CSP Consent Policy and Procedure

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INTRODUCTION

1.1 Policy statement

The purpose of this guidance document is to advise all staff of the principle of consent and that it is an important part of medical ethics based on the concept of the person and the fundamental dignity and equality of human beings. The notion of patients' rights was developed from the Universal Declaration of Human Rights which was first formalised in 1948.[1]

At Cotswold Surgical Partners, it is acknowledged that consent to treatment is the principle that a person must give permission before they receive any type of medical treatment, test or examination. This must be done on the basis of an explanation by a clinician. Consent from a patient is needed regardless of the procedure.

This policy should be read in conjunction with the following:

- DOH – Reference Guide to Consent for Examination or Treatment (2nd Ed.)
- GMC – Consent: Patients and Doctors Making Decisions Together
- Royal College of Surgeons for England – Consent

1.2 Status

This document and any procedures contained within it are non-contractual and may be modified or withdrawn at any time. For the avoidance of doubt, it does not form part of your contract of employment.

1.3 KLOE

The Care Quality Commission would expect any medical organisation to have a policy to support this process and this should be used as evidence of compliance against CQC Key Lines of Enquiry (KLOE)[2]. Specifically, Cotswold Surgical Partners will need to answer the CQC Key Questions on "Safe", "Effective" and "Caring"

The following is the CQC definition of Safe:

By safe, we mean people are protected from abuse and avoidable harm. *Abuse can be physical, sexual, mental or psychological, financial, neglect, institutional or discriminatory abuse.*

[1] World Health Organisation Patients' Rights
[2] https://www.cqc.org.uk

CQC KLOE S1 **1.1-1.4**	How do systems, processes and practices keep people safe and safeguarded from abuse?
S1.5	Do staff receive effective training in safety systems, processes and practices?
S6.2	What arrangements are there to manage risks appropriately, and to make sure that people are involved in decisions about any risks they may take?
S2.2	How do risk management policies and procedures minimise restrictions on people's freedom, choice and control, in particular for people who lack mental capacity?

The following is the CQC definition of Effective:

By effective, we mean that people's care, treatment and support achieve good outcomes, promote a good quality of life and are based on the best available evidence.

CQC KLOE E1	Are people's needs assessed and care and treatment delivered in line with current legislation, standards and evidence-based guidance to achieve effective outcomes?
E1.1	Are people's physical, mental health and social needs holistically assessed, and is their care, treatment and support delivered in line with legislation, standards and evidence-based guidance, including NICE and other expert professional bodies, to achieve effective outcomes?
E1.2	What processes are in place to ensure there is no discrimination, including in relation to protected characteristics under the Equality Act, when making care and support decisions?
E2.1	Do people have their assessed needs, preferences and choices met by staff with the right qualifications, skills, knowledge and experience?
E5.2	How does the service make sure that people can understand the information and explanations about their healthcare and treatment options, including medicines, and their likely outcomes?
E6.1	How are people involved in decisions about the environment?
E6.2	How do the premises meet people's diverse care, cultural and support needs?
E7.1	Do staff understand the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005 and the Children's Acts 1989 and 2004 and other relevant national guidance?

E7.2	How are people supported to make their own decisions in line with relevant legislation and guidance?
E7.3	How and when is possible lack of mental capacity to make a particular decision assessed and recorded?
E7.4	How is the process for seeking consent monitored and reviewed to ensure it meets legal requirements and follows relevant national guidance?
E7.5	When people lack the mental capacity to make a decision, how do staff ensure that best interests decisions are made in accordance with legislation?

The following is the CQC definition of Caring:

By caring, we mean that the service involves and treats people with compassion, kindness, dignity and respect.

CQC KLOE C1	How does the service ensure that people are treated with kindness, respect and compassion, and that they are given emotional support when needed?
C1.3	Do staff seek accessible ways to communicate with people when their protected and other characteristics under the Equality Act make this necessary to reduce or remove barriers?
C1.6	Do staff understand and promote compassionate, respectful and empathetic behaviour within the staff team?
C2.1	Do staff recognise when people need and want support from their carers, advocates or representatives to help them understand and be involved in their care, treatment and support? How do staff help people to get this support?
C2.3	Does the service give staff the time, training and support they need to provide care and support in a compassionate and personal way? Are rotas, schedules and practical arrangements organised so that staff have time to listen to people, answer their questions, provide information, and involve people in decisions?
C3.1	How does the service and staff make sure that people's privacy and dignity needs are understood and always respected, including during physical or intimate care?

1.4 Training and support

Cotswold Surgical Partners will provide guidance and support to help those to whom it applies to understand their rights and responsibilities under this policy. Additional support will be provided to managers and supervisors to enable them to deal more effectively with matters arising from this policy.

Consent training is available on the HUB.

Specific consent training is a core part of induction training on our Bluestream training platform and induction checklist.

Specific training on Mental Capacity is a core part of induction training on our Bluestream training platform and induction checklist.

2 Scope

2.1 Who it applies to

This document applies to all employees of Cotswold Surgical Partners and other individuals performing functions in relation to Cotswold Surgical Partners, such as those granted Practising Privileges status across all operating locations.

2.2 Why and how it applies to them

This document defines the phraseology associated with consent and provides detailed information for all clinical staff, ensuring they fully understand the need to obtain consent. It is to be read in conjunction with the referenced publications and staff are to adhere to the direction given within this policy.

Cotswold Surgical Partners aims to design and implement policies and procedures that meet the diverse needs of our service and workforce, ensuring that none are placed at a disadvantage over others, in accordance with the Equality Act 2010. Consideration has been given to the impact this policy might have with regard to the individual protected characteristics of those to whom it applies.

Cotswold Surgical Partners has retained the HR consultancy of Peninsula to ensure that legal requirements in accordance with Employment Legislation are complied with and to develop and promote effective employment policies and procedures with a view to creating within the business a climate of good employment practice, employee relations and equal opportunities for all staff.

Peninsula has also been retained to provide competent technical advice and practical support in the management of Health, Safety and Wellbeing within our business. This is supported by our commitment as a MindfulEmployer and a member of Health Assured's Employee Assistance program. Policy support can be provided from Peninsula.

3 Definition of terms[3]

3.1 Voluntary consent

[3] NHS England Consent to Treatment

The decision regarding whether or not to consent must be made by the individual and must not be influenced by healthcare professionals, friends or family members.

3.2 Informed consent

The patient must be given all the information regarding what the procedure or treatment involves. This includes the associated benefits and risks, information about alternative treatments and the consequences if the procedure or treatment is declined.

Cotswold Surgical Partners has processed and procedures in place to support this including, confirmation checks on booking, WHO checklists and the use of relevant consent forms prior to any procedure.

CSPC001 NHS consent form 4 (lacking capacity)
CSPC005 Consent form 1

3.3 Capacity

The person must be capable of giving consent which means they fully understand the information given to them and can use it to make an informed decision.

4 Policy

4.1 General overview

Consent must be voluntary and informed if it is to be deemed valid, whilst the person consenting must have the capacity to do so.

See extract from https://www.medicalprotection.org/uk/articles/consent-uk dated 6 January 2020:

Respect for patients' autonomy is expressed in consent law; to impose care or treatment on people without respecting their wishes and right to self-determination is not only unethical, but illegal.

For consent to be valid:

- *The patient must be competent and mental capacity is decision-specific. Assessment of a person's capacity should be based on his/her ability to understand, retain and weigh in the balance the information relevant to a particular decision. The person must also be able to communicate the decision.*
- *The patient must have sufficient information to make a choice as, without adequate information, patients are unable to make decisions about their treatment. Patients should be given time to ask questions. The GMC and the*

courts expect patients to be given all information material to their decision, with the proviso that it would not cause the patient serious harm.

- *The patient must be able to give their consent freely as pressuring patients into consenting to treatment invalidates the consent.*

Clinicians must respect the decision of an adult who has the capacity to make a voluntary and informed decision, regardless of the consequences. If, however, an adult does not have capacity, clinicians can administer treatment if it is in the best interest of the patient.

