Title: POLICY FOR CONSENT TO EXAMINATION, TREATMENT AND CARE

<table>
<thead>
<tr>
<th>Date approved:</th>
<th>Approved by:</th>
<th>Date of next review:</th>
<th>Policy Ref:</th>
<th>Issue:</th>
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<tr>
<td>29-09-2017</td>
<td>v10.0, Consent Steering Group</td>
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Lead Division / Lead Specialty: Surgery/ Trauma & Orthopaedics

Policy Category: Clinical Practice Policies & Guidelines

Author (post-holder): Clinical Lead for Consent, Mr Paresh Kothari (on behalf of the Consent Steering Group)

Sponsor (Director): Medical Director

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### ASSOCIATED DOCUMENTS:

#### Consent Forms in use in this Organisation:

- Form 1 – Patient agreement to investigation or treatment (FKIN030290)
- Form 2 – Parental agreement to investigation or treatment for a child or young person (FKIN030291)
- Form 3 – Patient/parental agreement to investigation or Treatment (procedures where consciousness not impaired) (FKIN030292)
- Form 4 – Form for adults who are unable to consent to investigation or treatment (FKIN030293)
- Form 5 – Form for photography and video/audio recordings (FKIN030315)

All available for staff to order from the Forms Management System in the usual manner

#### Patient information leaflets:

- Adults / Young Persons Patient Information Leaflet – Consent for your operation, procedure, investigation or care *(also available in Polish)*
- Childrens / Parents Patient Information Leaflet – Information about ward 25 and information regarding consent

Available for staff via the Patient Information intranet/external website
## Amendments table

<table>
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<tr>
<th>Version</th>
<th>Issue Date</th>
<th>Section(s) involved</th>
<th>Amendment</th>
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<tr>
<td>10.1</td>
<td>15-04-2019</td>
<td>Appendix K</td>
<td>Guidance for Health Professionals Completing Consent Form 4 added</td>
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<td>10.0</td>
<td>31-10-2017</td>
<td>• General</td>
<td>• Information reviewed and updated in-line with Montgomery v Lanarkshire Health Board Judgement.</td>
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<td>• General</td>
<td>• Oral consent changed to verbal consent</td>
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<td></td>
<td>• Training (Section 8) and throughout</td>
<td>• Revised to reflect current arrangements for training. Reference to generic and e-learning removed.</td>
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<td>• Monitoring (Section 9)</td>
<td>• Revised to reflect current arrangements for monitoring arrangements for this policy.</td>
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CONSENT AND CAPACITY – FUNDAMENTAL PRINCIPLES

- Staff must be trained and competent regarding consent and mental capacity prior to gaining consent (oral, non-verbal or written) for undertaking an examination, treatment or care for a patient.

  - Provide information about the examination, treatment or care that is proposed.

  - Document the information provided and any special measures taken to provide information e.g., interpreters, SALT.

Do you have reason to believe that the patient has not:
- Understood some or all of the information you gave them? OR
- Retained the information for long enough to make a decision? OR
- Weighed up the risks/benefits of having/not having the care or treatment or the various alternatives? OR
- Been able to communicate the outcome of their decision-making by any means?

OR
- Is the patient unconscious, heavily sedated or has a low GCS?

- Document that in your opinion the patient does not have the mental capacity to make the decision regarding the particular examination, care or treatment that is proposed, as they are unable to: understand/retain/weigh-up/communicate. This should be documented on the standard pro-forma: Appendix A – “Mental Capacity Two Stage test”, Trust MCA Policy or written in long hand within the medical notes.

- Ask the patient if they are happy to proceed with the examination, care or treatment that is proposed.

- The valid, informed consent (oral, non-verbal or written) that a patient provides is sufficient lawful authority for proceeding with the examination, care or treatment. NB: For consent to be valid it must also not be given under duress. If you have concerns about this consider safeguarding.

- Where a patient refuses examination, care or treatment this must be respected (unless certain provisions of the Mental Health Act apply).

- Document that consent obtained.

- Document that patient refused and offer appropriate alternatives.

- Proceed with examination, care or treatment.

- Document care given and any associated observations or anomalies.

