NATIONAL CONSENT POLICY

our **health** service

HSE National Consent Policy

This document is a:

Policy	X	Procedure		Protocol		Guideline	

Insert Service Name(s), Directorate and applicable Location(s):

All staff within the HSE and services funded by the HSE

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Section A

Introduction

This revised HSE National Consent Policy 2022 replaces Parts One and Two of the HSE National Consent Policy 2013 (revised 2019).

The HSE published its first National Consent Policy in 2013. This publication was based on two years of work by a multi-agency and multi-disciplinary advisory group and extensive national consultation. It had four parts:

- Part One dealt with the underpinning principles of a valid and genuine consent as it applies to the general adult population.
- Part Two dealt with consent as it applies to children and young people.
- Part Three dealt with consent in relation to research*.
- Part Four dealt with issues related to Do Not Attempt Resuscitation (DNAR) orders**.

This revised HSE National Consent Policy represents an extensive revision and rewriting of Parts One and Two of the 2013 Policy.

* Separate consent must be obtained for a 'person' to take part in health and social care research. This revised policy does not amend Part Three (Research) of the 2013 (revised 2019) HSE National Consent Policy. Until a new policy is developed for research, the existing Part Three will be attached to this policy.

**This revised policy does not amend Part Four (DNARs) of the 2013 (revised 2019) HSE National Consent Policy. Until a new policy is developed for DNAR, the existing Part Four and the HSE Guidance Regarding Cardiopulmonary Resuscitation and DNAR Decision-Making during the COVID-19 Pandemic will be attached to this policy (Appendix 1).

The section on 'Confidentiality and Data Protection' is now addressed in Appendix 2.

Part One of this policy deals with the general principles of consent. Part Two deals with children and young people. In this policy, a 'child' refers to someone under the age of 16 years and a 'young person' refers to someone aged 16 and 17 years. This policy is supported by a training module on consent on HSELand www.hseland.ie

Although the core principles underpinning valid informed consent and good practice are unchanged, this revised policy reflects important legislative and policy changes since 2013 including:

- The Health (Regulation of Termination of Pregnancy) Act 2018.
- The General Data Protection Regulation.
- The Data Protection Act 2018.
- The Freedom of Information Act 2014.
- The Children First Act 2015.

The Assisted Decision-Making (Capacity) Act 2015 (ADM) has been enacted and is scheduled to commence in June 2022[1]. The language in this revision – in particular, an emphasis on the importance of the will and preference of a person who may lack capacity – has been changed to align in preparation for the commencement of the 2015 Act.

However, because the relevant elements of the 2015 Act are not yet commenced, the policy is based on the law as it currently stands. This policy will be updated following commencement of the 2015 Act.

The revision reflects new case law and Court directions. For example:

- Part One, Section 6.3.2 (the section of Wards of Court) has been updated in accordance with new guidance from the High Court and the Office of the Wards of Court.
- Part One, Section 8.2 (the section of doctrine of necessity) has been updated in accordance with the decision in ***AC v Hickey & Ors*** [2019] IR 73.
- Part Two on children has been updated in accordance with amended Article 42 A of the Irish Constitution and the decision of the Supreme Court in ***Re JJ*** [2021] IESC 1.

A further change since 2013 relates to Part Two of the policy. While this policy retains the position that the age of consent to medical treatment is 16 years, it recognises that the legal basis for this has not been definitively established in the Irish Courts. Section 23 of the Non-Fatal Offences Against the Person Act 1997 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 parent or guardian.

The position in this policy is based on a reasonable (although not the only possible) interpretation of Section 23. Since the adoption of the HSE National Consent Policy, this position has not been subject to legal challenge or judicial comment. It is underpinned by extensive consultation with relevant stakeholders as to the appropriate position to adopt.

1 Government of Ireland (2020) Programme for Government: Our Shared Future (https://www.gov.ie/en/publication/7e05d-programme-for-government-our-shared-future/)

Part One: General Principles

1 Introduction

Consent is the giving of permission or agreement for a treatment, investigation, receipt or use of a service or participation in research or teaching. Consent involves a process of communication about the proposed intervention in which the person has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed intervention. Seeking consent should usually occur as an on-going process rather than a one-off event.

Adults who have to engage with healthcare workers have a fundamental ethical and legal right to control their own lives, to make informed decisions on matters that relate to them and to decide what happens to their own bodies. It is therefore essential that valid consent is obtained for health and social care interventions. Unless specifically authorised to do so, acting without first seeking their consent may be violating their legal and constitutional rights and may result in civil or criminal proceedings.

This consent policy has been prepared to set out in one comprehensive document:

- The rights of people who engage with healthcare workers; and
- The obligations on HSE staff and funded organisations to vindicate these rights.

Guidance is set out regarding the requirements for:-

- Valid informed consent;
- Information provision;
- Dealing with emergency situations; and
- Documenting consent.

1.1 Scope of this policy

The need for consent - and the application of the general principles in this policy - extends to all actions conducted by or on behalf of the HSE with people in all locations. Thus, it applies to:

- All treatment, investigation and screening, assessment and support services;
- Provision of social as well as health care;
- Involvement of a person in teaching;
- People in hospitals, in the community and in day, respite and residential care settings;
- Provision of remote health or social care services.

1.2 Organisation of this policy

Section A of this policy deals with the core elements of the policy which is set out in four parts as outlined below.

Part One of this policy deals with obtaining valid consent from adults. It includes obtaining consent from those who lack decision-making capacity, whose decision-making capacity is in question or who may need support with making a particular decision at a particular time.

Part Two of this policy deals with consent and decision-making for children and young people who are under the age of 18 years. Part Two of this policy should be read in conjunction with Part One.

Part Three of this policy deals with consent in relation to research.

Part Four of this policy deals with issues related to Do Not Attempt Resuscitation (DNAR) orders.

Section B of the policy outlines the governance, implementation framework and monitoring requirements for the policy in accordance with the HSE PPPG framework.

There are a number of supporting documents appended to the document which are as follows:

- Appendix 1 - HSE Guidance Regarding Cardiopulmonary Resuscitation and DNAR Decision-Making during the COVID-19 Pandemic.
- Appendix 2 provides information about confidentiality and data protection obligations.
- Appendix 3 provides legislative provisions impacting on consent.
- Appendix 4 details measures to facilitate communication with the person.
- Appendix 5 notes who are a child's legal guardians.
- Appendix 6 notes membership HSE National Consent Policy Steering Group.
- Appendix 7 notes membership HSE National Consent Policy Working Group – General Principles.
- Appendix 8 notes membership HSE National Consent Policy Working Group – Children and Young People.
- Appendix 9 notes organisations consulted about consent for 16 and 17 year olds.
- Appendix 10 provides a sample signature sheet for staff who have read the HSE National Consent Policy 2022.

1.3 Responsibilities of healthcare workers and organisations

All healthcare workers are responsible for ensuring that they adhere to consent processes as set out in this policy. All healthcare workers must be aware of and understand their responsibilities in terms of the consent process to ensure they gain valid consent for interventions. Healthcare workers must ensure that they have read, understood and incorporated this policy into practice.

Healthcare workers also have legislative reporting obligations under the National Vetting Bureau (Children and Vulnerable Persons) Acts 2012-2016; the Criminal Justice (Withholding of Information on Offences against Children and Vulnerable Persons) Act 2012. In the event of a conflict with this policy, these legislative obligations take priority and must be

complied with. Healthcare workers should refer to the relevant guidance on these measures. Healthcare workers should also be aware of their obligations under the HSE Adult Safeguarding Policy (2014), the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. Healthcare workers should also be aware of their obligations under their professional codes of practice.

All National Directors, Chief Officers and Hospital Group Chief Executive Officers of HSE and HSE funded organisations have a key role in ensuring that the necessary structures are in place to oversee compliance and are responsible for ensuring that the policy is implemented throughout their organisations (see Section B, Section 5.2).

1.4 Terminology used in this policy

For the purpose of this policy the term ‘person’ means a person who uses health and social care services. In some instances the term ‘patient’, ‘individual’ or ‘participant’ is used in this document instead of ‘person’ where it is considered more appropriate.

2 Informed consent in practice

2.1 Who should seek consent from a person?

The healthcare worker who is providing a particular health and social care intervention is responsible for ensuring the person has given consent for what is to be done.

The treating healthcare worker should usually give information and seek the person's consent. The task of providing information and seeking consent may in some circumstances be undertaken by another healthcare worker, as long as that healthcare worker:

- Is suitably trained and qualified;
- Has sufficient knowledge of the proposed intervention and of the benefits and risks;
- Is able to provide the information the person requires.

However, the healthcare worker who actually provides the particular intervention remains responsible for ensuring that the person has given a valid informed consent.[2]

Delegating the seeking of consent to a healthcare worker with inadequate knowledge of an intervention could mean that informed consent is not obtained.

If different aspects of the intervention are to be provided by different healthcare workers, each should obtain consent for their particular aspect of care.

2.2 When should healthcare workers seek consent?

The provision of information and the seeking and giving of consent involves a continuous process of keeping people up to date with any changes in their condition and the interventions proposed. The timing and possible need for revisiting or repeating consent discussion will depend on the nature and urgency of the intervention.

There are no legal provisions relating to the duration of consent for major interventions. However, it is good practice, where possible, to seek the person's consent to the proposed intervention well in advance, so that there is sufficient time to respond to the person's questions and provide adequate information. This is particularly important for elective (planned in advance rather than urgently necessary) interventions and where people have communication difficulties. Healthcare workers should then check, before the intervention starts, that the person:

- Is satisfied they can remember the treatment information given previously;
- Is satisfied they still understand what has been agreed;
- Has no questions or concerns; and
- Still consents to proceed.

This is particularly important if there is a time-lapse between the initial seeking and giving of consent and the actual date of an intervention. It is helpful to re-check that the person understands the information previously provided and address any further questions that might be raised about it.

2 See Medical Council of Ireland, Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2019) para. 13(1).

Consent for significant, sometimes major interventions such as an important surgical intervention should not be a once-off, 'last minute' event and should not be reduced to getting a hurried signature on a consent form. Accordingly, asking a person:

- To provide consent just before an intervention is due to start, at a time when they may be feeling particularly vulnerable and unable to ask relevant questions; or
- Seeking consent from someone who is sedated, in severe pain or extremely anxious creates doubt as to the validity of the consent. In particular, people should not be given routine pre-operative medication before being asked for their consent to proceed with a treatment.

Fresh consent, following provision of appropriate information, should be sought if:

- The person is not satisfied that they can remember and understand the earlier information; or
- The person's decision-making capacity is in question; or
- There is a change in the person's condition; or
- The information about the proposed intervention which may result in a change in the nature, purpose or risks associated with the intervention.

2.3 Scope of consent

A healthcare worker may only carry out an intervention that the person has consented to, unless it is an emergency. It is important that both the healthcare worker and the person concerned understand the scope of any decisions to be made. This is especially true if:

- Treatment will be provided in stages, with the possibility that changes to the treatment plan might be needed;
- Different healthcare workers will provide particular parts of an intervention, like anaesthesia and surgery;
- A number of different interventions are involved.

If there is a significant risk of a problem arising during an intervention when a person may not be in a position to make a decision, healthcare workers should discuss this in advance and ask the person how they should proceed. The healthcare worker should ask the person if there are any particular interventions they object to in the context of their proposed treatment, and this should be clearly documented in their healthcare record.

If the person agrees only to parts of the proposed intervention, there should be a clear process through which they can be involved in making decisions at a later stage.

2.4 How should consent be documented?

The validity of consent does not depend on the form in which it is given.[3] People may indicate their consent:

- Verbally;
- Non-verbally;
- In writing;
- By implication (such as where a person holds out their arm for a blood pressure reading).

Seeking consent is never merely getting a consent form signed; the signed consent form is just one means of documenting that a process of communication has occurred.

It is essential for healthcare workers to document clearly what was explained, discussed and agreed with the person. If different aspects of care are to be provided by different healthcare workers, each should document their own role in the consent discussion.

The healthcare record should describe and document clearly the manner in which the consent was provided.

There are some situations when it is best practice to get a signed consent from the person. If the person gives a verbal consent, but is unable to sign it, the healthcare worker should have another person (if possible) witness the consent. The healthcare worker and the witness should record the consent in the healthcare record.

These situations include if:

- The intervention is invasive, complex or involves significant risks;
- The intervention is an elective procedure;
- There may be significant consequences for the person's employment, or social or personal life;
- The intervention is innovative or experimental;
- Providing clinical care is not the primary purpose of the intervention e.g. clinical photographs for teaching purposes (which also requires consent to data processing);
- Blood testing following needle stick injury to staff.

If a consent form is used and the person is unable to write, a mark on the form to indicate consent is sufficient, if that is possible. It is good practice for the mark to be witnessed by a person other than the healthcare worker seeking consent. The fact that the person has chosen to make their mark in this way should be recorded in the healthcare record.

2.5 Consent in emergency situations

In some serious emergency situations, the degree of urgency of providing an intervention may be such that there is no time to provide information to a person prior to the intervention immediately necessary to save the life or prevent a serious detriment to the health of the person.

In these circumstances, the necessary intervention may be administered in the absence of the expressed consent of the person (unless the treating healthcare worker is aware of a valid and applicable advance statement refusing such treatment).

3 Please note that written consent is always obligatory for participation in clinical trials on medicinal products or medical devices. Please see Part 3 Consent to Research.

2.6 What happens if consent is refused?

If an adult with decision-making capacity to make an informed decision makes a voluntary and informed decision to refuse an intervention, the healthcare worker must respect this decision. They must do so even if the person's decision appears unwise and may result in their death. In such cases, it is particularly important to accurately document the discussions with the person in their healthcare record including:

- The intervention that has been offered;
- Whether an alternative intervention is acceptable to the person;
- The person's decision to refuse the intervention offered;
- Details of the full implications of the decision to refuse an intervention.

If the decision-making capacity of the person to refuse consent is in question the guidance in Part One, Sections 5 and 6 should be followed. Even if a person is determined to lack capacity to provide or refuse consent to a proposed intervention, his or her past and present will and preferences remain important and should be ascertained (Part One, Section 6.5). Healthcare workers should, in general, act to give effect to those will and preferences.

There are some circumstances in which a valid refusal of consent raises additional issues:

- Legislative provisions relating to isolation for infectious diseases;
- Treatment of a person involuntarily admitted to a care facility under the Mental Health Act;
- Refusal of the taking of blood and urine samples for Garda investigations.

There are more details about these provisions set out as Appendix 3.

2.7 What happens if consent is withdrawn?

A person with decision-making capacity is entitled to withdraw their consent at any time, including during the performance of an intervention. The person may show that they want the intervention to stop either verbally or non-verbally. Where possible, it is useful to agree in advance how the person should signal if they want the intervention to stop. For example, by raising their hand during a dental procedure or pressing the call bell during an MRI scan.

Where a person signals that they want to withdraw their consent during the intervention, the healthcare worker must:

- Stop the intervention;
- Establish the person's concerns;
- Explain the consequences of not completing the intervention; and
- Respect the withdrawal of consent if the person retains decision-making capacity.

If the person withdraws their consent during an intervention, the healthcare worker should document this in the person's healthcare record.

3. Defining valid consent

For consent to be valid, the person must:

- Have received sufficient information in a comprehensible manner about the nature, potential risks and benefits of the proposed intervention, of any alternative intervention and of not receiving the intervention;
- Not be acting under duress; and
- Have the decision-making capacity to make the decision (even if requiring support to do so).

The information to be provided for a valid consent and how it should be provided are discussed in Part One, Section 4.

3.1 Valid consent must be freely given

For consent to be valid the person must not be acting under duress which means that their agreement should be given freely.

Therefore the person must understand that they have a choice, including the choice to:

- Give consent;
- Refuse consent;
- Withdraw consent.

Duress refers to pressures or threats improperly imposed by others such that the person believes he or she has no alternative but to consent. 'Consent' obtained in this manner is not valid. However, this is distinct from the limitations on choice that illness can impose on persons.

Duress should be distinguished from providing the person, when appropriate, with:

- Strong recommendations regarding a treatment or lifestyle issue;
- Pointing out the likely adverse consequences of choices the person may make.

Persons may also be subject to pressure from third parties (which may include family, friends or healthcare workers) to accept or reject a particular intervention. If there is concern about possible undue pressure, healthcare workers need to meet with the person alone so that they can make their own decision freely. An independent advocate may be useful to ensure the person's own voice is heard. In assessing the effect of outside influences, it is useful to consider the strength of will and preferences of the person and their relationship with any party who may be exerting pressure on him or her.

If the healthcare worker has a reasonable belief that a person is under pressure or undue influence, they should explain their concerns to the person and should consider whether this is an abusive action under the HSE Adult Safeguarding Policy (2014) and, if so, manage it in line with the policy. Where matters fall outside of the scope of the National Safeguarding Policy, the matter may need to be referred to the Gardaí.

3.2 Principles to be applied when considering a person's decision-making capacity to provide consent

There are some important principles to be applied when considering the issue of a person's capacity to provide consent:

- An adult is presumed to have decision-making capacity to provide consent unless the contrary is shown;
- Healthcare workers should support people to make their own decisions whenever possible;
- A person should only be considered as unable to provide consent after all practicable steps to help them to make the decision have failed;
- Making what others regard as an unwise choice is not of itself evidence of a person lacking decision-making capacity;
- Decision-making capacity regarding consent is assessed only in relation to the intervention in question and only at the time in question (this is known as the 'functional' approach to capacity);
- It may be necessary, if the circumstances allow it, to provide information and support over a period of time in order to build the decision-making capacity of the person.

The approach to be taken when the capacity of the person to give or refuse consent is in question or if a person lacks decision-making capacity will be discussed in Part One, Sections 4 and 5 respectively.

4 Providing sufficient information in a comprehensible manner

The person must receive sufficient information in a manner that is comprehensible to them about the particular intervention. The meaning of sufficient information will depend both on:

- The nature of the intervention;
- The individual circumstances and the will and preferences of the person;

Healthcare workers need to consider the quality of communication and the best way to communicate with the person. This will help to make sure that information is provided in a way that the person understands.

These will be explained in further detail below.

4.1 What information should be provided about interventions?

How much information people want and need, and the support that they require, will vary depending on:

- Individual factors:
  - The needs, wishes and priorities of the person;
  - The person's level of knowledge about, and understanding of, their condition, prognosis and the treatment options available;
  - The person's ability to understand the information about the decision.
- The particular intervention:
  - The nature, complexity and urgency of the intervention, service or decision;
  - The likelihood of success or failure of an intervention to achieve the desired aim and the risks associated with taking no action or with taking an alternative approach;
  - Whether a proposed investigation or treatment is experimental or part of a research project or clinical trial;
  - If relevant, if costs will be incurred, how the costs can be met and where information about the costs may be obtained.

4.2 How and when information should be provided

The manner in which the healthcare worker discusses the intervention with the person is as important as the information itself. The relationship between the healthcare worker and the person should be a partnership based on:

- Openness;
- Trust;
- Clear communication.

Obtaining consent often involves and requires ongoing communication with the person rather than a 'once-off' discussion. It is essential that communication occurs at a time and place and in a manner that will maximise the person's ability to:

- Understand the information required for a valid consent;
- Communicate their choice.

See Appendix 4 for details on measures to facilitate communication with the person.

4.3 Risk disclosure and valid informed consent

A risk is significant where a reasonable person in the person's position would consider it to be significant. Healthcare workers must disclose such risks to the person. This is the legal standard applied by the Irish Courts.

However, the risks that an individual person considers significant and relevant to their decision-making, can only be determined by discussion with them and by considering their will and preferences ('Will' carries a stronger sense of determination or planning. It incorporates a person's values, personal beliefs and ultimate goals. "Preference" means "a greater liking for one alternative over another").

Factors such as a persons' occupation, lifestyle or culture may, for example, influence those risks that the person considers to be significant or particularly undesirable.

Common, even if minor, side effects and complications should be discussed as should serious adverse outcomes, even if rare and remote. These include any risk of:

- Death;
- Permanent disability (such as paralysis or blindness);
- Permanent disfigurement;
- Chronic pain;
- Need for continuing medication/treatment/medical equipment.

Information about risk should be given in a balanced way: a one in a thousand risk of a complication also means that 999 out of a thousand persons will not experience that complication. Some people will have difficulty with figures, and visual aids may help to maximise understanding of risk.

The fact that a person might be upset or refuse treatment or services as a result of receiving information as part of the consent process is not a valid reason for withholding information. In such circumstances, you should think about the best time and way to provide the information, including whether it would be helpful for the person to have support at the time.

4.4 Distinction between elective and non-elective treatments

The Irish Courts acknowledge a distinction between elective and emergency treatments. There is a greater duty to warn of potential negative outcomes the more elective the intervention is. An 'elective' intervention is planned in advance rather than recommended as a matter of urgency.

In an emergency, there may not be time for the healthcare worker to give detailed information, and the person may not be in a position to assimilate anything but the most important information about an intervention. In some emergency situations (Part One, Section 2.5 6) it may not even be possible for the healthcare worker to secure a valid informed consent before providing an intervention.

In the case of elective, non-essential surgery, the Irish Courts have held that if there is a risk, however exceptional or remote, of grave consequences involving severe pain for an appreciable time into the future and involving the possibility of further operative procedures, such possible consequences should be explained to the person.

4.5 Consent and Pregnancy

In addition to information relevant to their own health, those who are pregnant will need to receive sufficient information about the benefits and risks of interventions or of not intervening on the viability and health of a foetus or of the infant that will be delivered.

4.6 Where the person declines or wishes to limit the information they receive

Some people do not want to know in detail about their condition or the treatment. This should be respected as much as possible. The healthcare worker can do this by highlighting only the most serious and basic information about the intervention. However, there is an obligation on the part of the healthcare worker providing treatment to provide sufficient information to satisfy the requirement to secure an informed consent. The duty to warn of possible adverse consequences is particularly important where the person is having an elective procedure.

If a person refuses to receive detailed information about their condition or treatment, this and the reasons why should be carefully documented.

5 Decision-making capacity to provide or refuse consent

5.1 What is decision-making capacity?

Decision-making capacity is the person's ability to understand, at the time that a decision is to be made, the nature and consequences of the decision to be made by them in the context of the available choices at that time.

Decision-making capacity is issue specific.

This means that the person's capacity only relates to the decision to be made. For example, a person may not have the capacity to make a decision that involves a significant amount of clinical information or balancing of alternative options or competing considerations but may have capacity to make less complex or demanding decisions.

Capacity is time specific.

This means the person's capacity to make a decision should be assessed at the time the decision has to be made. A person's capacity to make a decision can fluctuate. A person may lack the capacity to make the decision in question at one time of the day but may have the capacity to make the same decision a few hours later.

A person's capacity may change over time. This may be due to a person's condition, a treatment or medication, an illness, an accident or injury, or due to ageing.

A person's ability to exercise their decision-making capacity may also be affected by the supports available to them. This may include supports to obtain and explain information in a way that is tailored to their needs.

5.2 Presumption of decision-making capacity

Every adult is presumed to have the decision-making capacity to decide whether to consent to, or refuse consent to, an intervention unless the contrary is shown (e.g. by an assessment of decision-making capacity or by a Court declaration making a person a Ward of Court).

An important implication of the presumption of decision-making capacity is that a person's capacity should not be called into question and assessments of capacity should not be performed without good reason. Such assessments are not required in the vast majority of cases where healthcare workers seek consent for an intervention. **Assessment of capacity should not be performed or regarded as routine or usual: a person does not have to prove their capacity to make a decision.**

It must not be assumed that a person lacks capacity to make a decision solely because of their:

- Age;
- Disability;
- Appearance;
- Behaviour;
- Medical condition (including intellectual disability, mental illness, dementia or scores on tests of cognitive function);

- Beliefs;
- Apparent inability to communicate.

Do not assume that a person is unable to make a decision because their choice seems unwise or unreasonable from the perspective of healthcare workers.

5.3 Duty to maximise capacity

Healthcare workers must make every possible effort to support people in making decisions for themselves. A person should not be considered unable to make a decision unless all practicable steps have been taken to help him or her to do so.

Such steps may include:

- Seeking the assistance of anyone the person asks to be consulted;
- Involving people who have a close, ongoing, personal relationship with the person, such as family or friends;
- Seeking the assistance of an independent advocate to support the person and to ensure that the person's own voice is heard. This may be helpful particularly when healthcare workers and those close to the person disagree with the person's will and preferences.

5.4 When a person makes an 'unwise' choice

A person making what seems to be an 'unwise' or risky decision to others, such as refusing consent to a proposed intervention, is not of itself an adequate reason to question decision-making capacity nor evidence that the person lacks decision-making capacity to make that decision.

In some cases, choices which appear unwise can be understood by reference to the person's circumstances and the goals and beliefs of the person.

5.5 When may a person's decision-making capacity be in question?

The presumption of capacity should not be challenged, and the person's capacity in relation to one or more specific decisions shouldn't be in question without a valid reason or "trigger". However, healthcare workers should not ignore clear evidence that a person may lack capacity to make a particular decision, especially if the consequence for them might be serious.

A number of factors may cause the person's capacity to make a specific decision to be questioned. These include:

- They are unable to communicate a clear and consistent choice;
- They make a decision that seems out of character, inconsistent with their known will and preferences or previously expressed wishes;
- They make a decision that seems objectively unwise – that is, one that cannot be understood by reference to his or her individual circumstances or wishes and beliefs – or irrational;
- The decision they propose to make goes against reasonable advice, without justification;

- It is often relevant to consider whether there is significant risk or potential long-lasting consequences for the person associated with the decision;
- The level of risk to the person and whether intervention would be appropriate and proportionate in the circumstances.

A trigger for assessing capacity may differ depending on the significance of the decision, the level of risk to the person and whether the intervention would be appropriate and proportionate in the circumstances.

It is not a requirement to identify a cause or reason for why the person's decision-making capacity is in question. However, it may be useful to determine whether the change is likely to be temporary or longer lasting. This is particularly relevant in determining whether a capacity assessment is needed at that time (Part One, Section 5.7).

5.6 Matters to be considered when a persons' capacity to make a decision is in question

If a person's capacity to make a decision is in question, the healthcare worker who needs the decision to be made must consider:

- The issue and time specific nature of capacity (Part One, Section 5.1);
- The presumption of capacity (Part One, Section 5.2);
- The duty to maximise capacity and that a person must not be considered unable to make a decision unless all practicable steps have been taken to help him or her to do so (Part One, Section 5.3);
- That a person must not be considered as unable to make a decision just because their decision is unwise (Part One, Section 5.4).

