CONSENT POLICY

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Policy Author and Job Role	Head of Risk and Assurance, (Circle Bath Hospital)

Version	**Date**	**Summary of Changes**
2	June 2012	Reformatted
3	June 16	Scheduled Review, Changes to Case Law and Legislation.
3.1	March 2017	Updated typographical errors
3.2	January 2021	Review date extended to April 2021. Minor updates in job titles (section 5) Content to be fully reviewed as part of Circle Health and BMI Healthcare policy integration
4	January 2025	Rebranded only, requires review so review date not updated.
5.	September 2025	Scheduled Review. Existing Circle Bath Hospital version content updated, including addition of content from Royal United Hospital Bath consent policy.

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KEY MESSAGES

- Seeking a patient's informed consent is a process, not just a signature
- There is now a legal duty for the health professional to ensure that any material risks have been discussed with the patient. A material risk is one that the patient would attach significance to, or to which a reasonable person would attach significance.
- Consent must be informed, voluntary & given by a patient with capacity to do so
- Assessment of a patient's 'capacity' is decision and time specific
- Consent can be withdrawn at any time
- Special rules apply for children, young people and patients who lack capacity

1. INTRODUCTION

Shared decision making and consent are fundamental to good medical practice. Serious harm can result if patients are not listened to or given the information they need, time and support to understand it, so they can make informed decisions about their care.

The purpose of this policy is to provide guidance for staff within Sulis Hospital Bath about the processes for obtaining informed consent. All staff have a responsibility that the principles outlined within this document are universally applied.

For informed consent to exist, there must be an effective relationship between the clinical team members and patient. Whatever the context in which medical decisions are made, clinicians must work in partnership with patients which is based on openness, trust and good communication. In so doing, clinicians must:

- Listen to patients and respect their views about their health
- Discuss with patients what their diagnosis, prognosis, treatment and care involve
- Share with patients the information they want or need in order to make decisions
- Maximise patients' opportunities, and their ability, to make decisions for themselves respect patients' decisions.

2. PURPOSE

This policy provides Sulis's approach to consent within which good clinical decision making should be based. It provides a robust framework to ensure a consistent approach to consent practices across Sulis Hospital and supports our statutory duties as set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11, the NHS Constitution (DH, 2009 and the GMC guidance 2008 on Consent: patients and doctors making decisions together and this comprehensive guidance should be used where additional clarification is needed.

The Mental Capacity Act 2005 & associated Code of Practice provide detailed information which is relevant to consent. The Policy should be read in conjunction with the Mental Capacity Act policy.

3. SCOPE

This policy establishes the legal and ethical principles of consent to examination or treatment and applies to all individuals employed by, and working within or on behalf of Sulis; such as work undertaken in a contractor, secondee, volunteer, student, locum or bank/agency capacity.

The policy applies to all decisions about care: from the treatment of minor and self-limiting conditions, to major interventions with significant risks or side effects.

4. DEFINITIONS

Capacity: is the ability to make a decision. This ability can vary depending on a patient's condition and how it changes over time, and on the nature of the decision to be made. All adults are presumed to have sufficient capacity to decide on their own medical treatment, unless there is significant evidence to suggest otherwise.

A person has capacity if they can do all the following:

1. understand information relevant to the decision in question,
2. retain that information,
3. use the information to make their decision,
4. communicate a decision.

Consent:

"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:

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

Risk refers to any adverse outcome, including side-effects or complications.

Advance Decision is a refusal of healthcare treatment made when the person is capable. It will only apply when the person lacks capacity. To be valid and applicable it should mention the proposed treatment and circumstances.

A signature on a form is not consent; it is part of the consent process. It can be evidence of understanding & acceptance of information given during the consent process. Patients with capacity may withdraw consent at any time before or during an investigation or treatment taking place.

Independent Medical Capacity Advocate:

This service helps Sulis to make decisions in the best interests of people who lack the capacity and who have no family or friends that it would be appropriate to consult about these decisions.