Further information can be obtained from:
- Trust’s “Policy for consent to examination, treatment and care”
- Trust’s “Mental Capacity Act (MCA) Policy”
- Safeguarding Adults Intranet site / Safeguarding Adults Team – ext 6059, vocera
- Consent Outcome Guardians:
  - Trust Lead for Consent – mobile via switchboard
  - Consultant Geriatrician – ext 2428 / 6050, mobile via switchboard
  - Head of Nursing (Theatres, Anaesthetics and Head & Neck) – ext 4025, vocera
Checklist for Obtaining Written Consent for Procedure from Adult Patients

Written consent should be obtained ideally before the procedure is due to happen, 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? Document in the notes whether the patient is able to understand and retain the information about, and implications of, the procedure. (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. 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. (2)

5. Explain the anaesthesia/sedation that will be required to the patient. Indicate this clearly on the form. (6)

6. If transfusion may be required during or after the procedure, as a result of it, explain this to the patient and indicate that clearly on the form. (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. 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.

10. 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.

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

The GMC has very clear requirements for doctors regarding clear documentation, laid out in the Duties of a Doctor:

- 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: http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

Note: This checklist refers specifically to the SFH Consent Form 1. The bold numbers in brackets are the numbered items on the Form itself.
1. INTRODUCTION

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 and related policies. 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**

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

Version 10 of this policy has been reviewed and updated as the law on informed consent changed following a Supreme Court judgment.

Doctors must now ensure that patients are aware of any “material risks” involved in a proposed treatment, and of reasonable alternatives, following the judgment in the case *Montgomery v Lanarkshire Health Board*.

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.

In a move away from the ‘reasonable doctor’ to the ‘reasonable patient’, the Supreme Court’s 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.

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

2. 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.
2.1 **Equality Impact Assessment (EIA)**

The Trust is committed to ensuring that none of its policies, procedures and guidelines discriminate against individuals directly or indirectly on the basis of gender, colour, race, nationality, ethnic or national origins, age, sexual orientation, marital status, disability, religion, beliefs, political affiliation, trade union membership, and social and employment status. An EIA of this policy has been conducted by the author using the EIA tool developed by the diversity and inclusivity committee. (See Appendix L).

3. **DEFINITIONS**

<table>
<thead>
<tr>
<th><strong>The Trust:</strong></th>
<th>Means the Sherwood Forest Hospitals NHS Foundation Trust.</th>
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<tbody>
<tr>
<td><strong>Staff:</strong></td>
<td>Means all employees of the Trust including those managed by a third party organisation on behalf of the Trust.</td>
</tr>
<tr>
<td><strong>Consent:</strong></td>
<td>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. Employing bodies may also be liable for the actions of their staff (DH 2009 Reference guide to consent for examination or treatment 2nd Edition).</td>
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<tr>
<td><strong>Valid Consent:</strong></td>
<td>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'.</td>
</tr>
<tr>
<td><strong>Acquiesce:</strong></td>
<td>To consent or comply passively or without protest (e.g. presents an arm for venipuncture)</td>
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<tr>
<td><strong>Information:</strong></td>
<td>Written, verbal or non-verbal</td>
</tr>
<tr>
<td><strong>Non-verbal:</strong></td>
<td>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.</td>
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Two Stage Test: The Two Stage Test (appendix in 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 – appendix in 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).

4. ROLES AND RESPONSIBILITIES

Clinical Lead for consent
- has the responsibility for
  - maintaining and updating this policy and the information within it

Divisional Clinical Directors
- have the responsibility for ensuring that
  - the Service Leads/ Clinical Governance Leads discharge their duties as described below.

Medical/ Nursing/ AHP Service Leads/ Clinical Governance Leads
- have the responsibility for
  - ensuring that the policy is followed within their areas of work
  - all staff within their specialty have undergone consent training as applicable

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 capable of performing the procedure or have knowledge of the procedure in question. The health professional must be competent and have had generic training to seek consent.

Health professional carrying out procedure
- The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.
All staff undertaking routine everyday care

- Have the responsibility for gaining consent prior to implementing any routine care. Although these examples are not exhaustive this may include: 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. All staff have the responsibility to undertake mandatory and update training on mental capacity including consent.

