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Ref: FOI/GS/ID 6364

Please reply to:
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15 July 2021

Freedom of Information Act 2000

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to antiseptic skin preparation prior to invasive surgery.

You asked:
1) Please confirm if Maidstone and Tunbridge Wells NHS Trust follows NICE guidance 125 (Surgical Site Infections: Prevention and Treatment) when carrying out antiseptic skin preparation?
a. If yes, please provide a copy of Maidstone and Tunbridge Wells NHS Trust s most up-to-date surgical site infection prevention protocol.
2) How does Maidstone and Tunbridge Wells NHS Trust communicate the category difference between antiseptic products that are medicines vs biocides and their intended use?
a. Please share any communication materials.
3) Can you please specify which antiseptic skin preparation products are used in Maidstone and Tunbridge Wells NHS Trust s operating theatres for the purposes of prevention of surgical site infections?
4) Does Maidstone and Tunbridge Wells NHS Trust obtain patient consent prior to surgical procedures?
a. If yes, please provide the written material that Maidstone and Tunbridge Wells NHS Trust uses to obtain consent.

Trust response:
1) Yes
1) a. Based upon Trust SSS data, NICE guidance 125 ,CQC, Surgical Site infections QS 2 and other best practice recommendations, a comprehensive action plan which includes pre -operative skin preparation protocols for elective and Trauma orthopaedic patients has been formulated. The action plan and associated SSI data sits within the audit department for monitoring purposes. All resulting actions were discussed and agreed by the 18 Orthopaedic Consultants at CG. Below is an extract from the action plan.

Document Title: ASSESSMENT OF COMPLIANCE WITH NATIONAL RECOMMENDATIONS
Title: HQIP; Surgical Site Infection Surveillance Service (PHE) 2018 - 19(Quality account) Audit ID: 1250/2021

Recommendation **What needs to be done?** *A recommendation may require more than one action to achieve the desired outcome.*	**Action(s) required to implement the recommendation** **How are you going to do it?** *Actions should be SMART stating clearly each task required.*	**Evidence of Implementation** **What evidence will you provide to the clinical audit team to demonstrate that the action has been implemented?**	**Person responsible for leading on the action** **Who is going to do it?** *(Name and grade / job title)*	**Date action to be completed** **When does this need to be done by?**	**Wider Learning** **Who would benefit from the shared learning from this audit?** Team / Service Directorate / Trust	**Outcome for patients / staff** **What impact will this change have on patients and or staff?**	**Level of risk** **Grade each action showing the level of risk if the action is NOT implemented**
PATIENT FACTORS							
1. All elective joint replacement patients to be advised they must have a shower using pre-wash provided, both the evening before and on the morning of admission.	Elective joint replacement patients are given Chlorhexidine pre-wash for use evening before & day of surgery when attending pre-assessment appointment	Pre-assessment documentation supports wash given to patient & instructions on how to use (PGD slip in notes)	Surgical Site Surveillance Nurse	1st January 2020 Completed	Team/Service	Compliance with NICE guideline 1.2.1 (Surgical Site infections: prevention & treatment 2019 & Surgical Site infections QS 2013 – statement 2)	3 - medium
2. All #NoF patients who undergo surgery are helped to have bed bath the day of surgery.	Nursing staff on Orthopaedic wards are to use warmed Clinell Chlorhexidine 2.6% body cloths to prep patients with #NoF	Perioperative care pathway – section on pre-operative decontamination – select 1. Shower last taken 2. Skin cleansing wipes	Surgical Site Surveillance Nurse	1st January 2020 Completed	Team/Service	Patients prepared for surgery in line with best practice guidelines	3 - medium
1. All patients undergoing Orthopaedic prosthetic implant surgery will be appropriately positioned and the operative site prepared whilst in the anaesthetic room. The area is scrubbed with antiseptic solution & isolation drapes applied	T&O Consultants to discuss with each other & with Theatre Matron	Decision discussed, recorded & implemented	T&O Surgeons and Theatre Matron Confirmed by Surgical Site Surveillance Nurse	July 2020 Completed	Team/Service		2 - low

2)
a. At their pre-assessment appointment elective orthopaedic joint replacement patients are given 2 bottles of chlorhexidine pre-wash along with written/pictorial instructions on how to use it the night before and the morning of admission. The same patients are also MRSA/MSSA screened at their pre-assessment and given information leaflets and verbal information on testing positive and decolonisation treatments used. Patients are informed that the treatment to eradicate the organism includes Chlorhexidine body wash for 5 days. The patients are also verbally informed they will be contacted if they test positive and will be asked to come and collect their treatment pack, which includes written/pictorial information on how to use the body wash, nasal ointment & throat wash. This is reiterated in the patient information leaflets they are given.

3) Maidstone and Tunbridge Wells NHS Trust use Chlorhexidine 2 % or Videne (Povidone Iodine) 10% depending on the procedure

4)
a. Yes please see following Policy.

Policy and Procedure for

Consent to Examination or Treatment

Target audience:	All Trust clinical staff'
Author:	Consultant Anaesthetist **Contact details:** Mobile: 07793 150486
Other contributors:	Legal Services Manager Matron for Safeguarding Adults Named Nurse for Safeguarding Children
Executive lead:	Medical Director
Directorate:	Theatres and Critical Care
Specialty:	Anaesthetics
Supersedes:	Policy and Procedure for Consent to Examination or Treatment (Version 5.0: September 2014) Policy and Procedure for Consent to Examination or Treatment (Version 5.1: October 2014) Policy and Procedure for Consent to Examination or Treatment (Version 5.2: January 2019)
Approved by:	Executive Team Meeting, 20th August 2019
Ratified by:	Policy Ratification Committee, 28th August 2019
Review date:	August 2023

Document history

Requirement for document:	• DH reference guide to consent for examination or treatment, July 2009 • General Medical Council (GMC) Consent Guidance (www.gmc-uk.org./ethical-guidance/ethical-guidance-for-doctors/good medical practice) • Montgomery v Lanarkshire 2015 • CQC standards Outcome 2, Fundamental standard 11 (Consent) and Fundamental standard 17 (Good Governance) • NICE: Consent – procedures for which the benefits and risks are uncertain 2003 • Children Act 1989 • Kent Safeguarding Children Procedures 2019 • To assist staff to meet legal and ethical duties to involve patients as much as possible in making decisions about their own health and care. To ensure staff and patients are fully informed as to the process of taking consent. To reduce the rates of litigation associated with the consenting process.
Cross references (external):	1. Department of Health (4 August 2009). Reference guide to Consent for Examination or Treatment 2. The Human Tissue Act 2004 3. Human Tissue Authority 2017 Codes of Practice. Code 1 – Consent. www.hta.gov.uk 4. Human Tissue & Embryology Authority (Oct 2013). Code of Practice 8 – Infertility and Consent. www.hfea.gov.uk/code 5. Mental Health Act 1983 – Code of Practice (2008) 6. Mental Capacity Act 2005 7. Children's Act 1989 8. Human Rights Act 1998 9. The Health and Social Care Act 2008 10. Department of Health. (2001). Consent What You Have a Right to Expect - Children & Young People. London: Department of Health. 11. Department of Health. (2001). Consent: What You Have a Right to Expect - A Guide for Adults. London: Department of Health 12. Department of Health. (2001). Consent: What You Have a Right to Expect - A Guide for Parents. London: Department of Health 13. Department of Health. (2001). Consent: What You Have a Right to Expect - a guide for relatives and carers. London: Department of Health 14. Department of Health. (2001). Good Practice in Consent Implementation Guide. 15. Department of Health. (2001). Reference Guide to Consent for Examination or Treatment. 16. Department of Health. (2001). Seeking Consent: Working with Children. 17. Department of Health. (2001). Seeking Consent: Working with Older People.

	18. Department of Health. (2002). Consent: What You Have a Right to Expect - Taking Blood Specimens. 19. Department of Health. (2003). Toolkit for Producing Patient Information. 20. Department of Health. (2004). Better information, better choices, better health: Putting information at the centre of health. 21. Department of Health. (2009). Information to assist in amending consent forms. 22. Department of Health. (2010). The NHS Constitution: The NHS belongs to us all. 23. General Medical Council. (2008). Consent: Patients and Doctors Making Decisions Together. 24. Nursing and Midwifery Council (NMC). Regulation in Practice (2008) & Midwives Rules and Standards (2012) 25. NHS Executive (2003). Good Practice in Consent - Achieving the NHS Plan Commitment to Patient-centred Consent Practice. 26. Department of Health (2009). Reference Guide to Consent for examination or treatment: Second edition. 27. NICE clinical guideline: Pre-operative tests for elective surgery (CG3) 28. NICE clinical guideline: Intrapartum care: Care of healthy women and their babies during childbirth (CG55) 29. NICE clinical guideline: Caesarean section (CG132) 30. NICE clinical guideline: Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation (CG135) 31. NICE (2003). Consent: Procedures for which the benefits and risks are uncertain 32. Montgomery v Lanarkshire Health Board 2015 33. Human Tissue Authority: Code of Practice – Consent July 2009 (Directive 002/2009)
Associated documents (internal):	• Accessible information policy and procedure [RWF-IMT-IG-POL-1] • Blood Transfusion Policy and Procedure [RWF-OPPPCSS-C-PATH1] • Consent form 7: Excluding blood transfusion [RWF-OWP-APP40] (Appendix 4 of the Policy and Procedure on the Management of Patients who Decline Treatment with Blood Components) • Deprivation of Liberty Safeguards (DoLS) Policy and Procedure [RWF-NUR-NUR-POL-3] • Interpreting and Translation Policy and Procedure [RWF-GQU-GOV-POL-1] • Medical Staff Clinical Supervision Policy and Procedure [RWF-OPPPCS-NC-WF21] • Mental Capacity Act Policy and Procedure [RWF-OPPPCS-C-NUR1] • Patient Information Policy and Procedure, Development & Production of Written [RWF-OPPPCS-NC-CG28] • Policy and Procedure on the Management of Patients who Decline Treatment with Blood Components [RWF-OPPPCSS-C-PATH2] • Safeguarding Children Policy and Procedure [RWF-OPPPCS-C-NUR6]

