**Consent Guidance**

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**Table of contents**

[1 Introduction 3](#_Toc91750325)

[1.1 Policy statement 3](#_Toc91750326)

[1.2 Status 3](#_Toc91750327)

[1.3 KLOE (England only) 3](#_Toc91750328)

[1.4 Training and support 4](#_Toc91750332)

[2 Scope 4](#_Toc91750333)

[2.1 Who it applies to 4](#_Toc91750334)

[2.2 Why and how it applies to them 5](#_Toc91750336)

[3 Definition of terms 5](#_Toc91750337)

[3.1 Voluntary consent 5](#_Toc91750338)

[3.2 Informed consent 5](#_Toc91750339)

[3.3 Capacity 5](#_Toc91750340)

[3.4 Age of consent 5](#_Toc91750341)

[3.5 Gillick competence 6](#_Toc91750342)

[3.6 Fraser guidelines 6](#_Toc91750343)

[4 Policy 6](#_Toc91750344)

[4.1 General overview 6](#_Toc91750345)

[4.2 Key principles for consent 7](#_Toc91750346)

[4.3 Giving consent 8](#_Toc91750347)

[4.4 Is a consent form enough? 8](#_Toc91750348)

[4.5 Recording consent in a patient’s clinical record 8](#_Toc91750349)

[4.6 When consent is not needed 9](#_Toc91750352)

[4.7 Implied consent 10](#_Toc91750353)

[4.8 Obtaining consent 10](#_Toc91750354)

[4.9 Delegation of responsibility for obtaining consent 11](#_Toc91750355)

[4.10 Consent for children and young people 11](#_Toc91750356)

[4.11 Safeguarding concerns for under 16-year-olds 12](#_Toc91750357)

[4.12 Contact details for young people 12](#_Toc91750358)

[4.13 Parental consent 13](#_Toc91750359)

[4.14 Immunisations 13](#_Toc91750360)

[4.15 Lack of mental capacity 13](#_Toc91750361)

[4.16 Summary 14](#_Toc91750362)

[Annex A – Consent form 15](#_Toc91750363)

# Introduction

## 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]](#footnote-1)

**At Knowle House and Tamerton Surgery, 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.)](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf)
* [Royal College of Surgeons for England – Consent](https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/)
* [GP Mythbuster – Gillick competency and Fraser guidelines](https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-8-gillick-competency-fraser-guidelines)
* [GP Mythbuster 49 – Consent for Minor Surgery in GP surgeries](https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-49-consent-minor-surgery-gp-surgeries)

## 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.

## KLOE (England only)

The Care Quality Commission would expect any primary care 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]](#footnote-2). Specifically, Knowle House and Tamerton Surgery 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.*

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| --- | --- |
| **CQC KLOE S1** | How do systems, processes and practices keep people safe and safeguarded from abuse? |
| **CQC KLOE S3** | Do staff have all the information they need to deliver safe care and treatment to people? |

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.*

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| **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? |
| **CQC KLOE E6** | Is consent to care and treatment always sought in line with legislation and guidance? |

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.*

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| **CQC KLOE C3** | How are people's privacy and dignity respected and promoted? |

## Training and support

The organisation 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 through: [Dashboard - Management System (bluestreamacademy.com)](https://elearning.bluestreamacademy.com/gpmis/)

# Scope

## Who it applies to

This document applies to all employees of the organisation and other individuals performing functions in relation to the organisation such as agency workers, locums and contractors.

Furthermore, it applies to clinicians who may or may not be employed by the organisation but who are working under the Additional Roles Reimbursement Scheme (ARRS).[[3]](#footnote-3)

## 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.

The organisation 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](https://www.legislation.gov.uk/ukpga/2010/15/contents). Consideration has been given to the impact this policy might have with regard to the individual protected characteristics of those to whom it applies.

# Definition of terms[[4]](#footnote-4)

## Voluntary consent

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.

## 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.

## 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.

## Age of consent

In law, the [Children Act 1989](https://www.legislation.gov.uk/ukpga/1989/41/contents) defines that it is a person's 18th birthday that draws the line between childhood and adulthood.

In health care matters, an 18-year-old enjoys as much autonomy as any other adult. To a more limited extent, 16 and 17-year-olds can also take medical decisions independently of their parents. The right of younger children to provide independent consent is proportionate to their competence. Therefore, a child's age alone is an unreliable predictor of any competence when making or considering a decision.