Any action where a person's capacity is in question should:

- Not occur unless it is necessary given the individual circumstances of the person;
- To the greatest extent possible give effect to the past and present will and preference of the person, that is, what the person wants or would have wanted;
- Be done in good faith and for the benefit of the person;
- Be done in a way that minimises the restriction of the person's rights and freedom of action;
- Have due regard to the rights of the person:
  - dignity
  - bodily integrity
  - privacy
  - autonomy
  - control over his or her financial affairs and property;
- Be proportionate to the significance and urgency of the situation;
- Be as limited in duration as is possible in the circumstances.

In most situations where a person's capacity to make a decision is in question, the doubt should be resolved by a timely assessment (Part One, Section 5.7).

5.7 Need for a capacity assessment when a person's capacity to make a decision is in question

The capacity assessment process can often be intrusive for the person being assessed. The healthcare worker should have reasonable grounds (reasons) to think that the person needs their capacity assessed before doing so.

In most situations where a person's capacity to make a decision is in question and a decision needs to be made, a timely capacity assessment is needed to resolve the doubt.

In some cases, an assessment is not needed because the specific decision no longer needs to be made or because the question regarding the person's capacity is resolved prior to an assessment as, for example, when the person's condition improves and there is no longer any reason to question capacity (Part One, Section 5.10).

There may be situations where the person's capacity to make a decision is in doubt but where a person's will and preference is clear and proceeding or attempting to proceed with the intervention contrary to that will and preference would not be realistic or proportionate to the significance and urgency of the situation.

A healthcare worker might conclude having considered all the factors noted in Part One, Section 5.6 that such an intervention cannot or should not proceed irrespective of the person being found to lack capacity. In this instance a capacity assessment is not needed.

5.8 Who should assess capacity?

This depends on the reason why the capacity assessment is being undertaken as described below.

The most appropriate person to assess capacity will often be the healthcare worker with the best understanding of the specific decision that needs to be made. This includes an understanding of:

- The choices available to the person;
- The likely consequences of each option;
- The consequences of taking no action.

For this reason, the responsibility for assessing capacity and for documenting that assessment generally rests with the healthcare worker proposing a particular intervention and seeking consent. In some complex situations, the healthcare worker may wish to seek expert assistance or a second opinion from another appropriately qualified healthcare worker. However, it is ultimately the healthcare worker proposing the intervention who should satisfy themselves whether or not the person has the capacity to make the decision.

It is important to note that it is **not only** doctors, including psychiatrists and geriatricians, who can carry out a capacity assessment. The responsibility for assessing capacity will rest with the appropriate member of the relevant healthcare professional, even if there may be circumstances in which the expertise of a medical professional may also be helpful.

Some decisions relate primarily to a particular healthcare profession and responsibility for assessing capacity will rest with a member of that profession, even if there may be circumstances in which the expertise of a medical professional will be helpful. Other decisions may involve different professions, and it is often the case that other professionals who know the person and their circumstances better will be best placed to perform the assessment.

5.9 Preparing for a capacity assessment

5.9.1 Understand the decisions to be made

The person assessing capacity must have a clear understanding of:

- The decision or decisions to be made;
- The options available to the person being assessed.

The specific decision to be made should be clearly defined and understood before the assessment. The person assessing capacity should consider what information would be needed for anyone making a similar decision.

The person assessing capacity must obtain sufficient information about the person's personal circumstances to enable an assessment of the person's understanding of:

- The choices available to them;
- The effects of certain decisions.

However, the person assessing capacity should only obtain enough information as is necessary and relevant to the decision in question, to prepare for the assessment.

5.9.2 Understand any support needs of the person

The person assessing capacity should consider whether the person has any specific difficulties which may be impacting their decision-making capacity, in particular their communication needs. The healthcare worker assessing capacity must ensure they are able to tailor their communication in a way appropriate to the needs of the person, or are able to access necessary supports, including specialist supports.

5.9.3 Prepare questions and lines of enquiry

It is important that the capacity assessment is specific to the context of the person and the specific decisions they need to make at the particular time. The healthcare worker assessing capacity should prepare questions that need to be addressed and clear up any points that matter about the decision to be made that will allow them to consider the four elements of functional capacity assessment (Part One, Section 5.10).

The person assessing capacity must ask enough questions to make an assessment about each element of functional capacity. This assessment should follow the guidance set out in this policy.

Where possible, the healthcare worker assessing capacity should attempt to have a discussion with the person about the decision and should take adequate time to build trust and rapport. It is important that the capacity assessment is specific to the context of the person and specific decisions they need to make.

5.9.4 Ensuring the person is prepared for the assessment

Before beginning an assessment, the healthcare worker assessing capacity must communicate with the person:

- That there is concern about their capacity to make a specific decision;
- What is involved in the capacity assessment process.

The healthcare worker must inform the person that the result of the capacity assessment will be either that:

- They have capacity to make the specific decision;
- That they lack capacity to make the specific decision.

If the person lacks decision-making capacity, the healthcare worker should let them know that the person may need someone to make this decision on their behalf (Part One, Section 6).

The healthcare worker assessing capacity must make sure the person has been provided with relevant information about the decision in a form and language appropriate to their needs. The person must also have been given information on the supports available to them.

The person must have adequate time to process and consider information relevant to the decision.

5.9.5 Consent to assess capacity

The healthcare worker assessing capacity must seek the consent of the person to undertake the capacity assessment. The healthcare worker assessing capacity must explain that the person has:

- A right to refuse to undergo the assessment;
- A right to stop at any stage.

If the person refuses to undergo a capacity assessment or refuses to engage in some or all aspects of a capacity assessment, the healthcare worker assessing capacity should try to establish the reasons for this and identify what can be done to help the person to participate fully. This may include:

- Reassuring the person that every effort will be made to facilitate and support them in making their own decision and that one of the reasons for the assessment is to identify the best way to do this;
- Making the person aware that they will have the opportunity to dispute the outcome of the assessment if they disagree;
- Depending on the circumstances, an offer of support from someone close to the person or an independent advocate should be provided;
- Whenever possible, allowing the person time to consider the matter by deferring the functional assessment.

There may still be situations where a person does not consent to having his or her capacity functionally assessed. The healthcare worker assessing decision-making capacity should not persist in trying to assess the person but should document the refusal and actions taken in trying to facilitate the assessment.

Where the person refuses to consent to the assessment this refusal should not automatically lead to a conclusion that the person lacks capacity. However, where a capacity determination is considered necessary and the person is unable or unwilling to participate, an application to Court may be needed for a determination as to the person's capacity based on observational information and collateral information gathered from other sources.

If the healthcare worker assessing capacity determines that the person is not capable of consenting to the assessment, they must determine whether or not to conduct or continue the assessment. The healthcare worker assessing capacity must act in good faith and determine whether the assessment is likely to be for the benefit of the person.

5.10 Functional assessment of capacity

The focus in a functional assessment of capacity is on the process, not on the outcome. The emphasis is on how a person makes a decision and not on whether or not it is a wise decision or whether others disagree with it.

When assessing a person's capacity to make a specific decision, the person assessing capacity is considering whether the person is able to:

- Understand information and facts relevant to the decision;
- Retain that information long enough to make a voluntary choice;
- Use or weigh-up that information as part of the process of making the decision;
- Communicate the decision.

The healthcare worker must assess and document each of the above elements. If the person does not meet one or more of these elements the person lacks decision-making capacity.

5.10.1 Understanding information relevant to the decision

The person should understand the information relevant to the decision. This includes understanding the reasonably foreseeable consequences of the choices available to them, including the consequences of doing nothing.

The healthcare worker assessing decision-making capacity should assess major discrepancies between the person's understanding, for example of their daily routine, living arrangements and care needs, and available records or information from third parties such as other people caring for the person.

The level of understanding of the relevant information that is required of the person must not be set too high. A broad, general understanding of what are the most essential points in the person's individual circumstances is what is required.

5.10.2 Retaining the relevant information

What matters is that a person can retain the relevant information for long enough to be able to use and weigh up the information to reach and communicate a decision. A consistent response may be sufficient as evidence that the person is able to retain information.

Where there is a question about the person's ability to retain information, it may be necessary to talk to the relevant person on more than one occasion. Where a person with memory difficulties needs time to make a decision, it may be useful to use memory aids such as:

- Writing down information;
- Using prompts;
- Providing a video or sound recording.

5.10.3 Using and weighing the relevant information

The person will need to use and weigh up the information relevant to the decision. This means the person needs to balance the benefits and risks of different options in accordance with their own goals and preferences to make the decision.

The weight to be attached to the information is for the person to decide. If a healthcare worker is uncertain whether a person is able to use or weigh information, it may be helpful to explore the reasons for making their decision in more detail, for example by asking about values and beliefs, their will and preferences, what matters most to the person that might influence apparently irrational or unwise decisions. For example, something a healthcare worker feels is most important, such as physical safety for example, may be outweighed by a person's desire for independence.

The standard of weighing up information should not be set too high. The person should be able to demonstrate that they have considered relevant information in the decision-making process. It is sometimes helpful to explore if they would change their decision if additional information, is offered. For example, "if this decision could result in you suffering serious medical consequences or death, would you consider doing something different?"

5.10.4 Communicating a decision

If persons have difficulties communicating their decision or being understood by others, every effort must be made to support them to communicate their decision by whatever means is available to them.

5.11 Making a determination of capacity and documenting the assessment

5.11.1 Documenting the outcome of the assessment

The healthcare worker assessing the person's decision-making capacity must document the relevant findings of the assessment. If a person is considered to lack decision-making capacity, the healthcare worker assessing capacity should give detailed, specific examples (direct quotes) of where the person did not meet one of the elements. The healthcare worker should also provide a view about whether the person is likely to regain decision-making capacity, taking into account the factors that may be affecting capacity.

5.11.2 Communicating the outcome of the assessment

The healthcare worker assessing decision-making capacity must inform the person, in writing and verbally, and in any other way that best suits that person's needs and preferences, of the outcome of the assessment. Where appropriate, the person should also be informed of what is likely to occur as a result.

5.11.3 Where the person disagrees with the outcome of the assessment

If the person disagrees with the outcome of the assessment, they should be offered the option of a second assessment and be supported in accessing this second assessment. If after this second assessment, the person continues to dispute the finding of the assessment, they should be advised of the possibility of seeking legal advice and independent advocacy.

5.12 What if the person's lack of capacity is temporary or fluctuating?

Fluctuating capacity is where a person may be unable to make the decision in question at one time of the day but be able to make the same decision a few hours later. If someone at that moment is unable to make a decision, unless the proposed intervention is urgent and essential, it may be possible to defer (delay) assessing their decision-making capacity. This could be done until:

- The person's condition is improves;
- A time when the person is lucid enough to give consent.

5.13 Where there is disagreement between professionals regarding the capacity of a person to make a decision

Sometimes disagreements arise between healthcare workers, whether of the same or different disciplines, regarding a person's capacity to make a particular decision. Many such disagreements can be resolved with discussion and further assessment.

It may have been unclear which relevant information the person needed to understand the decision to be made. In addition, for a person with fluctuating decision-making capacity, different healthcare workers may have assessed the person at different times. A joint assessment or discussion with another healthcare worker may be helpful.

Rarely, it may be necessary to look for legal advice or recourse to the Court, (Part One, Section 6.8). In such cases, all relevant opinions should be provided.

6 Making decisions if a person lacks decision-making capacity

There is currently no comprehensive legislative framework[4] (nor any Irish case law directly on the point) to govern how a decision about non-emergency treatment and care should be made for people who:

- Lack capacity to provide or refuse consent; and
- Who are not Wards of Court (or otherwise subject to Court orders) or detained under mental health legislation.

The doctrine of necessity applies where there is a need to take action for a person who lacks capacity to make a decision and the action is one that a reasonable person would take in the best interests of the person. It applies where a person, for whatever reason, lacks capacity to make decisions about medical treatment making it necessary for others with appropriate qualifications to take such decisions. In general, the doctrine is broad enough to permit, in a situation of urgency, actions taken in the interests of a person who lacks capacity.

In such cases, a number of general principles should be considered and applied.

6.1 General principles

When dealing with decisions concerning a person who lacks capacity, the healthcare worker should consider:

- Is this an emergency situation where the decision is a matter of urgency? (Part One, Section 6.2);
- Is there someone with the legal authority to make the decision on behalf of the person? (Part One, Section 6.3);
- Is the person's lack of capacity temporary or is capacity fluctuating? (Part One, Section 5.6);
- Is there someone who can help the person participate in decision-making? (Part One, Section 6.4);
- What are the past and present will and preferences of the person and what beliefs and values or other factors would he or she likely consider important in making a decision? (Part One, Section 6.5);
- What options, including the option not to intervene, would provide overall benefit for the person? (Part One, Section 6.6);
- Is there a valid and applicable advance statement or directive? (Part One, Section 7).

6.2 Emergency situations

In emergency situations where the intervention is a matter of urgency, where a person is deemed to lack capacity and there is no valid advance refusal of treatment (Part One, Section 7), the healthcare worker may treat the person provided the treatment is immediately necessary to:

- Save their life; and/or
- To prevent a serious deterioration of their condition.

The treatment provided in these circumstances should be the least restrictive of the person's future choices. While nobody else can consent on behalf of the person in this situation, it is good practice, if practicable, to inform those close to the person. They may be able to provide insight into the person's likely preferences.

4 The Assisted Decision-Making (Capacity) Act 2015 has not yet fully come into effect.

6.3 Is there someone with the legal authority to make the decision on behalf of the person?

6.3.1 Who has legal authority to make the decision?

No other person such as a family member, "next of kin", friend or carer and no organisation can give or refuse consent to a health or social care service on behalf of an adult person who lacks capacity to consent unless they have specific legal authority to do so. (This is not widely known, and family members, for example, may assume that they can provide or refuse consent when a person lacks capacity to make a decision).

Under current Irish law:

- An attorney who has been expressly given this power may make certain "personal care" decisions[5] on behalf of the person under an Enduring Power of Attorney made under the Power of Attorney Act 1996 (i.e. the current legislation governing powers of attorney). These do not include healthcare decisions.
- Where a person has been admitted to Wardship, a Committee of a Ward of Court has the power to make some decisions, but generally not to consent to medical treatment (unless there is specific provision in the Court order to allow for consent to medical treatment) on behalf of the person and any request for an intervention (in the absence of any power given in a Court order) must be made to the Office of the Wards of Court (Part One, Section 6.3.2).

Although a statutory framework is not currently in force for advance healthcare directives, a person may have authorised another to make such decisions on their behalf in an advance healthcare directive which applies to the circumstances which arise. The legal effect of this is discussed in Part One, Section 7.2.

6.3.2 If the person is a Ward of Court

Where a person is a Ward of Court, it is the Court which has authority to give or withhold consent to the interventions or administration of treatment on behalf of the Ward. As a matter of law, such decisions are made having regard to what is in the best interests of the Ward, having regard to all relevant considerations, including the past and present will and preference of the Ward.

If a Ward needs a healthcare intervention consisting of a relatively minor elective or non-emergency procedure,[6] the Registrar of the Office of the Wards of Court should be informed of this. Information to be provided should include whether:

a. The Ward has the decision-making capacity to decide for him or herself;

a. The will and preferences of the Ward regarding the intervention.

For significant treatment decisions, including major procedures such as surgery, a request for consent to the carrying out of treatment in respect of a Ward is usually made by the healthcare worker concerned to the Office of Wards of Court, addressed to the Registrar of Office of the Wards of Court or the Case Officer dealing with the Ward.[7]

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5 Section 4 of the Powers of Attorney Act 1996 provides that "personal care decision", in relation to a donor of an enduring power, means a decision on any one or more of the following matters:
(a) where the donor should live,
(b) with whom the donor should live,
(c) whom the donor should see and not see,
(d) what training or rehabilitation the donor should get,
(e) the donor's diet and dress,
(f) inspection of the donor's personal papers, and
(g) housing, social welfare and other benefits for the donor.

6 Examples include general eye examinations, dental checks, fillings and cleaning teeth, vaccine administration, x-rays and scans, cervical check, breast check, bowel screening, diabetic retina screening, suturing and administration of standard medication and antibiotics.

7 The Consent to Request for Medical Treatment form is available electronically and can be submitted to the office of the Wards of Court using the email address wards@courts.ie which is monitored throughout the day.

In some emergencies, it may not be possible to obtain timely consent. This may be because it is outside normal office hours (although the Office of Wards of Court makes every effort to provide out-of-office support) or because treatment is immediately necessary to save the life or prevent a serious detriment to the health of the Ward. In such circumstances, the necessary treatment may be administered without obtaining the consent of the Court, although the circumstances surrounding the administration of treatment should be recorded and the Registrar of the Office of the Wards of Court should be informed.

6.3.2.1 Where a Ward of Court has capacity to make the relevant decision

Some Wards will have capacity to make particular decisions, even if they may require support to do so. Their capacity to provide or refuse consent for the proposed intervention should be assessed and documented. If the Ward has capacity to make a decision, their decision should in general be respected.

However, in the following circumstances the Office of Wards of Court should be notified and its agreement obtained before the proposed intervention proceeds or is withheld in accordance with the will and preference of the Ward, as a Court application may be required:

- If refusal of an intervention does not seem to be in the best interests of a Ward, such as when it may have a significant impact on the health or wellbeing of the Ward or may threaten his or her placement;
- In cases where treatment is high risk or possibly controversial (e.g. amputation, non-therapeutic sterilisation insertion of PEG tube or nasogastric tube or experimental treatment);
- If the Ward's family members or committee do not agree with the Ward's decision.

6.3.2.2 Where a Ward of Court lacks capacity to make the relevant decision

Even if a Ward is determined to lack capacity to provide or refuse consent to a proposed intervention, his or her past and present will and preferences remain important and should be ascertained (Part One, Section 6.5). Healthcare workers should, in general, act to give effect to those will and preferences when it comes to deciding whether it is in the best interests of the Ward to proceed or not with a proposed intervention.

Where, having considered all relevant factors including the will and preferences of the Ward, a healthcare worker considers it is in the best interests of the Ward that the intervention should proceed, and this is consistent with the will and preference of the Ward, the intervention should proceed.

However, if the intervention represents a significant treatment decision, the Office of Wards of Court should be notified before the intervention proceeds.

The Office of the Wards of Court should be notified and its agreement obtained to withhold treatment if the will and preference of the Ward is that the intervention should NOT proceed and the healthcare worker considers it is in the best interests of the Ward that the intervention should not proceed having considered all relevant factors. In these instances a Court application may be required:

- If the refusal of an intervention may have a significant impact on the health or wellbeing of the Ward or may threaten his or her placement;
- If the Ward's family members or committee do not agree with the Ward's will and preference;
- If there is any dispute over what course of action is in the best interests of the Ward.

In such situations the Court and the Office of the Wards of Court will in general be guided by the views of the treating healthcare worker though the decision ultimately falls to be made by the Office of the Wards of Court or the High Court.

6.4 Who can support and enable the person to participate in decision-making?

Support will usually be given by people who have a close, ongoing personal relationship with the person, such as family or friends, or by anybody chosen by the person. The support of these people may be helpful in eliciting the person's values, beliefs and goals. If appropriate and practical to do so, the views of anyone the person requests to be consulted should be considered,

In some circumstances, the healthcare worker should consider involving an independent advocate to support the person who lacks capacity to participate in the decision-making process. This may be helpful to ensure that the person's own voice is heard particularly when healthcare workers and those close to the person disagree with the person's will and preferences.

6.5 What are the past and present will and preferences of the person?

It is essential to encourage and facilitate the person to participate as fully as possible in decision-making. Even if a person, despite support, lacks capacity to provide or refuse consent, his or her past and present will and preferences remain important, and healthcare workers should, in general, act to give effect to those will and preferences when it comes to deciding whether to proceed or not with a proposed intervention. The views of anyone the person asks to be consulted and of people who have a close, ongoing personal relationship with the person such as family or friends should be considered and may be invaluable in eliciting the persons past and present will and preference.

"Preference" means "a greater liking for one alternative over another". "Will" carries a stronger sense of determination or planning and can be regarded as incorporating a person's values, personal beliefs and ultimate goals.

Hence it is important to explore not only the current and past expressed preferences and desires but also the underlying beliefs and goals of the person and any other factors which the person would be likely to consider important, in so far as these can be determined.

6.6 Matters to be considered when a person lacks capacity to make a decision?

It is necessary to consider what option, including the option not to intervene, will be in the best interests of the person. Any action where a person lacks capacity to make their own decision should:

- To the greatest extent possible give effect to the past and present will and preference of the person;
- At all times be done in good faith and for the benefit of the person;
- Be made in a manner that minimises the restriction of the person's rights and, freedom of action;
- Have due regard to the rights of the person to dignity, bodily integrity, privacy, autonomy, and control over his or her financial affairs and property;
- Be proportionate to the significance and urgency of the situation; and
- Be as limited in duration as is possible in the circumstances.

6.7 Non-emergency situations

Irish legislation has not yet commenced to govern how a decision about non-emergency treatment and care should be made for people who:

- Lack capacity to provide or refuse consent; and
- Who are not Wards of Court or (or otherwise subject to Court orders) or detained under mental health legislation.

In most cases, uncertainty regarding how to proceed will be resolved by consideration of the general principles of this policy and, in particular, the past and present will and preference of the person.

In some circumstances, it may be possible to defer a decision to make additional efforts, for example by contacting those close to the person who are not immediately available, to ascertain the will and preferences of the person.

In other circumstances, this will not be possible, and it reasonable for the healthcare worker to proceed with the intervention if deemed to be in the best interests of the person. This is the case unless the past and present will and preference of a person who lacks capacity regarding a proposed intervention can be ascertained. If these can be ascertained then the following further considerations arise.

6.7.1 Where will and preference of person is in agreement with proposed intervention

If the past and or present will and preference of such a person is in agreement with a proposed intervention considered to be in the best interests of that person the intervention should proceed. The healthcare worker should document:

- Their efforts to support the person to make their own decision;
- The person's will and preference;
- The reasons why the action is to the overall benefit of the person.

Proceeding with an intervention based on the will and preference of the person and of their best interests is not the same as proceeding based on the person's consent to the intervention.

6.7.2 Where Will and preference of person is NOT in agreement with proposed intervention

Except in the circumstances discussed in Part One, Section 6.8, the will and preference of the person not to receive a proposed intervention should also be respected. Indeed, it would often be impractical, as well as undesirable, to do otherwise. In many cases, it is appropriate (and often successful) for the healthcare worker to make continued efforts, including involvement of those with a close ongoing relationship to the person, to enable the person to understand information regarding the intervention.

6.8 Circumstances where legal advice should be considered.

Legal advice should only be considered where the intervention of the Court would be helpful, practical and proportionate given the situation and individual circumstances of the person. This requires consideration of the broader interests of the person rather than a narrow focus on, for example, what would be clinically indicated.

Circumstances that could give rise to the necessity for legal advice include situations where:

- There are irreconcilable differences, for example, among those with a close ongoing personal relationship with a person, regarding the will and preference of the person;

- The healthcare worker is uncertain whether to, or wishes not to, give effect to the known past or present will and preference of a person;
- Detention or any use of force or restraint will be required to provide treatment or care;
- In some situations where the past and present will and preference of the person is not to receive a particular intervention, even where that intervention:
    - Is as unrestrictive as possible;
    - Is proportionate to the significance and urgency of the situation the person faces; and
    - Failure to provide that intervention might lead to a significant risk of loss of life or serious harm to the person or would otherwise be seriously adverse to the broader interests of the person such as by threatening their placement.

7 Advance healthcare plans and Advance Healthcare Directives

Sometimes people wish to plan in advance for decisions that may arise if they subsequently lack capacity to make such decisions, and this should be actively encouraged and facilitated by healthcare workers to help preserve the person's wishes and their will and preferences when they are no longer able to express them.

Advance planning by a person may include considering what specific interventions they would or would not want to receive in specified circumstances and who they would wish to be consulted about their will and preferences if they subsequently lacked capacity to make a particular decision. Although a person's advance request for a specific treatment must be taken into consideration during any decision-making process, there is no obligation to provide treatment that is not clinically indicated.

7.1 Advance healthcare planning

In some cases, a person will express their wishes about future care but does not make an Advance Healthcare Directive. This may occur, for example, if a person engages in discussions (advance healthcare planning) with healthcare workers who discuss the person's condition and prognosis, elicit their goals, will and preferences about what interventions would be appropriate if there were a deterioration in the person's condition and record this in the person's healthcare record.

An advance healthcare plan that does not meet the minimum criteria for an advance healthcare directive does not have the same status as an Advance Healthcare Directive. However, it often provides a helpful expression of the will and preference of the person and ought to be respected in appropriate cases. The same general principles noted in Part One, Section 7.2 apply when judging the validity and applicability of such advance plans.

7.2 Advance Healthcare Directive

A person can set out their wishes regarding healthcare treatment decisions, including treatment refusals, in case they are unable to make those decisions at some time in the future.

Any person aged 18 or older with decision-making capacity can make an Advance Healthcare Directive that will come into effect if they lack the capacity to make healthcare treatment decisions for themselves. The goal of an Advance Healthcare Directive is to enable a person's will and preferences to guide their healthcare treatment even when they no longer have the capacity to make treatment decisions for themselves. This can be important because in some situations, in the absence of an Advance Healthcare Directive, a person's will and preferences may not be known to their family members or to those providing healthcare treatment.

The person may have done this in writing, or using a voice recording or a video recording option. Advance Healthcare Directives are provided for in Part 8 of the Assisted Decision Making (Capacity) Act 2015 which is due to be commenced in 2022. The Assisted Decision-Making (Capacity) Act 2015, when fully commenced, will contain a clear set of minimum criteria for an Advanced Healthcare Directive to be valid under that Act and a valid and applicable refusal of treatment in an Advance Healthcare Directive will be legally binding on healthcare workers.

Apart from the Assisted Decision Making (Capacity) Act 2015 however there is a general constitutional principle that an adult who has decision-making capacity has the right to consent to and the right to refuse healthcare treatment. In appropriate circumstances, this legal principle may be relied upon to give effect to a person's previously recorded freely stated wishes about a future treatment decision.

