Guidelines for Consent to Clinical Examination and/or Treatment

HSE Mid-West Area Acute Hospitals

May 2009
Guidelines for Consent to Clinical Examination and/or Treatment

HSE Mid-West Area Acute Hospitals

Guidelines to be used in relation to obtaining patient’s consent

Approved by: Regional Consent Group

Approved on: April 2009

Chairperson of Regional Consent Group:
Mr. Hugh Flood:

Effective from: 6th July 2009

Revision Date: May 2011
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Guidelines for Consent to Clinical Examination and / or Treatment

HSE Mid-West Area Acute Hospitals

Executive Summary

May 2009
EXECUTIVE SUMMARY OF CONSENT GUIDELINES

Why do we need Consent? – (Refer to Section 4.0)

Consent is one of the most important issues in clinical practice. If a Clinician examines, treats or operates upon a person without that person’s consent in a situation where consent could and should have been obtained, then the clinician is committing an unlawful act. For example a nurse/midwife who catheterizes a patient or changes a wound dressing without oral consent is committing an unlawful act.

It is a basic rule of common law that consent must be obtained for clinical examination, treatment or investigation. The Irish Constitution reaffirms this rule, as does international law. Therefore, any exceptions to the rule would be subjected to intense judicial scrutiny since the purpose of the rule is to uphold one of the most basic of all rights i.e. the right to bodily integrity.

The argument for consent as an indispensable precursor to treatment is born out of the concept of Patient autonomy, which in turn is based upon the rights of individual self-determination and of bodily integrity under Article 40.3 of the Constitution.

When do clinicians need consent from patients? – (Refer to Section 1.0)

Before you examine, treat or care for competent adult patients you must obtain their consent. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: “can this patient understand and weigh up the information needed to make this decision?” Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.

Patients may be competent to make some health care decisions, even if they are not competent to make others.

Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw informed consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

How Does the Patient Give Consent? – (Refer to Section 7.0)

Obtaining a patient’s consent is a process. Consent can be written, oral or non-verbal. A signature on a consent form does not itself prove that the consent is valid, it merely records the patient’s decision.

Four Elements to Consent – (Refer to Section 7.0)

There are four elements to consent and these must all be present for consent to be valid.

- It must be given (or withheld) voluntarily without any element of duress.
• It must be given (or withheld) by an individual who has the legal capacity, in terms of age and mental competence, to do so.
• It must be given with the requisite information of risks, side-effects and alternatives advised so that the patient is able to make an informed decision as to whether or not to proceed with treatment/intervention.
• Any decision relating to the giving or withholding of consent by the patient must be based on sufficient relevant information.

Patients have an absolute right to decide what happens to them and Clinicians therefore have a corresponding legal obligation to provide sufficient information to ensure that such decisions are taken on an informed basis. Failure to discharge this obligation can result in civil actions and, in extreme cases, criminal proceedings for assault. Equally it is important to remember that you have an obligation not to delegate responsibility for securing consent to someone you know or suspect to be under qualified for the task.

Two Exceptions to the Common Law Rule - (Refer to Section 8.0)

It is generally acknowledged that there are two exceptions to the common law rule:

1. In an Emergency Life-Threatening Situation where the patient is unable to consent or to appreciate what is required the clinician may administer the necessary medical treatment in the absence of the expressed consent of the patient. This is known as the Doctrine of Necessity. The Clinician treats a patient in the best interests of the patient, where the treatment is necessary to save the life or preserve the health of the patient.

2. Therapeutic Privilege

Therapeutic privilege means that a Clinician can withhold information if he/she feels that it would be psychologically damaging to the patient to disclose. However, the therapeutic privilege does not extend to giving Clinicians the right to lie to their patients; Clinicians have an ethical duty to share information with their patients.

It is rare that a Clinician 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.

What Patients should be told – (Refer to Section 10.0)

Clinicians must ensure that patients know enough information to enable them to decide about treatment.

The clinician must disclose all material risks. A 'material risk' is one that a reasonable patient in the position of the person undergoing the procedure in question would regard as significant. Before patients are asked for their consent to any treatment, investigation or examination, they should be given the information required for "informed" consent; for example, information about the benefits and risks of the proposed treatment and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision and in a form they can understand, their consent may not be valid.

Is the patient's consent voluntary?

Guidelines for Consent to Clinical Examination and/or Treatment

May 2009
Consent must be given voluntarily: not under any form of duress or undue influence from clinicians, family or friends.

Timing of Consent: - (Refer to Section 12.0)

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. It is recommended that written consent must be obtained within three months of 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.

All discussions with the patient on the issue of consent should be clearly recorded in the Hospital Records. Ideally, the risk should be mentioned together with reference to the conversation between the Clinician and the Patient.

Can children consent for themselves? – (Refer to Section 14.0)

Since 1997, the provisions of section 23 of the Non-Fatal Offences Against the Person Act 1997 provides that a minor that has attained the age of 16 years can consent to surgical, medical or dental treatment. 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.

Before examining, treating or caring for a child/minor, the Clinician must seek consent. Young people aged 16 and 17 are deemed to have the competence to give consent for themselves except for psychiatric treatment.

Refusals of treatment - Can a competent patient refuse treatment? (Refer to Section 13.0)

Competent adult patients are entitled to refuse treatment, even where it would clearly benefit their health. A patient does not have to consent if he/she does not want to. This applies even where such a refusal is not considered by the clinician to be in the patient’s best interests. Where a decision to refuse treatment (for example on religious grounds) appears “irrational” the implications of this decision should be carefully explained. The decision, however, ultimately rests with the patient in these circumstances. For example a Jehovah’s Witness can refuse a blood transfusion even where this is essential for survival. Where the consequences of refusal are grave, it is important that patients understand this, and also that, for clinical reasons, refusal may limit future treatment options.

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. 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 considerations. In such cases it is particularly important to accurately record 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.
Adults who are not competent to give consent: - (Refer to Section 18.0 19.0)

No-one can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the Patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the Patient’s needs and preferences. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an ‘advance refusal’) and those circumstances arise, you must abide by that refusal.

This summary cannot cover all situations. For more detail, please consult:
Guidelines for Consent to Clinical Examination and/or Treatment, HSE Mid-West Area Acute Hospitals
Guidelines for Consent to Clinical Examination and / or Treatment

HSE Mid-West Area Acute Hospitals

Mid-Western Regional Hospital Dooradoyle, Limerick
Mid-Western Regional Maternity Hospital, Limerick
Mid-Western Regional Orthopaedic Hospital, Croom, Co. Limerick.
Mid-Western Regional Hospital Ennis, Co. Clare
Mid-Western Regional Hospital Nenagh, Co. Tipperary

Guidelines to be used in relation to obtaining patient’s consent

Approved by: Regional Consent Group

Approved on:

Chairperson of Regional Consent Group: Hugh Flood

Effective from:

Revision Date:

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Guidelines for Consent to Clinical Examination and/or Treatment
May 2009
General Guidelines on Clinical Consent

People are entitled to be treated with dignity, respect and honesty and to be involved in decisions about their health and wellbeing. The strategy will require all of the Healthcare staff to become more flexible, adaptable and innovative in our approach. The principles identified in the general guidelines on clinical consent will reflect the Health Service Executive’s (HSE) commitment to translating people centeredness into practical actions.

Mission and Values

The HSE West Network 7 Acute Hospitals Mission Statement is “to provide in partnership with all key stakeholders, high quality, value driven, patient centred services based on best practice, research and evidence which is sensitive and responsive to the needs of the population, service users and providers”. MWHB Strategy for Acute Hospitals Services (2004)

The Acute Hospitals (HSE West) subscribes to the following values as the hallmarks of the quality services it aspires to:-

- **Equity** – persons with identical needs should receive the same standard of treatment and care, regardless of where they live, where they are treated, what their outcomes are or what their political or religious beliefs may be.

- **Accessibility** – everyone should have ready access to the services they need, when they need them. In particular, services should be equally accessible to both public and private patients.

- **Effectiveness** – each patient should get the best possible outcome from his or her treatment and care.

- **Efficiency** – services should be organised and delivered in a way that gives best value for money. The aim of services should be to treat illness at the most appropriate level in the delivery system.

- ** Appropriateness** – should meet local needs, avoid developing unnecessary dependency on services or institutions and be flexible enough to cope with the need to change.

- **Responsiveness** – reflects the needs and entitlements of users.

- **Dignity** – reflects the standards of courtesy, confidentiality and respect for the privacy and dignity of the individual that society expects of the caring services.

- **Farsightedness** – by identifying, and pursuing through prevention and promotion programmes, opportunities to contribute to improvements in the health of the community.

MWHB Strategy for Acute Hospitals Service 2004
1.0 Introduction

The issue of consent in the context of medical care is highly complex and has been described as a "legal and practical minefield". Patients have an absolute right to decide what happens to them and healthcare professionals/Clinicians therefore have a corresponding legal obligation to provide sufficient information to ensure that such decisions are taken on an informed basis. Failure to discharge this obligation can result in civil actions and, in extreme cases, criminal proceedings for assault. Equally it is important to remember that healthcare professionals have an obligation not to delegate the responsibility for securing consent to someone they know or suspect are not competent to carry out the task.

It is important to appreciate that securing informed consent is a process – not an administrative task. "Getting a consent form signed" is not what it is about. The consent form exists to demonstrate evidence 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.

Recent years have seen dramatic changes in people's ability to gather and process information. Higher standards of education, improved economic conditions, e-mail and particularly the internet mean that many patients are now very capable of making choices about their treatment. It is no longer appropriate for healthcare professionals to take a wholly paternalistic approach to the issue of patient consent.

2.0 Scope of these Guidelines

The scope of these guidelines extends to all healthcare staff including: Doctors, Nurses/Midwives and Allied Health Professionals who work within the Acute Hospital setting. Consent to medical and surgical procedures must normally be obtained by a doctor who is experienced enough to be able to explain the procedure to the patients/parents/guardians and answer their questions about the procedure. Likewise, consent to a nursing procedure must be obtained by a nurse who can advise the patient and answer all questions raised. All clinical procedures require a level of consent and therefore, all clinicians will be involved at some stage in the consent process.

The scope also extends to patients, clients and next of kin, parents/guardians as they should be empowered to make decisions on the basis of sufficient information provided in a way that they understand.

3.0 Purpose of these Guidelines

This document was prepared by the Regional Consent Group involving 5 acute hospitals within the Mid-West Area as follows:

- Mid-Western Regional Hospital Dooradoyle, Limerick.
- Mid-Western Regional Maternity Hospital, Limerick.
- Mid-Western Regional Orthopaedic Hospital, Croom, Co. Limerick.
- Mid-Western Regional Hospital Ennis, Co. Clare.
- Mid-Western Regional Hospital Nenagh, Co. Tipperary.

Guidelines for Consent to Clinical Examination and/or Treatment

May 2009
The purpose of this document is to provide information to assist health care professionals to understand more clearly the issues relating to consent and thereby improve practices of best care within each of the five acute hospitals.

The Regional Consent Group have received permission from the Dublin North East Area to use their guidelines in relation to developing this guideline.

