Consent to Examination and Treatment Policy

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<th>Purpose of Agreement</th>
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<td>This policy sets out the standards and procedures in Solent NHS Trust which aim to ensure that health professionals are able to comply with the guidance issued by the Department of Health. This policy covers the principles of obtaining consent to examine and treat children and adults. It covers consent and mental capacity, and supports members of staff to meet their professional responsibilities to make sure that they get properly informed consent and document it before they carry out any action.</td>
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<tr>
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<td>Interim Head of Professional Standards and Regulation</td>
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<td>Document developed in consultation with</td>
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### Review Log

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SUMMARY OF POLICY

This policy sets out the standards and procedures in Solent NHS 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. The policy also includes those doing or participating in clinical research, evaluations, clinical audits and students on placements.

It sets out the standards and procedures in the Trust that have been put in place to ensure that health and social care professionals are aware of their obligations and are able to comply with statutory and professional guidance.

The policy does not cover the consent process for use of gametes, subsequent use of removed tissue, organ donation. These three areas are not practised within the Trust.

In addition this document provides guidance to ensure individuals and their human rights are respected and upheld. It should be noted that this policy applies to both adults and children.
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1. INTRODUCTION & PURPOSE

1.1 Introduction

1.1.1 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 individuals to determine what happens to them, and is a fundamental part of good practice.

1.1.2 Consent may be given verbally or in writing, it may be active or passive and implied (for example a patient presenting their arm for their pulse to be measured). Whether active or implied, valid consent must be freely given by someone who has received all sufficient information, and be capable of making the decision.

1.1.3 The context of consent can take many different forms, ranging from the active request by a patient of a particular treatment to the passive acceptance of a health professionals advice.

1.1.4 In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. Some patients, especially those with chronic conditions, become very well informed about illness and may actively request particular treatments.

1.1.5 In many situations there will be a number of ways of treating a condition, and the health care professional will help the patient to fully understand the options and decide between them the preferred option.

1.1.6 In many cases, ‘seeking consent’ is better described as ‘joint decision-making’: the patient and health professional need to come to an agreement on the best way forward, based on the patient’s values and preferences and the health professional’s clinical knowledge.

1.1.7 Paragraph 4.2 of the Nursing and Midwifery Council (NMC) Code of Conduct, 2015, states that registered members of staff must “make sure that [they] get properly informed consent and document it before carrying out any action”

1.2 Purpose

1.2.1 This policy sets out the standards and procedures in Solent NHS 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. The policy also includes those doing or participating in clinical research, evaluations, clinical audit and students on placements.

1.2.2 In addition this document provides guidance to ensure individuals and their human rights are respected and upheld.

2. SCOPE & DEFINITIONS

2.1 Scope

2.1.1 This policy applies to all directly and indirectly employed staff within Solent NHS Trust and other persons working within or on behalf of the organisation in line with the Trust’s Equality, Diversity and Human Rights Policy. This policy is also recommended to Independent Contractors as good practice.

2.1.2 It sets out the standards and procedures in the Trust that have been put in place to ensure that health and social care professionals are aware of their obligations and are able to comply with statutory and professional guidance.

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2.1.3 The policy does not cover the consent process for use of gametes, subsequent use of removed tissue, organ donation. These three areas are not practised within the Trust.

2.2 Exceptions

2.2.1 Certain statutes, including the Mental Capacity Act 2005 set out specific exceptions to the principles noted in the following sections. These are briefly noted below. Those concerned with the operation of such statutes should consult more detailed guidance.

2.2.2 Part 4 of the Mental Health Act 1983 (‘the 1983 Act’) sets out circumstances in which persons liable to be detained under the Act may be treated without consent for their mental disorder. The Mental Health Act Code of Practice (2015) offers guidance on consent and medical treatment in this context.

2.2.3 The Public Health (Control of Disease) Act 1984 provided that, on an order made by a magistrate, persons suffering from certain notifiable infectious diseases could be medically examined, removed to and detained in a hospital without their consent. A magistrate when ordering the detention of a person in a hospital could not order that a person undergo medical treatment. The treatment of such persons must be based on the common law principles previously described. The 1984 Act is now amended by the Health and Social Care Act 2008. Under part 2A there is express provision prohibiting regulations under new sections 45B or 45C from legislating for the administering of medical treatment by force. Nor will there be power for a magistrate to order compulsory treatment under new section 45G, which gives powers to magistrates to make orders in relation to persons who pose a threat to the health of others.

2.3 Definitions

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

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

2.3.2 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 (see Section 2.4 and 3.12 for guidance on assessment of capacity and section 3.15 for guidance in seeking consent in young people and children);
- someone authorised to do so under a Lasting Power of Attorney (LPA) (Appendix 1);
- someone who has the authority to make treatment decisions, such as a court-appointed deputy.

2.3.3 Acquiescence, where the person does not know what the intervention entails, is not ‘consent’.

2.4 Mental Capacity

2.4.1 Mental Capacity is the ability of an individual to make a particular decision, or take a particular action, at the time the decision or action needs to be made or taken.

2.4.2 The Mental Capacity Act 2005 provides a statutory framework to empower and protect people from the age of 16 who are not able to make their own decisions. A key principle of
the law is that every adult (from the age of 16) has the right to make their own decisions and is assumed to have capacity to do so unless it is proved otherwise.

2.4.3 The act protects people lacking capacity from having decisions made for them that are not in their best interests. This can happen when:

- Someone makes the decision, but does not know the person well. For example a doctor might start a treatment that the patient would normally refuse.
- A person exploits the patient with impaired capacity

2.4.4 There are five principles associated with capacity:

- A person has capacity unless proven otherwise using capacity tests
- The individual’s best interests come first, any decision must be as close as possible to what the individual would have normally wanted for him/herself
- A person can have help to make a decision. A decision can be put off or family members can support the individual while they think about it
- If a person has the capacity to make a decision, they have the right to make a decision that others might see as unwise
- If the decision has to be made for an individual, it should be the least disturbing and least dangerous option for them – the ‘least restrictive action’

2.4.5 To test capacity there are four questions which need to be answered:

1) **Does the individual understand the information**: To decide about a treatment the individual needs to understand what they might gain from it, what the risks are, any other treatments available, and what might happen if the individual doesn’t have any treatment

2) **Can the individual retain the information**: If an individual can understand the relevant information, but can’t remember it for more than a few seconds or minutes, they won’t be able to use it to make an informed decision

3) **Can the individual weigh up the information**: Can the individual compare the benefits and risks and use this to make the decision: The individual may be able to understand (test 1), remember it (test 2), but not be able to weigh facts as they normally would

4) **Can the individual communicate their decision**: The individual can do this by talking, writing, in sign language, by nodding or by blinking an eyelid

To have capacity the individual must answer yes to all of these questions

2.4.6 Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no-one else can give consent on their behalf, unless empowered to do so by a Lasting Power of Attorney or as a court-appointed deputy. Treatment may still be given if it is in their best interests and as long as it is not in conflict with an Advance Decision refusing such treatment (also known as Advance Directives or ‘Living Wills’ or for children, Advance Care Plan).

2.4.7 Consent is required for all diagnostic, therapeutic and surgical procedures and treatments that are complex, invasive or involve the risk of harm. Under the 2007 Mental Health Act changes, definitions of treatment are extended to include nursing, psychological interventions and rehabilitation. Informed consent is not required for simple and common procedures when the related risks are commonly understood, such as with a blood count. It is a professional’s responsibility to determine whether a procedure or treatment is complex, and thus requires informed consent. There are very few occasions where the law specifically requires written consent – for example, in relation to the storage and use of gametes and
embryos in fertility treatment. But in the main, a verbal consent is just as valid as written consent. If the treatment is part of a project or programme of research approved by this Trust fully informed, written consent must be obtained.

2.4.8 **Verbal and non-verbal/implied consent** - Consent may be expressed verbally or non-verbally: an example of non-verbal consent would be where a person, after receiving appropriate information, holds out an arm for their blood pressure to be taken. However, the person must have understood what examination or treatment is intended and why, for such consent to be valid.

2.4.9 **Voluntary consent** - For consent to be voluntary it must be given 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.

2.4.10 **Informed consent** - To give valid consent, the person needs to understand the nature and purpose of the procedure and be competent to consent to it. Any misrepresentation of these elements will invalidate consent. The individual should be informed of any ‘material’ or ‘significant’ risks or unavoidable risks, even if small, in the proposed treatment; any alternatives to it; and the risks incurred by doing nothing. Where relevant, information about anaesthesia should be given alongside information about the procedure itself. The professional informing the person of the procedure needs to have expertise in the area being discussed.