5. SCOPE OF POLICY

This clinical document applies to:

Staff group(s):
- It is the responsibility of all Sherwood Forest Hospitals NHS Foundation Trust staff including bank, volunteer, contractor and third party staff employed by the Trust, 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 procedure for consent is undertaken (for clinical and non-clinical purposes)

Patient group(s):
- All patient groups – adult, maternity and paediatric (including neonates)

Exclusions:
- None

Related Trust documents:
- Policy for the development and use of written information leaflets for patients
- SFH Mental Capacity Act Policy
- Policy for Maintaining Staff Wellbeing and Reducing Work Related Stress
- Confidentiality Policy
- Photography and video recording policy
6. CONSULTATION

The following individuals, groups of staff and Trust group(s)/ committee(s) have been consulted in the development/ update of this document:

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<th>Communication Channel: e.g.</th>
<th>Date:</th>
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<tr>
<td>- Medical Director/ Sponsor</td>
<td>Group meeting</td>
<td>28-07-2017</td>
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<td>- Divisional representation (Medicine; Urgent &amp; Emergency Care; Women &amp; Children)</td>
<td>Email</td>
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<td>- General Surgery</td>
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<td>Clinical Audit representative</td>
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<td>Research representative</td>
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<tr>
<td>Consent Steering Group</td>
<td>Group meeting</td>
<td>29-09-2017</td>
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7. GUIDANCE AND PROCEDURE

7.1 Consent

_The NHS Constitution (2012)_ 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. _The NHS Constitution_ sets out seven key principles to guide the NHS in what it does. 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.

Health professionals must ask and gain consent from a patient prior to undertaking any form of examination, treatment or care _The Nursing and Midwifery Council Code (2015)_ . 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. For routine every day care this may be by just explaining how a procedure is undertaken such as monitoring a blood pressure. The consent required for more complex examinations and treatments such as operations and invasive procedures requires a more structured approach to consent. The conversation and discussion must include any benefits and risks of the proposed treatment or alternatives which specifically relate to the individual patient and the procedure.

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. Employing bodies may also be liable for the actions of their staff (DH 2009 Reference guide to consent for examination or treatment 2nd Edition).

For information on consent for children and young people see section 7.9.

7.2 Consent and Capacity (Adult patients)

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. It 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. Health care 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) 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 interest checklist (Best Interests Checklist) 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 the 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 see section 7.13.

Please note 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.
- 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:

- decisions about the proposed withholding or withdrawal of artificial nutrition and hydration (ANH) from patients in a permanent vegetative state (PVS)
- 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 (2005).

7.3 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.

7.4 Has The Person Received Sufficient Information?

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

- The Trust has produced a patient information leaflet to give adults/young people to help them understand more fully what consent is. The leaflet includes information about the consent form, who can give consent, ‘best interests’, asking questions, photographs and video recordings, taking part in
research and refusals of treatment. Please see – “Consent for your operation, procedure, investigation or care”.

- A separate leaflet for children/parents is also available. This leaflet includes information about being admitted to the children’s ward as well as information about who has legal authority to consent for a child’s surgery. Please see – “Information about ward 25 and information regarding 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.

7.5 Provision of Information

The provision of information is central to the consent process. Before patients can come to a decision and give valid consent about procedures, treatment or care, they need comprehensive information. For routine every day care this may be a simple explanation. For more complex procedures and treatments patients should be informed 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 know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Any misinterpretation of these elements will invalidate consent.

For more complex procedures and treatments, it is good practice to allow time for the patient to consider the treatment options and to change their minds. Therefore the gaining of consent might not be concluded in one consultation but may be over a number of consultations/visits. In Appendix F 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.

Once a decision to have a particular procedure or treatment/investigation has been made, patients need information about 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.

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 given to patients shall be noted. Where relevant, information about anaesthesia should be given alongside information about the procedure or treatment/ investigation itself.

Where relevant, the person giving the information must be able to evidence 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.

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

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.

People increasingly want to participate in choosing their care, and literature for patients is a useful resource. Written information leaflets can be read and absorbed at a patient’s own pace. 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. It gives people time to go away, read the information and think about the issues involved.

For further information about written patient information leaflets please refer to the Trust’s “Patient Information Leaflet Policy”. This policy provides details about the written information endorsed by the Trust such as:

- Internally produced leaflets developed through the Trust’s patient information process
- The EIDO Healthcare INFOrm4U library of leaflets and
- Leaflets available via the NHS Choices website

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

- [Patient information leaflets (intranet)](intranet)
- [Patient information leaflets (external website)](external)

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.

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.
Provision for patients whose first language is not English

- This Trust is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children, family members or relatives to interpret for family members who do not speak English.