Although each Advance Healthcare Directive must be considered on its own facts and circumstances the Irish Courts have indicated a general view that an opinion of "freely stated wishes" about future care ought to be respected "in appropriate cases".

This means that, in general, Advance Healthcare Directives should be respected as evidence of an expression of the person's will and preferences provided that the directive clearly sets out the treatment decisions and the circumstances in which the advance healthcare directive is to apply.

If, however, there are ambiguities in relation to the validity and applicability of the Advance Healthcare Directive, legal advice should be sought and ultimately the matter may have to be referred to Court. Such ambiguities may include:

- Concerns as to whether the advance healthcare directive was made voluntarily;
- Concerns that the directive-maker, while he or she had capacity to do so, has done something clearly inconsistent with the directions set out in the advance healthcare directive;
- Concerns that the directive-maker may subsequently have revoked or attempted to revoke the Advance healthcare Directive;
- Doubt as to whether a treatment refusal was intended to apply in the circumstances which have now arisen;
- Concerns that a treatment refusal is based upon false assumptions;
- Concerns that the advance healthcare directive is too broad in its application and so it is not clear that it applies to the situation in question.

Even if there are ambiguities, the Advance Healthcare Directive may still have relevance because it conveys significant important information in relation to the person's will and preferences in relation to their healthcare treatment.

8 Detention of a person contrary to their will and preference

It is a fundamental constitutional principle that no citizen may be deprived of his or her personal liberty except in accordance with the law. For example, someone who says that they wish to leave a health or social care facility and is prevented or not facilitated is being deprived of their liberty. This is the case even if the healthcare worker:

- Acts with good intentions;
- Judges that the person lacks capacity;
- Believes the detention to be in the person's best interests.

In the case of *AC v Hickey & Ors* [2019] IR 73, the Supreme Court provided guidance on the appropriate course of action in such a case and this section is based on this guidance.

In *AC v Hickey & Ors*, the Supreme Court held that the constitutional right to liberty and freedom of movement applies to those who lack capacity to make a decision about where they should live as well as to every other citizen. Compliance on the part of a person who lacks capacity i.e. not trying or seeking to leave in accordance with their will and preference to do so does not justify detention. If the person is being held contrary to their expressed will and preference, there must be some other lawful authority to allow such decisions to be made for the person.

The duty of the HSE to respect the constitutional right to liberty and freedom of movement of persons in its care may extend to admission to non-HSE facilities depending on the HSE's role in arranging the admission. If unsure, and subject to any legal advice that may be obtained in a specific case, HSE staff should operate on a precautionary working assumption that the duty does extend to a non-HSE facility if the HSE has a role in arranging the admission.

8.1 General principles where a deprivation of liberty may occur

A person who has capacity to decide where they shall live cannot be detained against their will. The general principles of this policy apply when considering the capacity of a person to decide where they should live, including discharge decisions. In particular, the presumption of capacity is the starting point; the fact that healthcare workers or others may feel a decision to go home (the most common scenario) is unwise does not indicate lack of capacity; and a functional approach should be taken if capacity is in question.

The following principles apply if a person, despite support to make their own decision, lacks capacity to decide where they shall live:

- Nobody, regardless of capacity to decide for themselves, can be deprived of their personal liberty except in accordance with the law;
- The doctrine of necessity can justify only a short period of detention before assistance of the Court is sought. To deprive someone of their liberty is such a serious matter that assessments and applications to Court must proceed urgently if deemed necessary;
- The voice and wishes of the person – what he or she wants to do, as opposed to what healthcare workers or others such as family members want or think is to the benefit of the person - must be heard;
- Ensuring that the voice of the person is heard may require providing the person with an independent advocate. This is particularly the case if the preferences of the person are different to those of healthcare workers or to those of family members;

- The person or their legal representative must have access to the reports and affidavits on which any application to the Court is based and must be given an opportunity to challenge these;
- Where the risk to a person comes from a third party, it is preferable that appropriate legal measures should be directed at the person creating that risk, rather than unnecessarily depriving the person of his or her liberty.

These principles apply in all settings where health and social care are provided, including in the community, and where a deprivation of liberty may occur.

8.2 Doctrine of necessity

In *AC v Hickey & Ors* [2019] IESC 73, the Supreme Court held that while a hospital had no overriding power to detain someone, it did have some limited powers under the doctrine of necessity and that this doctrine provides legal justification for the short-term detention of a person in their own interest.

The Supreme Court has emphasized that this is a temporary justification for a detention that can only be relied on to deal with urgent situations as it lacks formal safeguards and procedures. If a health or social care facility has reason to believe that a person expressing a will and preference to leave may lack capacity to make a decision about where they should live, it must, if it has serious concerns for the person's welfare and wishes to prevent the person from leaving, arrange for the necessary assessments of decision-making capacity and seek the assistance of the Court within a "reasonably short time". While no clear time frame is provided in AC v Hickey & Ors, it was noted that a delay of two weeks in seeking such assistance would in most cases be too long.

8.3 Undue pressure and discharge decisions

In AC v Hickey & Ors the Court noted that if hospital authorities believe on reasonable grounds that third parties are unduly pressurising a vulnerable person to leave the hospital, it is legitimate to prevent such departure for a brief period while the situation, and the capacity of the person to make the decision, is assessed. The first question is whether the person truly wants to leave, or is in reality being removed by third parties in circumstances where there is a real risk to her health and welfare. If it is a case of removal, rather than a wish to depart, the hospital's duty of care extends to protecting her against such third parties. If she does indeed wish to go, and has capacity to make that decision, all that the hospital can do is attempt to persuade her that it is in her own interests to stay. If, however, the hospital is concerned that the person lacks capacity to make the decision, that issue must be addressed as set out in Part One, Section 8.2 above.

Part Two: Children and Young People

1 Introduction

This Part of the Policy is about the consent of children and young people. This is a very broad category which encompasses very young children as well as young people on the verge of legal adulthood. This category also encompasses children and young people living in many different kinds of family situations, and those in the care of the state. Although Irish law sometimes refers to a 'child' as someone under the age of 18 years, there are legal distinctions between someone under the age of 16 years and someone aged 16 and 17 years. For this reason, this policy uses the term 'child' to refer to someone under the age of 16 years and 'young person' to refer to someone aged 16 and 17 years.

This policy applies to issues relating to consent in relation to all children and young people. Where indicated below, it should be read in conjunction with the General Principles outlined in Part One.

This Part of the policy is informed by a recognition of the rights of children and young people. The Irish Constitution expressly recognises the rights of children and young people in Article 42A (1)[8] as well as rights of the family and of parents.

In Re JJ [2021] IESC 1, para. 131 the Supreme Court describes Art. 42A (1) as "an emphatic statement of the rights of the child". In Re JJ, the Supreme Court also affirmed at para. 132 that in decisions about medical procedures "the rights of the child come to the forefront."

The rights of children and young people are also protected under international and European human rights instruments which have been ratified and/or incorporated by the State (United Nations Convention on the Rights of the Child and the European Convention on Human Rights). Respect for the rights of children and young people rights also provides the basis for government policy in respect of children and young people.[9]

Relevant rights of children and young people which inform this part of the policy are:

- The requirement that in any matter relating to children and young people, the child/young person's best interests are of paramount importance.[10]
- Assessment of the best interests of a child or young person must include respect for their right to express their views.[11]
- Children and young people have a right to be heard.[12] This requires that the child and young person must be allowed to express their views and that these views are given due weight in accordance with the child and young person's age and maturity. This means that the child and young person should be given age-appropriate information about the intervention proposed and should be encouraged to be involved in any decisions made, even if they are not able to give a legal consent.
- There is no age limit on the right of the child and young person to express her or his views and where appropriate there should be recognition of, and respect for non-verbal forms of communication including:
    - Play;
    - Body language;
    - Facial expressions;
    - Drawing and painting;

8 Art. 42A.1 states that "[t]he State recognises and affirms the natural and imprescriptible rights of all children and shall, as far as practicable, by its laws protect and vindicate these rights."
9 See Better Outcomes, Brighter Futures: The National Policy Framework for Children & Young People 2014-2020; National Strategy on Children and Young People's Participation in Decision-Making 2015-2020.
10 Art. 3 of the UN Convention on the Rights of the Child.
11 Committee on the Rights of the Child General Comment No. 12.
12 Art. 12 of the UN Convention on the Rights of the Child.

- Children and young people have a right to the highest attainable standard of health.[13]
  Respect for this right requires that supportive policies are in place and that "children, parents and health workers have adequate rights-based guidance on consent, assent and confidentiality".[14]

All rights of children and young people equally apply to children/young people with a disability.[15]
Extra support for children and young people with disabilities may be necessary in order to ensure that their right to express their views on all matters affecting them is respected. Such support must be age-appropriate and tailored to the needs of the child.

This part recognises that the appropriate way to address consent and/or refusal varies in accordance with the age and maturity of the child and young person.

In addressing questions of consent and refusal of an intervention, this part distinguishes between young people (aged 16 and 17 years) and children (aged under 16 years).

For legal reasons, this part also distinguishes between consent to and refusal of an intervention.

13 Art. 24 of the UN Convention on the Rights of the Child.
14 Committee on the Rights of the Child General Comment No. 14 (2013) para. 21.
15 Art. 7 of the Convention on the Rights of Persons with Disabilities

2 Consent and Refusal: Young People

2.1 Consent to an Intervention

This policy adopts the position that the consent of a young person aged 16 and 17 years (who has decision-making capacity) is sufficient (except where the Mental Health Act 2001 applies: Part Two, Section 8 below). This is in line with long established current practice and with the Medical Council, Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2019) as well as with a reasonable interpretation of s. 23 of the Non-Fatal Offences Against the Person Act 1997: see introduction to this policy.

The consent of the young person should always be sought. Where the young person gives consent, this policy adopts the position that it is not necessary to obtain consent from his or her parent(s) or legal guardian(s). It is however good practice to involve parent(s) or legal guardian(s) in healthcare decision-making for young people, if the young person consents to this involvement.[16] If the young person prefers to have the decision made by their parents, parental consent will suffice. This policy recognises that parental or legal guardian involvement in healthcare decision-making of young people aged 16 and 17 years, while usual, is not always practical or feasible. While young people should be encouraged to involve their parents or legal guardians, if they choose not to do so, the consent of the young person may be accepted as valid consent.

The general principles for valid consent as outlined in Part One of this Policy apply to young people aged 16 and 17 years. The functional approach to the assessment of capacity to consent to an intervention outlined in Part One of this Policy applies to a young person aged 16 and 17 years in the same way as to an adult. If a young person is found to lack the capacity to consent on the basis of the functional test, his or her parents may give consent on his or her behalf until the young person reaches the age of 18 years.

2.2 Refusal of an Intervention

Refusal of treatment by a young person (who has the capacity to make this decision) is legally differentiated from consent to treatment[17] and the Court can overturn a young person's refusal of treatment if it considers this to be in the young person's best interests. For this reason, a young person's refusal of health or social care services should not be viewed as legally binding until the young person reaches the age of 18 years. However, the views of a young person should always be treated with respect in accordance with the young person's age and maturity.[18] This includes where the young person refuses an intervention. This means that, even where the healthcare worker considers the intervention to be in the young person's best interests and the young person's parents would consent to the intervention, the intervention should not proceed if the young person refuses this treatment or intervention.

The only possible exception to this is in an emergency situation where there is an immediate risk of death or serious injury to the young person and there is no time in which an application may be made to the Court for guidance. In such a situation, the intervention should be the minimum possible in order to preserve life/prevent serious injury while the guidance of the Court is sought.

16 Parental involvement is supported by the Constitution of Ireland, the European Convention on Human Rights and Art. 5 of the UN Convention on the Rights of the Child.
17 HSE v JM [2013] IEHC 12.
18 HSE v JM [2013] IEHC 12.

In a non-emergency situation, all reasonable effort should be made to involve the young person and to reach a consensus as regards the appropriate intervention. If possible, the young person should be provided with advocacy support in accordance with their wishes. Ultimately, if a resolution cannot be reached, legal advice should be sought. It may be necessary to refer a refusal of an intervention to Court.

3 Consent and refusal: children under the age of 16 years

3.1 Consent to treatment

Parents or legal guardians are generally considered to be best placed to make decisions in the best interests of their children. This means that the consent of parent(s) who are legal guardians and other legal guardian(s) to an intervention for children under the age of 16 years will generally be both necessary and legally effective.

3.1.1 Consent by children under the age of 16

In some other countries, the Courts have recognised that a child under the age of 16 years may give a legally valid consent if they are sufficiently mature to understand the nature of the proposed treatment (sometimes referred to as 'Gillick competence').[19]

The Irish Courts have not provided a definitive ruling on consent by children under 16 years. This means that as a general rule, the consent of a parent (s) or legal guardian(s) should be obtained before providing treatment to a child.

3.1.2 Emergency situations

In emergency situations, all reasonable efforts must be made to contact and seek the consent of the child's parent(s) or legal guardian(s). In some serious emergency situations, the degree of urgency of providing an intervention may be such that there is no time to contact the parent/legal guardian prior to providing the intervention immediately necessary to save the life or prevent a serious detriment to the health of the child.

At all times, the healthcare worker is obliged to act in the best interests of the child. Even after the intervention, all reasonable efforts must continue to be made to contact the parent or legal guardian. The healthcare worker should also document in the healthcare record:

- Circumstances of the emergency;
- The efforts made to contact the parents/guardians;
- The basis for the decision to treat.

3.1.3 Information requirements

The same requirements to provide adequate information and to ensure informed consent identified in Part One apply to parent(s)/legal guardian(s) whose consent is sought on behalf of a child.

In all cases, healthcare workers should recognise the caring relationship between parent and child in which parent(s)/legal guardian(s) act as advocates and care providers for their child and have expertise in the particular needs of their child.

The parent(s) or legal guardian(s) are entitled at all times to be treated with courtesy and respect.

19 This refers to the UK case, Gillick v Western Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402.

3.1.4 Dealing with a child's opposition to parental involvement

Parental authority to consent on behalf of their child is always subject to the child's right to be involved in all aspects of the decision-making process. In practice this means that you should always involve the child in the decision.

It may sometimes happen that a child under the age of 16 years wishes to access an intervention without parental involvement or consent. In such circumstances it is best practice for the healthcare worker to encourage and advise the child to communicate with and involve their parents or legal guardians. In this, it may be helpful to engage an advocacy service to support the child.

In the unusual circumstance where the child does not consent to parental involvement, a healthcare worker should act in the best interests of the child. While there is a presumption that parental involvement is in the best interests of the child, there may be exceptions to this. In deciding if a situation is an exception, the healthcare worker should take account of:

- The child's maturity and ability to understand the information relevant to making the decision and to appreciate its potential consequences;
- Whether the child's views are stable and reflect their core values and beliefs;
- The nature, purpose and usefulness of the treatment or social care intervention;
- The risks and benefits involved in the treatment or social care intervention; and
- Any other specific welfare, protection or public health considerations covered by relevant guidance and protocols such as the Children First Act 2015 and the Children First: National Guidance for the Protection and Welfare of Children 2017 (and/or any equivalent or replacement document/s). Where relevant, these must be applied.

If there is doubt as to whether the provision of an intervention without parental involvement or consent is in the best interests of the child, legal advice should be sought.

3.2 Refusal of treatment/intervention

In respect of refusal of an intervention, a distinction may be drawn between refusal by the child and refusal by parents or legal guardians.

3.2.1 Refusal by the child

The views of a child should always be treated with respect in accordance with the child's age and maturity. This includes where the child refuses an intervention.

In a non-emergency situation where a child refuses an intervention which a healthcare worker considers to be in the best interests of the child and the child's parent(s) consent to the treatment, the following steps should be taken:

- Where a very young child objects to an intervention, every effort should be made to reassure them and to minimise distress caused to them. However, where an intervention is in the very young child's best interests, having taken into account the balance between the potential benefits and the potential distress, and the parent(s) or legal guardian(s) provides consent, it is reasonable to proceed with the intervention.

- For an older child, if the intervention is not urgent, it should be deferred to allow for further dialogue with the child in accordance with the child's age and maturity. In accordance with their age and maturity, the child should be involved in all reasonable efforts to reach a consensus as regards the appropriate intervention.
- In situations where the child has a significant health or social care issue, or the intervention is of a serious nature, in accordance with the child's age and maturity, if the child wishes, they should be provided with advocacy support (including where appropriate external advocacy support) to assist them in explaining their position.
- Ultimately, a healthcare worker must act in the best interests of the child and where the healthcare worker has taken the necessary steps to ascertain the views of the child and has taken these on board, including the impact of proceeding with the intervention contrary to child's views on the child's welfare, the healthcare worker may proceed with the intervention on the basis of parental consent notwithstanding the child's refusal.
- In situations where an older child is strongly opposed to an ongoing intervention (e.g. nasogastric feeding or chemotherapy) and some degree of force, sedation or restraint would be required to administer the intervention, legal advice should be sought as to whether it is necessary for the matter to be referred to the Court.

3.2.2 Refusal by parents/legal guardians

Parent(s) or legal guardian(s) are generally considered best placed to safeguard the health and wellbeing of their children. In complex situations, case conferences (special meetings to discuss a person's care) involving the parent(s) or legal guardian(s) and all relevant healthcare workers are often a useful way of ensuring that parent(s) or legal guardian(s) and healthcare workers work in partnership in decision-making for the child. All reasonable efforts should be made to recognise and respect the views of parent(s) or legal guardian(s) as regards what is in the best interests of the child, including when these views differ from those of the service provider. Where a second opinion is sought by parent(s) or legal guardian(s) in order to assist their decision-making, this should be facilitated as far as possible by the service-provider.

Where parent(s) or legal guardian(s) refuse to consent to an intervention which the healthcare worker reasonably believes to be in the best interests of the child, every effort should be made to reach a consensus position as regards the best interest of the child. This may require involving one or more other healthcare workers, including the provision of independent second opinions, as well as mediation or other external supports (if these are available).

If, having taken these steps, it is not possible for the healthcare workers and the parent(s) or legal guardian(s) to reach an agreement as to what is in the best interests of the child, it may be necessary to seek legal advice as to whether an application to the Court is required.

In such a situation, the parent (s) or legal guardian(s) should be informed of their right to seek legal representation and to be heard in relation to the application. The healthcare worker has an obligation to act in the best interests of the child at all times. This means that if in the opinion of the healthcare worker the intervention is immediately required and there is no time to make an application to Court without exposing the child to an immediate risk of death or serious injury, the intervention should proceed notwithstanding the parental objection. In such a situation, the healthcare worker should record the basis for his or her evaluation that immediate intervention is required and the steps which they have taken on this basis.

4 The process for parental consent

This part of the policy outlines the process which Healthcare Workers should employ in giving effect to the requirement for parental consent.

4.1 One or two parent consent

In giving consent, parent(s) or legal guardian(s) have duties to protect their child's safety and welfare. In light of this, and in keeping with the prioritisation of the best interests of the child, the consent of one parent is usually sufficient. However, this is subject to the following exceptions:

- Where both parents or all legal guardians have indicated a wish and willingness to participate fully in decision making for their child, this must be accommodated as far as possible by the service provider. However, this also imposes a responsibility on the parent or legal guardians to make this wish known to the service provider in advance, and to be contactable and available at relevant times when decisions may have to be made for their child. If one parent or legal guardian is not contactable or available at the required time, and the intervention is in the best interests of the child, the intervention can proceed on the basis of the consent of one parent only.
- Where both parents or all legal guardians have indicated a wish to be involved in the consent process and there is a dispute between parents or the legal guardians as to the appropriate course of action, then unless the matter is urgent, the intervention should be deferred and an attempt should be made to reach a consensus decision. At all times, the primacy of the best interests of the child should be recognised. If a consensus between the child's parents or legal guardians cannot be reached, the healthcare worker should notify the parents or legal guardians that the healthcare worker intends to proceed with the course of action which the healthcare worker considers to be in the best interests of the child on the basis of the consent of one parent. The healthcare worker should inform the parent or legal guardian who has a contrary view that they may make an application to the Court for a direction to prevent this. In such circumstances, the healthcare worker should seek legal advice as to whether an application to Court should be made by the service provider particularly in cases where the intervention is high risk or has potentially serious consequences.
- Even where both parents or all legal guardians have not clearly indicated their wish to be involved in decision making, if the intervention is high risk or is likely to have serious consequences for the child, both parents or all legal guardians should be involved in the decision-making process if possible. The involvement of both parents or legal guardians should be documented in the healthcare record. However, if an intervention is required and the second parent or legal guardian cannot be contacted despite reasonable efforts to do so, the service provider has a duty to act in the best interests of the child and the intervention can proceed on the basis of consent by one parent or legal guardian only. In this case, the efforts made to contact the second parent and the reasons for proceeding on the basis of the consent of one parent only should be documented.

4.2 Parental consent in practice

4.2.1 Confirmation of the status of the accompanying adult

Where a child accesses a health or social care service in the company of an adult, the adult should be asked to confirm that they are the child's parent and/or legal guardian. If the adult confirms that they are the child's parent and/or legal guardian, this should be documented in the child's healthcare record. If the adult is unsure as to what this means, the healthcare worker should refer to the relevant part of this policy and provide an explanation based on this. If the adult indicates that they are not the child's parent or legal guardian, contact should be made with the child's parent and/or legal guardian in order to seek appropriate consent.

If the accompanying adult has a letter from the parents confirming that they has permission to provide consent on behalf of the parent, it is still good practice to attempt to make contact with the parent.

4.2.2 Consent by telephone/electronic means

Sometimes the parent or legal guardian is unable to attend but is willing to provide consent by phone or electronic means. In these circumstances, the healthcare worker can accept consent obtained from parents or legal guardians by phone, electronic means or otherwise than in person.

Consent obtained from parents or legal guardians by telephone, by electronic means or otherwise than in person, is acceptable in circumstances where the parent and/or legal guardian is unable to attend and is willing to provide consent by telephone or electronic means. As where the parent/legal guardian presents in person, the person should be asked to confirm that they are the parent/legal guardian of the child and if they confirm that they are, this should be recorded in the child's healthcare record. As a general principle, where practicable this conversation should be witnessed by another healthcare worker.

The same standards and principles of informed consent set out in Part One of this policy apply to consent obtained in this way.

4.2.3 Duration of consent

Where a parent or legal guardian provides consent to a specific intervention, the consent applies only to the specific intervention in question. Any further interventions require new consent.

It is good practice to obtain consent some time in advance of the intervention, and not on the day of the intervention. If the healthcare worker can do this, it will give parents or legal guardians the chance to reflect on the intervention, and formulate and ask any questions that they may have with regard to the intervention. So for example, in respect of consent to a surgical intervention, consent may be obtained in a range of different locations such as:

- The Outpatient Department;
- Private rooms;
- Home visits;
- Emergency Department in advance of the surgery.

The healthcare worker should get consent within a reasonable time of the intervention. On the day of the procedure the healthcare worker should make sure that the:

- Child's parents or legal guardians, or the young person in question, are happy that they recall and understand the content of the consent discussion;
- Child's parents or legal guardians, or the young person have an opportunity to ask questions that are answered, by a healthcare worker with the requisite expertise, to their satisfaction.

In such circumstances, the consent obtained prior remains valid.

4.2.4 Consent to vaccinations

Vaccination programmes have an important public health aspect. The same provisions for consent or refusal in respect of young people set out in Part Two, Section 2 and in respect of children set out in Part Two, Section 3 apply equally to the administration of a vaccine.

Where a vaccination programme is administered through the school system, a single consent to the series of vaccinations in a vaccination programme may be obtained from parents or legal guardians. Where this happens, parents or legal guardians should be explicitly informed of their right to revoke their consent and that their consent applies to **each** of the vaccination interventions unless this consent is revoked. Parents and legal guardians should also be permitted to consent to some vaccination interventions and refuse consent to others.

It is always important that consent to vaccination is informed. Where the vaccination programme is administered through the school system, informed consent may be facilitated through the information leaflet or online information provided. This leaflet should provide sufficient information for parents or legal guardians to enable them to come to a reasoned decision about consent to each of the vaccination interventions involved. So for example, specific information should be made available about the nature of each intervention (e.g. whether it involves a booster shot or a new vaccination) and the applicable risks and benefits. The leaflet should also inform parents or legal guardians of what they should do if there is a change in the child's medical condition between an original vaccine and a booster dose. An approximate time frame for when the vaccinations will take place should be provided to parents in advance. This information leaflet should be updated if there is a scientific change in the medical makeup of the vaccine or booster dose which would alter the risks of the vaccine or the original vaccine.

On the basis that appropriate information is provided in the information leaflet, parental consent can be presumed to be valid for each of the repeated booster doses or vaccinations specified in the information leaflet unless this consent has been revoked by the parent or legal guardian.

In general, the consent of one parent to vaccination will suffice unless both parents or all legal guardians have expressly indicated a wish to be involved in the process. If the vaccinator has been expressly notified that one parent agrees to vaccination but the other disagrees, the vaccination should not be carried out until both parents reach agreement (or, rarely, there is a specific Court approval that vaccination is in the best interests of the child).

In such situations, the parents or legal guardians should be advised to discuss matters between themselves to seek to resolve their dispute. Discussion with the child's General Practitioner may be helpful to address any concerns. The parents should also be encouraged to discuss vaccination with their child, whose own views are also important.

Every reasonable effort should be made to avoid vaccination of a child where there is parental disagreement about the

vaccination. In some situation, this may include contacting a local vaccination centre or the child's General Practitioner. It is, however, not possible, to guarantee success in this regard.

Where one parent or legal guardian has given consent and the healthcare worker is informed that this parent or legal guardian has died, this consent is no longer legally valid and a new consent should be obtained from the other parent or legal guardian.

5 Confidentiality and Information Sharing

Confidentiality is of central importance to the relationship of trust between healthcare workers and people who use services. This is equally true where the person is a child or young person. Confidentiality is also an important element of respect for the child's right to the highest attainable standard of health.[20]

Most of the time, parents/legal guardians will be involved in healthcare decisions in relation to their children and information will be shared between:

- Healthcare workers;
- Parent(s) or legal guardians;
- The child or young person.

However, in some situations, a parent or legal guardian may not have been involved in the decision-making and so may not have had access to this information. In this situation, where a parent or legal guardian seeks to obtain information about a child or young person, the healthcare worker should discuss the request for information with the child or young person. In most situations, the healthcare worker should encourage the child or young person to consent to the sharing of this information with the parent or legal guardian.