	• Use of cameras, video and audio recorders (including the use of smart phone and other mobile devices with recording functionality) on Trust premises policy and procedure [RWF-OPPPCS-NC-CG8]

Keywords:	consent	informed consent	advanced decision
	capacity	informed	advance
	permission	decision	Gillick
	expressed consent	withdrawal of consent	competent
	expressed	withdraw	

Version control:		
Issue:	**Description of changes:**	**Date:**
5.0	Reviewed following advice from Trust solicitors; key changes include update of source references, inclusion of reference to Cheshire West (2014), amendment to Consent 4 for people lacking capacity to consent to treatment, amendment to consent form 7 for people refusing treatment with blood or blood products (previously known as Jehovah's Witnesses), updating of monitoring process	September 2014
5.1	Appendix 5I added (consent form 9)	October 2014
5.2	Extension to April 2019 approved by the Chair of the Trust Clinical Governance Committee and Executive Lead for this policy (Medical Director) on 31st January 2019; no amendments made.	January 2019
6.0	Review by solicitors following *Montgomery* case, in conjunction with review of Consent forms in use in the Trust's Directorates; creation of flowcharts, addition of section relating to withdrawal of consent during a procedure. Amended in line with current GMC guidance	August 2019
6.1	Amendment to text in Appendix 1, section 2.0. Some PRC amendments hadn't been addressed by author prior to publication of version 6.0. Corporate Governance Assistant addressed these, published version 6.0 and requested author confirm accuracy or provide feedback; author subsequently identified minor non-material amendment to this section to clarify the monitoring and audit arrangements correctly.	April 2020
6.2	Addition of text to section 12.0, with reference to Consent form 7; PRC Chair confirmed amendment as non-material.	June 2020

Summary for

Policy and Procedure for Consent to Examination or Treatment

Consent is an ongoing process with the consent form being a part of the evidence of the process not the process itself.

Patients have the fundamental right to:

1. Receive sufficient verbal and written information to enable an informed decision to be made
2. Permit or refuse consent to any care or treatment
3. Withdraw consent at any time, even during the procedure

Healthcare professionals must seek consent for procedures; this can be implied, verbal or written.

Written consent must be obtained in the following circumstances:

1. 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 healthcare professionals would describe as 'side-effects' or 'complications')
2. The procedure involves general/regional anaesthesia or sedation
3. Providing clinical care is not the primary purpose of the procedure
4. There may be significant consequences for the patient's employment, social or personal life
5. The treatment is part of a project or programme of research approved by this Trust
6. The treatment is a new procedure

Valid consent implies the patient has capacity/or for those without capacity that their relative or legally appointed representative has been fully informed regarding the risks, benefits and alternative options of treatment or intervention (including no treatment; that consent has been given voluntarily without being under duress to accept or refuse an offered treatment, investigation or care.

Whenever and however consent is obtained this must be clearly documented in the patient's healthcare records.

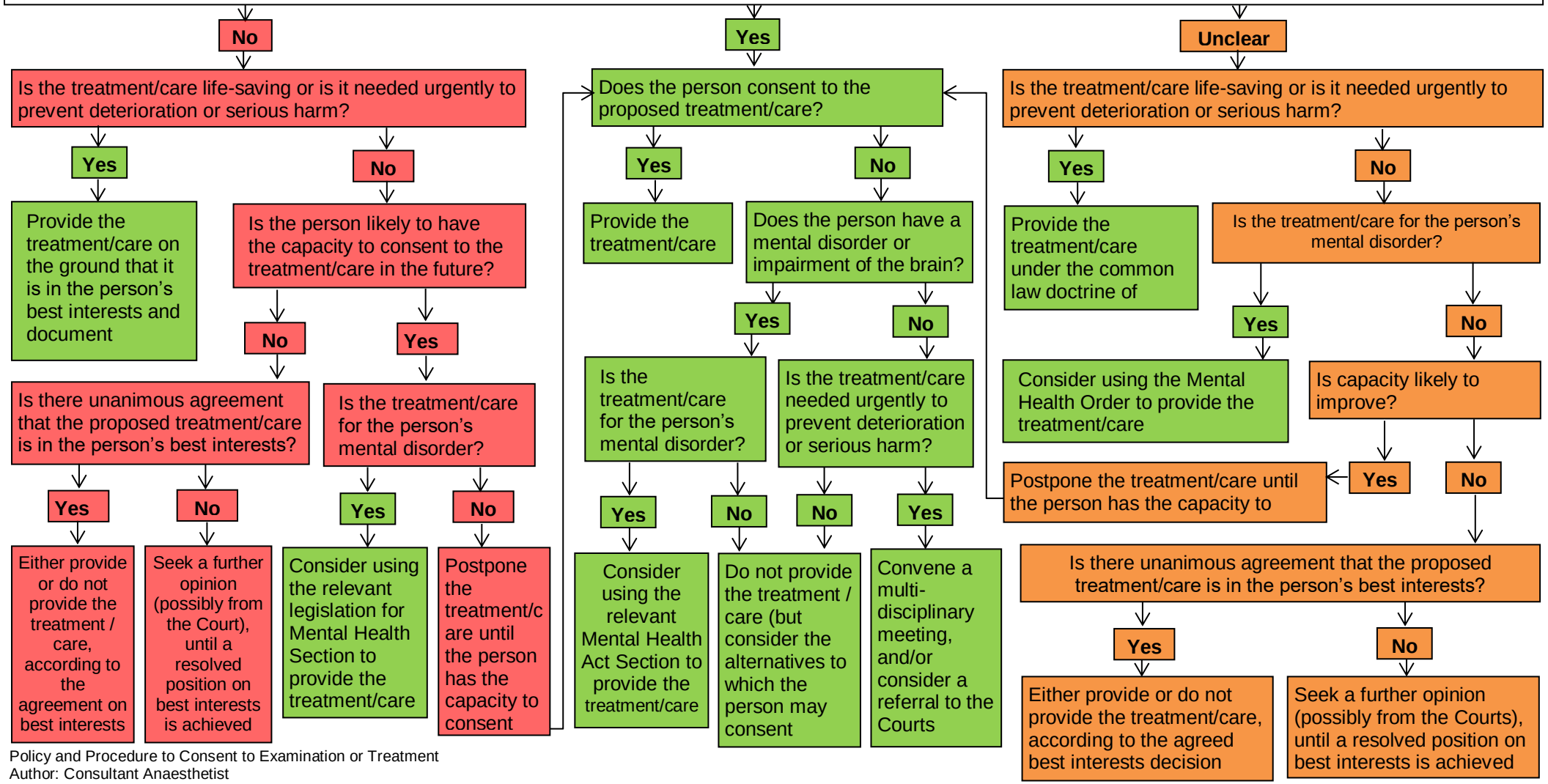
Contents

Flowchart 1: Actions when it is proposed to provide an examination, treatment or care for an adult and there is no valid advance refusal

(Note: Where a valid advance refusal exists, it must be respected and acted upon)

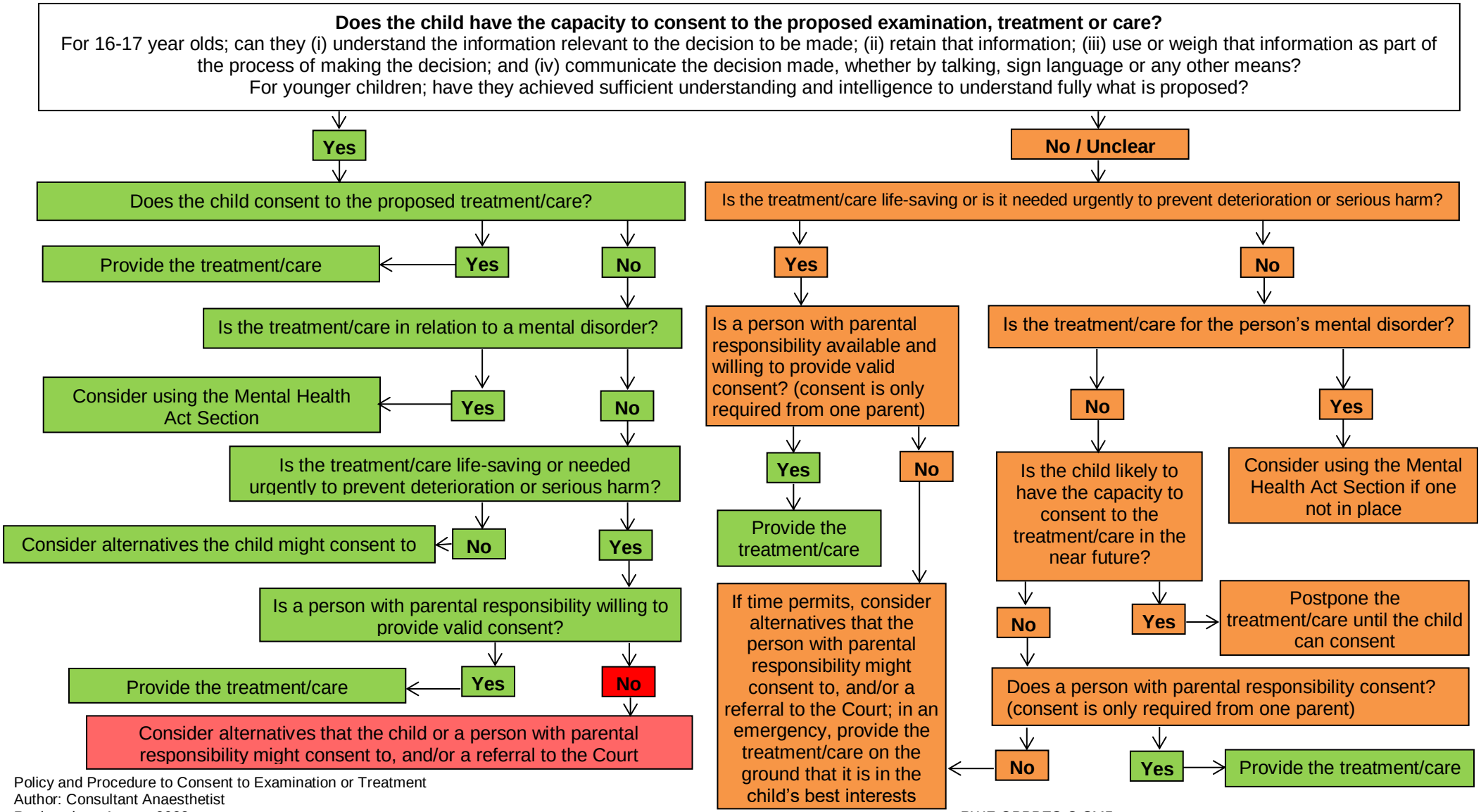
Is there a valid Lasting Power of Attorney for Health and Welfare for this patient? If so, contact with the Attorney with responsibility should be made before proceeding. If not, proceed with this flowchart.