You must give patients the information they want or need about:

(a) the diagnosis and prognosis
(b) any uncertainties about the diagnosis or prognosis, including options for further investigations
(c) options for treating or managing the condition, including the option not to treat
(d) the purpose of any proposed investigation or treatment and what it will involve
(e) the potential benefits, risks and burdens, and the likelihood of success, for each option; this should include information, if available, about whether the benefits or risks are affected by which organisation or doctor is chosen to provide care
(f) whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit
(g) the people who will be mainly responsible for and involved in their care, what their roles are, and to what extent students may be involved
(h) their right to refuse to take part in teaching or research
(i) their right to seek a second opinion
(j) any bills they will have to pay
(k) any conflicts of interest that you, or your organisation, may have
(l) any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer.
2.4.11 **Written Consent**

- 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.
- In addition, if a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature.
- It is rarely a legal requirement to seek written consent although The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances.
- However; it is good practice to seek written consent if any of the following circumstances apply:
  - A surgical intervention is intended
  - The treatment or procedure is lengthy, complex, or involves significant risks (the term ‘risk’ is used throughout to refer to any adverse outcome, including those which some health professionals would describe as ‘side-effects’ or ‘complications’)
  - The procedure involves general/regional anaesthesia or conscious sedation
  - Providing clinical care is not the primary purpose of the procedure
  - There may be significant consequences for the patient’s employment, social or personal life
  - An individual is being asked to consent to participation in an audio or video recording (even if only minor procedures are involved).

2.5 **Context of Consent**

2.5.1 **Sufficient Information**: patients must be given sufficient information to enable them to make up their minds about accepting or refusing the examination, treatment, or care being offered. Relevant information will include details of the procedure, risks, alternatives, and consequences of acceptance or refusal. Acquiescence where the person does not know what the intervention entails is not ‘consent’.

2.5.2 **Freely given (not under duress)**: Consent must be freely given in the absence of duress, or undue influence. Pressure to accept or refuse an intervention could come from partners or family members, as well as health or Social Care Professionals.

2.5.3 **Treatment or Procedures involving ‘significant risks’**: In this context ‘risk’ is used to refer to any adverse outcome, including those which some health professionals may describe as ‘side-effects’ or ‘complications’.

2.5.4 There are circumstances when an individual who is under the legal age of consent may be deemed competent to give consent in the absence of a parent or guardian with parental responsibility. This is a complex area of practice entailing an assessment of Fraser or Gillick competence in addition to other considerations all of which require specific expertise. The standard of practice required by Solent practitioners is covered in detail in Section 3.

3. **PROCESS/REQUIREMENTS**

3.1 **Obtaining consent**

3.1.1 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, and the conclusion reached, should be recorded in the case notes.

3.1.2 The seeking and giving of consent is usually a process, rather than a one-off event. In many cases it will be appropriate for a health professional to initiate a procedure or begin examination immediately after discussing it with the patient. In such cases, consent will often be given orally.

3.1.3 If a proposed procedure carries significant risks it will be appropriate to seek written consent

3.1.4 When a patient formally gives their consent to a particular intervention, this is only the endpoint of the consent process. Practitioners should consider the whole process of information provision, discussion, decision-making and documentation as part of ‘seeking consent’. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient’s condition.

3.2 Provision of information

3.2.1 Where possible treatment options should be discussed in advance of the actual procedures being carried out. This may be on just one occasion or it may involve a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages Discussion of the risks is vital and evidence of this discussion will be requested in the defence of any Clinical Negligence claim. 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. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen: where to go, how long they will be in hospital, how they will feel afterwards and so on.

3.2.2 The first stage is the provision of information, discussion of options and initial decision. The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensive information about their condition and about possible treatments/investigations, and the associated risks and benefits - including the risks/benefits of doing nothing. Practitioners must ensure that patients are aware of any "material risks" involved in a proposed treatment, and of reasonable alternatives, *(Montgomery v Lanarkshire Health Board, 2015)*

3.2.3 Information may be provided in writing and /or verbally with a record made of the information given in the patient record and the signed consent form if used. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

3.2.4 The practitioner in charge should ensure that patients have access to more detailed or specialist information, including with the support of the Patient Advice and Liaison Service (PALS). For those where the Mental Capacity Act 2005 or Mental Health Act 1983 are
applicable Independent Mental Capacity Advocates (IMCAs) and Independent Health Act Advocates (IMHAs) should also be involved. All patient information developed by services within Solent NHS Trust must be compliant with the NHS England Accessible Information Standards (2016).

3.2.5 The second stage of obtaining consent is the confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stages, as well as the confirmation stage.

3.3 Provision for patients whose first language is not English

3.3.1 Solent NHS 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 to interpret for family members who do not speak English.

3.3.2 For patients who require the services of an interpreter for any information regarding consent, or the translation of written information or tape recordings to be made in a different language, contact Access to Communication, Tel: 023 8024 1300.

3.4 Access to more detailed or specialist information

3.4.1 Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. Solent NHS Trust patients should be guided towards the following facilities to assist patients to obtain such information:  
- Patient Advice and Liaison service on tel: 0800 013 2319 (Free phone) or 023 8029 6929  
- NHS Direct Online

3.4.2 The Patient Advice and Liaison Service provide a confidential service, acting as a ‘gateway’ to independent expert guidance and on the spot advice. They will give advice on navigating NHS services and departments and finding the right pathway for the patient. They will help to explain what to do, who to contact and how to access a service. They are able to provide information on local NHS, social care services, voluntary sector organisations and national and local self help groups. They will provide this information or signpost the patient to it, thereby enabling a pathway between NHS care and general well-being.

3.5 Access to health professionals between formal appointments

3.5.1 After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they make their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone, than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient’s choice). Services should ensure that, where possible, contact details are available for patients to be able to access further information about their condition or treatment.

3.6 Open access clinics

3.6.1 Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. The clinician must ensure that they have the information they need before proceeding with an investigation or treatment.

3.6.2 In addition, a vast amount of information is now available on the Internet and the practitioner will guide the patient in the use of recommended patient information sites. These may include:

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3.7 Duration of consent

3.7.1 When a person gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person. However, if new information becomes available regarding the proposed intervention (for example, new evidence of risks or new treatment options) between the times when consent was sought and when the intervention is undertaken, a doctor or member of the healthcare team must inform the patient and reconfirm their consent. The practitioner must consider whether the new information should require the process of seeking consent to be repeated on the basis of this information. Similarly, if the patient’s condition has changed significantly in the intervening time it may be necessary to seek consent again, on the basis that the likely benefits and/or risks of the intervention may also have changed.

3.7.2 If consent has been obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent (assuming that they retain capacity) still wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

3.8 Restricted Consent

3.8.1 A patient has the right to give restricted consent, which in reality gives patients the ability to list any intervention which is not acceptable, without further specific consent. Restricted consent may involve patients wishing to consider further such procedures/treatments as progressing to major surgery following preliminary biopsy, or, in the case of Jehovah’s Witnesses, blood transfusion.

3.9 Refusal of Consent

3.9.1 If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment (whether contemporaneously or in advance), this decision must be respected, except in certain circumstances as defined by the Mental Health Act 1983. This is the case even where this may result in the death of the person (and/or the death of an unborn child, whatever the stage of the pregnancy). Refusal of treatment by those under the age of 18 is covered in paragraph 3.19.

3.9.2 The situation for children is more complex: see the Department of Health’s Seeking consent: working with children for more detail. The following paragraphs apply primarily to adults.

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

3.9.4 Where a patient has refused a particular intervention, the practitioner must ensure that they continue to provide any other appropriate care to which the patient has consented. They 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.

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3.9.5 If a patient consents to a particular procedure but refuses certain aspects of the intervention, the practitioner must explain to the patient the possible consequences of their partial refusal. If the practitioner genuinely believes that the procedure cannot be safely carried out under the patient’s stipulated conditions, they are not obliged to perform it. They 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, the practitioner must on request be prepared to transfer the patient’s care to that health professional. The practitioner must clearly document all discussions and decision making in the patient record.

3.10 Withdrawal of Consent

3.10.1 A person with capacity is entitled to withdraw consent at any time, including during the performance of a procedure. Where a person does object during treatment, it is good practice for the practitioner, if at all possible, to stop the procedure, establish the person’s concerns and explain the consequences of not completing the procedure. At times, an apparent objection may in fact be a cry of pain rather than withdrawal of consent, and appropriate reassurance may enable the practitioner to continue with the person’s consent. If stopping the procedure at that point would genuinely put the life of the person at risk, the practitioner may be entitled to continue until that risk no longer applies.

3.10.2 Assessing capacity during a procedure may be difficult and, as noted above, factors such as pain, panic and shock may diminish capacity to consent. The practitioner should try to establish whether at that time the person has capacity to withdraw a previously given consent. If capacity is lacking, it may sometimes be justified to continue in the person’s best interests, but this must not be used as an excuse to ignore distress or a valid withdrawal of consent.