If the child or young person does not consent to sharing information, the healthcare worker should consider whether it is in the best interests of the child or young person to share the information. There is a presumption (established in McK v Information Commission [2006] IEHC 2) that a parent or legal guardian is entitled to information about the medical care their child is receiving, and that providing this information best serves the interests of the child or young person. However, this does not apply in all circumstances and in *McK v Information Commissioner*, the Supreme Court held that "in considering the circumstances, [the child's] welfare is paramount". In deciding whether to provide information to a parent or legal guardian without the consent of a child or young person, the healthcare worker should take account of the age and maturity of the child or young person. For young people (aged 16 and 17 years), in general, information should not be shared without their consent.

For children, relevant factors in making a decision about whether to share information without the child's consent are:

- The child's age and maturity and ability to understand the information relevant to making the decision and to appreciate its potential consequences;
- Whether the child's views are stable and reflect their core values and beliefs;
- The nature, purpose and usefulness of disclosing the information;
- The risks and benefits involved in disclosure of the information; and
- Any other specific welfare, protection or public health considerations covered by relevant guidance and protocols such as:
  - Children First Act 2015;
  - Children First: National Guidance for the Protection and Welfare of Children 2017;
  - Any equivalent or replacement documents.

20 Committee on the Rights of the Child General Comment No. 14 (2013) para. 21.

The requirement for confidentiality applies in respect of sharing information about children or young people with a person who is not the child or young person's parent or guardian. In the absence of consent, confidential information may be disclosed only where there is a significant risk of harm or death to a third party.[21]

5.1 Legal Limits on the duty of confidentiality

There are some legal limits on the duty of confidentiality in respect of children or young people. In situations where these restrictions are likely to be relevant, a healthcare worker working with a child/young person should inform the child/young person that it is not possible to provide an absolute guarantee of confidentiality.

The legal limits on the duty of confidentiality are:

- Where a Freedom of Information Officer approves an application made by the parent or legal guardian under the Freedom of Information Act 2014 to access the healthcare records of their child (under the age of 18 years). In reaching their decision, the Freedom of Information Officer must take into consideration the legal presumption that the parent or legal guardian is acting in the best interests of the child or young person. They must also consider any grounds rebutting this presumption, including the views of the child or young person, their age and maturity, and the opinion of the healthcare worker on the best interests of the child or young person. Ultimately, the best interests of the child or young person is paramount.

Healthcare workers have legislative reporting obligations under:

- Children First Act 2015;
- National Vetting Bureau (Children and Vulnerable Persons) Acts 2012-2016;
- Criminal Justice (Withholding of Information on Offences against Children and Vulnerable Persons) Act 2012.

Healthcare workers should refer to the relevant guidance on these measures and should always comply with their statutory obligations.

21 CFA v AA [2018] IEHC 112.

6 The parent aged under 18 years

Parents or legal guardians are presumed to be the best decision-makers for their child and to act in their child's best interests. This presumption holds even if the parent is a child or young person under 18 years. All of the requirements in respect of parents identified in the previous sections apply where the parent is under 18 years.

Healthcare workers should support parent(s) aged under 18 years in making decisions in the best interest of their child. As with any decision made by parent(s) or legal guardian(s), if a healthcare worker is concerned that a decision made by a parent aged under 18 years is not in the best interests of the child, they should engage in dialogue with the parent(s) about the decision and take the steps outlined above to try to reach a consensus on the decision to be made. Ultimately, if a consensus cannot be reached, the healthcare worker should seek legal advice.

In some circumstances and depending on the nature of the relationship, it may be appropriate to involve other people, for example the child's grandparent(s) in the discussion of best interests. This should only be done with the consent of the parent(s) or legal guardians who are under 18 years.

7 Children in the care of Tusla - the Child and Family Agency

A child or young person may be admitted to the care of Tusla - the Child and Family Agency either:

- Voluntarily (where the parent(s) or legal guardians (s) have given consent to the admission);
- Under a care order from the Courts.

In all cases, the rules already set out above regarding the age of consent, emergency treatment, and the refusal of an intervention by the child or young person apply to the child or young person admitted to care of Tusla - the Child and Family Agency.

The same requirement regarding the child or young person's right to be involved in the decision-making and to have age-appropriate information also applies.

However, there are some differences in respect of parental consent. It is therefore important for Healthcare Workers to be aware of the specific consent-related issues in respect of children/young people in the care of Tusla - the Child and Family Agency.

7.1 Children/young people in voluntary care

For children and young people who have been voluntarily admitted to the care of Tusla - The Child and Family Agency, the legal rules as regards parental or legal guardian consent set out in Part Two, Section 3 above continue to apply.

7.2 Children/young people under a care order

A distinction should be drawn between a child (someone under the age of 16 years) and a young person (someone aged 16 or 17 years).

Where a young person is admitted to the care of Tusla - The Child and Family Agency under a care order (i.e. an order of the Court), the normal rules in respect of consent and refusal by a young person which are outlined in Part Two, Section 2 above apply.

Where a child is admitted to the care of Tusla - The Child and Family Agency under a care order, the normal rules in respect of parental or legal guardian consent which are outlined in Part Two, Section 3 do not apply. However, it is best practice to involve the child's parents in the decision-making process where possible, although always bearing in mind the right of the child to be involved and the primacy of the best interests of the child.

Where a child or young person is subject to an interim or emergency care order, an application may be made to the District Court in regard to consent to treatment/intervention, including that a healthcare worker involved with the child or young person's care is permitted to give consent to treatment/intervention.[22]

Where a child or young person is subject to a full care order (permanent or temporary), Tusla - the Child and Family Agency is authorised by the Court to consent to any necessary medical or psychiatric treatment, assessment or examination.[23] However, different interventions apply to admission and treatment under the Mental Health Act 2001. These are discussed in Part Two, Section 8 below.

[22] Child Care Act 1991, s. 47.
[23] Child Care Act 1991, s. 18.

Where a healthcare worker is informed that a child or young person is subject to a care order,[24] they should:

- Record this in the child or young person's healthcare record;
- If dealing with a young person, they should obtain the consent of the young person;
- If dealing with a child, they should get the consent of a representative of Tusla - the Child and Family Agency and should require the TUSLA representative to confirm that they have the legal authority to give consent on behalf of the child.

7.3 Children and young people in foster care

Where a child or young person is in foster care, the consent of Tusla - the Child and Family Agency is required for any treatment/intervention. Where a healthcare worker is informed that the child or young person is in foster care, they should:

- Record this in the child or young person's healthcare record;
- If dealing with a young person, the healthcare worker should obtain the consent of the young person in line with Part Two, Section 2 above;
- If dealing with a child, the healthcare worker should get the consent of a representative of Tusla: The Child and Family Agency and should require the TUSLA representative to confirm that they have the legal authority to give consent on behalf of the child.

Where a child or young person has been in foster care for five years or more, a foster carer may apply to the District Court for an order, giving them control over the child or young person as if they were their parent.[25] This includes giving consent to any necessary medical or psychiatric assessment, examination or treatment. Where a foster carer informs the healthcare worker that they have the authority to give consent under such an order, the healthcare worker should satisfy themselves that the foster carer has the necessary legal authority to consent to the intervention in question. One way in which this can be done is by requesting a copy of the order and checking this order to ascertain if the Court has placed restrictions on the foster parent's authority.

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24 Care Orders
Emergency Care Order – Section 13 of the Child Care Act 1991. An emergency care order places the child into the care of the HSE for a period of 8 days (or less if specified in the Order). Interim Care Order – Section 17 of the Child Care Act 1991 - An interim care order places a child into the care of the HSE for a period of no longer than 29 days, if the HSE and the parents (or guardians) do not consent to a longer period. If there is consent, the length of the Interim care order can exceed 29 days. An Interim Care Order can be extended if the court is satisfied that the grounds for making the order continue to exist; this extended Interim care order may be for a period of 29 days (or longer if the HSE and parents or guardians consent).
Care Order – Section 18 of the Child Care Act 1991 - The court must be satisfied that the child requires care and protection, which he or she is unlikely to receive unless the court makes the care order. The care order may be permanent or temporary and can continue up to age 18

25 Child Care Act 1991, s. 43A.

8 Mental health services

The vast majority of children and young people receive mental health services in the community,whether through General Practitioners or Child and Adolescent Mental Health Services (CAMHS). Some children and young people may also receive inpatient mental health care. A very small number of children and young people are admitted to an approved centre under the Mental Health Act 2001 and where this happens, their admission and treatment is covered by the statutory requirements of the Mental Health Act 2001 (see Part Two, Section 8.3).

All children and young people in approved centres (whether voluntary patients or an involuntary admission under the Mental Health Act 2001) must have an individual care plan, which must also address education requirements.[26] It is legally required that, where possible, this plan must be developed in conjunction with the child or young person.

In this section the policy addresses:

- Consent to treatment for a mental illness in the community of a child or young person; then
- Consent to admission to an approved centre (an inpatient mental health service) and treatment while an inpatient in an approved centre; then
- Admission and treatment under the Mental Health Act 2001.

The policy treats the issues of admission to an approved centre and consent to treatment when in an approved centre separately in terms of consent requirements.

8.1 Consent to treatment of a child or young person for a mental illness in the community

A valid consent to treatment is required where a child or young person is being treated for a mental illness in the community. The same provisions for consent/refusal in respect of young people set out in Part Two, Section 2 and parental consent in respect of children set out in Part Two, Section 3 apply equally to treatment for a mental illness.

8.2 Voluntary admission to an approved centre and treatment while in that centre

8.2.1 Consent to voluntary admission

In order for a child or young person to be voluntarily admitted to an approved centre, the consent of the child or young person's parents or legal guardians must be obtained. It is best practice to obtain the consent of both parents or all legal guardians.

If one or both parents or legal guardian(s) refuses to consent to the voluntary admission, the child or young person can only be admitted under the Mental Health Act (Part Two, see Section 8.3 below). If one parent or legal guardian consents to voluntary admission and the second parent or legal guardian cannot be contacted despite reasonable efforts and the healthcare worker is of the reasonable opinion that admission is in the best interests of the child or young person, the voluntary admission may proceed on the basis of consent by one parent or legal guardian only.

The authority of a parent or legal guardian to consent to voluntary admission to an approved centre is subject to the rights of the child or young person. These include the right of the child or young person to express their views and to have these views given due weight in accordance with the child or young person's age and maturity.

26 Mental Health Act 2001 (Approved Centres) Regulations 2006.

The child or young person's views are especially important in this context because admission to an approved centre may constitute a deprivation of liberty. If a young person (over the age of 16 years) refuses to consent or is resistant to admission to an approved centre, admission on the basis of parental consent should not proceed without legal advice.

8.2.2 Consent to treatment while voluntarily admitted to an approved centre

A valid consent to treatment is required where a child or young person is being treated for a mental illness while voluntarily admitted to an approved centre. The same provisions for consent/refusal in respect of young people set out in Part Two, Section 2 and parental consent in respect of childrenset out in Part Two, Section 3 apply equally to treatment for a mental illness.

8.3 Involuntary admission & treatment of children/young people under the Mental Health Act '01

The Mental Health Act 2001 sets out the legal framework for involuntary admission to and treatment of a child or young person under the age of 18 years in an approved centre. The Mental Health Act 2001 defines a child as a person under the age of 18 years other than a person who is or has been married.

8.3.1 Involuntary Admission under the Mental Health Act

An application for an involuntary admission under the Mental Health Act 2001 may only be made by the HSE and such an application will usually only be made where the child or young person's parents do not consent to voluntary admission. An application for an involuntary admission under the Mental Health Act 2001 may also sometimes be made where a young person objects to voluntary admission even though the young person's parents' consent.

A child or young person may only be involuntarily admitted under the Mental Health Act 2001 where they are found to be suffering from a mental disorder[27] and they require treatment that they are unlikely to receive unless the order for involuntary admission under the Mental Health Act 2001 is made.[28] The application for the involuntary admission (and all renewals) is made to the District Court.[29] In most cases, the District Court will make an order that the child or young person should have separate legal representation.

8.3.2 Consent to treatment when involuntarily admitted under the Mental Health Act 2001

Where a child or young person has been involuntarily admitted under the Mental Health Act 2001, neither parental consent nor the consent of the young person is legally required for treatment for the child or young person's mental disorder. Instead, decisions about treatment are made by the treating consultant psychiatrist in accordance with the Mental Health Act 2001. However, it is good practice to involve the parents or legal guardian insofar as this is possible. The child or young person also has the right to be involved in decision-making about treatment and to have his or her views treated with respect.

The Mental Health Act 2001 limits the consultant psychiatrist's authority to treat in the following ways:

- Psychosurgery and electro-convulsive therapy may only be provided where authorised by the District Court.
- During the period of involuntary admission, where medication has been administered to the child or young person for the purposes of ameliorating the mental disorder for a continuous period of 3 months, the administration of the medication may only continue if it is approved by the consultant psychiatrist responsible for the care and treatment of the child or young person **and** it is authorised (in a specified form provided by

27 The criteria for this are set out in Mental Health Act 2001, s. 3.
28 Mental Health Act 2001, s. 25(1).
29 Mental Health Act 2001, s. 25.

the Mental Health Commission) by another consultant psychiatrist, following referral of the matter by the treating consultant psychiatrist.[30]

30 Mental Health Act 2001, s. 61.

Part Three: Research

Separate consent must be obtained for a 'person' to take part in health and social care research. This revised policy does not amend Part Three (Research) of the 2013 (revised 2019) HSE National Consent Policy. Until a new policy is developed for research, the existing Part Three will be attached to this policy.

1 Introduction

Research has the potential to promote scientific advances, improve health services and contribute to the wellbeing of individuals and society as a whole. It allows policymakers and service providers to prepare for and respond to the risks posed by e.g. disease or environmental hazards and to verify that drugs and medical devices etc. are safe and effective. It has the potential to feed into the formation of policy and is concerned with a range of human experiences, perspectives and needs e.g. health, education, housing, family and community services as well as the social institutions created to meet those needs. Research is a regular part of the work undertaken by many HSE staff. There are various types of research which cover a range of activities, from laboratory research, clinical trials, observational studies and epidemiological investigations to surveys and interviews. Research can also assist the HSE with organising and providing services.

A number of international codes and standards as well as national and international legal instruments aimed at protecting research participants and ensuring high quality research have been developed in recent decades and these have been taken into account in formulating this policy.

Participation in research has the potential to offer participants direct benefits (e.g. improvements in health and well-being) and indirect benefits (e.g. greater access to professional care and support). The potential benefits of research can never be guaranteed. Therefore, it is important to ensure that any possible benefits of research are not overstated in order to avoid unrealistic expectations by prospective participants. Research, by its nature, also holds out the prospect of risk and it is essential that the risks of research be reasonable in light of any expected benefits.

A number of principles govern the ethical conduct of research, which aim to protect the wellbeing and rights of research participants. They include:

- Beneficence - maximising the potential benefits of the research and minimising the risks;
- Justice - the duty to neither neglect nor discriminate against individuals or groups who may benefit from research and to avoid placing an unfair burden of research participation on particular groups; and
- Respect for persons – the notion that individuals should be treated as autonomous agents and that individuals with diminished autonomy should be protected.

Respect for persons is most commonly manifested through the exercise of informed consent (hereafter referred to as consent), which requires that people's beliefs and opinions be valued, and that they be allowed to choose for themselves whether or not to participate in research.

All modern codes of ethics concerning research with human participants affirm the importance of consent. The goal of consent is to ensure that participants have sufficient information to be able to make decisions about research participation which are compatible with their individual interests and values.

Special consideration must also be given to the timing of the consent process. Prospective research participants should be given enough time to fully consider their participation and to ask questions.

2 General principles of consent for research

2.1 Content of the information to be provided

When preparing consent documentation, researchers must provide all of the information necessary for making an informed decision. Prospective research participants should be provided with the information in the following list, as appropriate. Not all of the listed information will be required for all research. However, in certain circumstances additional information may be required.

The proposed information should be submitted to a research ethics committee (REC)[31] for a consideration of whether it is adequate to achieve consent.

2.2 Explanation of the research study

The purpose of the study should be explained to research participants. They should be informed of the types of material/data required, the methods used to collect it and how the material/data will be utilised during the course of the study.

Research participants should be told how long their material/data will be retained and how it will be disposed of. They should also be informed how long/often they will be expected to attend the trial centre. Researchers should give a description of any other aspects of the study, e.g. whether questionnaires or diary cards will be used.

Participants should be informed whether or not they will be given feedback e.g. study results or any incidental findings (see Part Three, Section 8) as the study progresses. In instances where the material/data will be anonymous it should be made clear to prospective participants that feedback will not be possible.

It is important that consent be sought from research participants should there be secondary uses planned for the material/data e.g. future research studies.

2.3 Explanation of the risks and benefits

- Prospective research participants should be given an account of the foreseeable risks and benefits associated with participating in the research study. They should be assured that they can withdraw from the research study at any time and that their decision will not have any negative repercussions.

(For more information see Part Three, Section 10 on Withdrawal of Consent). The contact details of researchers should be provided to the research participant should s/he require clarification on any issue relating to the research.

2.4 Confidentiality

- Participants should be informed what information will be collected and for what purposes.
- Participants should also be told in what form the data will be stored (e.g. de- identified) and what measures the researchers will put in place to ensure confidentiality for the full life-cycle of the study.
- Research participants should be told which persons will have access to their data including third parties outside the jurisdiction.
- Participants should be advised in relation to the fate of their data at the end of the study.
- Participants should be advised of the risks of re-identification in the event of data security breaches.

[31] The Department of Health intends to designate the Health, Information and Quality Authority (HIQA) as the supervisory body for recognising and monitoring REC's. To this end, HIQA has established a Research Ethics Advisory Group with the aim of preparing national standards for RECs based on best international practice

2.5 Commercialisation

- Researchers should clearly explain to research participants whether or not they will receive payment (either financial or non-financial) for participating in the research project or have their expenses covered.
- Research participants should be made aware that they will not be entitled to a share of any profits that may arise from use of their material/data or products derived from it.
- Researchers should disclose any conflict of interest they may have e.g. a financial interest in the study.

(See Figure 1 for a list of sample information which might be included in a consent form)

Figure 1.

- A statement that the study involves research participants and an explanation of the purposes of the research.
- The expected duration of the participant's involvement.
- A description of the procedures to be followed/drug to be tested, and an identification of any procedures which are experimental.
- A statement that participation is voluntary including a statement offering the participant the opportunity to ask questions and to withdraw at any time from the research without consequences. In the case of withdrawal, information regarding what will happen to material/data should be provided.
- Information about who is organising and funding the research.
- A description of any reasonably foreseeable risk, discomfort or disadvantages.
- A description of any benefits to the participant or to others which may reasonably be expected from the research, avoiding inappropriate expectations.
- A disclosure of appropriate alternative procedures for treatment/diagnosis, if any, that might be advantageous to the participant.
- A statement describing the procedures adopted for ensuring data protection/ confidentiality/privacy including duration of storage of personal data.
- A description of how incidental findings are to be handled.
- A description of any planned genetic tests, including whether results will be disseminated to research participants.
- An explanation as to whether there are any treatments or compensation if injury occurs (where relevant) and, if so, what they consist of, or where further information may be obtained. Insurance coverage should be mentioned.
- Contact details to access information about the research and research participants' rights.
- An explanation of what will happen with the material/data at the end of the research and if the material/data are retained or sent/sold to a third party for further research.
- Information about what will happen to the results of the research.
- A statement regarding the potential commercialisation of the research (where applicable).

2.6 Who should seek consent?

The person obtaining consent should have sufficient knowledge about the research and be capable of answering questions from prospective participants.

Depending on the circumstances, prospective research participants may be approached directly (e.g. by advertisement) or indirectly (e.g. by the individual's GP). Where researchers are not also the service provider, best practice and data protection considerations require that the service provider should act as a gatekeeper and make the initial contact with the prospective participant and provide him/her with the contact details of the research team.

There may be situations where the researcher is also directly involved in providing care or support to the individual. Where this is the case, it is essential that any conflict of interest that might arise as a result of the original relationship be acknowledged and that any possibility that the individual might feel obliged to participate be averted. This might be achieved by having the consent either obtained or witnessed by a person who is independent of the research.

2.7 How should consent be documented?

For the majority of cases, prospective research participants should provide written consent. However, in cases where decision-making capacity is lacking, the research team should seek consent from the person's legal representative (for a more in–depth discussion see Part Three, Section 4 on adults lacking decision-making capacity and consent for research).

There may be certain circumstances where it is not possible for a prospective participant to provide written consent due to e.g. literacy levels or physical inability. In such cases a witness who is independent of the research should be present during the entire consent process and should sign the consent form. By signing the consent form, the witness acknowledges that the information provided to the individual was explained and that the consent was freely given. A video/audio tape recording of the consent interview might also be made with the permission of the research participant, however, researchers using this method must be mindful of their obligations to protect the confidentiality of the participant.

3 Children

Children should not be denied the possible benefits of research participation but instead should be afforded the opportunity to participate in research on matters that might affect them. Neither should children be exploited or inappropriately enrolled in research because they lack the capacity to consent to participation.[32]

For the purposes of participation in clinical trials, anyone over the age of 16 years can consent on his/her own behalf.[33] For all other research, the person must be over the age of 18 years in order to provide consent.

The following principles should be adhered to when conducting research involving children:

- The research should only include children where the relevant knowledge cannot be obtained by conducting research involving adults
- The purpose of the research is to generate knowledge about the health or social care needs of children
- The research does not pose more than minimal risk unless there is a prospect of direct benefit for the participants
- The research has been designed to minimise pain, discomfort, fear and any other foreseeable risk to the child or his/her stage of development
- Consent to the child's participation must be obtained from a parent/legal guardian
- Whenever s/he has sufficient competence to provide it, the child's assent must be sought in a child-appropriate manner; and
- A child's refusal to participate or continue in research should be respected.

There is an international consensus that children should not be exposed to more than minimal risk in the absence of direct benefit to the participants themselves. The standard of minimal risk requires that the probability and magnitude of the possible harms posed by participating in research are no greater than those encountered by participants in their everyday life or during the performance of routine physical or psychological examinations or tests.

Where the research entails only minimal risk, it is sufficient if the research offers the prospect of benefits either to the participants directly or to the group which is the focus of the research and to which the participants belong.

Where the research poses more than minimal risk, it should aim to generate new knowledge of sufficient importance for addressing the participants' conditions/needs. Such research should offer the prospect of direct benefits for the participants themselves and be commensurate with the level of foreseeable risk. The benefit-to-risk ratio presented by the research should be at least as favourable to participants as that presented by available alternative approaches.

It is sufficient for one parent/legal guardian to provide consent for a child's participation in research unless the REC has found that the risks involved in participation require the consent of both parent(s)/legal guardian(s). A parent or legal guardian who provides consent on a child's behalf should be given the opportunity, to a reasonable extent, to observe the research as it proceeds. Researchers must respect the developing capacity of children to be involved in decisions about their participation in research and, where appropriate, the child's assent to participation must be sought. It is important to note that a child's capacity and/or vulnerability may fluctuate depending on age, maturity and the type and complexity of the research being proposed.

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32 Researchers should refer to the Department of Children and Youth Affairs document Guidance for Developing Research Projects Involving Children which was published in April 2012

33 European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI no 190 of 2004, section 4

Older children, who are more capable of giving assent (i.e. children over the age of 7 years),[34] should be selected before younger children, unless there are valid scientific, age-related reasons for involving younger children first.

In order to assist children to make decisions, they should be informed as fully as possible, given their age and competence, about the nature of the study and the methods to be employed from the outset. Information for children five years and under should be predominantly pictorial. For older children, information sheets should be provided that explain briefly and in simple terms the background and aim of the study, so they can consider assent.

It should also contain an explanation that their parent(s)/legal guardian(s) will be asked for consent. The information should be written in clear and simple language and should be read to them. It should be explained to children that they may choose to withdraw from the study if they are uncomfortable with continuing.

The objection of a child to participate in research should be considered and adhered to unless the intervention being tested were to offer an important direct benefit to the child.

Parent(s)/legal guardian(s) who enrol their child in a study might believe that the research is designed to provide a direct therapeutic benefit to the child, as opposed to contributing to medical knowledge for the benefit of individuals in the future. This is commonly referred to as therapeutic misconception. Therefore, it is essential that researchers should be aware of the possibility of parental therapeutic misconceptions when determining how to explain the potential benefits and risks of research participation during the consent process.

In certain circumstances, it will not be possible for the researcher to guarantee confidentiality to the child due to mandatory reporting obligations. For instance, if a child reveals that they or others are at significant risk of harm, or the researcher observes or receives evidence of incidents likely to cause serious harm, the researcher must divulge this information to the appropriate authorities. This should occur only following discussion with the child. The child and his/her parent(s)/legal guardian(s) should be informed of this obligation during the consent/assent process and it should be highlighted in participant information leaflets. A strategy for information disclosure should be submitted to and approved by the REC in advance of the research being commenced.

3.1 Healthy children as participants

In certain types of research it may be necessary to involve healthy child participants to act as a control group. In such instances, healthy volunteers should be treated in the same manner as other child participants. The risks posed to healthy child participants should be no more than minimal in the absence of any direct benefit for this cohort.

3.2 Children in care

Research involving children in care is permitted once the criteria listed above are adhered to. In order to conduct research involving a child in care, researchers should first get consent from the responsible legal guardians e.g. a parent and/or the child's health/social care providers or someone with a duty of care to the child. This consent must be supplemented with the child's assent.

Given the vulnerability of children in care, researchers should consider appointing an advocate, agreed by the child. The task of the advocate would be to ensure that the child is not exploited, coerced or subjected to undue influence or harm during the course of the research and that the child has freely given his/her assent to participation.

[34] The Department of Children and Youth Affairs' document Guidance for Developing Research Projects Involving Children makes reference to the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research's report Research Involving Children (1977), which recommends seeking assent from children seven years or older

3.3 Neonates

Research involving full-term or pre-term neonates is, in principle, similar to research involving children as the decision-making power rests with their parent(s)/legal guardian(s) and, in general, the same rules apply. However, this type of research raises additional issues relating to consent, as the parent(s)/legal guardian(s) may be distressed following a difficult or premature birth. Nevertheless, because of the important benefits that might accrue from such research, if consent can be obtained from a parent/legal guardian of the child then, providing conditions in relation to levels of risk (as set out in the criteria above) are met and the research can be justified to a REC, the research can proceed.