Does the person have the capacity to consent to the proposed examination, treatment or care?
(i.e. can they (i) understand the information relevant to the decision to be made; (ii) retain that information; (iii) use or weigh that information as part of the process of making the decision; and (iv) communicate the decision made, whether by talking, sign language or any other means)



Flowchart 2: - Actions when it is Proposed to Provide an Examination, Treatment or Care for a Child (under the age of 18 years)

(Notes: *All* children should be as involved in decisions about their treatment/care as their understanding allows; 16 and 17 year olds, plus younger children who are 'Gillick competent', are presumed to have capacity; decisions on behalf of all other children should be made by someone with parental responsibility unless, in an emergency, no such person can be traced; persons with parental responsibility should be involved even when a child can provide his/her own consent – unless the child asks that this not be done)



1.0 Introduction, purpose and scope

The purpose of this policy is to enable staff to understand their ethical and legal responsibilities to involve patients as much as possible in making their own decisions about their health and care. The consent process is a partnership based on being open and honest about options available, where staff build a relationship of trust, utilising good communication skill and refined pathways.

Staff need to understand what is important to the patient, allow them to share their needs, wishes and values, identifying what is a priority for them and what their concerns may be.

Staff must act within the law and apply professional standards to their practice. This policy will cover common law, mental health and mental capacity legislation in simple terms, when they apply and the circumstances to which they apply. See Appendix 4 for '12 key points on consent: the law in England'.

The Montgomery v Lanarkshire [2015] case decided in the UK Supreme Court, defined that the standard for valid consent is that of the reasonable patient rather than that of a reasonable doctor, recognising the importance of patient autonomy. Therefore it is no longer a defence for healthcare professionals to provide information of risks based on what information other healthcare professionals would provide, but instead is based on what a reasonable person in the patients' position would want to know to make an informed decision and what that individual patient would want to know specifically. The second requirement requires adequate dialogue with the patient to determine what specific factors and risks are relevant to them.

1.1 Who does this policy apply to?

This document applies to all patients in this Trust and healthcare professionals having physical interactions with patients, ranging from seeking consent for simple care interventions (such as washing) to invasive surgical procedures. It is written in order to uphold respect for patient autonomy by ensuring the healthcare professional carrying out care or a procedure has obtained valid consent before undertaking the task.

Clinical staff should read appropriate sections of this document and consider the implications of how they perform their duties. They must complete mandatory training related to consent and any further training as required related to their duties, such as delegated consent.

1.2 Objectives

To ensure that all healthcare workers working in the Trust:

- Know their responsibility towards their patients, for the law and can demonstrate good practice in obtaining consent before any physical interactions take place.
- Can explain the process for obtaining valid consent.

- Are aware of their legal duties regarding the Mental Capacity Act for patients who lack capacity to make important decisions and where there is any doubt who to contact for assistance.
- Are aware of their legal duties regarding the Mental Health Act for patients with mental health conditions and where there is any doubt who to contact for assistance

2.0 Definitions/glossary

Term	Definition
Advance decision to refuse treatment (ADRT)	A decision to refuse specified treatment made in advance by a person who has the capacity to do so. This decision will then apply at a future time when the person lacks the capacity to consent to or refuse, to the specified treatment (*Section 24(1) Mental Capacity Act 2005 Code of Practice*). To apply in any particular situation the ADRT must have been both validly made and must be applicable to the current circumstances. Specific rules apply to decisions made in relation to life-sustaining treatment. For further information please refer to the Trust's *Mental Capacity Act Policy and Procedure and Deprivation of Liberty Safeguards (DoLS) Policy and Procedure.*
Best interests	Any decision made or anything done for a person who lacks capacity to make specific decisions, must be in the person's best interests (taking their previous wishes into account). There are standard minimum steps to follow when working out someone's best interest. These are set out in the Mental Capacity Act. **For further information refer to the** *Mental Capacity Act Policy and Procedure and Deprivation of Liberty Safeguards (DoLS) Policy and Procedure.*
Capacity	Is the ability to make a decision about a specific matter at the time the decision needs to be made. The legal test for capacity can be found in Section 2 and Section 3 of the Mental Capacity Act. For further guidance refer to the *Trust's Mental Capacity Act Policy and Procedure and Deprivation of Liberty Safeguards (DoLS) Policy and Procedure.*
Care	Provision of what is necessary for health, welfare, maintenance and protection of someone or something; to look after and provide for their needs.
Children	Anyone under the age of 16.
Consent	Is an affirmation or agreement to proceed (in the context of this policy relating to treatment/procedure or intervention.

Term	Definition
Decision maker	A person who may be required to make decisions or act on behalf of someone who lacks capacity.
Delegated authority	Delegated authority is an authority obtained from another that has authority since the authority does not naturally exist
Deprivation of Liberty Safeguards (DoLS)	Term used in the European Convention on Human Rights about the circumstances when a person's freedom is taken away and the safeguards that need to be put into place when this occurs.
Donor	A person who makes a Lasting Power of Attorney.
Gillick competency	A term originating in England and is used in medical law to decide whether a child (under 16 years of age) is able to consent to his or her own medical treatment, without the need for parental permission or knowledge.
Healthcare professional	A healthcare professional is a person who may operate within all branches of healthcare, including medicine, surgery, dentistry, midwifery, pharmacy, psychology, nursing or allied healthcare professions. A healthcare professional may also be a public/community health expert working for the common good of the society.
Huddle	Huddles are short, daily meetings in which a team (a Primary Care Provider and a Medical Assistant or other support staff) reviews their patient list for the day. They usually last no more than 10 minutes. Huddles enable a team to anticipate care needs and special situations, so that members of the care team can support each other through the day.
IMCA	Independent Mental Capacity Advocate. An individual who provides support and representation for a person who lacks capacity to make decisions about serious medical treatment or long term accommodation, where the person has no-one other than paid carers to support them – *(section 35 Mental Capacity Act 2005)This person will understand the patient and what their wishes may have been should they have had capacity.*
Lasting Power of Attorney for Health and welfare or property and financial affairs (previously known as Enduring Power of Attorney)	This is a delegation of the authority to make decisions for another person aged over 18 by an individual. There are two types of Power of Attorney created under the Mental Capacity Act 2005 *(section 9(1))* Personal Welfare (to include consent, discharge/future living arrangements) and Financial (which relates to money, property.)

Term	Definition
Material risk (as defined in Montgomery v Lanarkshire)	A significant potential for harm that a reasonable person would want to consider when making a decision about undergoing a medical or surgical treatment.
Medical competency	To encompass knowledge, skills, abilities to provide specific patient care. In relation to consent, this should mean the healthcare professional understands the options of treatment, the risks and benefits associated with those options in order to advise the patient.
Montgomery v Lanarkshire [2015] UKSC	A landmark case law relating to consent. The Montgomery *v* Lanarkshire case of March 2015 drew fresh attention to informed consent. Nadine Montgomery, a woman with diabetes and of small stature, delivered her son vaginally; he experienced complications owing to shoulder dystocia, resulting in hypoxic insult with consequent cerebral palsy. Her obstetrician had not disclosed the increased risk of this complication in vaginal delivery, despite Montgomery asking if the baby's size was a potential problem. Montgomery sued for negligence, arguing that, if she had known of the increased risk, she would have requested a caesarean section. The Supreme Court of the UK announced judgment in her favour in March 2015. The ruling overturned a previous decision by the House of Lords, which had been law since at least the mid-1980s. It established that, rather than being a matter for clinical judgment to be assessed by professional medical opinion, a patient should be told whatever they want to know, not what the doctor thinks they should be told.
Office of the Public Guardian	The Public Guardian is an officer established under section 57 of the Mental Capacity Act. The Public Guardian is supported by the Office of the Public Guardian which monitors deputies, keeps a register of deputies, lasting powers of attorney, enduring powers of attorney, and checks on what attorneys are doing and investigates complaints about attorneys or deputies. This replaces the public guardianship office previously in existence.
Risk	Any adverse outcome, including those which some healthcare professionals would describe as 'side-effects' or 'complications.'
Treatment	Care given to a patient for an illness or injury.

