



# Chapter 6

## Legal aspects of immunisation

This chapter has been adapted to include information supplied by the Health Service Executive, Quality and Risk Department.

## 6.1 Objectives

- To understand the consent process
- To understand why consent is required
- To understand what constitutes “informed consent”
- To identify the responsibilities of the medical profession and the participant in the consent process
- To determine the age of consent for immunisation
- To describe how consent should be recorded
- To describe how to record consent when the participant is illiterate
- To describe how to record consent when the participants first language is not English
- To describe who can give consent for children
- To describe sources of information to help decision making
- To describe the role of the office of Data Protection

## 6.2 Consent

Consent is the process whereby a competent patient or parent/guardian signifies their permission to undergo a medical or surgical procedure. Consent must always be obtained before immunisation. Consent must be given voluntarily and freely, after achieving an understanding of what is involved in the immunisation process.

The person providing consent should be offered as much information as they reasonably need to make their decision. It is considered good practice to provide the participant with the relevant information well in advance of the vaccination as this will give the participant the opportunity to read the information they have been given. It also gives them the opportunity to ask any questions that may arise. It is appropriate to discuss vaccination at the 6-week check up for babies. Giving and obtaining of consent should be viewed as a process and not a one-off event.

### 6.2.1 Why is consent required?

Consent acts as protection for both health professionals and individuals so if any questions are asked in the future there is a record available to show what the individual agreed to on the day of consent. It should also show what information was provided by the health professional at the time of consultation.

### 6.2.2 What constitutes informed consent?

Consent must be freely and voluntarily given, the patient must have the capacity to give a valid consent and the consent must be based on sufficient relevant information clearly setting out the benefits and risks associated with the procedure and any alternative options that may be available. The consent must normally be obtained by a clinician who is experienced enough to be able to explain the procedure to the patient, parent or guardian and to answer their questions.

In order that an individual can make a decision they must be aware of aspects relating to the vaccination or programme. The individual must be provided with the following information in order to give informed consent:

- the nature of the treatment - what vaccines will be administered and against which disease they provide protection
- What are the benefits and risks of immunisation and the risks of disease(s)
- What are the possible side effects of immunisation, when might they occur and how should they be treated
- Alternatives to vaccination.

The individual should be given the opportunity to ask questions about any of the above points. Following provision of the above information an agreement to proceed or not with immunisation should be made.

It is important that consent is obtained for each separate vaccination prior to their administration. If consent is obtained before the day of the vaccination it is important that on the day of vaccination consent should be reconfirmed even if the participant has no further questions or no new information has been published since consent was previously obtained.

### **6.2.3 Responsibility of the medical professional in the consent process**

It is vital that valid consent is obtained before an immunisation process can take place. If it transpires that invalid or no consent was obtained the person who administered the vaccine can be charged with criminal or civil assault or battery. To proceed with vaccination without correct consent being obtained is seen as a breach of the recipient's human rights.

### **6.2.4 Responsibility of the client giving consent**

It is the responsibility of the individual to read the information provided and ask any questions they may have of the health professional before they sign the consent form.

### **6.2.5 What is the age of consent?**

The Non-Fatal Offences Against the Person Act, 1997, Section 23 permits a minor who has attained the age of 16 to consent to treatment. At this age the individual is deemed to be sufficiently competent to give consent for a medical procedure. For any individual younger than this, parental consent is required e.g. for the administration of vaccinations.

In Ireland, the constitutional rights of a child under the age of 16 are exercised by the choice of the parents or a legally recognised guardian. Irish courts place emphasis on the rights of the family and the rights of the parents to decide what is in the best interests of their children. This is based largely on the rights given to the family by Articles 41 and 42 of the Constitution.

A child becomes an adult for the purposes of consenting to medical or surgical treatment when they reach the age of 16 years, in other words, the capacity of a minor to consent is determined by his/her chronological age.

### **6.2.6 How should consent be recorded?**

Competent individuals or guardians/parents need to show their consent to a vaccination or programme. This can be done through signing the accompanying consent form before the procedure begins. This form will be provided by members of the immunisation team.

It is important to state that written consent provides a permanent record, but either written or verbal consent is required at the point where vaccination is about to take place provided the individuals fitness and suitability has been established.

It should be noted that a signature on a consent form does not show conclusive proof that consent has been given for a particular immunisation. It is important that all decisions and discussions that have taken place are recorded and all information that has been supplied to support the decision should also be recorded. This ensures that should a dispute arise there will be evidence of what was agreed between the health professional and the participant.

### **6.2.7 How should consent be recorded when the client is illiterate**

If the individual giving consent is illiterate but competent it is important that their consent is recorded. This can be done by asking them to make their mark on the consent form; their mark should then be witnessed by someone other than the administering health professional. It should also be recorded that the individual giving consent has chosen to make their mark to give consent. Similarly if the individual is competent but is unable to make their mark or signature it is still important that they give consent. This detail needs to be recorded in the participant's notes and witnessed by someone other than the administering health professional. If consent has been validly obtained a lack of written consent should not prevent the immunisation being administered.

### **6.2.8 How should consent be recorded when the client's first language is not English**

In the case of individuals whose first language is not English a special effort should be made to ensure the individuals are aware of that to which they are consenting. The information required to make an informed decision should either be in their native language or a competent translator should be available to explain all procedures and information to the individual. It is important that consent is obtained using the correct methods. When the individual is signing consent, a translator should be available to ensure the all questions that the individual has have been fully answered before the consent form is signed.

### **6.2.9 Who can give consent for children?**

Under normal circumstances the parent(s) of the child can give consent for vaccination on their child's behalf.