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In the absence of nationally agreed practice guidelines and against a backdrop of evolving law and increasing public interest it is essential that all clinicians involved in securing patient consent examine their own practice. The Irish Medical Council has produced a “Guide to Ethical Conduct and Behaviour” (2004) and Section E of the Guidelines “Confidentiality and Consent” outlines clearly the guiding principles of Informed Consent. It is hoped that the information provided in this document together with the Medical Council Guidelines will assist professionals to understand more fully the issues relating to consent and thereby improve practices generally.

The Guidelines for Consent to Clinical Examination and / or Treatment in an Acute Hospital Setting in the HSE Mid West Area must be used in conjunction with other guidelines and policies in the HSE MWA to include:

- Infection Control Policy (2007)
- Infection Control Occupational Exposure Management including Sharps Policy and Procedure (2007)

4.0 The Legal Consent Process

There is some uncertainty about the Irish Courts’ approach to informed consent, which is unfortunate. Even in those countries such as Australia where the courts are unambiguous about their approach to informed consent, Clinicians remain unclear about matters. There is a shift however; in Irish Courts from a clinician-centred test, to decisions recently hinting at the adoption of a patient-centred test. There is also a shift away from the acceptance of authority to the rights of the individual and an insistence of openness and transparency.

The doctrine of consent operates to best reflect the self-autonomy of the patient. It is increasingly regarded now in many jurisdictions as a fundamental human right. In Ireland, this fact is well established. The Supreme Court has stated that:

“The requirement of consent to medical treatment is an aspect of a person’s right to bodily integrity under Article 40.3 of the Constitution”.

Guidelines for Consent to Clinical Examination and/or Treatment

May 2009
Before undertaking clinical treatment of any sorts whatsoever, a Clinician must obtain the consent of the patient.

“Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients”.


5.0 Common Law – Valid Consent

It is a basic rule of common law that consent must be obtained for clinical examination, treatment or investigation. The Irish Constitution reaffirms this rule, as does international law. Therefore, any exceptions to the rule would be subjected to intense judicial scrutiny since the purpose of the rule is to uphold one of the most basic of all rights i.e. the right to bodily integrity.
6.0 What Is Consent - Valid Consent

A valid consent is one that:

- must be given (or withheld) voluntarily without any element of duress;
- must be given (or withheld) by an individual who has the legal capacity, in terms of age and mental competence, to do so;
- must be given with the requisite information of risks, side-effects and alternatives as advised such that the patient is able to make an informed decision as to whether or not to proceed with treatment;
- any decision relating to the giving or withholding of consent must be based on sufficient relevant information.

7.0 Expressed or Implied Consent

7.1 Expressed Consent

Expressed consent can be given orally or in writing but it is worth repeating that giving the patient a consent form and simply asking him/her to sign it, without further consideration or interaction with the patient is neither acceptable practice nor fulfils the steps necessary to obtain a valid consent. A patient is entitled to receive sufficient information in a way that he/she can understand so that he/she can make a balanced judgement.

A question often asked is whether and when consent is required in writing. The UK Department of Health in a document entitled Good Practice in Consent Implementation Guide: Consent to Examination or Treatment (2001) has commented on the issue and it is worth taking some of their advice into consideration:

"For significant procedures, it is essential for health professionals to document clearly both a patient’s agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient’s notes if necessary), or through documenting in the patient’s notes that they have given oral consent."

7.2 Written Consent

Consent is often wrongly equated with a patient’s signature on a consent form.

A signature on a form is evidence that the patient has given consent, but is not proof of valid consent.

- If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature.
- Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is not a bar to treatment.
- Patients may, if they wish, withdraw consent after they have signed a form: if so please document in patient’s medical notes. (See Section 13.0 Withholding Consent)

It is rarely a legal requirement to seek written consent, but it is good practice to do so if any of the following circumstances apply:

- The treatment or procedure is complex, or involves significant risks (the term ‘risk’ is used throughout to refer to the possibility of any adverse outcome, including those which some health professionals would describe as ‘side-effects’ or ‘complications’).
- The procedure involves general/regional anaesthesia or sedation
- Providing clinical care is not the primary purpose of the procedure
- There may be significant consequences for the patient’s employment, social or personal life. It will not usually be necessary to document a patient’s consent to routine and low-risk procedures, such as providing personal care or taking a blood sample.

However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about similar care in the past) it would be helpful to seek written consent.

7.3 Implied Consent

Consent should only be implied from the specific behaviour of the patient. For example, the most common quoted situation is that of a patient extending his/her arm, thus implying that the patient consents to receiving an injection.
- However, a patient sitting up on a hospital bed or on a GP’s examination bed does not imply that the Healthcare Professional has carte blanche to treat the patient and carry out an examination whatsoever.
- Practitioners should be cautious about implied consent. It is acceptable in some situations, in most situations the requisite information should be given to a patient and their express consent ought to be obtained.

As stated, 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 the taking of routine observations and wound examinations. Similarly, the fact that a patient lies down for an examination, does not necessarily mean that the patient understands what the healthcare professional proposes to do and why (example where a Clinician needs to carry out a rectal or vaginal examination).

Likewise, a healthcare professional cannot assume that because a patient has consulted him/her regarding a medical complaint or condition, the patient has given implied consent to all types of treatment.

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

The process of consent should also be considered to ensure that the patient’s privacy is protected. Thus, when discussing the relevant issues with patients in order to obtain consent, such discussions should take place where a patient’s personal details are not, for example, overheard by others. It is important that the patient feels comfortable in the location where such matters are discussed. Such considerations are likely to assist in ensuring an open and transparent consent process.

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

There may be times when obtaining consent is not possible and therefore less necessary, such as in emergency scenarios where the patient is in extremis or unconscious (please refer to Section 11 Guidelines for Consent to Clinical Examination and/or Treatment May 2009).
8.2 p.12). There may also be times when consent, although actually given by the patient, was based on incomplete or inaccurate information, thereby raising the question, of whether consent in such circumstances is really consent at all?

7.4 Requirements for Valid Consent

The four requirements of consent, all of which will be dealt with in greater detail below, are that:

1) It must be given (or withheld) voluntarily
2) It must be given (or withheld) without any element of duress.
3) It must be given (or withheld) by an individual who has the legal capacity in terms of age and mental competence, to do so.
4) Any decision relating to the giving or withholding of consent by the patient should be based on sufficient information. (Informed Consent section 7.4.3). The patient should be aware of the requisite information of risks, side effects and alternatives so that he/she is able to make an informed decision as to whether or not to proceed with treatment.

7.4.1 Voluntarily

The patient/client must agree of their own free will to clinical treatment or investigations and must not have been subjected to the will of a third party i.e. a relative, such as to vitiate their consent. (refer to section 36 for information on consent and religious beliefs).

7.4.2 Capacity

To demonstrate capacity individuals should be able to:

- Understand in simple language what the medical treatment is;
- Understand the purpose of treatment, the nature of treatment and why it is being proposed; understand its principal benefits;
- Understand the risks and alternatives;
- 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 decision.

7.4.3 Informed

The Clinician has a general duty to the patient to disclose information. So the phrase ‘duty of disclosure’ can be seen as another way of expressing the term ‘informed consent’.

Informed consent is when the clinician discloses information and when the patient (or parent/guardian) understands, as far as possible, the nature and purpose of the procedure. This includes:

- Uncertainties about diagnoses
- Options for investigations prior to the procedure
- Material or significant risks involved
- Common or serious side-effects
- Expected outcome, including benefits and limitations of activities
- Alternatives to the procedure
Consequences of not having the procedure
Procedure will be carried out by the patient’s consultant or a member of his/her team.

8.0 Exceptions to the Rule for Obtaining Consent

It is generally acknowledged that there are two exceptions to the common law rule:

- Therapeutic Privilege
- Emergency Life-Threatening Situation.

8.1 Therapeutic Privilege

Therapeutic privilege means that a Clinician can withhold information if he/she feels that it would be psychologically damaging to the patient to disclose. It is rare for a Clinician to 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.

If a physician was conscious that an anxious man might refuse important treatment, if told of every single possible adverse outcome, the clinician might, according to his/her therapeutic privilege, be justified in withholding certain facts.

However, the therapeutic privilege does not extend to giving clinicians the right to lie to their patients; clinicians have an ethical duty to share information with their patients.

8.2 Emergency Life Threatening Situation – Doctrine of Necessity/Implied Consent

In an emergency life-threatening situation where the patient is unable to consent or to appreciate what is required the Clinician 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 the Clinician 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. The Clinician must demonstrate that he/she attempted to ascertain whether or not an advance directive existed which may be indicative of the patient’s wishes/consent.

There are two other reasons where the Clinician may retain information regarding a procedure from a patient.

8.3 When the Patient chooses not to hear all the information
(Refer to appendix 3)

A patient may wish not to participate in the decision making process concerning their treatment or care. The attending Clinician and other members of the clinical team will respect the wishes of the patient who is refusing detailed explanations, by withholding the information or discussing the procedure with the family.

If such a situation occurs the patient, if willing, should be asked to sign a waiver, stating that he does not wish to discuss the matter following advice being offered. This should also be clearly recorded in the healthcare record.
8.4 When the Patient has Prior Knowledge

Regardless of whether the patient has prior knowledge of the procedure, all risk 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.

The patient’s condition may have changed somewhat between the two procedures, or new risks and complications may have come to light in the recent up-to-date literature, which should be known to the clinician and should be explained to the patient.

9.0 Who Can Obtain Consent from Patients or Guardians?

Informed consent can be obtained and records secured only by persons suitably qualified or experienced enough to understand the proposed treatment and risks involved.

This individual must be in a position to respond to and answer any questions the patient may have, and give appropriate explanations regarding the procedure.

- Consultants should not delegate consent to junior colleagues who may not have the same or sufficient knowledge regarding the benefits or risks attached to certain procedures, especially in cases where the junior doctors may not have carried out the procedure in the past.

Usually, consent for medical and surgical procedures is obtained by the doctor. However, other clinical procedures do require a level of consent and therefore other clinicians including nurses/midwives and allied health professionals should follow the same principle. For example in the case of a patient requiring physiotherapy, the physiotherapist treating the patient should advise on the safe use of equipment and the benefits and risks associated with the treatment.

A clinician should not seek to obtain consent in circumstances where he/she feel they are not suitably qualified or experienced. If you have concerns in this regard you should ask a senior colleague for help. Failure to do this means that you are likely to be storing up problems for yourself, as the “consent” you secure from the patient may not, by definition, be fully informed and therefore, not valid.

10.0 What Patients Should be Told

It is clear that Irish Law on informed consent has shifted from a doctor-centred standpoint to that of the patient therefore Clinicians must ensure that patients know enough to enable them to decide about treatment.

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

- Given full details about their condition, diagnosis and prognosis including any doubts that may exist
- Told what the treatment is and its potential benefits
- Advised of the likely implications of not having the proposed treatment
- Informed of all treatment options
- Informed of any drug treatments
- Fully advised about what to expect and about common and serious side effects
- Told about any ancillary treatment and risks involved
- Told about follow up treatment, if any
- Specifically told if the treatment is part of a clinical trial or is in any other way experimental
- Given the name of the Clinician who will have overall responsibility for the patient and have it explained, where appropriate, that no guarantee about who will carry out the procedure is given
- Made aware he/she can withdraw consent at any time.