3.11 Mental Health Act 1983 (amended 2007) and Consent

3.11.1 It is important to note that if an individual is detained under a section of the Mental Health Act, Part 4 or Part 4A (Consent to Treatment) will apply. However; the Mental Health Act only allows for treatment that the purpose of which is to alleviate, or prevent a worsening of, the mental disorder or one or more of its symptoms or manifestations. This policy should be followed for any treatment that falls outside of the Mental Health Act and where there is any element of doubt the practitioner should seek further advice/guidance.

3.12 Mental Capacity Act 2005 and Consent

3.12.1 Under the terms of the 2005 Mental Capacity Act, all adults are presumed to have sufficient capacity to decide on their own medical treatment unless there is significant evidence to suggest otherwise. For further guidance see the Deprivation of Liberty Safeguards and Mental Capacity Act 2005 policy. There are five statutory principles that must be followed when making any decisions under the Mental Capacity Act.

- A person must be assumed to have capacity unless it is established that they lack capacity.
- A person is not to be treated as unable to make a decision unless all practicable steps to help him/her to do so have been taken without success.
- A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
- An act done or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his/her best interests.
- Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.

3.12.2 If someone makes a decision about treatment that most people would consider to be irrational, it does not necessarily mean they lack capacity. It is the process they go through in reaching the decision that is important. The capacity test always needs to be applied and a person can only be said to lack capacity if they have an impairment and are unable to undertake one of the four tests in 2.4.5.

3.12.3 It is possible for capacity to fluctuate. In such cases, it is good practice to establish, while the person has capacity, their views about any clinical intervention that may be necessary during a period of anticipated incapacity and to record these views. It should also be asked if a decision can be made at a time when they have capacity. It may be helpful to explore the use of Advanced Directives with the patient at this time.

3.12.4 In a situation where a patient lacks capacity certain treatments should automatically be referred to The Court of Protection. These are:

- 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 donation by an adult who lacks the capacity to consent.
- cases involving the proposed non-therapeutic sterilisation of a person who lacks the 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.

3.12.5 Guidance is also available in the Mental Capacity Act (2005) Code of Practice.

3.12.6 Under the Mental Capacity Act 2005, a person may wish to make an advance decision to refuse treatment or a statement of their preferences and wishes. Patients are able to give a Lasting Power of Attorney (LPA) to individuals. Under this legislation, an LPA in relation to the patient’s personal welfare can extend to giving or refusing consent to the carrying out or continuation of treatment, but will only extend to life-sustaining treatment if that is expressly contained in the LPA. The views of a person appointed under a Lasting Power of Attorney with regard to healthcare decisions will have legal effect. An Advance Directive/Decision is not valid if the Lasting Power of Attorney was created after the Advance Decision. The trust policy on advance decisions to refuse treatment should be referred to for further guidance.

3.12.7 If the person has not made a valid and applicable advance decision; decisions about that person’s treatment if they lack capacity must be made in accordance with the Mental Capacity Act 2005. This would include considering whether the person is likely to regain capacity and, if so, whether the decision can wait, as well as the statutory principle that all practical steps must be taken to enable the person to make their own decision.

3.12.8 Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented in form 4 (form for adults who are unable to

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consent to investigation or treatment Appendix 2), along with the assessment of the patient’s capacity, why the health professional believes the treatment to be in the patient’s best interests, and the involvement of people close to the patient. Reference should also be made to the Deprivation of Liberty Safeguards and Mental Capacity Act Policy. The process to be followed in assessing and recording capacity and Best Interest issues will depend on the complexity of the decision, any disagreement about whether it is in the person’s best interest and the risks involved. The standard consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient’s notes.

3.12.9 An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. The practitioner should involve appropriate colleagues in making such assessments of incapacity, such as specialist Learning Disability teams; Speech and Language Therapists, unless the urgency of the patient’s situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

3.12.10 Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult’s best interests. The Deprivation of Liberty Safeguards and Mental Capacity Act policy should be referred to in these situations. Where the consequences of having, or not having, the treatment is potentially serious, a court declaration may be sought. See Appendix 3 for details of how to do this.

3.13 Independent Mental Capacity Advocates (IMCA)

3.13.1 The Mental Capacity Act has introduced a duty on NHS bodies to instruct an 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. In matters that meet the definition of serious medical treatment, IMCAs are only able to represent and support people whose treatment is arranged by the NHS. They have the right to information about an individual and can see relevant healthcare records.

3.13.2 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 Mental Capacity Act 2005. For more information on IMCAs see Mental Capacity Act and Deprivation of Liberty Safeguards policy

3.14 Advanced Decisions to refuse Treatment

3.14.1 An advance directive gives patients the legal right to give or withhold consent to specific medical treatments prospectively. Some people with certain health conditions may have periods when they have capacity, and periods when they do not have capacity. In such circumstances, a person can make a ‘living will’ or ‘advanced directive’, stating how they would like to be treated, or not treated, in case of future incapacity.

3.14.2 Where this involves the refusal of treatment it has a specific authority under the Mental Capacity Act and is defined as an advance decision to refuse treatment. A valid and applicable advance decision to refuse treatment has the same force as a contemporaneous decision to refuse treatment.
3.14.3 If a person specifically states in their 'advanced directive' that they do not want to undergo a particular treatment, this is legally binding unless they are detained under the Mental Health Act 1983 at the time of making the decision or at the time of potential treatment.

3.14.4 Advanced decisions, interpretation and implications for clinical practice are covered in detail in Solent NHS ‘Advance Decisions to Refuse Treatment Policy’ and South Central Policy for Do Not Resuscitate (DNR). In addition, the British Medical Association (2007) has also issued guidance on the current legal position on advance directives.²

3.15 Treatment of children and young people

3.15.1 For the purposes of this guidance ‘children’ refers to people aged below 16 and ‘young people’ refers to people aged 16–17.

3.15.2 The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults.

3.15.3 When infants 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.

3.15.4 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. If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check. Some children who are under the care of the Local Authority (Looked after Children) have different “parental responsibility” regarding consent depending on their legal status. Advice should be sought to establish who has the right to consent from the child’s social worker.

3.15.5 Children who are subject to a care order (section 31); parents share parental responsibility with the local authority. It is a matter of negotiation between them who should give consent. The local authority should make attempts to consult with the parents and their consent sought.

3.15.6 Mental capacity and the presumption of the ability to make a decision for children over the age of sixteen is governed by the Mental Capacity Act 2005. As for adults, consent will be valid only if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16–17 may in certain circumstances be overridden by either a person with parental responsibility or a court.

3.15.7 If the 16/17-year-old is capable of giving valid consent then it is not legally necessary to obtain consent from a person with parental responsibility for the young person in addition to the consent of the young person. It is, however, good practice to involve the young person’s

² British Medical Association. 2007. Advance decisions and proxy decision-making in medical treatment and research. BMA. London
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family in the decision-making process, unless the young person specifically wishes to exclude them, if the young person consents to their information being shared.

3.15.8 Any child who is under the age of 16 years old can give consent (without the need of parental permission) if he or she “reaches a sufficient understanding and is of sufficient intelligence to be capable of making up his/her own mind on the matter requiring decision” (Gillick v Norfolk and Wisbech Area Health Authority and DHSS, 1986). This is sometimes described as being ‘Gillick’ or ‘Frazer’ competent.

3.15.9 Where advice or treatment relates to contraception, the child’s sexual or reproductive health, or abortion the healthcare professional should try to persuade the child to inform his or her parent(s), or allow the medical professional to do so. If however the child cannot be persuaded, advice and/or treatment should still be given if the healthcare professional considers that the child is very likely to begin or continue to have sexual intercourse with or without advice or treatment, and that unless they receive the advice or treatment then the child’s physical or mental health is likely to suffer. Practitioners should also refer to the statutory guidance on underage sexual activity and the risk of harm (HM Government, 2010, sections 5.25-5.31).

3.15.10 It would be seen as good practice to involve parents along with young people when decisions are being made, however this needs to be weighed against the young persons right to confidential treatment. Where the child under 16 lacks the capacity to consent to treatment consent should be sought by someone with parental responsibility or by the court.

3.15.11 Clear documentation is imperative, including how a decision was reached regarding whether a young person is FrazerCompetent or not and whether the person with parental responsibility has been involved in the consent process.

3.16 Refusal of treatment by those under the age of 18

3.16.1 If faced with a situation where a young person is refusing treatment, parents (those with parental responsibility) may still decide what is in their child’s best interest and consent on their behalf until they are 18 years old – see Appendix 4 and 5. Attempts should be made to resolve this situation involving both the parents and young person, with consideration for the least restrictive methods available.

3.16.2 Where a young person of 16 or 17 who could consent to treatment in accordance with section 8 of the Family Law Reform Act 1969, or a child under 16 but Frazer competent, refuses treatment, it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child/young person or to severe permanent injury. This could be by a court, an adult with parental responsibility or under the Mental Health Act 1983. The ‘Reference Guide to Consent for Examination or Treatment 2nd Edition’ should be consulted for further guidance.

