



Hospital Group South East

Guidelines for Consent to Clinical Examination and/or Treatment

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On behalf of the Hospital Network Quality and Risk Integrated Governance Team
Date: 17th November, 2008

Disclaimer

Each situation must be judged on its own merits and it is unreasonable for healthcare professionals to follow instructions in these guidelines without proper assessment of individual circumstances. The information contained within these guidelines is accurate and up to date at date of approval.

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Foreword

The World Health Organisation states that ‘*safety is a fundamental principle of patient care and a critical component of quality management.*’¹ Accurate and appropriate consent to clinical examination and/or treatment is one of the abiding principles of safe patient care.

Patients have an absolute right to decide what happens to them.² This principle is enshrined in both common and civil law and in the Constitution. Healthcare professionals, therefore, have a corresponding professional and legal obligation to provide sufficient information to ensure that such decisions are taken on an informed basis. Failure to discharge this obligation may result in civil actions and, in extreme cases, criminal proceedings for assault.

The Commission on Patient Safety and Quality Assurance in its recent report ‘*Building a Culture of Patient Safety*’ states ‘*that as a general principle, the Commission was of the view that every patient is entitled to open and honest communication regarding his/ her healthcare; every patient is entitled to be informed regarding diagnosis and prognosis, treatment options and chances of recovery if possible.*’³

It is important to appreciate that securing informed consent is an integral part of providing care and is not an administrative task. “*Getting a consent form signed*” is not what it is all about. The consent form exists to demonstrate that a process of communication has taken place during which the patient has learned about his/her illness and treatment options and reached a point where they can decide, on an informed basis, to proceed with, restrict, or decline the proposed intervention.

Richard Dooley
Network Manager

17th November 2008.

¹ World Alliance for Patient Safety Forward Programme October 2004, page 4
www.who.int-patientsafety-en-brochure_final.pdf

² This relates to patients who are of sound mind and body. Re A Ward of Court No. 2 1996

³ Report of the Commission on Patient Safety and Quality Assurance, July 2008, page 4.

1. Purpose:

It is the policy of the Carlow-Kilkenny Acute Hospital Services that all patients must be provided with sufficient information to allow them to make an informed choice about their treatment in accordance with current legislation and with current standards of good and evidence based practice.

The purpose of these guidelines is to provide healthcare professionals with direction to understand their professional, clinical and legal duty when obtaining consent from patients for examination and/or treatment.

The age of consent in Ireland is 16 (Section 23 Non-Fatal Offences Against the Person Act 1997).

2. Applies to:

All healthcare professionals in Carlow /Kilkenny Acute Hospitals who are involved in the process of obtaining consent from patients for examination and/ or treatment.

3. Responsibilities:

Healthcare professionals have a responsibility to obtain consent from competent patients before they examine, treat or care for the patient.

The healthcare professional carrying out the treatment /procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done.

It is important to remember that all healthcare professionals have an obligation not to delegate responsibility for securing consent to someone they know or suspect not to be competent for the task. It is the responsibility of all healthcare professionals to read, understand and comply with these guidelines.

Medical: Informed consent is underpinned by the duty of the doctor to provide information and advice in a format that prospective patients will understand and to discuss the relevant issues with the individual patients to aid their decisions.⁴

Nursing and Midwifery: It is necessary for patients to have appropriate information for making an informed judgement. Every effort should be made to ensure that a patient understands the nature and purpose of their care and treatment. Nurses and midwives should only obtain consent for procedures that they themselves will complete. Medical or other healthcare staff are responsible for obtaining consent for procedures or treatment that they will perform.⁵

Health and Social Care Professionals: It is the responsibility of Health and Social Care Professionals to refer to and comply with their professional Codes of Conduct.

⁴ A Guide to Ethical Conduct and Behaviour, 6th Edition, Medical Council of Ireland 2004

⁵ Recording Clinical Practice Guidance to Nurses and Midwives, An Bord Altranais 2002, page 5-6

4. Definitions:

There is no statutory definition of general consent in Irish Law. The Mental Health Act 2001 provides a definition of consent that applies to people detained under the Act.

4.1 Consent as Defined in the Mental Health Act 2001

In relation to psychiatric treatment only, consent in relation to a patient means consent obtained freely without threats or inducements where:

- The Consultant Psychiatrist responsible for the care and treatment of a patient is satisfied that the patient is capable of understanding the nature, purpose and likely effects of the proposed treatment *and*
- The Consultant Psychiatrist has given the patient adequate information in a form and language that the patient can understand, on the nature, purpose and likely effects of the proposed treatment.⁶

Consent is valid when it is

- (a) given by a person with capacity (i.e. who understands what is happening)
- (b) given voluntarily, without any element of duress,
- (c) given with the requisite information of risks, side-effects and alternatives such that the patient is able to make an informed decision as to whether or not to proceed with treatment and
- (d) given by someone entitled to give consent.

4.2 Capacity

Capacity means the ability to understand the nature and consequences of a decision in the context of available choices at the time the decision is to be made.⁷

To demonstrate capacity individuals should be able to:

- a) understand in simple language what the medical treatment is, its purpose and nature and why it is being proposed
- b) understand its principal benefits, risks and alternatives
- c) understand in broad terms what will be the consequences of not receiving the proposed treatment and retain the information for long enough to make an effective decision⁸
- d) retain the information for a sufficient period of time in order to consider it and arrive at a decision.

4.3 Voluntarism

An important component of consent is voluntarism, which may be defined as authentic choice in the absence of coercion. The patient's decision should be made freely.

⁶ Section 56, Mental Health Act 2001

⁷ Mental Capacity and Guardianship Bill 2007, Part 2, Section 7.1

⁸ British Medical Association Consent Tool Kit (BMA London, 2001)

4.4 Informed Consent

Consent is “*informed*” when the patient (or parent/guardian) understands, as far as possible the nature and purpose of the procedure⁹ including:

- a) any uncertainties about diagnoses
- b) any options for further investigations prior to the procedure/treatment
- c) any material or significant risks involved
- d) any common or serious side-effects
- e) the expected outcome, including benefits and limitations of actions
- f) any alternatives to the procedure
- g) the consequences of not having the procedure

The patient must agree of their own free will and are not forced or compelled by any religious beliefs, by relatives, etc. The healthcare professional obtaining consent must be satisfied, as far as is reasonably practical, that this is the case.

