

Consent Policy
Patients and healthcare professionals making decisions together

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Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

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Consultation

The following were consulted during the development of this document:
The Consent Steering Group developed this policy in conjunction with 78 individuals from Queen Elizabeth Hospital NHS Foundation Trust, James Paget University Hospitals NHS Foundation Trust, Norfolk & Norwich University Hospitals NHS Foundation Trust, representation from Healthwatch Norfolk and Richard Drew, a member of the Patient Panel. The process involved an Accelerated Design Event and 9 task and finish groups (a full list of participants is available on request).

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a policy applicable to the Acute Hospital Collaborative; please refer to local Trust's procedural documents for further guidance.

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Consent Policy

1. Introduction

1.1. Rationale

This policy has been developed to standardise the consent process and to improve patient safety and patient experience across the three Acute NHS Trusts in Norfolk and Waveney Integrated Care System (ICS); James Paget University Hospitals NHS Foundation Trust (JPUH), Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) and The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust (QEH) and referred to in this document as "the Trusts".

The aim of the Policy is to ensure that the Trusts are operating effective controls that protect the human rights and safety of patients, and to support good practice.

A person has a fundamental legal and ethical right to determine what happens to their own body. Valid consent is therefore absolutely central in all forms of health care, from undertaking a physical examination or providing personal care, through to performing major surgery. Seeking consent is also a matter of common courtesy between healthcare professionals and a person and staff must work in partnership with them.

The right to be given clear and transparent information about a recommended examination, treatment or investigation, including the risks and benefits associated with that treatment and available alternatives, and the right to accept or refuse examination, treatment or investigation is enshrined in the NHS Constitution.

1.2. Objective

The purpose of the policy is the desire to align the consent processes across the ICS to facilitate the movement of patients or staff between all three Trusts. It is intended to provide supplementary local information to national guidance and professional training, setting out the standards that must be upheld. It aims to provide advice and guidance to ensure that all healthcare professionals and trainees comply with professional and legal standards on seeking consent in their daily practice.

Healthcare professionals must work in partnership with their patients to ensure patients are involved in planning and making decisions in relation to their health and care.

The Department of Health, National Institute of Health and Clinical Excellence (NICE) and the various professional bodies such as the General Medical Council (GMC) have issued a range of guidance documents on consent and these should be consulted for details of the law and good practice requirements on consent. The law relating to consent has its origins in the common law, but other important legislation relating to this Policy include the Mental Capacity Act 2005, Mental Health Act 1983, and Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

1.3. Scope

This Policy applies across the Trusts and to all individuals involved with seeking consent to examination, treatment or investigation.

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1.4. Glossary/Terms Used

The following terms and abbreviations have been used within this document:

Term	Definition
Person	An individual seeking or undergoing treatment, investigation or examination within ICS. This individual is may also be known as a patient
Healthcare Professional	All individuals involved with seeking consent to examination, treatment or investigation under employment within the Trusts.
Children	People aged below 16 years
Young People	People aged 16 and 17 years
Healthcare Records	Electronic and/or paper health documentation forming an individual's record

2. Consent Processes

2.1. What is Consent?

The GMC (09 November 2020, page 6) describes consent as *“a fundamental legal and ethical principle. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can. The exchange of information between doctor and patient is essential to good decision making. Serious harm can result if patients are not listened to, or if they are not given the information they need - and time and support to understand it - so they can make informed decisions about their care.”*

Consent must be sought by all healthcare professionals. It is a continuous process and a person has the right to change their mind. Healthcare professionals must work in partnership with the person, listen to and respond to concerns and preferences. Different approaches may be necessary and the amount of information shared will vary dependent on the individual person's circumstances.

Healthcare professionals must be satisfied that they have a person's consent or other valid authority before examination, treatment or investigation.

Consent is a person's informed agreement for a health professional to undertake a physical examination, provide care and/or treatment. A person may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), verbally, or in writing.

For the consent to be valid, the person must have capacity to make the particular decision with sufficient and appropriate information and not be acting under duress. Where they lack capacity the framework of the Mental Capacity Act (2005) must be followed.

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2.2. When do we need to assess capacity?

The Mental Capacity Act (MCA) sets out the statutory framework for making decisions for people who lack capacity to make decisions themselves. Where a person lacks capacity, any decision must be made in that person's best interests.

A standard principle of the MCA is the presumption that the person is able to make their own decisions. All efforts should be made to support and encourage the person to make their own decisions.

A person is entitled to make a decision which may be perceived by others to be unwise or irrational, as long as they have the capacity to do so.

Under the MCA, the healthcare professional is required to make an assessment of capacity before carrying out any care or treatment if there is a reasonable belief someone lacks capacity.

Mental capacity is not fixed and may change over time, a person may still have the capacity to make a decision on another issue.

Please refer to the MCA Code of Practice for additional advice and guidance.

<https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice>

2.3. Assessing Capacity

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

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 the ability to make decisions in general.

A person is unable to make a decision if they cannot do one or more of the following:

- Understand the information given to them that is relevant to the decision
- Retain the information long enough to be able to make a decision
- Use or weigh up the information as part of the decision-making process
- Communicate their decision by any means

2.4. Process for Obtaining Consent

The process for obtaining consent will vary depending on the clinical situation and the person's circumstances. In many cases, it will be appropriate for a healthcare professional to initiate an examination, investigation, or treatment immediately after discussing it with the person. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the person's condition and whether there are any significant risks. If the person is willing for the technique to be used, they will then give their consent and the intervention can go ahead immediately. In many such cases, it is entirely

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appropriate for consent to be given verbally but it will still need to be recorded in the healthcare records.