11.0 Essential / Elective and Non-Essential / Elective Treatment

In any proposed treatment, requisite information must be given to a patient to enable him/her to consent or refuse consent to that treatment. However, clinicians should be aware of the distinction which the Courts have made in recent years between essential/elective and non-essential/elective treatment. This is because in general, the necessity for surgical treatment, and the risks of not having treatment, is less obvious than in an emergency case, and the decision for the patient will be more difficult. In the case of elective treatment 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.

There should be a distinction drawn between what a patient should be told before an elective operation and what he should be told before a non-elective operation.

12.0 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-mediated or sedated in preparation for a procedure or if the patient is in severe pain e.g. the patient in labour consenting to having an epidural for analgesia. In the case of planned elective surgery where there is unlikely to be a change in the patient’s condition, consent could be obtained from the patient during an outpatient consultation. The surroundings of an outpatient consulting room may reduce anxiousness and the patient is more likely to retain vital information. As can happen in today’s climate, if a lengthy delay occurs between the outpatient consultation and admission to hospital to undergo the procedure then consent should be obtained again on admission.
It is recommended that written consent should be obtained within three months of 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 Clinician or delegate should ideally ensure that the patient has an opportunity to discuss the planned procedure. The above considerations must also be given to non-elective procedures as delays can often occur between outpatient consultation and the procedure itself e.g. when a patient’s condition deteriorates to warrant earlier intervention or alternative procedure.

13.0 Withholding Consent- (Appendix 4)

A patient does not have to consent to undergo treatment if he/she does not want to. Flowing from the principles of autonomy and self determination is the intuitive corollary that a patient ‘of sound mind and adult years’ capable of giving consent to a given treatment is similarly free to refuse his consent to the same treatment. This is true even if the decision appears irrational to the onlooker and applies even where such refusal is not considered by the clinician to be in the patient’s best interests. Where a decision to refuse treatment (for example on religious grounds) appears “irrational” the implications of this decision should be carefully explained. The decision, however, ultimately rests with the patient in these circumstances.

In Ireland, the right to refuse medical treatment is enshrined in the ‘un-enumerated’ rights protected by the State under the Constitution and which have been held to include a right to bodily integrity.

Article 40.3.2 states that the state guarantees in its laws to respect and as far as practicable, by its laws to defend and vindicate the personal rights of the citizen. Article 40.3.2 states that the state shall, in particular, by its law protect as best it may from unjust attack and in the case of injustice done, vindicate the life, person, good name and property rights of every citizen.

In such cases it is particularly important to accurately document in the patient’s record any 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.

The clinician is obliged to disclose details of the alternative treatment, if available, and perhaps offer an opinion that it may not be in the patient’s best interest to refuse treatment, but nevertheless the patient should be informed of the alternatives and that the patient can then make up his/her mind whether or not he/she wishes to avail of the alternative treatment. In such circumstances, it is strongly advised to obtain the opinion of a suitably qualified colleague and to carefully document their views/input and the decision taken. It may also be appropriate to facilitate referral of the patient to another clinician for a second opinion.

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. The child’s welfare is paramount and it is the parents who must give consent to treatment for the child.
14.0  Additional Information for Children

14.1  Foster Children

The Childcare Policy Unit of the Department of Health and Children issued a circular dated 30th November 1999 to all Health Boards and Voluntary Hospitals on consent to medical treatment for foster children. The circular is attached herewith (Appendix 1, Consent to medical treatment for foster children).

The Child Care (Amendment) Act 2007 states that a foster parent or relative with whom the 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 Child.

14.2  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 be attached 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. Ideally both parents should be informed.

14.3  Children of Unmarried Parents

In the case of unmarried parents, it is the mother who is entitled to give consent to treatment, as the mother is 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 Infant Act, (1964) as amended by the Children Act, (1997), the unmarried father and mother can obtain joint custody of the child. The Declaration should state that they are parents of the child, agree to the appointment of the father/mother as guardian of the child and have entered into arrangements regarding custody of and access to the child. Furthermore, where an unmarried father has, pursuant to an order of the Court, been granted guardianship rights in relation to his child under the Guardianship of Infants Act, 1964 as amended by the Status of Children Act (1987) and the Children Act, (1997) then he would be entitled to give consent to medical treatment of his child.

14.4  Parental Refusal to Consent to Treatment of a Child

Where parental consent is being withheld in circumstances where the healthcare professionals are of the opinion that the treatment is necessary to preserve the life, health and/or safety of the child, immediate steps should be taken. All attempts to secure parental consent should be made and noted. The hospital staff can notify the Hospital Social Work Department who will liaise with the HSE Social Work Area Team where the child normally resides. Where all attempts to obtain parental consent have failed an emergency application to a Judge/or sitting Court can be made under the provisions of the Child Care Act (1991).
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. HSE should ensure that there is some system in place to facilitate this (section 17.0 Ward of Court). 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 it is 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. (See section 24.0: Consent for blood transfusion).

14.5 Children in the care of the Health Service Executive

If a child is under "Statutory Care", an Order has been made by the Court under Section 18 of the Child Care Act 1991 the appropriate body to give medical consent is the relevant Social Worker appointed to the child by the HSE In general the child’s parent or guardian is still entitled to give consent where they are contactable and co-operative with medical personnel. Best practice would be to try and include both parents when obtaining consent. This is the procedure to follow for elective scheduled procedures. When a child is under "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 child’s Social Worker should be notified.

15.0 Minors (16 Years of Age) and Medical Treatment

Since 1997, the provisions of section 23 of the Non-Fatal Offences Against the Person Act (1997) provides that a minor that has attained the age of 16 years can consent to surgical, medical or dental treatment.

15.1 Section 23 of the Non-Fatal Offences against the Person Act, 1997

This Section states that:

"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".

Thus for example, where an individual of 16 years of age requires an appendicectomy, he/she can consent to such treatment and parental consent is not required. This includes consent to an anaesthetic, which is ancillary to the treatment and also includes any procedure undertaken for the purpose of diagnosis. The Non-Fatal Offences against the Person Act (1997) presumes that the minor has the capacity to consent and thus understand the proposed treatment except in the case of psychiatric illness.

16.0 Minors Under 16 Years of Age

Children under the age of 16 years are presumed to be legally incompetent to make decisions about medical treatment and therefore such decisions must be made by parents/legal guardians.
There are circumstances where an individual under the age of 16 years may be able to give consent to medical treatment. In these circumstances, the individual under the age of 16 must have sufficient maturity, understanding and intelligence to enable them to fully appreciate the nature, purpose and likely consequences of undergoing or refusing to undergo the procedure that is being proposed.

However, it is important to note that the situation pertaining to the competence of the minor under the age of 16 has not been tested by Irish law and the courts in this country. In the absence of Irish judicial consideration of this matter, it would be prudent practice on the part of the Healthcare Professional/medical team to consider the views of a minor and to involve all relevant parties, i.e. the medical team, the minor and the parents/legal guardians, in the consent process.

In any situation where a parent or next of kin is entitled to make a decision in relation to medical treatment on behalf of a minor, such a decision must be reasonable and in the best interests of the child, if it is not, the court has the power to override such a decision. Confidentiality of patient records and treatment must be safeguarded at all times regardless of the age of the patient, unless the practitioner has cause for concern for their well being.

16.1 The Minor Parent

In respect of children i.e. any minor not competent to consent and those below the age of 16, it is the parent or legal guardian that will give consent on behalf of a child.

The special status of the family is recognised by Article 41 of the constitution and will be protected by the courts. The Constitution however, also recognises that parents have duties towards their children and states at Article 42.5 that “…where parents for physical or moral reasons fail in their duty towards their children, the State as guardian of the common good, by appropriate means shall endeavour to supply the place of the parents…”. Established statutory parental duties are also recognised and are now stated in the Children Act (2001) which states at Section 246(1) that:

“It shall be an offence for any person who has the custody, charge or care of a child wilfully to assault, ill-treat, neglect, abandon or expose the child, or cause or procure or allow the child to be assaulted, ill-treated, neglected, abandoned or exposed, in a manner likely to cause unnecessary suffering or injury to the child’s health or seriously to affect his or her well-being.”

The Act goes on to state that at Section 246(5):

“For the purposes of this section a person shall be deemed to have neglected a child in a manner likely to cause the child unnecessary suffering or injury to his or her health or seriously to affect his or her well-being if the person –

(a) fails to provide adequate food, clothing, heating, medical aid or accommodation for the child, or

1 The Act defines parents under section 3 as (a) in case one parent has the sole custody, charge of care of the child, that parent, (b) in case the child has been adopted under the Adoption Acts, 1952 to 1998 (or, if adopted outside the State, his or her adoption is recognised under the law of the State), the adopter or adopters or the surviving adopter, and (c) in any other case, both parents.

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Section 246(6) states in subsection (1) the reference to a child’s health or well-being “includes a reference to the child’s physical, mental or emotional health or well-being.”

In relation to medical treatment, where a parent refuses to consent to medical treatment on behalf of their child, which is in the best interests of the child, such a refusal, if regarded as unreasonable can be invoked to protect the interests of a child whose health is at risk.

Situations will arise where a child may require medical treatment where the parent him/herself is a minor e.g. a mother who is 15 years of age with her child who requires medical treatment. When such situation arises then:

(i) If the child of the parent requires emergency treatment – the formality of the consent process is dispensed with and the Healthcare Professional must treat the child.

(ii) If the child of the parent requires therapeutic treatment (but not emergency), then normally the consent of the adult parent is sought. However, where the parent is a minor him/herself, obtaining such consent presents a difficulty since it is uncertain whether or not a minor parent can consent to treatment for their child since minors are deemed to be legally incompetent to give consent. The situation has not been examined by the courts. In light of the legal uncertainty, it would be prudent practice to attempt to:

a) Obtain the consent of an appropriate next of kin who is competent to consent and which consent is in the best interests of the child;

b) Include all parties in the consent process (including the minor parent);

c) Ensure that if the next of kin does give consent that their signature and name is recorded on the consent form and;

d) Ensure that such situations are recorded in detail in the patient’s healthcare record/notes;

e) In case of doubt/uncertainty, it is recommended that healthcare providers seek further legal advice.

This advice is similar to that in the UK where other recent guidelines entitled Seeking Consent: Working with Children Department of Health, (2001) state:

“Sometimes, the person with parental responsibility may be available, but is not competent to give or withhold consent: for example if the person with parental responsibility is under the influence of drugs, or the mother of a child is herself under 16 and is not competent to make that particular decision... In such cases, if there is no-one else with parental responsibility available and the treatment cannot wait, it will be lawful to provide it on the basis that it is in the child’s best interests”.

17.0 Ward of Court (Semi Urgent/Elective)

In circumstances where a person is a Ward of Court, the Ward of Court’s Office issues a Certificate of Consent for medical treatment of the Ward on the basis of a medical opinion
provided to the Office outlining the need for treatment. A certificate will normally be issued if needed in a very short space of time. The Ward of Court’s Office may be contacted through HSE Mid-West legal representatives Dermot G. O’Donovan Solicitors (061 314744) Monday – Friday. When a person (not a minor) has been taken into wardship, it means that the President of the High Court has found, on the basis of medical evidence available to him, that the person is of unsound mind and incapable of managing his person or property.