## Gillick competence

Medical professionals need to consider Gillick competency if a young person under the age of 16 wishes to receive treatment without their parents' or carers' consent or, in some cases, knowledge.

Further reading can be sought from [NSPCC Learning](https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines#heading-top) or [GP Mythbuster 8 – Gillick competence and Fraser guidelines.](https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-8-gillick-competency-fraser-guidelines)

## Fraser guidelines

The Fraser guidelines apply specifically to advice and treatment about contraception, sexual health and termination of pregnancy. They may be used by healthcare professionals working with under 16-year-olds.

Further reading can be sought from [NSPCC Learning](https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines#heading-top) or [GP Mythbuster 8 - Gillick competence and Fraser guidelines.](https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-8-gillick-competency-fraser-guidelines)

# Policy

## 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 [medicalprotection.org](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.

## Key principles for consent

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.

The British Medical Association summarised landmark case [Montgomery Vs Lanarkshire Health Board](https://www.bmj.com/content/357/bmj.j2224) in 2015, this stated that doctors\* must not:

* Make assumptions about what a patient needed to know
* Must take reasonable care to ensure that the patient is aware of any material risks involved in any treatment, and of any reasonable alternative or variant treatments

The British Medical Association [Consent toolkit for doctors](https://www.bma.org.uk/advice-and-support/ethics/seeking-consent/seeking-patient-consent-toolkit) further details this case.

The Royal College of Surgeons has described [key principles for consent and supported decision making](https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/) and advises that any discussion about consent should:

* Aim to give the patient information they need to make a decision about what treatment or procedure (if any) they want
* Be tailored to the individual patient – this needs time to get to know the patient well enough to understand their views and values
* Explain all reasonable treatment options, along with their implications
* Include all material risks for each option. This ‘test of materiality’ includes whether:
	+ In this 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 likely attach significance to it

Furthermore, the General Medical Council provides [guidance](https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent) on consent and its guidance details information on how to:

* Assess capacity
* Record decisions
* Share information

The GMC guidance also reiterates the importance of providing information the patient can understand and that before beginning any treatment, the doctor or a member of the healthcare team should confirm that the patient still wants to proceed.

\*Note, for ‘doctors’ read ‘any clinician’.

## 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

## 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 and may simply be used as a checklist.

This is additionally confirmed at the [CQC GP Mythbuster No 49](https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-49-consent-minor-surgery-gp-surgeries) and therefore the form at [Annex A](#_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.

## Recording consent in a 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](#_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 hard copies or internet links, patient information leaflet and any other 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](https://digital.nhs.uk/services/terminology-and-classifications/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:

## 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* 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](https://www.gov.uk/government/publications/code-of-practice-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](http://www.legislation.gov.uk/ukpga/Geo6/11-12/29/contents).

## 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.

## 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](#_Annex_A_–) should be amended in accordance with UK Government [guidance](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138297/dh_103652.pdf) 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.

## 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 [BMA patient consent toolkit](https://www.bma.org.uk/media/2481/bma-consent-toolkit-september-2019.pdf)

## Consent for children and young people

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’.[[5]](#footnote-5)

There is a duty to keep the child’s best interests at the heart of any decision and the child or young person should be involved in the decision-making process as far as possible. 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.

It should be noted that whilst there is no lower age limit for Gillick competence or Fraser guidelines to be applied, it would rarely be appropriate or safe for a child who is under 13 years of age to consent to treatment without a parent’s involvement.

Further detailed information on obtaining permission for children and young people can be sought from [GP Mythbuster 8 – Gillick competence and Fraser guidelines](https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-8-gillick-competency-fraser-guidelines). Specific information detailing a child who withholds consent can be sought from [medicalprotection.org](https://www.medicalprotection.org/uk/articles/consent-uk).

## Safeguarding concerns for under 16-year-olds

If a young person under the age of 16 presents to a health care professional, then discloses a history raising safeguarding concerns:

* If they are not deemed to be Gillick competent, the health professional is obliged to raise the issue as a safeguarding concern and escalate their concerns through the safeguarding process
* If they are deemed to be Gillick competent and disclosure is considered essential to protect them from harm or to be in the public interest, the health professional should escalate concerns through the safeguarding processes
* In both cases, the health professional should inform the young person of this action, unless doing so could pose significant additional risk for their safe care.

It is reasonable for the local authority or police to decide whether it is appropriate to inform the parents of the concerns raised. In some circumstances, this may not be in the best interest of the young person.