If a proposed treatment or investigation carries any significant risks, it is appropriate to seek written consent; while for low risk forms of treatment and investigation, verbal consent may be sufficient. It is the person's right to be told whatever information they need and in a manner that they understand. Healthcare professionals must take into account whether the person has had a sufficient opportunity to absorb the information necessary for them to make any decisions. As long as it is clear that the person understands and consents, whether verbally or by a signature, the health professional may then proceed.

In most cases where written consent is being sought, investigation and/or treatment options will be discussed well in advance of the actual intervention being carried out. This may be on just one occasion (either within primary care or in a hospital), 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, risks and benefits and an initial verbal decision with potentially subsequent occasions where additional questions are answered and the final one being confirmation that the person still wants to go ahead. All the stages of the consent process must be documented in the healthcare records.

Consent forms can be, and often are, signed before a person arrives for treatment or investigation. However, a member of the healthcare team must check with the person if they have any further concerns, their condition has changed, and to confirm they still consent to the treatment or investigation.

If new information becomes available regarding the proposed intervention between the times when consent was obtained and when the intervention is undertaken, the healthcare professional must inform the person and re-assess their consent or refusal.

It must be remembered that for consent to be valid, the person must always feel that it would have been possible for them to refuse, or able to change their mind. It will rarely be appropriate to ask a person to sign a consent form after they have begun to be prepared for treatment or investigation, unless this is unavoidable because of the urgency of the person's condition.

The consent form can be used as a means of documenting the information stage(s), if appropriately designed to do so, as well as the confirmation stage. Healthcare professionals must ensure they record the detail of discussions with the person in the medical notes and/or in a letter to the person and/or on the consent form all of which is then kept with the person's healthcare records. The quantity and detail must be proportionate to the clinical situation and procedure. This must include the information discussed, any specific requests by the person, any written, visual or audio information given to the person and their responses, and details of any decisions that were made.

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2.5. Remote Consent

Where a person is not physically present (e.g. in a virtual or telephone consultation) to sign a consent form for an agreed treatment or investigation, the agreement must be documented within the healthcare record and the consent form must be completed in person on or before the day of the intervention. It is best practice to send a copy of all information including a blank consent form for the procedure to the person.

2.6. Open Access Clinics and consent

Where a person accesses clinics directly, it should not be assumed that their presence at the clinic implies consent to a particular examination, treatment or investigation. The healthcare professional must ensure that they have the information they need before proceeding with an examination, treatment or investigation.

2.7. Risks

2.7.1. Aspects of Risk in the consent process

The provision of information is central to the consent process. Before a person can come to a decision about treatment or investigation, they need comprehensive information about their condition. This should include potential or alternative treatments and investigations and the associated risks and benefits. The person may also need to know whether additional procedures are likely to be necessary, e.g. a blood transfusion.

Unless all of these elements are appropriately addressed, this may invalidate consent.

2.7.2. Discussing Benefits and Risks

Taken from decision making and consent (GMC: 09 November 2020, page 14):

“You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.

It wouldn't be reasonable to share every possible risk of harm, potential complication or side effect. Instead, you should tailor the discussion to each individual patient, guided by what matters to them, and share information in a way they can understand.

You should include the following information when discussing benefits and harms:

- *Recognised risks of harm that you believe anyone in the patient's position would want to know. You'll know these already from professional knowledge and experience.*
- *The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient's medical history, you'll know some of what you need to share already, but the dialogue could reveal more.*

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- *Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during discussion with the patient about what matters to them.*
- *Any risk of serious harm, however unlikely it is to occur.*
- *Expected harms, including common side effects and what to do if they occur.*

You should consider using visual or other explanatory aids to support patients to understand their personalised risk, taking account of their individual clinical and personal circumstances, compared with population level risk.”

This is likely to be easier to discuss in advance where possible.

2.7.3. Communication of Risk

When communicating information about risk, use clear language. If the person’s first language is not English, use an approved translator. Some people prefer descriptive words (common, rare etc.) to numbers. The healthcare professional must clarify what these words mean to an individual as interpretation may change depending on the risks involved. When using numbers, natural frequencies with the same denominator (1 in 1000, 15 in a 1000) are usually more easily understood than percentages or fractions. Pictorial descriptions can sometimes help make numbers clearer. At the end of the discussion, it is good practice to check the person’s understanding, for example by asking them to repeat what has been explained.

Taken from decision making and consent (GMC: 09 November 2020, page 16):

“You must answer patients’ questions honestly and accurately, and as fully as is practical in the circumstances. You must be clear about the limits of your knowledge and, if you can’t answer a question, explain whether it is something you are uncertain of or something that is inherently uncertain.

If you are uncertain about the diagnosis, or the clinical effect a particular treatment might have, or if the available evidence of benefits and harms of an option is unclear, you should explain this to the patient. Some things will become clearer after treatment starts, so you should discuss in advance what the arrangements will be for monitoring the effect of the treatment and reviewing the decision to provide it. You should also explore in advance what options the patient might prefer in the future, depending on how treatment progresses, and the factors that might influence their choice.”