Term	Definition
Unbefriended	A person who has no-one else to support them (other than paid for carers) and relates to those who lack the capacity to make specific decisions.
Young people / person	Anyone aged 16 to 17 years old

3.0 Duties

Person/Group	Duties
Chief Executive	• Ensures that the Trust complies with relevant legal and statutory requirements related to patient consent. Has overall responsibility for the care and services provided and who delegates to those listed below.
Medical Director	• Monitors compliance with this policy. • Drives the application of Mental Capacity Act and Deprivation of Liberty Safeguards with the Chiefs of Service. • Hold Chiefs of Service to account for ensuring that this policy is adhered to. • Acts as point of contact for queries and assistance.
Chief Nurse Safeguarding Adults Executive Lead	• Ensures the Trust fulfils its responsibilities in protecting patients' rights in relation to the MCA and Child Safeguarding.
Chief of Service	• Responsible for ensuring consent processes are followed within the Division. • Responsible for ensuring incidents, complaints and claims relating to consent are investigated and learnt from with appropriate action plans generated by Clinical Directors. • Appropriately escalates issues in regard to the practice of consent to the Medical Director.
Clinical Director	• Ensure this policy is followed within their Directorate. • Ensure all relevant staff have undertaken consent and MCA mandatory training. • Responsible for identifying appropriate people for taking delegated consent within their Directorate and for ensuring that the procedure for this is robust. • Ensure appropriate learning and actions taken regarding incidents/complaints and claims resulting from a failure to follow consent processes and appropriately escalates to relevant Chief of Services.
On-Call Manager	• Escalate issues regarding consent to Executive Manager or Medical Director that occur outside of normal office hours.
Lead consultant / Healthcare professional for sub specialty	• Agree specific risks for procedures that should be disclosed with the clinical team. • Agree the content of relevant patient information leaflets. • Ensure there is consistency, training and assessment in delegated consent.

Person/Group	Duties
Legal Services Department	• Provide appropriate legal advice regarding consent concerns. • Ensure consent forms used are approved through correct pathway via the Health Records Committee until such time as the e-consent package is fully working. • Ensure Training on consent is up to date and provided to all clinical staff. • Review delegated consent process.
Clinical Audit Department	• Facilitate regular clinical audits of consenting process in line with policy and to Directorate/Specialty leads.
Other relevant staff	• All staff involved in a care giving capacity must be familiar and apply the principals of this policy. • Ensure appropriate consent is given for any interventions carried out.

4.0 Training/competency requirements

Directorates must identify those staff required to undertake consent training and monitor compliance through annual appraisals. Medical staff/registered healthcare professional competency should be assessed in line with the Trust *Medical Staff Clinical Supervision Policy and Procedure*. A record of medical staff competency for consent for specific procedures will be maintained through the Learning & Development Team and will be subject to regular review during annual appraisal

All relevant staff involved in care giving should undertake the e-consent training program or undertake face to face training via the Clinical Update Mandatory training day every three years.

Those with delegated authority to obtain consent should provide the evidence of their competency undertaken by an experienced healthcare professional and have their practice appraised annually. They should also undertake the e-consent training or face to face training every three years and ensure they complete a competency record (see Appendix 11).

5.0 Process for obtaining consent

5.1 Who is responsible for seeking consent and competency?

If you are undertaking an investigation or providing treatment, it is your responsibility to discuss this with the patient. If this is not practical, you may delegate the responsibility to someone else, provided you make sure that the person you delegate to:

- Is suitably trained and qualified

- Has sufficient knowledge of the proposed investigation or treatment and understands the risks, benefits and alternatives involved
- Understands and agrees to act in accordance with this policy

If you delegate, then you are still responsible for making sure that the patient has been given enough time and information to make an informed decision and has given their consent before you start any investigations or treatment.

If you have been given delegated authority to obtain consent from a patient you must ensure to work within your competence and do not to agree to perform tasks which exceed that competence. Be aware of your own knowledge limitations.

If you feel that you are being pressurised to seek consent when you do not feel competent to do so, you should contact the relevant Clinical Director in the first instance.

5.2 A partnership

A good working relationship between the patient and the healthcare professional is a relationship based on openness, trust and good communication. Each party has a role to play in making decisions about treatment or care. There is no single way in which information should be imparted to a patient as each person is different and will have different levels of understanding; each patient will require varying levels of support. It is important to check with your patient as to how they wish the information given.

It is essential to give weight to the patient's wishes and knowledge of their own conditions in conjunction with the expertise of the healthcare professional. Assumptions must not be made about what information a patient may want or need, the clinical or other factors a patient might consider significant or their level of understanding of what is proposed.

Patients must be given information regarding the following issues:

- The diagnosis and prognosis.
- Any uncertainties about the diagnosis or prognosis, including options for further investigations.
- Options for treating or managing the condition, including the option not to treat.
- The purpose of any proposed investigations or treatments and what it will involve.
- The potential benefits, risks and the likelihood of success for each option, this must include information, if available, regarding whether the benefits or risk are affected by which healthcare provider or healthcare professional is chosen to provide the care.
- Whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.
- The people who will be mainly responsible for and involved in their care, their roles and to what extent students may be involved.
- Their right to refuse or to take part in teaching or research.

- Their right to seek a second opinion.
- Any costs involved (should not be relevant in the NHS sector).
- Any conflicts of interest you (as a healthcare professional) or the organisation may have
- Any treatment of interest you believe has a greater potential benefit for the patient than those you or your organisation can offer.

You should explore these matters with patients, listen to their concerns, ask for and respect their views and encourage them to ask questions.

Check whether the patient has understood the information given and ask whether they require further information before they make a decision. Be clear they can change their mind at any time.

Reasons for not sharing information

No one else can make a decision on behalf of an adult who has capacity. If a patient asks you to make decisions on their behalf or wants to leave decisions to a relative, partner, friend, carer or other person, you should explain that it is still important that they understand the options open to them and what the treatment will involve. If they do not want the information try to find out why.

If after discussions a patient still does not want to know in detail about their condition or treatment, you should respect their wishes as far as possible, but still give them the information they need to give their consent to a proposed investigation or treatment. This is likely to include what the investigation or treatment aims to achieve and what it will involve; for example whether the procedure is invasive, what level of pain or discomfort they might experience and what can be done to minimise it; anything they should do in preparation and if the procedure involves any serious risks.

If they continue to refuse even the most basic of information you must explain the potential consequences of not having it, particularly as it may mean their consent is not valid. Record the fact in the patient's healthcare records and indicate that further information can be shared at any time.

You should not withhold any information necessary for making decisions for any other reason including if a relative, partner or carer asks you to, unless you can conclude that giving of that information would cause serious harm to the patient. This does not mean that by giving information it will cause the patient to be upset or distressed but must be because this would cause the patient to be severely mentally or psychologically disturbed.

5.3 Sharing information

How you discuss a patient's diagnosis, prognosis and treatment options is often as important as the information given. You should:

a. Share information in a way that the patient can understand and wherever possible in a place and at a time when they are best able to understand and retain it.
b. Give information that the patient may find distressing in a considerate way.
c. Involve other members of the healthcare team in discussions with the patient.
d. Give the patient time to reflect, before and after they make the decision especially if the information is complex or if what you are recommending has material (significant) risks.
e. Make sure the patient realises there is a time limit on making their decision, who they can contact if they have any questions or concerns.

Give information in a balanced way. If you recommend a particular treatment explain why but do not put pressure on the patient to accept your advice.

You may need to support your discussions with patients by using written material or visual aids. Ensure that this information is accurate and up to date.

Check if the patient requires any additional support to understand information, to communicate their wishes, or to make a decision. You should bear in mind that some barriers to understanding and communication may not be obvious, for example, a patient may have unspoken anxieties, or may be affected by pain or other underlying problems. Make sure, wherever practical, that arrangements are made to give the patient any necessary support, possibly through the use of an interpreter or an advocate. Ensure you know if the patient has communication needs prior to the consultations and seek support in delivering the information in the correct manner. Look for ways of providing the patient with written or audio recording of discussions held.

5.4 Involving families, carers and advocates

You should try and facilitate the patient's wishes if they wish another person such as a relative to be involved in the discussions and follow guidance above in Section 5.3 about content of discussions to be had.

5.5 Difficulties in sharing information

It is appreciated that due to time constraints in clinics and limited resources, giving patients as much information or support in making decisions as possible may be difficult to achieve. It may assist to consider the roles that other members of the healthcare team may play and what other sources of information and support are available to the patient. These could be in the form of patient information leaflets, advocacy services expert patient programmes or support groups for people with specific conditions.

You should endeavour to ensure that patients with additional needs such as disabilities, have the time and support they need to make a decision. In all cases you must treat the patients fairly and not discriminate against them (for further support contact the Learning Disability Liaison Nurse – Philippa Harris, 01622 224821, mobile – 07561 789410, philippaharris1@nhs.net)

5.6 Discussing side effects, complications and other risks

Clear, accurate information about risks of any proposed investigation or treatment presented in a way patients can understand can help them make informed decisions. The amount of information about risk that you should share will depend on the patient and what they need to know (your discussions should focus on their individual situation and the risk to them).

In order to have effective discussions with patients about risk, you must identify the adverse outcomes that may result from the proposed options. This includes the potential outcome of taking no action. Risks can take various forms but usually include side effects, complications and failure of an intervention to have the desired outcome.

Risks can vary from common but minor side effects to rare but serious adverse outcomes possibly resulting in permanent disability or death. In assessing the risk to the individual you must consider the nature of the patient's condition, their general health and other circumstances. These variables may affect the likelihood of adverse outcomes occurring.

Understand the patient's view and preferences about proposed investigations or treatment and the outcomes they are most concerned about. Do not make assumptions about their understanding of a risk or the importance they attach to different outcomes these should be discussed with the patient.

You must discuss all material risks with the patient including the possibilities of serious adverse outcomes even if the likelihood is small, as well as explaining the more frequent less serious adverse outcomes. This should include what those outcomes will mean for the patient in reality, whether those outcomes will impact on the patient's future health or ability to undergo further treatment in the future.

Use language that the patient will understand, check their understanding and use simple and accurate information with accompanying visual or other aids to explain.