The process to be followed for Temporary Ward of Court to enable specific procedure/treatment to be carried out on a patient not competent to give informed consent in relation to semi-urgent/purely elective cases is:

1. Consultant/NCHD notify Business Manager of requirement
2. Consultant must provide written report detailing
   - History of illness
   - Need for surgical intervention
   - Consequences of not performing surgery
   - Risks of surgery
   - Next of kin
   - Marital status of the patient
   - What the patient has been told regarding surgery
   - What was the patient’s response
   - Consultant’s view on the patient’s ability to comprehend
4. Consultant and Psychiatric patient reports must be submitted to Solicitors via Business Manager
5. The Business Manager communicates with the Ward Manager and Consultant re developments
6. The Solicitors will then prepare Affidavit for Consultant to sign
7. The Solicitors will then present case to the High Court for ruling
8. The Court may appoint guardian ad litem for the patient. Essentially this person (solicitor) will visit the patient and interview same re procedure.
9. The Court approves order to proceed with Surgery
10. The Solicitor notifies the Business Manager, who confirms to the Consultant and Ward Manager that the High Court has approved Temporary Wardship and operation may go ahead. The order should be filed in the patient’s healthcare record.
11. If further treatment is required it is necessary to obtain another Temporary Wardship (refer to section 8.0 in the case of emergency situations)

18.0 Older People

Older people, like any other adult have rights that are enshrined in the Constitution of Ireland, the European Convention of Human Rights and the UN Convention of Human Rights and the UN Convention of Human Rights; this includes the right to make their own decisions.

Principles in providing services to older people are: independence, provision of information, right to decide and to be involved in decision making regarding care options, empowerment, dignity, individualised, client focused and accessibility to services. Healthy Ageing (2001).

In the majority of circumstance the application of these principles may be obvious and straightforward, their successful operation being dependent on the appropriate organisation of
services and the appropriate understanding of staff involved in the delivery of the services. However, it becomes more complex when certain other factors are taken into account. For example, issues related to dementia and diminished capacity, or issues related to a person's social context.

18.1 Older People and Consent

For the majority of older people who come into contact with Acute Hospital Services they have the same issues regarding consent as any other adult. These may usually be concerned with clinical treatment, and as such should be governed by the same procedures and guidance as for any adult. However, for a minority of older people who require higher levels of support, there is a range of other circumstances where consent arises. All aspects of consent can become more complex where there may be diminished capacity due to dementia.

Older people come into contact with Acute Hospital Services in a variety of situations and circumstances to include:

- In emergencies, a person may be admitted to Accident and Emergency;
- They may be in need of clinical treatment requiring admission to a medical/surgical/orthopaedic ward;
- They may be seen by specialist services on an out-patient basis or may require some ongoing nursing/medical treatment at home, which may be provided by a Public Health Nurse or visiting Registered General Nurse following their discharge from Hospital;
- A person may be vulnerable and at risk and may require services to respond to protect and support them outside the Acute Hospital Setting.

Regardless of the circumstances, older people must agree or disagree of their own free will to clinical treatment or clinical investigations and are not forced or compelled by any relatives or religious beliefs.

18.2 Dementia and Capacity to Consent

It is a substantial principle that any adult has the right to make decisions about their care and to consent or not consent to any treatment offered even though those subsequent decisions may be against the advice of their clinician. Therefore the person has the right to refuse clinical treatment or any care plan offered by a clinician. However, careful consideration needs to be given to the ability of the person to make informed decisions and their capacity to give consent.

It must be acknowledged that an elderly person's mental capacity can fluctuate or change over a period of time, and that a person can be assessed to have capacity to take responsibility for some decisions but not others. Therefore, when decisions or consent is required it is necessary that the person's capacity is assessed.

19.0 Adults with an Intellectual Disability (Appendix 3)

(Not necessarily of unsound mind or not detained under mental health legislation)

In the absence of specific legislation to direct healthcare professionals, the position in Ireland with regard to consent to treatment of adults with intellectual disabilities is unclear, and is a matter of great concern to all involved in their care. People with intellectual disability do not
have clear rights to make decisions. The law on deciding who has decision-making capacity is very inadequate and the arrangements for supported and substitute decision-making are non-existent. This creates major practical difficulties for parents and service providers. In general, in Ireland, an adult is a person who is aged over 18 years. Adults have the right to make decisions about their lives. People with intellectual disabilities have the same rights to self-determination as everyone else. However, they may not have the capacity to make certain decisions.

In practice, decisions are made on behalf of adults with intellectual disability by parents or by service providers. There is no formal system of assessment of the capacity of the person with intellectual disability to make decisions for him/her (unless there is an application to have the person made a Ward of Court (see section 17.0). Parents/carers and service providers effectively make the decisions that are needed. These range from decisions about where a person is to live or what he/she is to wear to decisions about medical treatment and social relationships including intimate relationships. The majority of decisions made are necessary, appropriate and in the best interest of the person but there is always the danger that they may infringe the rights of the person with the disability or may involve abuse, exploitation, or fraud. Parents and service providers have no legal authority to make such decisions. They are left in a very unsatisfactory situation where decisions have to be made but there is no one person with authority to make these decisions. A person with an intellectual disability may be denied medical treatment, which would be beneficial but is not essential because there is no one person with authority to make a decision. However, the following practices have evolved over the years:

- If the person’s mental condition is such that he/she is unable to consent to the proposed treatment/procedure, then the practice in this country has been to obtain the consent of the next-of-kin. However, while it may be the practice, there is in fact no legal or common law basis for it, and the practice is therefore open to challenge. Legally the correct way of proceeding is a wardship application.

- Where the patient lacks the capacity to give or withhold consent (as distinct from an inability to communicate their wishes) consideration should be given to whether the patient’s capacity is likely to return in the future (e.g. when the patient regains consciousness or becomes more lucid). Where this is likely and the proposed treatment can safely be deferred until that time this should be the course followed.

- Where capacity is not likely to return the treating clinician must act in the patient’s best interests. In such situations it should be remembered that “best interests” might not be limited to medical considerations only. Other issues such as the patient’s general well-being, wishes/views expressed prior to loss of capacity (if known) and religious convictions might also be taken into account.

- Where a decision is being taken about treatment in the absence of consent due to a patient’s lack of capacity to make a fully informed decision for themselves, it is important to remember that no one (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 clinician. However relatives should be included to the greatest extent possible in the decision making process and ideally decisions will reflect a consensus between the Clinician and those closest to the patient. During this consultation with relatives it must be remembered that it is only the patient’s best interests that should be considered – it is not appropriate to balance these against anyone else’s interests. If the need for the procedure is not life threatening, all possible measures must be taken to obtain consent from the patient.

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Where treatment is being given in the absence of the consent of a person with a learning disability, it is most important to carefully document the decision taken. Specifically it is important to record how it has been determined that the patient lacks capacity (e.g. patient's condition, consultation with other professionals). It is also important to record the decision making process undertaken (including discussion with relatives and consultation with other healthcare professionals) and why it is considered that the treatment is in the patient's best interests. Consultation with colleagues, to include Psychiatrist, Psychologist and cross-care groups, in these circumstances is highly advisable and their views/input should also be recorded. Any disagreement among healthcare professionals should also be documented.

In circumstances where there is no known next-of-kin (and the person lacks comprehension), but the Clinician believes that the proposed treatment/procedure is necessary to save the person's life or to ensure improvement or prevent deterioration in the person's condition, it is prudent for the treating Clinician to seek a second clinical opinion (also consider Psychiatrist, Psychologist and cross-care groups) prior to proceeding with the treatment. The clinical rationale for proceeding ahead with treatment should clearly be documented in the person's healthcare record.

20.0 Treatment for Mental Health Conditions / Disorders – (See Appendix 3)

Common Law principles apply i.e. to treat such adults for their mental disorder without obtaining their consent is unlawful unless it is an emergency, life-threatening situation.

However, Clinicians should be aware that when asked to make decisions about the care and treatment of the above persons, they are bound not only by the law, but also by their professional code of ethics. The medical profession's Code of Ethics demands that "doctors must do their best to preserve life and promote health." The Medical Council: A Guide to Ethical Conduct and Behaviour – 6th Edition (2004). When dealing with the above category of vulnerable persons, Clinicians must always be seen to have acted reasonably in the best interests of the patient. This should include a consideration of alternative (if any) and/or less invasive procedure to the ones proposed.

In any situation where a parent or next of kin is entitled to make a decision in relation to medical treatment on behalf of a minor, such a decision must be reasonable and in the best interests of the child. If it is not, the court has the power to override such a decision.

Confidentiality of patient records and treatment must be safeguarded at all times regardless of patients age, unless the practitioner has cause for concern for their well being.

Mental Health legislation provides that persons detained may under certain conditions have treatment for their mental illness not just without their consent, but against their wishes. Part 4 of The Mental Health Act (2001), enacted and now implemented, prescribes these conditions precisely. Best practice is that the same principles be adhered to in the meantime.

“Consent” in the Mental Health Act (2001) means consent obtained freely from the patient without threat or inducement.
Medication may be prescribed by a consultant Psychiatrist without the patient’s consent up to a period of three months, thereafter consent must be given by the patient or in the absence of consent a second consultant’s opinion must be obtained and documented.

Electroconvulsive Treatment may only be administered either with the consent of patient or in the absence of consent with a second consultant recommendation documented.

Psycho-surgery or other invasive treatments may only be administered with both consent and the approval of an independent tribunal.

The Mental Health Act 2001 has been in force since 1st September 2006 and the only appeal an involuntarily detained person can make from a decision of the Mental Health Tribunal is to the Circuit Court.

Persons detained under this legislation may still be competent to consent or otherwise to treatment for co-morbid conditions, the same tests of competence applying as apply to all other patients.

If a person is admitted on a voluntary basis, once in hospital he/she does not have precisely the same rights to autonomy as other members of the public. A patient who is a voluntary patient but wishes to leave the hospital may be detained for 24 hours to allow consideration of whether he/she should be involuntarily detained. If detained then the rules for involuntary admission or renewal of detention apply as they would for an involuntary patient.  

There is an expectation that the concept of capacity and guardianship will become an issue in the near future for the treatment of mental health conditions / disorders.

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2 A voluntary admission is defined as a person with a mental health problem requiring admittance to hospital by choice for treatment.

An involuntary admission is where a patient is admitted to hospital against their will. A patient can only be admitted to hospital against their will if they have a mental disorder. The law defines mental disorder, as follows:
The person has a mental illness, severe dementia or significant intellectual disability and there is a serious risk that they may cause immediate and serious harm to themselves or others or The person has a mental illness, severe dementia or significant intellectual disability and their judgment is so impaired that their condition could get worse if they were not admitted to hospital for treatment that could only be given to them in hospital and going into hospital would be likely to improve their mental health significantly.

Guidelines for Consent to Clinical Examination and/or Treatment

May 2009
21.0 Living Wills or Advance Directives (also legally known as Enduring Powers of Attorney)

Living wills allow a person to leave instructions about their possible medical treatment, in case they are no longer capable of making decisions or of communicating them. A living will outlines in clearly defined circumstances, that the patient does not wish to receive treatments such as resuscitation, or being kept alive indefinitely on a ventilator.