- 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.

- Face to face interpreting is also available in certain circumstances e.g. breaking bad news, paediatric appointments, mental health issues etc. This service can only be booked during working hours by contacting the Diagnostic and Outpatient management secretaries on ext 4168 or 3368.

- If any written information is needed in a different language or format, please contact the Patient Experience Team.

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 five core consent forms (1,2,3,4 & 5).

7.6 Who Should Seek Consent – written, verbal, non-verbal or by acquiescence (including delegated consent)

a) Seeking written consent

Only health professionals who have received the required training and are competent to do so, can gain written consent for a patient undergoing a treatment, procedure or investigation – See further details in Section 8, Training.

Where written consent is required, the clinician providing the treatment, procedure or investigation is 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. The General Medical Council (GMC) (2008) states that the task of seeking consent may be delegated to another person, 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.

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.

b) Delegated written consent for specialty specific procedures

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

Please note: 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.

c) Seeking consent verbally, non-verbally or by acquiescence

Where consent is being sought verbally, non-verbal or by acquiescence at the point a procedure, treatment or care will be carried out, this will naturally be done by the health professional responsible. Training for mental capacity (incorporating consent) is mandatory for all clinical staff. 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). Gaining consent in this way must still be documented in the patient’s notes.

d) Responsibility of health professionals

It is a health professional’s own responsibility:
- to ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so;
- 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 you feel that you are being pressurised to seek consent when you do not feel competent to do so then contact the Clinical Lead for Consent. For trainees, contact the Education/ Clinical Supervisor.
7.7 Process for following up those who have obtained consent for a procedure without being authorized to do so

Although this 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
- 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 ‘Policy for Maintaining Staff Wellbeing and Reducing Work Related Stress’ during a full investigation and will be expected to undertake generic training within the following 3 month period.

Following the investigation, if it has been identified that clinical staff have obtained consent when not authorised to do so notification will 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
- General Dental Council – registered dental practitioners

7.8 When Consent Should Be Sought

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

The seeking and gaining of written consent is usually a process rather than a one-off event – two or more stage process. 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. Clinicians should then check before the procedure starts that the person still consents.

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

Single stage process for gaining consent

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

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

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

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

Patients receiving elective treatment or investigations for which written consent is
appropriate should be familiar with the contents of their consent form before they
arrive for the actual procedure, and should have received a copy of the page
documenting the decision-making process. They may be invited to sign the form,
confirming that they wish treatment to go ahead, at any appropriate point before the
procedure: in out-patients, at a pre-admission clinic, or when they arrive for
treatment. If a form is signed before patients arrive for treatment, however, a
member of the healthcare team **must** check and confirm with the patient at this
point whether they have any further concerns and whether their condition has
changed. This is particularly important where there has been a significant lapse of
time between the form being signed and the procedure. When confirming the
patient’s consent and understanding, it is advisable to use a form of words which
requires more than a yes/no answer from the patient: for example beginning with
“tell me what you’re expecting to happen”, rather than “is everything all right?”

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

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. Confirmation of consent must be documented on the consent form if the
form has been signed by the patient prior to the day of the proposed procedure or
treatment/ investigation. 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.
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. 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. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.

In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council (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.

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. A hysterectomy should never be performed during an operation without explicit consent, unless it is necessary to do so to save life.

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 (2008) states that it is good practice to seek the views of the patient on possible additional procedures when seeking consent to the original intervention. This information must be written on the consent form and additional information written in the patient’s medical notes.

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.
7.9 Consent and Treatment of Children and Young People

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

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 doesn’t 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.

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.

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.

Children under 16 – the concept of Gillick competence

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, good practice to involve the child’s family in the decision-making process, if the child consents to their information being shared.

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.

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

7.10 The Patient’s Perspective and Exceptions to the Principle

When seeking consent the clinician should remember to try and view it from a patient’s perspective and that there may be exceptions to the principle. Please see:

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

7.11 Form of Consent (written, verbal, non-verbal or by acquiescence)

The validity of consent does not 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.

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.

7.12 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 CTiMP (Clinical Trial of an Investigational Medicinal Product) research staff must have also completed (within the previous 2 years) Good Clinical Practice (GCP) for Research training.
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](http://www.gmc-uk.org/guidance/ethical_guidance/5993.asp)

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](https://www.gmc-uk.org/guidance/ethical_guidance/5993.asp)). 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](http://www.fda.gov/downloads/Drugs/…). 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)](http://www.fda.gov/downloads/Drugs/…).