When it comes to sexual health, those under 13 are not legally able to consent to any sexual activity and therefore any information that such a person was sexually active would need to be acted on regardless of the results of the Gillick test.

## Contact details for young people

At Knowle House and Tamerton Surgery, we will consider requests from young persons who may wish for their personal contact details to be used to contact them as opposed to their parents or those who have parental control.

In these instances, we will always consider the patient’s capacity and whether this is in their best interest.

## Parental consent

In the case of immunisation, the consent of one adult is usually acceptable (Section 2(7) of the [Children Act 1989](https://www.legislation.gov.uk/ukpga/1989/41)) but, if one adult consents and the other disagrees, the immunisation should not be carried out unless both adults with parental responsibility agree to the immunisation or there is court approval for the immunisation to be administered as it is in the best interests of the child.

The Department of Health and Social Security (DHSS) also states that immunisation is an ‘important decision’ and immunisations should not be administered if two adults with parental responsibility cannot reach an agreement. In such cases, it is advised that the decision be referred to the courts.

At Knowle House and Tamerton Surgery, should there be a dispute, the senior partner and senior manager are to be consulted as to the most appropriate way to resolve the dispute. The advice of the clinician’s medical protection body should, where necessary, be obtained.

Specific information detailing parental withholding consent can be sought from [medicalprotection.org](https://www.medicalprotection.org/uk/articles/consent-uk).

## Immunisations

The general principles of consent apply to the administering of immunisations by either a GP or nurse. The process of obtaining consent should be the same whether the consent obtained is written, verbal or implied (e.g., holding out an arm to be vaccinated).

In accordance with the Green Book[[6]](#footnote-6): ‘There is no legal requirement for consent to immunisation to be in writing and a signature on a consent form is not conclusive proof that consent has been given, but serves to record the decision and the discussions that have taken place with the patient or the person giving consent on a child’s behalf’.

For a patient requiring a course of vaccinations, consent must be obtained each time they attend to have a vaccination.

## 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](http://www.legislation.gov.uk/ukpga/2005/9/contents). 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](https://practiceindex.co.uk/gp/forum/resources/mental-capacity-act-policy.1105/) or [www.mind.org.uk](https://www.mind.org.uk/information-support/legal-rights/mental-capacity-act-2005/deprivation-of-liberty/).

## 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 Knowle House and Tamerton Surgery are to adhere to this policy and, should doubt arise, they are to seek guidance from the Compliance and IT Manager.

# Annex A – Consent form

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| --- |
| **[INSERT ORGANISATION] CONSENT FORM****PATIENT AGREEMENT TO INVESTIGATION OR TREATMENT**  |
| This form is to be used for treatment, immunisation, examination or minor operation |
| **PATIENT DETAILS** |
| **Surname** |  | **Forename** |  |
| **Title** |  | **Sex** |  |
| **NHS No.** |  | **Date of birth** |  |
| **PROCEDURE DETAILS** |
| The clinician has discussed with the patient the following:* The nature of the procedure, techniques used and aftercare
* The associated benefits and risks
* Any follow-up procedures, examinations or other pertinent information
* The rights of the patient
 |
| **Name of clinician** |  | **Title (Dr, nurse, etc.)** |  |
| **Date of procedure** |  | **Location** |  |
| **Type of procedure** |  |
| **Clinician’s signature, print name and date** |  |  |
| **PATIENT CONSENT** |
| 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. |
| **Signature of patient** |  |
| **Date of signature** |  |

1. [World Health Organisation Patient Safety and Rights](https://www.euro.who.int/__data/assets/pdf_file/0018/133128/e94739.pdf) [↑](#footnote-ref-1)
2. [cqc.org.uk](https://www.cqc.org.uk/sites/default/files/20180628%20Healthcare%20services%20KLOEs%20prompts%20and%20characteristics%20FINAL.pdf) [↑](#footnote-ref-2)
3. [Network DES Contract specification 2021/22](https://www.england.nhs.uk/publication/network-contract-des-specification-2021-22/) [↑](#footnote-ref-3)
4. [NHS England Consent to Treatment](http://www.nhs.uk/conditions/consent-to-treatment/pages/introduction.aspx) [↑](#footnote-ref-4)
5. [Reference guide to consent for examination or treatment](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf) [↑](#footnote-ref-5)
6. [Green Book, Chapter 2 - Consent](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2) [↑](#footnote-ref-6)