5.7 Making decisions

5.7.1 You must explain clearly to the patients the scope of any decisions to be made especially if:

- Treatment will be provided in stages, with the possibility that changes or adjustments might be needed.

- Different healthcare professionals will provide particular part of an investigation or treatment such as anaesthesia or surgery.
- A number of different investigations or treatments are involved.
- Uncertainty about the diagnosis or the options might only be resolved once the investigation or treatment has started, when the patient may be unable to make decisions.

In such cases, discuss and agree with the patient how decisions will be made about whether to make changes to the investigations or treatment plan. Establish whether the patient agrees to all or only parts of the plan. If they agree to only parts make sure there is a clear process through which they can be involved in making decisions at a later stage.

You must not exceed the scope of the authority given by a patient except in an emergency. If that arises you must follow guidance at Section 6.4.

5.7.2 Making decisions about potential future events

Discuss with the patients the possibility of additional problems coming to light during an investigation or treatment when they might not be in a position to make a decision on how to proceed. If there is a significant risk of a problem arising then ask in advance what the patient would like to do if it does arise; for example, you are undertaking an exploratory procedure to look for a polyp, if found can you remove and test it? Ask if there are any procedures that the patient would not wish to have. It is important to ensure that this is fully documented on the consent form or in the healthcare records.

5.7.3 Ensuring decisions are voluntary

Patients can be placed under pressure by employers, insurers, relatives or others to accept a particular treatment or investigations. Be aware of this and situations where patients may be vulnerable. Do your best to make sure that these patients have considered the available options and reached their own decision. If they have a right to refuse they should be made aware of this.

5.7.4 Respect the patient's decision

You must respect a patient's decision to refuse treatment or investigation even if you think their decision is wrong or irrational. You should explain your concerns clearly to the patient and outline the possible consequences of that decision. You must not, however, put pressure on a patient to accept your advice. If you are unsure about the patient's capacity then follow the relevant guidance at Section 7 It should be noted however that you cannot be forced to undertake an investigation or treatment if you do not feel it is in the patient's best interests. This is where a second opinion or referral to another centre needs to be considered if another organisation could offer what is being asked for.

6.0 Single stage process

6.1 In many cases, it will be appropriate for a healthcare professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any material risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given verbally. An example would be if a patient attends an outpatient clinic and requires an intimate examination or blood test, verbal consent should be obtained and documented.

If a proposed procedure carries significant risks, it is appropriate to seek written consent, and healthcare professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the healthcare professional may then proceed. In all cases the patient's individual circumstances should be taken into account.

6.2 Two or more stage process

6.2.1 In most cases where *written* consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different healthcare professionals. The consent process will have at least two stages: the first being the provision of information, discussion of options and initial (verbal) 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. If the provided information is given supported by an appropriate patient information document, this should be documented clearly that the patient has received this. The information document must be supported by clear verbal communication of the material risks involved and the intervention to be done.

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

If a form is signed before patients arrive for treatment, however, a member of the healthcare team **must** check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the

procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?"

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

6.3 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 the anaesthetic is an integral part of most surgical procedures, hence the risk of death or other severe general complications should be part of the surgical consent. It is not best practice to discuss the risk of death with a patient when they are anxious on the morning of surgery this would be best addressed at a pre-assessment clinic in advance of any complex surgery. However it is appropriate at this time to discuss risks specific to the patient for anaesthetic options such as epidural risks or dental damage. 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 to make a proper decision about whether or not to undergo anaesthesia. Patients should therefore receive a general leaflet about anaesthesia in out-patients, and possibly have the opportunity to discuss anaesthesia in a pre-assessment clinic (POA). It may be appropriate for a discussion with an anaesthetist in the POA clinic for particularly high risk patients. It should be made clear to elective patients that if they have anaesthesia specific concerns, then they should contact the POA clinic, where advice may be provided directly or discussion with an anaesthetist arranged.

The anaesthetist should ensure that the discussion with the patient in POA or on the morning of surgery has taken place and that their consent is documented:

- in the anaesthetic record
- in the patient's healthcare record or on the consent form

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

6.4 Emergencies

In emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other. It may be appropriate to use the patient's healthcare records to document any discussion and the patient's consent, rather than using a Consent 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. For surgery the consent process must be completed before the patient is transferred to the theatre complex.

In an emergency if a patient is unconscious or unable to give consent for other reasons, the situation may dictate that the procedure is undertaken speedily in which case the healthcare professional can proceed in the 'best interests' of the patient. Remember that if the patient has written a valid Advanced Decision to Refuse Treatment or appointed a Lasting Power of Attorney for health and welfare then these must be taken into consideration if they are relevant to the circumstances (e.g. a Jehovah's Witness might have a valid Advanced Decision regarding advanced blood transfusion refusal).

7.0 Capacity to consent

7.1 Under the Mental Capacity Act 2005, you should start with the presumption that all patients have capacity and want to make their own decisions and strive to enable this. It should be recognised that capacity can fluctuate and is specific to the decision that is to be made. Each patient should be assessed and maximised to be enabled to make decisions.

To have capacity a patient must be able to understand relevant information, be able to retain that information, be able to weigh that information to consider the consequences of having or not having the proposed intervention and then to be able to communicate that decision.

Capacity is decision and time specific; hence a patient may have capacity to consent to examination, but not to major surgery. (*i.e. they may not be able to fully understand if they have just woken up as opposed to later in the day.)*

All patients over 16 years of age are presumed to have capacity unless there is evidence to the contrary. In cases of 16 and 17 year old adolescents, consideration of the Children's Act 1989 must be taken into account and advice sought from the Named Nurse for Safeguarding Children. A patient with capacity retains the right to make irrational and unwise decisions. In situations where an adult's capacity has been assessed, following the Mental Capacity Act 2007 Code of Practice guidance, and deemed to lack the ability to consent to the specific treatment/care being offered (either temporarily or permanently) no other person can consent on their behalf unless appointed under a Lasting Power of Attorney (LPA) for health and welfare - (***see the Mental Capacity Act Code of Practice (MCA Code of Practice*)** or if there is a

Court appointed Deputy (CAD)**.** Evidence of the LPA must be provided to the treating healthcare professional by way of a signed and registered document from the Office of the Public Guardian, a copy of which should be stored within the healthcare records. For further information on the assessment of capacity refer to the Trust's *Mental Capacity Act Policy and Procedure and Deprivation of Liberty Safeguards (DoLS) Policy and Procedure.*

Patients are also able to specify treatments which they do not want to accept in advance of losing capacity in the form of a valid and applicable Advance Decision to Refuse Treatment (ADRT- MCA Code of Practice) (*formerly known as an Advance Directive/Living Will*). If a patient lacks capacity and there is no LPA, no ADRT and no Court appointed Deputy then the healthcare team must act in the patient's best interests. This means having discussions with relatives or friend regarding the patient's wishes. If they are unbefriended then the healthcare team must request the support of an IMCA. Where there is any element of doubt, advice must be sought from the Legal Services Department or from the on-call manager if out of hours.

7.2 Expressions of consent

Before accepting a patient's consent, you must consider whether they have been given the information they want or need, and how well they have understood the details and implications of what is proposed. This is more important than how their consent is expressed or recorded.

Patients can give consent orally or in writing or they may imply consent by complying with a proposed examination or treatment for example rolling up sleeves for a blood test.

In the case of minor or routine investigations or treatments if you are satisfied the patient understands what you propose to do and why it is usually enough to have oral or implied consent. This should be recorded in the healthcare records.

In the cases that involved higher risk, it is important you get the patient's written consent. This is so that everyone involved understands what was explained and agreed.

By law you must get written consent for certain treatments such as fertility or a post-mortem. You must follow the laws and codes of practice that govern these situations as outlined below and in Table 1.

7.3 You should also obtain written consent from the patient if:

- 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 healthcare professionals would describe as 'side-effects' or 'complications').
- The procedure involves general/regional anaesthesia or sedation.
- Providing clinical care is not the primary purpose of the procedure.
- There may be significant consequences for the patient's employment, social or personal life.

- The treatment is part of a project or programme of research approved by this Trust.
- The treatment is a new procedure.

If it is not possible to get written consent, i.e. in an emergency, or if the patient needs the treatment to relieve serious pain or distress, you can rely on oral consent. However, you must still give the patient the information they want or need to make a decision. You must record the fact that they have given consent in the healthcare records.

7.4 **Documentation**

When completing a consent form, the name of the procedure and any additional procedures that are likely to be required must be documented. The phrase "+/-proceed" is not adequate. The procedure or procedures that are likely to be required should be named and listed.

Completed consent forms should be kept with the patient's healthcare records along with details of your discussions, requests for information by the patient and any written, visual or audio information given to the patient as well as decisions made by the patient.

Reviewing decisions

Before beginning treatment, you or a member of the healthcare team should check that the patient still wants to go ahead. You must respond to any new or repeated concerns or questions the patient raises. This is particularly important if:

- a significant time has passed since the initial decision was made
- there have been material changes in the patient's condition or in the aspect of proposed investigation or treatment
- new information has become available for example about the risks of treatment or alternative treatment options

Any changes to a consent form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional. A copy of the form should be handed to the patient. You must ensure that the patient is kept informed about the progress of their treatment and that they are able to make decisions at all stages, not just the initial stage. If treatment is ongoing, you should make sure that there are clear arrangements in place to review decisions and if necessary make new ones.

Table 1: Examples of procedures where written consent is required (this list is not exhaustive)

	Consent must be sought in the following circumstances	**Indicative examples**
1	The treatment or procedure is complex, or involves significant risks	Angioplasty Spinal analgesia/ pain control

2	The procedure involves general/regional anaesthesia or sedation	Endoscopy Manipulation under anaesthetic Hip replacement
3	Providing clinical care is not the primary purpose of the procedure	Bone marrow donation
4	There may be significant consequences for the patient's employment, social or personal life and wellbeing	Vasectomy, HIV test
5	The treatment is part of a project or programme of research approved by this Trust	Any invasive procedure or treatment where risks and benefits are under review. Consent taking is specific to each trial and the person undertaking Consent must have undertaken both the Good Clinical Practice (GCP) and trial specific training and be on the trial delegation log. For further guidance please contact the Research Department.

