CONSENT TO EXAMINATION, TREATMENT AND CARE POLICY

POLICY

Reference	CPG-TW-CONSENT		
Approving Body	v11.0, Patient Safety Committee v11.1, Consent Steering Group		
Date Approved	v11.0, 13th July 2022 v11.1, 16th September 2022		
For publication to external SFH website	**Positive confirmation received from the approving body that the content does not risk the safety of patients or the public:**		
	YES	**NO**	**N/A**
	X		
Issue Date	18th October 2022		
Version	v11.1		

Summary of Changes from Previous Version

v11.1

- Update to process for obtaining legal advice for adults and children – section 6.10

v11.0, Full periodic review/ update undertaken and includes:

- agreed recommendations following a 360 assurance internal audit on patient consent; reference to updated professional guidance; and reference to good practice standards from NICE NG197 for Shared Decision Making.

The pertinent amends include:

- Strengthened roles/ responsibilities for Trust Lead for Consent/ Consent Group
- Added roles/ responsibilities for Patient Safety Committee
- Strengthened roles/ responsibilities for: Medical, Nursing and AHP Service Leads/ Clinical Chairs/ Service Directors/ Heads of Service/ Department Leaders (section 4) including:
  - having and maintaining lists of procedures for the purpose of seeking and gaining consent (to include form of consent/ grade of medical staff who can gain the consent/ who this can be delegated to and minimum grade of staff able to gain it; (example format at new Appendix I to help) and
  - having and maintaining records of training where written consent is required (example documentation at new Appendix H to help)
- Strengthened 'information and the patient's perspective' including interpretation services (section 6.4)
- Reference to using divisional lists of procedures and training records added to help with process for following up those who have obtained consent for a procedure without being authorised to do so (section 6.6 with reference to example format for lists at new Appendix I to help)
- Strengthened information on when patients change their mind/ are undecided and added information for repeat attenders (section 6.7)
- Introduced use of BRAN to help with shared decision making (section 6.9)
- Included information/ process for specialty/ procedure specific pre-printed consent forms (section 6.9.6 and Appendix G – information previously in a separate document on the intranet)

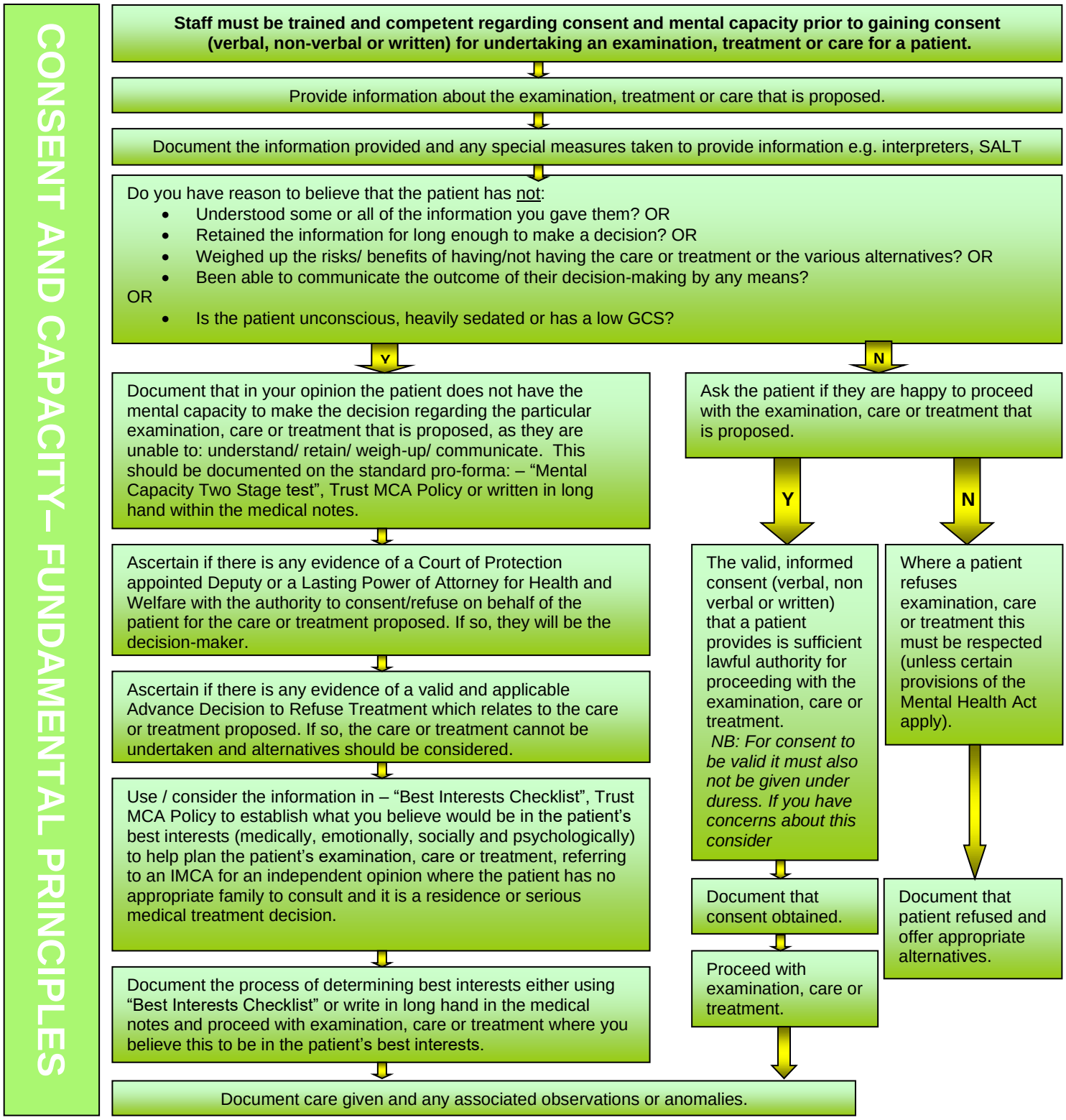
	• Added information for using pre-printed stickers on consent forms for recording a number of risks (section 6.9.7) • Strengthened information about using investigative images, clinical photography and video/audio recordings for education, publication and research in line with Photography and Video Recording Policy (section 6.13.2) • Updated 'Monitoring Compliance and Effectiveness' (section 8) with emphasis on specialties/ divisions providing evidence/ assurance of monitoring the following: o the consent documentation audit on AMaT o consent qualitative audit; o the divisional lists of procedures; o the status of staff training (for those who need to seek and obtain written consent as part of their role) and ensuring use of competency assessment documentation as applicable o requirements for specialty/ procedure specific training packages where written consent is required • 'Training and Implementation' (section 9) updated to include the new agreed standards for mandatory training (for staff seeking and gaining written consent), periodic refresher training and evidence of competency (example documentation at new Appendix H to help) • Removed research pathways as these are now maintained locally as associated documents
Supersedes	v11.0, Issued 23rd August 2022 to Review Date July 2025
Document Category	• Clinical
Consultation Undertaken	v11.1 • Members of the Consent Steering Group v11.0 Discussion of proposed amendments with members of the Consent Group in-line with the 360 assurance internal audit report recommendations (July 2021): • 24/9/2021; 22/10/2021; and 19/11/2021 Draft circulated 27th January 2022 to: • Divisional Clinical Chairs • Divisional General Managers • Divisional Heads of Nursing/ Midwifery • Divisional Clinical Governance Leads • Service Directors/ Heads of Service • Specialty Clinical Governance Leads/ Contacts • Consent Group Members • Other specialists • Safeguarding Lead • Specialist Learning Disabilities Nurse • Lead for Mental Capacity Act • Trust Solicitor • Research & Innovation Representative • Director/ Deputy of Medical Education (18-02-2022) • Foundation Training Programme Directors (18-02-2022) Discussion of proposed amendments with members of the Consent Group: • 25/03/2022; and 20/05/2022

	Draft circulated to members of the Consent Group: • 30-06-2022
Date of Completion of Equality Impact Assessment	19-05-2022
Date of Environmental Impact Assessment (if applicable)	Not Applicable
Legal and/or Accreditation Implications	• CQC Regulation 11 (2014), core fundamental standard with breaches leading directly to prosecution without serving a warning notice. • Mental Capacity Act (2005) • Professional Registration bodies
Target Audience	Trustwide – all staff involved in taking implied, verbal and written consent for examination, treatment or care of a patient.
Review Date	July 2025
Sponsor (Position)	Medical Director
Author (Position & Name)	Trust Lead for Consent, Mr Paresh Kothari
Lead Division/ Directorate	Surgery (Division of lead author)
Lead Specialty/ Service/ Department	Trauma & Orthopaedics (Specialty of lead author)
Position of Person able to provide Further Guidance/Information	Trust Lead for Consent

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
1. Consent Form 1 – Patient Agreement to Investigation or Treatment (for an adult)	Nov 2019
2. Consent Form 2 – Parental Agreement to Investigation or Treatment for a Child or Young Person	April 2020
3. Consent Form 3 – Patient/ parental agreement to investigation or treatment (procedures where consciousness not impaired)	Dec 2019
4. Consent Form 4 – Form for adults who are unable to consent for investigation or treatment	April 2019
COVID-19 and planned procedures/course of treatment where written consent is required (patient leaflet)	Oct 2021
Documentation/ Forms used in Research & Innovation Dept	Feb 2021
1. PERSONAL Legal Representative Consent Pathway (Research studies)	Feb 2021
2. PROFESSIONAL Legal Representative Consent Pathway (Research studies)	Feb 2021
3. Procedure without Consent Pathway (Research studies)	Nov 2019
4. Valid informed consent assessment – Research and Innovation	Feb 2021
5. SOP 21 – obtaining informed consent for research patients	
Template control	June 2020

CONTENTS

Consent & Capacity: Meeting Legal and Regulatory Requirements



Further information can be obtained from:

- **Trust's "Consent to examination, treatment and care policy"**
- **Trust's "Mental Capacity Act (MCA) Policy"**
- **Safeguarding Adults intranet site / Safeguarding Adults Team – ext 6059, vocera**
- **Trust Lead for Consent via PPC or switchboard (see Lead Author on front sheet of policy)**

Aide Memoire for Obtaining Written Consent for Procedure from Adult Patients

Note: This checklist refers specifically to sections 1-13 of SFH Consent Form 1. The bold numbers in brackets are the numbered items on the form itself.

Written consent should be obtained before the procedure is due to take place, except in emergency situations. It should be done **before** the patient arrives in theatre or the treatment room where the procedure is due to happen.

1. Does the patient have capacity? **Capacity is presumed unless there is doubt**. If a patient has capacity to understand, retain, weigh up the information and communicate their decision about, and implications of, the procedure complete the form and document the discussion in the patients notes. (If they do not have capacity for this decision, then you will need to **document** this in the notes and complete a Consent Form 4)

2. Explain the procedure to the patient including risks, benefits and, if appropriate, alternative options which specifically relate to the individual patient and the procedure as well as what would happen if the choice was to do nothing. **Document this clearly and LEGIBLY on the consent form. *(3 & 4)***
   - Do not use acronyms/ abbreviations
   - Ensure that it is clear on the form if the procedure may proceed/convert

   If the patient is high risk, ensure that is discussed with them and family if appropriate. **Document this discussion in the notes.**

3. Place patient stickers in all the places required on both copies of the consent form. ***(1)***

4. At the top of the form, print your name as the Medical professional – this is **not** a signature box. Print your role. This is the name of the health professional with overall responsibility for the patient and may not necessarily be the person completing the form and gaining consent from the patient. ***(2)***

5. Explain what type of anaesthesia/sedation that will be required. Indicate this clearly on the form. ***(6)***

6. If transfusion is likely to be required during or after the procedure, as a result of it, explain this to the patient and indicate that clearly on the form. Explain the risks/ benefits of radiation. ***(4)***

7. If written information in the form of a leaflet is given to the patient, please complete that section. ***(5 & 7)***

8. Sign and date the form. **Print** legibly your name and Job Title ***(10)***. Fill in contact details ***(11)***

9. If using a face to face interpreter ask them to sign/ print/ date the form but if using telephone interpreter, print their name and code ***(12)***

10. Give the patient the form and the time to read through it and be sure they have understood everything. They should read the “Statement of Patient”, then sign it, print their name and write the date. ***(13)*** Make sure they understand that they can change their mind at any time.

11. Give the patient the white copy to retain. Circle the “YES” at the bottom of the page to confirm they have received it. Do not circle unless they take the copy. ***(8)***

12. Explain that any images/ recordings will be used for clinical purposes only. But additional consent must be given if they could be used for additional purposes (ie education/ publication/ research) and this must be documented ***(9)***

13. File the completed form appropriately ready for use when procedure takes place.

The **GMC** has very clear requirements for doctors regarding clear documentation:

- *19 Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events that you are recording or as soon as possible afterwards.*

The full GMC explanatory guidance for consent can be found at:
Domain 1: Knowledge skills and performance - ethical guidance for MAPs and AAs - GMC (gmc-uk.org)

1.0 INTRODUCTION

Obtaining consent is a fundamental, legal and ethical principle and constitutes one of the Care Quality Commissions core fundamental standards (CQC April 2015, Regulation 11). All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they can. The exchange of information between doctors and other health professionals with patients is essential to good decision making. Serious harm can result if patients are not listened to or if they are not given the information they need and time and support to understand it so they can make informed decisions (GMC Nov 2020).

Doctors and other health professionals must ask for and gain consent from a patient prior to undertaking any form of examination, treatment or care (NMC, Oct 2018; GMC, Nov 2020). Patients may indicate consent non-verbally (for example holding out their arm to have their blood pressure monitored), verbally or in writing.

The Department of Health has issued a range of guidance documents on consent which should be consulted for details of the law and good practice requirements on consent, see references. Included are:

- *DH (2001) Good practice in consent implementation guide: consent to examination or treatment* – including "12 key points for consent, the law in England"
- *DH (2009) Reference guide to consent for examination or treatment second edition*

NICE (June 2021) has published guidance on *Shared Decision Making* which promotes ways for healthcare professionals and people using services to work together to make and reach decisions about treatment and care. However, patients are also free and able to change their mind or withdraw their consent at any time and it is for the healthcare professional to ensure that consent is still valid at the time of the intended procedure.

