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Health Service Executive

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13th July 2021

Deputy Neasa Hourigan
Dail Eireann,
Leinster House,
Kildare Street,
Dublin 2.
e-mail: neasa.hourigan@oireachtas.ie

Dear Deputy Hourigan

The Health Service Executive has been requested to reply directly to you in the context of the following parliamentary question, which was submitted to this department for response.

PQ 23000/21

To ask the Minister for Health the current wording used in HSE administrative and patient forms provided to guardians of children, adult patients and advocates of adults with disabilities on the sharing of personal information with other services and Departments; and if he will make a statement on the matter.

HSE Response

Assessment of Need

The Disability Act 2005 provides for an assessment of the needs of eligible applicants occasioned by their disability. Please see the attached Application for Assessment of Need under Disability Act 2005 form

PART 1 of the form refers to consent to allow access to files and reports. The wording is as follows:

"I consent to allow access to all files and reports (including any information held on either the National Intellectual Disability Database or the National Physical and Sensory Disability Database) that exist within any of the agencies listed, that the Assessment Officer may consider necessary for the purposes of assessment and subsequent service provision.

- *The Health Service Executive (HSE);*
- *HSE contracted service providers;*
- *Education service providers;*
- *The National Council for Special Education;*
- *The National Educational Psychological Service;*
- *Better Start (AIM)*

I also consent to the sharing of this information with those health and education professionals involved in the assessment of need and subsequent provision of services".

The forms and further information is available at:

https://www.hse.ie/eng/services/list/4/disability/disability-assessment/

The National Policy on Access to Services for Children & Young People with Disability & Developmental Delay ensures that children are directed to the appropriate service based on the complexity of their presenting needs rather than based on diagnosis. Many children with a disability who have support needs can be effectively supported within mainstream child health services. This policy provides a single point of entry, signposting parents and referrers to the most appropriate service (Primary Care for non-complex functional difficulties and Children's Disability Network Teams for complex functional difficulties).

While many children will access therapy services via Primary Care, a proportion with more complex needs are referred to disability services.

National HSE Disability and Primary Care are working together collaboratively with Community Health Organisations via their Chief Officers to support implementation of the HSE's National Policy on Access to Services for Children with a Disability or Developmental Delay.

Please see the attached national access policy form. Page 4 of the form seeks consent for the holding and or sharing of information as appropriate.

In addition, please see the attached HSE Privacy Impact Assessment (PIA) Form which includes sample Disability Services Data Protection Information Leaflet (page 34) for children's disability services moving to CDNTs.

Day Services

With regard to Day Service provision, I also attach the Information Data Protection, Occupational Guidance, Adult Day and Rehabilitative Training Services for your information.

The leaflet advises that the HSE will
1. Obtain relevant information and reports including medical reports that exist within the services listed below
- The Health Service Executive (HSE);
- HSE contracted service providers;
- Education Service Providers;
- The National Educational Psychological Service.
- General Practitioners/Medical Consultants

2. Share this information, in strict confidence, for this purpose with third parties including statutory and voluntary organisation such as; the Department of Social Protection, Department of Education and Skills, SOLAS, and any HSE funded disability service providers involved in the provision of services appropriate to you.

3. Store and Disclose the information and reports obtained in accordance with Data Protection Legislation.

It is important to note that in addition to National HSE forms, each CHO and service provider will have their own forms for various services provided.

I also attach the HSE National Consent policy v 1.3 2019 for your information.

Recent Primetime Investigates programme on 25th March 2021.

With regard to your query on the sharing of personal information with other services and Departments and possible reference to to the recent Primetime Investigates programme on 25th March 2021.

The HSE regrets the distress recent media reports may have had on the families involved.

In this regard, the HSE notes the open letter to stakeholders from the Secretary General of the Department of Health which is available via:

https://www.gov.ie/en/press-release/a55a7-open-letter-to-stakeholders-secretary-general-of-the-department-of-health/

I wish to clarify the position that all staff working for the HSE or funded S38/39 agencies, are bound by regulation, policy and codes of practice as referenced in the HSEs Service Arrangement.