The [Medicines for Human Use (Clinical Trials) Regulations (2004)](http://www.fda.gov/downloads/Drugs/…) 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 (see Appendix G).

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) (see Appendix H). The PrLR must have undergone the
relevant training and completed the nomination form (in Appendix J) 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 (see Appendix I).

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 Team, extension 3313.

- (All links in this section were last accessed 13.07.2017)

7.13 Documentation

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 specialist 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 this, they 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 access to appropriate colleagues to answer questions they cannot handle themselves.

Confirmation of a patient's consent should not be recorded until all the questions 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 2nd 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.

**Consent forms**

Standard consent forms, forms for adults who are unable to consent for themselves and the form for photography/video-audio recording are available in clinical areas (ordered via the Forms Management System in the usual manner).

**Consent forms 1, 2 and 3**

There are three versions of the standard consent form:
- form 1 for adults or competent children;
- form 2 for parental consent for a child or young person; and
- form 3 for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care.

The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary.

**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 K.
Consent form 5 – Clinical photography and video/audio recordings for clinical and non-clinical purposes

The Trust has adopted the policy that written consent must be obtained for all photography and video recordings (convention or digital). For planned operations, treatments and procedures consent is gained for “investigative images” using the relevant consent forms above. However, where photography and video/audio recordings are required to be taken in isolation of a planned procedure, written consent must be obtained using consent form 5. This form can also be used in instances where patients lack capacity as a decision specific two stage test and best interest checklist is incorporated into the form. Although the list is not exhaustive, example situations for using this form include: photography of pressure ulcers; wound monitoring; evidence (e.g. non-accidental injury) or to aid diagnosis. Consent form 5 can also be used to gain written consent where the recordings are to be used for non-clinical purposes e.g. video recording the insertion of a sub-dermal contraceptive implant for making an e-learning educational training package. For further information on photography and video recordings please see the Trust’s “Photography and video recording policy”. Please also see section 7.16 below.

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.

7.14 Refusal of Treatment

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.

7.15 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 of the Human Tissue Act 2004 - see Appendix E (DH 2005)
Contact for further information: Laboratory Manager, Pathology Department, King’s Mill Hospital.

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

General information

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.

As previously stated, the Trust has adopted the policy that written consent must be obtained for all photography and video recordings (convention or digital). 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.

Education, publication and research

Whether a patient can be identified or not and you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording by completing consent form 5. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made 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.

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 using consent form 5 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”.

8 TRAINING

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 (SFH Mental Capacity Act Policy) and this must be referred to as part of the training in order that the person gaining consent is competent.

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

Training for mental capacity (incorporating consent) is mandatory for all clinical staff 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).
Training to gain written consent

F1 doctors cannot take written consent for any procedures. However, the education department provide in-house structured training as part of the junior doctor’s core training programme.

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. Local induction programmes must include:

- 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
- Identification of procedures requiring written consent
- Identification of procedures for which the consent process may be delegated
- For each procedure – identification of the risks, benefits and alternatives with an emphasis on individual patient requirements (Montgomery judgement)
- 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.

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.

9 EVIDENCE BASE/ REFERENCES

- The Mental Health Act 1983 (as amended by the Mental Health Act 2007)
- DH (March 2013) NHS Constitution – The NHS belongs to us all (last accessed 13th July 2017)
- General Dental Council Principle 3 – Obtain valid consent GDC. (last accessed 13th July 2017)
• Human Fertilisation and Embryology Act 1990 as amended by the [Human Fertilisation and Embryology Act (2008)](last accessed 13\textsuperscript{th} July 2017)
• Human Tissue Authority (April 2017) [Codes of Practice – Code A Guiding principles and the fundamental principle of consent](London: DH (last accessed 13\textsuperscript{th} July 2017))
• [International Conference of Harmonisation (ICH) (June 1996) Guideline for Good Clinical Practice](last accessed 13\textsuperscript{th} July 2017)
• [The Medicines for Human Use (Clinical Trials) Regulations 2004](last accessed 13\textsuperscript{th} July 2017)
• NHS Choices website – [End of Life Care - Advance Decisions](last accessed 13\textsuperscript{th} July 2017)
• Nursing & Midwifery Council (2015) [The Code: professional standards of practice and behaviour for nurses and midwives](NMC. (last accessed 13\textsuperscript{th} July 2017)
• Montgomery v Lanarkshire Health Board (March 2015) [Judgement](last accessed 25\textsuperscript{th} July 2017)
• Gillick Competency and Fraser Guidelines – Gillick v West Norfolk, 1984