This policy sets out the standards and procedures in this Trust, which aim to ensure that health professionals are able to comply with these standards. While this policy is primarily concerned with healthcare, social care colleagues working on Trust premises should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.

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

Therefore, during the consent process, doctors must ensure that patients are aware of any "material risks" involved in a proposed treatment, and of reasonable alternatives (*Montgomery v Lanarkshire Health Board, March 2015)*.

This is a marked change to the previous "Bolam test", which asks whether a doctor's conduct would be supported by a responsible body of medical opinion. This test will no longer apply to the issue of consent, although it will continue to be used more widely in cases involving other alleged acts of negligence.

Consent is a continuing process rather than a one-off decision. It is important that patients are given continuing opportunities and enough time to ask further questions and to review decisions about their health care.

This policy is issued and maintained by the Medical Director on behalf of the Trust, at the version defined on the front sheet, which supersedes and replaces all previous versions.

2.0 POLICY STATEMENT

This policy provides a framework within which all Trust employees will comply when seeking consent for examination, treatment and care. All Trust employees include: Consultants and doctors of all grades; nurses of all grades; all relevant allied health professionals and any other staff involved in the delivery of care. The policy also includes procedures to be undertaken for using investigative images, clinical photography and video recordings.

This clinical document applies to:

Staff group(s):

- It is the responsibility of all staff to adhere to this policy when in a situation concerning consent, whether this is verbal, non-verbal, written or acquiescence.

Clinical area(s):

- All clinical areas across all sites (King's Mill Hospital, Newark Hospital, Mansfield Community Hospital)
- All other areas where the process for consent is undertaken by Trust staff (e.g. home visits and outreach locations)

Patient group(s):

- All patient groups – adults and patients under the care of the maternity and paediatric services (including neonates and young people)

Exclusions:

- None

3.0 DEFINITIONS/ ABBREVIATIONS

The Trust:	Means the Sherwood Forest Hospitals NHS Foundation Trust.
Staff:	Means all employees of the Trust including volunteers, contractors and those managed by a third party organisation on behalf of the Trust.
Consent:	It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation or providing personal care for a person. This principle reflects the right of patients to determine what happens to their own bodies and is a fundamental part of good practice. A healthcare professional (or other healthcare staff) who does not respect this principle may be liable both to legal action by the patient and to action by their professional body and occasionally the criminal law. Employing bodies may also be liable for the actions of their staff (DH 2009 Reference guide to consent for examination or treatment 2nd Edition).
Valid Consent:	For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (this will be the patient or someone with parental responsibility for a patient under the age of 18, someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has the authority to make treatment decisions as a court appointed deputy). Acquiescence where the person does not know what the intervention entails is not 'consent'.
Acquiesce:	To consent or comply passively or without protest (e.g. presents an arm for venepuncture)
Non-verbal:	Consent may be expressed using non-verbal communication, which may include actions such as: nodding head, blinking eyes, presenting an arm for venipuncture. However, the person must have understood what the examination, treatment or care is intended and why for such consent to be valid.
Two Stage Test:	The Two Stage Test (documentation/ form associated with the Trust's Mental Capacity Act Policy) is for use by health professionals to include a record of capacity assessment in the patient records and if necessary as addendum to specialist reports.
Best Interests:	An act done or decision made under the Mental Capacity Act for or on behalf of a person who lacks capacity must be done or made in his/her best interests (see Best Interest Check List – documentation/ form associated with the Trust's Mental Capacity Act Policy.
Investigative Images:	Are any images which are made when a patient undergoes certain types of procedures used to aid diagnosis and treatment during an episode of care. Examples include X-rays, MRI scans, CT scans and Ultrasound scans. Images/ recordings may also be taken during procedures such as endoscopies and sleep studies. Images are also produced by photography and video recordings (conventional and digital).
AAGBI	Association of Anaesthetists of Great Britain and Ireland
DH	Department of Health
DMT	Divisional Management Team
GDC	General Dental Council
GMC	General Medical Council
IMCA	Independent Mental Capacity Advocate
MCA	Mental Capacity Act
NMC	Nursing and Midwifery Council
PPC	Patient Pathway Coordinator
RCN	Royal College of Nursing
RCS	Royal College of Surgeons
SALT	Speech and Language Therapist
RAG rating system (relates to training packages)	• Red – overdue • Amber – due within 3 months • Green – in date

4.0 ROLES AND RESPONSIBILITIES

4.1 Trust Lead for Consent/ Consent Group have responsibility for:

- keeping up to date with law and practice on consent
- providing expert advice on any issue relating to consent
- maintaining and approving the Trust's Consent Policy and associated documentation (ie Consent Forms 1-4)
- identifying, reviewing, agreeing and maintaining (as applicable) the mandatory e-learning training package
- identifying, reviewing and agreeing the standard elements for the Trustwide consent documentation audit
- advising on the requirements for qualitative consent audit
- agreeing and maintaining an annual work plan and Terms of Reference (both formally reviewed/ updated at least annually)
- providing relevant information on issues raised at Consent Group meetings to the divisions via the divisional group representatives (standard item on divisional clinical governance group meeting agendas)
- providing an update report on progress with the work plan to the Patient Safety Committee at least annually.
- Escalating any issues raised at Consent Group meetings to the Patient Safety Committee as required.
- Undertaking any other subject related business as directed by the Patient Safety Committee.

4.2 Patient Safety Committee has responsibility for:

- Overseeing the work plan, Terms of Reference and update report received from the Consent Group at least annually but as per the committee's work plan.
- Seeking assurance from the Consent Group that high standards of consent are provided by the Trust and in particular that adequate and appropriate governance structures, processes and controls are in place throughout.
- Requesting the Consent Group to undertake any subject related business as necessary
- Escalating any issues in relation to consent as required to the Quality Committee
- Forwarding a summary of any Consent Group reports to the Quality Committee following receipt and oversight.

4.3 Medical Director/ Chief Nurse have the responsibility for ensuring:

- the Trust has an up-to-date consent policy and that compliance with the law and professional conduct surrounding consent is maintained.

4.4 Divisional Management Teams have the responsibility for ensuring that:

- the Service Leads/ Directors/ Heads of Service/ Department Leaders discharge their duties as described below
- a highlight report is provided to the Consent Group via their Divisional Consent Group Representative every 6 months which includes confirmation of the requirements for their respective divisional list of procedures, training/ training records (for staff who need to seek and gain written consent), training packages and audit activity using the standard report format provided by the Consent Group.

4.3 Specialties – through Medical, Nursing and AHP Service Leads/ Service Directors/ Heads of Service/ Department Leaders have the responsibility for:

- ensuring that the policy is followed within their areas of work
- having and maintaining a divisional list of procedures requiring consent to include: the form of consent (written/ verbal and if needs documentation in notes); who can seek and obtain written consent for them (minimum grade of medical staff); and who the process for seeking and obtaining written consent can be delegated (minimum grade of registered/ non-registered staff) – suggested format for lists can be found at Appendix I.
- having a process in place for reviewing and updating above divisional lists for approval by Divisional Management Teams on an annual basis
- ensuring that all staff within their division/ specialty who need to seek and obtain written consent have undergone consent training as applicable to their role and maintaining register(s) of training/ periodic refresher training – this includes having records for doctors in training rotating through the specialties.
- having a process in place to monitor consent training requirements for staff who need to seek and obtain written consent within their division/ specialties/ departments
- ensuring that procedure/ department specific training for taking written consent is included at local induction (see section 8 for elements to include) as well as having appropriate training packages/ documentation for recording the training and subsequent competency. Example procedure/ department specific consent competency documentation can be found at Appendix H
- having a process in place for reviewing and updating local consent training packages above for approval at specialty/ departmental level at least every 3 years.
- ensuring that all doctors in training have their competency documentation signed off within the first weeks of joining the specialty

4.6 All staff seeking written consent

- It is always best for the person actually treating the patient to seek the patient's consent. However, the person actually treating the patient may wish to delegate this to a health professional who is not capable of performing the procedure but has the knowledge of the procedure in question. The health professional must be competent and have had the relevant training to seek consent and must ensure full and accurate record keeping using the appropriate consent form and recording relevant information in patient medical notes.

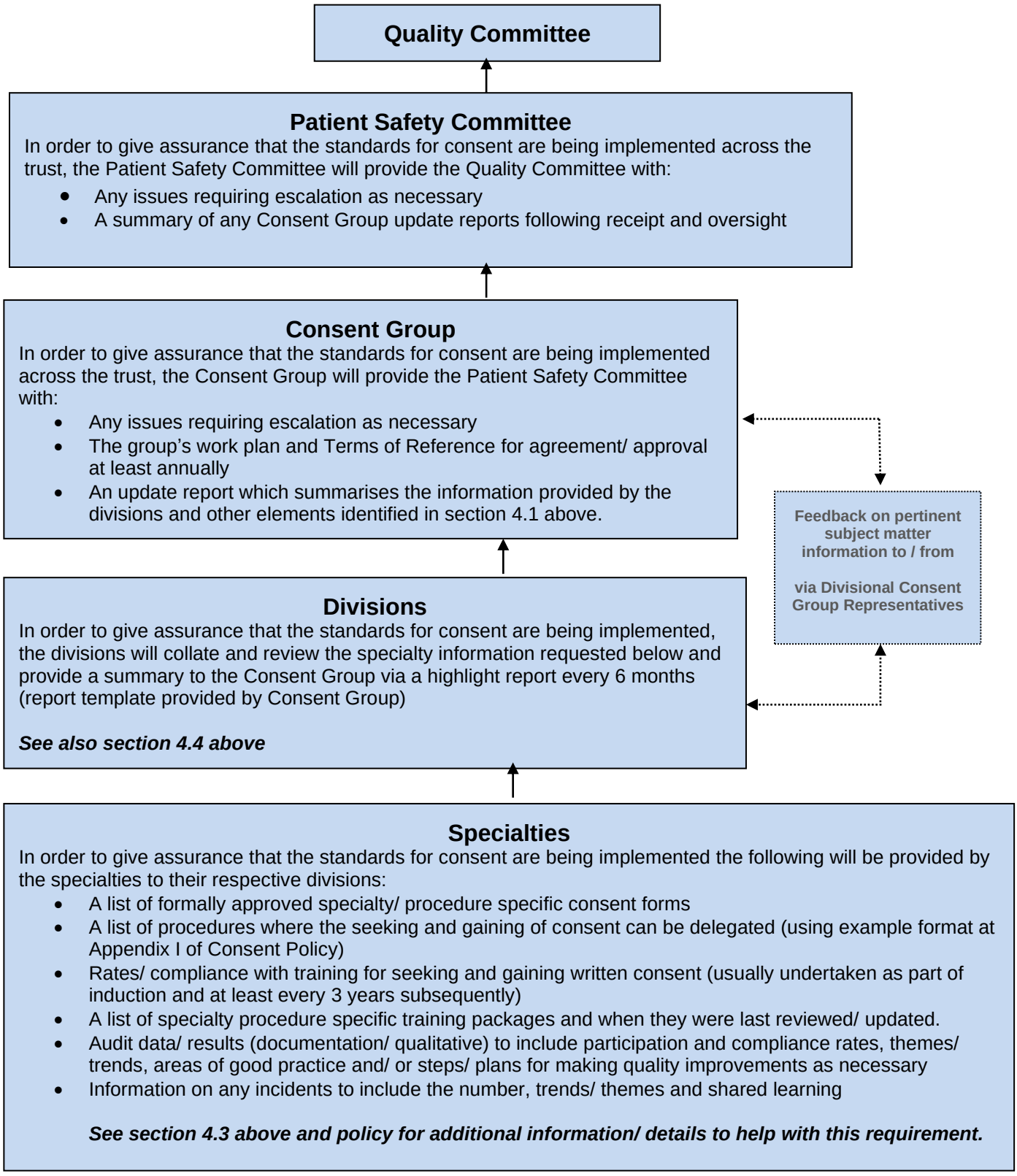
4.7 Health professional carrying out procedure is ultimately responsible for:

- ensuring that the patient is genuinely consenting to what is being done and that the correct process for gaining consent has been followed as it is they who will be held responsible in law if this is challenged later.

4.8 All staff undertaking routine everyday care are responsible for:

- gaining consent (verbally or non-verbally) prior to implementing any routine care. Once consent has been gained, it is good practice to document this in the patients' notes and for practical reasons (unless there are any fluctuations/ changes), this can be documented once per shift/ duty period. Although these examples are not exhaustive this may include tasks such as: taking a blood pressure, assisting with personal care such as washing, dressing and feeding, facilitating the transfer of patients from a chair to a wheelchair and taking samples of blood. For this, all staff have the responsibility to undertake mandatory and update training on mental capacity including consent. See section 8, Training and Implementation for further information.

4.9 Governance Structure for Consent



5.0 APPROVAL

Following appropriate consultation as recorded on the front sheet, this policy (v11.0) has received approval from the Consent Group and final higher level approval from the Patient Safety Committee.

6.0 DOCUMENT REQUIREMENTS (POLICY NARRATIVE)

6.1 Introduction to Consent

It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a person or it must be provided on a lawful basis if acting in the absence of a person's valid consent. This principle reflects the right of patients to determine what happens to their own bodies, and is a fundamental part of good practice. A healthcare professional (or other healthcare staff) who does not respect this principle may be liable both to legal action by the patient and to action by their professional body. Employing bodies may also be liable for the actions of their staff (DH 2009 Reference guide to consent for examination or treatment 2nd Edition).

The NHS Constitution (March 2012, updated Jan 2021) establishes the principles and values of the NHS in England. It sets out rights to which patients, public and staff are entitled, and pledges which the NHS is committed to achieve, together with responsibilities which the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively. Some of the rights and NHS pledges to the public and patients include having the right to:

- be treated with dignity and respect, in accordance with human rights;
- accept or refuse treatment that is offered and not to be given any physical examination or treatment unless valid consent has been gained; where the person does not have capacity to give their consent it must be obtained from a person legally able to act on the persons behalf or be in the persons best interests;
- be given information about the proposed treatment in advance, including any significant risks and any alternative treatments which may be available, and the risks involved in doing nothing.

Doctors and other health professionals must ask for and gain consent from a patient prior to undertaking any form of examination, treatment or care (NMC Oct 2018; GMC Nov 2020, HCPC 2016). This includes requiring consent verbally, non-verbally or by acquiescence for routine everyday procedures such as: dressing wounds and taking a patient's blood pressure; observing (examining) a rash or mole; or providing personal care such as assistance with washing and dressing.

Whether undertaking a routine procedure or major surgery, the patient must be given as much information as they require to consent.

Valid consent requires these three elements to be present:

1. the person has been provided with appropriate information about the care and treatment and any potential options or choices in a format they can understand;
2. the decision is made without duress/undue influence; and
3. the decision maker has capacity to make and communicate the decision at that time.

6.2 Consent and Capacity (Adult Patients)

Valid informed consent cannot be taken when the patient lacks the mental capacity for that decision at that time. The Mental Capacity Act (2005) provides a framework for the decision making process and a lawful basis for acting where, because of a lack of capacity, there is no valid consent.

Capacity is *time* and *decision specific*. A person may have capacity for one decision but not for another or many decisions.

Under the Mental Capacity Act (2005), **a person must be assumed to have capacity** unless it is established that they lack capacity. If there is any doubt about a patient's capacity, then the healthcare professional should assess the capacity of the patient to make the decision in question. The Act outlines five statutory principles and is intended to be enabling and supportive of people who lack capacity, not restricting or controlling of their lives (further information on the five statutory principles can be found in the Trust's Mental Capacity Act (MCA) Policy.

The Act aims to protect people who lack capacity to make particular decisions, but also to maximise their ability to make decisions, or to participate in decision-making, as far as they are able to do so. Healthcare professionals will need to apply these principles when working with people who may lack capacity to make decisions – for further information please see the Trust's Mental Capacity Act (MCA) Policy.

An assessment of a person's capacity must be based on their ability to make a specific decision at the time it needs to be made, and not their ability to make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things:

- understand the information given to them that is relevant to the decision
- retain that information long enough to be able to make the decision
- use or weigh up the information as part of the decision-making process
- communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

This assessment and the conclusions drawn from it should be documented on the relevant proforma (Trust's two stage test/ best interest checklist – MCA Form 1 for Nurses/ AHPs or MCA Form 2 for Doctors) or recorded in long hand in the medical notes.

Once a patient is assessed as lacking capacity to make a decision the Act requires the "decision maker" to make a "best interests decision" on their behalf. The "Decision Maker" is the person responsible for carrying out the care, procedure or treatment. This could be a different person in relation to each decision. See MCA Code of Practice 5.8–5.10. The decision maker has the responsibility to work out what would be in the best interests of the person who lacks capacity and plans their care/ treatment accordingly.

The Trust's "Mental Capacity Act (MCA) Policy" provides a **Best Interests Assessment** which should always be referred to and the relevant information documented in relation to all decisions being made in a person's best interests. The checklist documentation does not always have to be completed but all aspects of it must be considered. However, in all instances of decision making the minimum information to be documented in the patient records is:

- How the decision was reached
- What the reasons for that decision were
- Who was consulted in relation to the decision
- What particular factors were taken into account

The more serious the decision, potentially the more information requires documenting in relation to how the decision was reached.

All the elements of the best interest check list and other relevant information must be used and to plan individualised care or treatment in the patients best interests. All plans of care and treatment must be recorded in the relevant documentation.

Once a patient has been assessed and it has been confirmed they lack capacity, consent form 4 must be completed when taking written consent. For further details of consent forms see section 6.9.

Please note if a patient lacks capacity the healthcare professional proposing the procedure/ treatment must:

- **clarify whether or not the patient has a Lasting Power of Attorney (Health and Welfare) which covers the proposed procedure/ treatment. If the patient has a lasting Power of Attorney they must be consulted and included in the discussions and will make the decision about the proposed procedure/ treatment as if they were the patient. The only exceptions to this are outlined in the Mental Capacity Act Code of Practice (2005).**
- **check whether or not there is a valid and applicable Advanced Decision to Refuse Treatment (ADRT).**
- **check if a Court of Protection Deputy has been appointed.**
- **if time permits, consult an Independent Mental Capacity Advocate (IMCA) for people lacking capacity who have no one else to support them (other than paid care staff) whenever a member of the healthcare team is proposing to provide serious medical treatment. Further information and how to refer can be found on the Trust's Safeguarding Adults intranet site.**

Where treatment is complex and/or people close to the patient express doubts about the proposed treatment, a second opinion should be sought, unless the urgency of the patient's condition prevents this. The Court of Protection deals with serious decisions affecting personal welfare matters, including healthcare. The Court can be asked to make a decision in cases where there are doubts about the patient's capacity and also about the validity or applicability of an advance decision to refuse treatment. Cases involving any of the following should be referred to the Court for approval:

- cases involving organ, bone marrow or peripheral blood stem cell (PBSC) donation by an adult who lacks capacity to consent
- cases involving the proposed non-therapeutic sterilisation of a person who lacks capacity to consent to this (e.g. for contraceptive purposes) and
- all other cases where there is a doubt or dispute about whether a particular treatment will be in a person's best interests (including cases involving ethical dilemmas in untested areas).

For further information about mental capacity including Lasting Powers of Attorney, Advanced Decisions to Refuse Treatment, Court of Protection Deputies and Independent Mental Capacity Advocates (IMCAs) please refer to the Trust's Mental Capacity Act (MCA) Policy and The Mental Capacity Act Code of Practice (2007).

6.3 Is The Consent Given Voluntarily?

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

Once it has been determined that a person has the capacity to make a particular decision at a particular time, a further requirement (under the common law) for that consent to be valid is that it must be given voluntarily and freely, without pressure or undue influence being exerted upon them.

When people are seen and treated in environments where involuntary detention may be an issue, such as prisons and mental hospitals, there is a potential for treatment offers to be perceived coercively, whether or not this is the case. Coercion invalidates consent, and care must be taken to ensure that the person makes decisions freely. Coercion should be distinguished from providing the person with appropriate reassurance concerning their treatment or pointing out the potential benefits of treatment for the person's health. However, threats such as withdrawal of any privileges, loss of remission of sentence for refusing consent or using such matters to induce consent may well invalidate the consent given, and are not acceptable.

6.4 Information and the Patient's Perspective

This section covers the following:

- Provision of information and a patient's perspective;
- General information on consent;
- Procedure/ treatment specific information;
- Written patient information leaflets;
- Provision of information for patients whose first language is not English;
- Face to face appointments/ patients with additional needs (eg learning disability);
- Access to health professionals between formal appointments

6.4.1 Provision of information and a patient's perspective

The provision of information is central to the consent process and applies in whatever setting the interaction takes place, including remote consultations. Patients have the right to be listened to and to be given information they need to make a decision and the time and support they need to understand it. Shared decision making is a collaborative process that involves a patient and their healthcare professional working together to reach a joint decision about care. It could be care the person needs straightaway or care in the future, for example, through advance care planning (GMC, Nov 2020; NICE, June 2021).

When seeking consent the clinician should remember to view it from a patient's perspective and that there may be exceptions to the principles (DH Nov 2001). Please see:

- Appendix B – Seeking consent remembering the patient perspective
- Appendix C – Other Exceptions to the Principles.

Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who make the capacitous decision to follow the health professionals advice. There will always be an element of clinical judgement in determining what information should be given.

Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this must be documented on the consent form and within the medical notes.

However, the *presumption* must be that the patient wishes to be well informed but not the presumption on what the patient might want or need. They must take reasonable steps to ensure that patients are provided with the information about the risks and benefits of the various options particularly those which are material/ specifically relate to the individual patient and the procedure (RCS, Nov 2018; GMC, Nov 2020).

The exchange of information and meaningful dialogue between patients and healthcare professionals is key to shared decision making (GMC, Nov 2020; NICE, June 2021).

Therefore, before patients can come to an informed decision and give valid consent about procedures, treatment or care, they need comprehensive information which they can understand.

- For routine every day care this may be a simple explanation of how a procedure is undertaken and why it is needed, such as monitoring a blood pressure. But it must be made clear to patients they can say no at any time and the Health Professional must stop the proceedings immediately. Health Professionals must also be alert to any signs that a patient may be confused or unhappy about what is being done (GMC, Nov 2020).

- For more complex procedures and treatments such as operations and invasive procedures, a more structured approach is required and informed written consent is likely to be required. Healthcare professionals must try and find out what matters to patients so they can share relevant information about the risks and benefits which specifically relate to the individual patient and the procedure (including the risks/benefits of doing nothing). They also need to be informed about additional procedures which are likely to be necessary as part of the procedure, for example a blood transfusion or the removal of particular tissue. They also need to be informed about the risks and benefits of any radiation involved during the procedure/ course of treatment. Any misinterpretation of these elements will invalidate consent (GMC, Nov 2020).

For more complex procedures and treatments, it is also good practice to allow sufficient time for the patient to consider the treatment options and they must be informed that they can change their mind at any point in the process, including on the day of the procedure/ treatment.

Therefore the gaining of consent might not be concluded in one consultation but may be over a number of consultations/visits. In Appendix E there is a suggested format to follow which may help health professionals to document the discussion relating to the treatment options for the patient and patient information given. These notes should be made at the time of the discussion and when the information is given.

6.4.2 General information on consent

When consent is required, whether it is written, verbal or non-verbal, it is good practice to give general information about consent.

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

- *DH (2009) Reference guide to consent for examination or treatment 2nd Edition* provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent.

- *DH (2001) Good practice in consent implementation guide: consent to examination or treatment* includes the "*12 key points on consent: the law in England"* and has been distributed widely to health professionals working in England. This document summarises those aspects of the law on consent which arise on a daily basis. For more information please refer to Appendix D of this policy.

Where written consent is gained, general information about consent is provided on the reverse side of the patient's white copy of the consent form (forms 1,2 & 3).

With the emergence of the COVID-19 pandemic and for patients undergoing more complex procedures which require written consent, hospital activity and the ability to continue with such planned care and urgent surgery will vary. This may have the potential to alter a patient's experience and therefore additional information is now required on the timings of procedures/ courses of treatment; the increased risks of contracting or transmitting coronavirus whilst in hospital; and the potential for increased risks of serious complications. Where written consent is required, these must be discussed with patients and the conversation summarised in patient's notes and/ or the patient given the following leaflet: ***COVID-19 and planned procedures/ course of treatment where written consent is required***.

The above principles will also apply to any future pandemics.

6.4.3 Procedure/ treatment specific information

Once a decision has been made, patients need information about the particular procedure or treatment/investigation to which they are consenting and what will happen such as: where the procedure/ investigation will take place, how long it will take, will they need to stay in hospital – if so how long for, how they will feel afterwards and so on (DH, 2009; RCS, Nov 2018; GMC, Nov 2020).

Wherever possible, it is good practice to offer patients written information about the procedure or treatment/ investigation (or their condition) however, there may not always be written information available, therefore documenting the discussion in the medical notes is important. If written information is offered, this must be documented in the medical notes at the time of the discussion also. If written consent is required there is also a section on the consent form where the details of any written/ printed leaflets offered to/ accepted by patients must be noted along with the leaflet code.

Where relevant, information about anaesthesia should also be offered alongside information about the procedure or treatment/ investigation itself and relevant information also documented.

Where relevant, the person providing the information must be able to evidence (through documenting in the patients notes and/ or on the relevant consent form) that verbal information, and where able written information, specifically relating to the risks, benefits, alternative treatments and the option of not to treat has been discussed which specifically relate to the individual patient and the procedure.

6.4.4 Written patient information leaflets

Good written patient information can give patients confidence and thus improve their overall experience as a patient and also remind them of what their health care professional told them. Also, written information leaflets can be read and absorbed at a patient's own pace. It gives people time to go away, read the information and think about the issues involved.

The Trust has a contract with ***EIDO Healthcare*** which is an external company that provides a patient information leaflet repository specifically written to promote the informed consent process. Access is via the Patient Information section on the Trust's intranet. Their leaflets are split by specialties as well as including a category for disease prevention. The leaflets can be downloaded/ printed to give patients. All the information leaflets within EIDO have the Trust logo clearly marked at the top together with all the minimum requirements as stated within this policy. The leaflets are reviewed and updated on an annual basis so staff are advised to ensure they are using the most up to date ones.

Staff looking to develop new information for patients should review the information on EIDO to see if there is suitable information they can use before creating their own – the process and standards for which can be found in the Patient Information Development and Distribution Policy.

The above Trust policy excludes guidance on the use of externally produced information. However, it states that clinical staff have responsibility to use information from reliable sources, for example NICE, the Department of Health, NHS England, Royal Colleges, charitable organisations, foundations/societies, research companies and pharmaceutical companies.

The Trust's internally produced patient information leaflets can be located on the internal Patient Information intranet site and/ or the external website using these links:

- Patient Information (intranet site)
- Patient information leaflets (external website)

Please remember it is the responsibility of the person offering the written information to ensure that it is the most appropriate and up-to-date information for the patient. Considerations must include a patients age, language (see 6.4.5 below) and any other additional needs (see 6.4.6 below). Where written information leaflets are offered to patients, the title and code if available must be recorded on the consent form along with indicating if the leaflet was accepted or declined.

Where care is being planned in a patient's best interests the person/ people who knows them the best will be present to help support understanding of the information given.

6.4.5 Provision of information for patients whose first language is not English

Healthcare professionals must ensure that any information is suitable for the individual patient (RCS, Nov 2018; GMC, Nov 2020; NMC, Oct 2018).

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. Except in time-critical circumstances (see further below), it is not appropriate to use children, family members or relatives to interpret for family members who do not speak English.

The Trust has a contract for interpreting and translation services with a company called thebigword (thebigword) and with the Notts Deaf Society for British Sign Language interpreting.

'Thebigword' is able to provide interpreting in over 250 different languages, from the most common to the rarest dialects. In our locality the languages most often requested include Polish and Russian.

The contract we have with 'thebigword' has been approved by our Information Governance Department and Caldicott Guardian and meets our confidentiality requirements.