Under The Guardianship of Infants Act, 1964, the mother is given automatic parental responsibility for the child. The father is also given parental responsibility if he is married to the mother at the time of the child's birth or if they marry after the birth of the child or if both adults adopt the child together. However, if a child is born outside marriage the mother is given automatic responsibility for all decisions relating to the child.

Under certain circumstances guardianship of the child may be changed e.g. if one parent dies the remaining parent will automatically assume sole guardianship of the child or another guardian can also be appointed by the court.

### **6.2.10 What is the position in regard to children of legally separated parents in relation to consent?**

Where the parents of a child are legally separated, either parent can give consent to medical treatment except in a situation where a Court, in determining the conditions attached to the legal separation, conferred sole custody on one parent and gave directions or imposed conditions in relation to medical treatment. In such a situation the rights of the parent having legal custody would prevail.

### **6.2.11 What is the position in regard to consent for medical treatment for foster-children?**

The law in this area has been changed recently with the passing of the Child Care (Amendment) Act, 2007 which inserts a new Section (43A) into the Child Care Act 1991. This provides that a foster parent who has been taking care of a child for not less than five years may apply to the Court for an order giving them more control and authority over the child, including authority to consent to any necessary medical treatment. The making of such an order must have the consent of the HSE, must be done in the child's best interests and where appropriate, the child's own wishes must

be taken into account. The Court Order, if granted, has the effect of giving the foster parents the same power and control over the child as if the foster parents were the child's own natural parents. A foster child over 16 years of age may consent in his or her own right to medical treatment in the same manner as for any child of that age by virtue of the provisions of the Non Fatal Offences Against the Person Act, 1997. Where the foster child is under 16 years of age and has been in the care of the foster parents for less than 5 years, the consent of the child's natural parents and of the HSE will normally be required.

#### **6.2.12 What is the role of parents in giving consent for medical treatment of children in the care of the HSE?**

Where a child is under the statutory care of the HSE, the child will be subject to an Order by the Court under Section 18 of the Child Care Act, 1991 and in such a situation the HSE will have the necessary authority to give consent to any medical procedure. The child's social worker is usually the appropriate person to give such consent. The child's parent of guardian may still have a legal entitlement to give consent where they are contactable and co-operative with medical personnel but the child's interests are, as always, the paramount consideration.

### **6.3 Sources of information to help in decision making.**

There are a number of resources that might be consulted in order to help make an informed decision. These include leaflets and factsheets, the Immunisation Guidelines for Ireland, the Health Protection website [www.hpsc.ie](http://www.hpsc.ie) and the National Immunisation Office website [www.immunisation.ie](http://www.immunisation.ie). The manufactures' Summary of Product Characteristics (SPC) can also be consulted.

### **6.4 Data Protection**

The office of the Data Protection Commissioner was established under the 1988 Data Protection Act. The Data Protection Amendment Act, 2003, updated the legislation, implementing the provisions of EU Directive 95/46. The Acts set out the general principle that individuals should be in a position to control how data relating to them is used.

"Data controllers" - people or organisations holding information about individuals on computer or in structured manual files - must comply with certain standards in handling personal data, and individuals have certain rights.

The Data Protection Commissioner is responsible for upholding the rights of individuals as set out in the Acts, and enforcing the obligations upon data controllers. The Commissioner is appointed by Government and is independent in the exercise of his or her functions. The Commissioner makes an annual report to the Oireachtas, the Irish Parliament. Individuals who feel their rights are being infringed can complain to the Commissioner, who will investigate the matter and take whatever steps may be necessary to resolve it.

The Commissioner also maintains a register, available for public inspection, giving general details about the data handling practices of many important data controllers, such as Government Departments and State-sector bodies, financial institutions, and any person or organisation who keeps sensitive types of personal data.

Personnel involved in data entry and maintaining registers are obliged to be fully informed of Data Protection issues and act in accordance with same.

## 6.5 Useful resources

Data Protection Commissioner (Ireland) <http://www.dataprotection.ie/viewdoc.asp?DocID=4>

Department of Health and Children. Consent to medical and surgical procedures.

[http://www.dohc.ie/public/information/legal\\_matters\\_and\\_health/consent\\_to\\_medical\\_and\\_surgical\\_procedures.html](http://www.dohc.ie/public/information/legal_matters_and_health/consent_to_medical_and_surgical_procedures.html)

Irish Statute Book. Guardianship of infants act, 1964. <http://www.irishstatutebook.ie/1964/en/act/pub/0007/index.html>

National General Practice Information Technology Group (GPIT) Ireland. [http://www.gpit.ie/patient\\_consent.html](http://www.gpit.ie/patient_consent.html)

National Immunisation Office. Health Service Executive Ireland. <http://www.immunisation.ie>.

NHS. Department of Health. Consent – What you have the right to expect. 2005

[www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/consent/consentgeneralinformation/fs/en](http://www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/consent/consentgeneralinformation/fs/en).

Royal College of Nursing (UK). Informed consent in health and social care research (2001) available from: [www.rcn.org.uk/publications/pdf/informed\\_consent\\_in\\_health\\_and\\_social\\_care\\_research.pdf](http://www.rcn.org.uk/publications/pdf/informed_consent_in_health_and_social_care_research.pdf)

The Office for Health Gain. (2000) Meningococcal C vaccine. Guidelines for practitioners including standards of good practice.

World Health Organisation. Research ethics review committee. The process of seeking informed consent. (2004) [http://www.who.int/rpc/research\\_ethics/Process\\_seeking\\_IF\\_printing.pdf](http://www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf)