**Consent Guidance**

**Table of contents**

[1 Introduction 2](#_Toc185410485)

[1.1 Policy statement 2](#_Toc185410486)

[1.2 Status 2](#_Toc185410487)

[2 Definition of terms 2](#_Toc185410488)

[NHS England provides the following definitions: 2](#_Toc185410489)

[3 Policy 3](#_Toc185410490)

[3.1 General overview 3](#_Toc185410491)

[3.2 Key principles for consent 3](#_Toc185410492)

[3.3 Giving consent 4](#_Toc185410493)

[3.4 Consent forms 4](#_Toc185410494)

[3.5 Recording consent in a patient’s clinical record 4](#_Toc185410495)

[3.6 When consent is not needed 4](#_Toc185410496)

[3.7 Obtaining consent 5](#_Toc185410497)

[3.8 Delegation of responsibility for obtaining consent 5](#_Toc185410498)

[3.9 Consent for children and young people 6](#_Toc185410499)

[3.10 Under 16 safeguarding considerations 6](#_Toc185410500)

[3.11 Contact details for young people 6](#_Toc185410501)

[3.12 Parental consent 7](#_Toc185410502)

[3.13 Immunisations 7](#_Toc185410503)

[3.14 Lack of mental capacity 7](#_Toc185410504)

[Annex A – Consent form 8](#_Toc185410505)

# Introduction

## Policy statement

The purpose of this guidance document is to ensure that, in **accordance with the** [Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11](https://www.cqc.org.uk/guidance-providers/regulations/regulation-11-need-consent)**,** all people using Coast Health, and those lawfully acting on their behalf, have given consent before any care or treatment is provided. Staff will obtain consent lawfully and ensure that the person who obtains the consent has the necessary knowledge and understanding of the care and/or treatment that they are asking consent for.

## Status

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 regarding the individual protected characteristics of those to whom it applies.

This document and any procedures contained within it are non-contractual and may be modified or withdrawn at any time.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. Furthermore, 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.

# Definition of terms

## [NHS England](https://www.nhs.uk/conditions/consent-to-treatment/#:~:text=voluntary%20–%20the%20decision%20to%20either,medical%20staff%2C%20friends%20or%20family) provides the following definitions:

* **Voluntary consent**: The decision to either consent or not to consent to treatment must be made by the person and must not be influenced by pressure from medical staff, friends or family.
* **Informed consent:** The person must be given all the information regarding what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments and what will happen if the procedure or treatment does not go ahead.
* **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.
* **Children and consent:** People aged 16 or over are entitled to consent to their own treatment. Children under the age of 16 can consent to their own treatment if they are Gillick Competent. NHS England’s [Children and young people webpage](https://www.nhs.uk/conditions/consent-to-treatment/children/) provides additional information.

[CQC GP Mythbuster 8: Gillick competency and Fraser guidelines](https://www.nhs.uk/conditions/consent-to-treatment/children/) provides the following definitions:

* **Gillick competence:** Is concerned with determining a child’s capacity to consent. Children under 16 can consent if they have sufficient understanding and intelligence to fully understand what is involved in a proposed treatment.
* **Fraser guidelines:** Specifically relate only to contraception and sexual health. They may be used by healthcare professionals working with under 16-year-olds.

# Policy

## General overview

NHS England explains that for consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. If an adult has the capacity to make a voluntary and informed decision to consent or refuse a particular treatment, their decision must be respected.

If a person does not have the capacity to make a decision about their treatment and they have not appointed a lasting power of attorney (LPA), the healthcare professional(s) treating them can proceed to give treatment if they believe this is in the person’s best interests.

## 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.

At this organisation, clinicians are to adhere to the General Medical Council (GMC) [Decision making and consent guidance](https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/decision-making-and-consent/the-seven-principles-of-decision-making-and-consent) which details the seven principles of decision making and consent:

1. All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.
2. Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.
3. All patients have the right to be listened to, and to be given the information they need to make an informed decision and the time and support they need to understand it.
4. Doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.
5. Doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.
6. The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.
7. Patients whose right to consent is affected by law should be supported to be involved in the decision-making process and to exercise choice if possible

## Giving consent

A patient may give their consent in the following ways:

|  |  |
| --- | --- |
| **Type** | **Action** |
| 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 |
| Implied or non-verbal | A patient may also give non-verbal consent as long as they understand the treatment or examination about to take place. An example would be to hold out an arm for a blood test.  Implied consent is still valid within a clinical setting. |
| 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. | |

## Consent forms

[Medical Protection](https://www.medicalprotection.org/uk/articles/eng-consent-the-basics) explains that completed consent forms provide some evidence that consent was obtained but they do not constitute as proof that the consent was valid.

A consent form template can be found at [Annex A](#_Annex_A_–) or the electronic version of the consent form on the clinical system may be used.

## Recording consent in a patient’s clinical record

When recording consent in the patient’s clinical record (and not using the form at Annex A), the following information is to be recorded:

* What was discussed with the patient about the proposed procedure
* Any alternative treatment plans
* Likely benefits and risks
* An indication the patient has given consent

## When consent is not needed

[NHS England Consent to Treatment](https://www.nhs.uk/conditions/consent-to-treatment/) details the exceptions when treatment may be able to proceed without the person's consent, even if they are capable of giving their permission.

## 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 that 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
* When 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

The DHSC [Reference guide to consent for examination or treatment](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf) explains that a child under the age of 16 may be Gillick competent to give consent to medical examinations, treatments or procedures.

The [MPS](https://www.medicalprotection.org/uk/articles/consent-uk) advises that if the child is not Gillick competent, the parents can consent on behalf of the child, even if the child is refusing the treatment. However, clinicians should consider carefully whether overriding the consent of a distressed child, given the clinical circumstances at the time, is necessary. If sufficient time is given, the parents will be able to encourage the child that the intervention will be beneficial.

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.

A competent child is legally entitled to withhold consent to treatment. However, if the treating clinician believes that the withholding of consent may be detrimental to the patient’s wellbeing, legal advice may be required. It may be necessary for a court to determine whether treatment can be given against the wishes of the competent young person.

It should be noted that while 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.

## Under 16 safeguarding considerations

[CQC GP Mythbuster 8: Gillick competency and Fraser guidelines](https://www.cqc.org.uk/guidance-providers/gps/gp-mythbusters/gp-mythbuster-8-gillick-competency-fraser-guidelines) outlines the actions to be taken should a patient disclose safeguarding concerns.

## Contact details for young people

At this organisation, 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 will be considered. In these instances, the organisation always considers the patient’s capacity and whether this is in their best interest.

## Parental consent

[NHS England](https://www.nhs.uk/conditions/consent-to-treatment/children/) provides guidance on parental responsibility and consent, including parental disagreements.

[The Green Book](https://assets.publishing.service.gov.uk/media/65290228244f8e00138e7524/Green-book-chapter-2-consent-12oct23.pdf), Chapter 2, covers the principles of consent for immunisation, explaining that 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.

Should there be any dispute, a senior clinician and the Organisation Manager are to be consulted as to the most appropriate way to resolve the dispute. The advice of the medical protection body should, when necessary, be obtained.

## Immunisations

In accordance with [The Green Book – Consent](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2), there is no requirement for consent to immunisation to be in writing, but it is good clinical practice to record that a discussion has taken place and consent has been obtained. The completion of a consent form is not a substitute for the provision. 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”.

NHS England provides detailed guidance on [Assessing capacity and consent to treatment](https://www.nhs.uk/conditions/consent-to-treatment/capacity/). Additional guidance can be found in the organisation’s [Mental Capacity Act Policy](file:///\\21736-serv3\shared\Letters\PRACTICE%20POLICIES\.STAFF%20HANDBOOK%20AND%20ASSOCIATED%20POLICIES%202018\2024\Mental%20capacity%20act%20policy%20UPDATES.docx) and [www.mind.org.uk](https://www.mind.org.uk/information-support/legal-rights/mental-capacity-act-2005/deprivation-of-liberty/).

# Annex A – Consent form

|  |  |  |  |
| --- | --- | --- | --- |
| **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** |  | **Role** |  |
| **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** |  | | |