5. DUTIES

Medical Director, RUH	As Executive Lead for Consent, the Medical Director is ultimately responsible for: • Ensuring that this policy complies with requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11. • Through the Clinical Governance Sub-Committee, seeking assurance that Sulis Hospital is compliant with the requirements Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11. • They are accountable for ensuring the adequacy of systems related to consenting patients.
Medical Advisory Committee (MAC) Chair & Hospital Director	• Ensuring that there are appropriate frameworks, processes & systems, and training in place within the facility to ensure that the requirements of this policy are met. • Through the Clinical Governance & Risk Management Committee (CGRMC), seeking assurance that the facility is compliant with the requirements Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11 • Ensure that there is a committee structure in place within the facility that would support the escalation of potential significant risks concerning consent.

Head of Nursing and AHPs	- Ensuring that all appropriate staff have attended consent (including mental capacity) training. - If the clinical specialty chooses to undertake delegated consent, they must: - Clearly identify the healthcare professionals who will be undertaking delegated consent - Identify the procedure for which delegated consent will be taken - Ensure that the healthcare professionals are provided with procedure specific consent training which will be delivered in a manner deemed appropriate by the specialty - Ensure that the healthcare professionals have been competency assessed to undertake delegated consent for the procedures identified and for which they have received training - Audit consent practice and develop recommendations to improve the quality of services provided. - Ensure that there is a governance structure in place that would support the escalation of concerns relating to consent practices. - Taking prompt and appropriate action when necessary to prevent any breaches with the requirements of this policy. - Communicate areas of concern to the Clinical Governance & Risk Management Committee (CGRMC) and provide assurance that an action plan is in place to mitigate any risk, oversee the implementation of the action plan.
Consultants	Ensure that all consent is undertaken in line with the GMC Consent: General Medical Council Professional standards. Decision making and consent Nov 2020 https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors--- decision-making-and-consent-english_pdf-84191055.pdf ● Ensure that where other healthcare practitioners (including junior medical staff and nurses) are undertaking delegated consent under the supervision of the consultant, they have received the appropriate training and competency assessment.
Other Healthcare Practitioners	☐ Ensure that they have attended consent (including mental capacity) training and have been assessed as competent to undertake consent. ☐ Ensure that they comply with the requirements of this policy.

6. PROVISION OF INFORMATION

While some interventions require a patient's signature on a form, for many minimally or non-invasive interventions you can rely on a patient's verbal consent, as long as you are satisfied, they have had the opportunity to consider any relevant information and decided to go ahead. Verbal consent should be recorded in their notes. You should:

1. Explain what you're going to do and why,
2. Make clear the patient can say no, and stop immediately if they do,
3. Be alert for any sign that they may be confused or unhappy about what you are doing.

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion, or it might be over a series of consultations with several different health professionals.

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.

You must give patients the information they want or need to make a decision. This will usually include:

1. Diagnosis and prognosis,
2. Uncertainties about the diagnosis or prognosis, including options for further investigation,
3. Options for treating or managing the condition, including the option to take no action,
4. the nature of each option, what would be involved, and the desired outcome,
5. The potential benefits, risks of harm, uncertainties about and likelihood of success for each option, including the option to take no action.

You should not rely on assumptions about the information a patient might want or need or the importance a patient might attach to different outcomes.

Clinicians have a duty of care to warn of material risks involved in a procedure. Case law (Montgomery 2015) described a material risk as "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

Other examples of information that might be relevant and should be shared with patients include:

1. Whether an option is an innovative treatment designed specifically for their benefit,
2. Whether there is a time limit on making their decision and what the implications of delaying might be,
3. The names and roles of key people who will be involved in their care, and who they can contact (and how) if they have questions or concerns,
4. Their right to refuse to take part in teaching or research,
5. Their right to seek a second opinion,
6. Any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer.

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

1. Recognised risks of harm that you believe anyone in the patient's position would want to know,
2. The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring,
3. Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them,
4. Any risk of serious harm, however unlikely it is to occur.
5. Expected harms, including common side effects and what to do if they occur.

Patient information leaflets are a useful means of providing information for the patient on the risks, benefits and alternatives to procedures. All patient information leaflets should be developed as per the Accessible Information Standards.