An essential point to understand is that 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. It would therefore be advisable that the Clinician prior to taking the details of the advance directives from the patients, should be satisfied that this patient is of sound mind and that the Advance Directives are given at his/her own free will and is not subject to any undue influence by any third party.

Once a Clinician, ideally a Consultant or if not possible an experienced Registrar, is satisfied that the patient is competent to make their wishes known about future treatment of a condition that has not yet arisen, or a current condition that may deteriorate into the future, he should, ideally in the presence of a nurse, clearly record the Advance Directives in the healthcare record.

The Clinician must be satisfied that the competent patient intends the Advance Directives to remain effective when, or if they become incompetent. The patient should be fully advised of the disadvantages and advantages of the implication of his/her Advance Directives, like for example not to resuscitate him/her if unconscious and the implications of same, or not to be kept alive indefinitely on a ventilator.

Again ideally the next of kin, particularly partners of the patient, whether husband or wife, should be involved in this decision making process with the patient's consent, but ultimately the final decision must of course rest with the patient in making his/her Advance Directives.

It should also be recorded in the healthcare record that the Consultant did discuss the advantages and disadvantages of the proposed Advance Directives.

The Clinician must understand that the Advance Directives still continue to represent the wishes of the patient once communication becomes impossible, or the patient is no longer of sound mind. However, a Clinician should check carefully the date upon which a Living Will or Advance Directives were recorded in the healthcare record. If it was not done very recently, then there should be a full investigation of how long ago the Advance Directives were made, the knowledge the patient had when making the Directives and the circumstances surrounding the making of the Directives and especially whether or not the condition that the patient is now suffering from was specifically catered for by the patient in giving the Directives. The Clinician should also consider if there is any evidence in the record that the patient was contemplating changing his/her mind since either signing the Directives, or recording in the chart the patient's specific wishes.

The essential criteria is that where a situation falls within the full terms of the Advance Directives, then the Clinical should treat it as the definitive and final wishes of the patient and act accordingly.

Obviously in Ireland an Advance Directives refusing treatment where one's life is being severely compromised does not prevent the health care professional from providing basic care, such as keeping the patient clean and warm and providing pain relief and this has been endorsed by the Supreme Court in the case of "Re A Ward of Court" 1996. Basic care also includes hydration and nutrition as per Medical Council Guidelines. Furthermore, an Advance Directive cannot
allow a Clinician to commit an act to end a patient’s life and if such a request is made then the entire Directive is ineffective.

One note of caution and it can, but rarely does happen, where partners, whether they are husband and wife or common law spouses, may both enter into a Living Will or Advanced Directives but that one party to the relationship may be dominant and the other party may not fully understand what the Living Wills/Advance Directives mean. It is essential that the clinician addresses both parties separately and ultimately is satisfied that one party is not unduly influenced by the other party.

A point to understand about Living Wills and Advance Directives is that there is no statute governing advance directives in Ireland. The Irish courts have not considered the matter explicitly, other than in cases involving Jehovah Witnesses.

22.0 Where Communication with the Patient is Not Possible – (Appendix 3)

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 colleagues with expertise in learning disabilities or speech and language.

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 following a stroke a family member maybe 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 themselves decide what might be best for the patient.

This applies equally to circumstances where – due to a language barrier – an interpreter (whether related to the patient or not) is assisting in the communication process. Whenever possible, information (both verbal and written), should be available to patients in their first language.

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.

In all circumstances where communication is not possible healthcare professionals must act in the best interests of the patient. In such situations it should be remembered that “best interests” might not be limited to medical considerations only. Other issues such as a patient’s general well-being, wishes/views previously expressed (if known) and religious convictions might also be taken into account.

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 clinician. However relatives should be included to the greatest extent possible in the decision making process and ideally decisions will reflect a consensus between the Clinician and those closest to the patient. During this consultation with relatives it
must be remembered that it is only the patient’s best interests that should be considered – it is not appropriate to balance these against anyone else’s interests.

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.

23.0 Resuscitation

Under Article 2 of the European Convention on Human Rights, Strasbourg 20th January (1966) every person has the right to life. A patient has the right to be resuscitated if he/she has a reasonably good prognosis and if the procedure that they are undergoing has a reasonable possibility of success. If a patient was asked before a procedure what their wishes would be in the event of a cardiac arrest, and it was established that the patient would not like to be resuscitated, then their wishes would prevail.

It should also be established that the patient has the mental capacity to understand and make such a decision. Evidence of this should be entered into the patient’s healthcare record. Ideally, decisions about whether to attempt to resuscitate a particular patient should be made in advance, as part of the overall care planning for the patient and, as such, are discussed with the patient along with other aspects of future care.

23.1 Incapacitated Adult

No person is legally entitled to give consent to medical treatment on behalf of an adult who lacks decision-making capacity. Where the patient lacks capacity and has not previously expressed a wish to be treated, the Clinician must act in the patient’s best interests. The patient’s age alone should not be a determining factor in assessing their best interests.

In such situations it should be remembered that “best interests” might not be limited to medical considerations only. Other issues such as the patient’s general well-being, wishes/views expressed prior to loss of capacity (if known) and religious convictions might also be taken into account.

Relatives and concerned others should be assured that their views on what the patient would want will be taken into account in the decision making process but they cannot insist on treatment or non-treatment. Clinicians cannot be required to give medical treatment which is contrary to their clinical judgement.

23.2 Children and Young People

The views of children and young people must be taken into account in the decision making process about attempting resuscitation. Parents cannot expect Clinicians to provide treatment contrary to their professional judgement, but Clinicians can try and accommodate parent’s wishes while protecting the wishes and the best interests of the child. If a disagreement regarding resuscitation arises between the Clinician and the parents of a child, despite numerous
attempts to reach agreement, legal advice should be sought. All communication regarding the issue of resuscitation must be documented in the healthcare record.

23.3 “Do Not Resuscitate” decisions

If the patient is fully competent a decision as to a “Do Not Resuscitate Order” should rest with the patient, not the clinician. The following points can lead to withholding cardiopulmonary resuscitation (CPR):

1. The refusal of the mentally competent patient to medical treatment
2. Patient’s known or ascertainable wishes
3. The likely event that CPR is likely to be succeeded by a poor quality of life, which is not be in the best interests of the patient
4. If treatment was not in accordance with the professional judgements of medical staff.

It is only in emergency situations where no advance decision has been made or known that points 3 and 4 above should be considered.

Where a decision is being taken about withholding life-prolonging treatment (in the absence of expressed consent) 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 clinician. However relatives should be included to the greatest extent possible in the decision making process and ideally decisions will reflect a consensus between the Clinician and those closest to the patient. During this consultation with relatives it must be remembered that it is only the patient’s best interests that should be considered – it is not appropriate to balance these against anyone else’s interests.

A ‘not for resuscitation’ decision should be documented in the patient’s record. This note should normally be signed by the patient’s Consultant/Registrar, following an appropriate level of consultation with other healthcare professionals.

Any decision not to administer resuscitation should be reviewed in light of the patient’s progress and not seen as a “one-off” decision.

24.0 Blood Transfusions

In a situation where a patient requires a blood transfusion as part of medical treatment, verbal consent must first be obtained. In addition, written information on the procedure should where possible be given to the patient. An accompanying information leaflet should ideally contain the following: (refer to MWA Hospitals Blood Transfusion Manual located on all wards)

- What the procedure is and what it entails;
- The purpose and the benefits associated with a blood transfusion;
- The risks associated with such a procedure;
- What are the safety measures to ensure uncontaminated blood;
- The reactions that may be experienced while undergoing a transfusion and the associated treatments;
- What are the alternatives to a blood transfusion;
In the case where the clinician is dealing with a minor whose parents are refusing consent to a blood transfusion (refer to section 14.4).

25.0 Consent for Clinical Trials and Research

Essentially, participants must be informed of the risks of the trial or research as well as the purpose of the trial and the qualifications of the healthcare professional. Written consent must be obtained. All risks and discomforts must be explained to the patient. Consent can be withdrawn at any time and there must be a strict cooling off period between the provision of the information and the commencement of the trial. There is an absolute duty on the Clinician to disclose all known risks to the participant. This is governed by the two acts of the Oireachtas, Control of Clinical Trial Act, 1987 and the Clinical Trials and Drug Act, 1990 as well as by the Directive 2001/20/EC Pursuant to Statutory Instruments Number 190 of 2004 entitled “European Communities (Clinical Trials of Medicinal Products for Human Use) Regulations 2004.

26.0 Clinical Photography and Other Recordings

Photographic or video recordings which have been made for the purpose of treating or assessing the patient may not be used for any other purpose without the written consent of the patient. All clinical photography and other recordings must comply with the provisions of the Data Protection Acts (1988 and 2003) and be stored in a secure manner. Any person undertaking patient photography does so on the understanding that all images that are produced will be regarded as medical records and are therefore protected in the same manner. Each healthcare institution must have a policy dealing with this issue, which must be read and adhered to by all staff. (Consult guideline available in OPD).

A full and detailed explanation of the purpose of the photographs and how they will be used must be given to the patient in the form of a written leaflet in addition to appropriate written consent being obtained before any photography takes place. There are special circumstances where the attending consultant may not require consent. Examples of these circumstances are the following:

- Suspected non-accidental injury to a child
- Deceased patients whose next of kin is not known.
- Visual evidence for legal reasons
- Persons obtaining treatment under false pretences

Written consent must also be obtained from a parent or guardian when undertaking clinical photography or recordings of a minor (less than the age of 16) 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.

Consent must also be obtained in the case of an unconscious patient. Photographs may be taken but should not be used until signed consent has been obtained. In the event of recovery the physician must inform the patient that photographs have already been taken and the reason why they were taken. In the event of the patient refusing to sign a consent form for the release of the recordings, the images must be destroyed. If the patient is likely to be permanently unable to give consent, agreement must be sought from the next of kin. No such recording must be made if the purpose of the recording could have equally been met by recording another patient who can
give or withhold consent. In the event of the death of a patient, confidentiality must be maintained. The next of kin of a deceased patient has the right to withdraw consent at any time regarding the use of these images. It is also recommended that such images not be kept for longer than is necessary. It is not sufficient that black bands be used across the eyes in facial images to conceal identity. Any clues from which a patient may be identified must also be removed. Patients have the right to withdraw consent at any time during the recording, after which the images must be destroyed. Patients must be made fully aware of the implications of the recording entering the public domain. Patients have the right to have information about them altered or deleted if appropriate.

27.0 Provision for Patients Whose First Language is not English

These patients must receive the appropriate written and oral information they need in order to make a rational decision. Provision must also be made for staff to communicate appropriately with patients. Interpreters must be informed of the obligation of confidentiality and if deemed necessary and desirable be asked to sign a confidentiality agreement. The signing of such an agreement will ensure that the healthcare provider has discharged its duty by protecting as best it can the patient’s confidentiality and demonstrating that it has done so. (Please contact patient services to arrange interpreting services).