4.5. Expressed or Implied

Consent may be expressed or implied. Expressed consent can be given orally or in writing but it is important to remember that giving the patient a form and simply asking him/her to sign it is not acceptable practice. Oral consent is usually used to obtain permission for less serious procedures.

Consent should be regarded as implied only by the specific conduct of the patient, *for example*, a patient sitting up on a hospital bed does not automatically imply that the healthcare professional has complete discretion to treat the patient. Healthcare professionals should be cautious about implied consent. Implied consent can be given, for example, when a patient extends an arm to have blood taken. However, this gesture in itself does not eliminate the right of the patient to an explanation prior to taking blood. Other examples include (1) the taking of routine observations and (2) wound examinations. In the same way that a patient may lie down for an examination, this does not necessarily mean that the patient understands what the healthcare professional proposes to do and why.

4.6 Legal Guardian

‘A person having the right and duty of protecting the person, property or rights of another who has not full legal capacity or otherwise incapable of managing his own affairs e.g. the parent of a minor’¹⁰. A legal guardian is a guardian recognised in law.

4.7 Doctrine of Necessity

The doctrine of necessity applies to an emergency situation where a doctor treats a patient, in the absence of consent, in the best interests of the patient, where the treatment is necessary to save life. This is a common law rule developed through case law

⁹ The word "procedure" is used here to include operations, investigations, pharmaceutical treatment, examinations and any other situation or procedure in which the patient, parent or guardian should be asked for permission before it is carried out.

¹⁰ Murdoch’s Dictionary of Irish Law

4.8 Treatment as defined under Mental Health Legislation

Treatment in relation to a patient includes the administration of physical, psychological and other remedies relating to the care and rehabilitation of a patient under medical supervision, intended for the purposes of ameliorating a mental disorder.¹¹

Patient – any reference to a '*patient*' throughout this document relates to all patients – both adults and children, unless stated otherwise.

¹¹ Section 2.4.3. Reference Guide to the Mental Health Act 2001

5. Procedures:

5.1 Communicating with Patients

Healthcare professionals must ensure that patients know enough to enable them to make a decision regarding the proposed examination, treatment, and/or procedure. The healthcare professional must disclose all material risks. A ‘**material risk**’ is one that a reasonable patient in the position of the person undergoing procedure in question would regard as significant.¹²

In the case of elective surgery, the duty to disclose information to the patient is much more onerous, particularly where there may be serious or material risks associated with the proposed procedure/treatment.

Before being asked for their consent to any treatment, investigation or examination patients should be given the information required for informed consent including:

- a) Details of the diagnosis and the likely prognosis if the condition is left untreated
- b) Purpose of the proposed investigation and treatment including benefits, all known risks of incidence > 1:1000 (including pain) and side effects.
- c) Options for treatment or management of the condition, including the option not to treat.
- d) Inform the patients of how the treatment and outcomes will be monitored and reassessed – follow up procedures, effects on lifestyle etc.
- e) Inform the patient of the name of the doctor who will have overall responsibility for the patient
- f) Explain, where appropriate, that no guarantee about who will carry out the procedure has been given
- g) Inform the patient that they can withdraw consent at any time
- h) Inform the patient that they always have the right to a second opinion.
- i) Inform the patient if the treatment is part of a clinical trial or is in any other way experimental.

This ‘*patient-centred*’ approach was confirmed by Judges Kearns in *Fitzpatrick v White* (2007)¹³ “*If there was a significant risk which would affect the judgement of a reasonable patient, then in the normal course it would be responsibility of a doctor to inform the patient of that significant risk, so that the patient could determine for himself or herself the course he or she should adopt*”.

5.2 Timing of Consent

Consent should always be obtained prior to the proposed treatment or procedure.

Under no circumstances should consent be obtained from a patient who has been pre-medicated or sedated in preparation for a procedure.

In the case of planned elective surgery where there is unlikely to be a change in the patient's condition, consent should where possible be obtained from the patient during an outpatient consultation. This is a time when the patient is more likely to retain the information regarding details and risks of a procedure and capacity is more likely to be present, as opposed to shortly before a clinical procedure when capacity may be absent or diminished due to stress, pain or anxiety.¹⁴

¹² Mills, S. 2002 Clinical Practice and the Law Chapter 4 Consent p78

¹³ *Fitzpatrick v White* (2007) I.E.S.C. 51 (Supreme Court)

¹⁴ *Fitzpatrick v White* (2007) I.E.S.C. 51 (unreported, Supreme Court, Kearns J., Macken J., Finnegan J., November 15, 2007.

It is recommended that written consent must not be obtained more than **three months** before the expected procedure date. In the event of this time frame having lapsed, the patient must be re-consented. Likewise, if there is a change in the patient's condition between the consultation and admission resulting in a significant change in the nature, purpose or risks associated with the procedure consent must be obtained again.

On admission to hospital for an elective procedure, the attending healthcare professional must once again interview and inform the patient of significant risks associated with the procedure. All information given should be documented in the health care record.

5.3 Where communication with the patient is not possible

As a general rule it should never be assumed that a person does not have the capacity to give or withhold consent. Difficulty in communicating should not be confused with inability to make informed decisions. Every effort should be made to facilitate communication with patients. Unless the need for treatment is so urgent as to render it impossible, it may be appropriate to use others in the communication process, such as interpreter services, colleagues with expertise in learning disabilities or speech and language therapists.

Where necessary or appropriate, consideration should also be given to the use of communication aides and other forms of non-verbal communication.

