

CONSENT PROTOCOL

Introduction

The purpose of this protocol is to set out the practice's approach to consent and the way in which the principles of consent will be put into practise. It is not a detailed legal or procedural resource due to the nature and complexity of the issues surrounding consent.

Where possible, a clinician must be satisfied that a patient understands and consents to a proposed treatment, immunisation or investigation, as well as the nature, purpose, benefits and risks of the procedure. Drawings, interpreters, videos or other means may be used to help ensure that the patient understands the situation, and has enough information to give 'Informed Consent'.

Implied Consent

Implied consent will be assumed for many routine physical contacts with patients. Where implied consent is to be assumed by the clinician, in all cases, the following will apply:

- An explanation will be given to the patient with regards to what the clinician is about to do, and why.
- The explanation will be sufficient for the patient to understand the procedure.
- In all cases where the patient is under 18 years of age, a verbal confirmation of consent will be obtained and entered into the medical record.
- Where there is a significant risk to the patient, "Expressed Consent" is to be obtained in all cases (see below).

Expressed Consent

Expressed consent (written or verbal) will be obtained for any procedure which carries a risk that the patient is likely to consider as being substantial. A note will be made in the medical record detailing the discussion about the consent given and the risks of the procedure. A Consent Form [*] may be used for the patient to express consent (see below) which should then be attached to the clinical record.

Obtaining Consent

- Consent (Implied or Expressed) will be obtained prior to the procedure, and prior to any form of sedation.

- The clinician will ensure that the patient is competent to provide a consent (i.e. is 16 years old or over) or has “Gillick Competence” if under 16 years. Further information about Gillick Competence and obtaining consent for children is set out below.
- Consent will include the provision of all information relevant to the treatment.
- Questions posed by the patient will be answered honestly, and information necessary for the informed decision will not be withheld unless there is a specific reason to withhold. In all cases where information is withheld then the decision will be recorded in the clinical record.
- The person who obtains the consent will be the person who carries out the procedure (i.e. a nurse carrying out a procedure will not rely on a consent obtained by a doctor unless the nurse was present at the time of the consent).
- The person obtaining consent will be fully qualified and will be knowledgeable about the procedure and the associated risks.
- The scope of the authority provided by the patient’s consent will not be exceeded unless in an emergency.
- The practice acknowledges the right of the patient to refuse consent, delay the consent, seek further information, limit the consent, or ask for a chaperone.
- Clinicians will use a Consent Form [*] where procedures carry a degree of risk or where, for other reasons, they consider it appropriate to do so (e.g. malicious patients).
- No alterations will be made to a Consent Form once it has been signed by a patient.
- Clinicians will ensure that consents are freely given and not under duress (e.g. under pressure from other present family members etc.).
- If a patient is mentally competent to give consent but is physically unable to sign the Consent Form, the clinician should complete the Form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

Other aspects which may be explained by the clinician include:

- Details of the diagnosis, prognosis, and implications if the condition is left untreated.
- All options for treatment, including the option not to treat.
- Details of any subsidiary treatments (e.g. pain relief).
- Patient experiences during and after the treatment, including common or potential side effects and the recovery process.
- Probability of success and the possibility of the need for further treatments.
- The option of a second opinion.

Immunisations

Informed consent must be obtained prior to giving an immunisation. There is no legal requirement for consent for 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 discussions that have taken place with the patient, or the person giving consent on a child's behalf.

Consent for children

Everyone aged 16 or over is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him/her to understand fully what is proposed" (known as Gillick Competence), then he/she will be judged competent to give consent for him/herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign a Consent Form for themselves, but they may like a parent to countersign as well.

For children under 16 (except for those who have Gillick Competence as noted above), someone with parental responsibility should give consent on the child's behalf by signing accordingly on the Consent Form .

Mental Capacity Act

The **Mental Capacity Act (MCA)** 2005 became fully effective on 1st October 2007 in England & Wales and provides a framework to empower and protect people who may lack capacity to make some decisions for themselves. 'A person who lacks capacity' is defined as a person who lacks capacity to make a particular decision or take a particular action for themselves at the time the decision or action needs to be taken.

The lack of this capacity could be due to a mental health condition, a severe learning disability, a brain injury, a stroke or unconsciousness due to an anaesthetic or sudden accident and may be on either a temporary or a permanent basis.

The MCA makes clear who can take decisions in which situations, and how they should go about this.

Anyone who works with or cares for an adult who lacks capacity must comply with the MCA when making decisions or acting for that person. Within primary care the provisions will apply to GPs, nurses and those to whom a referral may be made.

The underlying philosophy of the MCA is to ensure that those who lack capacity are empowered to make as many decisions for themselves as possible and that any decision made, or action taken, on their behalf is made in their best interests.

Deprivation of Liberty Safeguards

Deprivation of Liberty Safeguards (DoLS) are currently the subject of consultation, and The Law Commission will publish its final recommendations by the end of 2016. Full details can be found through the link below:

https://www.gov.uk/government/publications/deprivation-of-liberty-standards-dols-consultation-response?utm_source=The

The DoLS form part of the Mental Capacity Act, aiming to make sure that people are receiving care in a way that does not inappropriately restrict their freedom, ensuring decisions made on their behalf are in their best interests. They also ensure that arrangements only deprive someone of their liberty in a safe and correct way, and that this is only done when it is in the best interests of the person and there is no other way to look after them. It applies to vulnerable people aged 18 or over who have a mental health condition and do not have the mental capacity to make decisions about their own care or treatment.

Those planning care should always consider all options, which may or may not involve restricting the person's freedom, and should provide care in the least restrictive way possible. However, if all alternatives have been explored and it is believed necessary to deprive a person of their liberty in order to care for them safely, permission must be obtained by following strict processes. These processes are the Deprivation of Liberty Safeguards, and they have been designed to ensure that a person's loss of liberty is lawful and that they are protected.

The key elements of the safeguards are:

- To provide the person with a representative
- To give the person (or their representative) the right to challenge a deprivation of liberty through the Court of Protection
- To provide a mechanism for deprivation of liberty to be reviewed and monitored regularly

See also: Mental Capacity Act Policy ^[*].

Resources

Consent Form (For Patient) ^[*]

Mental Capacity Act Policy ^[*]