3.16.3 In serious or complex situations a court may be asked to make a decision.

3.17 Child Emergencies

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

3.18.1 It will not usually be necessary to document a patient’s consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient it may be advisable to document patients consent.

3.18.2 Consent to treatment should be documented for more invasive treatments/investigations. It should be documented in the patient record that the intervention/treatment or investigation was discussed and included the probable outcomes, possible complications or side effects (if relevant) and that the patient gave consent. Whenever possible this should be completed contemporaneously.

3.18.3 Each Solent NHS Trust service should identify the procedures for which they require practitioners to document the consent process.

3.18.4 For patients whose first language is not English it is recommended to record the language in which the interpreting was undertaken, in order to avoid a scenario where “the wrong language was used”.

3.18.5 Recording the interpreter’s organisation of employment is desirable in order that ‘Access to Communication’ may use this information and address any unmet languages, thereby reducing the need for independent interpreting agencies.

3.18.6 All clinicians should be made aware of the documentation processes in respect of all type of consent.

3.19 Consent Forms

3.19.1 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, have been assessed, are aware of their own knowledge limitations and are subject to audit. This training must be given by the person competent to undertake the procedure themselves and as such is service-specific and is organised at service level when required.

3.19.2 Local standard operating procedures should be developed for health professionals who obtain consent but do not carry out the procedure. Details should include;

- The process for identifying staff who are not capable of performing a procedure but are authorised to obtain consent for that procedure
- The process for the delivery of procedure specific training on consent, for staff to whom the consent process is delegated and who are not capable of performing the procedure needs to be included e.g. Termination of Pregnancy (ToP).
- Identify those members of staff who obtain consent for procedures they are incapable of performing
- Specific training they have received to ensure they are able to give the correct information to the patient.
3.19.3 Standard consent forms and forms for adults who are unable to consent for themselves are reproduced in Appendices 2, 4, 5 & 6 and are available for download from the DoH website. These forms can be adapted for local use, please refer to DoH guidance for more information.

- Consent Form 1. Patient consent to investigation or treatment (Appendix 6)
- Consent Form 2. Parental agreement to investigation or treatment for a child or young person (Appendix 4)
- Consent Form 3. Patient/Parental consent to investigation or treatment (procedures where consciousness not impaired) (Appendix 5)
- Consent Form 4. For adults who are unable to consent to investigation or treatment (Appendix 2)

3.19.4 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.

3.19.5 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.

3.19.6 Patients may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure. 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. If this access to advice is not available the procedure should not go ahead until someone with appropriate expertise can answer the questions posed by the patient.

3.19.7 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, a form of words should be used which requires more than a yes/no answer from the patient: for example “tell me what you’re expecting to happen”, rather than “is everything all right?”

3.19.8 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.

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

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

3.20 Seeking consent for anaesthesia

3.20.1 Where an anaesthetist is involved in a patient’s care, it is their responsibility to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient’s notes or on the consent form.

3.20.2 Where the clinician undertaking the procedure is personally responsible for anaesthesia (e.g. where local anaesthesia or conscious 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.

3.21 Dental Care

3.21.1 Patients complete FP17/PR to consent to examination and treatment for dental care found at http://www.nhsbsa.nhs.uk/1145.aspx. Where routine dental care is being provided with adjunctive local anaesthesia the Department of Health form FP17DC (or printed treatment plan generated from the R4 dental software) is used for Band 2 and 3 therapies.

3.21.2 Additional written consent is used for conscious Sedation using Department of Health model consent forms 1-4 which have been adapted for use within Special Care Dental Service. Where general anaesthesia or conscious sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In general anaesthesia settings, the anaesthetist and dentist will therefore share that responsibility.

3.21.3 If it is suspected that an adult lacks the capacity to consent to dental care, their capacity should be formally assessed and a record of this assessment made in their records. Where appropriate persons close to the patient or an IMCA should be consulted in order to reach a best interests decision on how to provide dental care.

3.21.4 Where it is decided that dental care under conscious sedation or general anaesthesia is in the person’s best interests then Form 4 should be completed.

3.22 Consent to visual and audio recordings

3.22.1 Consent should be obtained for any visual or audio recording, including photographs or other visual images. Staff should refer to the ‘Management of Audiovisual Records Policy’ for further information.

3.22.2 The purpose and possible future use of the recording must be clearly explained to the person or parental guardian before their consent is sought for the recording to be made.

3.22.3 If it is to be used for teaching, peer review, audit or research, people must be aware that they can refuse without their care being compromised and that when required or
appropriate it can be anonymised. The General Medical Council (GMC) should be referred to, by medical and non-medical practitioners, for detailed advice, including situations when permission is not required and about obtaining consent to use recordings as part of the assessment or treatment of patients and for training. (www.gmc-uk.org/consent).

3.22.4 Recordings and consent forms need to be retained in compliance with the Department of Health’s NHS Code of Practice: Records Management - Part 2, which Solent NHS Trust has adopted. Staff should also refer to the ‘Records Management & Lifecycle Policy’.

3.23 Termination of Pregnancy

3.23.1 The written consent of a patient whose pregnancy is to be terminated should always be obtained. The consent of the partner or putative father is not a legal requirement. Patient’s who are 16 years of age may consent to treatment. The Medical Defence Union has advised that when a patient is under 16 years her parents should be consulted, unless the patient forbids the practitioner to do so. The parents’ refusal should not, however, prevent a termination to which the patient herself consents and which is considered to be clinically necessary. Conversely, a termination should never be carried out in opposition to the patient’s wishes, even if the parents demand it.

3.23.2 If the patient cannot consent to a termination of pregnancy because of mental incapacity, the terms of the Abortion Act 1967 (as amended) should be complied with; otherwise a declaration from the court authorising the termination will be required.

3.24 Sterilisation

3.24.1 The advantages and disadvantages of this form of contraception should always be explained to the patient, who should, in particular, be advised that it may not be possible to reverse the operation and also that no guarantee can be given that the operation will be totally effective in preventing conception. Written consent of the patient must always be obtained but the consent of the spouse is not a legal requirement.

3.24.2 If the patient is mentally incapable of giving consent to sterilisation the court’s approval should always be obtained before operating.

3.25 Clinical Research, Clinical Audit and Evaluation

3.25.1 Audit

In general, the clinical audit process requiring access to personal data (including patient records), may be carried out within the Trust, without explicit consent from the patient, provided that the staff operate within a robust Confidentiality Code of Conduct and provided that the audit will contribute to improved patient care or assurance around standards of care. The Clinical Audit team will review all applications for clinical audit and these will be judged for any other requirements for consent.

Written and informed consent is required from each patient or staff member taking part in a service evaluation (although this can be implied via completion of a questionnaire). Formal consent sheets and full information sheets about the information should be provided to the patient/participant. For further information on consent for clinical audit and service

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Policy for Consent to Examination and Treatment
3.25.2 **Research**

Fully informed, formal written consent is required from each patient taking part in a clinical research or evaluation project. The nature and purpose and what is known about the effects of any procedure(s) involved must be explained fully to the patient and written information provided. The fact that the patient is participating in the project and the information that has been given to them, must be noted in the case notes. All research must have been approved by an NHS Research Ethics Committee via the Health Research Authority and the Trust R&D department, in accordance with Research Governance Framework for Health and Social Care, second edition.

3.26 **Emergencies**

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

3.27 **Clinical Holding**

3.27.1 Clinical Holding should only be used as a last resort and should be the minimum response necessary for the shortest possible time, to make the patient and others as safe as possible.

3.27.2 The Care Quality Commission (CQC) has produced a guide designed to help providers of health and adult social care to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (part 3) and the Care Quality Commission (Registration) Regulations 2009 (part 4). In situations where a patient lacks capacity the Mental Capacity Act 2005 has a very broad definition of what constitute restraint and the Trusts Deprivation of liberty Safeguards and Mental Capacity Act 2005 policy should be referred to.

3.27.3 In addition, the RCN has also recently published guidelines “Restrictive physical intervention and therapeutic holding for children and young people”\(^5\)

3.27.4 Only staff who received appropriate training in restraint should be involved in clinically holding patients.

3.27.5 When young children or toddlers are required to be held for procedures, e.g. immunisation, this should be undertaken by the parent/carer.

4 **ROLES & RESPONSIBILITIES**

4.1 **Solent NHS Trust has a responsibility to:**

- Ensure that all staff members offering service users examination, treatment or care, adhere to this policy. There is no primary legislation governing consent, however under common law touching a patient without valid consent may constitute a criminal or civil offence.
- Provide all staff involved in the implementation of the policy and the care of patients, with competency-based education and training in order to update their knowledge in relation to the appropriate use of consent in patient care.