If the person insists they do not want to know about the risks of a treatment or investigation (including anaesthesia), the consequences of this should be explained. This discussion should be recorded in writing and the person given the opportunity to change their mind. A person should understand that there may be risks but should not have a detailed explanation forced upon them if unwilling.

Exceptional circumstances where not all relevant information is shared

Taken from decision making and consent (GMC: 09 November 2020, page 13):

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“There may be circumstances in which you decide not to share all relevant information with a patient straight away. If you delay sharing information necessary for making a decision, you should let the patient know there’s more to discuss and make sure arrangements are made to share the information as soon as it’s appropriate to do so. You must make a record of the information you still need to share, your reasons for not sharing it now, and when it can be shared.

You should not withhold information a patient needs to make a decision for any other reason, including if someone close to the patient asks you to. In very exceptional circumstances you may feel that sharing information with a patient would cause them serious harm and, if so, it may be appropriate to withhold it. In this context ‘serious harm’ means more than that the patient might become upset, decide to refuse treatment, or choose an alternative. This is a limited exception....” and legal advice must be sought from the local Trust’s Legal Services Department.

2.8. Additional Procedures

On rare occasions it may become apparent during an operation that the person would benefit from an additional procedure that was not within the scope of the original consent. It may be justified to perform this additional procedure if a delay would be unreasonable because there is a significant threat to that person’s wellbeing but it should not be done as a matter of convenience. The GMC states it is good practice to seek the views of the person on possible additional procedures when seeking consent for the original intervention.

If a person has refused certain additional procedures before the anaesthetic, then this must be respected if the refusal is applicable to the circumstances.

2.9. Human Tissue

The Human Tissue Act (2004) regulates the removal, storage and use of human tissue from the living and from the deceased with consent being the fundamental principle underpinning the lawful retention and use of such. It does not apply to therapeutic samples such as blood for tests or tissues taken for histological diagnosis only. Any intervention involving the use of human tissue must be consented to in accordance with the requirements of the Act.

Prior to an intervention, it is the duty of the healthcare professional seeking consent to discuss all aspects of the intervention with the person, including the use of tissue where appropriate. Such details should be recorded in the healthcare records and/or on the consent form. A person should be given the opportunity to refuse permission for tissue taken to be used for educational or research purposes during surgery or another procedure.

The Human Tissue Act (2004) lists the ‘scheduled purposes’ for which consent is required and that consent must be ‘appropriate’ i.e. from an appropriate person as identified in the Act. Additional information is available at the Human Tissue Authority’s (HTA) website.

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2.10. Clinical Photography and Visual / Audio Recordings

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

There are three levels of consent for images/recordings (Institute of Medical Illustrators (IMI): 2006):

1. For use in the medical records only
2. For use in teaching healthcare staff and students
3. For publication

Institute of Medical Illustrators (IMI) (2006) *National Guidelines Consent to Clinical Photography* Available at https://www.imi.org.uk/wp-content/uploads/2019/01/IMINatGuidelinesConsentMarch_2007.pdf Accessed on: 17/11/2020

2.11. Who is Responsible for Seeking Consent?

The named consultant or healthcare professional in charge of the person's episode of care will remain ultimately responsible for the quality of medical care provided including obtaining consent. The task of obtaining consent may be delegated to another competent healthcare professional, however, this individual must be trained and/or competent in obtaining consent.

The healthcare professional providing the treatment or investigation is responsible for ensuring that the person has given valid consent before the intervention begins.

If consent has been obtained by a healthcare professional who is not authorised to do so, this must be reported via the individual Trust's Incident Reporting system and the healthcare professional's supervising mentor informed.

2.12. All Healthcare Professionals

The healthcare professional carrying out the intervention is accountable for ensuring the person taking consent is competent to do so.

It is a health professional's own responsibility to work within their own competence and not to agree to perform tasks which exceed that competence.

All incidents concerning consent must be reported on the local Trust's Incident Management system.

2.13. Does it matter how the person gives consent?

Consent can be given in written, verbal or non-verbal format. The purpose of a consent form is to record the person's decision and provide evidence of the consent process. It is not a binding contract but will confirm that discussions have taken place.

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A person may withdraw consent at any time after they have signed a form.

2.14. Access to health professionals between formal appointments

After an appointment with a healthcare professional in any setting, a person may think of further questions which they would like answered before they make their decision. It should be possible to easily access further information without necessarily making another appointment or waiting until the date of treatment or investigation.

2.15. Consent to interventional radiology

In these technical treatments or investigations, the referring healthcare professional must take responsibility for the first elements of informed consent. They must explain to the person how the intervention fits into the plan of care, any alternatives, and the material risks associated with the intervention for which they are being referred. This information should be included in any patient information leaflet and any associated procedure specific consent form.

On the day of the procedure, the validity of the consent previously given is to be checked and any additional questions or changes in circumstances must be addressed. The practitioner must be assured that valid consent has been given or refused.

2.16. Consent for anaesthesia

Where an anaesthetist is involved in a person's care, it is their responsibility to ensure that appropriate consent for anaesthesia is taken, having discussed the benefits and risks. The anaesthetist must document the discussion with the person and record consent in the person's healthcare records such as on an anaesthetic chart.

Where the healthcare professional providing the care is responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), they are responsible for ensuring that the person has consented to it.

2.17. Consent for investigation or treatment involving radiation exposure

A person or their representatives must be provided with adequate information relating to the benefits and risks associated with the radiation dose from exposure, prior to the exposure taking place.

When radiation exposure is included as part of another investigation or treatment these risks must be documented in the consent form.

2.18. Capture, Storage and Retention of Gametes

Special conditions apply to the consent for the capture, storage and retention of gametes, please refer to the Human Fertilisation and Embryology Acts.

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2.19. Consent to screening

Consent to participation in national screening programmes will follow the relevant national guidance.

2.20. Consent to post mortem

The Human Tissue Authority license requires that the making of a post mortem examination and any retention or use of tissue from the deceased requires formal consent except when performed under the jurisdiction of the coroner or the police. <https://www.hta.gov.uk/policies/consent-post-mortem-examination-and-tissue-retention-under-human-tissue-act-2004>. The code of practice indicates in order of priority who may give consent and guidance regarding information and consent process.

2.21. Consent to transfusion

For an acute transfusion or a chronic transfusion programme valid consent must always be obtained and documented in the person's healthcare record by the healthcare professional.

Consent must include informing the person of the risks, benefits and alternatives to blood transfusion and that they can no longer donate blood.

When valid consent is not possible prior to transfusion the person must be informed of the transfusion at the first clinically appropriate opportunity.

Prior to discharge all those who have received a transfusion should be provided with the relevant blood transfusion patient information leaflet.

For refusal of transfusion for religious or other reasons please see 4.23.

For further reading:

Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) *Consent for Blood Transfusion Oct 2020*. Available at: <https://www.transfusionguidelines.org/transfusion-practice/consent-for-blood-transfusion> accessed on 28 April 2021

NICE Blood transfusion NICE guideline [NG24]18 November 2015
<https://www.nice.org.uk/guidance/ng24/chapter/Recommendations>

2.22. Consent to research

Each clinical trial must use the nationally approved Research Ethics Committee and Health Research Authority consent form. <http://hra-decisiontools.org.uk/consent/>.

2.23. Duration of Consent

When a person gives valid consent to an intervention, that consent remains valid unless it is withdrawn by the person, or circumstances have changed such that the process must be revisited.

It is good practice to confirm consent when significant time has elapsed.

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2.24. Refusal of Consent to Care and Treatment

A competent adult is entitled to refuse any treatment or investigation at any time. A person can make irrational and unwise decisions but this does not mean they lack capacity. The only exceptions are the circumstances governed by the Mental Health Act 1983 (amended 2007). When a person is assessed as having a mental disorder which may impair informed consent, further specialist assessment should be sought to ascertain whether there is need for intervention under the Mental Health Act. The situation for children is more complex and advice from the local Trust's Legal Services Department should be sought in any difficult circumstances.

The following paragraphs apply primarily to adults:

Any refusal of treatment or investigation, at any time, must be clearly documented in the healthcare records.

Where a person has refused a particular treatment or investigation, the healthcare professional must continue to provide all other appropriate care. The healthcare professional must also ensure that the person understands they are free to change their mind and accept treatment or investigation in future; but they must be advised of the consequences of any delay.

If a person gives consent to a particular procedure but refuses certain aspects of the intervention, the healthcare professional must explain to the person the possible consequences of their partial refusal. If the healthcare professional genuinely believes that the procedure cannot be safely carried out under the person's stipulated conditions, the healthcare professional is not obliged to perform it. The healthcare professional must, however, continue to provide all other appropriate care. Where another healthcare professional believes that the treatment or investigation can be safely carried out under the conditions specified by the person, the initial healthcare professional must be willing to transfer the person's care.

2.25. Withdrawal of Consent

A person is entitled to withdraw consent at any time, including during the performance of the procedure. It is important to agree in advance how a person might indicate withdrawal of consent during the procedure such as by raising a hand.

Where it appears that a person is or maybe withdrawing consent, it is good practice, if possible, to stop the procedure and establish what the person's concerns are and explain the consequences of not completing the procedure. Withdrawal of consent may reflect the effects of discomfort or pain which could be ameliorated. A healthcare professional may be justified in completing the procedure if in the person's best interests. Assessing capacity during a procedure is difficult and involving the wider team in making this assessment is important. If stopping the procedure at that point would genuinely put the person's life at risk, the healthcare professional may be entitled to continue until that risk no longer applies.

Where consent is withdrawn, the healthcare professional must review the clinical situation with the person and agree a forward plan.

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There must be clear documentation in the healthcare records in all cases.

2.26. Advance decisions to refuse treatment

Advance decisions to refuse treatment (ADRT) that are both valid and applicable under the requirements of the MCA will be legally binding for everyone involved in the care of the individual. The MCA and Code of Practice clearly define that the responsibility for making an advance decision lies with the person making it.

For an ADRT to be valid, the person must have had full capacity at the time it was made and the decision must specifically apply to the current circumstances.

Other provisions also apply:

- The person who made the ADRT must specifically acknowledge that they intend to refuse treatment even where their life may be at risk.
- The ADRT must be in writing.
- The decision must be signed by the person making the ADRT.
- The signature must be witnessed.
- An ADRT made after the appointment of a personal welfare Attorney takes precedence.
- Appointment of a personal welfare Attorney after an ADRT takes precedence.
- A person with capacity can withdraw an ADRT at any time by any means.
- Where there is doubt about the applicability or validity of an ADRT, further advice should be sought from the local Trust's Legal Services department.