4 Adults lacking decision-making capacity and consent for research

In accordance with the functional approach to capacity (see Part One), there may be instances where a person might have limited capacity and may require assistance in deciding whether or not to participate in research. In such cases, researchers must ensure that efforts are made to assist people in reaching their decision and that they are provided with the appropriate tools to maximise their decision-making ability.

The objectives as well as the potential risks and benefits of the research should be explained as fully as possible to the prospective participant given their level of understanding. The information should be provided using easily comprehensible language and the prospective participant should be informed of the right to withdraw from the study at any time without there being any negative repercussions.

There may be some instances where the capacity to consent to research participation is lacking. Adults who lack decision-making capacity must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of capacity to consent be used to inappropriately include them in research. However, special measures should be taken to protect their rights and interests.

The following principles should be adhered to when conducting research involving adults lacking decision-making capacity:

- The research should only be undertaken if the required knowledge cannot be obtained by conducting research involving adults with decision-making capacity
- The research is expected to provide a direct benefit to the participants or to provide knowledge about the cause or treatment of the impairing or similar condition. Where there is no prospect of direct benefit for participants, the risks involved should be no more than minimal (For more information on minimal risk see Part Three, Section 3 on Children)
- Consent for participation must be sought from the person's legal representative
- A REC must approve the participation of adults lacking decision-making capacity in research taking all of the above factors into consideration
- The explicit wish of a participant to refuse participation in or to be withdrawn from the study should be respected.

Where a prospective research participant lacks decision-making capacity but has some ability to understand the significance of the research, the researcher should ascertain the wishes of that individual with respect to his/her participation.

Under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004,[35] [36] consent for research participation on behalf of an adult lacking decision- making capacity must be obtained from the person's legal representative. A legal representative has been defined as a person not connected with the conduct of the trial who by virtue of his/her family relationship with that adult, is suitable to act as the legal representative and is willing and able to do so or (if there is no such individual) a person who is not connected with the conduct of the trial, who is a solicitor nominated by the relevant health care provider.

35 In July 2012 the European Commission published a proposal to repeal the Clinical Trials Directive 2001/20/EC and for new legislation relating to the conduct of clinical trials on Medicinal Products for Human Use. The new legislation, which is expected to come into effect in 2016, will take the form of a Regulation which will ensure that, in the main, the rules governing clinical trials will be identical throughout Europe . Other aspects, such as the structure and function of RECs and eligibility for the role of legal representative will be decided at a national level

36 It is also important to note that the European Commission is in the process of reviewing EU legal frameworks relating to medical devices and on the protection of personal data

Outside of clinical trials, there is currently no legal framework for a person who lacks decision- making capacity to participate in research. In the absence of any such legal regulations, it is recommended that as a matter of best practice the same principles should apply to both clinical trials and other forms of research. This means that consent for participation in any form of research on behalf of an adult lacking decision-making capacity must be obtained from the person's legal representative, as defined above.

Refusal to participate in a research project by an individual lacking decision-making capacity should be respected.

5 Vulnerable research participants

It is important to recognise that research involving human participants requires special justification in the case of potentially vulnerable people. Certain groups may continually be sought as research subjects, owing to their ready availability in settings where research is conducted, or the conditions they suffer from. Such groups should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition. Vulnerability is sensitive to context and individuals may be vulnerable in one situation but not in another.

5.1 Research in emergency situations

Research in emergency situations involves individuals who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g. traumatic brain injury) cannot provide consent. In emergency situations, when it is not possible to obtain the consent of the prospective participant, then the consent of the participant's legal representative should be sought. (See Section 4 on Adults lacking decision-making capacity and consent for research.) If there is no legal representative present then the individual can only be enrolled in research if the following criteria are met:

- The research addresses the emergency needs of the individual involved;
- The experimental interventions have a realistic probability of benefit equal to or greater than standard interventions; and
- The risks associated with the research are reasonable in view of the critical nature of the condition and the risks associated with standard interventions.
- Participants who regain capacity (or their legal representatives once located) should be given all the relevant information and their consent to continued participation should be obtained as soon as is reasonably possible. The option to withdraw and to seek the destruction of any biological material or data collected as part of the study should also be given.

5.2 People highly dependent on medical care

While research involving people who are highly dependent on medical care (e.g. people in intensive care or the terminally ill) is valuable, their reliance on medical treatment may impact on their willingness to consent to research participation and this raises significant ethical issues. Therefore, such research should only be undertaken when:

- It is likely that the research will lead to an increased understanding of, or an improvement in, the care of that population; and
- Any risk or burden of the proposed research to a particular participant is justified by the potential benefits that might accrue to him/her.

There should be an explicit recorded explanation that not participating in or withdrawing from the research will not adversely affect either the quality of care received or the relationship with the medical team.

When undertaking studies involving people highly dependent on medical care, researchers must be mindful of the potential for unrealistic expectations of benefits and must ensure that the prospect of benefit from research participation is

not exaggerated. Where the research involves terminally ill people, their needs and wishes to spend time as they choose, particularly with family members, must be respected.

For research involving people who are highly dependent on medical care:

- Steps should be taken to minimise the risk that stress or emotional factors may have on the person's understanding of the research or his/her decision to participate; and
- Researchers must ensure that the dependency of prospective participants on the medical personnel providing treatment does not compromise the voluntariness of their consent.

People who are highly dependent on medical care may have impaired capability for verbal or written communication. Provision should be made for them to receive information and to express their wishes, in other ways.

Where the researcher is also the service provider, it should be considered whether a person who is independent of the research should make the initial approach and/or seek consent from potential participants.

In cases where people who are highly dependent on medical care lack the decision-making capacity required for consent the criteria listed in Part Three, Section 4 should be adhered to.

5.3 People in dependent or unequal relationships

Dependent or unequal relationships might include those between: health and social care professionals and residents in care; teachers and students; penal institutions and prisoners; employers and employees; or governments and refugees.

Being in a dependent or unequal relationship may influence a person's decision to participate in research. While this influence does not necessarily invalidate the decision, it necessitates close inspection of the process through which consent is negotiated. In the consent process, researchers should, wherever possible, invite prospective participants to discuss their participation with someone who is able to support them in making their decision. Where prospective participants are especially vulnerable or powerless, consideration should be given to the appointment of a participant advocate (see Section on Children in Care 3.2). It may also be appropriate that consent is obtained by a person who is independent of the research. People in dependent or unequal relationships might be vulnerable to being over-researched because of the relative ease of access to them as research populations.

Researchers should take account of this vulnerability in deciding whether to seek out members of these populations as research participants.

A person who wishes to decline an invitation to participate in research or withdraw from a study should not suffer any negative consequences such as discrimination, reduction in care, dismissal from employment, exam penalties or any other disadvantage. Researchers must protect the confidentiality of participants, especially in settings such as shared workplaces, educational institutions, hospitals or prisons.

Researchers should be mindful that in some relationships of dependency, participants may have an unrealistic expectation of the benefits of research and must ensure that the prospect of benefit from research participation is not exaggerated.

6 Categories of research

6.1 Genetic research

The Disability Act 2005 (part 4) states that consent for the processing of any genetic data to be derived from testing must be obtained.

The act also stipulates that a person shall not process genetic data unless all reasonable steps have been taken to provide the data subject with all of the appropriate information concerning:

- The purpose and possible outcomes of the proposed processing; and
- Any potential implications for the health of the data subject which may become known as a result of the processing.

As a result of the highly sensitive nature of genetic data, it is important that researchers formulate a strategy regarding third party disclosure, in particular to family members. The results of genetic research might create a need for alternative life decisions, including those concerning reproductive choices or those with the potential to improve health e.g. dietary modification or career choices. When participants or their relatives are to be informed about genetic data that may be important for their health or lifestyle choices, the disclosure strategy should provide access to genetic and clinical advice/ counselling, or clearly recommend to participants that they seek these services. Advice about the results of genetic research needs to include a clear explanation of the difference between research and clinical testing, and to clarify any need for the clinical confirmation of research results by an accredited laboratory.

Where people are asked to consent to the collection of their genetic material or data for research, they should be advised:

- That, by its nature, genetic material is in principle identifiable, even if personal identifiers are not collected or are removed
- That they are free to decline participation without giving reasons
- About arrangements to ensure the privacy and confidentiality of their genetic data with regard to both family members and others
- Whether the research may reveal information of potential importance to their future health, or the future health of their blood relatives
- That a genetic test may reveal unexpected relationships, such as non-paternity (i.e. a different biological father); and
- That, if it is proposed to approach blood relatives, consent to do so will first be sought from the participant.
- Identifiers of genetic material or related data:
- Should not be removed without the consent of participants, if removal would make it difficult to communicate personal results; and
- Should be removed if participants request it, provided they have been informed that the material or data would remain potentially identifiable

- Researchers should not transfer genetic material or related data to any researcher not engaged in the research project unless:
    - Where the material or data is identifiable, participants have been informed about the transfer and have explicitly consented to it; or
    - A REC has judged that the conditions for transfer have been met (for more information on consent and controlling access to data see Part Three, Section 9).

6.2 Epidemiological research

A REC may waive the requirement for consent if the expected benefit of the research is real and substantial. Such waivers may also be approved when the existence of a signed consent form would be an unjustified threat to the subject's confidentiality.

Categories of epidemiological research for which consent might be waived include:

- The use of anonymous material/data
- Studies using health-related registries that are authorised for such use; and
- Cluster randomised trials (i.e. where groups are randomised as opposed to individuals). For example, villages, hospitals, families or classrooms may be randomised. Reasons for performing cluster randomised trials vary. Sometimes the intervention can only be administered to a group, for example an addition to the water supply (fluoride) or a public education campaign.

6.3 Covert research

Covert research cannot, by definition, involve obtaining consent in advance because informing potential participants would render the research overt and may change its outcome e.g. observation of teenagers' drinking habits. A distinction should be made between covert research and deception. Covert research refers to studies undertaken without the knowledge of the research subjects e.g. where a researcher observes the routine actions of others. Deception, on the other hand, refers to situations where the researcher deliberately misrepresents his/her intentions to the research participants.

There is consensus that covert research should not be undertaken routinely, rather it should occur only where it can provide a unique form of evidence that cannot be gathered in any other way or where important issues of sociological significance are being addressed. While serious ethical and legal issues arise in relation to covert research, the use of covert methods may be justified in certain circumstances. For example, difficulties arise when research participants change their behaviour because they know they are being observed.

Where consent has not been obtained prior to the research it should, where possible, be obtained at a later time. In cases where participants who are asked to give retrospective consent express concerns about their inclusion in a project, the researcher should give them the option of removing their data from the study.

For research where identifiable data (e.g. images, video recordings) is being collected, then the consent of prospective research participants must be sought.

6.4 Research in public health emergencies

The requirement for consent might be waived in public health emergencies, where a health threat and possible treatments/alleviations must be identified as quickly as possible. For instance, a waiver may be permissible, where a delay caused by the time needed to obtain consent from a person suffering from a new strain of pandemic influenza or other biological, chemical, radiological or nuclear agent, might not only jeopardise his/her health but also the health of others within the population.

6.5 Multi-jurisdictional research

When multi-jurisdiction research is being undertaken, additional ethical considerations might arise. While researchers should be cognisant of the local research ethics requirements, they should comply with this policy and act in accordance with Irish legislation.

When multi-jurisdictional research is to be conducted, local cultural values should be acknowledged in the design and conduct of the research. Irrespective of cultural traditions, consent must always be given by the prospective research participant. In certain cases it may be appropriate to seek the agreement of a person(s) invested with a certain authority within the community.

Researchers must do their utmost to communicate information accurately and in a comprehensible and appropriate way. Where formal written consent from the participant is not possible, the following should be observed:

- A community representative trained by the research team should be made available; and
- The oral approval should be witnessed by the trained and independent community representative. S/he will verify that the purpose of the research has been explained to the participant and that that the consent was freely given.

Researchers should be mindful that in some countries, participating in research may be the only way that individuals can access healthcare and they must ensure that this circumstance does not act as an undue inducement to research participation.

6.6 Research involving archival material

Researchers may want to use biological material or data that was previously accumulated for clinical purposes or that was collected by other researchers. This raises privacy issues, such as whether the archival material or data contains personal identifiers, or whether it can be linked to such identifiers and, if so, by whom. If consent was required for the original collection or use of the archival material or data then secondary uses may be constrained by the conditions specified in the initial consent. Consequently, it is essential that the consent process anticipate, where feasible, any foreseeable plans for future research using the material or data.

There are, however, certain circumstances under which archival biological material or data may be used for research purposes where consent is not required. For instance, where archival biological material or data was obtained from persons for research or clinical purposes, where the material or data is not individually identifiable (i.e. anonymous), and where there are no potential harms to the person from whom the material or data was obtained, consent requirements may be waived.

Where existing material or data is individually identifiable, researchers should make every reasonable effort to obtain consent from individuals for the use of their archival biological material or data. A REC may waive the consent requirement subject to conditions outlined below.

Researchers who have not obtained consent from participants for secondary use of their archival material or data should only use such material or data if they can satisfy a REC that:

- The use of the material/data without the participants' consent is unlikely to adversely affect the welfare of individuals involved
- The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the material/data
- The researchers will comply with any known preferences previously expressed by individuals about any use of their material/data
- It is impossible or impracticable to seek consent from individuals to whom the material/data relates; and
- It is important to note that the word "impracticable" refers to excessive difficulty or onerousness that jeopardises the conduct of the research as opposed to inconvenience.

As a condition of access, archival biological material or data should be de-identified by the data controller (for more information see Part Three, Section 9 Consent and controlling access to data).

6.7 Research involving deceased people

Human biological material obtained during the course of a post-mortem examination can prove extremely valuable for research purposes. An individual may provide prior consent for the use of his/her biological material for research that will be carried out after his/her death. However, this scenario is uncommon, therefore, the consent form furnished to the next-of-kin prior to a post- mortem examination should include a section which allows relatives of the deceased to give or refuse consent for the use of any retained tissue and/or organs for research purposes.

A designated person with training in bereavement should be made available to speak to relatives and explain the procedures involved in an understandable and sympathetic manner. Families must be assured that their decision will be respected.

7 Consent for future uses

It is important that consent documentation allows prospective participants to make a decision whether or not to allow their material or data to be used in the future. In order for such decisions to be as fully informed as possible, prospective research participants should be presented with a multiple choice or layered consent form. Layering the consent form allows individuals to select from a graduated set of consent options with respect to the storage and future use of their material or data.

A layered consent form might include options such as:

- Permission for material/data to be stored for possible future research related to the current study only if consent is obtained at the time of the future research;
- Permission for material/data to be stored for possible future research related to the current study without further consent being required;
- Permission for material/data to be stored for possible future research unrelated to the current study only if consent is obtained at the time of the future research; or
- Permission for material/data to be stored for possible future research unrelated to the current study without further consent being required.

Where prospective research participants are to be recruited in a clinical setting, a clear distinction should be made between consent for any clinical procedures or tests and consent to research participation. In practice, this means separate discussions should take place and separate consent documentation should be provided.

Research participants should be informed of the extent to which confidentiality will reasonably be maintained during future research. If prospective research participants refuse to consent to the biobanking or future use of their material or data, then the material or data should be destroyed on completion of the planned research project.

- In order to protect the interests of research participants whose material or data might be stored, institutions and researchers that maintain biobanks must:
- Ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely and securely; and
- Establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorised access.

Biobank custodians have an obligation to respect an individual's expressed preferences. Where an individual does not want biological materials used for future research, custodians should remove these biological materials and/or data from any collections used or made available for research. Research participants whose biological material is (or is intended to be) stored in a biobank must be informed of their right to withdraw their material and/or data without any negative repercussions. It is recommended that researchers offer prospective research participants a set of graded options for withdrawal, such as, no further contact from researchers or complete withdrawal.

- No further contact: participants would no longer be contacted by the researchers or data controllers but their previously provided biological material/data would still be available for use in the current research and/or future research.

- Limited further use: participants' biological material would be destroyed but the previously collected data derived from that material would be available for further use in the current research and/or future research. Participants might also be given the option to identify the types of research they would or would not want their material/data to be used for.
- No further use: all biological material/data previously collected could no longer be used by researchers but would instead be destroyed.

Whatever option is selected by an individual should be adhered to. It is important to note that the subsequent use of biological material or data collected for a specified purpose may not proceed without first receiving REC approval.

In the case of longitudinal studies, children who are recruited as research participants should be asked for consent to their continued participation in research on reaching the age of maturity (i.e. 18 years). (For more information on Reconsent see Part Three, Section 11).

8 Consent and incidental findings

The term “incidental findings” refers to the unanticipated discoveries made in the course of research but that are outside the scope of the research. Medically relevant incidental findings are findings that have been interpreted as having significant implications for the participant, whether health-related, psychological or social.

As part of the consent process, prospective research participants should be provided with the option of whether or not they wish to have medically relevant incidental findings disclosed to them. Should prospective participants indicate a desire not to be given medically relevant information, then this decision should be documented and respected.

When medically relevant incidental findings are likely, researchers should develop a plan indicating how they will disclose such findings to participants and submit this plan for REC review.

The plan should identify the circumstances under which research results would warrant disclosure, a strategy for managing such disclosure, and include arrangements for appropriate medical advice or referral when disclosure is made. Disclosure of research results should be done in a sensitive manner with the consent of the participant. Incidental findings and/or research results (especially in the case of genetic research) should be confirmed by an accredited laboratory.

In cases where incidental findings are regarded to be of vital and immediate clinical significance (e.g. tumours, blood clots, aneurysms), the researcher involved has a duty of care to that individual. Prospective research participants must be advised that such a duty of care exists during the consent process.

Researchers should be especially aware of their obligations to protect the confidentiality of research participants when releasing data to third parties. For instance, in the case of genetic research, family members may need to be informed of potential genetic risks. Similarly, data may be of interest to other researchers or biobanks.

Provided that consent is in place, transfer of identifiable data to such third parties is permissible and provided a comparable level of security and protection of privacy can be ensured. (For more information on Consent and controlling access to data see Part Three, Section 9).

The Disability Act 2005 (Part 4) provides that insurers cannot request, take into account or process the results of genetic tests (for a more in-depth discussion of genetic research see Part Three, Section 6.1).

Certain types of information may be made available to public health officials for important purposes, for example, the reporting of infectious diseases, without the explicit consent of the individual.

9 Consent and controlling access to data

Research participants who have given appropriate consent have a right to expect that identifiable data about themselves, either provided or discovered in the course of research, will not be shared with others without their consent.

Anonymous data is beyond the scope of the Data Protection Acts, therefore, consent is not required in order to conduct research using this form of data. However, use of anonymous data is not always possible, or indeed desirable, in a research context.

De-identifying data (i.e. where identifiable information is substituted with a code to which only the data controller would have the key) is another way of protecting confidentiality. In order to safeguard a research participant's rights to privacy, data should be de-identified by the data controller as early as possible. In the case of HSE-run facilities, the HSE is the data controller.

In cases where research is to be undertaken by external third parties (e.g. researchers who are not directly involved in the care of the prospective research participants), where identifiable information will be used then the explicit consent of the prospective research participants must be obtained. In cases where research is to be undertaken by external third parties and the data has been de- identified, prior to being transferred, the consent of the research participant for such a transfer is not required.

10 Withdrawal of consent

Prospective research participants must be informed from the outset that they can withdraw from a study at any time, that they need not offer any explanation for wishing to withdraw and that their decision will not impact on the services being provided to them.

Where an individual wishes to have his/her biological material or data withdrawn from a study, every effort should be made to respect his/her wishes. However, it is recognised that this might not always be feasible e.g. once the research results have been published or disseminated in other ways, such as by being deposited in a publicly accessible database.

Therefore, consent documentation should clearly indicate what circumstances would prohibit the withdrawal of biological material or personal data.

In the case of anonymous biological material/data, prospective research participants should be informed during the consent process that it will not be possible to withdraw their material and/ or data.

11 Reconsent

The consent process should consist of a continued exchange of information for the duration of a study. When substantial changes occur in the conditions or the procedures of a study, researchers should once again seek the consent of the participants. It is imperative that research participants be informed when there is new information that might affect their willingness to continue participation. There are a number of reasons why reconsent may be required which include but are not limited to cases where:

- The research protocol has been substantially altered;
- New safety information has come to light;
- Alternative treatments have become available;
- A child participant reaches legal maturity (i.e. 18 years or 16 years in the case of clinical trials);
- A formerly incapacitated adult has regained capacity; or
- A substantial period of time has elapsed since the original consent was obtained (e.g. longitudinal study).

A strategy for reconsenting participants should be presented to the REC responsible for reviewing and approving the study.

12 Research where consent may not be required

As noted above, certain types of research may not require the consent of the research participant by virtue of a legal basis (e.g. research in public health emergencies) or because a REC has waived the requirement for consent (e.g. population based research). It should be noted that in the latter case, the waiver applies only to de-identified material/data.

Waiver of consent is to be regarded as an exception to the rule and studies seeking waiver of consent must receive REC approval. Before a waiver of consent may be granted the researcher must satisfy the REC that:

- The overall benefit to research is real and substantial;
- The benefits from the research justify any risks of harm associated with not seeking consent;
- It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
- There is no known or likely reason for thinking that participants would not have consented if they had been asked;
- There is sufficient protection of their privacy; and
- There is an adequate plan to protect the confidentiality of data.

It is important to note that the word “impracticable” refers to excessive difficulty or onerousness that jeopardises the conduct of the research as opposed to inconvenience.

13 Remuneration of research participants

13.1 Reimbursement

Research participants may be reimbursed for lost earnings, travel costs and other expenses incurred. Another acceptable form of reimbursement might be the provision of free medical services. Compensation for the time and inconvenience involved in research participation (e.g. payment at minimum wage levels) might also be permissible as research participants should not be expected to bear the costs that relate to taking part in a study. However, it is important to note that compensation is understood to mean a recompense for losses sustained e.g. time away from work.

Any reimbursements or compensation that might be offered to prospective participants should first be approved by a REC in order to ensure that they are reasonable and do not reflect any undue inducement by encouraging people to act against their better judgment or take unnecessary risks.

13.2 Payment

There may be instances where research participants will be paid for any inconvenience and time given to the study. Payment may be financial (not limited to reimbursement, compensation or nominal levels) or non-financial e.g. entry into prize draws, gift vouchers, book tokens. Payment that is disproportionate to the time involved or is likely to encourage participants to take risks, is ethically unacceptable. The timing of payments must be such that they do not constitute undue inducement. Where researchers wish to offer payment to prospective research participants, they must justify to a REC their reasons as well as the amount/reward being offered. Payments or rewards that undermine a person's ability to exercise free choice would be deemed to invalidate his/her consent.

14 Audit

In general, audit does not require informed consent. If audit is to be conducted by those involved in the care of the individual or their support staff (e.g. clinical audit staff) then explicit consent is not required provided that the individual:

- Has access to information outlining the possibility that their personal data may be disclosed for local clinical audit; and
- Has been given an opportunity to opt out.

Where clinical audit is to be conducted by an external third party, then the data must be de- identified (therefore no consent would be required). In cases where identifiable data is necessary for clinical audit purposes, the data may only be disclosed to third parties with the explicit consent of the individuals concerned.

There are a number of key differences between audit and research:

	Research	**Audit**
Purpose	To provide new knowledge e.g. to set or change clinical standards.	To measure practice against evidence- based standards.
Methodology	Addresses clearly defined questions hypotheses using systematic and rigorousprocesses. Designed so that it can be replicated and results can be generalised to other groups.	Addresses clearly defined audit questions using a robust methodology, usually asking whether a specific standard has been met. Results are specific and local.
Data Analysis	Requires data analysis (i.e. quantitative/ qualitative) to make inferences.	Simple statistics (e.g. means, frequencies) to compare audit cycles.
Ethical Approval	Required.	May not be required.
New Treatments	May involve a completely new treatment or practice.	Will never involve a completely new treatment or practice.
Randomisation	May involve allocating individuals randomly to different treatment groups.	Will never involve allocating individuals randomly to different treatment groups.
Sample Size	Statistically powered calculation.	Sufficient number of cases to influence practice based on findings.
Outcome	Improved knowledge.	Strategies in place to improve clinical practice.

Part Four: Do Not Attempt Resuscitation

This revised policy does not amend Part Four (DNARs) of the 2013 (revised 2019) HSE National Consent Policy. Until a new policy is developed for DNAR, the existing Part Four and the HSE Guidance Regarding Cardiopulmonary Resuscitation and DNAR Decision-Making during the COVID-19 Pandemic will be attached to this policy (see Appendix 1).

1 Introduction

Cardiopulmonary resuscitation (CPR), including chest compressions, defibrillation (with electric shocks), the injection of drugs and ventilation of the lungs, is an important and potentially life- saving intervention for victims of cardiorespiratory arrest. Positive developments in recent years that have resulted in improved outcomes include CPR training for the public and the widespread availability of automated external defibrillators.

CPR, when instituted rapidly, is a valuable intervention for reducing the burden of sudden cardiac death. For this reason, when an individual's expressed wishes regarding CPR are unknown and/or in an emergency situation there is a presumption in favour of providing CPR. The likelihood of success with CPR depends on factors such as the underlying health status of the individual, the cause of the cardiac arrest, and how quickly CPR is started. However, it is important for both service providers and the public to be aware that the overall survival rate after CPR is relatively low: following cardiorespiratory arrest in a hospital the chances of surviving to hospital discharge are about 13-20%; following out of hospital cardiorespiratory arrest, the survival rate is lower. The success rate is particularly poor in those with severe acute non-cardiac illness or those with multiple chronic illnesses. There is a risk that the individual may be left with long-term brain damage and disability, especially if there is delay between cardiorespiratory arrest and the initiation of the CPR. Finally, CPR can be a relatively traumatic procedure and in extreme cases adverse effects may include bone fractures and organ rupture.

These considerations have prompted extensive national and international debate regarding the appropriate use of this procedure. Existing local and regional guidelines in Ireland relating to CPR and do not attempt resuscitation (DNAR) orders show a lack of consistency in how resuscitation decisions are made and documented and a lack of clarity about the roles and responsibilities of different parties (i.e. the individual, those close to the individual if he/she is unable to participate and healthcare professionals) within the decision-making process. Hence, it is considered that there is a need for national guidelines in this area.