7. POLICY STATEMENT –

Recording Decisions

Keeping an accurate patient records of decision making will inform future care and help you to explain and justify your decisions and actions. This includes decisions to take no action.

Consent forms are a prompt to share key information and standardise a record of decision making. Filling in a consent form is not a substitute for a meaningful dialogue tailored to the individual patient's needs.

Form 1: For adults or competent children
Form 4: Is provided for adults who are unable to consent to investigation or treatment.

Unless treatment or care begins immediately after a patient has given consent, you should review a patient's decision immediately before providing treatment or care, particularly if:

1. You haven't personally had a discussion with the patient because they were initially seen by a colleague,
2. Significant time has passed since the decision was made,
3. The patient's condition has changed,
4. You have reason to believe the patient might have changed their mind,
5. Any aspect of the chosen treatment or care has changed,
6. New information has become available about the potential benefits or risks of harm of any of the options that might make the patient choose differently.
7. A **two-week cooling off period is mandatory for any cosmetic procedure.**

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. For elective procedures patients should receive information about anaesthesia in advance of the procedure and have the opportunity to ask questions. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record.

7.1 Emergencies

In an emergency, if a patient is unconscious or they lack capacity and it is not possible to find out their wishes, you can provide treatment that is immediately necessary to save their life or to prevent a serious deterioration of their condition. If there is more than one option, the treatment you provide should be the least restrictive of the patient's rights and freedoms.

7.2 Refusal of Treatment

A person may have made an advance decision to refuse particular treatment in anticipation of future incapacity. The Mental Capacity Act (2005) Code of Practice chapter 9 sets out the requirements that such a decision must meet to be valid and applicable.

https://assets.publishing.service.gov.uk/media/5f6cc6138fa8f541f6763295/Mental- capacity-act-code-of-practice.pdf

Healthcare professionals must follow an advance decision if it is valid and applicable, even if it may result in the person's death. The Act also protects healthcare professionals from liability for the consequences of withholding or withdrawing a treatment if at the time they reasonably believe that there is a valid and applicable advance decision. If there is genuine doubt or disagreement about an advance decision's existence, validity or applicability, the case should be referred to the Court of Protection, see appendix 2. While a decision is awaited from the courts, healthcare professionals can provide life-sustaining treatment or treatment to stop a serious deterioration in the patient's condition.

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

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

Due to the complexity of this subject area, the best practice principles of consent to examination and treatment have been incorporated into the appendices of this policy; in order to ensure that all key principles are easily accessible and clearly defined.

Appendix 1	Valid Consent
Appendix 2	Documenting Consent
Appendix 3	When should consent be sought?
Appendix 4	Who is responsible for seeking consent?
Appendix 5	Refusal of Treatment
Appendix 6	Withdrawal of consent
Appendix 7	Subsequent use of removed tissue
Appendix 8	Consent to visual and audio recordings
Appendix 9	12 key points on consent, the law in England.
Appendix 10	Current forms in use in this organisation
Appendix 11	How to seek a court declaration

8.TRAINING

Within 8 weeks of commencement of employment (regardless of whether permanent, seconded or other), all appropriate staff must demonstrate that they have undertaken consent (including mental capacity) training and that they are competent to undertaken consent.

9.MONITORING OF COMPLIANCE WITH THE POLICY

Audits will be undertaken of the processes described in the policy on a regular basis. Clinical audit will be carried out in line with the Clinical Audit Policy and reported through management lines and committees as set out in the Governance and Assurance Framework.

Monitoring will be undertaken as specified in site or procedure specific policies which may relate to consent to meet regulatory requirements. Where consent issues are identified during investigation, look-back exercise may be undertaken on incidents involving consent issues and learning shared.

10. REFERENCES

1. https://www.gov.uk/government/publications/consent-privacy-policy/consent-policy

2. The Department of Health Reference guide to consent for examination or treatment (second edition) 2009, https://www.gov.uk/government/publications/reference- guide-to-consent-for-examination-or-treatment-second-edition

3. Mental Capacity Act (2005) Code of Practice https://assets.publishing.service.gov.uk/media/5f6cc6138fa8f541f6763295/Mental- capacity-act-code-of-practice.pdf

11. REVIEW

This policy will be subject to a planned review every three years. There may be updates required in the interim arising from release of new national regulations or guidance. These updates will be made as soon as practicable.