Where, for example, a patient is having difficulty communicating, it may be the case that a family member/carer is best equipped to interpret the patient's wishes. Whenever a third party is assisting with patient communication it is important that they understand their role as that of translating the patient's wishes only and not attempting to decide themselves what might be best for the patient. **It is the responsibility of the healthcare professional to make this clear to the family member/carer.**

5.4 Where a patient has limited or no proficiency in English

Interpreter services should be used where necessary. Whenever possible, information (both verbal and written), should be available to patients in their first language. It is advisable to discuss the importance of confidentiality with the interpreter. **It is inappropriate to use family members/friends especially where situations are of an intimate or confidential nature.** Where a patient has basic English and doubts arise regarding their ability to understand information communicated to them, an interpreter service should be used. It is the responsibility of the staff member to source and engage an interpreter through HSE contracted companies. It is important to remember that not using the appropriate communication tool may lead to an adverse event occurring to the patient.

Where the proposed treatment could safely be deferred and where communication might be easier in the future (e.g. when a particular communication aide becomes available or an interpreter can be accessed) the treatment should be postponed.

Where a decision is being taken about treatment in the absence of consent due to an inability to communicate it is important to remember that nobody (including spouse, siblings and children of the patient) can give or withhold consent. The decision about treatment in these circumstances ultimately rests with the treating healthcare professional.

Where treatment is being given in the absence of consent due to inability to communicate it is most important to carefully record the attempts that have been made to communicate, the decision making process undertaken (including discussion with relatives and consultation with other healthcare professionals) and the reasons for proceeding. Consultation with colleagues in these circumstances is highly advisable and their views/input should also be recorded. Any disagreement among healthcare professionals should also be documented.

5.5 Hard of Hearing or Deaf Patients

Hard of hearing or deaf patients should be provided with appropriate communication support in every consultation and at every stage of their treatment process. The use of a properly trained interpreter is important in order to ensure the quality of the service. Such interpreters must adhere to a strict code of ethics and confidentiality.

5.6 Vision Impaired Patients

Vision impaired patients should be provided with appropriate communication support in every consultation and at every stage of their treatment process. The consent form must be signed by the attending physician and a witness who may be a member of the healthcare team involved in the delivery of the patients care. The witness verifies that the patient has received information in relation to the proposed procedure/treatment. Documentation of all communications between physician and patient must be entered into the healthcare record.

5.7 Exceptions to the process of obtaining consent

It is generally acknowledged that there are two exceptions to the above process:

- Therapeutic Privilege
- Emergency

Therapeutic privilege means that a healthcare professional can withhold information if he/she feels that it would be psychologically damaging to the patient to disclose. It is rare that a healthcare professional should rely on this particular privilege in justifying the reasons for not telling a patient certain facts in relation to the proposed treatment. This privilege should very rarely, if ever, be exercised.

Emergency - in an emergency life-threatening situation where the patient is unable to consent or to appreciate what is required a healthcare professional may administer the necessary medical treatment in the absence of the expressed consent of the patient. This is known as the Doctrine of Necessity. This is a common law doctrine developed through case law. It applies to an emergency situation where a healthcare professional treats a patient, in the absence of consent, in the best interests of the patient, where the treatment is necessary to save the life or preserve the health of the patient.

5.8 When the patient chooses not to hear all the information.

When the patient chooses not to hear all of the information, he/she may not wish to participate in the decision making process concerning their treatment or care. The attending physician and other members of the clinical team will respect the wishes of the patient who is refusing detailed explanations, by withholding the information. The procedure can be discussed with the family, if prior consent to this has been given by the patient.

If such a situation occurs, it should be clearly recorded in the healthcare record. It should be noted that the patient may change their mind at any time before treatment.

5.9 When the patient has prior knowledge

Regardless of whether the patient has prior knowledge of the procedure, all risks and post operative complications should be explained, discussed and clarified with the patient, even where it is considered to be common knowledge. If the patient has undergone the procedure previously, a review of the procedure prior to signing of the consent form may be all that is required. This largely depends on the length of time that has passed since the patient underwent the initial procedure. If new risk or complications have arisen in the meantime and are known to the healthcare professional, this should be explained to the patient.

5.10 Refusal of Consent

Patients must be allowed to decide whether they agree to a proposed treatment even if a refusal will result in harm to them. Similarly, patients must be allowed to withdraw consent to treatment at any time.¹⁵

Competent adults are entitled to refuse treatment. This applies even where such refusal is not considered by the healthcare professional to be in the patient's best interests. Where a decision to refuse treatment (for example on religious grounds) appears "*illogical*", the implications of this decision should be carefully explained to the patient and the information documented in the patient's healthcare record. **When such a situation arises advice must be sought from senior colleagues.** The decision to refuse treatment ultimately rests with the patient in these circumstances.

In the recent High Court decision *Fitzpatrick & Anor-v-K. & Anor*¹⁶, Justice Laffoy stated '*If as a competent adult, a patient refuses to accept treatment and no issue arises as to the capacity of the patient to make that decision, the clinician's duty is discharged. However, if an issue arises as to the capacity of the patient to refuse treatment, the duty of the clinician to advise on and provide the appropriate treatment remains.*'

It is the responsibility of the clinician to take steps to have the capacity issue resolved, with the assistance of the court if necessary

The hospital is required to take steps to have the capacity issue resolved with the assistance of the court in the following situations;

- Where an adult patient is incompetent:
- Where the patient is a minor and the parents are refusing consent, and
- Where the patient is an adult and competent but a doubt arises as to his or her capacity to refuse treatment

In Ireland, the right to refuse medical treatment is enshrined in the unenumerated rights protected by the state under the Constitution and which have been held to include a right to bodily integrity.

In such cases it is particularly important to accurately record in the patient's medical chart the discussions with the patient, including the treatment that has been offered, the patient's decision to decline and the fact that the implications of this decision have been fully outlined.

¹⁵ "*The consent which is given by an adult of full capacity is a matter of choice. It is not necessarily a decision based on medical consideration. Thus, medical treatment may be refused for other than medical reasons or reasons most citizens would regard as irrational, but the person of full age and capacity may make the decision for their own reasons.*" Re A Ward of Court No. 2 1996 Denham J

¹⁶ *Fitzpatrick & Anor v K. & Anor* (2008) IEHC 104

The healthcare professional is obliged to disclose details of an alternative treatment, if available, and may offer an opinion that it may not be in the patient's best interests, but nevertheless the patient should be informed of the alternatives. It may also be appropriate to facilitate referral of the patient to another healthcare professional for a second opinion.