It is acknowledged that no single policy or guidelines can address all the complex individual clinical situations that will arise in healthcare. This policy document discusses issues pertaining to CPR and DNAR orders within the broader context of consent. It is not intended as guidance for technical and practical considerations relating to resuscitation procedures; therefore, such issues are not dealt with in this policy.

The aim of the national policy is to provide a decision-making framework that will facilitate the advance discussion of personal preferences regarding CPR and DNAR orders and to ensure that decisions relating to CPR and DNAR orders are made consistently, transparently and in line with best practice. Where a decision is made to attempt CPR, it should be performed competently and any decision to restrict the extent and/or duration of the CPR attempt should be based on balancing the benefits and risks of continuing CPR. Unethical and inappropriate practices such as "slow-coding" and "sham resuscitations" where a full resuscitation is deliberately not attempted must not be performed.

This policy document should be read in conjunction with other relevant guidance, including the Medical Council's, Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2009) and An Bord Altranais, The Code of Professional Conduct for each Nurse and Midwife (2009).

2 Definition and scope of resuscitation decisions

2.1 Do not attempt resuscitation or do not resuscitate

Throughout this document the term “do not attempt resuscitation” (DNAR) orders will be used as opposed to “do not resuscitate” (DNR) orders. This change has been made in an effort to underscore the uncertainty surrounding the success of CPR: “do not resuscitate” may imply that resuscitation would likely be successful if it were undertaken, whereas “do not attempt resuscitation” emphasises that the success of any resuscitation intervention is less clear cut and situation dependent.

2.2 Scope of DNAR orders

A decision not to attempt CPR applies only to CPR. It does not apply to any other aspect of treatment and all other treatments and care that are appropriate for the individual should continue. If a decision is made to restrict the nature or extent of CPR, this should be carefully documented and communicated effectively to all members of the healthcare team caring for the individual.

However, while a decision may be made to attempt CPR in the event of cardiorespiratory arrest it may not be clinically appropriate to provide certain other intensive treatments and procedures. For example, prolonged support for multi-organ failure (e.g. artificial ventilation and renal dialysis) in an intensive care unit (ICU) may be clinically inappropriate if the individual is unlikely to survive this, even though his/her heart has been re-started.

Decisions relating to CPR must be made separately for each individual based on an assessment of his/her case. An individual should not be obliged to put a DNAR order in place to gain admission to a long-stay care setting, such as a nursing home. Such an obligation could be seen as discriminatory and a breach of that individual’s autonomy.

This policy is applicable to all those who provide services on behalf of the HSE, which includes the ambulance service, acute and community hospitals, long-stay care settings as well as individuals being cared for in their own homes.

3 General principles

3.1 Need for individual decision making

Decisions about CPR must always be made on the basis of an individual assessment of each case and not, for example, on the basis of age, disability, the subjective views of healthcare professionals regarding the individual's quality of life or whether he/she lives in the community or in long-term care. The individual's own views and values are centrally important.

In particular, individuals are the best judges of their own quality of life; healthcare professionals and families may underestimate the quality of life of, for example, those with disabilities. However, quality of life is not the main criterion on which resuscitation decisions should be based and it is also necessary to consider the likelihood of CPR being successful as well as balancing the benefits and risks involved.

3.2 Involving the individual in discussions regarding CPR

Decisions pertaining to CPR and DNAR orders should be made in the context of the likelihood of success and the potential risks as well as the individual's overall goals and preferences for his/her treatment and care. Determination of the former requires discussion with the individual him/ herself.

Decisions relating to CPR and DNAR orders are complex and potentially emotive therefore, it is important for such issues to be dealt with in an open, honest and sensitive manner.

On-going communication between individuals, those close to them (where appropriate) and healthcare professionals is essential in achieving this goal (Part Four, Section 6.5).

3.3 Involving family or friends in discussions regarding CPR

If the individual wishes to have the support or involvement of others, such as family or friends, in decision making, this should be respected. If a person has decision-making capacity then his/her family or friends should only be involved in discussions regarding his/her treatment and care with that individual's consent. If the individual is unable to participate in discussions due to his/her physical or cognitive condition, those with a close, on-going, personal relationship with the individual may have insight into his/her previously expressed preferences, wishes and beliefs. They may also have their own views as to the appropriateness or otherwise of interventions, based on their knowledge of the individual's circumstances. In general, the closer the relationship to the individual, the greater weight should attach to such views. However, the role of those close to the individual is not to make the final decision regarding CPR, but rather to help the senior healthcare professional to make the most appropriate decision. Where CPR is judged inappropriate, it is good practice to inform those close to the patient, but there is no need to seek their 'permission' not to perform CPR in these circumstance (see also Part One Section 6.3.1).

3.4 Decision-making capacity

Best practice utilises a functional approach to defining decision-making capacity whereby capacity is judged in relation to the particular decision to be made, at the time it is to be made.[37] Decision-making capacity also depends on the ability of

[37] See Part One Section 5 for further provisions on the assessment of capacity

an individual to comprehend, reason with and express a choice with regard to information about a specific treatment (e.g. the benefits and risks involved or the implications of not receiving the treatment).

However, where an individual lacks decision-making capacity, his/her previously expressed wishes should be considered when making a decision. Whether the benefits would outweigh the risks for the particular individual should be the subject of discussion between the senior healthcare professional and those close to the individual. Only relevant information should be shared with those close to an individual unless, when he/she previously had decision-making capacity he/she expressed a wish that information be withheld.

3.5 Provision of information

Good decision-making requires accurate information, tailored as much as possible to the individual, about the likely benefits and risks of CPR. There is evidence that members of the general public, and indeed a proportion of healthcare professionals, tend to overestimate the survival rate and overall success of CPR, and that the provision of accurate prognostic information influences decisions regarding the appropriateness of CPR.

3.6 Decision-making regarding CPR and DNAR orders

It is important that the healthcare professional involved in the decision-making process has the requisite experience, training, knowledge and communication skills to coordinate this process. In general, this duty rests with the most senior healthcare professional with responsibility for an individual's treatment and care, which would be a consultant or registrar in the hospital setting or the individual's GP in other healthcare settings. He/she should usually consult with other healthcare professionals who may have helpful insights into the individual's condition.

Situations may arise where a decision regarding CPR has to be made quickly and the most senior healthcare professional is unavailable. In such circumstances, decision-making responsibility can be delegated to other less senior healthcare professionals, who should notify and discuss with their senior colleague as soon as possible.

4 When should CPR and DNAR decisions be considered?

Advance care planning, including making decisions about CPR, is an important part of good clinical care for those at risk of cardiorespiratory arrest and is preferable to making decisions only after a crisis has arisen. Hence, the likelihood of cardiorespiratory arrest occurring should be taken into account when determining how, when and if to consider the need for CPR/DNAR discussions or decisions for an individual. Three broad groups can be identified based on the likelihood of cardiorespiratory arrest within the foreseeable future:

- Cardiorespiratory arrest is considered unlikely;
- Cardiorespiratory arrest, as a terminal event, is considered inevitable
- Cardiorespiratory arrest is considered possible or likely.

4.1 Cardiorespiratory arrest is considered unlikely

For most people, within the general population, the likelihood of cardiorespiratory arrest within a given period is very small. In general, these would be healthy individuals for whom cardiorespiratory arrest would represent an unanticipated emergency situation. Moreover, given the low likelihood of arrest, it is unlikely that the issues of CPR and DNAR orders would have been raised previously with such individuals since healthcare professionals are not required to discuss every possible eventuality with every individual. Instead, the general presumption in favour of CPR should operate in the unlikely event of an arrest. However, if an individual indicates that he/she wishes to discuss CPR, then this should be respected.

However, a small cohort of individuals within the general population may have prepared an advance healthcare directive refusing CPR under specific circumstances. The wishes of such individuals should be respected if the directive is considered valid and applicable to the situation that has arisen.[38]

4.2 Cardiorespiratory arrest, as a terminal event, is considered inevitable

Some individuals may be so unwell that death is considered to be imminent and unavoidable. For such individuals, cardiorespiratory arrest may represent the terminal event in their illness and the provision of CPR would not be clinically indicated (i.e. would not restart the heart and maintain breathing for a sustained period). Attempting CPR in such circumstances may cause harm to the individual, increase his/her suffering and/or result in a traumatic and undignified death. This should be explained sensitively but honestly to the person (or those close to the person).[39] They should be helped to understand the severity of their condition, the inappropriateness of CPR and that a DNAR decision is necessary. Implementing a DNAR order for those close to death does not equate to "doing nothing"; all care provided should follow a palliative approach and focus on easing that individual's suffering and making him/her as comfortable as possible.

[38] There is currently no specific legislation pertaining to advance healthcare directives in Ireland. However, the Irish courts have established that an individual with capacity has the right to refuse treatment to facilitate a natural death. The weight of legal opinion has been interpreted to mean that an advance healthcare directive made by an individual, when he/she had capacity, would be upheld. In addition, the Medical Council Guide to Professional Conduct and Ethics for Registered Practitioners (2009) also recognises advance healthcare directives

[39] This requirement to inform the person (or those close to the person) departs from the HSE National Consent Policy and reflects the interpretation of the European Convention on Human Rights set out in R (Tracey) v Cambridge University NHS Foundation Trust [2014] EWCA Civ 822 which may reasonably be expected to apply in Ireland.

4.3 Cardiorespiratory arrest is considered possible or likely

For certain individuals there may be an identifiable risk of cardiorespiratory arrest occurring as a result of their clinical condition. These include individuals with acute severe illness and those with severe or multiple coexisting medical conditions or diseases.
Advance care planning, including consideration of issues such as CPR/DNAR is often appropriate for such individuals and should occur in the context of a general discussion about the individual's prognosis and the likelihood that CPR would be successful, as well as his/her values, concerns, expectations and goals of care.

Most CPR discussions and decisions will occur in this group. However, it must be emphasised that this is not a homogenous group, as the likelihood of success from CPR varies widely, and this necessarily influences how discussions are conducted.

5 Presumption in favour of providing CPR

As a general rule, if no advance decision not to perform CPR has been made, and the wishes of the individual are unknown and cannot be ascertained, there is a presumption in favour of providing CPR, and healthcare professionals should make all appropriate efforts to resuscitate him/her. In these circumstances, the extent and/or duration of the CPR attempt should be based on the clinical circumstances of the arrest, the progress of the resuscitation attempt and balancing the risks and benefits of continuing CPR.

In some instances where CPR has been started, additional information may subsequently become available which makes continued CPR inappropriate, for example clinical information which indicates that CPR is unlikely to be successful, or information regarding the individual's preferences. As was discussed in Part Four, Section 4.2, there will be some individuals for whom no formal DNAR decision has been made, but where attempting CPR is clearly inappropriate because death is imminent and unavoidable, for example, in the final stages of a terminal illness. In these circumstances, it is reasonable for healthcare professionals not to commence CPR.

Some healthcare facilities may not provide all aspects of CPR such as defibrillation. In the event of a cardiorespiratory arrest occurring in such a facility, basic CPR and a call to the emergency services should occur in the absence of a prior decision not to perform CPR. The extent of the CPR interventions available in such facilities should be notified to prospective residents or users of the facility, and if there is dissatisfaction with how cardiorespiratory arrests will be responded to then an alternative arrangement should be made if possible.

6 Balancing the benefits and risks of providing CPR

The decision to use any treatment, including CPR, should be based on the balance of risks and benefits to the person receiving the treatment and on that individual's own preferences and values. When discussing CPR with individuals, it is important to ensure that they understand the relevant benefits and risks. While acknowledging the uncertainty inherent in many medical predictions, healthcare professionals still have an obligation to provide an opinion, based on their expertise.

Principles to be applied in reaching a decision about CPR[40]

- Decisions about CPR must be made on the basis of an individual assessment of each person's case.
- The likely clinical outcome of attempting CPR should be considered, including the likelihood of successfully re-starting the individual's heart and breathing for a sustained period, and the level of recovery that can reasonably be expected after successful CPR.
- Advance care planning, including making decisions about CPR, is an important part of good clinical care for those at risk of cardiorespiratory arrest.
- Communication and the provision of information in a sensitive manner are central to discussions about CPR and should be undertaken by the most senior healthcare professional available.
- It is not necessary to initiate a discussion about CPR with an individual if there is no reason to believe that he/she is likely to suffer a cardiorespiratory arrest.
- Where no explicit decision has been made in advance there should be an initial presumption in favour of CPR.
- Where the expected benefit of attempted CPR may be outweighed by the risks, the individual's informed views are of paramount importance. If the individual lacks decision-making capacity those close to him/her should be involved in discussions to explore his/her wishes, feelings, beliefs and values.
- If an individual with decision-making capacity refuses CPR, or an individual lacking decision-making capacity has a valid and applicable advance healthcare directive refusing CPR, this should be respected.
- DNAR decisions apply only to CPR and not to any other aspects of treatment and care.

6.1 Respecting an individual's refusal of CPR

If an individual with decision-making capacity refuses CPR, this should be respected, irrespective of whether the healthcare professional feels it is a wise decision or not. Similarly, if an individual lacking decision-making capacity has a valid and applicable advance healthcare directive refusing CPR this should also be respected (Part Four, Section 4.1).

40 This information has been modified from: Lannon R and O'Keeffe ST (2010). Cardiopulmonary resuscitation in older people – a review. Reviews in Clinical Gerontology 20: 20–29;British Medical Association, Resuscitation Council (UK) and Royal College of Nursing (2007). Decisions relating to cardiopulmonary resuscitation: A joint statement from the British Medical Association, the Resuscitation Council (UK) and the Royal College of Nursing. British Medical Association, London, 24p

Ultimately, while such refusals of CPR should be respected, it does not follow that people (whether contemporaneously or in an advance healthcare directive) can demand whatever treatments they want, regardless of their effectiveness (Part Four, Section 6.4). A healthcare professional is not obliged to provide a treatment that is not clinically indicated, which includes CPR.

6.2 When the balance between risk and benefit is uncertain

In some cases, the healthcare professional may be uncertain whether the potential benefits of CPR outweigh the risks. In these situations, the preferences and values of the individual are of paramount importance, and the healthcare professional should acknowledge the uncertainty, outline the benefits and risks of each option and assist the individual in coming to a decision. In situations where attempting CPR is considered to have a reasonable chance of successfully restarting the heart and breathing and the individual has decided that the quality of life that can reasonably be expected would be acceptable then his/her wishes should usually be respected (see also Section 6.1).

6.3 When the risks outweigh the benefits

In other circumstances, the healthcare professional may judge that the risks associated with CPR outweigh the potential benefits and that a DNAR order should be put in place. However, there is often considerable variability in how strongly and the degree of certainty with which this judgement is held.

In these situations, it is appropriate for the healthcare professional to explain the reasons behind this judgement, including any uncertainty, to recommend that a DNAR order should be written, and to seek the views of the individual in this regard.

6.4 When there is disagreement about the balance of benefits and risks of CPR

While in many cases, the individual and healthcare professional will agree that a DNAR order is appropriate or inappropriate; this may not always be the case.

Many disagreements result from miscommunication and misunderstandings, such as an unrealistic expectation by an individual of the likely success rate of CPR or an underestimation by the healthcare professional of the acceptability of the current or predicted future quality of life of the individual. In many such cases, continued discussion will lead to agreement, and an ultimate decision should be deferred pending further discussion. If disagreement persists, an offer of a second, independent opinion should be made. Where all previous efforts at resolution have proven unsuccessful it may be necessary for parties to consider obtaining legal advice. The same procedure should be carried out if those close to an individual who lacks decision-making capacity do not accept a DNAR decision.

6.5 Where an individual does not want to discuss CPR and DNAR orders

Situations may arise where an individual does not want to discuss CPR/DNAR orders. In some cases such refusals may be linked to the timing of the discussion and the individual should be given the opportunity to defer the discussion and revisit the issues of CPR and DNAR orders at a later time. However, if an individual refuses to participate in the discussion, his/her wishes should be respected. If the individual would prefer that the healthcare professional discuss the decision with somebody else such as a relative, partner or friend, this should be respected. However, it should be emphasised that the role of those close to the individual is not to make the final decision relating to CPR, but rather to help the senior healthcare professional to make the most appropriate decision.

6.6 DNAR orders and readily reversible cardiorespiratory arrests

In certain situations, an individual with a DNAR order may suffer a cardiorespiratory arrest from a readily reversible cause unconnected to his/her underlying illness. In such cases CPR would be appropriate, while the reversible cause of arrest is treated. For example, choking restricts an individual's intake of oxygen, which could potentially lead to a cardiorespiratory arrest if not treated promptly. The initial response should concentrate on removing the cause of the tracheal blockage, but in the event of a subsequent cardiorespiratory arrest, CPR should be provided.

Where an individual with a DNAR order in place is to undergo a medical or surgical procedure, it may be appropriate to review the DNAR order given the potential for cardiorespiratory arrest to occur under anaesthesia. In such situations, should a cardiorespiratory arrest occur, there should be a presumption in favour of providing CPR. Therefore, in advance of procedures involving anaesthesia it may be advisable to temporarily suspend an individual's DNAR order. The process of reviewing the DNAR order should involve discussion with the individual as part of the consent process in advance of the procedure. If the DNAR order is to be suspended this decision should be clearly documented as well as the time at which the DNAR order is to be re-instated. If an individual wishes his/her DNAR order to remain valid during the procedure, despite the increased likelihood of cardiorespiratory arrest, this might significantly increase the overall level of risk associated with the procedure. This issue of elevated risk should be highlighted to the individual, by his/her healthcare team, as part of the overall discussion regarding the procedure. However, if the individual is willing to accept the additional risk then the healthcare professional should continue with the procedure.

7 DNAR decisions and children

In any matter relating to children, the child's best interests are of paramount importance.[41] This policy advocates for a child-centred approach to be taken in relation to any decision in the area of health and social care services as they relate to children.

It is important that respect for the child's autonomy is integrated into all decision-making in the same way as for adults. This does not mean that the interests and views of parent(s)/legal guardian(s) will be displaced, as in most instances the child's interests will be best represented by its parent(s)/legal guardian(s), although their interests are not the same. However, respect for the autonomy of the child entails the facilitation, wherever possible, of the child's right to make his/her own decisions.

As discussed in Part Two of this policy, involving children in decision-making may be different from obtaining consent in the adult context due to the age or capacity of the child to understand and participate in the decision and the role of the parents/ legal guardians in decision-making. However, even where children are unable to give a valid consent for themselves, they should nonetheless be as involved as possible in decision-making as even young children may have opinions about their healthcare and have the right to have their views taken into consideration by giving their assent to the proposed treatment or service. This principle is in keeping with legal and international human rights standards and ethical guidance which provide that the child's wishes should be taken into account and, as the child grows towards maturity, given more weight accordingly.

Acting in children's best interests generally involves sustaining their lives and restoring their health to an acceptable standard, which may include attempting CPR.

In general, if a child suffers a cardiorespiratory arrest before a definite decision about resuscitation has been made there should be an initial presumption in favour of attempting CPR. However, situations may arise where attempting CPR is unlikely to be successful or the risks associated with CPR would significantly outweigh the benefits of providing it. In such circumstances attempting CPR may no longer be in the child's best interests and a DNAR order should be put in place.

Given the additional complexity and the emotionally-demanding nature of decisions relating to CPR for children this process should be underpinned by a number of fundamental guiding principles:

- Parent(s)/legal guardian(s) and the healthcare team should work in partnership when deciding about CPR, with decisions being made on the basis of consensus;
- Where appropriate, given the child's level of knowledge, understanding and experience, he/she should also be involved and participate in the decision-making partnership;
- Therefore, children should be informed and listened to and their ascertainable views and preferences should be taken into consideration;
- The final decision reached should be in the best interests of the child.

In some instances, consensus may be reached on a child's proposed treatment and care plan following a detailed discussion about his/her condition and prognosis, the likelihood of CPR being successful as well as the benefits and risks associated with CPR. However, disagreements with parent(s)/legal guardian(s) may be more likely to arise where a healthcare professional considers that the provision of CPR would be clinically inappropriate. In such cases continued communication and obtaining a second opinion from an independent senior healthcare professional may help to resolve

[41] For a more detailed discussion regarding the issue of who can give consent on behalf of a child, see Part Two of this policy

the disagreement. Nonetheless, if the disagreement persists, healthcare professionals should seek ethical and legal advice and court involvement may ultimately be required to reach a solution.

8 Documenting and communicating CPR/DNAR decisions

A decision whether or not to attempt CPR should be clearly and accurately documented in the individual's healthcare record, along with how the decision was made, the date of the decision, the rationale for it, and who was involved in discussing the decision.

It is recommended that service providers should develop specific mechanisms for the documentation and dissemination of decisions relating to resuscitation.[42]

[42] For example, the development of a standardised and colour-coded DNAR card, to be included in an individual's records, to help highlight his/her DNAR status

9 Reviewing DNAR orders

The need to review a DNAR order will depend on the rationale for the decision and should be considered within the context of an individual's condition and overall care. Therefore, it may be appropriate to review decisions relating to CPR when:

- The individual's clinical condition changes;
- The individual's preferences regarding CPR change;
- An individual who previously lacked decision-making capacity regains his/her capacity;
- Clinical responsibility for the individual changes (e.g. where he/she is being transferred or discharged).

Any review and any subsequent decision made should be documented accordingly.

Section B

1 Initiation

1.1 Purpose

Anybody who has to engage with healthcare workers has a fundamental legal and ethical right to control their own lives, to make informed decisions on matters that relate to them and to decide what happens to their own bodies. It is therefore essential that valid consent is obtained for health and social care interventions.

The purpose of this policy is to set out the rights of people who engage with healthcare workers and the obligations on HSE staff and HSE funded organisations to vindicate these rights in relation to consent. The policy sets out the principles, governance requirements, roles and responsibilities and processes to be applied for the management of consent in all service areas. The policy is consistent with legislative and regulatory requirements.

1.2 Scope

The need for consent - and the application of the general principles in this policy - extends to all actions conducted by or on behalf of the HSE with people in all locations. This policy is intended to cover all HSE and HSE funded services provided in Ireland including but not limited to:

- Hospital Groups
- Community Healthcare Organisations
- National Ambulance Services
- National Services e.g. National Screening Services, National Transport Medicine Programme, Irish Blood Transfusion Service
- HSE Funded Agencies e.g. Section 38/39 agencies

It applies to:

- All treatment, investigation and screening, assessment and support services;
- Provision of social as well as health care;
- Involvement of a person in teaching;
- People in hospitals, in the community and in day, respite and residential care settings.

1.3 Objective(s)

The key objective of this policy is to ensure that valid consent is obtained for all health and social care interventions by:

- Promoting the importance of obtaining valid, informed consent
- Supporting and enabling staff and services to engage in effective and meaningful communication to gain valid consent.
- Ensuring that healthcare workers know when and how to obtain consent for health and social care interventions.
- Ensuring that healthcare workers know how consent should be documented
- Promoting a culture of ongoing communication to gain valid consent for all interventions.

1.4 Outcome(s)

The expected outcomes of this policy are as follows:

- To ensure that healthcare workers are aware that people who access our services have a fundamental legal and ethical right to control their own lives, to make informed decisions on matters that relate to them and to decide what happens to their own bodies.
- To establish a culture where valid and informed consent is obtained for all health and social care interventions.
- That consent is obtained for an intervention in a timely manner and documented appropriately by healthcare workers.
- That healthcare workers know what to do if consent is refused or withdrawn, and that the rights of the person are respected.
- That there is a consistent process for obtaining consent for an intervention.
- All health and social care services within the scope of this policy meet their professional, ethical, regulatory and legal requirements in relation to obtaining consent from people who use their services.
- All health and social care services have clear governance arrangements in place in relation to the implementation of this policy.

1.5 PPPG Development group

Two working groups were established – one on the General Principles of consent and one for Children and Young People to develop the policy (see Appendix 6 and 7 for membership).

A number of specific organisations were consulted in relation to consent for 16 and 17 year olds, and these are detailed in Appendix 8.

1.6 PPPG Governance group

A HSE National Consent Policy Steering Group, co-chaired by Professor Mary Donnelly and Professor Shaun O'Keeffe was established to provide governance and oversight on the development of the policy (for membership, please see Appendix 5). This group reported to Dr. Philip Crowley, HSE National Director, Strategy and Research.

1.7 Supporting evidence

Many of the principles of best practice which underpin the HSE National Consent Policy 2022 derive from the learning from serious case enquiries, complaints, reports, case law and reviews over the past 30 years. This learning has also influenced legislation and national guidance in relation to consent in Ireland.

1.7.1 Relevant legislation and Policies Procedures, Programmes and Guidelines (PPPG's).

PPPG's

- The HSE Incident Management Framework and Guidance 2020.
- The HSE National Open Disclosure Policy
- Your Service Your Say: The Management of Patient Feedback for Comments, Compliments and Complaints. HSE Policy 2017.
- National Standards for the Conduct of Reviews of Patient Safety Incidents 2017.
- National Standards for Residential Care Settings for Older People in Ireland 2016.
- National Standards for Safer Better Maternity Services 2016.
- National Standards for Residential Services for Children and Adults with Disabilities 2013.
- National Standards for Safer Better Healthcare, 2012.
- The National Healthcare Charter 2012: "You and Your Health Service".
- The HSE Policy for the Prevention and Management of Critical Incident Stress 2012.
- HSE Standards and Recommended Practices for Healthcare Records Management 2011.
- The HSE Trust in Care Policy 2005.
- Data Protection Policy V1.1 2019

Legislation

- Lunacy Regulation (Ireland) Act 1871
- Health (Regulation of Termination of Pregnancy) Act 2018,
- General Data Protection Regulation and the Data Protection Act 2018,
- Freedom of Information Act 2014
- Children First Act 2015.
- The decision in AC v Hickey & Ors [2019] IR 79
- Bunreacht Na h-Éireann
- The decision of the Supreme Court in Re JJ [2021] IESC
- Government of Ireland (2020) Programme for Government: Our Shared Future (https://www.gov.ie/en/publication/7e05d-programme-for-government-our-shared-future/)
- The Assisted Decision-Making (Capacity) Act 2015[43]

1.7.2 PPPGs replaced by this PPPG

This policy replaces HSE National Consent Policy 2019 V.1.3. Part 3 and 4 of this policy will remain in place until separate standalone policies for research and DNAR are developed.

[43] While it is noted that the 2015 Act has not fully commenced this policy has been written based on the underlying principles of the 2015 Act. When the Act fully commences this policy will be subject to further amendments. In this regard, it is noted that many of the provisions of this Act have not yet commenced.