A member of staff may be involved in the process of helping a person to make an ADRT by providing relevant information as they would in any consent process, but the decision must be the person's own. Staff should not be involved in the witnessing of such documents but should advise the person to find an independent witness.

If a member of staff is made aware of an ADRT or Power of Attorney this must be easily visible in the person's healthcare records.

2.27. Recommended Summary Plan for Emergency Care and Treatment (ReSPECT)

The ReSPECT process creates personalised recommendations for a person's clinical care and treatment at a future point in time including emergencies.

The ReSPECT document does not constitute a legally binding consent to or refusal of care or treatment. It is used by healthcare professionals to guide decision making about care and treatment (including potentially life sustaining treatments). Where such treatments are declined in advance by a valid and applicable ADRT, e.g. blood products, this is legally binding on treating healthcare professionals.

Where a ReSPECT form includes a decision not to attempt cardiopulmonary resuscitation (CPR), there should be a discussion with the person (or their

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representative/ independent mental capacity advocate (IMCA) should they lack capacity) as part of the consent process for any procedure or operation about any circumstances where this may not be followed.

If a person wishes to maintain a decision not to attempt CPR during any operation or procedure, the healthcare professional proposing that procedure must ensure the person is clear about the risks associated with the procedure and may need to reconsider whether such a procedure remains a valid option in these circumstances.

The ReSPECT form can be used during the consent process to discuss what is most important to the person, including any particular priorities and preferences the person has for their care. This might include certain treatments that they might not wish to receive during or post procedure.

2.28. Ceiling of care – discontinuance of treatment

The principles around consent are the same for all interventions including the decision not to continue with a course of treatment. Persons with capacity may make this decision on their own behalf either at the time or via an advance decision.

If the person lacks capacity, the decision not to continue must be made in the best interests of the person.

No person has the right to demand and receive any treatment that is not clinically indicated or is futile, including CPR. In the event of significant disagreement, a second opinion must be sought by consulting with colleagues. If this is inconclusive please consult the Local Trust's Legal Services Department.

2.29. Emergency Situations

In event of an emergency the initial healthcare professional should do what is necessary to sustain life, limb or organ. If possible, consultation with the person or more senior healthcare professional should take place. In life-threatening emergency situations consent is not always necessary when immediate action is required and the person temporarily lacks capacity to make the decision. The rationale for the decision and the action taken must be documented.

In an emergency situation, where there is doubt as to the appropriateness of treatment, there should be a presumption in favour of life-sustaining treatment until time is available for all those concerned with the care of the person to assess the situation and contribute to a multi-disciplinary decision involving the relatives, carers and friends.

When a person has capacity in an emergency, it may be appropriate to use the person's healthcare records to document any discussion and the person's consent, rather than using a form. The urgency of the person's situation may limit the quantity of information that they can be given, but should not affect its quality.

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3. Adults without capacity

3.1. General Principles

Where there is a reasonable belief that an adult may lack capacity, a full mental capacity assessment must be undertaken and be clearly documented in the person's health record. It 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.

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

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

No person may under English law give consent to the examination, treatment or investigation of an adult who lacks capacity to give consent themselves, unless they have the authority to make treatment decisions as a Court Appointed Deputy or have been authorised to do so under a Lasting Power of Attorney. The MCA sets out the circumstances in which it is lawful to carry out such examination, treatment or investigation.

3.2. Duration of lack of capacity

All practical steps should be taken to enable a person to make a decision for themselves. Because consent is a continuous process, whilst the person has capacity it is good practice to establish and record their views about any anticipated clinical interventions (MCA).

An assessment of capacity is based on the person's ability to make a specific decision at a particular moment in time. A person may have capacity to consent to some interventions but not to others, or may have capacity at some times and not others. A person's capacity to consent may be temporarily affected by factors such as confusion, panic, shock, fatigue, pain or medication.

Capacity must not be confused with a healthcare professional's clinical and/or subjective opinion of the person's decision.

3.3. Making a best interests decision

When a person is assessed as lacking capacity, any decisions made must be in the person's best interests. Making a best interests decision should be based on what is reasonably believed the person's decision would be (their wishes, feelings and/or

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expressed preferences) if they had capacity and should be person-centred rather than clinically driven.

There is a duty to consult those close to the person to be able to contribute and represent them where practicable.

Healthcare professionals' record keeping should demonstrate that decisions have been based on all available evidence taking into account any conflicting views.

The person's best interests should be reviewed regularly: what is in their best interests may change over time.

In cases of significant disagreement or doubt about an individual's mental capacity or best interests a second opinion must be sought by consulting with colleagues. If this is inconclusive please consult the Local Trust's Legal Services Department.

For more information, please refer to the local Trust's Mental Capacity Act and Deprivation of Liberty Policy and MCA Code of Practice.

3.4. Lasting power of attorney – health and welfare

Under the MCA, a person aged 18 or over may appoint an Attorney to look after their health and welfare decisions should they lack capacity in the future. The authority of the Attorney to make decisions on behalf of the person must be set out in a written Lasting Power of Attorney (LPA), which must be registered with the Office of the Public Guardian before it can be used. The Attorney may only act when the person's capacity has been lost.