28.0 Hearing Impaired Patients

Hearing impaired patients should expect to be provided with appropriate communication support at every consultation and at every stage of their treatment process. The use of a properly trained interpreter is important to ensure the quality of the service. Such interpreters must adhere to a strict code of ethics and confidentiality. (Please contact Patient Services).

29.0 Visually Impaired Patients

Provision must also be made for blind patients to communicate appropriately in order to obtain informed consent. This may take the form of a tape recorder to secure consent. This recording must accompany an additional consent form, which must be signed by the attending physician and a witness who may be a member of healthcare team involved in the delivery of the patient’s care. Information regarding proposed procedure must be given in audio form in order for the patient to make a rational decision. The recording of the consent must be stored in a secure setting to protect patient confidentiality. Documentation of all communications between physician and patient must be entered into the healthcare record.

30.0 Needlestick Injury/Staff Exposure to Blood Borne Viruses

Where a blood sample is to be taken from a patient for the purpose of testing for HIV written consent is not routinely required.

Where a healthcare worker has sustained a needlestick injury or exposure to blood borne viruses a blood sample needs to be taken for testing for Hepatitis B, Hepatitis C and HIV if the status of the source patient is not known. Refer to the Infection Control Occupation Exposure Management including Sharps Policy and Procedure June 2008.
31.0 Patient Information Sheet

On admission for elective procedures it is recommended that the patient should be presented where possible with an admission information sheet, which will be individualised for their particular case. The language should be easy to understand and consist of ‘lay man’ terms. The print should be large to aid those who are visually impaired.

32.0 Protection of Healthcare Records

Clinicians must ensure that his/her patients’ healthcare records are protected from improper disclosure while in his/her possession. If a patient gives consent to the disclosure of records, the Clinician must ensure that the patient understands the consequences of such disclosure, what will be disclosed, the reasons for the disclosure and the consequences of having given consent. Medical information must only be disclosed in accordance with the conditions of the patient’s consent. Normal professional interdisciplinary communication is to be expected e.g. other healthcare professionals as part of multi-disciplinary team. The Clinician may not disclose any medical details concerning a patient’s condition to anyone else without the consent of the patient, for example, disclosing details to the patient’s family or preparing a medical report for a solicitor or an insurance company. (Refer to hospitals healthcare records policy and Data Protection legislation for information).

33.0 Post-Mortems

In the case of a non-coroner post mortem, it is important to ensure that relatives understand what a post-mortem is and why it is undertaken. The discussion should include details of what a post-mortem entails. An information booklet is available to assist relatives in making their decision to consent to a non-coroner’s post-mortem. In the case of a coroner’s post-mortem, relatives need to be made aware that consent is not required for the post-mortem. However, a good level of communication with families at the time of death and during the post-mortem process is required. The Faculty of Pathology of the Royal College of Physicians of Ireland (2008) has issued extensive guidelines for post-mortem consent and retention of tissue. These guidelines deal with all relevant issues and all clinicians should be familiar with them.

Types of Post-mortem Examination

There are 2 types of post-mortem:

- Post-mortem examination required by the Coroner.
- Consented/Hospital Post-mortem Requested by Hospital Doctors

Post-mortem Examination required by the Coroner (please see information booklet)

When a death occurs suddenly or unexpectedly or is due to some unnatural cause, the death must be reported to the Coroner. The Coroner is an independent official with responsibility under the law for the medico-legal investigation of certain deaths. A Coroner must inquire into the circumstances of sudden, unexplained violent and unnatural deaths as well as deaths that occur during/after a surgical operation or other medical procedure. This may require a post-mortem examination sometimes followed by an inquest.
The Coroner's enquiry is concerned with establishing whether or not death was due to natural or unnatural causes. If a death is due to unnatural causes then an inquest must be held by law. If a Coroner directs that a post-mortem take place, the next of kin is legally bound to give written consent. However their wishes will be noted. If the Coroner decides that a post-mortem is required, the pathologist will be asked to carry this out and report findings to the Coroner. In these circumstances, the pathologist acts for the Coroner and is independent of the hospital. The Coroner will subsequently issue the medical certificate of death. If an inquest is required, then it can be held at a later date when all of the results from the post-mortem are available.

**Consented/Hospital Post-mortem Requested By Hospital Doctors (Appendix 5)**

Consented post-mortem examinations can be either full or limited. For more detailed information refer to the Post-Mortems Examinations Booklet.

### 34.0 Retention of Tissues

Small pieces of tissue may be taken by biopsy for pathological examination and diagnosis, and larger amounts of tissue may be removed surgically during operations for malignant or other diseases. This is usually discarded as clinical waste, but may alternatively be archived and made available for scientific research, medical training and audit of Laboratory procedures. The lead Clinician should advise patients of this practice and discuss it as part of obtaining their consent. Details of procedures on the biopsy of tissue and its use, storage and disposal are available from the Laboratory (contact Laboratory Quality Department).

### 35.0 Disposal of Limbs

Organs or segments of organs/tissues that contain disease are a major teaching resource for doctors and students of the health sciences. Such learning can only take place with the co-operation of families of the deceased.

**Removal/Retention**

- It is not necessary to retain any organ/tissue in most post-mortem examinations. Occasionally however, it is not possible to examine an organ/tissue at the time of the post mortem. Therefore it may be necessary to retain temporarily the organ/tissue (e.g. the heart) or portions of organs/tissues for detailed examination in order to make a diagnosis.

- Written consent is required from the next of kin for the retention of organs/tissues, unless a post-mortem is directed by law at the request of the Coroner.

- In this case, the Coroner may give consent to the retention of an organ provided it is necessary to determine the exact cause of death. However, if it is not necessary to determine the exact cause of death, informed consent of the next of kin must be obtained.
Storage
- The Pathology Department on behalf of the Hospital is the custodian of the organ/tissue.
- The organ/tissue must be kept in safe and secure conditions in the Hospital.
- The identity of the organ and the diagnosis is confidential and should be treated in the same manner as all other medical records.
- Organ/s and tissue samples should be preserved and retained no longer than is necessary.

Disposal
- Next of kin who at the time of death indicated that they wish to make their own arrangements for disposal of an organ will be contacted when the organs are available. The organ/s should be placed in a special container and stored in the mortuary for collection. Otherwise organs, blood fluids, and tissue samples retained by the Hospital will be disposed of in accordance with hospital policy Infection Control Occupational Exposure Management, including Sharps Policy and Procedure March (2007).
- The Hospital will maintain full records of the burial site and details of all retained organs.
- When a patient is going for removal of a limb their instructions regarding disposal of the limb must be clearly written on the consent form. (See Nursing Care of a patient undergoing amputation of a limb or digit 2006).

36.0 Jehovah’s Witnesses

This section of the guideline on Jehovah Witnesses should be read in conjunction with the entire guideline with particular reference to Section 13 (Withholding Consent), Section 16 (Minor under 16 Years of Age), Section 11 (Essential/Elective and Non-Essential Elective Treatment) and Section 21 (Living Wills or Advance Directives).

Most Jehovah’s Witnesses will not accept a transfusion of whole blood or its major derivatives. This includes fresh frozen plasma (FFP), packed cells, white blood cells and platelets. Absolute rules regarding blood products, however, do not exist and some Witnesses may accept the use of plasma protein fraction (PPF) or components such as albumin, immunoglobulin and haemophilic preparations with each Jehovah Witness deciding individually whether to accept these. Other clinical interventions may have to be dealt with on a personal basis: organ transplantation, for example, is not specifically forbidden for Jehovah’s Witnesses and each individual is expected to reach his/her own decision.

Recent knowledge of the risk of transmission of disease and other complications of blood transfusion have in many cases been cited as further support for the Jehovah’s Witnesses’ refusal to accept blood transfusion.

Jehovah’s Witnesses are generally well informed, both about their legal position and the options for treatment. Any competent adult is entitled to accept surgery but also to exclude specifically certain aspects of management such as the administration of a blood transfusion. Most practising Jehovah’s Witnesses will carry with them a clear Advance Directive prohibiting blood transfusion. Many have also executed a more detailed Healthcare Advance Directive (living will) with comprehensive personal instruction on a variety of matters and have lodged copies with their general practitioner as well as family and friends. It is important to realise that individual Jehovah’s Witnesses may have different views and the doctor’s obligation is to respect the wishes of the individual patient.
An advance medical directive by a competent adult, if properly signed and witnessed, must be respected unless there is some reason to believe that the patient has changed their view since the directive was executed. Each Jehovah’s Witness patient should be consulted with to find out which aspects of treatment are acceptable and which are not.

To administer blood to a patient who steadfastly refused to accept it either by the provision of an advance directive or by its exclusion in a consent form is unlawful, ethically unacceptable and may lead to legal consequences. In the management of trauma or when dealing with an unconscious patient whose status as a Jehovah’s Witness may be unknown, the doctor caring for the patient will be expected to perform to the best of his ability and this may include the administration of blood transfusion. However, there may be opinions put forward by relatives or associates of the patient suggesting that the patient would not accept a blood transfusion even if that resulted in death. Such relatives must be invited to produce evidence of the patient’s status as a Jehovah’s Witness. It is not uncommon for Jehovah’s Witnesses to lodge a copy of their advance directives with their General Practitioner, who should be contacted.

It is essential that clinicians who are aware that an elective patient is a Jehovah’s Witness should alert other colleagues as soon as possible in order to ensure that everybody is prepared to manage the patient’s care.

The Jehovah’s Witnesses have established a number of Hospital Liaison Committees in key locations in Great Britain and Ireland (Dublin, Telephone No 01 8403977). Representatives of these Committees are available at any time to advise or assist with the management of individual Jehovah’s Witnesses. The Hospital Liaison Committees may have a schedule or physicians prepared to manage these patients.

Full pre-operative investigations and consultation with the patient should take place as early as possible, in order to ascertain the degree of limitation on intra-operative management.

At the pre-operative visit it is very important to take the opportunity to see the patient without relatives or members of the local community who may influence and impede full and frank discussion on the acceptability of certain forms of treatment. At this stage, treatments which are regarded as acceptable should be established and the patient made fully aware of the risk of non-acceptance of blood or blood products. Agreed procedures and non-acceptable treatments should be entered into the clinical notes and signed as a record.

At the patient’s request, members of the Hospital Liaison Committee for Jehovah’s Witnesses may be part of these discussions. Their prime role should be to avoid confrontation and assist understanding on both sides.

A Jehovah’s Witness patient has the right to grant or withhold consent prior to examination or treatment. They should be given sufficient information in ways they can understand about the proposed treatment and the possible alternatives. The Jehovah’s Witness patient’s beliefs must always be respected. They should be given the opportunity to decide whether they will agree to the treatment and they are informed that they can refuse or withdraw consent.

37.0 Pregnancy Testing

In line with the NICE guidelines all women of child-bearing age should be asked if they may be pregnant. They must be made aware of the risks to the foetus of any proposed treatment, operation, or investigation. A pregnancy test may be carried out with the women’s consent if there is any doubt about whether she may be pregnant. Confirmation of verbal consent should be documented in the healthcare record.
References

Child Care Act 1991

Child Care Act 1997

Childcare (Amendment) Act 2007, Section 36

Children Act 1987 and 1997

Clinical Trials and Drug Act 1990

Control of Clinical Trial Act 1987 (Clinical Trials of Medicinal Products for Human Use Regulations 2004 2001 / 20 / EC)

Data Protection (Amendment) Act 2003 or Data Protection Act 1998

Department of Health (2001) Seeking Consent: Working with Children

Department of Health UK (2001) Consent to Examination or Treatment

Department of Health UK Good practice in consent implementation guide; consent to examination or treatment. November 2001

European Convention on Human Rights: (1966); Article 2


Guidance on the Use of Clinical Samples Retained in the Clinical Laboratory 2007

Healthy Ageing (2001)

Infection Control Occupational Exposure Management including Sharps Policy and Procedure (2007)

Infection Control Policy (2007)


Mental Health Act 2001

Mid Western Area Hospitals Blood Transfusion Manual


MWRH (2006), Nursing Care Plan of Patient Undergoing Amputation of a Limb or Digit

NHO Code of Practice for Healthcare Records Management 2007

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Non-Fatal Offences Against the Person Act 1997

The Faculty of Pathology of the Royal College of Physicians of Ireland (2003) The Use of Biological Material in Research.

Post mortem examinations booklet

The Use of Routine Pre-operative tests for Elective Surgery, NICE Clinical Guideline 3, January 2003
Consent to Medical Treatment for Foster Children

3rd November, 1999

Chief Executive Officer  
Each Health Board

Consent to Medical Treatment for Foster Children

Dear Chief Executive Officer,

I am directed by the Minister for Health and Children to set out the position in regard to the above matter as follows:

Urgent Medical Treatment

The advice of the Attorney General's Office has been sought on the matter. That office has indicated that foster carers have the capacity to consent to urgent medical treatment which, in the clinical judgement of the medical practitioner, is necessary in the interest of the patient's welfare. In any event, in an emergency situation, the doctor is entitled to intervene on his own authority, without the consent of a person in loco parentis. In considering whether the child's welfare demands that the treatment be given urgently, the child's rights to prompt medical treatment and, more generally, to have his or her welfare considered is paramount.

The consent of the foster parent to urgent treatment may be deemed to extend to ancillary procedures which, while they may not be of themselves necessary to preserve the life or health of the child, are nevertheless a necessary part of the treatment of the child. For example, the application of an anaesthetic to a child before setting a broken bone or extracting a tooth.

Non Urgent, Elective Procedures

(a) The Child in Voluntary Care

In relation to children under 16 years, consent should be sought from the child's natural parents. If this is not forthcoming, it may be appropriate to seek directions from the court under section 47 of the Child Care Act, 1991.

In relation to children who are 16 years old and over, the provisions of section 23 of the Non Fatal Offences Against the Person Act, 1997 should be borne in mind. This section provides that a minor who has attained the age of 16 years can consent to any surgical, medical or dental treatment. There may be circumstances, either because it is in the best interest of the patient or because of a doubt the medical practitioner may have as to the competency of the child to give consent, where the consent of the child over 16 may need to be accompanied by the consent of the child's parent or guardian.
If this consent from the parent or guardian is not forthcoming it may be appropriate to seek directions from the court in the matter.

A refusal of treatment by a child over 16 does not override the consent of a parent or guardian to that treatment. However, where there is such refusal, it may be appropriate for the Board to apply to the court for directions in the matter. If there is any doubt as to how section 23 should be applied, in relation to the particular circumstances of a case legal advice should be sought.

(b) Emergency Care Order or Interim Care Order

In relation to children who are under 16 years of age, the health board can seek directions under section 13(7) or section 17(4) of the Child Care Act, 1991, as appropriate. Directions can also be sought by the health board or by any person under section 47 of the Child Care Act, 1991. If a child is 16 years of age or over, section 23 of the Non Fatal Offences Against the Person Act, 1997 will apply as set out above. If there is a doubt about how section 23 should be applied, in relation to the particular circumstances of a case legal advice should be sought from the court.

(c) Care Order

In relation to children under the age of 16 in respect of whom a care order has been made, the health board can consent to elective treatment if it is in the best interests of the child. It may be prudent however to consult the child's natural parents and in appropriate circumstances seek directions from the court in the matter.

In relation to children of 16 years and over, in respect of whom a care order has been made, the provisions of section 23 of the Non Fatal Offences Against the Person Act, 1997 apply. If there is a doubt about the competency of the child to consent, such consent may need to be accompanied by the consent of the Board. It may also be prudent to consult the child's natural parents or guardian. Where there is refusal of treatment by a child over 16, it may be appropriate for the board to apply to the court for directions in the matter.

Finally, whenever an issue in relation to the welfare of the child arises, consideration should be given to the provisions of section 3(2)(b)(ii), of the Child Care Act, 1991.

I would appreciate if you could bring this circular to the attention of all relevant staff. Please note that this circular supercedes this Department's circular of 27 November, 1998 in this matter.

Yours sincerely

Eamon Corcoran
A/Principal Officer
Child Care Policy Unit

cc: Each Programme Manager, Each CEO/Secretary/Manager each Voluntary Hospital
Mid-Western Regional Hospitals Consent to Treatment Form

Patient Consent to Investigation, Treatment or Operation/Procedure

Name of Patient: __________________________________________
Address: ________________________________________________
Hospital No: ___________________________ Date of Birth _______
Consultant’s Name: _______________________________________

Type of Proposed Investigation, Treatment or Operation/Procedure: ______________________________

Section 1 – For Completion by Healthcare Professional *
I confirm that I have explained to the

☐ Patient
☐ Parent (for patients under 16 yrs)
☐ Legal Guardian

in terms which I believe he/she understands the following:

☐ The proposed investigation, treatment or operation/procedure
☐ The benefits of the proposed investigation, treatment or operation
☐ The risks associated with the proposed investigation, treatment or operation
☐ The risks associated with a decision not to proceed with the proposed investigation, treatment or operation.
☐ Such appropriate and alternative options to the proposed investigation, treatment or operation
☐ The administration of general, local or other anaesthetic as appropriate for any of these purposes.
☐ During the course of the proposed investigation, treatment or operation it maybe necessary to carry out further intervention.
☐ Clinical photography/Recordings.
☐ During the course of the proposed investigation, treatment or operation, tissue specimens maybe taken and retained for examination.

No assurance has been given that the proposed investigation, treatment or operation will be performed by any particular surgeon/physician.

Healthcare Professional’s Signature: __________________________ Bleep#____________________

Healthcare Professional’s Name in Print ________________________________________________

Date: ________________
Section 2 — For Completion by Patient, Parent or Guardian (only after Section 1 has been completed by the Healthcare Professional)

1. I have listened to and understood the explanation that I have been given in relation to the above investigation, treatment or operation and I hereby give my consent to the investigation, treatment or operation as proposed.
2. I know that I can ask for clarification of anything that I do not understand.
3. I have checked the details on this form and confirm that they are accurate.
4. I also understand that any procedure in addition to that described on this form will only be carried out if it is necessary to save my life, prevent serious harm to my health and/or maintain my health.

Signature of Patient/Parent or Guardian: ____________________________________________

(Date as appropriate)

Date: __________________________________________________________________________

Section 3— For Completion by Patient, Parent or Guardian on admission for procedure (only if Section 1 & 2 have been completed by the Healthcare Professional prior to admission)

☐ I have been given the opportunity to discuss my proposed treatment, operation or investigation and clarify my concerns.

Patient’s Signature: __________________________________ Date: ________________

Healthcare Professional’s Signature: __________________________ Bleep # __________

Date: __________________________________________________________________________

Healthcare Professional’s Name in Print: ____________________________________________

Specific Instructions:

Guidelines for Consent to Clinical Examination and/or Treatment

May 2009

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Appendix 3

Advice on cases in which it seems that the patient may not understand the information provided, or may not wish for full information.

It is the responsibility of the person obtaining consent (e.g. Healthcare Professional) to facilitate the process so that the patient achieves an understanding of the information on the options and makes an informed decision.

Informed consent requires a person to
(a) take in information relating to treatment options
(b) understand the information and remember it
(c) make a decision
(d) communicate the decision to the Healthcare Professional.

There are many factors that can affect an individual’s capacity to understand, make a decision and give consent. These include:
- Hearing ability (including noise interference from a busy hospital)
- Anxiety and Stress
- Embarrassment
- Alternative focus (thinking about something else)
- Intellectual ability
- Language barriers (different native language, medical jargon)
- Shock (being overwhelmed by one message and not hearing full information)
- Pain, physical discomfort
- Medication that has sedative properties

Some of the factors are easier to detect and manage (e.g. if the noise level is high, go to a quiet room) than others. The following is information on the psychological factors influencing the process and guidelines on how to recognise when these factors are operating (e.g. identifying an anxious patient) and how to assist the patient in achieving a good understanding in this situation.

Anxiety is a natural human response in the face of stress. Stress is anything that a person perceives to be a negative influence on his or her life (e.g. the possibility of loss in functioning, chronic illness, making the wrong decision, pain). Individuals vary enormously in how stress is experienced and how it is expressed. Similarly, people cope with stress in different ways and what works well for one person might not be helpful for another person. (The reason for the variability includes a multitude of factors such as the individual’s temperament, personal history, previous similar experiences, other current stressful factors, supportive resources, attitudes and beliefs, to name but a few). Anxiety and stress can negatively affect an individual’s capacity to take in information and make a decision. Despite the variability in the human experience, there are general guidelines that the Healthcare Professional can follow which are facilitative and supportive to most patients and particularly those who are anxious (as detailed in Guideline 2 below).

Intellectual ability. The process involved in giving consent is intellectually complex. The four main stages as mentioned above include: (a) taking in information (b) understanding it, (c) making a decision (d) remembering the information. There may be a lot of information to take in, which can be confusing and tiring for the patient. Understanding treatment options is often difficult for individuals as it relies on the concept of risk and probability information. Making a decision can be particularly difficult when there are benefits and costs to a number of options.
Even though the process is complicated, many individuals of lower intellectual ability can be facilitated to understand the options and make a decision.

An individual who has a moderate or severe learning disability would probably find the process of understanding treatment options and making a decision too difficult. In these situations, where it is not possible to obtain consent from the patient, all efforts should be made to facilitate the person in being aware and involved in their care as much as possible. If, having followed the recommendations below, the Healthcare Professional is still unsure about the patient’s level of understanding because of lower intellectual ability, fluctuating capacity or because of a psychiatric disorder, it is appropriate at that stage to refer to a Clinical Psychologist or a Psychiatrist.

The following are guidelines that are applicable in the situation of obtaining consent where the patient is anxious and/or does not understand the information. The following model may be useful in selecting the appropriate guideline to follow:

If there are indications that a patient does not understand the information from the Healthcare Professional, then determine whether the reason for the lack of understanding is due to lower intellectual ability or anxiety (or another of the factors noted above). If it appears to be due to anxiety, follow the guideline on management of a patient who is anxious. If the patient does not seem to understand because of lower intellectual ability, follow the guideline on facilitating an individual of lower intellectual ability.
Indicators that a patient may not understand information from Healthcare Professional.