1.8 Regulation

- The National Standards for Safer Better Healthcare 2012
- The Medical Council of Ireland's Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2019;
- The Nursing and Midwifery Board of Ireland: Code of Professional Conduct and Ethics for Registered Nurses and Midwives December 2021
- The Social Care Workers Registration Board Code of Professional Conduct and Ethics 2019
- Pharmaceutical Society of Ireland Code of Conduct for Pharmacists 2019

2 Development of PPPG

The HSE National Consent Policy 2022 represents an extensive revision and rewriting of Parts 1 and 2 of the 2013 and 2019 Policy.

This policy reflects consideration of important legislative and policy changes since 2013 including the Health (Regulation of Termination of Pregnancy) Act 2018, the General Data Protection Regulation and the Data Protection Act 2018, Freedom of Information Act 2014 and Children First Act 2015.

The Assisted Decision-Making Capacity (ADM) Act 2015 has been enacted and is scheduled to be commenced in June 2022. The language in this revision – in particular, an emphasis on the importance of the will and preference of someone who may lack capacity – has been changed to align in preparation for the commencement of the 2015 Act. It is anticipated that further amendments to this policy will be required on commencement.

However, because the relevant elements of the 2015 Act have not yet commenced, the Policy is based on the law as it currently stands. The Policy will be updated following commencement of the 2015 Act.

The revision reflects new case law and Court directions. For example, the section of Wards of Court has been updated in accordance with new guidance from the High Court and the Office of the Wards of Court; the section of doctrine of necessity has been updated in accordance with the decision in AC v Hickey & Ors [2019] IR 73; Part 2 on children has been updated in accordance with amended Article 42 A of the Irish Constitution and the decision of the Supreme Court in Re JJ [2021] IESC 1.

3 Governance and approval

The HSE National Consent Policy 2022 is governed by the National Director for Strategy and Research with guidance and advice from the HSE National Consent Policy Steering Group.

The HSE National Consent Policy 2022 was revised by the HSE National Consent Policy Steering Group, HSE Services, patients and patient representatives.

The HSE National Consent Policy 2022 is co-ordinated and managed by the HSE National Office of Human Rights and Equality Policy and reflects the strategic and policy direction established by the HSE and is consistent with Irish legislation, regulation, policies and strategy.

The HSE National Consent Policy 2022 was approved by the HSE National Director for Strategy and Research and the HSE Chief Clinical Officer.

4 Communication and dissemination

The HSE National Consent Policy 2022 will be available on the HSE National Consent Policy website, and will be disseminated in accordance with the HSE National Consent Policy communications plan. This plan includes the following:

- Learning events including policy briefings, masterclasses and seminars;
- Webinars and conferences will be coordinated by the HSE National Office for Human Rights and Equality Policy to staff and services as required;
- There will be a launch of the policy and a general broadcast to all HSE staff.

Various additional media strategies will also be utilised to circulate key messages in relation to the policy to staff and people who use health and social care services.

5 Implementation

5.1 Education and training

An education programme has been developed including e learning, webinars and launch of the policy.

A suite of supporting summary and easy read document will be developed for staff and for people who use health and social care services.

The HSE National Office of Human Rights and Equality Policy will champion, advance, support and provide strategic advice on the on-going implementation of the HSE National Consent Policy.

5.2 Accountability- Lead person(s) responsible for the Implementation of this Policy and Interventions

National Directors, Chief Officers and Hospital Group Chief Executive Officers are responsible for ensuring that the policy is implemented throughout their Community Health Care Organisations, HSE Hospitals, National Services and HSE Funded services.

Senior management and all line managers have a key role in ensuring that the necessary structures are in place to oversee compliance. Key responsibilities are outlined in Part One, Section 1.3.

5.2.1 Line Managers

It is the role and duty of all line managers at all levels in the organisation to:

- Ensure that they and the staff reporting to them are aware of their obligations in respect of the policy and to comply with this policy;
- Ensure that this policy is involved in the induction with new staff;
- Provide support and assistance to staff who have a query or concern in relation to consent practices;
- Ensure that staff are documenting consent interventions in accordance with this policy;
- Ensure that they and the staff reporting to them are clear as to their professional, ethical, regulatory and legal responsibilities and obligations in relation to consent;
- Promote a culture of open communication, honesty and transparency in the workplace;
- Ensure that they and the staff reporting to them have completed the consent e-learning programme on HSELanD;
- Document the completion of training on HSELanD;
- Ensure staff are facilitated to attend training and learning events on the National Consent Policy
- Monitor and audit compliance with this policy;
- Identify and proactively manage incidences of non-compliance and underperformance;
- Ensure that learning from the consent process is included in the service Quality Improvement Plan.

5.2.2 All staff

It is the role and duty of all staff to:-

- Read this policy and to understand their professional, ethical, regulatory and legal responsibilities and obligations in relation to consent;
- Comply with this policy;
- Complete the consent e-learning programme on HSE land as relevant to their role;
- Keep up to date with training and learning events on the policy
- Ensure the consent process is adequately documented in the records of people who use their services;
- Promote a culture of open communication, honesty and transparency in the workplace;
- Notify non-compliance of this policy to their line manager.

6 Monitoring, Audit and Evaluation

Training records must be maintained within all services. This includes staff attendance at training and completion of the online e-learning modules available on HSeLanD.

National audits of completion of training will be undertaken annually through an analysis of HSELanD and training and learning programmes delivered through the National Office for Human Rights and Equality Policy.

The HSE has developed a suite of national care experience questionnaires which includes aspects on consent which will be monitored. This will inform learning and improvement at local and national level.

Managers are required to monitor and audit the local implementation of this policy.

Implementation of the policy shall be audited periodically at national level.

7 Revision

Revision of this document will be undertaken and co-ordinated by the HSE National Office of Human Rights and Equality Policy on a 3 yearly basis, or more frequently if necessary to reflect changes to legislation, regulation or other relevant policy.44 The review of the document will include feedback from healthcare workers and people who use our services in relation to the effectiveness of the policy.

44 This policy will be reviewed when the Amending Draft Heads of Bill for the Assisted Decision Making (Capacity) Act 2015 have been passed. It will also be amended when the HSE National Consent for Research Policy is amended and updated and when the DNAR policy has been revised and updated

Glossary

Adoption

Irish adoption provides that the child (under 18 years) becomes the child of the adopter(s) as if born to them, with all the rights and duties of parent(s) and children in relation to each other.

Adult

A person over the age of 18 years.

Advance Healthcare Directive

An Advance Healthcare Directive is an advance expression made by a person with decision-making capacity which sets out their preferences concerning healthcare treatment decisions that may arise if a person subsequently lacks decision-making capacity. An Advance Healthcare Directive must include a number of formalities so as to be valid and applicable.

Advance Healthcare Planning

Advance healthcare planning can be described as a process of discussion and reflection about the goals, values, will and preferences for healthcare treatment occurring in the context of an anticipated deterioration in the person's condition. Advance healthcare plans are generally not legally enforceable (unless they are in the form of an Advance Healthcare Directive).

Adverse outcome

An adverse outcome refers to any suboptimal or less favourable outcome experienced by a person.

Advocate

A person nominated by an individual adult to speak on their behalf and represent their views. Advocacy comes in different forms. This may include informal support or independent advocacy services. Advocacy should always be independent from the service providing care or support.

Anonymous data

Data collected without identifiers such as name, address or date of birth and that can never be linked to an individual.

Approved centre

A service registered by the Mental Health Commission to provide in-patient treatment to people suffering from mental illness.

Assent

An expression of willingness or affirmative agreement to an intervention given by a young person/adult who cannot provide legally valid consent. The assent procedure should reflect all practicable efforts to support the young person/adult to understand and communicate what their agreement would involve.

Assessment of Decision-Making Capacity

An assessment of decision-making capacity is where a person's ability to understand the nature and consequences of a decision to be made by him or her is assessed in accordance with the functional test (see Part One, Section 5.10).

Autonomy

The right to make decisions and take actions that are in keeping with one's beliefs and values.

Bioethics

A multidisciplinary activity dealing with the ethical implications of biological research and medicine.

Biobank

A centralised archive of human biological material from which materials are made available for research purposes.

Cardiopulmonary Resuscitation (CPR)

Cardiopulmonary resuscitation (CPR) is a treatment which attempts to restart a person's heart and maintain breathing where the person's heart or breathing has stopped. Cardiopulmonary resuscitation usually involves chest compressions, ventilation of the lungs, attempted defibrillation with electric shocks and the injection of drugs.

Cardiorespiratory arrest

Cardiac arrest is the cessation of cardiac contraction. Respiratory arrest is the cessation of effective oxygenation and ventilation. Cardiorespiratory arrest is a combination of cardiac and respiratory arrest.

Child

In this policy we use the terms 'child' or 'children' when referring to someone up to the age of 16

Coercion/Duress

Forcing a person to behave in a particular way by use of threats or intimidation or some other form of pressure or force to consent or refuse treatment.

Committee

A "Committee" in the Wardship context is the Court-appointed representative of the Ward whose role is to act on his or her behalf in line with directions given by the Court. There are two kinds of Committee: (a) The Committee of the Person who has the responsibility for decisions in relation to the personal care of the Ward (b) The Committee of the Estate who has responsibility in managing the financial affairs of the Ward. Both responsibilities can reside in the same person.

Consent

Consent is the giving of permission or agreement for a treatment, investigation, receipt or use of a service or participation in research or teaching (intervention). Consent involves a process of communication about the proposed intervention in which the person has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed intervention.

Data processor

Data processor refers to a person who processes personal data on behalf of a data controller but does not include an employee of a data controller who processes such data in the course of his/ her employment.

Data controller

Means a person or organisation who (alone or with others) determines the purposes for which and the manner in which any personal data are, or are to be, processed. A data controller can be the sole data controller or a joint data controller with another person or organisation.

Data subject

Refers to the person to whom personal data held relates, including: employees, customers, suppliers.

De-identified data

Data are separated from personal identifiers, for example, through the use of a link e.g. a code. Access to the link is strictly controlled. As long as a link exists, data are considered indirectly identifiable as opposed to being anonymous.

Decision-Making Capacity

Decision-making capacity is the person's ability to understand, at the time that a decision is to be made, the nature and consequences of the decision to be made by the person in the context of the available choices at that time.

Directive-Maker

The directive-maker is the person who makes the advance healthcare directive.

Do Not Attempt Resuscitation (DNAR) Order/ Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) Order

A Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) Order is a written order stating that cardiopulmonary resuscitation should not be attempted if a person suffers a cardiac or respiratory arrest.

Elective

An 'elective' intervention is one which is planned in advance.

Electroconvulsive therapy (ECT)

Brain stimulation (an electric current which passes to the brain through electrodes placed on the head) which may be used to treat severe depression.

Enduring Power of Attorney

This is a legal agreement made in accordance with the requirements of the Powers of Attorney 1996 Act (until commencement of the Assisted Decision-Making (Capacity) Act 2015) whereby a Donor (the person who has decision-making capacity) gives authority to an Attorney (the person to whom authority is given) to act on their behalf in the event that the donor lacks decision-making capacity at any time in the future.

Personal care decisions made under an EPA are limited to matters such as place of residence, dress, diet, training and rehabilitation, and housing, welfare and other benefits for the person. Under the existing law, the Enduring Powers of Attorney Act 1996, decisions pertaining to healthcare are excluded.

Family

May include immediate biological family and/or other relatives, spouses, partners (including civil, same sex and de facto partners).

Foster care

Foster care is caring for someone else's child in one's own home – providing family life for a child who, for one reason or another, cannot live with his or her own parents, either on a short or a long term basis.

Functional Assessment of Decision-Making Capacity

The functional assessment of decision-making capacity is discussed in Part One, Section 5.10. The assessment of decision-making capacity on a functional basis means that the emphasis is on the specific decision to be made, at the time the decision has to be made (issue-specific and time-specific).

General Practitioner (GP)

A doctor based in the community who provides initial, on-going and continuous personal medical care, with responsibility for integrating care, treating people with acute, minor or chronic illnesses, and referring those with serious conditions to a hospital when specialist treatment is likely to be necessary, and of benefit.

Healthcare Treatment

Healthcare treatment means an intervention that is or may be done for a therapeutic, preventative, diagnostic, palliative or other purpose related to the physical or mental health of the person and includes life-sustaining treatment.

Healthcare workers

Healthcare workers refers to the various health and social care staff who support people while they are receiving healthcare treatment, investigation, using a health or social care service or taking part in research or teaching. These include for example doctors, dentists, psychologists, nurses, midwives, paramedics, social workers and social care staff. The term also covers all health and social care professions whether or not the profession is a designated profession within the meaning of Section 3 of the Health and Social Care Professionals Act 2005.

Interpreter

A person who facilitates communication between users of different languages by use of oral translation or sign-language methods, either simultaneously or consecutively.

Intervention

The provision of treatment or investigation, whether physical or psychological, or personal or social care for a person or the involvement of a person in teaching.

Involuntary admission

An involuntary admission is where a person is admitted to an approved centre (a psychiatric facility) under the Mental Health Act 2001.

Legal Guardian

A person who is entitled to exercise rights and who has duties in respect of someone under the age of 18 years.

Legal representative

In the context of a clinical trial, a legal representative is a person not connected with the conduct of the trial who by virtue of his/her family relationship with an adult lacking decision-making capacity, is suitable to act as the legal representative and is willing and able to do so or (if there is no such individual) a person who is not connected with the conduct of the trial, who is a solicitor nominated by the relevant health care provider.

Life-Sustaining Treatment

This is any clinically appropriate medical treatment, technology, procedure or medication that is administered to forestall (prevent or delay) the moment of death. These treatments may include, but are not limited to, mechanical ventilation, artificial hydration and nutrition, cardiopulmonary resuscitation (CPR), haemodialysis, chemotherapy, or certain medications including antibiotics (although antibiotics are not routinely considered to be life-sustaining treatment).

Major procedure

A significant healthcare intervention, usually complex and high-risk.

Mental Health Commission

The Mental Health Commission was established under the Mental Health Act 2001 to promote, encourage and foster high standards and good practices in the delivery of mental health services in Ireland.

Minor

Formal legal description of someone under the age of majority, which in Ireland is 18 years.

Office of the Wards of Court

The Office of the Wards of Court which is based in the Courts service manages the day to day administration of Wardship matters including the maintenance of Court files. The Office is supervised by the Registrar.[45]

Person

For the purpose of this document the term 'Person' means a person who uses health and social care services. In some instances the term 'patient' 'individual' is used in this document instead of 'Person' where it is considered more appropriate.

Personal Data

Means any information relating to an identified or identifiable person (data subject). An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier.

Preference

A greater liking for one alternative over another.

Prognosis

The likely long-term outcome of a person's medical condition.

Psychosurgery

The selective surgical removal or destruction of nerve pathways for the purposes of influencing behaviour.

Reasonable person

A person who exercises average care, skill, caution and judgement.

[45] https://www.courts.ie/content/office-wards-court

Registered Medical Practitioner

A person who holds a basic medical qualification, and who is registered under Section 46, 47, 48, 49 or 50 of the Medical Practitioners Act 2007.

Registrar of Wards of Court

The Registrar of Wards of Court supervises the day to day administration of the Office of the Wards of Court. Under the practice established by the President of the High Court, the Registrar with the authority from the President provides consent to the carrying out of "non-controversial" procedures (for example, routine investigations procedures or treatment of fractures or lesions (cuts) after an accident).

Service provider

Any person, organisation or part of an organisation delivering health and social care services.

Significant or Material risk

A significant potential for harm that a reasonable person would want to consider when making a decision about an intervention.

Treatment

Treatment means an intervention that is or may be done for a therapeutic, preventative, diagnostic, palliative (care when a person is facing a life-limiting illness) or other purpose related to the physical or mental health of the person and includes life-sustaining treatment.

Unwise Decisions

An unwise decision is a decision which may be perceived as being ill-advised or risky. This may reflect a difference in values, goals and preferences between the person and the person interacting with them. The decision may have adverse consequences for the person.

Ward of Court

A Ward of Court is a person who a Court has deemed to be of "unsound mind and is incapable of managing his or her own person and affairs".[46]

Wardship

Wardship is the process whereby an application is made to the Court to hold a formal inquiry into the question of a person's decision-making capacity. The person who is the subject of such application is known as the Respondent.

[46] As defined in the Lunacy Regulation (Ireland) Act 1871

If, after such an inquiry, a person was declared by the Court to be of "unsound mind and incapable of managing their person and property", they are described as a Ward of Court. As such, the Court assumes overall control of the person's affairs and must make decisions on the person's behalf in their best interests. The Wardship process operates under the following legislation:

- Courts (Supplemental Provisions) Act 1961, section 9
- Rules of the Superior Courts, Order 67
- Circuit Court Rules, Order 47 and
- The Lunacy Regulations (Ireland) Act 1871.

Section 6(2) of the Assisted Decision-Making (Capacity) Act 2015 (when commenced) will repeal the Lunacy Regulation (Ireland) Act 1871, subject to the terms and saver provided for in Part 6 of the 2015 Act.

Will

It incorporates a person's:

- Values;
- Personal beliefs;
- Ultimate goals.

'Will' carries a stronger sense of determination or planning than 'preference'

Valid

Valid is the state of being officially legally binding or acceptable.

Witness

A witness is a person who has observed an event taking place.

Young person

In this policy, this is a person aged 16 and 17 years

Appendices

Appendix 1 - HSE Guidance Regarding Cardiopulmonary Resuscitation and DNAR Decision-Making during the COVID-19 Pandemic

1. Background

This guidance is for healthcare workers (HCW's) regarding advance care planning and cardiopulmonary resuscitation (CPR) decision-making including making Do Not Attempt Resuscitation (DNAR) decisions. It is provided in the context of the COVID-19 pandemic.

This guidance should be read in conjunction with other relevant guidance, including the Health Service Executive (HSE) National Consent Policy 2019[47], the Department of Health (DoH) Ethical Framework for Decision-Making in a Pandemic, the DoH Ethical Considerations Relating to Critical Care in the context of COVID-19 and the DoH Ethical Considerations for Personal Protective Equipment (PPE) Use by Health Care Workers in a Pandemic.[48]

This guidance is applicable to all care environments where services are provided for and on behalf of the HSE including acute hospitals, the ambulance service, community hospitals, residential care settings, general practice and home care.

2. Specific context for this guidance

The fundamental principles of good clinical practice remain the same during COVID-19.

- Non-discrimination - Decisions should be made on a case by case basis and should not be based on factors such as age, disability, race, ethnicity or place of residence. Any distinction based solely on age, disability or place of residence is discriminatory and is contrary to human rights principles. Similarly, there should be no discrimination for or against people who have or are suspected to have COVID-19.
- Advance care planning - Having honest, open and sensitive discussions with people about their condition and prognosis in a language that they can understand, eliciting their goals and preferences, and making decisions having regard to their wishes about what interventions would be appropriate if there were a deterioration in their condition are always important.
- Balancing Benefit and Harm - Decision making that takes account of people's own goals and preferences regarding the appropriateness of CPR in the event of a cardiorespiratory arrest requires balancing the likelihood of benefit with that of harm from performing CPR in each individual case. If the recommendation is that resuscitation would not be appropriate in a particular case, this recommendation should be made only to ensure that the person is not subjected to an unwanted, or inappropriate and harmful intervention, not to deprive a person of something that would benefit them or to ration care.

47 https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf
48 https://www.gov.ie/en/publication/a02c5a-what-is-happening/

COVID-19 presents some new challenges. Although many people will be asymptomatic or have relatively mild symptoms, a substantial minority, particularly those who are older, frailer or have significant comorbid conditions, will develop severe illness. Our knowledge about COVID-19, and how best to treat these individuals, is growing rapidly. Our present state of knowledge suggests:

- People with severe COVID-19 who have a cardiorespiratory arrest as a result have poor survival rates and poor functional outcomes, and this affects the balance between the likelihood of success of performing CPR and its potential for harm.
- When people with severe COVID-19 require critical care, it may be for a relatively prolonged period. Those who survive such critical illness may have significant worsening of physical and cognitive function, when compared to their pre-COVID status, and this should be taken into account when considering the appropriateness of an intervention.
- Residents of residential care facilities are disproportionally affected by COVID-19. Where possible and appropriate, informed and updated advance care plans taking account of the goals and preferences of residents should be in place and these should inform all clinical decisions.
- COVID-19 raises specific safety concerns for healthcare workers (HCWs) in relation to the provision of CPR as there can be a serious risk of aerosol exposure and infection from some procedures.

This guidance will specifically address these issues with reference to new and existing information.

3. Advance care planning

3.1 General principles of advance care planning

Advance care planning entails

- having honest, open and sensitive discussions with people about their condition and prognosis in a language that they can understand,
- eliciting their goals and preferences, and
- making decisions having regard to their wishes about what interventions would be appropriate if there were a deterioration in the person's condition.

Advance care planning is an important aspect of good clinical practice. It allows people to have more choice and more control over their care, to avoid invasive interventions that they don't want and results in better care and better symptom relief in end-of-life situations.[49]

Advance care planning applies equally to everyone irrespective of decision-making capacity. Everyone should be supported to set out their goals and preferences, while they are well and able to do so. If the person wishes or if this requires the support or involvement of others, such as trusted friends and family, key workers or advocates, this should be provided. Advance care planning is an important guidance to HCW's[50] about how and what care should be provided. Advance care planning may be done in writing or by video/audio recording.

In circumstances where the person is unable with support to express fully their own goals and preferences, any view that they can express will be central to any plan developed, and discussion between HCW's and trusted people close to the person about the person's goals and preferences often allows an appropriate advance care plan for their future care to be developed.

Advance care planning can be initiated by the person themselves or it is sometimes done in collaboration with HCW's - depending on where they reside - as part of their overall individual assessment and care plans. If an advance care plan has been drawn up without the involvement of the person this should be revisited. People should be given the time to think and talk about advance plans without pressure or coercion: it is never acceptable in advance care planning to put pressure on a person to make an advance plan and/or to accept or refuse treatment as part of that plan.

While advance care planning is important for everyone to consider, there are certain circumstances when it is particularly important:

- When the person wishes to discuss advance care planning;
- When the person has a life-limiting advanced progressive illness;
- When it is considered possible that the person may die in the next year;
- If the person, or those close to him or her, seem to have expectations which are unduly optimistic or inconsistent with clinical judgment;
- When there is a significant deterioration in the person's condition.

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49 For useful resources on advance care planning see:
https://hospicefoundation.ie/programmes/public-awareness/think-ahead/
https://hospicefoundation.ie/programmes/advance-care/
https://respectingchoices.org/

50 This includes all categories of people working in healthcare.

If the person does not have an advance plan already made in any of the circumstances listed above, or it has been completed but isn't available, it is the responsibility of the senior clinical decision maker to ensure that advance care discussions occur in a timely manner. The senior clinical decision maker is often but not exclusively the registered medical practitioner responsible for the person's medical care, which will depend on where care is being provided at that time.

3.2 Advance healthcare directives

If a person lacking decision-making capacity has an advance healthcare directive refusing CPR relevant to their current situation, this should be respected. The provision for an advance healthcare directive, a legally binding statement of the kind, extent, and limit of medical and surgical treatment a person might want in the future, contained within the Assisted Decision Making (Capacity) Act (2015), is not yet in force. Nevertheless, if a person lacking decision-making capacity has a valid and applicable[51] advance healthcare directive refusing CPR, this should be respected. Such statements represent an important indication of the person's wishes and preferences.

3.3 Advance care planning and COVID-19

In the current pandemic, HCW's are under great pressure to make urgent, clinically complex decisions. Some people who have COVID-19 can deteriorate quickly, and it is the responsibility of the senior clinical decision maker to ensure that advance care discussions occur in a timely manner when a person has or is suspected to have COVID-19. This will ensure that the person's goals and preferences can be considered, and that care is provided in the most suitable environment.

The need for HCW's to wear equipment such as masks and restrictions on visiting, in accordance with public health guidance, may make effective communication with people and those close to them, more difficult during COVID-19 but it remains essential. Discussions about advance care usually happen face to face but during COVID-19, mobile devices or other technology can be used where necessary to facilitate communication. Patients should have the same opportunity to be involved in these discussions as they would if they happened face to face, and the same opportunity to control the information that is disclosed and to whom it is disclosed.

[51] An advance healthcare directive is valid if made voluntarily at a time when the directive maker had the necessary decision-making capacity to do so. An advance healthcare directive refusing CPR is applicable if the directive-maker no longer has the decision-making capacity to give or refuse consent to CPR, the circumstances in which the advance healthcare is to apply are materially the same and the directive contains a statement that it is to apply even if the directive-maker's life is at risk as a result.

4. Do Not Attempt Resuscitation (DNAR) decision-making

4.1 General principles of DNAR decision-making

Advance care planning includes consideration of cardiopulmonary resuscitation (CPR) and Do Not Attempt Resuscitation / DNAR. Decisions about CPR must always be made on the basis of an individual assessment of each individual case and not, for example, solely on the basis of age or disability. Any distinction based solely on such criteria is discriminatory and is contrary to human rights principles:

- DNAR decisions should be made in the context of the person's overall goals and preferences for treatment and care as well as the likelihood of success and the potential risks and harms.
- Determination of the person's goals and preferences requires discussion with the person themselves.
- If the person is unable to participate in discussions after being given appropriate supports to do so, those close to them may have knowledge of their previously expressed goals and preferences. However, the role of those close to the person is not to make the final decision regarding CPR or to 'consent' to a DNAR decision as this authority does not exist under current Irish law. The purpose of these discussions is to help the senior clinical decision maker make the most appropriate decision having regard to the goal and preference of the person.

4.2 DNAR decisions and COVID-19

There should be no discrimination for or against persons who have or are suspected to have COVID-19 in relation to DNAR decisions. Individualised care is at the heart of good clinical practice. The pandemic does not justify any HCW deviating from that approach by making DNAR decisions on a group basis. Such a decision would be contrary to all guidance and human rights principles.

4.3 DNAR decisions and intensive care unit (ICU) admission

As a general rule, a decision not to attempt CPR applies only to CPR. A DNAR decision does not mean that other interventions such as oxygen support or mechanical ventilation will not be provided.