5.11 Documentation of Consent

All information provided to the patient in relation to the proposed procedure or treatment must be documented in the patient's healthcare record. The entry should be dated, timed and signed by the healthcare professional providing the information. If a patient refuses to consent to the proposed procedure or treatment, this must also be documented.

Documenting the consent process is important to ensure an accurate record of the events that took place.

5.12 Children/Minors

Anyone less than 18 years old is considered a minor / child in Irish law.

5.12.1 Minors

Minors between their 16th and 18th birthdays may give their own consent to medical, dental and surgical procedures (see Non-Fatal Offences Against the Persons Act 1997¹⁷). This includes consent to an anaesthetic, which is ancillary to the treatment and also includes any procedure undertaken for the purpose of diagnosis. The minor must have the mental and intellectual capacity to understand the proposed treatment. However, there may be circumstances where it is in the best interest of the minor, or where there is a doubt on the part of the doctor as to the mental competency of the patient to give consent, to also obtain the consent of the minor's parent or guardian. Ultimately, this is a decision for the healthcare professional to make.

5.12.2 Children Under 16

For children below the age of 16, a parent or legal guardian can/must consent for treatment of the child. The consent of only one parent is necessary. The other parent does not have a veto. In relation to unmarried fathers, see section on Unmarried Parents.

Those giving consent on behalf of a child must:

- a) Have the capacity to consent to the intervention/procedure in question
- b) Must be acting voluntarily, and
- c) Must be appropriately informed.

Even when the child lacks capacity to consent on his/her own behalf, it is good practice to involve the child as much as possible in the decision-making process. An older child may wish to co-sign a consent form with the parents.

Children under the age of 16 years may wish for advice and treatment without the consent of their parents. If a parent / guardian agree that a child may attend for treatment unaccompanied this should be recorded in the patient's healthcare record. Every effort should be made to include the parents in the decision/treatment process. Legally, parental/guardian consent is required.

¹⁷ "The consent of a minor who has attained the age of 16 years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his or her person, shall be as effective as it would be if he or she were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his or her parents or guardian".

Children may protest and clearly indicate that they do not want treatment. This is often motivated by fear and anxiety. It is important to listen to and acknowledge the child's concerns. It may be possible to change the treatment or delay the procedure, which may be more acceptable to the child. It is essential at all times to work in close collaboration with the child's parents/carers and/or those who have a close relationship with the child in addressing and overcoming any anxieties being expressed by the child.

In the case of a mother under 16 years, she can consent to the treatment of her own child.

5.12.3 Foster Children

The Childcare Policy Unit of the Department of Health and Children issued a circular dated 30th November 1999 to all HSEs and Voluntary Hospitals on consent to medical treatment for foster children.

The Child Care (Amendment) Act 2007 states that a foster parent or relative, with whom a child has been placed by the HSE, under a Section 36 order, may apply to the court under Section 43A of the Act for an order authorising them to have, on behalf of the HSE, control over the child as if they were the child's parents. If granted, the foster parent or relative has the right to give consent to any necessary medical or psychiatric examination, treatment or assessment with respect to the Child¹⁸.

5.12.4 Children of Legally Separated Parents

If the parents of a child are legally separated, either parent can consent to medical treatment. However, if the Court, in dealing with the legal separation conferred sole custody on one parent, a condition or direction would normally attach with regard to medical treatment for the child. For instance, if the child required medical treatment while on an access visit to the other parent, the parent who had sole custody should be contacted.

5.12.5 Unmarried Parents

In the case of unmarried parents, it is the mother who is legally entitled to give consent to treatment, as the mother is usually the sole legal guardian. The law, however, provides that where an unmarried father and an unmarried mother have jointly completed a Statutory Declaration pursuant to the Guardianship of Infants Act, 1964 as amended by the Children Act, 1997, there may be joint guardianship and both, in such circumstances, are eligible to give consent. In order to give consent to the treatment of his child, an unmarried father should be appointed guardian of his children, either by statutory declaration¹⁹ or by order of the court.

5.12.6 Parental Refusal to Consent to Treatment of a Child

Where parental consent is being withheld in circumstances where the doctors are of the opinion that the treatment is necessary to preserve the health and safety of the child, the first step to be taken is to inform the parents of the necessity for the treatment.

If the parents continue to refuse then immediate steps should be taken by the hospital to notify the Child Care Social workers of the HSE area in which the hospital is located.

In this situation two options are available to healthcare professionals;

- to make an application to have a child made a Ward of Court, and
- to invoke a Care Order under the Child Care Act 1991.

It is important to note that the court may only intervene with the parental decision of a married couple regarding the welfare of their infant in exceptional circumstances.²⁰

¹⁸ Child Care (Amendment) Act 2007, Section 36

¹⁹ Guardianship of Infants Act, 1964 as amended by the Status of Children Act 1987 and the Children Act, 1997

²⁰ NWHB v HW and CW 2001 3 IR 622

5.12.7 Ward of Court Application Children

Wardship should be sought through the High Court. This is used mainly in an emergency situation for both inpatients and outpatients. This decision must be made by the healthcare professional. The requesting Doctor must contact the General Manager in relation to making an application to the High Court. The General Manager will contact the hospital's Solicitor who will proceed with the application.

5.12.8 Application for a Child Care Order under Child Care Act, 1991.

An application for a Child Care Order can be made by the HSE before a Judge. The Order may be temporary and limited specifically to the period required to administer the treatment to the child. The Order may be made at any time, day or night, by a District Court Judge and at short notice. It should be remembered that parents do have the legal right to consent/refuse consent on behalf of their child and the courts will only override such a decision if regarded as unreasonable. In times of necessity, parents will understandably be emotional and if parents are not calmly and properly informed of the treatment, they may decide not to give their consent. Thus, the first step is, if possible and if time allows, to attempt to secure the consent from the parents.

Either of these orders can be made day or night.