- Confused or dazed appearance
- Lack of eye contact. Eye contact is an indication that person is listening. It can also indicate that a person is understanding. However, lack of eye contact may be due to embarrassment rather than lack of understanding. Other factors (reddened face) will help distinguish between a failure to understand and embarrassment.
- No verbal or non-verbal feedback. When a Healthcare Professional outlines serious or significant risks, it is usually the case that a patient will react non-verbally and/or verbally. The patient may stare in shock, look down or away or become pale. The absence of these frequently observed (and natural) responses may point towards the possibility that the patient is not understanding or processing the information.
- Inappropriate feedback (e.g. laughing and telling the Healthcare Professional he/she is stupid or ridiculous, due to denial or disbelief). It is important to distinguish this behaviour from a reasonable (and often appropriate) challenge such as “Are you experienced enough to know?” or a request for a second opinion.
- Responding “yes” to all questions. Where the Healthcare Professional suspects this is happening, ask the patient to expand on his/her ‘yes’ answer “When you say yes, can you tell me more about what you were thinking?”.
- The patient does not respond when the Healthcare Professional requests the patient to outline in his/her own words what was explained. “I need to be sure that I have explained the options well and that you understand what I have said. Could you explain in your own words what are the options, as if you were telling a friend?” This is to check comprehension of information (understands what it means in his or her context), ability to retain information (memory capacity), the ability to apply it to one’s individual circumstances and the capacity to weigh options against each other. Note that failing to give an account may also be due to anxiety, distress, or shock.
- The patient provides an extremely limited recount of the information given by the Healthcare Professional; so much so that it is inaccurate and is unable to expand further even with facilitation (“You said you will fix me”). In this situation, the Healthcare Professional needs to say “Well, we hope you will be able to xxx when we are finished but what did I say about the (small) concerns that might make things not work out so well?...#What sometimes can happen to people who come to me for this same treatment, which could also have a chance of happening to you?” The patient needs to be able to note that possible side effects and/or complications that exist.
- The patient is blindly biased about one option and refuses to give the briefest explanation of how and why this option is favoured. (i.e. no balancing of options may indicate very limited judgement capacity). The patient is entitled to favour one option above another even where it appears to be a wrong choice in the Healthcare Professional’s opinion, but it is important to get an understanding of how he/she came to decide on it.
- The patient adds extra, inaccurate information in recounting the information (“You said that you will xxx...and I won’t feel any pain at all”).
Appendix 3 (b)

Advice on facilitating a patient who appears to be anxious when obtaining consent for treatment.

Although a patient's anxiety will temporarily interfere with his/her capacity to process information and make a decision, this difficulty can be minimised.

- Acknowledge that many patients experience the process as extremely anxiety provoking and possibly over-whelming. Many patients I see feel very frightened when we are talking about what would be involved in this procedure. Feeling worried is very understandable and unfortunately, part of what is involved.
- Enquire as to how the patient has experienced hearing the information. (“Can I ask you, how are you feeling right now, having heard what I’ve said about this treatment so far?”)
- Empathise. This needs to be sincere and genuine, or the patient may hear it in a condescending tone. (“That is certainly difficult. Am I right in thinking you feel perhaps a mixture of different feelings … worry, uncertainty, sadness” (as appropriate).
- Offer to talk over the information again, initially giving a summarised overview.
- The style of the Healthcare Professional needs to emphasise that the patient’s concerns are legitimate and they will need to work together (as a team) to go through what are the specific concerns in a calm and relaxed manner.
- When the patient has taken the general overview of the procedure and has taken the information on board, repeat the overview but this time provide more detailed information, all the time acknowledging the patient’s possible reactions to the information (“It is very very difficult to think about what could go wrong because it is so frightening. We sometimes feel that we cannot bear to think about anything that has even a very small chance of going wrong. But it is important to know about the possible side effects to make a good decision”).
- Before finishing the meeting, ask the patient how he/she is feeling at that stage and check what he/she intends to do next and whether there are supports available (meet relative or friend, make a call, have a cup of tea etc.).
- Explain when the patient will be seen again, whether there will be an opportunity for questions (ideally this needs to be possible) and whether it will be the same Healthcare Professional or someone else. Where a patient is prepared for unanticipated situations (e.g. different Healthcare Professional next time), he/she feels assured that they have been informed appropriately, which builds confidence and in turn helps the patient to cope even in the complex hospital environment.

This whole process will help reduce the patient’s anxiety. Anxiety interferes with mental thinking ability when it is not managed. The Healthcare Professional has helped to manage it by acknowledging that it is real and a part of the process. (Ironically) this actually serves to stop the escalation in anxiety because the person knows that he or she is not ‘going crazy’. Humans respond to the calm approach of the Healthcare Professional by relaxing and trusting the process (of taking in the information, which may eventually give a sense of control to the patient about what is happening) rather than fearing it. The reduction in anxiety results in an increase in the patient’s processing capacity to enable him/her to consider the information and make a valid informed decision about the procedure.
Advice on communicating information to individuals of lower intellectual ability and facilitating their decision making.

- Speak slowly.
- Repeat and summarise regularly.
- Check that the person is following at regular intervals ("I’m going to check that you understand what I’m saying every few minutes. If you are not sure, I will explain it again. You can ask me questions at any time. Is that okay?").
- Offer to have another person sit in on meeting who may help in facilitating the individual’s understanding but continue to follow these guidelines if another person does join the meeting (rather than simply giving the explanation to the relative or friend).
- Use broad explanations initially to establish the concept. People of lower intellectual ability have a capacity to understand and make choices, particularly if they are facilitated. The basic concept of preference (advantages, disadvantages) is a good start to explaining about options, because preference is a very familiar concept for most people of all ability levels. Where the choice is about complex issues, the individual can be facilitated to understand by building a schema or scenario.
- Frame and structure the information. This relies on the use of ‘signposts’ to help the person understand the information and attach appropriate weightings. ("There are advantages and disadvantages to both treatment options. As well as the information that I will give, you need to think about what you view as the really big advantages and the really big disadvantages for you to help you decide which treatment is best for you").
- Frame and structure the decision-making process. "Okay, today I’m telling you about treatment X and treatment Y. What you will need to do is to think about what we talked about today — what I said, what you said. That is all important. Then you might start to think that you favour one of the treatments for some reason. That is fine. You might also come up with more questions. Don’t worry if you think you have asked them already. We will answer them again. You might then go away and think about it again and then say ‘yes, I’m going to do this.’ and then you will tell me what you’ve decided and what made you choose that option.”
- Use a story-like format and make connections with other people’s experiences (to help the person generalise what he/she have learned and to facilitate the process of abstraction). “You came to see me because you had a pain in xxx. Lots of people come to see me with this type of pain. I tell all these people, we can do x or y. Some people go for x because it… (quicker, don’t have to stay in hospital) and some people go for y because… It’s hard to decide. What do you think?
- Use visual information (pictures, diagrams, sequence of events pictorially) if the person’s visual processing system appears to function better than verbal processing (using words — talking).
- Listen for the framework/perspective that the patient constructs with the information given and build on that framework with further details. This facilitates the process of making sense of the information for the patient. It also helps the Healthcare Professional to check whether the patient has made any incorrect assumptions in processing the information. The patient’s general capacity to make judgements and decisions may be informally checked by asking the patient to outline a previous difficult decision and the factors that made it difficult “Mr. X, could I ask you for a moment to think about a hard decision (choice) you have made and why you decided to do what you did do”. If the person cannot spontaneously recall any decisions, he or she may be given a number of possible circumstances (e.g. deciding how to spend a free day, deciding whether to do something, deciding on a present for someone)
Appendix 3 (d)

Advice about the psychological issues when the patient does not want or does not appear to want further or full information.

- When the patient starts crying and becomes distressed, this may not necessarily indicate that he/she does not want to hear further information but time is needed to acknowledge the patient's distress and help calm him/her before explaining that there are some further details to be given. Explain that these will be given slowly and the Healthcare Professional will check in with the patient as they proceed. If the patient requests the Healthcare Professional not to continue at that stage, he/she is indicating that he/she cannot take on board further information at that time.

- If the patient directly states that he or she does not want to hear further details and says "just do it I don't want to hear any more", this needs to be respected in the first instance by acknowledging it and not continuing at that point.

- Having acknowledged to the patient that his/her wish is not to hear further details and the possible reactions that he/she may be experiencing on hearing the information, explain that it is considered wrong for the Healthcare Professional not to give the main points. Explain that this information will be brief and not go into a lot of detail. Ask the patient is it okay to continue at this point. Provide only the essential information. Thank the patient for listening.

- If the patient does not agree to the Healthcare Professional proceeding, this must be respected.

- The question of whether the patient has had adequate information to give consent and has the capacity to do so on the basis on information given, should be discussed with a colleague/the consultant. Considerations about the course of action to be followed when this happens need to be made by the Consultant responsible for the patient.
MID-WESTERN REGIONAL HOSPITALS REFUSAL OF TREATMENT

I confirm that I have explained to the patient the nature and purpose of this operation/procedure/treatment and the implications of not having this treatment.

Signed: ____________________ Bleep # __________ Date: __________

Healthcare Practitioner

My Healthcare Professional _________________________ has advised that I have the following operation/procedure/treatment: ________________________

The nature and purpose of this operation/procedure/treatment has been explained to me by Dr. ________________________

By signing this form I confirm that I refuse to undergo this operation/procedure/treatment and understand the consequence.

Signed: ____________________ Date: __________

Patient
**Consent to Post-Mortem Form**

**HOSPITAL:**

**ADDRESS:**

**EMERGENCY COUNSELLOR / OFFICER**

**NAME:**

**Tel Number:**

**Deceased’s Name:**

**Address:**

**Hospital No:**

**Date of Birth:**

**Date of admission to hospital:**

**Date of Death:**

**Name of person giving consent:**

**Name - in capitals:**

**Address:**

**Relationship to deceased:**

---

I hereby give my consent to the performance of a post-mortem examination on the body of:

**Signature:**

**Date:**

I am not aware that the deceased has expressed any objection to this procedure.

I understand that this examination is carried out to establish:

1. The cause of death
2. Clarify the extent of a disease process
3. Examine the effects of treatment, which may involve retention of tissue and/or organs for detailed laboratory examination.
4. It has been explained to me that tissues and organs that are removed during the post-mortem may be of value in medical education and research.

I confirm that I have been given and understand the Post-Mortem Information Sheet.

When you have made your informed decision please circle Yes / No as appropriate.

| 1. Do you wish to have a copy of the post-mortem results provided and explained to you? | YES | NO |
| 2. I agree that tissue/organ may be retained at post-mortem | YES | NO |
| 3. I agree that tissue/organ retained at post-mortem may be made available for the education of healthcare staff | YES | NO |
| 4. I agree that tissue/organ retained at post-mortem may be made available for medical research | YES | NO |
| 5. I understand a limited post-mortem may not result in a full explanation of an illness but may nonetheless, provide important information | YES | NO |
| 6. Are there any limitations you wish imposed on the post-mortem examination? | YES | NO |
| 7. If so, please specify your wishes | | |
Temporarily retained organs
(please note organs may be retained for a period of time) will either be returned to you or disposed of by the hospital in a dignified manner in accordance with hospital policy. Please specify your choice.

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I am satisfied that the consent to post-mortem as written in this document has been freely given on an informed basis.

Relatives Signature: ______________________

Staff Member

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