10  **MONITORING COMPLIANCE AND EFFECTIVENESS**

The consent policy will be monitored with a focus on completion of documentation and the patient experience of consent as follows:

<table>
<thead>
<tr>
<th>Minimum Requirement to be Monitored</th>
<th>Responsible Individual</th>
<th>Process for Monitoring e.g. Audit</th>
<th>Frequency of Monitoring</th>
<th>Responsible Individual or Committee/ Group for Review of Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>(WHAT – element of compliance or effectiveness within the document will be monitored)</td>
<td>(WHO – is going to monitor this element)</td>
<td>(HOW – will this element be monitored (method used))</td>
<td>(WHEN – will this element be monitored (frequency/ how often))</td>
<td>(WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)</td>
</tr>
<tr>
<td>Elements identified in audit for <strong>Consent Documentation</strong></td>
<td>Each relevant specialty</td>
<td>Audit via Meridian system</td>
<td>Monthly</td>
<td>Results monitored through governance structures and escalated/ actioned as appropriate.</td>
</tr>
<tr>
<td>Elements identified in audit for <strong>Patient Element</strong></td>
<td>Each relevant specialty</td>
<td>Audit via Meridian system</td>
<td>Monthly</td>
<td>Results monitored through governance structures and escalated/ actioned as appropriate.</td>
</tr>
</tbody>
</table>

11. **DISTRIBUTION**

This policy will be held within the relevant document library of the Trust’s ‘Policies, Procedures and Guidelines’ intranet site.

12. **COMMUNICATION**

Communication of the update or any changes to this policy will be through the earliest monthly Team Brief and/ or weekly staff bulletin.
13. AUTHOR AND REVIEW DETAILS

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<tr>
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<td>15&lt;sup&gt;th&lt;/sup&gt; April 2019</td>
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<tr>
<td>Date to be reviewed by:</td>
<td>September 2020</td>
</tr>
<tr>
<td>To be reviewed by:</td>
<td>Clinical Lead for Consent, Mr Paresh Kothari</td>
</tr>
<tr>
<td>Executive Sponsor:</td>
<td>Executive Medical Director</td>
</tr>
<tr>
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<td>v10.0 Issued 31&lt;sup&gt;st&lt;/sup&gt; October 2017 to Review September 2020</td>
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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
   o 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.
   o 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)
   o 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.
   o 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.
   o 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 1\textsuperscript{st} 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 4\textsuperscript{th} 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 parental responsibility if he is named, or becomes named, on the child’s birth certificate from 15\textsuperscript{th} 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


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

Treatment options

1. do nothing – risks and benefits
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

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 G – PERSONAL Legal Representative Consent Pathway

Patient fulfils eligibility criteria

Is a person who has a close personal relationship with the patient available? E.g. next of kin / family member or friend?

- YES
  - Follow Professional Representative Consent Path
  - NO

- NO
  - Patient cannot be recruited. Standard treatment is given.
  - YES
    - Is the person willing and able to take on the responsibilities of Personal Legal Representative?
      - NO
        - Is there a reason to presume that this patient would NOT be willing to participate?
          - YES
            - If yes, patient is not recruited to trial
          - NO
            - If / when patient regains competence, inform of participation and provide patients information sheet and obtain consent for use of information.
      - YES
        - Explanation to be given in person by a member of the trial team.
          - Written consent to be signed by Personal Legal Representative.
          - If / when patient regains competence, inform of participation and provide patients information sheet and obtain consent for use of information.

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Issue Date: 15th April 2019
Review Date: September 2020
Appendix H – PROFESSIONAL Legal Representative Consent Pathway

**Patient fulfils eligibility criteria**

- **YES**
  - **Is a Professional Legal Representative available who has undergone appropriate training? This person would be a senior staff member appointed by Trust via Research & Development?**
    - **NO**
      - Follow the procedure for consulting with an Independent Doctor or procedure for research study entry without consent pathway.
    - **YES**
      - Has the Professional met with the Principle Investigator, received written documentation of the trials, had the study protocol explained and had the opportunity to ask questions and completed a nomination form (appendix J).