With a Health and Welfare LPA, the Attorney can make decisions that are as valid as those made by the person themselves and can consent to or refuse treatment. The Attorney must adhere to all the principles of the MCA.

If there are concerns about the validity of the document or that the Attorney is not acting in the best interests of the person, advice should be sought from the local Trust's Legal Services Department.

The LPA may specify the limits to the Attorney's authority and must state whether or not this includes the authority to make decisions about life-sustaining treatment.

Despite the significant powers an Attorney has, they can only act in the best interests of the person. If there is a significant disagreement between the Attorney and the healthcare professional, this may require referral to the Court of Protection.

3.5. When a person lacks capacity and has no family and/or is unbefriended

In order to make a best interests decision an Independent Mental Capacity Advocate (IMCA) must be instructed for decisions around serious medical treatment. An IMCA referral should be submitted regardless of whether emergency decisions need to be made.

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3.5.1. Role of the IMCA:

- The MCA introduced a duty for NHS bodies to instruct an IMCA to advocate for the person in serious medical treatment decisions
- The IMCA is there to represent the interests of the person but cannot make a decision or consent to treatment on behalf of the person. Instruction of an IMCA should take place as soon as possible
- An IMCA referral should be submitted by the responsible healthcare professional regardless of whether emergency decisions need to be made but must not delay the urgent decision making to save life unless indicated by an Advance Decision

3.5.2. Serious medical treatment

Serious medical treatment is defined in the Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (General) Regulations 2006 as treatment which involves providing, withdrawing or withholding treatment in circumstances where one or more of the following apply:

- 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 them
- in a case where there is a choice of treatments, a decision as to which one to use is finely balanced
- what is proposed would be likely to involve serious consequences for the patient.

3.6. Court appointed deputies

When a person lacks capacity to make a decision relating to their personal welfare, the Court of Protection may make an order taking a decision on their behalf upon application and in certain circumstances. The Court can alternatively appoint a Deputy to make decisions for the person who lacks capacity.

Court involvement will only be required in the most difficult of cases. Where healthcare professionals think it is necessary to involve the Court of Protection, they must contact the local Trust's Legal Services Department.

3.7. Things to remember

Healthcare professionals must consider:

- Whether the person's lack of capacity is temporary or permanent. If the lack of capacity is temporary, consider whether the decision could wait or if there is an alternative treatment that can be given to support the person until they regain capacity
- Which options for treatment would provide overall clinical benefit for the person
- Which option, including a decision not to treat, would be least restrictive of the person's future choices

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- Evidence of the person's previously expressed preferences, whether verbal or written
- The views of anyone the person wishes to be consulted, or who has legal authority to make decisions on their behalf or has been appointed to represent them
- The views of people close to the person on the person's preferences, feelings, beliefs and values, and whether they consider the proposed treatment to be in the person's best interests
- Explaining to relatives that they are seeking information about the person but not asking them to make a decision on the person's behalf
- What is known about the person's wishes, feelings, beliefs and values
- The views of a personal welfare Attorney or Deputy appointed by the Court of Protection to make decisions for the person

4. Children and Young People

There are different legal rules governing consent and refusal of treatment for children and young people depending on their age, ability to give consent and their family circumstances. These rules are different from those which govern adults.

For the purposes of this policy and in line with the Department of Health's Reference guide to consent for examination and treatment second edition (2009), 'children' refers to people aged below 16 years and 'young people' refers to people aged 16 and 17 years.

4.1. Consent in Young People

Young people are presumed in law to be capable of consenting to their own investigation or treatment. A young person may lack capacity because of an impairment or disturbance in the functioning of the mind or brain in the same way as an adult and the MCA and best interest decisions apply (see section 3).

Parental consent is not required for young people. Best practice states that Healthcare professionals should encourage young people to inform their families and consultation should take place with the young person's parents/those close to them where appropriate. However, if a competent child requests confidentiality this should be respected unless the healthcare professional considers that failing to disclose information would result in significant harm to the child.

Refusal by a competent young person may in certain circumstances be overridden by either a person with parental responsibility or a court.

4.2. Consent in Children

In order to give consent to examine, investigation or provide treatment to a child, consent must be given by a person with the legal authority to do so. There may be more than one person who can consent. It is important that the health professional identifies who is legally able to give consent on behalf of the child.

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Children under the age of 16 are not deemed automatically legally competent to give consent. The courts have determined that such children can be legally competent if they meet Gillick competency. That is, having sufficient understanding and intelligence to understand fully what is proposed and to be able to make an informed decision. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made as the understanding for different interventions will vary.

4.2.1. Children who are Gillick Competent

If the child is Gillick competent and is able to give consent voluntarily after receiving appropriate information, then that consent is 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 agrees. This decision should be respected unless there is a clear risk of harm to the child. In that situation please consult the local Trust's Legal Services Department.

If a child seeks advice or treatment related to contraception or an abortion, the healthcare professional should advise the child to inform their parents or responsible person. If the child declines to inform their parents, treatment can be given if the healthcare professional considers it to be in their best interests.

4.2.2. Children who are not Gillick Competent

Where a child under the age of 16 years is not Gillick competent, consent can be given on their behalf by a person with parental responsibility. It is good practice even where a child lacks capacity to involve the child in the decision making process.

It must be noted that not all parents have parental responsibility for their children (please see section 4.3. Parental Responsibility). If there is any doubt whether an individual has parental responsibility for that child, this must be checked.

In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity and be acting according to the welfare and best interests of the child. If the healthcare professional is concerned that either is not the case, then advice should be sought from the local Trust's Legal Services and Safeguarding Departments.

In an emergency if it is impossible to obtain consent in time and the treatment is vital to the survival or health of the child, it is justifiable to treat a child who lacks capacity without the consent of a person with parental responsibility.

If a child is the subject of a care or supervision order from the Court, treatment decisions can be taken by the Social Services Department, the Social Worker or any appropriate person named in the Order. Urgent treatment may be given in the best interests if delay in obtaining consent as above is experienced.

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4.3. Parental Responsibility

A person with 'parental responsibility' (PR) are entitled to give consent on behalf of their children. PR may also be held by the Courts (via the Local Authority) for children subject to an interim care order, emergency protection order or child assessment order, or by the Local Authority for children on a care order. The law emphasises the need for parents (or others) to work actively for what is best for the child, not themselves.

PR means all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his property.

A child's mother will always have PR, although the Family Courts can limit the extent to which she can exercise this. PR applies:

- a) Where a child's father and mother were married to each other at the time of the child's birth, they shall each have PR for the child.
- b) Where a child's father and mother were not married at the time of the child's birth, the father can acquire PR for the child if:
 - They are named as the child's father on the birth certificate registered on or after 1 December 2003;
 - They and the child's mother make an agreement (a PR agreement made in the correct form and recorded in the prescribed manner) providing them to have PR for the child;
 - The Court, on the father's application, orders that they shall have PR for the child;
 - The child's father marries the child's mother at any time after the child's birth.

A local authority acquires parental responsibility for a child when it is granted a care order under The Children Act (1989). It shares PR with those other people who have PR for the child. Other relatives can also be granted PR by the Court such as step-parents, or grandparents. Health professionals should ask to see the Court Order which details this.

More than one person may have PR for the same child at the same time. A person who has PR for a child at any time shall not cease to have that responsibility solely because some other person subsequently acquires PR for the child. Where more than one person has PR for a child, each of them may act alone and without the other (or others) in meeting that responsibility, however it must be considered whether there is a decision which requires the consent of more than one person in a matter affecting the child. The court has determined that certain clinical decisions are so serious that they cannot be made without obtaining consent from all those with PR for a child, e.g.: circumcision in an example of a procedure that the court has determined cannot be performed without the consent of all those with PR for the child.

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4.4. Consideration of Voluntariness

It is important to establish that the decision given by a child or young person is being given voluntarily because children may be more prone to undue influence by adults around them. A healthcare professional who suspects this is the case must discuss it with their local Trust's Safeguarding Team.

4.5. Refusal of Treatment

Where a young person or a child under 16 years old but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled by those with PR or the court if the refusal would lead to the death or severe permanent injury.

A competent adult is entitled to refuse any treatment, however the situation for children is more complex and advice from the local Trust's Legal Services Department must be sought in any difficult circumstances.

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

4.6. Withdrawal of Treatment

It is not a legal requirement to continue a child's life-sustaining treatment in all circumstances. For example, where the child is suffering an illness where the likelihood of survival even with treatment is extremely poor, and treatment will pose a significant burden to the child, it may not be in the best interests of the child to continue treatment.

The decision not to continue with life-sustaining treatment must be made in the best interests of the child. All best interests' decisions should be interpreted more broadly than medical interests, and should include emotional and other factors. There is a strong presumption in favour of preserving life, but not where treatment would be futile. There is no obligation on healthcare professionals to give treatment that would be futile. If there is disagreement between those with parental responsibility for the child and the healthcare team concerning the appropriate course of action, seek advice from the local Trust's Legal Services Department.

4.7. Research

The parent(s) may give consent for their child, where the child lacks capacity, to be entered into a trial where there is evidence that this will be beneficial to the child as standard therapy. The 'welfare principle' described above should also be considered and an intervention must involve only minimal burden to the child.

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

5. Provision of Information

The provision of information is central to the consent process.

- The information must be what the reasonable person can expect to be told rather than what the reasonable healthcare professional would be expected to say.

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- A person needs sufficient and appropriate information about their condition and about possible treatments/investigations before they can come to a decision. The associated risks and benefits of all options must be explained, including doing nothing.
- A person also needs to know whether additional procedures that may be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue.

5.1. Communication

Some people may need special consideration to ensure understanding of the information provided; and high quality, two-way communication is essential in the consent process.

5.1.1. Learning Disability

All efforts must be made to communicate with person with learning disabilities using media suitable to that individual, for example via Easy-read literature and pictures. Further advice can be sought from the local Trust's Learning Disability and Autism Liaison Specialist Teams and Policy and Operational Guidance.

5.1.2. Communication Difficulties

All efforts must be made to maximise the ability for healthcare professionals to communicate with a person with communication difficulties. These people may need extra time to understand the information and enable them to reach and communicate their decision.

5.1.3. People whose first language is not English

The Trusts are committed to ensuring that a person whose first language is not English receive the information they need and are able to communicate appropriately with healthcare professionals. It is not routinely appropriate to use family members or friends to interpret for those who do not speak English unless it is imperative. For information relating to interpreting services and booking please refer to the local Trust's interpreting policy.