12. ASSOCIATED DOCUMENTS

This policy should be read in conjunction with the following Sulis documents:

- Mental Capacity Act Policy
- Integrated Governance Policy
- Clinical Audit Policy
- Patient Information Policy
- Safeguarding Children and Adults Policy
- Standard of Medical Record Keeping Policy
- Interpretation Policy
- Procedure and site specific Standard Operating Procedures relating to treatment
- Adverse incident policy

12. EQUALITY IMPACT STATEMENT

Sulis is committed to ensuring that it treats its employees fairly, equitably and reasonably and that it does not discriminate against individuals or groups on the basis of their ethnic origin, physical or mental abilities, gender, age, religious beliefs or sexual orientation. Please refer to the following Equality Impact Assessment tool.

Appendix 1: Valid Consent

1. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (this will be the patient or someone with parental responsibility for a patient under the age of 18, someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has the authority to make treatment decisions as a court appointed deputy). Acquiescence where the person does not know what the intervention entails is not 'consent'.

Does the person have capacity?

2. The Mental Capacity Act 2005 defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary. 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, and that impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made.

3. An assessment of a person's capacity must be based on their ability to make a specific decision at the time it needs to be made, and not their ability to make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things:
    - understand the information given to them that is relevant to the decision
    - retain that information long enough to be able to make the decision
    - use or weigh up the information as part of the decision-making process
    - communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

4. People may have capacity to consent to some interventions but not to others or may have capacity at sometimes but not others. Under the Mental Capacity Act, a person must be assumed to have capacity unless it is established that they lack capacity. If there is any doubt, then the healthcare professional should assess the capacity of the patient to take the decision in question. This assessment and the conclusions drawn from it should be recorded in the patient's notes.

5. A person's capacity to consent may be temporarily affected by factors such as confusion, panic, shock, fatigue, pain or medication. However, the existence of such factors should not lead to an automatic assumption that the person does not have the capacity to consent.

6. Capacity should not be confused with a healthcare professional's assessment of the reasonableness

of the person's decision. Under the Mental Capacity Act and the common law, a person is not to be treated as unable to make a decision merely because they make an unwise decision. A person is entitled to make a decision which may be perceived by others to be unwise or irrational, as long as they have the capacity to do so.

7. However, if the decision that appears irrational is based on a misperception of reality, as opposed to a different value system to that of the health practitioner – for example a patient who, despite the obvious evidence, denies that his foot is gangrenous, or a patient with anorexia nervosa who is unable to comprehend their failing physical condition – then the patient may not be able to comprehend, weigh or make use of the relevant information and hence may lack the capacity to make the decision in question.

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

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

Is the consent given voluntarily?

9. To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the person either to accept or refuse treatment. Such pressure can come from partners or family members, as well as health or 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.

10. The test of capacity is set out in the Mental Capacity Act (see paragraph 3 above). Once it has been determined that a person has the capacity to make a particular decision at a particular time, a further requirement (under the common law) for that consent to be valid is that it must be given voluntarily and freely, without pressure or undue influence being exerted upon them.

11. When people are seen and treated in environments where involuntary detention may be an issue, such as prisons and mental hospitals, there is a potential for treatment offers to be perceived coercively, whether or not this is the case. Coercion invalidates consent, and care must be taken to ensure that the person makes decisions freely. Coercion should be distinguished from providing the person with appropriate reassurance concerning their treatment or pointing out the potential benefits of treatment

for the person's health. However, threats such as withdrawal of any privileges, loss of remission of sentence for refusing consent or using such matters to induce consent may well invalidate the consent given and are not acceptable.

Has the person received sufficient information?

12. To give valid consent, the person needs to understand the nature and purpose of the procedure. Any misrepresentation of these elements will invalidate consent. Where relevant, information about anaesthesia should be given alongside information about the procedure itself.

13. 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 is appropriately trained in the procedure, the fact that it is carried out by a student 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 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.