Further information can be found in the Staff Guide for Interpreting (and Translation) Services but in summary:

- The telephone interpreting service is available 24/7. Users have an access code. For those without access codes contact the Diagnostic and Outpatient management secretaries on ext 4168 or 3368 during normal working hours, or out of working hours contact the Duty Nurse Managers via switchboard.

- In general, face to face interpreting should only be used in certain circumstances e.g. breaking bad news, mental health issues, paediatric appointments, patient education/ counselling and interpretation during an actual procedure eg endoscopy/ surgery under local anaesthetic or any other circumstances where its need is recognised by the healthcare professional. This service can only be booked during working hours by contacting the Diagnostic and Outpatient management secretaries on ext 4168 or 3368. The staff there will complete a request form (copy available in above guide), it is therefore important you have the relevant information to hand. All interpreters are sessional workers and are used as and when needed. It is therefore advisable to make the booking as much in advance as possible, ideally at least 48 hours in advance. Thebigword may be able to provide an interpreter with only two hours notice, however, that would limit their options in order to match our requirements, such as age, gender, etc.
- ***In time critical circumstances, it is the responsibility of the patient's healthcare team to ensure that every reasonable effort has been made to ensure availability of an interpreter where necessary. All steps taken must be recorded in patient notes.***
- ***If necessary, in an emergency situation, Trust staff can be used to interpret.***
- If any written information is needed in a different language or format, please contact the Patient Information Officer on ext 6927 or the Diagnostics and Outpatient management secretaries on ext 4168 or 3368. There is a cost associated with this service.

6.4.6 Face to face appointments/ patients with additional needs (eg learning disability)

As well as patients whose first language is not English, healthcare professionals must ensure that any appointments and information is suitable for individuals with other additional needs that may impair effective communication such as eyesight/ hearing, literacy levels and learning difficulties (RCS, Nov 2018).

Due to the coronavirus pandemic, there has been a move towards telephone / video calls for some appointments so not all are face to face (although this must happen where significant surgery is proposed). Every effort must be made to identify where a patient must attend a face to face appointment, particularly if they have additional needs, such as those who may require a relative/ friend to accompany them to help with any impairments/ barriers and their understanding.

For patients with a learning disability, services need to be flexible to support their needs such as having an early/ late/ double appointment slot. And it can be arranged in advance for the specialist nurse to be available to help with communication and preparation for the consent process.

For further information and pathways for pre-operative assessment/ out-patient appointments and planned admissions, see the Trust's Learning Disability Policy.

6.4.7 Access to health professionals between formal appointments

After appointments with health professionals, patients will often think of further questions which they would like answered before they make their decision. Where possible, the patient should contact their medical/ surgical team by telephone or make another appointment via the relevant secretary to discuss the concerns directly. Contact details should be noted on the consent form. If a patient is unable to make direct contact, they should make enquiries via the Patient Experience Team – the contact numbers for King's Mill Hospital and Newark Hospital are pre-printed on the Trust's four core consent forms (1, 2, 3 & 4).

6.5 Who Should Seek Consent

This section covers the following:

- Who should seek consent – verbally, non-verbally or by acquiescence
- Who should seek written consent
- Who can be delegated the seeking of written consent

Only healthcare professionals who have undertaken the required training and are competent to do so, can seek consent – for details on relevant training, see section 8.
(RCS, Nov 2018; GMC, Nov 2020; DH 2009)

6.5.1 Who can seek consent verbally, non-verbally or by acquiescence

Where consent is being sought verbally, non-verbal or by acquiescence it is usually at the point a procedure, treatment or care will be carried out – this will naturally be done by the Health Professional responsible for the intervention. Training for mental capacity (incorporating consent) is part of mandatory training for all clinical staff and includes a competency assessment, meaning all clinical staff can seek consent like

this. The underlying principle of the training is that consent is required before undertaking any procedure, treatment or care. However, if there is doubt about the patient's understanding of the proposed intervention then the healthcare professional must undertake a two stage test for capacity. If the assessment shows lack of capacity then the proposed intervention must be planned in the patient's best interests using the best interest assessment/ checklist (see the Trust's MCA Policy). Gaining consent in this way must be documented in the patient's notes. Consent to general care and treatment should normally be documented on a daily basis in the patients notes. For nursing staff, this would be the nursing notes; for doctors this would be the medical notes and for other professions within their respective place for record keeping purposes.

6.5.2 Who can seek written consent

As per section 6.4.1, it is more likely that written consent is required for more complex procedures and treatments such as operations and invasive procedures. It is also more likely that a more structured approach is required meaning that the seeking and gaining of consent might not be concluded in one consultation but may be over a number of consultations/ visits

Only healthcare professionals who have undertaken the relevant consent training ***and*** specialty/ procedure specific training and have evidence of competency can seek such consent.

- Training is via the Trust agreed mandatory e-learning package which includes a competency assessment at the end.
- Specialty/ procedure specific training is undertaken within each specialty/ department and must also include a competency assessment.

But unlike seeking verbal or non-verbal consent or consent by acquiescence, it is not always the healthcare professional actually carrying out the intervention who will seek written consent for it from the patient – see section 6.5.3 below for further information on delegation.

However, the Health Professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done as it is they who will be held responsible in law if this is challenged later.

They are also responsible for ensuring that the person has given valid consent before treatment begins, although the consultant responsible for the person's care will remain ultimately responsible for the quality of medical care provided.

6.5.3 Who can be delegated the seeking of written consent

Team work is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

The GMC (2020) states that the task of seeking consent may be delegated to another person who may not be capable of performing/ undertaking the actual procedure, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require. The practitioner who eventually carries out the investigation or treatment must also be able

to determine whether the person has the capacity to make the decision in question and what steps need to be taken if the person lacks the capacity to make that decision (See MCA 2005 Code of Practice - chapter 2).

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

Consent training for foundation and medical/ surgical trainees is undertaken within their mandatory training. Evidence of this is within their e-portfolio/ Surgical ISCP (Intercollegiate Surgical Curriculum Programme) / Medical training programme.

It is a healthcare professional's own responsibility:

- to ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so;
- to work within their own competence and not to agree to perform tasks which exceed that competence; and
- to ensure they maintain patients' confidentiality during the process for gaining consent as per the Trust's Confidentiality Policy.

If a you feel that you are being pressurised to seek consent when you do not feel competent to do so then contact the Trust Lead for Consent. For trainees, contact the Education/ Clinical Supervisor.

6.6 Process for following up those who have obtained consent for a procedure without being authorised to do so

As per the roles and responsibilities in section 4.3, the Medical/ Nursing and AHP Service Leads/ Clinical Chairs/ Service Directors/ Heads of Service have the responsibility for maintaining a list of specific procedures requiring written consent, who (what grade/ level of staff) can seek and obtain written consent for them and to whom (what grade/ level of staff) the process for seeking and obtaining written consent can be delegated. See Appendix I for suggested format of the divisional lists.

Although the following list is not exhaustive, the occasions where consent is obtained for a treatment, procedure or investigation without the person being authorised to do so will be identified by:

- The Trust's incident reporting procedures (incident raised on Datix)
- Complaints by patients
- Clinical audit.

A full investigation will be held into every occurrence of consent being obtained where the person gaining consent does not have the authorisation to do so. Those staff who have obtained consent for a procedure without being authorised to do so will be supported as per the Managing Work Related Stress Policy and Sickness Absence and Wellbeing Policy during a full investigation and will be expected to undertake the relevant training within the following three month period.

Following the investigation, if it has been identified that healthcare professionals have obtained consent when not authorised to do so notification, following discussion and

agreement with the Medical Director/ Chief Nurse, may be forwarded to the appropriate governing body as follows:

- General Medical Council – registered doctors
- Local Education and Training Board – for trainee doctors not registered with GMC
- Nursing and Midwifery Council – registered nurses
- The Health and Care Professions Council – Allied Health Professionals
- General Dental Council – registered dental practitioners

6.7 When Consent Should Be Sought (Single stage/ Two or more stages) and Confirmation of Consent

This section covers the following:

6.7.1 Single stage process for gaining consent

The seeking and gaining of consent verbally, non-verbally or by acquiescence for routine every day procedures and care, is usually undertaken prior to the activity being performed – **single stage process**.

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 significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given verbally. Another example would be routine everyday care which may include personal care (such as washing, dressing and feeding), taking samples of blood or monitoring a patient's blood pressure. Again, in many cases consent will be given verbally, non-verbally or by acquiescence.

6.7.2 Two or more stage process for gaining consent (provision of information and confirmation)

The seeking and gaining of written consent is usually a process rather than a one-off event – **two or more stage process**.

If a proposed procedure carries significant risks, it will be appropriate to seek written consent. Health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient has the capacity to understand, retain, weigh up the information and communicate their decision and consents, the health professional may then proceed. However, this may not be possible in emergency situations.

For major interventions, it is good practice where possible to seek the person's consent to the proposed procedure well in advance, when there is time to respond to the person's questions and provide adequate information which is material to an individual patient's needs – this is more fully described in section 6.4.1. The patient then also has time to consider the pros and cons (have a 'cooling off period') before making the final decision that they are happy to proceed. As previously mentioned in section 6.4.1, it must also be made clear to a patient that they can change their mind at any point in the process, even on the day of the procedure/ treatment.

If, on the day of the procedure/ treatment, a patient is unsure/ uncertain of their decision then it is generally safer to reschedule for a later date once the consent has been re-visited and the patient is happy to proceed. The healthcare professional also needs to use their discretion and observational skills to ensure they are happy to proceed and if not a further 'cooling off period' may be required. However, if the delay will cause harm, the procedure/ treatment may still need to go ahead with all relevant members of the healthcare team being aware and involved – all decisions must be clearly documented. Ultimately, the healthcare professional undertaking the procedure/ treatment must make that decision.

In no circumstances should a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment.

Before the procedure starts, clinicians must confirm that the person still consents.

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 therefore 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 with that specific procedure (and any additional procedures needed which have already been consented for).

The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure and should have been offered and accepted the white patient copy of the page documenting the decision-making process (forms 1,2 & 3). This will have been signed by the patient (and healthcare professional seeking the written consent) before the day of the operation and not on the actual day.

A member of the healthcare team who is part of the procedural team on the day **must** check and confirm with the patient at this point whether they have any further concerns and whether their condition has changed. 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?"

It is particularly important to confirm consent where there has been a significant lapse of time between the form being signed and the procedure, though the original consent can be valid if there are no material changes in circumstances.

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.

A member of the patient's procedural healthcare team on the day the procedure is being performed ***must*** confirm consent so long as they have undertaken the relevant training and have been signed off as being competent to do so. This confirmation of consent must be documented on the consent form. The staff member confirming consent must be able to answer any further queries the patient may have or they must seek help to ensure the patient's queries are answered.

For patients having their procedure/ treatment in the operating department, it must be the operating surgeon or operating practitioner who confirms the patient's consent, for which there is a box on the consent form to indicate this. This is supported by the Royal College of Surgeons, Nov 2018.

6.7.3 Repeat attenders

When a person gives valid consent to an intervention/ course of treatment, in general that consent remains valid for an indefinite duration unless there has been a material change in the circumstances or it is withdrawn by the person. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, the GMC (Nov 2020) guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent. If there are doubts with capacity, consent should be re-sought.

6.7.4 Seeking consent for anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist (i.e. on the morning/day of the procedure/ treatment). At such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a leaflet outlining all the different types of anaesthesia or specific anaesthetic leaflet (such as spinal or general) at their appointment in the out-patients department or pre-operative assessment unit (AAGBI, 2017). The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record and/or in the patient's notes. As with the procedure specific written information, there is also space on the consent form for recording the title (and code) of any written information pertaining to anaesthesia offered to the patient. Where the clinician providing the care is personally responsible for anaesthesia (eg where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council (GDC) states that it currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility (GDC, Sept 2013).

6.7.5 Additional procedures

During an operation it may become evident that the patient could benefit from an additional procedure that was not within the scope of the original consent. If it would be unreasonable to delay the procedure until the patient regains consciousness (for example because there is a threat to the patient's life) it may be justified to perform the procedure on the grounds that it is in the patient's best interests. However, the procedure should not be performed merely because it is convenient.

If a patient has refused certain additional procedures before the anaesthetic (for example, specifying that a mastectomy should not be carried out after a frozen section biopsy result) this must be respected if the refusal is applicable to the circumstances. **The GMC (Nov, 2020) states that although there may be an opportunity, once an intervention is underway, to carry out another intervention clinician must not exceed the scope of a patient's consent, except in an emergency/ if it is in the patient's best interests.** Any additional procedures which the patient refuses to have done, must be written on the consent form in the space provided (just above the patient's signature) and additional information written in the patient's medical notes.

6.7.6 Emergencies

Clearly in emergencies, the two stages (discussion of options/ information and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

6.8 Consent and Treatment of Children and Young People

This section covers the following:

- General information
- Births registered in England and Wales
- Births registered in Scotland
- Births registered in Northern Ireland
- Births registered outside the United Kingdom
- Children under 16 – the concept of Gillick competence vs West Norfolk & Wisbech Area Health Authority (1986)
- Children – refusal of treatment

6.8.1 General information

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. Ensure the discussion is documented within the child's/ young person's medical notes.

Only persons with 'parental responsibility' are entitled to give consent on behalf of their children. Consent of only one person with 'parental responsibility' is required – but generally all of those with parental responsibility should be aware of the intervention and be given the opportunity to be informed about the process. Where those with parental responsibility cannot agree, they should be assisted to work through their differences.

You must be aware that not all parents have parental responsibility for their children. If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check. This will help to ensure the appropriate person attends the pre-operative clinic as well as attending hospital on the day of surgery. This is essential as this person will need to confirm the consent already given. If this does not happen, the child may not be able to receive treatment. There may be an instance when it is not possible to have the person who gave initial consent accompanying the child for treatment. In exceptional circumstances, if this occurs an informed and valid consent must be obtained again.

6.8.2 Births registered in England and Wales

If parents are married to each other at the time of the birth, or if they have jointly adopted a child, then they both have parental responsibility. Parents do not lose parental responsibility if they divorce, and this applies to both the resident and the non-resident parent.