8.0 Patient information leaflets

8.1 Wherever possible, and for all high volume or high risk procedures, healthcare professionals should ensure that Trust approved patient information leaflets are available. Trust patient information leaflets are developed following templates and procedures set out in the Trust's *Development and Production of Written Patient Information Policy and Procedure* and the *Accessible Information Policy and Procedure* published on the Trust Intranet (Q-Pulse). These templates and procedures ensure that all Trust patient information leaflets contain information regarding risks, benefits and alternatives options where appropriate, and also information about what will happen, where to go, how long patients will be in hospital, how they will feel afterwards etc.

Trust leaflets will enable the healthcare professional to provide high quality information. Available approved leaflets are published on the Trust intranet under 'Policies & guidelines'. These can be downloaded and printed as required and some are available from central stock. Please contact the Patient Information Assistant if you are unsure how to obtain stock. A note of which patient information leaflet is given should be written on the consent form or documented in the healthcare records. Version control is maintained electronically.

Sources of information provided by the Trust:

- Consultants and other medical staff
- Specialist nurses
- Specialist clinics including the Pre-assessment service.
- Patient information leaflets

- Procedure specific consent forms with specific risks printed.
- Alternate formats including Braille, tapes and languages (available on request)

8.2 Provision for patients whose first language is not English

This Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children, young people or family members to interpret for family members who do not speak English due to the potential for undue influence on the information provided or for the decision made or important factors to be missed out. For help and assistance in obtaining translation services use the Trust hyperlink: http://mtwintranet/popular/translation-services/

9.0 Access to healthcare professionals between formal appointments

After an appointment with a healthcare professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they make their final decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice). A contact name and contact number should be inserted in the consent form. Please check with your head of department for details. A record should be made of such discussions within the healthcare records.

10.0 Open access clinics/One Stop Clinic

Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. Trust healthcare professionals treating patients under a direct access scheme should ensure that all referring healthcare professionals such as GPs are aware of the need to inform and prepare patients for the appointment. Hospital staff should support referring healthcare professionals to do this by providing information leaflets for them to give or by providing patients with information prior to their appointment. It is the responsibility of the healthcare professional undertaking the procedure to ensure and document that patients have had sufficient time and information to give informed consent.

11.0 Procedures to follow when a patient lacks capacity to give or withhold consent

Making decisions about treatment and care for patients who lack capacity is governed by the Mental Capacity Act 2005 (England and Wales). The Act sets out the criteria and procedures to be followed in making decisions when patients lack capacity to make those decisions for themselves. It also grants legal authority to certain people to make decisions on behalf of patients who lack capacity.
The procedures that follow are consistent with the law across England and Wales. It is important that you keep up to date with and comply with, the laws and codes of practice that apply where you work. If you are unsure about how the law applies in a particular situation, you should consult with the Matron for Safeguarding Adults or the Legal Services Department.

You must work on the presumption that every adult patient has the capacity to make decisions about their care, and to decide whether to agree to, or refuse, an examination, investigation or treatment. You must only regard a patient as lacking capacity once it is clear that, having been given all appropriate help and support, they cannot understand, retain, use or weigh up the information needed to make that decision or communication their wishes.

You must not assume that a patient lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness) their beliefs, their apparent instability to communicate or the fact that they make a decision that you disagree with.

11.1 Maximising a patient's ability to make decisions

A patient's ability to make decisions may depend on the nature and severity of their condition or the difficulty or completely of the decision. Some patients will always be able to make simple decisions but may have difficulty if the decision is complex or involves a number of options. Others may be able to make decisions at certain times but not at other

because of fluctuations in their condition impair their ability to understand, retain or weigh up information or communicate their wishes.

If a patient's capacity is affected in this way you must follow earlier guidance (Section 7) in how to maximise their abilities by any means available i.e. you should have consideration to what additional support is required and if appropriate seek assistance of the Learning Disability Liaison Nurse, Dementia Lead Nurse or Safeguarding Matron.

You must take all reasonable steps to plan for foreseeable changes in a patient's capacity to make decisions by:

- discussing treatment options in a place and at a time when the patient is best able to understand and retain the information.
- asking the patient f there is anything that would help them remember information or make it easier to make a decision such as bringing a relative, partner, friend, carer or advocate to the consultation or the proposed investigations or having written or audio information about their condition/or the proposed investigation / treatment.
- speak to those close to the patent and to other healthcare staff about the best ways of communicating with the patient, taking account of confidentiality issues.

If a patient is likely to have difficulty retaining information, you should offer them a written record of your discussions detailing what decisions were made and why.

You should record any decisions that are made while the patient has capacity in understand and review them. You must bear in mind that advance refusals of treatment must be recorded, signed and witnessed.

11.2 Assessing capacity

You must assess capacity to make a particular decision at the time it needs to be made. You must not assume that because a patient lacks capacity to make a decision on a particular occasion, that they lack capacity to make any decisions at all, or will not be able to make similar decisions in the future.

You must take account of the advice in the Mental Capacity Act Codes of Practice. If your assessment is that the patient's capacity is borderline (i.e. fluctuating between having capacity and no capacity), you must be able to show that on the balance of probabilities that it is more likely than not that they lack capacity.

If your assessment leaves you in doubt seek advice from:

- other healthcare professionals caring for the patient such as nurses, physiotherapists, carers or relatives who may be more aware of the patient's usual ability to make decisions and their particular communication needs
- colleagues with relevant experience such as psychiatrists, neurologists, dementia nurse or speech and language therapists.

If you are still unsure about the patient's capacity to make a decision, you must seek advice from Legal Services Department with a view to asking a court to determine capacity.

In making decisions about the treatment and care of patients who lack capacity you must:

- make the care of your patient your first concern
- treat patients as individuals and respect their dignity
- support and encourage patients to be involved, as far as they want to and are able, in decisions about their treatment and care
- treat patients with respect and not discriminate against them

You must also consider:

- whether the patient's lack of capacity is temporarily or permanent.
- which options for treatment would provide overall clinical benefit for the patient.
- which option, including the option not to treat, would be least restrictive of the patient's future choices.
- any evidence of the patient's previously expressed preferences such as an advance statement or decision.
- the views of anyone the patient asks you to consult or who has legal authority to make a decision on their behalf or has been appointed to represent them.
- the views of people close to the patient on the patient's preferences, feelings, beliefs and values and whether they consider the proposed treatment to be in the best interest of the patient.
- what you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values.

11.3 Resolving disputes/disagreements

You should aim to reach a consensus about a patient's treatment and care, allowing enough time for discussions with those who have an interest in the patient welfare. Sometimes disagreements arise between members of the healthcare team or between the healthcare team and those close to the patient. It is usually possible to resolve them by involving an independent advocate, consulting a more experienced colleague, holding a case conference using the Trust's complex care pathway, refer to the Trust Ethicist (Ann Munro) to provide an independent chair/mediated conversations through a best interest meeting. You should take into account the different decision-making roles and authority of those you consult and the legal framework for resolving disagreements.

If a significant disagreement continues you should consider seeking legal advice on applying to the Court of Protection or requesting an independent review. Patients, those authorised to act for them, and those close to them, should be informed as soon as possible of any decision to start proceedings and allow them the opportunity to participate or be represented.

Occasionally, having followed the steps set out under the Trust's *Mental Capacity Act Policy and Procedure and Deprivation of Liberty Safeguards (DoLS) Policy and Procedure* there may not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. If after undertaking a best interest meeting with the patient/patient's representatives and all relevant healthcare professionals, a consensus is not reached and there is a dispute as to best interests, then a court declaration may be sought. If a serious deterioration in condition or loss of life is imminent it is lawful to take appropriate steps to sustain life pending a Court decision. In urgent situations legal guidance can be obtained through the Patient Safety Department / Legal Services Department or out of hours through the Trust's solicitors by contacting the Executive on Call. Further advice can also be gained from the Matron for Safeguarding Adults or the Trust Ethicist.

In emergency situations it is not always possible to find out a patient's wishes and you can treat them without their consent providing the treatment is immediately necessary to save their life or prevent a serious deterioration. The treatment you provide should be the least restrictive of the patient's future choices for as long as incapacity is present. If the patient regains capacity whilst still having treatment you should inform them of what has been done and why.

11.4 Where an adult patient does not have the capacity to give or withhold consent to a significant intervention:

This fact should be documented on Form 4 (Appendix 8: form for adults who are unable to consent to investigation or treatment), along with:

- The assessment of the patient's capacity; and
- Why the healthcare professional believes the treatment to be in the patient's best interests, and
- The involvement and outcome of discussions with the people close to the patient, or an IMCA if appropriate.

Healthcare professionals should refer to the Trust's *Mental Capacity Act Policy and Procedure and Deprivation of Liberty Safeguards (DoLS) Policy and Procedure* for further information on capacity assessments and guidance on best interests. The other Trust approved consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, MCA assessment and relevant information should be entered in the patient's healthcare records.

12.0 Department of Health consent forms

There are four versions of the Department of Health (DH) standard consent form:

- **Form 1** for adults or competent children (Appendix 5).
- **Form 2** for parental consent for a child or young person (Appendix 6).

- **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. (Appendix 7)
- **Form 4** for patients lacking capacity (as described above). This now includes the assessment of mental capacity. Consent Form 4 should not be used without the required Mental Capacity assessment pertinent to this particular decision being documented. (Appendix 8)

In addition there are a number of procedure specific consent forms approved by the Trust which are listed in Appendix 10.

If the procedure being undertaken requires written consent. one of the described approved consent forms must be used. If the patient is also refusing blood products then 'Consent form 7: Excluding blood transfusion' [RWF-OWP-APP40] must be used in addition to the approved consent form.