5.2. Access to more detail

Healthcare professionals must check that a person have had all their questions answered. If a person requests more detailed information than an individual can provide, access to additional support must be obtained. Any members of staff who do not feel competent to provide sufficient information must not do so.

5.3. People who decline information

Taken from decision making and consent (GMC: 09 November 2020, page 30):

"If a patient has chosen an option but doesn't want to discuss the details, you should explain they will need to have some information about what it would involve before you can proceed, such as:

- a) *whether the procedure is invasive*

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- b) *what level of pain or discomfort they might experience and what can be done to minimise this*
- c) *anything they should do to prepare for the intervention*
- d) *if it involves any risk of serious harm.*

You should try to find out why they don't want to be involved in decision making and explore whether you can do anything to reassure and support them. They might be anxious about the decision or overwhelmed by the information and need time or support to process it.

If, after trying to discuss options with them along the lines set out above, your patient insists that they don't want even this basic information, you will need to judge whether their consent is valid so that you can proceed. This is more likely to be the case if the proposed option is a well-established intervention commonly used for treating the condition they have, and there's reason to believe the patient wants to be treated or cared for rather than take no action..."

In rare circumstances, Healthcare Professionals may seek advice from a second opinion, multiple disciplinary team or the local Trust's legal services department.

Where a person declines to receive the information from a healthcare professional, this must be documented in the healthcare records.

6. Training to take consent

All healthcare professionals must understand the core principles of consent.

Healthcare professionals who are required to obtain consent must receive appropriate generic and specific training which must be readily available. Training content will include updates to the consent policy, relevant legal framework and guidance. Specific training must cover the relevant scope of practice and appropriate delegation with defined accountability and responsibility.

6.1. Assessment for obtaining consent by non-medical healthcare professionals who are not capable of performing the clinical procedure or where obtaining consent is delegated

Healthcare professionals who are non-medical staff or where consent is delegated to them must be assessed against the specific procedure in order to be able to take consent from patients.

Along with reference to this policy, procedure specific training for non-medical healthcare professionals as determined by each individual Trust, or those where consent is being delegated, is assessed by staff who are competent to carry out the procedure within that area and using the competency assessment documentation (Appendix A).

When completed and signed, the original practical competency document must be retained within the personal file of the healthcare professional who has been assessed.

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Reassessment is required if consent for the specific procedure is not taken in a 12 month period by the healthcare professional.

7. Seeking consent for students and training

A person must be made aware and consent sought by a healthcare professional before an examination, treatment or investigation is going to be undertaken, assisted or observed by a student or for training purposes. Where a student proposes to conduct a physical examination that is not essential to the person's care then it is mandatory to explain that the purpose of the examination is to further the student's training. The involvement of students and trainees for this purpose may be declined and the refusal must not impact on the person's care.

8. Monitoring compliance

A unified audit of the consent process must be undertaken annually at each Trust and reviewed by the Consent Steering Group to agree recommendations for further action.

9. References

- Department of Health (2009). Reference guide to consent for examination or treatment (second edition). [online] GOV.UK. Available at: <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>. [Accessed 2 Jun. 2021].
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- Mental Capacity Act 2005
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- NHS Constitution

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- Nice.org.uk. (2015). Recommendations | Blood transfusion | Guidance | NICE. [online] Available at: <https://www.nice.org.uk/guidance/ng24/chapter/recommendations>. [Accessed 2 Jun. 2021].
- Office of the Public Guardian (2013). Mental Capacity Act Code of Practice. [online] GOV.UK. Available at: <https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice>. [Accessed 2 Jun. 2021].
- Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- The Children Act (1989)

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10. Equality Impact Assessment (EIA)

Type of function or policy	Existing
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Division	Corporate	Department	Risk and Patient Safety Team
Name of person completing form	Gemma Lynch	Date	19/07/2021

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	None	None	N/A	No
Pregnancy & Maternity	None	None	N/A	No
Disability	None	None	N/A	No
Religion and beliefs	None	None	N/A	No
Sex	None	None	N/A	No
Gender reassignment	None	None	N/A	No
Sexual Orientation	None	None	N/A	No
Age	None	None	N/A	No
Marriage & Civil Partnership	None	None	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?	No Change			

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.

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Appendix A: Assessment Form for obtaining consent by non-medical staff who are not capable of performing the clinical procedure or delgated

Name of Healthcare Professional	
Assessor's Name	
Procedure	
Date Competency Assessment undertaken	

Supervised and Observed Practice				
		Observation 1 Date/Time	Observation 2 Date/Time	Observation 3 Date/Time
1.	Adequately demonstrates the process of obtaining consent for the procedure			
2.	Adequately describes the benefits, risks, alternatives and any questions for the procedure for which you are being assessed to obtain consent.			
3.	Adequately demonstrate the completion of the documentation process for consent			

Assessor Statement			
I have assessed..... and have found them to be proficient in the skill of taking consent forprocedure.			
Assessor's signature		Print Name	
Assessor's designation		Date (dd/mm/yyyy)	

Healthcare Professional's Statement			
I am confident in my ability to take consent for.....			
I acknowledge my accountability to maintain my competence in line with the requirements of my professional body.			
Healthcare Professional's signature		Print Name	
Healthcare Professional's designation		Date (dd/mm/yyyy)	

Retain the original in the employee's personal file which must be able to be produced when requested.