This is not automatically the case for unmarried parents. According to current law, a mother always has parental responsibility for her child. A father, however, has this responsibility only if he is married to the mother when the child is born or has acquired legal responsibility for his child through one of these three routes:

- (from 1st December 2003) by jointly registering the birth of the child with the mother
- by a parental responsibility agreement with the mother
- by a parental responsibility order, made by a court.

Living with the mother, even for a long time, does not give a father parental responsibility and if the parents are not married, parental responsibility does not always pass to the natural father if the mother dies.

6.8.3 Births registered in Scotland

A father has parental responsibility if he is married to the mother when the child is conceived, or any time after that date. An unmarried father has parental responsibility if he is named on the child's birth certificate (from 4th May 2006). Alternatively, unmarried fathers can also be named following a re-registration of the birth.

6.8.4 Births registered in Northern Ireland

A father has parental responsibility if he is married to the mother at the time of the child's birth. If a father marries the mother after the child's birth, he has parental responsibility if he lives in Northern Ireland at the time of the marriage. An unmarried father has parent responsibility if he is named, or becomes named, on the child's birth certificate from 15th April 2002.

6.8.5 Births registered outside the United Kingdom

If a child is born overseas and then comes to live in the United Kingdom, the parental responsibility rules apply for the UK country in which they live.

It is important to remember that when consent is being given by the person with parental responsibility for a child that person is informed that it should be they who accompany the child when he/she arrives for treatment. Again this is to ensure that any changes in the child's condition since the initial consent was given, or any further concerns that may have arisen are addressed.

Please also see Appendix A – Consent for medical examination or treatment when a child is in the care of the Local Authority.

6.8.6 Children under 16 – the concept of Gillick competence vs West Norfolk & Wisbech Area Health Authority (1986)

In the case of Gillick competence, 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 of under 16 may be Gillick competent to consent to medical treatment, research, donation or any other activity that requires their consent.

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, important to involve the child's family in the decision-making process, as a person with parental responsibility can override the child's decision.

Consideration is also required when a child is in the care of the Local Authority. See additional information in Appendix A – Consent for Medical Examination or Treatment when a Child is in the Care of the Local Authority.

6.8.7 Children – refusal of treatment

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults. See the Department of Health's (2009) Reference guide to consent for examination or treatment second edition for more detail.

For young people aged 16 and 17, there are occasions when the courts will override the refusal of a child even though they have the capacity to make a decision. If a child refuses treatment that is judged to be essential for their wellbeing, seek urgent legal advice as a solicitor is needed to help with this process, see section 6.10 for the processes (in-hours / out-of-hours).

6.9 Documentation

This section covers the following:

- Validity/ form of consent
- Written consent – completing consent forms
- Consent forms
- Consent forms 1,2 & 3 (including BRAN)
- Consent form 4 – Procedures to follow when patients lack capacity to give or withhold consent
- Pre-Printed Specialty/ Procedure Specific Consent Forms
- Pre-printed stickers for recording a number of risks for some procedures
- Documenting consent for routine everyday care and treatment plans

6.9.1 Validity/ form of consent

The validity of consent does not merely depend on the form in which it is given. Written consent merely serves as evidence of consent: if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make the consent valid. Remember, taking consent is a process/ journey.

Although completion of a consent form is in most cases not a legal requirement, (exceptions include certain requirements of the Mental Health Act 1983 and of the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act (2008)), the use of such forms is good practice where an intervention such as surgery is to be undertaken. Where there is any doubt about the person's capacity, it is important, **before** the person is asked to sign the form, to establish both that they have the capacity to consent to the intervention and that they have received enough information to enable valid consent to be given. Details of the assessment of capacity (the Trust's two stage test) and the conclusion reached, should be recorded in the case notes.

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

It is good practice to obtain written consent for any significant procedure, such as a surgical operation.

6.9.2 Written consent – completing consent forms

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

All staff who obtain written consent (whether this is the person undertaking the treatment or investigation, or if the person has been delegated the responsibility for gaining a patient's consent), receive consent training. Within their training, staff who have been delegated the responsibility for gaining consent are advised to contact the relevant member of staff who can answer the patients' questions when appropriate.

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

Confirmation of a patient's consent should not be recorded until all questions (if there are any) are answered to the satisfaction of the patient.

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

Completed written consent forms should be kept with the patient's notes (gold copy) and the second copy given to the patient (white copy). Any changes to a form, made after the form has been signed by the patient, should be signed in full and dated by both patient and health professional on both copies. It would be considered best practice to complete a new form, except for minor changes.

6.9.3 Consent forms

Standard consent forms are available in clinical areas (ordered via the Forms Management System in the usual manner using the respective FKIN reference number).

6.9.4 Consent forms 1, 2 and 3 (including BRAN)

There are three versions of the standard consent form:

- form 1 for adults or competent children;
- form 2 for parental consent for a child or young person; and
- form 3 for cases where it is envisaged that the patient will remain alert throughout the procedure

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.

To help with shared decision making (NICE 2021), the relevant information discussed with a patient should be documented using the BRAN format with the information being personalised for each patient and their own individual health needs:

- Benefits
- Risks
- Alternative
- Nothing

6.9.5 Consent form 4 – Procedures to follow when patients lack capacity to give or withhold consent

Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, form 4 (form for adults who are unable to consent to investigation or treatment) should be used. The standard consent forms should never be used for adult patients unable to consent for themselves.

Guidance for Health Professionals Completing Consent Form 4, can be found in Appendix F.

6.9.6 Pre-Printed Specialty/ Procedure Specific Consent Forms

If staff in a specialty/ department wish to develop their own specialty or procedure specific consent forms, staff should follow process found at Appendix G:

- Pre-Printed Specialty/ Department – Development, Approval and Printing Process

6.9.7 Pre-Printed stickers for recording a number of risks for some procedures

An alternative to a procedure specific consent form, is the option of using stickers particularly if it is for recording a number of risks for a specific procedure. Recording the information by hand may be time consuming particularly for procedures commonly undertaken.

The stickers can be stuck on the consent form in the relevant section but content on the sticker should still be discussed with the patient. This will enable consistency across the department, help where junior doctors are delegated seeking of written consent and promote efficiency. If an individual patient has a particularly higher risk for something than other patients, where necessary additional information can be recorded.

Once it has been agreed to use stickers, they can be drafted, consulted on and be approved at specialty level. If specialties feel they require discussion at divisional level then it is their responsibility to arrange this.

Agreement for the development and use of stickers for this purpose does not require discussion/ approval at the Consent Group.

It is the specialties/ departments responsibility to source the relevant funds for printing the stickers.

Specialties also need to have in place a trigger/ process for reviewing and updating the stickers periodically.

6.9.8 Documenting consent for routine everyday care and treatment plans

Although, it will not usually be necessary to document a patient's consent to routine low-risk procedures, everyday care and treatment plans on every occasion (such as providing personal care or taking a blood sample) it is good practice to document a patient's overall consent to such care and procedures when planning their care. If you have concerns that the patient may lack capacity, undertake the two stage capacity test and plan care in the patient's best interests.

6.10 Refusal of Treatment/ Transfer of Patient to Another Healthcare Professional/ Legal Advice

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. An adult patient with capacity is entitled to refuse any treatment, except in circumstances governed by the *Mental Health Act 1983*. Where capacity is in doubt, the healthcare professional proposing the treatment must assess capacity and if the assessment shows lack of capacity, the decision must be made in the patient's best interests using the least restrictive option which may include the option of not to treat.

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

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

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

If legal advice is required regarding consent decisions/ refusals of adults or children, please follow the in-hours/ out-of-hours processes as follows:

- In-Hours: Phone the Trust Solicitor and the Safeguarding Team via switchboard
- Out of Hours: Phone silver on-call and discuss the situation with them. If it is agreed that legal advice is needed switchboard have contact numbers to obtain specialist advice. They will use the following cascade. However if there is no

response to the first (or subsequent) contact attempt switchboard must be recontacted and asked to try the next number.

- Trust solicitor
- Trust senior legal advisor
- 1st external solicitor 24/7 advice line
- 2nd external solicitor 24/7 advice line

6.11 Research And Innovative Treatment

All staff involved with the consent process in relation to a patient's involvement with a research study must have completed a generic or e-learning consent training package, have completed Consent for Research training and have evidence of their competency for each research study.

If it is a Clinical Trial of an Investigational Medicinal Product (CTiMP) research staff must have also completed (within the previous two years) Good Clinical Practice (GCP) for Research training. https://learn.nihr.ac.uk/mod/page/view.php?id=9555

The most recent and up to date informed consent form must be used which has all of the relevant regulatory, ethical and local approvals. This should be used in conjunction with the corresponding Patient Information Sheet (PIS). The PIS is used to aid discussion around the study and help to provide the potential participant with sufficient detail in order to make an informed decision.

The following web links provide additional information specific to consent and research -

- The GMC provides guidance on consent to research: http://www.gmc-uk.org/guidance/ethical_guidance/5993.asp
- Health Research Authority – Applying a proportionate approach to the process of seeking consent at : https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/applying-proportionate-approach-process-seeking-consent_R3gbJKn.pdf
- RCN (2004, updated March 2009 3rd edition) "Research Ethics – guidance for nurses" https://www.qub.ac.uk/elearning/EBN/EBNFilestore/Filetoupload,595987,en.pdf

Informed consent is at the heart of ethical research. Studies involving individuals must have appropriate arrangements for obtaining consent, and the study must have valid ethical approval (Research Governance Framework, 2005). The same legal principles apply when seeking consent from a person for research purposes as when seeking consent for investigations or treatment. Respect for patients'/participants' rights and dignity requires that valid informed consent is obtained prior to participation in a research study. This is emphasised by the Declaration of Helsinki and forms the basis of all the International Conference of Harmonisation for Good Clinical Practice (ICH GCP) guidelines. Essential to this process is the provision of information. Valid, informed consent is absolutely central to the validity of research. GMC (2008) advises that patients 'should be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties' (pg. 53). Clinical trials are also covered by the Medicines for Human Use (Clinical Trials) Regulations (2004).

The Medicines for Human Use (Clinical Trials) Regulations (2004) requires that certain conditions and principles are applied to enable an adult that lacks capacity to be part of a clinical trial. The European Union (EU) Directive (2001/20/EC) requires that, prior to participation in a research study, written consent from a legal representative of any person unable to consent for him or herself be obtained. The exact details of how consent will be

obtained or how patients lacking capacity will be enrolled will need to be clearly stated in the research protocol reviewed by the Research Ethics Committee. The Research Ethics Committee must have granted favorable opinion and approval must have been obtained from the Trust through the Research and Innovation (R&I) Department prior to the start of the research study.

In the first instance, the legal representative of a person unable to give consent should be close to that person, aware of his/her wishes and be independent of the research. This person would be termed the Personal Legal Representative (PeLR). Professionals and paid careers are excluded from this position.

If this is not possible, or there is no one sufficiently close to the potential participant who is willing or able to take on the role, or if a person close enough to individual cannot be contacted before it is medically necessary to give the intervention, then a person who is independent from the trial, nominated by the Trust and accessed via the Research and Innovation Department, may be appointed as Professional Legal Representative (PrLR). The PrLR must have undergone the relevant training and completed the Valid informed consent assessment form – Research and Innovation for each trial they anticipate acting as a PrLR.

If this is not possible, then the researcher may enter an individual into the research study using a procedure that is approved by the Research Ethics Committee. In this case consent must be obtained by the clinician from either a PeLR or PrLR as soon as is reasonably practical. If these individuals indicate that they feel the patient should not participate in the research study they must be withdrawn and the process fully documented.

If/when the patient is determined to have regained capacity then informed consent must be gained for the research study. If they do not wish to give consent they must be withdrawn from the study. The process must be fully documented.

If a 'medicine' is not being tested, research has to be compliant with the MCA 2005. A patient who lacks capacity may not be enrolled onto a research study not involving medicine, unless the research concerns an impairing condition affecting the patient or the treatment of that condition.

When a patient who consented to participate in a trial which began before 1st October 2007 loses capacity after giving consent (s)he may continue to participate providing the provisions for appointing an advocate as set out in the procedure for consulting with an independent doctor are followed and adhered to.

For further information regarding the relevant pathways and specific documentation required for research studies please contact the Trust's Research & Innovation Department, extension 3313.

The Research and Innovation Department locally maintain the relevant pathways/ forms used in their practice as listed at the bottom of the front/ governance sheet of this policy.

6.12 Tissue

The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues and the Human Tissue Act became law in 2004. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all. At present, this Trust requires that patients should be given the opportunity to refuse

permission for tissue taken from them during surgery or other procedure to be used for education or research purposes.

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method.

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

For further details see Human Tissue Act 2004 – (DH 2005)
Contact for further information: Laboratory Manager, Pathology Department, King's Mill Hospital.

6.13 Investigative Images, Clinical Photography, Video/ Audio Recordings (Conventional or Digital)

This section covers the following:

- General information
- Education, publication and research
- Gaining consent after images have been made

6.13.1 General information

The Trust has adopted the policy that written consent is not required for photography and video recordings (convention or digital) which are for medical records.

If undertaken, investigative images, photographs and video/ audio recordings are usually made for **clinical purposes** and form part of a patient's record. Although consent to certain investigations, such as X-rays, is implicit in the patient's consent to a procedure, health professionals should always ensure that they make clear in advance if any images, photographs or video recordings will result from that procedure. E.g. a photograph may be taken using a bronchoscope whilst a patient is undergoing the procedure for a bronchoscopy. The photograph may then be used to view the image more closely after the procedure. There is a section in consent forms 1, 2 & 3 for the Health Professional seeking consent to confirm they have explained this to the patient.

Therefore investigative images, photographs and video/ audio recordings which are made for treating or assessing a patient, for clinical purposes, 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. This includes photographs and video/audio recordings where patients may not be identifiable.

6.13.2 Education, publication and research

As part of the process for seeking written consent for an investigation, procedure or course of treatment, there is also a section on the consent form for 'additional uses' and the forms specifically state: education, publication and research (whether the

patient can be identified or not). It asks if the patient/ parent agrees to all/ any of them to be used for and all have options for YES/ NO/ Not Applicable and again there is place for the Health Professional seeking consent to confirm this has been asked/ explained.