In such instances, clinicians should seek guidance from the patient's relatives or friends using CSPC001.

Clinicians must be mindful that a patient's capacity to give consent may be temporarily affected by factors such as pain, fatigue, illness or the side effects of medication. In such cases, clinicians must not assume the patient does not have the capacity to consent. Consent can be attempted as another date/time with the support of the patient and those involved in their care.

Following the Montgomery ruling in 2015 by the Supreme Court, we understand that "*The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments".*

"The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

4.2 Giving consent

Consent can be given by a patient in two ways:

- Verbally – consenting to an examination or procedure such as an injection by word of mouth

- Written – signing a consent form for minor surgery or other procedures

4.3 Is a consent form enough?

As detailed at section 4.1, sufficient information must be given for the patient to make their choice. Simply having a signed consent form only provides evidence that consent was obtained at that time, it does not constitute proof that the consent was valid.

This is additionally confirmed at the CQC's Nigel's surgery 49 and therefore the form at Annex A has been created to state that the patient has been fully briefed about the procedure and states the following:

"I understand the need for and consent to the procedure detailed above. I confirm that I have been given all the required information about the procedure, including techniques, aftercare, benefits, risks and the required follow-up process.

I also have been advised of my rights as a patient".

Any consent form should be used in conjunction with the clinician completing a full clinical record.

4.4 Recording consent in the patient's clinical record

It is imperative that the clinician records the key elements of their discussion with the patient with regard to consent. Should there ever be any dispute as to whether valid consent was obtained, the key issue will not be whether the patient did or did not sign a form but whether they were given all the information needed to make a considered decision.

From a legal perspective, it is essential that a full record of any discussion with regard to the likely outcome of any treatment or procedure is detailed. The presence of this within the medical record will ensure that evidence of how the patient reached their considered decision was made.

Should the form at Annex A not be used, then the patient record should be comprehensive and include the following:

- Brief summary of the discussion with the patient
- Details of any decision(s) that were made
- Any requests made by the patient
- Any information given to the patient including a handout, visual or audio information

If it has been some time since the initial or last consent agreement was made, or should the patient's condition have changed, or if new information has become available since a patient gave consent, the clinician must again go through the process of obtaining new or further patient consent.

The entry is to be made using an appropriate SNOMED CT consent code.

The generic 'Consent' code is SCTID: 61861000000100, although it should be noted that there are many other codes that can be used which are more specific to the type of consent given by searching:

SNOMED-CT Code browser

4.5 When consent is not needed

There are a few exceptions when treatment may be able to proceed without the person's consent, even if they are capable of giving their permission.

NHS England's *Consent to Treatment* (see footnote 5) details the following reasons why it may not be necessary to obtain consent:

- The patient needs emergency treatment to save their life but they are incapacitated, for example, they are unconscious. However, the reasons why treatment was necessary should be fully explained once they have recovered

- There is an immediate need for an additional emergency procedure during an operation and there has to be a clear medical reason why it would be unsafe to wait to obtain consent

- The patient with a severe mental health condition, such as schizophrenia, bipolar disorder or dementia, lacks the capacity to consent to the treatment of their mental health (under the Mental Health Act 1983)

  In these cases, treatment for unrelated physical conditions still requires consent which the patient may be able to provide despite their mental illness

- The patient needs hospital treatment for a severe mental health condition but self-harmed or attempted suicide while competent and is refusing treatment (under the Mental Health Act 1983)

  In these instances, the person's nearest relative or an approved social worker must make an application for the person to be forcibly detained in hospital and two doctors must assess the person's condition

- There is a risk to public health as a result of rabies, cholera or tuberculosis (TB)

- A person who is severely ill or infirm and living in unsanitary conditions can be taken to a place of care without their consent.

  This falls under the National Assistance Act 1948.