- **NO**
  - Patient cannot be recruited. Standard treatment is given.

**Is there not another PeLR / PrLR available who has received the information about this trial?**

- **YES**
  - Explanation to be given by member of the trial team. Written consent to be signed by Professional Legal Representative.
    - If person is not available in person verbal consent can be obtained by telephone. Written consent will need to be obtained as soon as possible.
    - If / when relatives or friends arrive; they will be informed of participation and provided with the relevant information sheet.
- **NO**
  - If yes, please follow the appropriate pathway.
    - If no, is there a reason to presume that this patient would NOT be willing to participate?
      - If yes, patient is not recruited to trial.
      - If no, see procedure without consent pathway.
Appendix I – Procedure without Consent Pathway

Patient fulfils eligibility criteria

Does the research study involve the use of a medicine?

YES

Patient cannot be recruited. Standard treatment is given.

NO

Researcher can use ‘procedure without consent’ or ‘consultation if approved by ethics’.

Once PeLR / PrLR become available consent must be gained from one of these individuals. If they feel it is not appropriate then patient must be withdrawn from study.

If PeLR / PrLR involvement is not practical the researcher will obtain the agreement of a ‘registered medical practitioner’ who is involved in the organisation or conduct of the research project e.g. doctor caring for the patient.

Written agreement is required by both parties and a reason why this route was adapted.
Appendix J – Professional Legal Representative (PrLR) Nomination Form

Study Title:

......................................................................................................................................................
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......................................................................................................................................................
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Principle Investigator:

PRINT NAME: .................................................................................................................................
SIGNATURE: ..................................................................................................................................

Nominated Professional Legal Representative:

PRINT NAME: .................................................................................................................................
SIGNATURE: ..................................................................................................................................
POSITION: ........................................................................................................................................

Confirmation of discussion re. Study Detail to Nominees and by whom:

PRINT NAME: .................................................................................................................................
SIGNATURE: ..................................................................................................................................
POSITION: ........................................................................................................................................
DATE: ................................................................................................................................................

Confirmation of Training in relation to role and by whom:

PRINT NAME: .................................................................................................................................
SIGNATURE: ..................................................................................................................................
POSITION: ........................................................................................................................................
DATE: ................................................................................................................................................
Sherwood Forest Hospital NHS Foundation Trust Research & Development Authorisation:

PRINT NAME: ...........................................................................................................

SIGNATURE: ............................................................................................................

POSITION: ..............................................................................................................

DATE: ......................................................................................................................

Study Personnel Aware:

LEAD CONTACT: ....................................................................................................

DATE INFORMED: ....................................................................................................
Appendix K

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 straightforward 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:

- 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;
- in a case where there is a choice of treatments, a decision as to which one to use is finely balanced; or
- 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:

- cause, or may cause, serious and prolonged pain, distress or side effects;
- have potentially major consequences for the patient; or
- have a serious impact on the patients future life choices

Examples of serious medical treatment may include:

- certain terminations of pregnancy in relation to a person who lacks capacity to consent to such a procedure;
- 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;
- 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;
- an experimental or innovative treatment for the benefit of a person who lacks capacity to consent to such treatment; and
- a case involving an ethical dilemma in an untested area
Appendix L –

Equality Impact Assessment (EqIA) Form (please complete all sections)

Guidance on how to complete an EIA

Sample completed form

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>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?</th>
<th>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?</th>
<th>c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race and Ethnicity:</td>
<td>None</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Gender:</td>
<td>None</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Age:</td>
<td>None</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Religion:</td>
<td>None</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Disability:</td>
<td>Assistance can be given to patients who have visual impairment or a learning disability in line with other trust policies and procedures.</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Sexuality:</td>
<td>None</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Pregnancy and Maternity:</td>
<td>None</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Gender Reassignment:</td>
<td>None</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Marriage and Civil Partnership:</td>
<td>Specific information in relation to children and young people is in line with legal requirements.</td>
<td>As above</td>
<td>As above</td>
</tr>
<tr>
<td>Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation):</td>
<td>None</td>
<td>As above</td>
<td>None</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

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, 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, Clinical Lead for Consent/ Consultant Surgeon in Trauma & Orthopaedics

Signature:

Date:
22-09-2017