Patients must know that they are free to stop the recording at any time (where able) and that they are entitled to view it if they wish, before deciding whether to continue 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 for clinical purposes, 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.

6.13.3 Gaining consent after images have been made

Where a patient is temporarily unable to give or withhold consent because, for example, they are unconscious, the situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes. 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.

For further information please contact Clinical Illustration on extension 3649/ 3650 and/ or refer to the Trust's: "Photography and Video Recording Policy".

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

	Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
1	Elements identified in the Trustwide audit for ***Consent (Documentation)*** (based on the current consent form/s)	Specialties	Audit via AMaT	Minimum of 20 sets of notes/ consent forms every 6 months	• Results monitored through specialty/ divisional governance structures and escalated/ actioned as per governance/ committee structures as appropriate. • Information included in six monthly highlight report to the Consent Group
2	Qualitative Consent Audit	Divisional Management Teams	Audit	Minimum of 20 every 6 months	• Results monitored through specialty/ divisional governance structures and escalated/ actioned as per governance/ committee structures as appropriate. • Information included in six monthly highlight report to the Consent Group
3	Divisional list of procedures requiring consent – in place and up to date	Medical, Nursing and AHP Service Directors/ Heads of Service/ Department Leads	Divisional process to review/ update/ collate divisional list	Minimum of annually	• List provided at least annually for approval by Divisional Management Team • Information included in six monthly highlight report to the Consent Group

	Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
4	Mandatory consent training and refresher training (for staff who need to seek and gain written consent): a) e-learning b) procedure specific	Medical, Nursing and AHP Service Directors/ Heads of Service/ Department Leaders	Divisional/ specialty process to review status for staff training in consent (relevant to their role) within divisions/ specialties/ departments	Minimum of every 6 months	• Information provided at least every six months to the Divisional Management Team • Information included in six monthly highlight report to the Consent Group
5	Procedure specific consent training packages (for procedures requiring written consent) in place and up to date (including how often refresher training must be undertaken)	Medical, Nursing and AHP Service Directors/ Heads of Service/ Department Leaders	Lists of packages showing their status (using RAG rating system) and including how often refresher training should be undertaken to be reviewed regularly to identify and action those requiring review/ update	Individual packages to be reviewed/ updated by their review date or earlier in the light of any practice changes. Full list of packages to be reviewed/ updated at least annually (including status) and submitted to DMT for oversight.	• Divisional Management Team (DMT) oversight of specialty lists of procedure specific training packages • Information included in six monthly highlight report to the Consent Group

8.0 TRAINING AND IMPLEMENTATION

8.1 Staff groups (not exhaustive)

Prior to seeking and gaining consent, all clinical staff as applicable to their role, must undertake consent training and be competency assessed to do so (NMC, Oct 2018; GMC, Nov 2020; RCS, Nov 2018). Although the list is not exhaustive, this includes the following staff groups:

- Consultants
- Specialist registrars
- Doctors in training
- Registered Nurses
- Specialist nurses
- Midwives
- Allied health professionals
- Healthcare assistants

8.2 Training to gain consent verbally, non-verbally or by acquiescence for everyday care/ procedures

The Mental Capacity Act is the lynchpin for ensuring that patients can give valid consent. The Trust has a policy on the MCA and the code of practice (Mental Capacity Act (MCA) Policy) and this must be referred to as part of the training in order that the person gaining consent is competent.

- Training for mental capacity (incorporating consent) is mandatory for all clinical staff (new and substantive) and is undertaken on induction for new starters and mandatory training. The underlying principle of the training is that consent is required before undertaking any procedure, treatment or care. However, if there is doubt about the patient's understanding of the proposed intervention then a two stage test for capacity must be undertaken. If the assessment shows lack of capacity then the proposed intervention must be planned in the patient's best interests using the best interest checklist (see the Trust's Mental Capacity Act (MCA) Policy). The training is competency assessed.
- Refresher training to update knowledge is required annually and is competency assessed.

8.3 Training to seek and gain written consent and confirmation of consent

The training for new and substantive staff who need to obtain written consent as part of their role; staff delegated the process of obtaining written consent but who are not capable of performing/ undertaking the actual procedure but have the relevant knowledge; and staff confirming consent must undertake:

- The mental capacity act training as above for obtaining consent verbally, non-verbally or by acquiescence for everyday care/ procedures

AND

- the Trust agreed mandatory e-learning consent package (accessible via the e-learning intranet site) which includes a competency assessment.

- Refresher training by completion of the agreed mandatory e-learning consent package (as above) to update knowledge is required every three years and will again be competency assessed.

AND

- Specialty/ procedure specific training as applicable to the individual staff member's role and must include the relevant local competency assessment(s).
- Refresher training for specialty/ procedure specific training is to be completed at periodic intervals as indicated by the various specialties across the divisions in-line with their local training packages.

8.4 Doctors in training

- Generic training on written consent is delivered to Doctors in training on induction
- F1 doctors cannot take written consent for any procedures without supervision, however, the medical education department provide in-house structured training as part of the junior doctor's core training programme.

8.5 Specialty/ Procedure specific training

Each specialty is responsible for ensuring that procedure specific training is delivered on induction to trainees who rotate through the specialty and permanent staff as applicable. Each specialty is also responsible for ensuring refresher training is delivered at agreed periodic intervals.

Local induction programmes must include the following elements on consent:

- Awareness of the Trust's consent policy
- Core principles of the consent process, including the specific requirements of the Mental Capacity Act
- Availability and access of written information for patients – to include but not limited to in-house leaflets and EIDO leaflets
- Using the relevant divisional list of procedures requiring consent for:
  - Identification of procedures requiring ***written*** consent
  - Identification of procedures for which the consent process may be ***delegated***
- Using the relevant procedure specific training packages where written consent is required and for each procedure:
  - identification of the risks, benefits, alternatives with an emphasis on individual patient requirements ("Montgomery ruling") and what would happen if nothing was done (ie no intervention/ procedure was chosen)
  - Which member(s) of staff to contact who will be able to answer a patient's questions if any queries arise
  - Records of training and evidence of competency assessments.

Patient safety is paramount which makes it the responsibility of individual staff to voice concerns if they are not happy to gain consent for something or where needed seeking advice from a senior colleague.

8.6 Records for Specialty/ Procedure Specific Training

Records of training and competency assessments for specialty/ procedure specific training must also be maintained and monitored at specialty and divisional level (see Monitoring Compliance and Effectiveness – section 7)

An example competency assessment form can be found at Appendix H

- Any member of the patient's healthcare team can confirm consent so long as they have undertaken the relevant training and have been signed off as being competent to do so.

8.7 Consent Training Enquiries

- **Any enquiries in relation to consent training should be directed to the Trust Lead for Consent. For trainees, contact the Education/ Clinical Supervisor.**

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix J
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base/ References:

Legislation/ Government/ National Guidance/ Good Practice

- DH (2001) Good practice in consent implementation guide: consent to examination or treatment DH (last accessed 15th November 2021)
- DH (2005) Human Tissue Act 2004 DH (last accessed 15th November 2021)
- DH (2005) Research Governance Framework for Health & Social Care 2nd Edition (last accessed 15th November 2021)
- DH (2009) Reference guide to consent for examination or treatment second edition (last accessed 15th November 2021)
- DH (March 2012, updated 1st Jan 2021) NHS Constitution for England (last accessed 15th November 2021)
- Gillick Competency and Fraser Guidelines – Gillick v West Norfolk, 1986
- Health and Social Care Act (2008) (last accessed 15th November 2021)
- Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act (2008) (last accessed 15th November 2021)
- Human Tissue Authority (July 2021) Codes of Practice – Code A Guiding principles and the fundamental principle of consent London: DH (last accessed 15th November 2021)
- Mental Capacity Act (2005) HMSO (last accessed 15th November 2021)
- Mental Capacity Act (2005): Code of Practice (2007) (Dept of Constitutional Affairs: TSO. London. UK) (last accessed 15th November 2021)
- Montgomery v Lanarkshire Health Board (March 2015) Judgement (last accessed 15th November 2021)
- NHS Choices website – End of Life Care - Advance Decisions – last updated October 2020 (last accessed 15th November 2021)
- NICE (June 2021) NG197 Shared Decision Making (last accessed 15th November 2021)

Professional Registration/ Royal College

- General Dental Council (Sept 2013) Principle 3 – Obtain valid consent GDC. (last accessed 15th November 2021)
- General Medical Council (GMC) (Nov 2020) Decision making and consent – guidance on professional standards and ethics for doctors (last accessed 15th November 2021)
- Health and Care Professions Council (HCPC) (Jan 2016) Standards of conduct, performance and ethics.
- Nursing & Midwifery Council (31st March 2015, updated 10th Oct 2018) The Code: professional standards of practice and behaviour for nurses, midwives and nursing associates NMC. (last accessed 15th November 2021)
- Royal College of Anaesthetists/ The Associate of Anaesthetists of Great Britain and Ireland (AAGBI) (Jan 2017) Consent for Anaesthesia (last accessed 16th November 2021) (last accessed 15th November 2021)
- Royal College of Surgeon's (Nov 2018) Consent: Support Decision Making – a guide to good practice

Section 6.12 – 'Research and Innovative Treatment' (last accessed 20/12/2021)

- General Medical Council (GMC) (March 2013) Good Practice in Research (Summary) http://www.gmc-uk.org/guidance/ethical_guidance/5993.asp
- International Conference of Harmonisation for Good Clinical Practice (2021) - ICH Guideline E6 on Good Clinical Practice
- Medicines for Human Use (Clinical Trials) Regulations (2004).
- NHS Health Research Authority (Jan 2017) – Applying a proportionate approach to the process of seeking consent at : https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/applying-proportionate-approach-process-seeking-consent_R3gbJKn.pdf
- NHS Health Research Authority (2005) Research Governance Framework.
- Royal College of Nursing (RCN) (2004, updated March 2009 3rd edition) "Research Ethics – guidance for nurses" https://www.gub.ac.uk/elearning/EBN/EBNFilestore/Filetoupload,595987,en.pdf

Related SFHFT Documents:

- Data Protection, Confidentiality and Disclosure Policy
- Learning Disability Policy
- Managing Work Related Stress Policy
- Mental Capacity Act (MCA) Policy
- Sickness Absence and Wellbeing Policy
- Patient Information Development and Distribution Policy
- Photography and video recording policy

11.0 KEYWORDS

Mental capacity, guideline, for, on, process, one stage, two or more stages, seek, seeking, gain, gaining, obtain, obtaining, confirmation of,

12.0 APPENDICES (list)

APPENDIX A – CONSENT FOR MEDICAL EXAMINATION OR TREATMENT WHEN A CHILD IS IN THE CARE OF THE LOCAL AUTHORITY

(This policy is consistent with Nottinghamshire Social Services Department policy and procedure guide – Number 4.150)

Consent is always required before a health professional can examine or treat a child below the age of 16 years. This consent is obtained from the person with parental responsibility. For some children parental responsibility is shared by the Local Authority i.e. "Looked After" where there is a legal order in place.

However if the child is Gillick competent they are able to give their own consent (see "Gillick Competencies –Guidance" below).

If a competent child gives consent for treatment a person with parental responsibility cannot over-ride that consent (although if a competent child refuses treatment it can be legally authorised by the person with parental responsibility).

Even when a child lacks capacity to give consent on their own behalf it is always good practice to involve them in the process.

NB: Section 2(9) of the *Children Act 1989* states that a person with parental responsibility "may arrange for some or all of it to be met by one or more persons acting on his behalf".

1 OBTAINING CONSENT:

1. ***Planned investigative or surgical procedures***
   - Even if parental responsibility for a child is shared by the Local Authority the expectation is that the parent will provide consent. On rare occasions the parent may not be in contact with the child; in these circumstances consent should be obtained from the Local Authority.
   - **In Nottinghamshire this is ordinarily delegated to a** Group Manager or Children's Service Manager *who is expected to attend the hospital to discuss the procedure with the doctor and sign the consent form. This is to ensure an informed and valid consent is obtained. This may be one instance when it is not possible to have the person who gave initial consent accompanying the child for treatment. In exceptional circumstances, if this occurs an informed and valid consent must be obtained again. Arrangements will need to be made with the relevant Children's Services Manager to attend on the day of treatment to give consent. The child will be accompanied for the treatment by their foster carer or their social worker who do not have authority to give consent.*
2. **Emergency investigative and surgical procedures (non life or limb threatening)**
   - Again if the parent with parental responsibility is unable to consent the consent of the Group Manager or Children's Service Manager must be sought Out of hours the Emergency Duty Team (EDT) must be contacted. **The EDT Team Manager is the authorised officer in the absence of a more senior officer.**
   - *EDT will contact the Group Manager or Children's Service Manager and will arrange for him/her to discuss the child's condition and need for imminent intervention with the doctor* **if they are available and able to do so.**
   - The Group Manager or Children's Service Manager will either attend the hospital in person or delegate the authority to give consent to a member of the EDT. **In Nottinghamshire this authority is ordinarily delegated to the EDT where the situation arises out of hours**

- Some children are **'Looked After'** (accommodated **under Section 20 of the Children Act 1989**) on a "voluntary" basis. In this instance parental responsibility remains with the parents and not with the Local Authority. It is important therefore that the legal status of accommodated children is always ascertained. **However if the parents, or any other person with parental responsibility are not available, e.g. they are dead or their whereabouts are not known, then the authorised Social Care officer can consent in urgent situations.**

NB: If children are accommodated **by agreement under S.20** some **authority to consent** may have been delegated to the foster carer by the parents. **Carers may also have delegated authority to consent where the child is subject to a care order under Section 31 of the Children Act 1989. However this is limited to routine medical and dental examination and treatment and** does not allow them to give consent for a general anaesthetic**, or significant surgical or invasive procedures.**

3. Emergency investigative and surgical procedures (life or limb threatening)

- In this instance two health professionals (preferably consultants) will make the decision to undertake or deliver the appropriate treatment in order to preserve life or limb. At the earliest opportunity the person performing the emergency invasive and surgical procedures will discuss with the Locality Manager/Children's Service Manager (or EDT out of hours).