Note: The parent(s) have a right to legal representation and the hospital should inform the parent(s) of this right and assist them as appropriate. When seeking the assistance of the court in such matters it is important to keep the parents informed and to consult with them throughout the process.

The question as to whether a baby's constitutional rights should take precedence over the mother constitutional right to free practice of her religion and her autonomy remains undecided. This question would arise in the event if a new born baby would be left parentless in the event of its mother's death. If this situation arises, legal advice should be sought via the General Manager.

5.12.9 Unaccompanied children

Children who arrive at the hospital without parents should not be examined except in an emergency. The parents/guardians should be contacted and asked to come to the hospital. In an emergency, the child should be examined and treated if delay would put the child in further danger. This should be recorded in writing, and there should always be a chaperone present during the examination.

A child may arrive with a teacher or group leader who is "*in loco parentis*" (in the place of a parent). This means that the adult has been given the legal right to give consent for emergency medical treatment. The adult should have a document, signed by a parent/guardian, to this effect. Every attempt should be made to get consent from the parents directly. An interpreter may be necessary.

5.12.10 Children in the care of the HSE

If a child is under "*Statutory Care*", an Order has been made by the Court under Section 18 of the Child Care Act 1991, and the HSE is entitled to give medical consent. The Designated Officer is the appropriate person to give consent. In general the child's parent or guardian is still entitled to give consent where they are contactable and co-operative with medical personnel.

When a child is in voluntary care the parent remains the medical guardian and is responsible for giving medical consent. If there is difficulty locating the parents or obtaining consent the HSE should be notified.

5.12.11 Documentation of Consent

All information provided to the child/parent/guardian in relation to the proposed procedure or treatment must be documented in the healthcare record. The entry should be dated, timed and signed by the healthcare professional providing the information.

5.13 Mental Health Act and the Doctrine of Consent

5.13.1 Treatment in the Absence of the Consent of the Patient

The Mental Health Act 2001 acknowledges and provides for circumstances in which consent to treatment may be dispensed with. This may only occur in circumstances where, in the opinion of the consultant psychiatrist responsible for the care and treatment of the patient:

- (a) the patient, by reason of his or her mental disorder, is incapable of giving consent and
- (b) the treatment is necessary to safeguard the life of the patient, to restore his or her health, to alleviate his or her condition, or to relieve his or her suffering.

The capacity of a patient to give informed consent is left to the discretion of the treating consultant psychiatrist in the light of his or her clinical opinion.

Specific rules are laid down by the Mental Health Act 2001 in relation to the consent required for certain forms of treatment.

5.13.2 Administration of Medication

A patient admitted involuntarily may be administered medication with or without his or her consent for the purposes of ameliorating his or her mental disorder. After a continuous period of three months, it is proposed to continue to administer that medication; the consent of the patient is required. Such consent must be given in writing (**Appendix 1**).

If the patient is either unable or unwilling to give such consent the administration of that medication may only be continued where the consultant psychiatrist responsible for the care and treatment of the patient approves the administration and refers the matter to a second consultant psychiatrist who authorises it.

Both consultant psychiatrists must complete FORM 17 (Treatment without consent Administration of Medication for more than 3 months involuntary Patient (adult)) (Section 60) stating that they approve or authorise the therapy as appropriate. This form will confirm that they have examined the patient, and the consultant psychiatrists should state on the Form 17 that the administration of medication would be of benefit to the patient and give reasons for their opinion.

The consent of the patient or the approval and authorisation by the consultant psychiatrists for the continuation of the administration of medication will be valid for a period of three months. If it is considered appropriate and necessary to administer the medication for a further period after the expiration of the three months the consent of the patient must be sought again. Where the patient is unable or unwilling to give such consent the above procedure must be followed once more and a new Form 17 completed. Section 60 Mental Health Act 2001

5.13.3 Electro Convulsant Therapy (ECT)

A patient will be considered capable of giving informed consent for ECT (including anaesthesia) unless there is evidence to the contrary.

Prior to obtaining consent for a programme of ECT from the patient, the Consultant Psychiatrist responsible for the care and treatment of the patient, will be satisfied that the patient has capacity to provide consent i.e. that the patient:

- a) understands the nature of ECT
- b) understands why ECT is being proposed
- c) understands the benefits, risks and alternatives to receiving ECT
- d) understands the broad consequences of not receiving ECT
- e) can retain the information long enough to make a decision to receive or not receive ECT
- f) can make a free choice to receive ECT
- g) can communicate the decision to consent to ECT

A written record of assessment of capacity to consent to ECT will be kept in the patients' healthcare record.

5.13.4 Obtaining consent from patient who has capacity to consent

Consent for each application of ECT and anaesthesia will be obtained in a written form, the "ECT Consent Form" (see Mental Health Commission ECT Consent Form). The anaesthetist will consent the patient for each anaesthetic again using the "ECT consent form"

The patient will be made aware that he/she can refuse to give consent or withdraw consent for ECT at any time.

A relative, carer or guardian **cannot** consent for ECT on behalf of the patient

Informed consent for anaesthesia will be obtained in a written form from the patient by the anaesthetist. Where the anaesthetist is not a consultant anaesthetist, he or she will be under the supervision of a consultant anaesthetist.

Consent will be obtained in writing for each treatment session by a registered medical practitioner under the supervision of the consultant psychiatrist responsible for the care of the patient. This consent will be taken **prior to each** ECT treatment session and recorded in the patients' healthcare record.

Specific consent for maintenance/continuation ECT will be obtained and reviewed after six months

5.13.5 Information

Information relating to ECT treatment will be given to the patient by the consultant psychiatrist responsible for the care and treatment of the patient. In order to enable the patient to give informed consent, this information must include the following:

- a) The nature of the treatment of ECT
- b) Description of process of ECT
- c) Purpose of treatment with ECT
- d) Intended benefit of treatment with ECT
- e) Likely adverse effects of ECT including the risk of short-term cognitive impairment
- f) Possible consequence of not having ECT
- g) Treatment alternatives to ECT
- h) Confirmation that the patient will be offered alternative treatment to ECT if he/she decides to withhold consent

Information will be provided in a clear and concise manner in oral and written format. Where necessary an interpreter will be provided. The patient will be given an opportunity to ask questions, which will be answered by the healthcare professional.

The patient may be given time to reflect on the information should he or she so wish.

The patient will be informed that he/she may have access to an advocate of his/her choosing.

5.13.6 Absence of capacity to consent

The consultant psychiatrist will determine if the patient's lack of capacity to consent for such treatment is related to their mental illness and if so may make a recommendation for their status to be changed to an involuntary patient

Where an involuntary patient is unable to give consent or is unwilling to give consent **Section 59 (1) (b) of the Mental Health Act 2001** applies:

59 (1) A programme of electro-convulsive therapy shall not be administered to a patient unless either-

(a) The patient gives his or her consent in writing to the administration of the programme of therapy, or

(b) Where the patient is unable or unwilling to give such consent -

The programme of therapy is approved (format specified by the Mental Health Commission) by the consultant psychiatrist responsible for the care and treatment of the patient,

and

The programme of therapy is also authorised (format specified by the Mental Health Commission) by another consultant psychiatrist following referral of the matter to him or her by the first mentioned psychiatrist

Form 16: "Treatment Without Consent Electroconvulsive Therapy Involuntary Patient (Adult)" will be completed by both consultant psychiatrists and placed in the patient's healthcare record. A copy will also be sent to the Mental Health Commission.

It is good practice, with consent of the patient, to inform the patient's family of the proposed treatment and involve them in the decision making process.

5.13.7 ECT form

An ECT form will be completed by the patient's treating consultant psychiatrist or registered medical practitioner under the supervision of the consultant psychiatrist.

This form will be incorporated into the patient's healthcare record.

5.13.8 Ward of Court

The Wardship system, for both inpatients and outpatients, is the currently recognised legal mechanism for healthcare decision-making on behalf of incapacitated adults in Ireland.

If a Ward of Court needs medical treatment, the approval of the court must be obtained. The requesting Doctor must contact the General Manager in relation to making an application to the High Court. The General Manager will contact the hospital's Solicitor who will proceed with the application.

However, if emergencies arise where it is not possible to obtain court approval, the 'doctrine of necessity' applies.

5.14 Advance Directives or Living Wills

An advance healthcare directive (*'Living Will.'*²¹) is a statement made by a competent adult relating to the type and extent of medical treatments he/she would or would not want to undergo in the future should he/she be unable to express consent or dissent at that time.

There is no law governing advance directives in Ireland, however, to date; advance directives have not been challenged in an Irish court. It should be noted that the weight of Irish Case Law supports respecting the individual's right to self determination in healthcare decision making.²²

If a patient or family member informs a healthcare professional that an advanced directive has been drawn up, **the patient's Consultant must immediately be informed.** The patient's wishes as expressed in an advance directive should be respected provided that certain conditions are met.

- a) the doctor must be satisfied that the patient was competent when making the Advance Directive, was of sound mind and not subject to any undue influence or coercion from a third party. If there is any doubt, the doctor should endeavour to make enquiries with the patient's family or general practitioner as to the patient's competency at the time s/he made the Advance Directive.
- b) the doctor should be satisfied that the circumstances outlined in the Advance Directive are applicable to the current reality /situation. If different medical circumstances ensue which were not anticipated by the patient, the Advance Directive would most likely be ineffective.
- c) the doctor must ensure that the date of the Advance Directive is relatively contemporaneous. If it was not done very recently, it would be advisable to discuss with the patient that the Advance Directive still reflects fully their wishes.
- d) the doctor should discuss fully with the patient the implications of the Advance Directive.

The expressed information should be discussed with the patient and all discussions and agreement should be documented in the healthcare record.

5.15 Blood Transfusions

In a situation where a patient requires a blood transfusion as part of medical treatment, the healthcare professional should explain to the patient the proposed transfusion treatment and obtain verbal consent. This must then be documented in the medical notes. The HSE South Blood Transfusion Information for Patients Leaflet must be given to the patient (available in all wards).

If a patient does not wish to have a blood transfusion alternative methods such as the option of autologous donation or cell salvage should be discussed with the patient.

In recent High Court decision²³ Ms Justice Laffoy ruled that a blood transfusion could be given if medically necessary, but only where no other alternative methods were available. There must be discussion and consultation with the patient or parents/ guardians of a child.

²¹ The Bioethical Council for Bioethics Is it time for Advance Healthcare Directives? Opinion, page 1

²² In the matter of a Ward of Court (withholding medical treatment) (No.2) (1996) 2 IR 79 and Jacob M. v St. Vincent's Hospital & Anor, High Court 2003 1 IR 321

²³ Fitzpatrick & Anor v K. & Anor, (2008) IEHC 104

5.16 Jehovah's Witnesses and the Doctrine of Consent

A Jehovah's Witness patient has the right to grant or withhold consent to examination or treatment.²⁴ Their beliefs must always be respected and they should be given the opportunity to decide whether they agree to the treatment and they may refuse or withdraw consent to treatment at any time.

It is essential that healthcare professionals who are aware that a patient is Jehovah's Witness should alert other colleagues in order to ensure the optimum care for the patient.

In the management of trauma or when dealing with an unconscious patient whose status of Jehovah's Witness may be unknown, treatment may include the administration of blood transfusion. (Doctrine of Necessity applies)

In certain cases, it may be necessary to obtain a court order to provide necessary treatment to the patient. This is initiated through the General Manager's Office (see Ward of Court section above). The hospital is required to take steps to have the capacity issue resolved with the assistance of the court in the following situations

- Where an adult patient is incompetent:
- Where the patient is a minor and the parents are refusing consent, and
- Where the patient is an adult and competent but a doubt arises as to his or her capacity to refuse treatment

When seeking the assistance of the court in such matters it is important to keep the parents informed and consult with them throughout the process.

If a Jehovah's Witness patient attends the hospital for consultation prior to treatment/ procedure or delivery, the issue of whether or not the patient will accept a blood transfusion in an emergency should be addressed at this time.