\(^5\)RCN. 2010. Restrictive physical intervention and therapeutic holding for children and young people. London

*Policy for Consent to Examination and Treatment*
4.2 **Service Managers have a responsibility to:**
- In conjunction with lead clinicians, clearly identify those procedures where written consent is required, or verbal consent is obtained and explicitly documented in the clinical records. They should ensure that clinicians performing procedures are aware of these requirements and where written consent is indicated, the forms that should be used. Forms must comply with recommended best practice.
- Ensure all healthcare staff including, allied health and social care professionals within the service are aware of this policy and that they have been offered training in the use of the policy.
- Ensure staff within the service are aware of the record keeping required.

4.3 **Employees have a responsibility to:**
- Be accountable for all aspects of their practice. All Registered Healthcare Professionals have a professional responsibility to maintain up to date evidence-based care; this includes maintaining a working knowledge of their responsibilities in relation to the consent process.
- Ensure that the patient is genuinely consenting to what is being done; it is the employee who will be held responsible in law if this is challenged later.
- Recognise and understand their personal responsibility in safeguarding people who use the services.
- Discharge their duties in accordance with their role, level of expertise and the requirements of their professional body where applicable.
- Have evidence of regular updating. This must be demonstrated through informed evidence-based practice and documentation of attendance at relevant training.
- Ensure their approach to care is interdisciplinary, involving all those needed in the management of the patient.

4.4 **Students and Trainees**
- It is particularly important that a person is aware of the situation when students or trainees carry out procedures to further their own education. Where the procedure will further the person’s care – for example taking a blood sample for testing – then, assuming the student/trainee is appropriately trained in the procedure, the fact that it is carried out by a student/trainee does not alter the nature and purpose of the procedure. It is therefore not a legal requirement to tell the person that the clinician is a student, although it would always be good practice to do so. In contrast, where a student/trainee proposes to conduct a physical examination that is not part of the person’s care then it is essential to explain that the purpose of the examination is to further the student’s training, and to seek consent for that to take place.

5 **TRAINING**

5.1 Consent training for medical staff is available through Southampton University Hospitals Trust. General consent, Mental Capacity Act and Deprivation of Liberty Safeguards training is given to all staff as a ‘one off’ event in Corporate Induction. Specific training for staff working with vulnerable adults and children is also offered as a bespoke session where an additional training need has been identified as a requirement locally or where identified through incident or complaint analysis. Safeguarding adults and children training is delivered every other year to appropriate staff.

5.2 Registered professionals would be expected to understand and inact the consent process in line with the requirements of their professional bodies.

6  EQUALITY & DIVERSITY

6.1 Solent NHS Trust embraces and accepts its legal, social and moral responsibility in relation to Equality, Diversity and Human Rights. The Organisation is committed to delivering equality of opportunities for all service users, carers and staff and wider communities and to the elimination of ALL forms of discrimination. An Equality Impact assessment has been completed at Appendix 7 and no negative impact has been identified.

7.  SUCCESS CRITERIA / MONITORING THE EFFECTIVENESS OF THE POLICY

7.1 Consent will be audited annually as part of the Audit Programme. Appendix 8 details the three audit tools and the guidance for their use. Audits will be carried out in the third quarter of each year with findings and action plans presented to, and then monitored by, the Clinical Effectiveness Group. When actions are completed, outcome documents will be sent to the Clinical Audit Manager to be reported to the Information Governance & Performance Committee.

7.2 In addition, the results of patient surveys, which will routinely ask patients about aspects of consent will also help provide an accurate representation of SH’s compliance to this policy as well as those standards set out by the NHSLA7.

8  REVIEW

8.1 This document may be reviewed at any time at the request of either at staff side or management, but will automatically be reviewed 3 years from initial approval and thereafter on a triennial basis unless organisational changes, legislation, guidance or non-compliance prompt an earlier review.

9  REFERENCES

- BMA. Medical Ethics Today - The BMA’s handbook of ethics and law, second edition. 2009.
- Deprivation of liberty safeguards - Code of Practice to supplement the main Mental Capacity Act 2005 Code of Practice. 2007. London, Stationery Office
- DoH. Model policy for consent to examination or treatment. 2009. London, Stationery Office
- Fraser; Respondent v. West Norfolk and Wisbech Area Health Authority. 1986
9.2 Solent NHS Trust Documents

- Advance Decisions to Refuse Treatment Policy.
- Deprivation of Liberty Safeguards and Mental Capacity Act Policy.
- Safeguarding Adults Policy.
- Safeguarding Children Policy.
- Privacy, Dignity and Respect Policy.
- Management of Audiovisual Records Policy.
- Records Management & Lifecycle Policy.
- Equality, Diversity & Human Rights Policy.
Appendix 1

A lasting power of attorney is a legal document that lets a person appoint someone they trust as an ‘attorney’ to make decisions on their behalf. It can be drawn up at any time while they have capacity, but has **no legal standing until it is registered with the Office of the Public Guardian.** A registered LPA can be used at any time, whether the person has the mental ability to act for themselves or not.

There are two types of LPA:

- Property and Affairs LPA
- Personal Welfare LPA

**Property and Affairs LPA**
A Property and Affairs LPA allows a person to choose someone to make decisions about how to spend their money and the way their property and affairs are managed.

**Personal Welfare LPA**
A Personal Welfare LPA allows a person to choose someone to make decisions about their healthcare and welfare. This includes decisions to refuse or consent to treatment on their behalf and deciding where they live. These decisions can only be taken on their behalf when the LPA is registered and they lack the capacity to make the decisions themselves.

**Access to Medical Records**
This change could affect many areas of healthcare and should also be taken into account when either a ‘Subject Access Request’ (an access request for the records of a living patient) under the Data Protection Act 1998 is received, or an Access to Health Records request under the Access to Health Records Act 1990 (an access request for the records of a deceased patient) is received.

**Enduring Power of Attorney (EPA)**
A person given power under an EPA before 1 October 2007 can still use it and apply to have it registered. This person has a duty to apply to register the EPA as soon as they believe that a person is becoming or has become mentally incapable of making financial decisions for themselves. If a person has an unregistered EPA and still have the capacity to make decisions for themselves, they can make a Personal Welfare LPA to run alongside it.
Appendix 2

Form 4. Form for adults who lack the capacity to consent to investigation or treatment’

<table>
<thead>
<tr>
<th>Patient details (or pre-printed patient identifier label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s surname/family name..................................................</td>
</tr>
<tr>
<td>Patient’s first names ..............................................................</td>
</tr>
<tr>
<td>Date of birth ..............................................................................</td>
</tr>
<tr>
<td>Responsible health professional..................................................</td>
</tr>
<tr>
<td>Job title ......................................................................................</td>
</tr>
<tr>
<td>NHS number (or other identifier).................................................</td>
</tr>
<tr>
<td>☐ Male ☐ Female ..........................................................................</td>
</tr>
<tr>
<td>Special requirements .....................................................................</td>
</tr>
<tr>
<td>(eg other language/other communication method) .........................</td>
</tr>
</tbody>
</table>

All sections to be completed by health professional proposing the procedure

A Details of procedure or course of treatment proposed......................
............................................................................................................
............................................................................................................
(NB see guidance to health professionals overleaf for details of situations where court approval must first be sought)

“B Assessment of patient’s capacity (in accordance with the Mental Capacity Act)
I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment because of an impairment of the mind or brain or disturbance affecting the way their mind or brain works (for example, a disability, condition or trauma, or the effect of drugs or alcohol) and they cannot do one or more of the following:

• understand information about the procedure or course of treatment
• retain that information in their mind
• use or weigh that information as part of the decision-making process, or
• communicate their decision (by talking, using sign language or any other means)

Further details: for example how above judgements reached; which colleagues consulted; what attempts made to assist the patient make his or her own decision and why these were not successful.”
............................................................................................................
............................................................................................................

“C Assessment of patient’s best interests
I am satisfied that the patient has not refused this procedure in a valid advance decision. As far as is reasonably possible, I have considered the person’s past and present wishes and feelings (in particular if they have been written down) any beliefs and values that would be likely to influence the decision in question. As far as possible, I have consulted other people (those involved in caring for the patient, interested in their welfare or the patient has said should be consulted) as appropriate. I have considered the patient’s best interests in accordance with the requirements of the Mental Capacity Act and believe the procedure to be in their best interests because:...........
............................................................................................................
............................................................................................................

(Where incapacity is likely to be temporary, for example if patient unconscious, or where patient has fluctuating capacity)
The treatment cannot wait until the patient recovers capacity because:.............
D Involvement of the patient’s family and others close to the patient

The final responsibility, unless the person has a Court of Protection appointed Deputy or an attorney, for determining whether a procedure is in an incapacitated patient’s best interests lies with the health professional performing the procedure. However, it is good practice to consult with those close to the patient (e.g., spouse/partner, family and friends, carer, supporter or advocate) unless you have good reason to believe that the patient would not have wished particular individuals to be consulted, or unless the urgency of their situation prevents this. “Best interests” go far wider than “best medical interests”, and include factors such as the patient’s wishes and beliefs when competent, their current wishes, their general well-being and their spiritual and religious welfare.