14. Although informing people of the nature and purpose of procedures enables valid consent to be given as far as any claim of battery is concerned, this is **not** sufficient to fulfil the legal duty of care to the person. Failure to provide other relevant information may render the practitioner liable to an action for negligence if a person subsequently suffers harm as a result of the treatment received.

15. The requirements of the legal duty to inform patients continues to develop in case law. In 1985, the House of Lords decided in the Sidaway16 case that the legal standard to be used when deciding whether adequate information had been given to a patient should be the same as that used when judging whether a doctor had been negligent in their treatment or care of a patient: a doctor would not be considered negligent if their practice conformed to that of a responsible body of medical opinion held by practitioners skilled in the field in question. This is known as the 'Bolam test'. Whether the duty of care had been satisfied was therefore primarily a matter of medical opinion. However, Sidaway also stated that it was open to the courts to decide that information about a particular risk was so obviously necessary that it would be negligent not to provide it, even if a 'responsible body' of medical opinion would not have done so.

16. Since Sidaway, judgments in a number of negligence cases (relating both to the provision of information and to the standard of treatment given) have shown that courts are willing to be critical of a 'responsible body' of medical opinion. It is now clear that the courts will be the final arbiter of what constitutes responsible practice, although the standards set by the healthcare professions for their members will still be influential. In Chester v Afshar, a majority of the House of Lords held that a neurosurgeon who failed to warn a patient of the small risk of injury inherent in surgery, even if properly performed,

was liable to the patient when that risk materialised, even though the risk was not increased by the failure to warn and the patient had not shown that she would never have had an operation carrying the same risk. The Lords departed from the traditional 'but for' test of causation on the basis that, exceptionally, policy and justice required a modification to causation principles. The fundamental principle underlying the decision was the right of a patient to make an informed choice as to whether – and if so, when and by whom –to be operated on.

17. In considering what information to provide, the health practitioner should try to ensure that the person is able to make an informed judgement on whether to give or withhold consent. Case law on this issue is evolving. It is therefore advisable to inform the person 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. A Court of Appeal judgment stated that it will normally be the responsibility of the doctor to inform a patient of 'a significant risk which would affect the judgment of a reasonable patient'. Following *Chester v Afshar*, it is advisable that healthcare professionals give information about all significant possible adverse outcomes and make a record of the information given.

18. The GMC provides guidance on the type of information that patients may need to know before making a decision and recommends that doctors should do their best to find out about patients' individual needs and priorities when providing information about treatment options. It advises that discussions should focus on the patient's 'individual situation and risk to them' and sets out the importance of providing the information about the procedure and associated risks in a balanced way and checking that patients have understood the information given. BMA guidance advises that if in doubt about the amount of information to give a patient, doctors 'should contact their hospital lawyers or their medical defence organisation'.

19. In the very rare event that the healthcare professional believes that to follow the guidance in paragraphs 17 and 18 in full will cause the patient serious harm, the GMC guidance states that this view, and the reasons for it, should be recorded in the patient's notes. When such concerns arise, it is advisable to discuss the issue within the team caring for the patient. In individual cases the courts may accept such a justification but would examine it with great care. The mere fact that the patient might become upset by hearing the information, or might refuse treatment, is **not** sufficient to act as a justification.

20. Some people may wish to know very little about the treatment that is being proposed. If information is offered and declined, it is good practice to record this fact in the notes. However, it is possible that individuals' wishes may change over time, and it is important to provide opportunities for them to express this. GMC and BMA guidance encourages doctors to explain to patients the importance of knowing the options open to them while respecting a person's wish not to know, and states that basic information should always be provided about what the treatment aims to achieve and what it will involve.

Additional procedures

21. During an operation it may become evident that the person could benefit from an additional procedure that was not within the scope of the original consent. If it would be unreasonable to delay the procedure until the person regains consciousness (for example because there is a threat to the person's life) it may be justified to perform the procedure on the grounds that it is in the person's best interests. However, the procedure should not be performed merely because it is convenient. For example, a hysterectomy should never be performed during an operation without explicit consent, unless it is necessary to do so to save life.

22. If a person has refused certain additional procedures before the anaesthetic (for example, specifying that a mastectomy should not be carried out after a frozen section biopsy result), then this must be respected if the refusal is applicable to the circumstances The GMC guidance states that it is good practice to seek the views of the patient on possible additional procedures when seeking consent for the original intervention.

Appendix 2: Documenting Consent

1. 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.

Written consent

2. Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent but is not proof of valid consent. 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. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

3. It is rarely a legal requirement to seek written consent, but it is good practice to do so if any of the following circumstances apply:
   - The treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications')
   - The procedure involves general/regional anaesthesia or sedation
   - Providing clinical care is not the primary purpose of the procedure
   - There may be significant consequences for the patient's employment, social or personal life
   - The treatment is part of a project or programme of research approved by this Trust
4. 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.
5. 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 (for example if they have declined, or become very distressed about, similar care in the past), it would be helpful to do so.
6. Where it would be good practice to obtain written consent to the particular treatment or

intervention proposed, and the patient has capacity to give or withhold that consent, a Consent to Treatment form should be completed. The standard consent forms are reproduced in Appendix 11 and are available to order as standard stock items. There are three versions of the standard consent form: **form 1** for adults or competent children; **form 2** for parental consent for a child or young person; and **form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any decisions in advance about additional procedures because they will be in a position to make any such decisions at the time if necessary.

Procedures to follow when patients lack capacity to give or withhold consent

7. 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 consent to investigation or treatment), 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. 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.

   Where a patient aged under 18 does not have the capacity to give or withhold consent, then consent may be obtained from some-one with 'parental responsibility'. Consent should be documented in form 2.

8. An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. You should involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability teams and 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.

9. Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Where the consequences of having, or not having, the treatment are potentially serious, a court declaration may be sought. See Appendix 13 for details of how to do this.

Availability of forms

10. Standard consent forms and forms for adults who are unable to consent for themselves are reproduced in Appendix 11 and are available in most clinical areas. There are three versions of the standard consent

form: **form 1** for adults or competent children, **form 2** for parental consent for a child or young person and **form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary.

Appendix 3: When should consent be sought?

1. When a patient formally gives their consent to a particular intervention, this is only the endpoint of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making 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.

Single stage process

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

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

Two or more stage process

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

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. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patients arrive for treatment, however, a member of the healthcare team **must** check with the patient at this point whether they have any further concerns and whether their condition has changed.

This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?"

6. 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.

Treatment of older children

- 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 s/he will be competent to give consent for himself or herself.

- If a child under 16 in fact lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, then someone with parental responsibility may give consent on their behalf. If a child aged 16-18 lacks capacity to consent to treatment, then s/he can be treated, provided that the MCA is complied with; essentially, acting in best interests; assessed in consultation with family/carers, where possible and appropriate. In law, health professionals only need the consent of one appropriate person before providing treatment. As a matter of good practice, however, health professionals are advised always to seek a competent child's consent before providing treatment unless any delay involved in so doing 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 DH guidance "Seeking consent: working with children", available at www.dh.gov.uk/consent.

Appendix 4: Who is Responsible for seeking Consent?

1. The Health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later. Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, teamwork is a crucial part of the way Sulis operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

Delegated Consent

2. Delegated consent is whereby the consent for the procedure is taken by a healthcare professional who is not competent to perform the procedure but has received procedure specific consent training to take delegated consent for this procedure. The organisation recognises that there will be occasions where the undertaking of delegated consent can be beneficial to the wider team and support the wider development of healthcare professionals. However, these circumstances will be limited to those procedures which will be identified by the Clinical Unit concerned. If the Clinical Unit chooses to undertake delegated consent, they must:

- Clearly identify the healthcare professionals who will be undertaking delegated consent
- Identify the procedure for which delegated consent will be taken
- Ensure that the healthcare professionals are provided with procedure specific consent training which will be delivered in a manner deemed appropriate by the specialty
- Ensure that the healthcare professionals have been competency assessed to undertake delegated consent for the procedures identified and for which they have received training

Completing Consent Forms

3. 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.