5.17 Needlestick Injury/ Staff Exposure to Blood Borne Viruses

In the event of a staff member sustaining an injury from a needle or similar exposure to blood or body fluids from a patient, the hospital is faced with a situation where it has two sets of patients' rights which need to be balanced, i.e. those of the "source patient" and those of the "employee patient".

Testing the source patient's blood enables the organisation to assess whether there is a risk to the employee

In such circumstances the source patient will be asked to give consent to a sample of his/her blood being taken for the purposes of Hepatitis B&C and HIV testing. As part of this consent process the importance of the test from the employee patient's perspective should be explained to the source patient. It is important that appropriate counselling or other support services that the source patient may need are provided.

If the source patient is not competent to give consent, confirmation must be sought from the source patient's Consultant that his/her patient is incompetent and a decision must be taken to apply the Doctrine of Necessity. The source patient's blood may then be taken and tested and the results shared with the employee patient's treating Consultant. The Consultant should record in the source patient's records the circumstances in which the blood samples were taken and tested as well as recording the nature of discussions between the Consultant and the source patient. If the source patient subsequently recovers competence a full explanation of what has taken place should be provided.

²⁴ Jacob M. v St. Vincent's Hospital & Anor, High Court 2003 1 IR 321; Fitzpatrick & Anor v FK and Anor 2006

If the source patient is competent but withholds consent and a sample of his/her blood has already been taken for other purposes, **this blood may NOT be tested** for Hepatitis B&C and HIV. In this scenario, the Consultant should discuss the issues with the source patient pointing out the plight of the employee patient and the possible need for medical treatment for the employee patient. If the source patient continues to refuse to grant the consent, then the Consultant must firstly inform the Hospital Manager, who will decide whether or not a court order is required. As before, a complete explanation of the process must be documented in the patient's healthcare record.

A competent patient has the right to withhold consent, no matter how unreasonable or irrational it is, notwithstanding the potential threat to the health of the employee patient.

With regard to staff exposure to blood borne viruses, there may be circumstances which fall outside the remit of this policy. In such circumstances, legal advice should be sought through the Hospital Manager.

5.18 Unlicensed Medicinal Products

Any medication sold or supplied on the Irish market must have a special licence that guarantees its quality, safety and efficacy. The Irish Medications Board (IMB) is the competent authority for medications' licensing in Ireland. Anyone who manufactures or markets a medication can only do so in accordance with a product authorisation license granted by the IMB except where exempted under the Medicinal Preparations (Licensing & Sale) Regulations 1998. There are some situations where a medication does not have such a license, or the medication is intended for use in a manner other than that specified on its license. A medication without such an authorisation is commonly referred to as an unlicensed medication.

The Consultant should review the relative risks involved with the use of unlicensed medications and decide whether or not the patient should be informed that the medication(s) is not licensed for use in the Republic of Ireland. If the patient is informed, the consent for its use must be sought. A note to such effect and the rationale for use of same should be recorded in the patient's healthcare record. Further advice can be obtained through the Pharmacy Department.

5.19 Clinical Photography and other recordings

As a general rule, informed consent, must be obtained before clinical photography is undertaken. The healthcare professional must first give a detailed explanation as to why the images/recordings are required. Consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure healthcare professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

Clinical photography or recording can be undertaken for the following reasons:

- a) To aid diagnosis / treatment
- b) For use in healthcare record
- c) For use in teaching healthcare staff and students
- d) For publication. (The patient should be warned that, once published, consent cannot be withdrawn as the images are in the public domain.)

It is accepted, however, that in some circumstances clinical photography might be legitimately required at a time when the patient is unable to give consent, for example, under anaesthesia. In these circumstances, the photograph can be taken but images withheld until consent has been obtained. If consent is not obtained, the images must be destroyed immediately.

All clinical photography and other recordings must be stored in a safe and secure manner.

There are special circumstances where the attending consultant may authorise the taking of Clinical Photography and other recordings without consent, e.g:

- a) Suspected non-accidental injury to a child
- b) Unconscious patient
- c) Deceased patients whose next of kin is not known

Written consent must also be obtained from a parent or guardian when undertaking clinical photography or recordings of a minor and must only be carried out by a senior member of medical or nursing staff. If a child is not willing for a recording to be used, it must not be used, even if parental or guardian consent has been obtained.

5.20 Retention of Tissue

Whilst it is standard practice to retain tissue removed (of necessity) during a procedure for the purpose of pathological (histological) evaluation, the express consent of the patient must be obtained where it is proposed to use any tissue so excised for the purpose of research.

5.21 Post-Mortems

In the case of a post mortem, it is important to ensure that relatives understand what a post mortem entails. The HSE South Eastern Region has issued extensive guidance for non-coroners and coroners' post mortem practices²⁵. These guidelines, which are available on every ward, deal with all relevant issues and should be adhered to.

5.22 Consent for Clinical Trials

All clinical trials must be approved by a HSE Research Ethics Committee. There are specific rules for those involved in clinical trials, which are legislated for by the Control of Clinical Trial Act 1987 and the Clinical Trials and Drug Act 1990 as well as by the European Communities (Clinical Trials of Medicinal Products for Human Use) Regulations 2004 Regulations 2004 - 2006.

Informed consent must be obtained from every person prior to clinical trial participation.

With regard to obtaining consent for clinical trials and research, participants must be informed of the:

- a) risks
- b) possible adverse reactions
- c) purpose of the trial
- d) qualification of the healthcare professional
- e) time period involved
- f) the manner in which the substance or preparation being tested in the trial is to be administered

There is **an absolute duty** on the healthcare professional to disclose all known risks to the participant.

A participant in a clinical trial may withdraw consent at any time even if they have previously consented.

²⁵ Protocol Guideline for Hospital and other relevant agencies in providing a Quality Response to Families in Relation to Coroners Post Mortem Practices, HSE (2006); and Protocol Guideline for Hospital and other relevant agencies in providing a Quality Response to Families in Relation to Non-Coroners Post Mortem Practices, HSE (2006).

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APPENDICES

Appendix 1

Guidelines Relating to the Process of Obtaining Consent

This guidance is provided for healthcare professionals obtaining patients' consent for examination, treatment and procedures. Its aim is to ensure that all patients are given consistent and adequate information.