The HSE would not knowingly share personal information in breach of clinician/client confidentiality or otherwise unlawfully and we take our obligations in this regard very seriously. Additionally, clinicians are equally bound by a code of ethics aligned with their respective professional body. Reminders have issued through the Community Health Offices on the requirement for assurance that all staff are aware of their responsibilities in this regard.

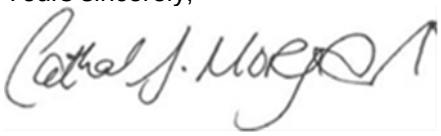
Notwithstanding the above, the HSE appreciates that the programme which aired is a cause of worry and concern to families and children with disabilities. We further note the Department's appointment of Mr Donie O'Shea as an Independent Support Liaison Officer to engage directly with the families involved in the allegations made on the programme as a support mechanism.

In addition, the HSE is liaising with the Department of Health in relation to the issues raised by the programme to determine whether any breaches of clinician/client confidentiality have occurred specific to the cases as known to them.

The HSE is informed that the Department confirmed that no more than 35 families are involved in open litigation related to these allegations. It is our understanding that these families will be contacted shortly through their solicitor offering the opportunity to engage directly with the Independent Support Liaison Officer.

The HSE wishes to underscore the collective effort being made nationally and regionally to fundamentally reform how we deliver services for people with a disability and our commitment to uphold the UN Convention on the Rights of People with a Disability. Under the Transforming Lives policy, this has been a driving force of strong collaborative efforts over many years and where real progress has and continues to be made.

Yours sincerely,



Dr. Cathal Morgan,
Head of Operations - Disability Services,
Community Operations

Tús Áite do Shábháilteacht Othar
Patient Safety First

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive
Quality and Patient Safety Division

National Consent Policy

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I would also like to express my sincere thanks to Angela Hughes and Larraine Gilligan of the Quality and Patient Safety Division of the HSE for their hard work, diligence, and support in ensuring the completion of the policy and supporting documentation. I am also grateful to Dr Philip Crowley, John Kenny and Wini Ryan for their help and support during this project.

Finally sincere thanks to all of the staff, service users and members of the public who made submissions during the consultation phase of this work and who were significant stakeholders in the development of this Policy.

Dr Deirdre Madden

Chair, National Consent Advisory Group.

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Glossary

Adoption

Adoption in Ireland provides for the permanent transfer of parental rights and duties from the birth parents to the adoptive parents. An adopted child is considered to be the child of the adopters as if born to them in lawful wedlock.

Adult

A person over the age of 18 years.

Advance care planning

A process of discussion between a service user and his/her care providers about future medical and social care preferences in the event that the service user is unable to speak for him/herself due to an emergency or serious illness.

Advance healthcare directive

A statement made by a service user with decision-making capacity relating to the type and extent of healthcare interventions he/she would or would not want to undergo in the event that the service user is unable to speak for him/herself due to an emergency or serious illness.

Advocate

An advocate refers to an individual tasked with empowering and promoting the interests of people by supporting them to assert their views and claim their entitlements and, where necessary, representing and negotiating on their behalf.

Anonymous data

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

Glossary

Approved centre

A hospital or inpatient service that is registered by the Mental Health Commission.

Assent

An expression of willingness or affirmative agreement to a health or social care intervention given by a young person who is not legally authorised or has insufficient understanding to be competent to give full consent. The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their agreement would involve.

Autonomy

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

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.

Capacity

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

Cardiopulmonary resuscitation (CPR)

Cardiopulmonary resuscitation (CPR) is an attempt to restore breathing (sometimes with support) and spontaneous circulation in an individual in cardiorespiratory arrest. CPR usually includes chest compressions, attempted defibrillation with electric shocks, injection of drugs and ventilation of the lungs.

Glossary

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

A person under the age of 18 years, unless that person has attained full age through marriage.

Coercion/Duress

Forcing someone to behave in a particular way by use of threats or intimidation or some other form of pressure or force.

Consent

Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication in which the service user has received sufficient information to enable him/her to understand the nature, potential risks and benefits of the proposed intervention or service.

Data controller

Data controller refers to a person who, either alone or with others, controls the contents and use of personal data.

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 subject

Data subject refers to an individual who is the subject of personal data.

Glossary

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.