   If any clinical team wishes that information be provided by health professionals who do not themselves carry out the procedure, then paragraph two above applies.. Any health professional providing information to the patient must demonstrate a thorough understanding of the procedure, and of its risks and benefits; being in a position to address any question that might reasonably be anticipated.

4. If the patient signs the form in advance of the procedure (for example in outpatients 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.

Ideally, for elective procedures the healthcare professional should provide the information at the outpatient consultation or in the pre-operative assessment clinic. Final confirmation that the patient understands and consents to the procedure should be obtained by an appropriately trained healthcare professional at the time of admission.

Some procedures are primarily technical investigations carried out at the request of referring clinician (e.g. invasive radiological procedures). In these cases, the referring clinician must explain to the patient how the procedure fits into the plan of care and what alternatives exist. The practitioner performing the procedure (or an appropriately trained and delegated individual who is capable of performing the procedure) must then explain the procedure itself, including any appropriate risks.

Responsibility of health professionals

5. It is a health professional's own responsibility:
   - to ensure that when they require colleagues to seek consent on their behalf, they are confident that the colleague is competent to do so; and
   - to work within their own competence and not to agree to perform tasks which exceed that competence.

If you feel that you are being pressurised to seek consent when you do not feel competent to do so, advice can be sought from the following parties:

Line Manager
Supervising Consultant
Clinical Lead/Lead Nurse
Medical Director
Quality & Assurance Team
Safeguarding Lead Doctor/Nurse

Appendix 5: Refusal of treatment

1. If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983.

   Under the Mental Capacity Act 2005, with effect from 1 October 2007 If an adult patient lacks capacity, they may have refused treatment in an Advance Decision; the terms of which should then be honoured, if it is valid and applicable to the circumstances. A designated decision maker, acting on behalf of an adult patient who lacks capacity, also has the right to refuse treatment on behalf of the patient; though the right to refuse life-saving treatment will depend on express authorisation to do so having been given under the terms of the Lasting Power of Attorney.

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. Essentially, whilst in law the refusal of a child under 16 to consent may be overridden by the consent of a person with parental responsibility, health professionals are encouraged always to try to obtain a competent child's consent before providing treatment, unless any delay involved in so doing would put the child's life or health at risk. It is recognised that decision-making with older children will often be a matter of negotiation between the child, those with parental responsibility and clinicians. Efforts should be made to ensure that children don't feel that decisions are being made over their heads. The following paragraphs apply primarily to adults.

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, you (and where possible the patient) should note this on the form.

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

5. If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you

genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

Appendix 6: Withdrawal of Consent

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.

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 should not be used as an excuse to ignore distress.

Appendix 7: Subsequent use of removed tissue

1. The Human Tissue Act 2004 repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992.

2. The 2004 Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display. It also covers the **removal** of such material from the deceased. (It does not cover removal of such material from living patients – this continues to be dealt with under the common law and the Mental Capacity Act 2005.)

3. The 2004 Act regulates removal, storage and use of human tissue. This is referred to in the Act as 'relevant material' and is defined as material that has come from a human body and consists of, or includes, human cells. Cell lines are excluded, as are hair and nail from living people. Live gametes and embryos are excluded as they are already regulated under the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008.

4. The Human Tissue Act 2004 lists the purposes for which consent is required in Schedule 1, and they are referred to as 'scheduled purposes'. The consent required under the Act is called 'appropriate consent', which means consent from the appropriate person, as identified in the Act. Where there has been a failure to obtain or misuse of consent, penalties of up to three years imprisonment or a fine, or both, are provided for in the Act.

5. Full details on the requirements of the Human Tissue Act 2004 and the HTA's codes of practice are on the HTA's website at www.hta.gov.uk. These should be consulted to ensure compliance.

Appendix 8: Consent to visual and audio recordings

1. Consent should be obtained for any visual or audio recording, including photographs or other visual images. The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made. If it is to be used for teaching, 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. GMC guidance gives more 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 or research.

2. Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure. Whilst photography and video recordings may not be physically invasive, nor are they generally thought to carry significant physical risk to the patient, it should be remembered that they can be invasive of the patient's privacy, and there may be a risk that their subsequent use could adversely affect the patient's employment, social or personal life (e.g. through inappropriate publication). As such it is good practice generally to consider the need to obtain express written consent.

3. Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

4. Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.

5. If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

6. The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

7. If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of some-one close to the patient. You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

Appendix 9: 12 Key points on Consent: The law in England

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.
2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent but may indicate a need for further information or explanation.
3. Patients may be competent to make some health care decisions, even if they are not competent to make others.
4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

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

Who is the right person to seek consent?

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

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example, information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information

as they reasonably need to make their decision, and in a form, they can understand, their consent may not be valid.

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

Does it matter how the patient gives consent?

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

Refusal of treatment

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

Adults who are not competent to give consent

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

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

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment*, available from the NHS Response Line 08701 555 455 and at www.dh.gov.uk/consent.

Appendix 10: Consent Forms Used in this Organisation

1. The consent forms commonly used in Sulis facilities are:

   A. Consent Form 1 Patient Agreement to Investigation or Treatment

   B. Consent Form 2 Parental Agreement to Investigation or Treatment of a Child or Young Person

   C. Consent Form 4 Form for Adults Who are Unable to Consent to Investigation or Treatment

Appendix 11: How to seek a court declaration

Treatment of a patient who lacks capacity should proceed on the basis of what is in that patient's best interests (which are wider than merely his/her medical best interests). The views of the patient's family and carers should be elicited where possible, but they cannot consent on behalf of the patient. They can neither insist upon any particular course of action, nor can they veto it.

If the consequences of having, or not having, the treatment are potentially serious (e.g. as in the case of sterilisation of an adult with learning disability), then a court declaration may be sought.

It is generally prudent to obtain a second consultant opinion. Consideration should also be given to any alternative treatment, and an assessment made of the relative potential risks and benefits to the patient.

An application to the Court is a complex undertaking, involving major input from the clinicians involved in the patient's care. An Official Solicitor is appointed to represent the patient and protect his/her rights. The cost of seeking a Court Declaration falls to Sulis.

Procedure

Where a clinician is proposing treatment of an adult who lacks capacity, which may be viewed as controversial or the consequences of which may be serious, s/he should:

- Review any hospital medical records available in respect of the patient; and
- Meet the patient with his/her parents, carers or guardians to assess his/her medical and social situation.
- If the proposed treatment appears to be in the patient's best interests, then:
- If the patient is under the regular care of other consultants e.g. psychiatrists in the field of learning disability, communicate with them and elicit their views; and
- If the patient is not already under the supervision of a psychiatrist in the field of learning disability, consider making a referral for an assessment of competence to consent
- Inform the Risk & Assurance Team who will be responsible for:

A. Contacting legal counsel with a view to obtaining a Declaration Order;

B. Maintaining liaison between the clinician proposing the treatment, any other specialists involved in the patient's care and legal counsel.

The clinician proposing treatment should be prepared to speak with the legal counsel and may need to formulate a detailed statement to support the application which will be considered by the Official Solicitor and the Court. (The parents and other clinicians significantly involved in the patient's care may also be asked to provide statements).

The clinician proposing treatment should also be prepared to attend the Court hearing, to give evidence in person, though this may not be necessary in relatively straightforward cases, and where there is no dissent.

Appendix 12
EQUALITY IMPACT ASSESSMENT TOOL

	Equality Impact Assessment Tool	**Yes/No**	**Comments**
1.	Does the policy affect one group less or more favorably than another on the basis of:		
	☐ Race	No	
	☐ Ethnic origins (including gypsies and travellers)	No	
	☐ Nationality	No	
	☐ Gender	Yes	Possibly for transgender clients
	☐ Culture	No	
	☐ Religion or belief	No	
	☐ Sexual orientation including lesbian, gay and bisexual people	No	
	☐ Age	No	
	☐ Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
2.	Is there any evidence that some groups are affected differently?	Yes	Prisoners
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	Yes	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so, can the impact be avoided?	No	
6.	What alternatives are there to achieving the policy/guidance without the impact?	No	
7.	Can we reduce the impact by taking different action?	No	