(to be signed by a person or persons close to the patient, if they wish)

I/We have been involved in a discussion with the relevant health professionals over the treatment of………………………………………………..(patient’s name).

I/We understand that he/she is unable to give his/her own consent, based on the criteria set out in this form. I/We also understand that treatment can lawfully be provided if it is in his/her best interests to receive it.

Any other comments (including any concerns about decision)

…………………………………………………………………………………………………………………………………………………………

Name ...........................................Relationship to patient .................

Address (if not the same as patient)……………………………………………………

Signature ............................................. Date..............................

If a person close to the patient was not available in person, has this matter been discussed in any other way (e.g., over the telephone?)

☐ Yes  ☐ No

Details:………………………………………………………………………………………………………………………………………………

“Independent Mental Capacity Advocate (IMCA)

For decisions about serious medical treatment, where there is no one appropriate to consult other than paid staff, has an Independent Mental Capacity Advocate (IMCA) been instructed?

Yes  No

Details:

Signature ............................................. Date..............................

Policy for Consent to Examination and Treatment
E The patient has an attorney or deputy
Where the patient has authorised an attorney to make decisions about the procedure in question under a Lasting Power of Attorney or a Court Appointed Deputy has been authorised to make decisions about the procedure in question, the attorney or deputy will have the final responsibility for determining whether a procedure is in the patient’s best interests.

I have been authorised to make decisions about the procedure in question under a Lasting Power of Attorney / as a Court Appointed Deputy (delete as appropriate). I have considered the relevant circumstances relating to the decision in question (see section C) and believe the procedure to be in the patient’s best interests.
Any other comments (including the circumstances considered in assessing the patient’s best interests)

Signature:………………………………………

Signature of health professional proposing treatment
The above procedure is, in my clinical judgement, in the best interests of the patient, who lacks capacity to consent for himself or herself. Where possible and appropriate I have discussed the patient’s condition with those close to him or her, and taken their knowledge of the patient’s views and beliefs into account in determining his or her best interests.

I have/have not sought a second opinion.

Signature:……………………………………… Date: .. ..............................
Name (PRINT) .............................. ....... Job title ........ ..............................

Where second opinion sought, s/he should sign below to confirm agreement:

Signature:……………………………………… Date: .. ..............................
Name (PRINT) .............................. ....... Job title ........ ..............................
Guidance to health professionals

This form should only be used where it would be usual to seek written consent but an adult patient (16 or over) lacks capacity to give or withhold consent to 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 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). 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 Department of Health’s Reference guide to consent for examination or treatment (www.dh.gov.uk/consent).

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 Mental Capacity Act 2005. More information about the Act is given in the Code of Practice1. Treatment can be given to a patient who is unable to consent, only if:

• the patient lacks the capacity to give or withhold consent to this procedure AND
• the procedure is in the patient’s best interests.

Capacity

A person lacks capacity if they have an impairment or disturbance (for example, a disability, condition or trauma, or the effect of drugs or alcohol) that affects the way their mind or brain works which means that they are unable to make a specific decision at the time it needs to be made. 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 taking 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 take a particular complex decision, but be able to take other more straight-forward decisions or parts of decisions.

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

Best interests

The Mental Capacity Act requires that a health professional 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 health professional 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 health professional must not be motivated by a desire to bring about the person’s death.
The Act also requires that, as far as possible, health professionals must consult other people, if it is appropriate to do so, and take into account of 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 and anyone engaging in caring for patient and their family and friends.

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. 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 and must make decisions in the person’s best interests.
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. Cases involving:
- 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 (include cases involving ethical dilemmas in untested areas) should be referred to the Court for approval. 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.
Appendix 3

How to seek a court declaration

The Mental Capacity Act 2005 (MCA) requires that organisations identify people who lack, or are thought to lack, mental capacity in order that special measures can be employed to assist them in making decisions. The Act aims to establish a legal framework for decision making for people over 16 years of age who lack capacity to make particular decisions. Only those who lack, or are reasonably believed to lack capacity to make specific decisions is covered by the Act’s provisions.

If there is no consensus on whether a particular treatment is in the best interests of an incapacitated adult, if the consequences of having or not having the treatment are potentially serious, a court declaration may be sought.

In Southampton Healthcare the first requirement is for the relevant Associate Director to be informed or the on-call senior manager if the situation arises out of office hours. They will make the necessary contacts with the Organisation’s solicitors.

Further information can be obtained from the Office of the Public Guardian www.publicguardian.gov.uk (Tel: 0845 330 2900).
Appendix 4

Form 2. Parent (Or Person Who Has Parental Responsibility) agreement to investigation or treatment for a child or young person

To be retained in patient’s notes

<table>
<thead>
<tr>
<th>Patient details (or pre-printed patient identifier label)</th>
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</thead>
<tbody>
<tr>
<td>Patient’s surname/family name.................................................................</td>
</tr>
<tr>
<td>Patient’s first names .................................................................</td>
</tr>
<tr>
<td>Date of birth .................................................................</td>
</tr>
<tr>
<td>Responsible health professional.................................................................</td>
</tr>
<tr>
<td>Job title .................................................................</td>
</tr>
<tr>
<td>NHS number (or other identifier).................................................................</td>
</tr>
<tr>
<td>□ Male □ Female</td>
</tr>
<tr>
<td>Special requirements .................................................................</td>
</tr>
<tr>
<td>(eg other language/other communication method)</td>
</tr>
</tbody>
</table>

**Name of proposed procedure or course of treatment** *(include brief explanation if medical term not clear)*.................................................................

**Statement of health professional** *(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)*

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits

...significant, unavoidable or frequently occurring risks” ..........................

Any extra procedures which may become necessary during the procedure

□ blood transfusion...........................................................................

□ other procedure (please specify)

...I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

□ The following leaflet/tape has been provided

...This procedure will involve:

□ *general and/or regional anaesthesia* □ *local anaesthesia* □ *sedation*

Signed:................................. Date .. .............................

Name (PRINT) ......................... ...... ................................. Job title ...... ...........

**Contact details** *(if patient wishes to discuss options later)* ..........................

**Statement of interpreter** *(where appropriate)*

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed .............................................................  Date ..................................

Name (PRINT) ..........................................................  ................................

**Top copy accepted by patient:** yes/no *(please ring)*

Policy for Consent
Statement of parent

Please read this form carefully. If the procedure has been planned in advance, you should already have your own copy of the previous page which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you and your child. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form and I confirm that I have ‘parental responsibility’ for this child.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that my child and I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of the situation prevents this. (This only applies to children having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save the life of my child or to prevent serious harm to his or her health.

I have been told about additional procedures which may become necessary during my child’s treatment. I have listed below any procedures which I do not wish to be carried out without further discussion. ……………………………………………………………………………………………………………

Signature ............................................. Date..........................................

Name (PRINT) ................................. Relationship to child..............................

Child’s agreement to treatment (if child wishes to sign)

I agree to have the treatment I have been told about.

Name .................................................. Signature ..........................

Date ......................

Confirmation of consent (to be completed by a health professional when the child is admitted for the procedure, if the parent/child have signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the child and his or her parent(s) that they have no further questions and wish the procedure to go ahead.

Signed:............................................... Date ......................

Name (PRINT) ......................... ............ Job title ................. ............

Important notes: (tick if applicable)
See also advance directive/living will (eg Jehovah’s Witness form)

Parent has withdrawn consent (ask parent to sign /date here) ………………………

Guidance to health professionals (to be read in conjunction with consent policy)

Consent Form 2
This form should be used to document consent to a child’s treatment, where that consent is being given by a person with parental responsibility for the child. The term ‘parent’ has been used in this form as a shorthand for ‘person with parental responsibility’. Where children are legally competent to consent for themselves (see below), they may sign the standard ‘adult’ consent form (form 1). There is space on that form for a parent to countersign if a competent child wishes them to do so.

Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. The courts have stated that if a child under the age of 16 has “sufficient understanding and intelligence to enable him or her to understand fully what is proposed”, then he or she will be competent to give consent for himself or herself. If children are not able to give consent for themselves, some-one with parental responsibility may do so on their behalf.

Although children acquire rights to give consent for themselves as they grow older, people with ‘parental responsibility’ for a child retain the right to give consent on the child’s behalf until the child reaches the age of 18. Therefore, for a number of years, both the child and a person with parental responsibility have the right to give consent to the child’s treatment.

As a matter of good practice you should always seek a competent child’s consent before providing treatment unless any delay involved in doing so would put the child’s life or health at risk. Younger children should also be as involved as possible in decisions about their healthcare. Further advice is given in the Department’s guidance Seeking consent: working with children. Any differences of opinion between the child and their parents, or between parents, should be clearly documented in the patient’s notes.

“Where a young person of 16 or 17 or a Gillick competent child under 16, refuses treatment, it is possible that such a refusal could be over-ruled if it would in all probability lead to the death of the child or to severe permanent injury. It would be prudent, to obtain a court declaration or decision if faced with a competent child or young person who is refusing to consent to treatment, to determine whether it is lawful to treat the child.”

Parental responsibility

The person(s) with parental responsibility will usually, but not invariably, be the child’s birth parents. Parental responsibility for a child is dependent on the child’s date of birth. For children born after the 1 December 2003, both parents will have parental responsibility provided that they are named on the birth certificate. For children born before this date, the child’s father would only automatically have parental responsibility if he was married to the mother. Otherwise he would acquire parental responsibility through a Parental Responsibility Agreement with the mother or a Parental Responsibility Order through the courts. A married step parent or civil partner may also obtain parental responsibility in this way. If the parents divorce, both parents retain parental responsibility for the child.
If the child is subject to a Care Order, the Local Authority has parental responsibility which is shared with the parents. Parental Responsibility may be delegated to others e.g. authorising schools to give treatment for minor ailments. In an emergency a person without parental responsibility (e.g. a grandparent) may do ‘what is reasonable in all the circumstances of the case for the purpose of safeguarding or promoting the child’s welfare’.

**Information**

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for children and their parents when making up their minds about treatment. The courts have stated that patients should be told about ‘significant risks which would affect the judgement of a reasonable patient’. ‘Significant’ has not been legally defined, but the GMC requires doctors to tell patients about ‘serious or frequently occurring’ risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly.

**Guidance on the law on consent**

See the Department of Health publications Reference guide to consent for examination or treatment and Seeking consent: working with children for a comprehensive summary of the law on consent (also available at www.dh.gov.uk/consent).
Appendix 5

Form 3. Patient/Parental consent to investigation or treatment (procedures where consciousness not impaired)

To be retained in patient’s notes

<table>
<thead>
<tr>
<th>Patient details (or pre-printed patient identifier label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s surname/family name.................................................</td>
</tr>
<tr>
<td>Patient’s first names ..........................................................</td>
</tr>
<tr>
<td>Date of birth .............................................................................</td>
</tr>
<tr>
<td>Responsible health professional ............................................</td>
</tr>
<tr>
<td>Job title ....................................................................................</td>
</tr>
<tr>
<td>NHS number (or other identifier) ..............................................</td>
</tr>
<tr>
<td>☐ Male  ☐ Female .........................................................................</td>
</tr>
<tr>
<td>Special requirements .............................................................</td>
</tr>
<tr>
<td>(eg other language/other communication method) .......................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of procedure (include brief explanation if medical term not clear)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have explained the procedure to the patient/parent. In particular, I have explained:</td>
</tr>
<tr>
<td>The intended benefits ..................................................................................................................</td>
</tr>
<tr>
<td>significant, unavoidable or frequently occurring risks”..............................................................</td>
</tr>
<tr>
<td>I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of those involved.</td>
</tr>
<tr>
<td>☐ The following leaflet/tape has been provided ........................................................................</td>
</tr>
</tbody>
</table>

Signed: ........................................... Date ..............................................
Name (PRINT) ........................................... Job title ....................................

<table>
<thead>
<tr>
<th>Statement of interpreter (where appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe s/he/they can understand.</td>
</tr>
</tbody>
</table>

Signed ........................................... Date.................................Name (PRINT).............

<table>
<thead>
<tr>
<th>Statement of patient/person with parental responsibility for patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>I agree to the procedure described above.</td>
</tr>
<tr>
<td>I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.</td>
</tr>
<tr>
<td>I understand that the procedure will/will not involve local anaesthesia.</td>
</tr>
</tbody>
</table>

Signature ...................................................................... Date ..............................................
Name (PRINT) ............................................................. Relationship to patient .................

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient/parent has signed the form in advance)

Policy for Consent
I have confirmed that the patient/parent has no further questions and wishes the procedure to go ahead.

Signed: ........................................ Date ......................
Name (PRINT) .................................. Job title .........................
Copy accepted by patient/parent: yes/no (please ring)

**Guidance to health professionals** (to be read in conjunction with consent policy)

**Consent Form 3**

This form documents the patient’s agreement (or that of a person with parental responsibility for the patient) to go ahead with the investigation or treatment you have proposed. It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care: for example for drug therapy where written consent is deemed appropriate. In other circumstances you should use either form 1 (for adults/competent children) or form 2 (parental consent for children/young people) as appropriate.

Consent forms are not legal waivers – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients also have every right to change their mind after signing the form.

**Who can give consent**

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has “sufficient understanding and intelligence to enable him or her to understand fully what is proposed”, then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally ‘competent’ younger children, may therefore sign this form for themselves, if they wish. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child’s care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

**When NOT to use this form (see also ‘This form’ above)**

If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if: they are unable to comprehend and retain information material to the decision and/or they are unable to weigh and use this information in coming to a decision. You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

**Information**

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds about treatment. The courts have stated that patients should be told about ‘significant risks which would affect the judgement of a reasonable patient’. ‘Significant’ has not been legally defined, but the GMC requires doctors to tell patients...
about ‘serious or frequently occurring’ risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this overleaf or in the patient’s notes.

**The law on consent**

See the Department of Health’s Reference guide to consent for examination or treatment for a comprehensive summary of the law on consent (also available at www.dh.gov.uk/consent).
Appendix 6

Form 1: To be retained in patient’s notes

<table>
<thead>
<tr>
<th>Patient details (or pre-printed patient identifier label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s surname/family name: ..................................................................................</td>
</tr>
<tr>
<td>Patient’s first names: .................................................................................................</td>
</tr>
<tr>
<td>Date of birth: ...............................................................................................................</td>
</tr>
<tr>
<td>Responsible health professional: ..................................................................................</td>
</tr>
<tr>
<td>Job title: ......................................................................................................................</td>
</tr>
<tr>
<td>NHS number (or other identifier): ..................................................................................</td>
</tr>
<tr>
<td>☐ Male ☐ Female</td>
</tr>
<tr>
<td>Special requirements: ..................................................................................................</td>
</tr>
<tr>
<td>(eg other language/other communication method)</td>
</tr>
</tbody>
</table>

Name of proposed procedure or course of treatment (include brief explanation if medical term not clear) ..............................................................

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits ........................................................................................................

“significant, unavoidable or frequently occurring risks”..............................................

Any extra procedures which may become necessary during the procedure

☐ blood transfusion........................................................................................................

☐ other procedure (please specify)

..........................................................................................................................

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

☐ The following leaflet/tape has been provided

..........................................................................................................................

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

Signed:.................................................. Date .. ......................

Name (PRINT) ................. ............ Job title ........... ............

Contact details (if patient wishes to discuss options later) ...........................................

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed .................................................. Date ..................................

Name (PRINT) .........................

Top copy accepted by patient: yes/no (please ring)
Patient identifier/label

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the first page of this consent form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

Patient’s signature ........................................ Date........................
Name (PRINT) ..................................................................................

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signature ........................................ Date ........................
Name (PRINT) ..................................................................................

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed:.................................................. Date .. ............

Policy for Consent
Name (PRINT) ………………………. ………   Job title ……..

Important notes: (tick if applicable)

☐ See also advance directive/living will (eg Jehovah’s Witness form)

☐ Patient has withdrawn consent (ask patient to sign /date here) ……………

Guidance to health professionals (to be read in conjunction with consent policy)

Consent Form 1
What a consent form is for
This form documents the patient’s agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoire to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent
See the Department of Health’s Reference guide to consent for examination or treatment for a comprehensive summary of the law on consent (also available at www.dh.gov.uk/consent).

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has “sufficient understanding and intelligence to enable him or her to understand fully what is proposed”, then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally ‘competent’ younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child’s care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form
If the patient is 18 or over and lacks the capacity to give consent, you should use form 4 (form for adults who lack the capacity to consent to investigation or treatment) instead of this form. A patient lacks capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot:
• understand information about the decision to be made
• retain that information in their mind
• use or weigh that information as part of the decision-making process, or
• communicate their decision (by talking, using sign language or any other means).
You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to so under a Lasting Power of Attorney or as a court appointed deputy.”

**Information**

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about ‘significant risks which would affect the judgement of a reasonable patient’. ‘Significant’ has not been legally defined, but the GMC requires doctors to tell patients about ‘serious or frequently occurring’ risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the first page of the form or in the patient’s notes.
### Appendix 7

**Equality Impact Assessment**  
**RETAIN THIS TEMPLATE AS EVIDENCE**

#### Step 1 – Scoping; identify the policies aims

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What are the main aims and objectives of the policy?</td>
<td>The aims of the policy include:</td>
</tr>
<tr>
<td></td>
<td>i. To set out the standards and procedures required by Solent NHS Trust to ensure that health professions comply with the law and good practice requirements in relation to consent to examination and treatment.</td>
</tr>
<tr>
<td></td>
<td>ii. Promote good care management of individuals.</td>
</tr>
<tr>
<td></td>
<td>iii. Ensure involvement and consultation with the patient and relatives/carers as appropriate, at all stages of the consent process.</td>
</tr>
<tr>
<td>2. Who will be affected by it?</td>
<td>1. Patients who access Solent NHS Trust services.</td>
</tr>
<tr>
<td></td>
<td>2. Staff directly and indirectly employed staff within Solent NHS Trust and other persons working within the organisation in line with the Trusts Equal Opportunities Policy.</td>
</tr>
<tr>
<td>3. What are the existing performance indicators/measures for this? What</td>
<td>The standards set out by the NHSLA(^8) form the basis of what needs to be measured in this policy.</td>
</tr>
<tr>
<td>are the outcomes you want to achieve?</td>
<td>The organisation has contributed to the development of clear protocols with relevant health and social care partners within other audits, such as recording keeping and patient surveys.</td>
</tr>
<tr>
<td></td>
<td>The Trust monitors and reviews current practices to ensure effective consent processes are in place.</td>
</tr>
<tr>
<td>4. What information do you already have on the equality impact of this</td>
<td>None</td>
</tr>
<tr>
<td>policy?</td>
<td></td>
</tr>
</tbody>
</table>
5. Are there demographic changes or trends locally to be considered?  
Not at present

6. What other information do you need?  
None

**Step 2 - Assessing the Impact; consider the data and research**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Answer (Evidence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Could the policy unlawfully against any group?</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>2. Can any group benefit or be excluded?</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>3. Can any group be denied fair &amp; equal access to or treatment as a result of this policy?</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>4. Can this actively promote good relations with and between different groups?</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>5. Have you carried out any consultation internally/externally with relevant individual groups?</td>
<td></td>
<td>x</td>
<td>Consulted with Clinical Directors, Chief Medical Officer, Chief Nurse, Clinical Services, Equality &amp; Diversity lead, Mental Capacity Act lead, HR, Policy Steering Groups</td>
</tr>
<tr>
<td>6. Have you used a variety of different methods of consultation/involvement?</td>
<td></td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

If there is no negative impact – end the Impact Assessment here. Assessment ended

**Step 3 - Recommendations and Action Plans**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the impact low, medium or high?</td>
<td></td>
</tr>
<tr>
<td>2. What action/modification needs to be taken to minimise or eliminate the negative impact?</td>
<td></td>
</tr>
<tr>
<td>3. Are there likely to be different outcomes with any modifications? Explain these?</td>
<td></td>
</tr>
</tbody>
</table>

**Step 4- Implementation, Monitoring and Review**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What are the implementation and monitoring arrangements, including timescales?</td>
<td></td>
</tr>
<tr>
<td>2. Who within the Department/Team will be</td>
<td></td>
</tr>
</tbody>
</table>
responsible for monitoring and regular review of the policy?

Step 5 - Publishing the Results

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How will the results of this assessment be published and where? (It is essential that there is documented evidence of why decisions were made).</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 8
Consent Audit Guidance

The audit has attempted to be broad enough to cover all areas of practice within Solent Healthcare and focused enough to still be meaningful; consequently local teams will need to interpret it in line with the work they undertake and any local protocols or practice. I am happy to support with this as needed and relate it to the national guidance for the area of your work.

One reason the audit is needed is to ensure that as an organisation we do not translate mental capacity as being only the business of mental health services. Many non MH services will have patients were mental capacity to consent to the treatment is an issue, either temporarily (for example due to confusion, being unconscious, effects of medication or intoxication etc...) or more permanently; likewise, with children and non-child services. It is important that the proper processes are followed as mental capacity and children’s legislation and policy makes clear.

Forwarding details of the audit to your essential standards owner with examples of information shared with patients, any local protocols or guidance will give good evidence for outcome 2.

Where the term ‘treatment plan’ is used this refers to one off treatments as well as courses of treatments.

For teams that have large caseloads the sample size will not give conclusive evidence that the processes are followed in all cases but will give some evidence of processes being in place or not and some examples of this occurring. Extending the audit, where possible areas of concern are identified, could be an action plan. Below is further guidance in relation to Part 1.

<table>
<thead>
<tr>
<th>Consent</th>
</tr>
</thead>
</table>
| 1) Is there valid consent to the current treatment plan?  
This will have been recorded in a way appropriate to the treatment: ranging from written consent to implied consent. It is valid if  
   i) the person had capacity,  
   ii) they were not under undue influence  
   iii) the way it was recorded was appropriate to the type of intervention. What is appropriate should comply with Solent Healthcare Consent policy, national guidance and local processes and protocols for that area of work. The auditor will need to make a judgement and may also wish to give their reasons for the judgement. |
| 2. When written consent is applicable the appropriate consent form from the Trust Policy has been filed in the patient record. |
| 3. If there is a course of treatment is there evidence of the treatment being reviewed.  
This includes the person’s consent to the treatment being reviewed. As above the consent can range from being implied to written. |
4. Is there sufficient information in an appropriate form for the patient to make an informed decision on consent to treatment.
This is badly worded and should read, ‘Is there evidence the patient has been given sufficient information in an appropriate form...’
What is sufficient will depend on the intervention. Whether it is in an appropriate form will depend on the communication needs of the patient. It can include written, verbal or other means of communication and should be sensitive to those whose first language is not English. It should comply with Solent Health care Consent policy, national guidance and local processes and protocols for these issues. The auditor will need to make a judgement and may also wish to give their reasons for the judgement.

5. If a patient has refused consent to treatment has this been documented?
This can mean a patient who has refused a recommended course of treatment, a patient who has refused a recommended course but agreed to another or a patient who has started a course of treatment and then informed the professional they have stopped it. It is aimed at one of the outcomes in outcome 2:

‘respecting and taking account of a decision by the person who uses the service to refuse or withdraw consent’ (part of 2A)

It also covers a part of 2B, which is about respecting decisions people make about their care.

This question will not show when these have occurred but not been recorded, nor when a patient has not followed a treatment plan and not communicated this to the professional. However, it will give some evidence of cases where a patient’s choices are being recorded and respected. Your service may have already collected this evidence in a way more appropriate to the service; if this is the case then please attach the evidence as opposed to answering this question.
Quarter Three – Consent and Mental Capacity Act Audit

Objectives
This audit is developed from the requirements for all services regarding consent; these incorporate the requirements of the Mental Capacity Act and the Children’s Act. For services where a person is treated under the Mental Health Act this should be recorded in the exceptions column.

This audit, with an attached action plan, will form robust evidence towards meeting the requirements of Outcome 2 of the CQC Essential standards; it should be used as such. If the performance accelerator owner for the service submits this with, relevant local protocols, training statistics and 1 or 2 anonymous cases it is likely to demonstrate that most components of the outcome are met: of course, depending on the outcome of the audit and the quality of the evidence submitted.

Part 1 refers to consent; Part 2 & 3 refers to MCA and Children’s Act

Consent and MCA Audit for Adult services complete parts 1 & 2
For Children’s complete part 3
**Part 1**  
Select 10 sets of records per team  
Is there evidence of the following regarding consent documents in patient records?

<table>
<thead>
<tr>
<th>Consent</th>
<th>Yes</th>
<th>No</th>
<th>Exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is there valid consent to the current treatment plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. When written consent is applicable the appropriate consent form from the Trust Policy has been filled in the patient record</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. If there is a course of treatment is there evidence of the treatment being reviewed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Is there sufficient information in an appropriate form for the patient to make an informed decision on consent to treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. If a patient has refused consent to treatment has this been documented</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Part 2 Mental Capacity Act**

On the day you undertake the audit select 5 sets of records where the patient lacks mental capacity to consent to treatment plan. If you are unable to identify 5 sets of records then identify as close to 5 as possible.

<table>
<thead>
<tr>
<th>Consent</th>
<th>Yes</th>
<th>No</th>
<th>Exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is there documental evidence of capacity assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Is there evidence that the treatment plan has been</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>decided in line with the statutory best interest process</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Is there evidence of any valid and appropriate advance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decisions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a Was this followed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Is there evidence of an applicable last power of Attorney</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Part 3 – Children’s Act
Select 10 sets of records per form
Is there the following?

<table>
<thead>
<tr>
<th>Consent</th>
<th>Yes</th>
<th>No</th>
<th>Exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence that the child’s ability to consent has been considered.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information regarding the treatment has been presented in appropriate form for the age and understanding of the child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where the child is able to consent this has been documented properly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where a child is unable to consent there is evidence that a person with parental responsibility has given consent</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>