The healthcare professional should explain the following whilst obtaining consent and completing the consent form. Consent should always be obtained prior to the proposed treatment or procedure.

1. Name of proposed procedure or course of treatment

Name and briefly explain the intervention and state the reasons it is being offered (i.e. for the treatment of name of condition or disease).

2. The proposed procedure

The patient should receive a description of what the procedure is likely to involve, including:

- expected length of stay in hospital
- medication
- surgery (including site and size of any incision and any likely scarring)
- the need for intimate examination during the procedure
- pain
- approximate period of recovery
- likely impact on daily and personal life (e.g. time off work, driving, lifting, sexual activity)
- tissue or organ removal
- tissue examination (storage/disposal)
- use of video or photographic recording.

This explanation should be supported by dedicated patient information if available

3. Intended benefits

Clearly describe to the patient how s/he can expect the intervention to help her condition or illness.

4. Serious or frequently occurring risks

The healthcare professional must disclose all known risks inherent in the proposed treatment, however small their likelihood of occurring

In order to ensure that patients understand the level of risk involved, it is best to avoid using verbal descriptors (e.g. high/low risk) or expressions of percentages when discussing risk. It is preferable to use natural frequencies and express risk in relative terms (e.g. if 100 people have this procedure, five of them will have this complication). The healthcare professional should bear in mind that individuals (both clinicians and patients) vary in their perceptions of and attitudes to risk.

The healthcare professional should also inform the patient of any risks associated with his/her own health and medical history, and record them on the form and in the healthcare record for example, obesity, previous surgery, pre-existing medical conditions, smoking, etc. If the patient chooses, the patient should be given the opportunity to discuss his/her own additional risks with another appropriate medical specialist before consenting. It is recommended that clinicians make every effort to separate serious from frequently occurring risks.

4.1 Serious risks

Serious risks, which occur with varying frequency in certain circumstances may include:

- death
- venous thrombosis/pulmonary embolism
- haemorrhage
- return to theatre
- trauma to bowel, bladder and ureter.

Reference should also be made to risks specific to the planned procedure

4.2 Frequent risks

Frequently occurring risks include:

- infection
- bruising
- scarring
- adhesions
- bleeding
- anaemia
- fatigue

Any consequences specific to the intended procedure should be described.

5. Any extra procedures which may become necessary during the procedure

5.1 Blood transfusion

Inform the patient of the frequency of blood transfusion being required during or following specific operations and record this in the healthcare record. Inform the patient if an autologous blood transfusion can be used.

5.2 Other procedures

Explain to the patient that, during a procedure, complications may sometimes arise whereby, if no further procedure is performed, the patient's life or quality of life could be compromised. Additional procedures which may need to take place during pelvic surgery should have been discussed with the patient in full.

They may include:

- tissue sampling of a lump
- proceeding from laparoscopy to laparotomy.

6. What the procedure is likely to involve, the benefits and risks of any available alternative treatments, including no treatment`

The healthcare professional should already have:

- described to the patient what the procedure is likely to involve
- provided the patient with information on alternative interventions (such as other medical, surgical or less invasive procedures) and their risks and benefits
- discussed with the patient the risks and benefits of having no treatment.

These points should be reinforced at the time of signing of the consent form.

7. Refusal of consent

Competent adults are entitled to refuse treatment. When this situation occurs it is important to consult and discuss all concerns with the patient. Alternatives to the proposed treatment / procedure should be discussed with the patient. Advice should be sought from a senior colleague. In certain situations it may be necessary to apply for a court order in order to render treatment to a patient. When seeking the assistance of the court in such matters it is important to keep the patient informed and consult with them throughout the process. All discussions and actions taken should be documented in the patient's healthcare record.

8. Information leaflet/tape

You should provide the patient with relevant supporting information about the procedure (either in writing or in another format appropriate for her needs if available) and record this in the healthcare record.

9. Anaesthesia

The healthcare professional should inform the patient of the type of anaesthesia to be used and that s/he will have an opportunity to discuss it in more detail with an anaesthetist before the procedure.

10. Procedures which should not be carried out without further discussion.

Please ensure that the patient tells you of any specific procedures which s/he does not wish to be carried out without further discussion and that these are recorded.

11. Confidentiality

Please ensure that the confidentiality of the patient is respected all times

12. Interpreter services

Please ensure that interpreter services are used where appropriate. Details are available at ward/departmental level.

It is important to remember that consent is much more than a signature on a form. If a healthcare professional has any doubt about obtaining a valid consent they should discuss their concerns with a more senior colleague.

Appendix 2

Documenting Consent in the Healthcare Record

NHO Code of Practice for Healthcare Records Management. Version 2.0 (illustrated). 2007

Section Two: Documenting consent in the healthcare record

Consent must:

- Be easily and clearly identifiable either on a consent form, which is retained as part of the healthcare record, or in the case of verbal consent documented within the healthcare record.
- Contain no abbreviations.
- Clearly state the examination/procedure/treatment/care involved and the risks and benefits of that procedure/ treatment/ care.
- Clearly identify the patient by name and their medical record number.
- Clearly identify who has granted or refused consent and/or their relationship to the patient in the case of parent/guardian.
- Have a documented record of what appropriate patient information or relevant discussions has been provided to the patient/guardian detailing the procedure/ /treatment/care, risks, benefits and/or alternative.
- Have a documented record of how this information has been provided (e.g. patient information leaflets, verbally etc.).
- Be dated and signed by the healthcare professional obtaining the consent, including full name and grade.
- Verbal consent must be documented in the healthcare record and must clearly identify the witness, as relevant, e.g. by name and grade.
- The consent form, signed and dated by the patient and doctor, is part of the clinical notes and should be filed with them.

Patient wishes

- The involvement of the patient in decisions about his or her care should be documented in the record under ‘patient wishes’.
- Living Wills or Advance Directives must be clearly recorded in the notes, alongside any resuscitation statements.
- The person who wishes to give Advance Directives must be over 18 years of age and must be of sound mind at the time of making the Advance Directives.

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