4.6 Implied consent

Implied consent is where a patient does not give either verbal or written consent but the actions of the patient demonstrate consent, such as:

- A patient rolling up a sleeve to have their blood pressure taken

- A patient holding out an arm to have a blood sample taken

- A patient opening their mouth to have their throat examined

Patients can withdraw consent at any time and, if this occurs, clinicians must stop the procedure safely, listen to the concerns of the patient and explain the consequences of not finishing the procedure.

It should be noted that implied consent is still valid within a clinical setting.

4.7 Obtaining consent

It is the responsibility of the clinician carrying out the procedure or examination to obtain consent from the patient. The amount of information the clinician needs to provide varies on a case-by-case basis but the clinician will in all scenarios:

- Try to ascertain the patient's individual needs and wishes
- Ensure the patient has the capacity to consent
- Explain the requirement for and purpose of the procedure, examination or treatment
- Discuss the options available to the patient including the option not to proceed
- Give an explanation of the benefits and associated risks or side effects
- Discuss the possibility of any issues which may arise during the process
- Answer any questions the patient may ask prior to consenting
- Explain that the clinician conducting the examination, procedure or treatment will obtain the patient's consent
- Remind the patient that they can withdraw consent at any time
- Reassure the patient that the examination, treatment or procedure is for their benefit but that the overall choice to proceed rests with them
- Offer the patient the option of a second opinion
- Provide advice regarding the post-examination, treatment or procedure recovery process
- Where applicable, a consent form will be completed and signed by the patient

The form at Annex A should be amended in accordance with UK Government guidance as appropriate to accommodate:

- Parental agreement to the investigation of or treatment for a child
- Combined patient/parental agreement to investigation or treatment
- Adults who are unable to consent to an investigation or treatment.

This list is not exhaustive and clinicians must ensure that the patient has been given all the necessary information available in order for them to make a voluntary, informed decision.

4.8 Delegation of responsibility for obtaining consent

The clinician undertaking the procedure or treatment may delegate the responsibility for seeking patient consent to someone else provided that they are satisfied that the person to whom this delegation is given:

- Has sufficient knowledge and understands the risks involved in the proposed investigation or treatment
- Is suitably trained and qualified and acts in accordance with the guidance contained in the GMC publication on Consent

4.9 Consent for children and young people

Cotswold Surgical Partners does not offer a service to those below the age of 18. The below can be noted for reference purposes.

Young people aged 16 to17 are presumed to be capable of consenting to medical examinations, treatments or procedures. As per adults, consent will only be deemed valid if it is given voluntarily by an appropriately informed young person.

The General Data Protection Regulation (GDPR) does not alter the principle of Gillick competence. A child under the age of 16 may be Gillick competent to give consent to medical examinations, treatments or procedures. Gillick competence shows that a child under the age of 16 who 'has sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention'.[4]

However, it is deemed good practice to involve the family or carers of the child in the decision-making process providing the child is content for this information to be shared.

Children under 16 may have the capacity to consent to some examinations, treatments and procedures but not others. Therefore, parental consent should be sought and recorded accurately when it is deemed they are not Gillick competent. Additionally, parental consent is not necessary when a child is receiving counselling or preventative care.

Specific information detailing a child who withholds consent can be sought from www.medicalprotection.org/uk/articles/consent-uk

[4] Reference guide to consent for examination or treatment

4.10 Lack of mental capacity

Patients who do not have the capacity to make an informed, voluntary decision are protected under the Mental Health Act (MHA) 2005. The MHA only applies to those patients living in England and Wales.

A person is defined as lacking capacity if 'they are unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain'.

Patients lacking capacity have the following rights:

- All decisions will be made in the best interest of the patient
- The liberty of a patient will only be taken in very specific situations. This is referred to as a deprivation of liberty and will only be used if it is the least restrictive way of keeping a patient safe or ensuring the correct medical treatment is provided
- To have support from an advocate. This is someone who acts on the patient's behalf but does not have legal authority to make personal or financial decisions on behalf of the patient
- To have a deputy appointed by the court to make personal or financial decisions for the patient
- To receive guidance from the Court of Protection

The MHA 2005 requires that appropriate steps are taken to enable the patient to make the decision for themselves. These include:

- Providing relevant information, including choice regarding alternative treatment/procedures
- Communicating in an appropriate way, i.e. presenting information in a different manner so it is easier for the patient to understand
- Putting the patient at ease, discussing the matter when the patient feels confident to do so, such as in the morning or afternoon
- Seeking additional support so the patient has a friend or relative who is able to help them to understand and make a choice

For detailed information relating to the deprivation of liberty, refer to the Mental capacity act policy or https://www.mind.org.uk/information-support/legal-rights/mental-capacity-act-2005/deprivation-of-liberty/

4.11 Summary

Patients have a moral and legal right to determine what happens to their own bodies. Seeking and obtaining valid consent is a fundamental process in healthcare; it is the patient's agreement for the clinician to provide care.

All staff at Cotswold Surgical Partners are to adhere to this policy and, should doubt arise, they are to seek guidance from Mr Reynolds, plastic surgeon.

5 Annex A – Consent form – CSPC005

Cotswold Surgical Partners, Unit 13 Interface Business Park, Royal Wootton Bassett, Wiltshire SN4 8SY
Tel: 0808 280 3560 Email: bswccg.csp@nhs.net

CONSENT FORM 1

Patient Details

NAME OF PROCEDURE UNDER LOCAL ANAESTHETIC.....

.....

I confirm that I have explained to the patient, the procedure and local anaesthetic required in terms, which in my judgement are suited to the understanding of the patient.

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

Name of Doctor ..... ☐ **Check NO PACEMAKER**

Check list: ☐ Pain ☐ Bleeding ☐ Infection ☐ Other ☐ Incomplete excision
☐ Scar ☐ Persistent symptoms ☐ Poor result ☐ Further operation

PATIENT

1. Please read this form and the notes below very carefully.
2. If there is anything that you do not understand about the explanation, or if you want more information, you should ask the doctor.
3. Please check that all the information on this form is correct. If it is and you understand the explanation, then sign the form.

I am the patient, I AGREE

- To have this procedure, it has been explained to me by the doctor named on this form
- To the administration of a local anaesthetic for the operation

I UNDERSTAND

- That the operation may sometimes be unsuccessful and that there is a small chance that the symptoms may persist or be worse after the operation
- That procedures may lead to pain, bleeding, scarring or infection

I HAVE TOLD

Signature:.....

Patient's Name.....

Date.....

CONSENT FOR CLINICAL PHOTOGRAPHY

We may photograph a lesion(s) before and after removal. We use these photographs to discuss management of your case with our consultant colleagues in the hospital. All photographs are anonymised. All photographs are stored in a secure server that has no public access.

I consent to medical photography in the above circumstances at Cotswold Surgical Partners, signed by the patient or nominated/designated person with responsibility.

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

NOTES TO DOCTORS

A patient has a legal right to grant or withhold consent prior to examination or treatment. Patients should be given sufficient information, in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment, and they may refuse or withdraw consent to treatment at any time. The patients' consent to treatment should be recorded on this form (further guidance is given in HC (90)22: A guide to Consent for Examination or Treatment.

NOTES TO PATIENTS

The doctor is here to help you. He or she will explain the proposed treatment and what alternatives are. You can ask any questions and seek further information.
You can refuse treatment. You may ask for a relative, friend or nurse to be present.

1 Copy - CSP
1 Copy - Patient

COTSWOLD
SURGICAL PARTNERS
QUALITY CARE, LOCALLY DELIVERED

Cotswold Surgical Partners, Unit 13 Interface Business Park, Royal Wootton Bassett, Wiltshire SN4 8SY
Tel: 0808 280 3560 Email: bswccg.csp@nhs.net

GUIDANCE TO HEATH PROFESSIONAL (TO BE READ IN CONJUNCTION WITH CONSENT POLICY)

This Form
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 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 them to understand fully what is proposed", then they will be competent to give consent for themselves. 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 themselves, someone with parental responsibility may do so on their behalf. Even where a child is able to give consent for themselves, 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 for themselves.

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 if 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.doh.gov.uk/consent).