Procedure specific consent forms can be accessed via the Health Records Department (see Appendix 10); other generic consent forms are included as appendices to this policy and uploaded to the Trust policy database on the intranet, under 'Policies & guidelines'.

Any procedure specific consent forms including printed specific risks and benefits of procedure or electronic consent forms, must include the data set from the DH forms. Specific material risks relevant to the specific patient must be documented.

It is the intention of the Trust to explore the use of electronic consent process as part of the digital strategy. Any pilot of e-consent will follow the principles laid out in this policy (in the interim any new forms must be approved by the Health Records Committee).

12.1 Consent forms and the Operating Theatre

- Written consent must be completed and signed prior to the patient being sent for from theatres. This is to ensure there is no undue duress once the patient is within the theatre complex.
- The operating list should show the same procedure that is recorded on the consent form.
- During the WHO huddle briefing the consent status of all the patients must be included. At this stage the lead surgeon must confirm each operation and whether it's the left or right side (if relevant) on the operating list for each patient. During the anaesthetic WHO checklist the consent form must match the operating list procedure, if there are discrepancies then the surgeon must review prior to anaesthesia. Where there is doubt the surgeon must discuss with the patient before anaesthesia commences.

- The consent form will be checked with the patient as part of anaesthetic WHO checklist, or the surgeon if Form 4, and in theatre checked by the scrub nurse and surgeon by direct viewing.
- Procedures must be specific. Any reference to 'and proceed' must be documented fully with the potential options clearly explained to the patient. Where there is the potential for an operation 'to proceed' to a level where there may be increased scarring, loss of function, loss of fertility or a significant change to daily living, these issues must be documented.
- The consent applies to the operation agreed. If additional pathology is found during the operation, then further surgery to deal with that problem should not be done, unless there is an immediate risk to life. Where there is no immediate threat to life, then the findings should be discussed with the patient following recovery from the operation and options for further treatment discussed.

13.0 Refusal of treatment

13.1 If the process of seeking consent is to be a meaningful one, refusal must be **one of the patient's options. A competent adult patient is entitled to refuse any** treatment, even if death will be an outcome, except in circumstances governed by the *Mental Health Act 1983 (MHA)*. A patient who is sectioned or detained under the MHA may still have capacity to consent to treatment or to refuse treatment for physical illness and will need to be assessed and managed under the provisions of the MCA 2005. Any patient with capacity retains the right to make irrational and unwise decisions, unless the treatment is subject to the provisions of the Mental Health Act 1983. Detention under section from the MHA 1983 only makes treatment compulsory for mental health conditions such as admission or Electroconvulsive treatment; it does not make surgical treatments (such as appendectomy) compulsory. Hence normal consent or best interests under the MCA 2005 apply. Chapter 13 of the MCA Code of Practice contains further guidance. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail. The following paragraphs apply primarily to adults.

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

Where a patient has refused a particular intervention, healthcare professionals must ensure that they continue to provide any other appropriate care to which they have consented. Healthcare professionals 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, healthcare professionals must explain to the patient the possible consequences of their partial refusal. If healthcare professionals genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, they not obliged to perform it. Healthcare professionals must, however, continue to provide any other appropriate care. Where another healthcare professional believes that the treatment can be safely carried out under the conditions specified by the patient, the original healthcare professional must be prepared to transfer the patient's care on request.

If healthcare professionals have concerns for the patient's wellbeing as a result of refusal of care, they should escalate this to the Consultant in charge of their care, Department Manager or Matron. Legal advice may be required from the Legal Services Department in certain circumstances (e.g. anorexia and refusal of nutrition).

14.0 Refusal or withdrawal during a procedure

A patient can refuse or withdraw treatment at any time, including during a procedure. Where a patient does object during a procedure, the healthcare professional should if possible stop the procedure. They must then establish the patient's concerns and explain the consequences of either stopping or continuing and assess the patient's capacity to refuse treatment. The objection may be due to pain and simple reassurance or analgesia may be required, rather than a formal withdrawal of consent. If the patient appears to have capacity whether under sedation or not and clearly indicates they wish the procedure to be discontinued then this must be done immediately unless stopping the procedure would put the patient's life in danger. In this circumstance the operator may be entitled to continue until the risk no longer applies. This should be documented in the healthcare record with details of the patient's concerns.

If the healthcare professional feels that capacity is lacking it may be appropriate to continue based on the patient's best interests if a specific part of the treatment or investigation is important to complete or if not continuing puts the patient at risk of harm. This should be documented in the healthcare records.

15.0 Treatment of children

15.1 Involving children and young people in making decisions

You should involve children and young people as much as possible in the discussions about their care, even if they are not able to make decisions on their own.

A young person's ability to make decisions depends more on their ability to understand and weigh up options, than on their age. When assessing a young person's capacity to make decisions you should bear in mind the following:

- A young person under 16 may have capacity to make decisions, depending on their maturity and ability to understand what is involved
- At 16 years old a young person can be presumed to have capacity to make most decisions about their treatment and care.

The legal position concerning consent and refusal of treatment by those under the age of 18 years old is different from the position for adults. For the purposes of this policy 'children' refers to people aged below 16 years old and 'young people' refers to people aged 16 to17 years old.

Healthcare professionals should consider the following questions in conjunction with the paragraphs below:

- Has the child or young person been given the relevant information in an appropriate manner (such as age appropriate language)?
- Have all practicable steps been taken to help the child or young person make the decision? The kind of support that might help the decision-making will vary, depending on the child or young person's circumstances. Examples include:
    - Steps to help the child or young person feel at ease
    - Ensuring that those with parental responsibility are available to support their child (if that is what the child or young person would like)
    - Giving the child or young person time to absorb information at their own pace, and
    - Consider whether the child or young person has any specific communication needs (and if so, adapting accordingly).
- Can the child or young person decide whether to consent, or not to consent, to the proposed intervention?

15.2 Young people aged 16 to 17 years

The MCA applies to people aged 16 years or over, so young people must be assumed to have capacity to make the decision about a proposed admission to hospital and/or treatment unless it is established that they lack capacity, as is the case with adults. As for adults, consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16 to17 years may, in certain rare circumstances, be overridden by either a person with parental responsibility or a court.

However if you are considering relying on parental consent to carry out a procedure when a young person with capacity is refusing the

treatment you should discuss the position with the Legal Services Department or the on-call manager, if out of hours.

The MCA also states that a person must not be regarded as unable to understand the information relevant to the decision if they are able to understand an explanation of it given in a way that is appropriate to their circumstances. It is therefore essential that steps are taken to enable a person to understand information, such as using simple language and visual aids.

In order to establish whether a young person aged 16 or 17 has the capacity to consent to the proposed intervention, the same criteria as for adults should be used. Please refer to the Trust's *Mental Capacity Act Policy and Procedure and Deprivation of Liberty Safeguards (DoLS) Policy and Procedure.*

If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of, the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over. If however they are unable to make the decision for some reason other than a mental disorder, for example because they are overwhelmed by the implications of the decision, then their parents may be able to consent on their behalf. It may be unclear whether a young person lacks capacity within the meaning of the Act. In those circumstances, it would be prudent to seek a declaration from the court.

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

15.3 Children under 16 - the concept of Gillick competence

In the case of *Gillick*, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention. This is sometimes described as being 'Gillick competent'. A child under 16 years (i.e. 15 years or below) may be Gillick competent to consent to medical treatment, research, donation or any other activity that requires their consent.

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

In some cases, for example because of a mental disorder, a child's mental state may fluctuate significantly, so that on some occasions the child appears Gillick competent in respect of a particular decision and on other occasions does not. In cases such as these, careful consideration should be given as to whether the child is truly Gillick competent at the time that they need to take a relevant decision.

When considering whether a child has the competence to decide about the proposed intervention, healthcare professionals may find it helpful to consider the following questions:

- Does the child understand the information that is relevant to the decision that needs to be made?
- Can the child hold the information in their mind long enough so that they can use it to make the decision?
- Is the child able to weigh up that information and use it to arrive at a decision?
- Is the child able to communicate their decision (by talking, using sign language or any other means)?

If the child is Gillick competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child's family in the decision-making process, if the child consents to their information being shared.

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

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

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

15.4 Child or young person with capacity refusing treatment

Where a young person of 16 or 17 who has mental capacity to consent to treatment, or a child under 16 but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child/young person or to severe permanent injury.

The courts have, in the past, found that parents can consent to their competent child being treated even where the child/young person is refusing treatment. However, this is a contentious area as the -Human Rights Act 1998 and the Mental Capacity Act 2005 indicate that children and young people can make their own decisions. In urgent situations legal guidance can be obtained through the Legal Services Department or out of hours through the Trust's solicitors by contacting the Executive on Call. Further advice can also be gained from the Matron for Safeguarding Adults or the Trust's Named Nurse for Safeguarding Children. It may be considered necessary to obtain a court declaration if faced with a competent child or young person who is refusing to consent to treatment, to determine whether it is lawful to treat the child.

Where the treatment involved is for mental disorder, consideration should be given to using the Mental Health Act.

A life-threatening emergency may arise making consultation with either a person with parental responsibility or the court impossible. Alternatively, the person with parental responsibility refuses consent despite such emergency treatment appearing to be in the best interests of the child. In such cases the courts have previously 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 but an application must be made to the Court to resolve any dispute as soon as possible.

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

15.5 Parental responsibility

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check. Advice can be sought from Legal Services Department.

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, who 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 designated in a care order in respect of the child
- Same-sex partners will both have parental responsibility if they were civil partners at the time of the treatment, e.g. donor insemination or fertility treatment.
- For same-sex partners who aren't civil partners, the second parent can get parental responsibility by either:

- Applying for parental responsibility if a parental agreement was made; or
- Becoming a civil partner of the other parent and making a parental responsibility agreement or jointly registering the birth.

