Version	Date Published	Review Status
2.1	Jan 2014	Updated March 2017

Changes from the previous version are marked with a line in the margin

Reviewed and updated 6th Nov 2018

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'.

As a result of the **Montgomery Judgement in 2015**, consent must be clarified regarding not just the available options, but also the risks. The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in proposed treatment, and of reasonable alternatives. A risk is "material" if a reasonable person in the patient's position would be likely to attach significance to it, or if the doctor is or should reasonably be aware that their patient would be likely to attach significance to it.

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.
- The clinician should explain the proposed treatment and any alternatives available to the patient, the risks and benefits of each option, and support the patient choice about which treatment best meets your needs.
- 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.

(In Scotland the Adults with Incapacity (Scotland) Act 2000 provides similar legislation for people over the age of 16. In Northern Ireland, decision-making is governed by the common law. The Northern Ireland Assembly is working towards statutory provisions for treating adults lacking mental capacity but it is not known when this will be introduced.)

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

The Deprivation of Liberty Safeguards (DoLS) can only apply to people who are in a care home or hospital. This includes where there are plans to move a person to a care home or hospital where they may be deprived of their liberty. The care home or hospital is called the *managing authority* in the Deprivation of Liberty Safeguards.

Where a managing authority thinks it needs to deprive someone of their liberty they have to ask for this to be authorised by a *supervisory body*. They can do this up to 28 days in advance of when they plan to deprive the person of their liberty.

For care homes and hospitals the supervisory body is the local authority where the person is ordinarily resident. Usually this will be the local authority where the care home is located unless the person is funded by a different local authority.

The managing authority must fill out a form requesting a standard authorisation. This is sent to the supervisory body which has to decide within 21 days whether the person can be deprived of their liberty.

The supervisory body appoints assessors to see if the conditions are met to allow the person to be deprived of their liberty under the safeguards. They include:

- The person is 18 or over (different safeguards apply for children).
- The person is suffering from a mental disorder.
- The person lacks capacity to decide for themselves about the restrictions which are proposed so they can receive the necessary care and treatment.
- The restrictions would deprive the person of their liberty.
- The proposed restrictions would be in the person's best interests.
- Whether the person should instead be considered for detention under the Mental Health Act.
- There is no valid advance decision to refuse treatment or support that would be overridden by any DoLS process.

If any of the conditions are not met, deprivation of liberty cannot be authorised. This may mean that the care home or hospital has to change its care plan so that the person can be supported in a less restrictive way.

If all conditions are met, the supervisory body must authorise the deprivation of liberty and inform the person and managing authority in writing. It can be authorised for up to one year.

The person does not have to be deprived of their liberty for the duration of the authorisation. The restrictions should stop as soon as they are no longer required.

Conditions on the standard authorisation can be set by the supervisory body. These must be followed by the managing authority.

Standard authorisations cannot be extended. If it is felt that a person still needs to be deprived of their liberty at the end of an authorisation, the managing authority must request another standard authorisation

See also: Mental Capacity Act Policy [*].

Reviewed and updated 6th Nov 2018

Resources

Consent Form (For Patient) [*]
Mental Capacity Act Policy [*]