Other decisions may impact upon decisions about CPR. For example, if, due to their medical condition and prognosis, admission to an intensive care unit (ICU), and interventions such as intubation and mechanical ventilation would not be appropriate, it may also not be appropriate to provide that patient with CPR should they suffer a cardiorespiratory arrest, since the required follow up management in the intensive care unit would not be available.[52] This should be explained to the person (or those close to the person).

Decisions regarding the clinical appropriateness of admission to ICU are primarily a matter for intensive care doctors who have expertise in making such decisions. If a clinical deterioration is anticipated, it is helpful if the senior clinical decision maker caring for, and familiar with, the person and their condition and goals and preferences discusses the possible appropriateness of ICU with the relevant intensive clinicians to inform advance care planning and decision-making.

[52] In such circumstances, it may be warranted to carry out a limited form of resuscitation, for example to convert a shockable rhythm

4.4 What information do people require about CPR?

People's preferences for or against CPR are often related to perceptions of the likelihood of success of this intervention. Many people overestimate the effectiveness of CPR and misunderstand the harms it can inflict. The success rate of CPR is especially poor in those with severe acute non-cardiac illness or those with multiple chronic illnesses or those who suffer a cardiorespiratory arrest outside of hospital. In particular, CPR is not a treatment for what has been termed 'ordinary dying'.[53]

It is important that people are informed of the likelihood of a successful outcome in their individual circumstances. This should be explained sensitively but honestly to the person (or those close to the person) in language they can understand. "Successful" means more than survival: it includes consideration of possible prolonged care in the ICU after CPR and the potential for, perhaps permanent, significant functional and cognitive decline for some people.

4.5 Situations where a DNAR decision may be indicated

If a person with decision-making capacity refuses CPR, this should be respected, irrespective of whether it may seem a wise decision or not, and a DNAR decision documented. Similarly, if a person lacking decision-making capacity has a valid and applicable[54] advance healthcare directive refusing CPR, this should also be respected and a DNAR decision documented.

When a person lacks decision-making capacity, and does not have a valid and applicable advance healthcare directive, but those close to the person with knowledge of their previously expressed goals and preferences consider that he or she would not want CPR, a DNAR decision should be documented by the senior clinical decision maker if clinically appropriate.

In some circumstances, the senior clinical decision maker may judge that the harms of CPR outweigh the potential benefits and that a DNAR decision is appropriate. He or she should explain this to the person and seek his or her views.[55]

Some people may be so unwell that death may be imminent and unavoidable and/or a cardiorespiratory arrest would represent the terminal event in their illness or decline. In such circumstances, a DNAR decision is necessary as CPR would not be clinically indicated but may cause harm to the person and increase their suffering. This should be explained sensitively but honestly to the person (or those close to the person). They should be helped to understand the severity of their condition, the inappropriateness of CPR and that a DNAR decision is necessary.[56] It should be emphasised that a DNAR decision in these circumstances does not equate to "doing nothing" and that all other appropriate care will be provided. This may include, for example, where clinically indicated provision of intravenous fluids, antibiotics, oxygen, admission to hospital or treatment in an intensive care unit, as well as palliative care.

4.6 When the senior clinical decision makers and person (or those close to the person) disagree about the balance of benefits and risks of CPR

53 Launer J. Reducing futile attempts at resuscitation. Postgraduate medical journal. 2017 Apr 1;93(1098):239-40.

54 An advance healthcare directive is valid if made voluntarily at a time when the directive maker had the necessary decision-making capacity to do so. An advance healthcare directive refusing CPR is applicable if the directive-maker no longer has the decision-making capacity to give or refuse consent to CPR, the circumstances in which the advance healthcare is to apply are materially the same and the directive contains a statement that it is to apply even if the directive-maker's life is at risk as a result.

55 This requirement to inform the person (or those close to the person) departs from the HSE National Consent Policy and reflects the interpretation of the European Convention on Human Rights set out in R (Tracey) v Cambridge University NHS Foundation Trust [2014] EWCA Civ 822 which may reasonably be expected to apply in Ireland.

56 As per the above footnote.

Many disagreements result from miscommunication and misunderstandings e.g. some individuals hold unrealistic expectations in respect of the likely success rate of CPR while some HCWs underestimate or overestimate the acceptability of the current or predicted future quality of life of the individual to the individual themselves. In many such cases, continued discussion will lead to agreement, and an ultimate decision should be deferred pending further discussion. If disagreement persists, a second, independent opinion from a senior colleague should be sought.

There is no obligation to provide a medical or surgical treatment, including CPR, if it is not clinically indicated.[57] Rarely, if efforts at resolution of disagreements have proven unsuccessful and there is agreement from two senior clinical decision makers that CPR is not clinically indicated and may cause harm to the person and increase his or her suffering, a DNAR decision should be made and documented even if the person (or those close to him or her) does not agree. The person must be informed, and the reasons behind this decision should be carefully recorded.

If efforts at resolution of disagreements have proven unsuccessful and there is genuine uncertainty as to the balance of risks and benefits for the person or, in the case of the person who lacks decision-making capacity, as to what the person's own wishes and preferences would have been, it may be necessary to consider obtaining legal advice or to have recourse to the courts.

4.7 Reviewing a DNAR decision

Some DNAR decisions are made in the context of a severe acute illness. Such decisions should be kept under review, especially if the person's clinical condition, including their ability to express their own goals and preferences, improves significantly. In some cases, it may be helpful to put down a date for review of the decision although that should not preclude earlier reconsideration.

Other DNAR decisions are made because of severe chronic diseases or where a person is approaching the end of life. These circumstances are unlikely to change and it is not necessary that such DNAR decisions are reviewed unless the person wishes and indicates this.

57 National Consent Policy Part 4, 6.1

5. Performance of CPR during the COVID-19 outbreak

If CPR is performed on people with COVID-19, there is the potential for HCWs to be exposed to bodily fluids, and for some procedures (e.g. chest compressions, tracheal intubation or ventilation) to generate an infectious aerosol. In those circumstances, CPR should not be commenced without the appropriate PPE recommended in national guidelines.[58] This may cause a delay of some minutes to starting CPR and may lead to worse outcomes from CPR.[59]

In the interest of HCW safety, people with known and with suspected (e.g. awaiting swab results) COVID-19 must be treated alike. In some units, for example, in residential care facilities, evidence of general widespread transmission may mean that all occupants need to be treated as potentially positive for COVID-19.

5.1 CPR decisions when there are inadequate stocks of PPE available

Ethical Considerations for PPE Use by Health Care Workers in a Pandemic notes that:[60]

"HCWs may be faced with a situation where a Covid-positive patient requires an intervention, and where HSE guidance indicates that use of PPE is necessary, but where there are inadequate stocks of PPE available"

It is acknowledged that different procedures involve different levels of risk, and that assessment of the relative risk/benefit ratios needs to be taken on a case-by-case basis by the HCW faced with the situation in question. Factors to be taken into account are:

- The acuity of the needs of the patient;
- Probability, and intensity, of individual HCW's exposure to Covid-19;
- Any professional guidelines issued on the particular intervention relevant to the current circumstances;
- Alternative possibilities of treatment that do not create the same level of exposure;
- The possibility of delaying the particular treatment until a time when PPE is available;
- The degree of risk being undertaken by individual HCWs;
- The personal situation of each HCW, for example, on the basis of a pre-existing condition or other vulnerability.

While every effort is being made to address the issue of inadequate stocks of PPE by the HSE, this issue may arise in some limited contexts including CPR. If a cardiorespiratory arrest occurs in these circumstances and there is no prior DNAR, the likelihood of success from CPR (see 4.2), and the degree of risk to a HCW performing CPR need to be considered. If the risk to a HCW is significant in the absence of appropriate PPE, it is acceptable for him or her not to initiate CPR while awaiting assistance or advice, for example from the emergency services. HCW's making such decisions, often in an emergency and under great pressure, should receive the support of colleagues and managers.

5.2 Duration of resuscitation

The extent and/or duration of the CPR attempt should be based on the clinical circumstances of the arrest, the progress of the resuscitation attempt and balancing the risks and benefits of continuing CPR. In circumstances where initial

58 https://www.gov.ie/en/publication/58d3de-ethical-considerations-for-ppe-use-by-health-care-workers-in-a-pande/
59 https://hse.drsteevenslibrary.ie/c.php?g=679077&p=4846207
60 https://www.gov.ie/en/publication/58d3de-ethical-considerations-for-ppe-use-by-health-care-workers-in-a-pande/

resuscitative efforts have failed to restore circulation, it may become apparent that the likelihood of a successful outcome is very low, and termination of CPR becomes appropriate. These include some out of hospital cardiopulmonary arrests especially those that are unwitnessed or where the person has a non-shockable rhythm, (asystole and pulseless electrical activity), or, a shockable rhythm that does not respond to defibrillation.[61] Consultation, even remotely, with a doctor or with the emergency service, may assist in decision making in some cases.

[61] Out of Hospital Cardiorespiratory arrest Register (OHCAR). https://www.nuigalway.ie/ohcar/

6. Special considerations in out of hospital cardiorespiratory arrests[62]

The same approach to decision making, including making advance care plans, applies in all settings.

In the context of a COVID-19 outbreak that has particularly affected residential care facilities, it is especially important that advance care plans and decisions about what interventions would be appropriate if there were a deterioration in the person's condition are made, and if possible and appropriate updated, for all residents in order to ensure that they do not receive inappropriate or harmful treatment.

Out of hospital cardiorespiratory arrests present particular challenges to HCWs who encounter them while performing their duties especially if they occur unexpectedly and there is no known advance plan or DNAR decision and no quick access to medical assistance and advice. Many out of hospital arrests occur in residential care facilities or other healthcare facilities. If an emergency such as a cardiorespiratory arrest does occur in such a setting, and no prior decision not to intervene has been made, the general principle is that service users should call the emergency services and provide whatever care they can in the meantime.

Rarely, as is noted in the National Consent Policy (6.4): 'there will be some individuals for whom no formal DNAR decision has been made, but where attempting CPR is clearly inappropriate because death is imminent and unavoidable, for example, in the final stages of a terminal illness. In these circumstances, it is reasonable for healthcare professionals not to commence CPR'.

7. Dissemination of advance care plans and DNAR decisions

If an advance care plan or DNAR decision is made, it is important that procedures are in place locally to ensure that these are complied with in the event of a cardiorespiratory arrest. This will allow staff who may not be familiar with the person to rapidly determine the most appropriate care for the person in an emergency.

An agreed local procedure is also required to ensure an advance care plan or DNAR decision made in one setting and intended to apply in another setting can be communicated if the person moves to a new setting, and the senior clinical decision maker for that person should make every effort to ensure that this procedure is followed.[63] For DNAR decisions, this requires that staff in the second setting are aware of the DNAR decision and can be confident that it was made appropriately. This would require, at a minimum, information on who had made the decision, why, whether the person had been involved (and if not, why), whether it was signed and witnessed and whether a review was envisaged. If the person has capacity, they should be asked if their wishes have changed.

8. Conclusion

The COVID-19 pandemic presents some new challenges in making advance care plans and in cardiopulmonary resuscitation decision-making. These can be met using the fundamental principles of good clinical practice, existing guidance and recent new COVID-10 specific guidance. By doing so this will help to ensure that the people who use our services remain central to the decisions about their healthcare and treatment choices and HCW's will be supported in carrying out these decisions.

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62 We are grateful to Siobhán Masterson, Martin Quinn and Professor Andrew Murphy of the Out of Hospital Cardiac Arrest Register (OHCAR) for providing updated analyses of the outcomes following out of hospital cardiac arrests

63 https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/national-rapid-discharge-guidance-for-patients-who-wish-to-die-at-home.pdf

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Appendix 2 – Confidentiality and data protection obligations

Confidentiality and data protection

The HSE Data Protection Policy explains the legal responsibility of the HSE, as a Data Controller, and of its employees under the GDPR and Data Protection Acts 1988-2018 including the circumstances in which the explicit consent of data subjects is required for processing of personal data - https://www.hse.ie/eng/gdpr

Appendix 3 – Legislative provisions impacting consent

Infectious Diseases

Under the provisions of the Health Act 1947 as amended by the Health (Preservation and Protection and Other Emergency Measures in the Public Interest) Act 2020, if a person is a probable source of infection with an infectious disease and is a potential risk to public health, his or her isolation may be necessary as a safeguard against the spread of infection. In the event that he or she cannot be effectively isolated in their own home, an authorised Medical Officer may order the person's detention and isolation in a specified hospital (or other place), until it is certified that the person is no longer a probable source of infection. However, the legislation does not allow a person to be treated if they refuse to consent to treatment. Where the purpose of the detention is to prevent the spread of Covid-19, the specific provisions of the Health (Preservation and Protection and Other Emergency Measures in the Public Interest) Act 2020 must be complied with.

Mental Health Act 2001

Where the person has been involuntarily admitted to an approved centre under the Mental Health Act 2001, the interventions in respect of treatment and consent must comply with the provisions of that Act.

Where the person who has been admitted under the 2001 Act requires any other treatment or intervention not related to their mental health, the general principles of consent apply as discussed in this policy.

Blood and urine samples for the purposes of Garda investigations into driving under the influence of alcohol and/or drugs

The general principles regarding consent apply when testing for intoxicants. When such testing is clinically indicated, the urgency of the situation in which such testing commonly occurs means that explicit discussion of the pros and cons of the particular test is not required.

However, specific legal rules apply to the taking of blood and urine samples for the purposes of Garda investigations into driving under the influence of alcohol and/or drugs. These apply where an "event" (as specified in the Road Traffic Act 2010) has occurred in a public place and, as a result, a person is injured and is admitted to or attends at a hospital. Under section 14 of the Act (as amended by the Road Traffic Amendment Act 2014), where a Garda is of the opinion that a person was driving or attempting to drive, the Garda may require the person to permit a designated doctor or nurse to take a blood specimen or provide a urine sample. Before doing this, the Garda must consult with the doctor treating the person and if the doctor advises that the requirement would be prejudicial to the person's health, the Garda may not make the requirement.

Where the person refuses to permit the sample to be taken, the Act does not provide for the forcible taking of a sample. However, the person's refusal to comply with the requirement to provide a sample is a criminal offence. Refusal is not an offence where the person is under the care of a doctor or nurse and the doctor or nurse refuses on medical grounds to permit the taking of the sample. Where it appears to the Garda, that, for medical reasons, the person cannot be the subject of, or is incapable of complying with, the requirement, the Garda may direct the doctor or nurse to take a blood specimen.

Appendix 4 - Measures to facilitate communication with the person

Obtaining consent requires effective communication with the person facing a decision. The following measures are often helpful.

- Timing: If practicable, choose the time of day when the person is most alert and able to make the decision. While there is often a 'core' amount of information that must be understood, it may be helpful to break down information into smaller sections and pausing to allow each to be understood.
- Environment: Choose the best physical location such as a quiet room and minimise distractions such as phones ringing or noise from a television.
- Supporter: Some persons may wish to have someone close to them or an advocate present during discussion, and this should be facilitated where possible. If a person has an Attorney in relation to the decision to be made, he or she should be present during discussions.
- Manner of communication: Speak clearly and slowly and use simple and concise language avoiding medical terminology and jargon where possible. The use of concrete examples, reiteration of key points and pausing to check the person's understanding are helpful.
- Use of printed or other educational material: Standardised informational material should always be additional to and not instead of an oral explanation, and persons should be told if their circumstances might modify the relevance of the information contained. Written information should be in simple language. Those with literacy difficulties may need support to access such material.
- Use of communication aids: or those with communication difficulties, more specific assistance may be required. Ask the person or someone close to them if there are supports that could be provided to help the person understand, retain and respond to the information being shared with them. Try to gather this background before meeting with the Person so that appropriate communication supports or accessible documentation to facilitate the conversation can be gathered in advance. Specific communication assistance may be helpful for some, such as use of pictures, drawings, communication boards, yes/no signals and using sign, lámh or another sign system specific to the person. Those close to the person may be able to advise on the best approach

Additional measures may be required in specific circumstances:

- **Persons with limited English language proficiency**
  Except in emergency situations, an interpreter proficient in the person's language is required to facilitate the person giving consent for interventions that may have a significant impact on his or her health and well-being. A professional interpreter should be used where practicable. The use of family (in particular of children and young people) and friends should be avoided if at all possible.
- **Deaf and hard of hearing persons**
  Deaf and hard of hearing persons should be asked how they would like information to be provided. Some people with impaired hearing can lip read, some use hearing aids and others may require sign language interpreters. Information can also be made more accessible using text and email applications. .Use of a clear mask can facilitate this even if healthcare professional wears a mask for infection control reasons. If required, a sign language interpreter should be obtained.

- **Blind and visually impaired people**
  People with a visual impairment should be asked how they would like information to be provided. There are a range of formats that can be used to make written information accessible to people with visual impairments. These include large print, Braille, writing in thick black marker pen and use of audio information. Information can also be made more accessible using text and email applications.

For further information on communication supports, please view the HSE National Guidelines on Accessible Health and Social Care Services at https://www.hse.ie/eng/services/yourhealthservice/access/natguideaccessibleservices/natguideaccessibleservices.pdf and Accessible Information for All published by the Citizen Information Board https://www.citizensinformationboard.ie/downloads/accessibility/Accessible_Information_For_All.pdf.

Appendix 5 – Who are a child's legal guardians?

Note: This is a summary of a complex legal position: the relevant provisions are set out in the Guardianship of Children Act 1964 as amended by the Child and Family Relationships Act 2015.

- Where a child's mother and father are married **both are the legal guardians.**
- If a child's mother and father marry after the child's birth, **the father automatically becomes the child's legal guardian.**
- Where a child has been jointly adopted, **the adoptive parents are the child's legal guardians.**
- Where a child's mother and father are not married:
  - **The child's mother is an automatic legal guardian;**
  - The child's father **is an automatic legal guardian if from 18 January 2016, he has lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the child's birth;** or
  - If the child's father has not become a guardian by satisfying the cohabitation requirement, **he may become a guardian if the mother and father of the child may make a statutory declaration to the effect that they agree to the appointment of the father as legal guardian**, or
  - **The father may apply to Court to be appointed legal guardian.**
- In respect of same-sex couples, **the child's biological parent is a legal guardian.**
  - The biological parent's partner or spouse **may apply to the Court become a legal guardian in accordance with the requirements set out below.**
  - Where a same-sex couple has a child through Donor Assisted Human Reproduction (not including surrogacy) after 4 May 2020 and has complied with the provisions of Part 2 of the Children and Family Relationships Act 2015 (i.e. they have used a recognised fertility clinic and have signed all the relevant consents and declarations), **the spouse, civil partner or cohabitant of the mother will be the legal parent of the child.** In this situation, **the spouse or civil partner of the biological parent will automatically be a legal guardian.** A cohabitant will be a legal guardian if they fulfil the residence requirement **(i.e. have lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the child's birth).**
- Where a child is born through surrogacy, **the surrogate mother is the legal guardian at birth**. If the commissioning father's sperm was used in the surrogacy procedure, **he may apply to the Court for a declaration of parentage; once granted, this would immediately entitle him to apply to the Court for guardianship.** The commissioning mother, or a commissioning father whose sperm was not used in the procedure, **may apply to the Court for legal guardianship once she/they have fulfilled the legal requirements set out in the next bullet point.**
- Any adult may apply to Court for legal guardianship:
  - **If he or she is married to or in a civil partnership with, or has been cohabiting for at least 3 years, with the child's parent and has shared parental responsibility for the child's day-to-day care for at least 2 years,** or

- **If he or she has provided for the child's day-to-day care for a continuous period of more than 12 months and the child has no parent or guardian who is able or willing to act as guardian.**

- Following a separation or divorce, **both parents remain the child's legal guardian even if the child is not living with them and they have not been awarded custody of the child.**
- A guardian may nominate another person to act **as temporary guardian in the event of the guardian's incapacity. This is subject to Court approval.**
- A guardian may, in their will, **appoint a person to act as the child's guardian in the event of the guardian's death.**

Appendix 6 - Membership HSE National Consent Policy Steering Group

Professor Mary Donnelly (Co-chair), School of Law, UCC

Prof Shaun O'Keeffe (Co- chair), Consultant Geriatrician, HSE, Galway University Hospitals

Ms Pamela Benson, Head of Legal Services, TUSLA

Ms Margaret Brennan, Assistant National Director, Quality and Patient Safety, Acute Operations

Ms Carmel Buckley, Office of Nursing and Midwifery Services Director

Ms Mary, Condell, Solicitor, National Patient Forum Representative

Ms Anne Marie Cullen, Solicitor, Office of Legal Services

Ms Paula Day, Risk Manager, Children's Health Ireland

Ms Mary Deasy, Deputy Data Protection Officer

Ms Áine Flynn, Director, Decision Support Service Ms

Ms. Caoimhe Gleeson, National Programme Manager, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Ms Jacqueline Grogan, Project Manager, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Dr David Hanlon, National Clinical Advisor & Group Lead, HSE Primary Care

Ms Caroline Howorth, Speech and Language Therapy Manager, Health and Social Care Professional Rep

Mr Donal Hurley, Principal Social Worker, National Safeguarding Office

Ms. Loretta Jenkins, General Manager, Quality and Patient Safety

Dr Lucy Jessop, Director of Public Health, HSE National Immunisation Office,

Prof Brendan Kelly, Consultant Psychiatrist, Trinity College Dublin and Tallaght University Hospital

Ms. Kate Killeen White, Chief Officer, CHO 5

Ms Máire Lennon, A/ Head of Legal Services, HSE Office of Legal Services

Dr Barry Lyons, Consultant Anaesthetist, Children's Health Ireland

Ms. Elaine McCaughley, Training and Education Co-ordinator, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Mr Pádraig McLoone, Risk & Incident Compliance Officer, HSE

Mr Chris Meehan, ICT Security Officer, HSE Office of the Chief Information Officer

Ms Deirdre Shanagher, Nursing Homes Ireland

Dr Deirdre Smithwick, Clinical Director, Clinical Director Programme

Dr Ana Terres, Head of Research and Development, Strategy and Research, HSE

Ms. Marie Tighe, Project Manager, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Ms Angela Tysall, Programme Manager, National Open Disclosure Office

Ms Michele Rooney, National Patient Forum Representative

Appendix 7 - Membership HSE National Consent Policy Working Group – General Principles

Prof Shaun O'Keeffe (Chair), Consultant Geriatrician, HSE, Galway University Hospitals

Ms Carmel Buckley, Area Director, Office of Nursing and Midwifery Services Director Representative

Dr Nader Farvardin, Assistant National Oral Health Lead, Primary care

Ms Patsy Fitzsimmons, Senior Manager, Decision Support Service,

Ms Mary Godfrey, State Claims Agency, Senior Clinical Risk Advisor (from September 2021)

Ms Jacqueline Grogan, Project Manager, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Ms Caroline Howorth, Speech and Language Therapy Manager, Health and Social Care Professional

Mr Donal Hurley, Principal Social Worker, National Safeguarding Office

Ms. Loretta Jenkins, General Manager, Office of Quality and Patient Safety, HSE

Ms Marie Kehoe O'Sullivan, HSE National Disability Specialist, HSE Disability Services,

Prof Brendan Kelly, Consultant Psychiatrist, Trinity College and Tallaght University Hospital

Ms Máire Lennon, A/Head of Office of Legal Services, Office of Legal Services

Ms. Elaine McCaughley, Training and Education Co-ordinator, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Ms Patricia Rickard Clarke, Chair, Safeguarding Ireland

Ms Deirdre Shanagher, Strategic Clinical Nurse Expert with Regulatory Compliance, Nursing Homes Ireland

Dr Jeremy Smith, Consultant Anaesthetist, College of Anaesthetists and Clinical Lead, National Anaesthesia Programme

Ms Elaine Teague, Director of Quality Improvement and Safety Development, St Michael's House

Ms Angela Tysall, Programme Manager, National Open Disclosure Office

Ms. Marie Tighe, Project Manager, HSE National Office for Human Rights and Equality Policy, Research and Strategy

*Ms Ann Duffy, Senior Clinical Risk Advisor, State Claims Agency, resigned July 2021. Ms Mary Godfrey, Senior Clinical Risk Advisor, State Claims Agency, replaced this position in September 2021.

Appendix 8 - Membership HSE National Consent Policy Working Group – Children and Young People

Professor Mary Donnelly (Chair), School of Law, UCC

Mr Brice Antao, Clinical Lead, National Paediatric Network, Children's Health Ireland,

Ms Nicola Barry, Principal Psychologist CYP Services, St Michael's House

Ms Pamela Benson, Head of Legal Services, TUSLA

Ms Anne Marie Cullen, Solicitor, Office of Legal Services HSE

Ms. Caoimhe Gleeson, National Programme Manager, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Ms Teresa Kearns, Assistant Director of Nursing, Children's Health Ireland, Temple Street,

Dr Mary Davin Power, Senior Clinical Risk Adviser, Medicsec Ireland and ICGP

Dr Lucy Jessop, Director of Public Health, HSE National Immunisation Office,

Ms Marie Kehoe O'Sullivan, HSE National Disability Specialist, HSE Disability Services,

Dr Barry Lyons, Consultant Anaesthetist, Children's Health Ireland,

Ms. Elaine McCaughley, Training and Education Co-ordinator, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Dr Aileen Murtagh, Child and Adolescent Consultant Psychiatrist, St. Patricks Mental Health Services-Willow Grove

Ms. Marie Tighe, Project Manager, HSE National Office for Human Rights and Equality Policy, Research and Strategy

Ms Colette Tracey, Public Health Nurse, Immunisation Team, Mullingar.

*Ms Sarah Lennon, Inclusion Ireland, Interim CEO until July 2020

Appendix 9 - Organisations consulted on consent for 16 and 17 year olds

1. Children's Health Ireland
2. College of Paediatrics & the National Clinical Programme for Children
3. College of Psychiatrists of Ireland
4. Department of Children, Equality, Disability, Integration and Youth
5. Department of Health
6. Irish College of General Practitioners
7. Mental Health Commission
8. Office of Legal Services HSE
9. Special Rapporteur on Child Protection
10. State Claims Agency/National Treasury Management Agency
11. TUSLA/Child and Family Agency

Appendix 10 – Sample Signature Sheet- HSE National Consent Policy

Signature Sheet

I have read, understood and agree to adhere to the attached policy

Name (Block Capitals)	Signature	Job Title	Date

Signature Sheet

I have attended training relevant to my role on the HSE National Consent Policy

Name (Block Capitals)	Signature	Job Title	Date

our **health** service

www.hse.ie/nationalconsentpolicy