In order for the person with parental responsibility to be able to consent, they must have capacity themselves.

16.0 Clinical photography and conventional or digital video recordings

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

Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. 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. You should use **Form 5** (Appendix 9) in addition to the relevant standard consent form to do so. 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 someone 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. For further details consult the Trust policy on *Use of cameras, video and audio recorders (including the use of smart phone and other mobile devices with recording functionality) on Trust premises policy and procedure.*

In some circumstances such as when safeguarding concerns are raised photographic evidence of injuries, and /or bodily condition may be required to assist in a safeguarding investigation. Where this is the case if the patient has mental capacity and can consent to this, their consent should be gained and documented. If they do not have mental capacity to consent for photographs to be taken it will need to be decided what is in their best interest. You must document your rationale for this in the patient's healthcare records. (Seek advice from the Matron for Safeguarding Adults, or Head of Information Governance or if a patient under the age of 18 years the Trusts Named Nurse Safeguarding Children or the Legal Services Department.

17.0 Use of tissue

The Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes. Patients can object to particular uses or the removal of particular tissues in writing. If they choose to object, a copy of the consent form should be sent with the request and specimen to the laboratory to ensure compliance with the patient's wishes. A register of such patients and their specimens will be kept in the pathology department and computer records and reports will record the objection. (See Human Tissue Authority: Code of Practice https://www.HTA.gov.uk)

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but the opt-out policy above applies.

Tissue samples may be used for quality assurance purposes without requiring specific patient consent *provided* there is an active policy of informing patients of such use. This is essential to ensure the high

quality of service, which all patients have the right to expect. Samples of tissue used in this way are always anonymised.

18.0 Consent for post-mortem examination

The Trust endorses the Human Tissue Act (HTA) 'Guiding principles and the Fundamental Principle of Consent' https://www.hta.gov.uk/sites/default/files/HTA%20Code%20A_1.pdf

No hospital post-mortem examination should be undertaken without valid consent of the person ranked as highest in the hierarchy of qualifying relationships (henceforth known as HQR) as defined below:

1. spouse or partner (including civil or same sex partner)
2. parent or child
3. brother or sister
4. grandparent or grandchild
5. niece or nephew
6. stepfather or stepmother
7. half-brother or half-sister
8. friend of long standing

Care must be taken to ensure the hierarchy of consent is observed. Careful judgement is needed as to the most appropriate person to give consent. The HTA Code of Practice – Consent gives details of appropriate persons able to give consent. Identifying who is most appropriate to give consent is not straightforward and staff should not make assumptions.

Consent forms for post-mortem are available from the Mortuary to those who have received specific training and guidance on how to seek consent.

Consultants should have a thorough knowledge of the purpose and procedure for post-mortem examination, and the management of bereavement, before seeking consent. Specific training and guidance is available through an e-learning package and should be identified as part of Consultant appraisal.

Consent for post-mortem should usually be sought by the consultant responsible for the care of the patient, who knows the medical problems and unresolved aspects that merit investigation. Consultants with limited experience of the post-mortem procedure should seek the support of a Consultant with greater knowledge. The Designated Individual (HTA) for the Trust may also be contacted.

Consent for post-mortem is separate to consent for retention of tissues or organs and relatives should be supported to make individual decisions about both issues.

In the unusual event that tissue is required to be stored or used for anatomical examination or public display, recommendations of the Human Tissue Act Codes of Practice must be followed at all times.

APPENDIX 1

Process requirements

1.0 Implementation and awareness

- Once ratified, the Chair of the Policy Ratification Committee (PRC) will email this policy/procedural document to the Corporate Governance Assistant (CGA) who will upload it to the Trust policy database on the intranet, under 'Policies & guidelines'.
- A monthly publications table is produced by the CGA which is published on the Trust intranet under 'Policies & guidelines'. Notification of the posting is included on the intranet 'News Feed' and in the Chief Executive's newsletter.
- On reading of the news feed notification all managers should ensure that their staff members are aware of the new publications.
- The approved document must be cascaded through the Directorates to all staff by the Clinical Directors, ADN's and matrons.
- The policy and procedures must be discussed at the junior doctors' induction programme to raise awareness.
- Directorate will identify any additional training needs and request appropriate training.
- Generic training is delivered to all healthcare professionals on induction.

2.0 Monitoring compliance with this document

- An annual Trust-wide audit of the consent process is undertaken by Directorates facilitated by the Clinical Audit Department in conjunction with the Legal Services Department.
- These results is discussed through the Directorate Clinical Governance and reported through the Divisional Governance Board and Clinical Audit and Overview Scrutiny Committee.
- Training Statistics in regard to consent is provided by Learning and Development on a monthly basis to each Directorate lead.

Archiving arrangements for information given to patients

Patient information leaflets are held on the Trust approved document management database on the intranet, under 'Policies & guidelines', which retains all superseded files in an archive directory in order to maintain document history. See also *Development & Production of Written Patient Information Policy and Procedure*.

3.0 Review

This policy and procedure and all its appendices will be reviewed at a minimum of once every four years.

4.0 Archiving

The Trust approved document management database on the intranet, under 'Policies & guidelines', retains all superseded files in an archive directory in order to maintain document history.

APPENDIX 2

CONSULTATION ON: Policy and Procedure for Consent to Examination or Treatment
Please return comments to: Wendy Bates – wendy.bates@nhs.net
By date: 2nd August, 2019

Job title:	**Date sent dd/mm/yy**	**Date reply received**	**Modification suggested? Y/N**	**Modification made? Y/N**
The following staff must be included in all consultations:				
Corporate Governance Assistant	24.07.19 15.08.19	24.07.19 15.08.19	Y Y	Y Y
Counter Fraud Specialist Manager (tiaa)	24.07.19			
Energy and Sustainability Manager	n/a			
Chief Pharmacist and Formulary Pharmacist	20.07.19			
Formulary Pharmacist	n/a			
Staff-Side Chair	n/a			
Complaints & PALS Manager	20.07.19			
Emergency Planning Team	24.07.19			
Head of Staff Engagement and Equality	n/a			
Health Records Manager	20.07.19			
All individuals listed on the front page	20.07.19			
The relevant lead for the local Q-Pulse database	n/a			
All members of the approving committee (Executive Team Meeting).	19.08.19			
Other individuals the author believes should be consulted				
Medical Director and Deputies	20.07.19	16.08.19	Y	Y
Chief Nurse and Deputies	20.07.19			
Head of Research	20.07.19			
All Consultant staff	20.07.19	5.08.19	Y	Y
All Directorate CD, HOS & Senior Management	20.07.19			
Consent Working Group	20.07.19	24.07.19	Y	Y
Patient Safety Manager	20.07.19			

Job title:	Date sent dd/mm/yy	Date reply received	Modification suggested? Y/N	Modification made? Y/N
Safeguarding Lead for Children	20.07.19	25.07.19	Y	Y
Transfusion Lead	20.07.19	29.07.19	Y	Y
Outcomes and Innovation Manager	20.07.19	25.07.19	Y	Y
The following staff have given consent for their names to be included in this policy and its appendices: Philippa Harris, Wendy Bates, Ann Munro				

APPENDIX 3

Equality impact assessment

This policy includes everyone protected by the Equality Act 2010. People who share protected characteristics will not receive less favourable treatment on the grounds of their age, disability, gender, gender identity, marital or civil partnership status, maternity or pregnancy status, race, religion or sexual orientation. The completion of the following table is therefore mandatory and should be undertaken as part of the policy development, approval and ratification process.

Title of document	Policy and Procedure for Consent to Examination or Treatment
What are the aims of the policy?	This policy issues guidance on the process of taking consent, who should undertake it and when. This ensures that patients and relatives are fully informed regarding the risks, benefits and alternative options involved in their treatment.
Is there any evidence that some groups are affected differently and what is/are the evidence sources?	Yes -refer to document
Analyse and assess the likely impact on equality or potential discrimination with each of the following groups.	Is there an adverse impact or potential discrimination (yes/no).
Gender identity	If yes give details.
People of different ages	No
People of different ethnic groups	No
People of different religions and beliefs	No
People who do not speak English as a first language (but excluding Trust staff)	No

People who have a physical or mental disability or care for people with disabilities	No - interpreters and translators available on request
People who are pregnant or on maternity leave	No - see Mental Capacity Act for patients without capacity
Sexual orientation (LGB)	No
Marriage and civil partnership	No
Gender reassignment	No
If you identified potential discrimination is it minimal and justifiable and therefore does not require a stage 2 assessment?	No
When will you monitor and review your EqIA?	Alongside this document when it is reviewed.
Where do you plan to publish the results of your Equality Impact Assessment?	As Appendix 3 of this document

FURTHER APPENDICES

The following appendices are published as related links to the main policy/procedure on the Trust approved document management database on the intranet, under 'Policies & guidelines':

No.	Title	Unique ID	Title and unique id of policy that the appendix is primarily linked to
4	12 key points on consent: the law in England	RWF-OWP-APP32	This policy
5	Consent form 1 - Patient agreement to investigation or treatment	RWF-OWP-APP34	This policy
6	Consent form 2 - Parental agreement to investigation or treatment for a child or young person	RWF-OWP-APP35	This policy
7	Consent form 3 - Patient/parental agreement to investigation or treatment (procedures where consciousness not impaired)	RWF-OWP-APP36	This policy

No.	Title	Unique ID	Title and unique id of policy that the appendix is primarily linked to
8	Consent form 4 - Form for adults who are unable to consent to investigation or treatment	RWF-OWP-APP37	This policy
9	Consent form 5 - Recordings for clinical purposes	RWF-OWP-APP38	This policy
10	List of Health Records Committee ratified procedure specific consent forms	RWF-OWP-APP33	This policy
11	Consent competency framework and record sheet	RWF-OWP-APP45	This policy