EDT Contact telephone Numbers:

- All local EDT contact numbers are available on the Child Protection/Safeguarding Children intranet site in the *Telephone Numbers/Bases* folder.

Gillick Competence – Guidance

- The young person must understand the health professional's advice.
- **Be sure** the health professional cannot persuade the young person to inform his or her parents/carers or allow the doctor to inform the parents that he or she is requiring investigative or surgical procedures.
- **Ensure** the investigative procedure or surgical intervention is required
- Without the appropriate investigative or surgical procedures the young person's health will/ may be detrimentally affected.
- The young person's best interest requires the health professional to proceed with the investigation or surgical procedure without parental/carer consent.

2 PARENTAL RESPONSIBILITY:

The person(s) with parental responsibility will usually, but not invariably, be the child's birth parents. People with parental responsibility for a child include: the child's mother; the child's father if married to the mother at the child's conception, birth or later; a legally appointed guardian; the local authority if the child is on a care order; or a person named in a residence order in respect of the child. Please see the information below which is repeated from the main policy.

Births registered in England and Wales

If parents are married to each other at the time of the birth, or if they have jointly adopted a child, then they both have parental responsibility. Parents do not lose parental responsibility if they divorce, and this applies to both the resident and the non-resident parent.

This is not automatically the case for unmarried parents. According to current law, a mother always has parental responsibility for her child. A father, however, has this responsibility only if he is married to the mother when the child is born or has acquired legal responsibility for his child through one of these three routes:

- (from 1st December 2003) by jointly registering the birth of the child with the mother
- By a parental responsibility agreement with the mother
- By a parental responsibility order, made by a court.

Living with the mother, even for a long time, does not give a father parental responsibility and if the parents are not married, parental responsibility does not always pass to the natural father if the mother dies.

All parents (including adoptive parents) have a legal duty to financially support their child, whether they have parental responsibility or not.

Births registered in Scotland

A father has parental responsibility if he is married to the mother when the child is conceived, or any time after that date. An unmarried father has parental responsibility if he is named on the child's birth certificate (from 4th May 2006). Alternatively, unmarried fathers can also be named following a re-registration of the birth.

Births registered in Northern Ireland

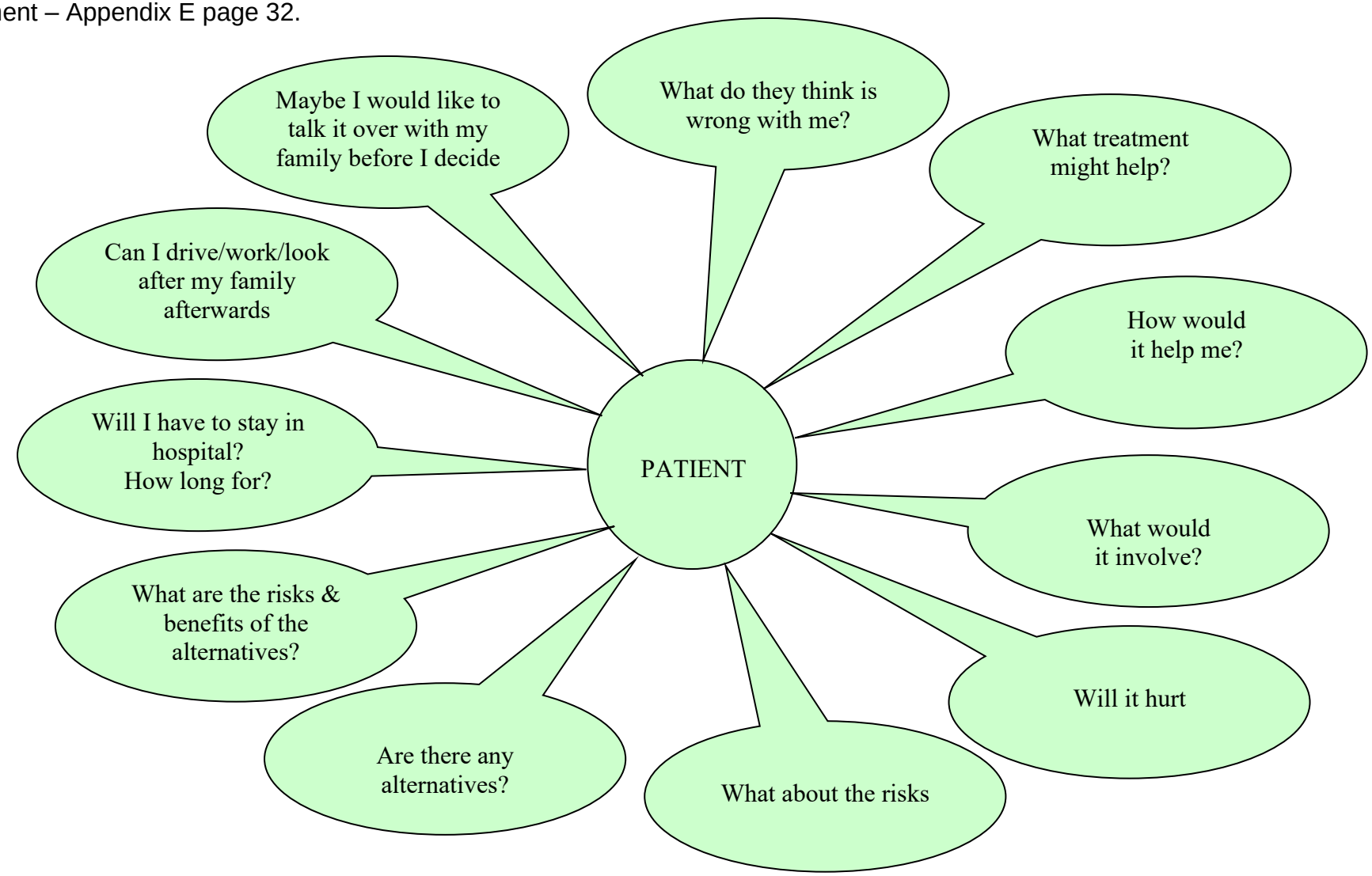
A father has parental responsibility if he is married to the mother at the time of the child's birth. If a father marries the mother after the child's birth, he has parental responsibility if he lives in Northern Ireland at the time of the marriage. An unmarried father has parent responsibility if he is named, or becomes named, on the child's birth certificate from 15th April 2002.

Births registered outside the United Kingdom

If a child is born overseas and then comes to live in the United Kingdom, the parental responsibility rules apply for the UK country in which they live.

Appendix B – Seeking consent: remembering the patient's perspective

Reference/ copied from: Department of Health (November 2001) Good practice in consent implementation guide: Consent to examination or treatment – Appendix E page 32.



Appendix C – Other Exceptions to the Principles

1 Certain statutes set out specific exceptions to the principles noted. These are briefly noted below. Those concerned with the operation of such statutes should consult more detailed guidance.

2 Part IV of the Mental Health Act 1983 sets out circumstances in which patients detained under the Act may be treated without consent for their mental disorder. It has no application to treatment for physical disorders unrelated to the mental disorder, which remains subject to the common law principles described in previous chapters. Chapters 15 and 16 of the Mental Health Act Code of Practice offer guidance on consent and medical treatment in this context.

2.1 Neither the existence of mental disorder nor the fact of detention under the 1983 Act should give rise to an assumption of incapacity. The patient's capacity must be assessed in every case in relation to the particular decision being made. The capacity of a person with mental disorder may fluctuate.

2.2 Significant reforms to the 1983 Act have been described in the White Paper, Reforming the Mental Health Act, published in December 2000. However, these reforms should not affect the principle that treatment for physical disorders, unrelated to the mental disorder for which the patient is receiving compulsory treatment, does not come within the scope of mental health legislation.

3 The Public Health (Control of Disease) Act 1984 provides that, on an order made by a magistrate, persons suffering from certain notifiable infectious diseases can be medically examined, removed to, and detained in a hospital without their consent. Although the Act has a power for regulations to be made concerning the treatment of such persons without their consent, such regulations have not been made and thus the treatment of such persons must be based on the common law principles previously described.

4 Section 47 of the National Assistance Act 1948 provides for the removal to suitable premises of persons in need of care and attention without their consent. Such persons must either be suffering from grave chronic disease or be aged, infirm or physically incapacitated and living in insanitary conditions. In either case, they must be unable to devote to themselves (and are not receiving from others) proper care and attention. The Act does not give a power to treat such persons without their consent and therefore their treatment is dependent on common law principles.

Appendix D – 12 key points on consent: the law in England

Reference/ copied from: Department of Health (November 2001) Good practice in consent implementation guide: Consent to examination or treatment – Appendix A pages 27 & 28.

12 key points on consent: the law in England

When do health professionals need consent from patients?

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

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

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

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

Can children consent for themselves?

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

Who is the right person to seek consent?

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

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

Is the patient's consent voluntary?

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

Does it matter *how* the patient gives consent?

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

Refusals of treatment

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

Adults who are not competent to give consent

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

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

Appendix E – Suggested format for noting the discussion of treatment options and patient information

Treatment options

1. do nothing – risks and benefits (these must be recorded on an individual basis depending on the patient's individual circumstances)
2. alternative options e.g. conservative treatment, watch and wait for a particular time frame
3. surgery – describe procedure – common risks and benefits including level of risk of death. This information must be pertinent to the patient and their individual circumstances.
4. Additional procedures that may be required eg blood transfusion
5. Use of radiation eg xrays/ background imaging

Once the patient has decided, make sure that a note is made that the patient has been informed that they can change their mind at any time.

Make a note of the patient information that has been given. This can be noted on the consent form

- Does it include the risks and benefits, alternatives and the option of 'not to treat'?
- Is it written or verbal information?
- If it is written information does it include the title and where possible the reference/ code and version?

If information has been declined make a note of why the patient has declined it and whether a relative or carer has been given the information.

Appendix F

Guidance for Health Professionals completing Consent Form 4

Introduction

Consent Form 4 form should only be used where it would be usual to seek written consent from an adult patient (16 or over) who lacks capacity to give or withhold consent to the particular treatment. If an adult **has** capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal. Where treatment is very urgent (for example if the patient is critically ill), it may not be feasible to fill in a form at the time, but you should document your clinical decisions appropriately afterwards. If the adult now lacks capacity, but has made a valid advance decision to refuse treatment that is applicable to the proposed treatment, then you must abide by that refusal. For further information on the law on consent, see the *DH (2009) "Reference guide to consent for examination or treatment second edition"*. If treatment is being provided under the authority of Part IV of the *Mental Health Act 1983*, different legal provisions apply and you are required to fill in more specialised forms (although in some circumstances you may find it helpful to use this form as well).

When treatment can be given to a patient who lacks the capacity to consent

All decisions made on behalf of a patient who lacks capacity must be made in accordance with the five key principles of the Mental Capacity Act 2005: (More information about the Act is given in the Code of Practice).

1. **Presumption of Capacity**
   A person must be assumed to have capacity unless it is clear that she/he lacks capacity to make a decision.

2. **Maximising decision-making**
   A person is not to be treated as unable to make a decision unless all practical efforts to help them have been made without success.

3. **Unwise decisions**
   A person is not to be treated as unable to make a decision because he/she makes an unwise decision. The Code of Practice distinguishes between unwise decisions where a person has capacity to make them and repeated unwise decisions that cause concern and unwise decisions that require investigation.

4. **Best interests**
   An act done or decision made under the Mental Capacity Act for or on behalf of a person who lacks capacity must be done or made in his/her best interests.

5. **Least restrictive option**
   Before an act is done or a decision is made on behalf of a person lacking capacity it should be considered whether these purposes can be achieved in a way that is less restrictive of that person's rights and freedom of action.

Assessing Capacity

A person lacks capacity if they have an impairment or disturbance that affects the way their mind or brain works which means that they are unable to make a specific decision at the time it needs to be made. For example:

- Neurological Disorder
- Mental Disorder
- Stroke
- Delirium, Unconsciousness
- Other
- Learning Disability
- Dementia
- Head Injury
- Substance use

It does not matter if the impairment or disturbance is permanent or temporary. A person is unable to make a decision if they cannot do one or more of the following things:

- Understand the information given to them that is relevant to the decision.
- Retain that information long enough to be able to make the decision.
- Use or weigh up the information as part of the decision-making process.
- Communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

You must take all steps reasonable in the circumstances to assist the patient in making their own decisions. This may involve explaining what is involved in very simple language, using pictures and communication and decision-aids as appropriate. People close to the patient (spouse/partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates (as distinct from an IMCA as set out below) or supporters. Sometimes it may be necessary for a formal assessment to be carried out by a suitably qualified professional.

Capacity is 'decision-specific': a patient may lack capacity to make a particular complex decision, but be able to make other more straight-forward decisions or parts of decisions.

Capacity can also fluctuate over time and you should consider whether the person is likely to regain capacity and if so whether the decision can wait until they regain capacity.

Best interests

"Best interests" go far wider than "best medical interests", and include factors such as the patient's general well-being, emotional and social interests and their spiritual and religious welfare.

The Mental Capacity Act requires that a best interests decision maker **must** consider all the relevant circumstances relating to the decision in question, including, as far as possible considering:

- the person's past and present wishes and feelings (in particular if they have been written down)
- any beliefs and values (e.g. religious, cultural or moral) that would be likely to influence the decision in question and any other relevant factors
- the other factors that the person would be likely to consider if they were able to do so.

When determining what is in a person's best interests, a decision maker must not make assumptions about someone's best interests merely on the basis of the person's age or appearance, condition or any aspect of their behaviour. If the decision concerns the provision or withdrawal of life-sustaining treatment, the decision maker must not be motivated by a desire to bring about the person's death.

The Act also requires that, as far as possible, decision makers must consult other people, if it is appropriate to do so, and take into account their views as to what would be in the best interests of the person lacking capacity, especially anyone previously named by the person lacking capacity as someone to be consulted, anyone holding an LPA/ appointed as a Deputy and

anyone engaging in caring for the patient. Those people should be asked, in particular, about what the patient's wishes would have been, and what would have been important to them.

It is important to take into account whether the patient will be compliant with the proposed treatment or not, and what the practical implications of overcoming non-compliance would be, including the additional impact this may have on the patient.

It is also important to ensure that all reasonable options are made available for a patient who lacks capacity for a particular decision, just as they should be for a patient who is able to make a decision for themselves. A best interest decision can only be valid if it takes into account all the appropriate options, including the possibility of doing nothing.

Independent Mental Capacity Advocate (IMCA)

The Mental Capacity Act introduced a duty on the NHS to instruct an Independent Mental Capacity Advocate (IMCA) in serious medical treatment decisions when a person who lacks capacity to make a decision has no one who can speak for them, other than paid staff. (See additional information further below) IMCAs are not decision makers for the person who lacks capacity. They are there to support and represent that person and to ensure that decision making for people who lack capacity is done appropriately and in accordance with the *Act*.

Lasting Power of Attorney and Court Appointed Deputy

A person over the age of 18 can appoint an attorney to look after their health and welfare decisions, if they lack the capacity to make such decisions in the future. Under a Lasting Power of Attorney (LPA) the attorney can make decisions that are as valid as those made by the person themselves. The LPA may specify limits to the attorney's authority and the LPA must specify whether or not the attorney has the authority to make decisions about life-sustaining treatment. The attorney can only, therefore, make decisions as authorised in the LPA, only once the person has lost the capacity to make that particular decision and must make any decisions in the person's best interests. In considering best interests, the attorney has the same obligations as any other decision maker to consult, where appropriate, anyone who has been named by the person to be consulted, or anyone engaged in caring for the patient or interested in his or her welfare.

The Court of Protection can appoint a deputy to make decisions on behalf of a person who lacks capacity. Deputies for personal welfare decisions will only be required in the most difficult cases where important and necessary actions cannot be carried out without the court's authority or where there is no other way of settling the matter in the best interests of the person who lacks capacity. If a deputy has been appointed to make treatment decisions on behalf of a person who lacks capacity then it is the deputy rather than the health professional who makes the treatment decision and the deputy must make decisions in the patient's best interests.

Second opinions and Court involvement

Where treatment is complex and/or people close to the patient express doubts about the proposed treatment, a second opinion should be sought, unless the urgency of the patient's condition prevents this. The Court of Protection deals with serious decisions affecting personal welfare matters, including healthcare, which were previously dealt with by the High Court. The Court can be asked to make a decision in cases where there are doubts about the patient's capacity about the validity or applicability of an advance decision to refuse treatment, or of an LPA/ Deputy, or where there is a dispute over a patient's best interests.

Some situations **MUST** be referred to Court (COP Practice Direction 9E), including:

- decisions about the proposed withholding or withdrawal of artificial nutrition and hydration (ANH) from patients in a persistent vegetative state (PVS) or minimally conscious state
- cases involving organ, bone marrow or peripheral blood stem cell (PBSC) donation by an adult who lacks capacity to consent
- cases involving the proposed non-therapeutic sterilisation of a person who lacks capacity to consent to this (e.g. for contraceptive purposes) and
- The Practice Direction also provides for the Court to decide all other cases where there is a doubt or dispute about whether a particular treatment will be in a person's best interests (including cases involving ethical dilemmas in untested areas), and where the case involves "serious medical treatment", defined below:

- "Serious medical treatment" means treatment which involves providing, withdrawing or withholding treatment in circumstances where:
  a) in a case where a single treatment is being proposed, there is a fine balance between its benefits to the patient and the burdens and risks it is likely to entail for him;
  b) in a case where there is a choice of treatments, a decision as to which one to use is finely balanced; or
  c) the treatment, procedure or investigation proposed would be likely to involve serious consequences for the patient.

- "Serious consequences" are those which could have a serious impact on the patient, either from the effects of the treatment, procedure or investigation itself or its wider implication. This may include treatments, procedures or investigations which:
  a) cause, or may cause, serious and prolonged pain, distress or side effects;
  b) have potentially major consequences for the patient; or
  c) have a serious impact on the patients future life choices

- Examples of serious medical treatment may include:
  a) certain terminations of pregnancy in relation to a person who lacks capacity to consent to such a procedure;
  b) a medical procedure performed on a person who lacks capacity to consent to it, where the procedure is for the purpose of a donation to another person;
  c) a medical procedure or treatment to be carried out on a person who lacks capacity to consent to it, where that procedure or treatment must be carried out using a degree of force to restrain the person concerned;
  d) an experimental or innovative treatment for the benefit of a person who lacks capacity to consent to such treatment; and
  e) a case involving an ethical dilemma in an untested area

Appendix G

PRE-PRINTED SPECIALTY/ DEPARTMENTAL CONSENT FORMS – Development, Approval and Printing Process

1. Development/ approval

Through the governance structures, Specialties should discuss and agree:

- which procedures they require specialty specific consent forms for and why they are needed
- any serious or frequently occurring risks for each procedure which are to be pre-printed on the consent form
- the expected number of forms likely to be needed of each procedure for a one year period
- where the forms need to be located for use in practice
- management of the forms (eg author; funding; person to take through process; person to monitor usage and printing)
- a draft of the proposed form(s) using a consent form template (details below)

Specialties are advised to obtain a consent form template from Clinical Illustration and prepare the draft(s). Following agreement at specialty level, the draft form(s) should be submitted for discussion and agreement at the Consent Steering Group via the Group Secretary. A member of the specialty must attend the meeting to present the item, answer any queries which may arise and feedback agreed recommendations/ next actions regarding progression. They must also inform the group members of the number of forms likely to be needed for a one year period (for each procedure/ form) and confirm that discussion and agreement to progress with the form(s) has been held/ minuted at specialty level.

2. Templates

Unless agreed otherwise, each form must:

- be developed using one of the Trust's standard/ generic consent forms (1, 2 or 3); and
- include the following document control:
  - A reference (using a unique number for each form, provided by the specialty)
  - Where in the medical records the form should be filed (this has historically been the 'operation records')
  - The author (by role/ job title)
  - Issue Date (Month Year) – Specialties may also wish to include a version next to the Issue Date eg: (Dec 2018 v1.0)
- Forms do not need a review date adding but the Specialty must ensure that the information/ content is maintained by making amendments as needed and adjusting the issue date (and version if used) accordingly.

The three standard consent form templates can be obtained from the Clinical Illustration department. If help is required to format specialty forms, assistance may be available through Clinical Illustration so please phone the Department to discuss and agree the requirements.

3. Funding

- The relevant Specialty is responsible for funding the production/ printing of their own specialty specific consent forms

4. Specifications for the Trust's main consent forms 1, 2 & 3

- Size: A3 landscape; 420mm x 297mm
- Paper: 2part ncr set Yellow / White 60/57gsm
- Print: part 1 front and reverse (Tumble turn), part 2 front only
- Finishing: tip glued at head, 2 file holes LHE, Board backed with wraparound writing shield, 25 sets per pad

5. Printing

- Following approval and identifying funds, a request for printing quotes should be raised on E-Series, stating the exact details with respect to the quantity, size, paper type/ colour(s) and attach a copy of the final form
- To help ensure cost effectiveness, Procurement will then obtain up to three quotes, liaise with the Specialty to confirm requirements and the order placed.

Please note: Unlike the Trust's four main consent forms, specialty specific pre-printed consent forms will not go on the Forms Management system.

6. Re-Prints

It is the responsibility of the Specialty to monitor usage of their forms and ensure stocks are replenished when low.

7. Amending Specialty Consent Forms

If minor amendments are required to the content of Specialty consent forms, these should be managed within the Specialty and the issue date (and version if used) adjusted accordingly.

Where it is deemed that significant amendments are required, then the proposal/ draft should be submitted to the Consent Steering Group for discussion and agreement.

8. If changes are made to the Trust's generic forms

If any significant changes are made to the Trust's generic forms, the expectation is that Specialties will make the same changes when their forms are next due for reprinting.

9. Contacts: (correct at June 2022)

Mr Paresh Kothari	Trust Lead for Consent/ Chair of Consent Group paresh.kothari@nhs.net	Ext 3646 or mobile phone via switchboard
Sue Dale Governance Support Unit	Admin Support for Consent Steering Group/ Governance Representative sue.dale1@nhs.net	Ext 4718
Lisa McCourt	Chief Medical Photographer and Clinical Illustration (CI) Manager Sfh-tr.clinical.illustration@nhs.net	Ext 3649 / 3650

Procedure Specific Consent Competency Documentation (Example)

This example form can be adapted locally to record competency for a single procedure or to record competency for several procedures

Doctors, Nurses, Midwives and Allied Health Professionals who need to take written consent as part of their role; or who are delegated the task of taking consent; or who are confirming consent must either:

i. **Access and complete the e-learning training package available via the Trust's e-learning intranet.**
   OR
ii. **Show previous competency documentation (particularly for new staff joining the Trust and it must be of an equivalent/ acceptable standard)**

Evidence of completion/ competency for the above must be:

- **retained by the healthcare professional for their own records/ portfolio**
- **sent to the healthcare professional's line manager for inclusion in their personal file**
- **provided to the relevant specialty prior to undertaking procedure specific training**

In addition to this, anyone who is obtaining consent for a procedure must receive and document specific training for that procedure and evidence their competency using this form.

Doctors in training, Nurses, Midwives and Allied Health Professionals must not take written consent for any procedures until they have been signed off as competent to do so.

The full policy "Consent to Examination, Treatment and Care Policy" can be found on the Trust's intranet.

Completed procedure specific competency documentation (ie this completed form) to be retained by practitioner for personal records and copies must be sent to (specialty to specify):

-
-
-

Procedure Specific Consent Competency Documentation (continued)

- **The Assessor must be a senior healthcare professional experienced in gaining consent and undertaking the procedure.**

TREATMENT/ PROCEDURE: ……(record or mark as N/A)
OR
LIST OF PROCEDURES: ……(see list below or mark as N/A)

Specialty:	
Name of Trainee:	
Designation:	
Name of Assessor:	
Designation:	

There is no set number of observations a trainee must be supervised for. It is advised a minimum of 3, but it is dependent on the skills of the trainee, procedure and discussion with the assessor. Specialties are responsible for agreeing any variants.

Treatment/ Procedure	Competent	Signature of Assessor

Procedure Specific Consent Competency Documentation (continued)

Assessment of Competence to Take Written Consent for (tick one option below)
The specific procedure recorded on previous page
The list of procedures recorded on previous page

Specialty:	
Name of Trainee:	
Designation:	
Name of Assessor:	
Designation:	

THEORY

	Date
Aware of SFHT Consent Policy	
Awareness of appropriate consent form to be used	
Essential laws related to consent	

PRACTICAL DEMONSTRATION

	Date
Introduced self to patient	
Verified patients identity and intended procedure	
Explanation of proposed procedure/s	
Explanation of risks / benefits of the procedure/s	
Identification of alternative procedure / no treatment	
Sources of information patient may wish to access	
Completion of appropriate consent form	
Documents the episode	

	Signature & date
The above named individual has been fully trained in this named treatment/ procedure / these named treatments/ procedures and is competent to obtain valid written consent for it/ them.	**ASSESSOR**
Allied Health Professional/Nurse Manager	

Appendix I – Suggested format for divisional lists of procedures for the purpose of seeking and gaining consent (to include: specific procedures requiring consent; the form of consent; who can seek and obtain the consent and who can be delegated the process for seeking and obtaining the consent).
Example for Surgery Division provided to include generic procedures and procedures undertaken within the specialty of Trauma and Orthopaedics:

SURGERY DIVISIONAL LIST OF PROCEDURES FOR THE PURPOSE OF SEEKING AND GAINING CONSENT

Version: X.X Last Updated: dd/mm/yyyy vX.X Approved by DMT: dd/mm/yyyy Review Due: Month/ Year

Responsible Person: Name/ Designation

Specialty	Procedure	Form of Consent - Written/Verbal (*and if needs documenting in notes*)	Minimum Grade of MEDICAL Staff to Obtain Consent:	JOB TITLE of the MINIMUM GRADE of REGISTERED STAFF or NON REGISTERED STAFF able to take delegated consent (i.e. nurse, specialist nurse, radiographer, healthcare assistant)
Generic procedures in Surgery Division	Biopsy (percutaneous)	Verbal/ Written	F2 Doctor	N/A
	Venepuncture	Verbal	F2 Doctor	Nurse
	Cannulation	Verbal	F2 Doctor	Nurse
	Insertion of a CVP line on ward	Verbal	F2 Doctor	N/A
	Soft tissue aspiration	Verbal	F2 Doctor	N/A
	Arterial blood sampling	Verbal	F2 Doctor	N/A
	Urethral catheterisation	Verbal (document in medical notes)	F2 Doctor	Healthcare Assistant
Trauma and Orthopaedics	Removal of external fixator	Verbal (document in medical notes)	F2 Doctor	Yes, T&O Sp Nurse
	Removal of K-wires	Verbal (document in medical notes)	F2Doctor	Yes, T&O Sp Nurse
	Moulded plasters under Entonox	Verbal (document in medical notes)	F2 Doctor	Yes, T&O Sp Nurse
	Common hip fractures – dynamic hip screw fixation and hemiarthroplasty	Written	F2 Doctor	No
	Aspiration and injection of knee joints	Verbal	F2 Doctor	Yes, T&O Sp Nurse

Appendix J – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Consent to Examination, Treatment and Care Policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: 19/05/2022			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	None	The policy is written to ensure equality for all patients when undertaking the process for gaining consent.	None
Gender	None	As above	None
Age	None	As above	None
Religion	None	As above	None
Disability	Assistance can be given to patients who have visual impairment or a learning disability in line with other Trust policies and procedures.	As above	None
Sexuality	None	As above	None
Pregnancy and Maternity	None	As above	None
Gender Reassignment	None	As above	None
Marriage and Civil Partnership	Specific information in relation to children and young people is in line with legal requirements.	As above	None

Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	None	As above	None

What consultation with protected characteristic groups including patient groups have you carried out?

- None

What data or information did you use in support of this EqIA?

- None

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- None

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

Low Level of Impact

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: Mr Paresh Kothari, Trust Lead for Consent/ Consultant Surgeon in Trauma & Orthopaedics

Signature:

Date: 19/05/2022