Do not attempt resuscitation (DNAR) order

A do not attempt resuscitation (DNAR) order is a written order stating that resuscitation should not be attempted if an individual suffers a cardiac or respiratory arrest.

Family

May include the 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.

Health and social care professional

Health and social care professional is generally used as an umbrella term to cover all the various health and social care staff who have a designated responsibility and authority to obtain consent from service users prior to an intervention. These include doctors, dentists, psychologists, nurses, allied health professionals, social workers.

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 service user or the involvement of a service user in teaching and research.

Legal guardian

A person with formal rights and responsibilities in respect of someone who lacks legal capacity.

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.

Major procedure

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

Minor

A person who is less than 18 years of age, who is not or has not been married.

Personal data

Data relating to a living individual who is or can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller.

Reasonable person

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

Service provider

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

Glossary

Service user

For the purpose of this document the term ‘service user’ 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 ‘service user’ where it is considered more appropriate.

Significant/Material risk

A risk may be seen as significant/material if a reasonable person in the patient's position would attach significance to it.

Part One
General Principles

1. Introduction

Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention. Consent must be obtained before starting treatment or investigation, or providing personal or social care for a service user or involving a service user in teaching and research (all defined as 'interventions' for the purpose of this policy). This requirement is consistent with fundamental ethical principles, with good practice in communication and decision-making and with national health and social care policy. The need for consent is also recognised in Irish and international law.

1.1 Scope of this policy

The need for consent, and the application of the general principles in this policy, extends to all interventions conducted by or on behalf of the HSE on service users in all locations. Thus, it includes social as well as health care interventions and applies to those receiving care and treatment in hospitals, in the community and in residential care settings. How the principles are applied, such as the amount of information provided and the degree of discussion needed to obtain valid consent, will vary with the particular situation. In some situations, permission, as matter of common courtesy and of respect for the service user, rather than consent may be required e.g. to enter a person's home, and should be obtained in keeping with relevant HSE codes of conduct[1]. Knowledge of the importance of obtaining consent is expected of all staff employed or contracted by the HSE.

1.2 Ethical issues regarding consent

The ethical rationale behind the importance of consent is the need to respect the service user's right to self-determination (or autonomy) – their right to control their own life and to decide what happens to their own body.

[1] HSE Doc 2.1: Code of Standards and Behaviour (V3) (2009)

Those providing health and social care can often claim greater expertise in decisions regarding the 'means' to achieve the 'end' of better health, such as what medication will best treat blood pressure or whether admission to long-term care is advisable, although service users retain ultimate decision-making authority and must consent to the intervention.

Service users are the experts in determining what 'ends' matter to them, including how they should live their everyday lives, decisions about risk-taking and preference for privacy or non-interference. With rare exceptions, the competent service user's right to refuse an intervention applies even when their decision seems unwise to the health and social care professional.

While respect for autonomy is very important, it is not the only ethical principle relevant to consent. Health and social care professionals also have a responsibility to try and maximise the health and well-being of, and to minimise harm to, service users and others. They also have an obligation to ensure the fair and appropriate use of resources. This means that service users (whether contemporaneously or in an advance healthcare directive) cannot demand whatever interventions they want, regardless of their effectiveness.

1.3 Health and social care decision-making

The relationship between those who provide health and social care and the service user should be a partnership based on openness, trust and good communication. Almost every health and social care intervention involves decisions made by service users and those providing their care.

Good decision making requires a dialogue between parties that recognises and acknowledges the service user's goals, values and preferences as well as the specialist knowledge, experience and clinical judgment of health and social care professionals.

1.4 Consent in Irish law

It is a basic rule at common law that consent must be obtained for medical examination, treatment, service or investigation. This is well established in Irish case law and ethical standards. The requirement for consent is also recognised in international and European human rights law and under the Irish Constitution.

Therefore, other than in exceptional circumstances[2], treating service users without their consent is a violation of their legal and constitutional rights and may result in civil or criminal proceedings being taken by the service user.

No other person such as a family member, friend or carer and no organisation can give or refuse consent to a health or social care service[3] on behalf of an adult service user who lacks capacity to consent unless they have specific legal authority to do so[4].

Health and social care professionals have a responsibility to keep themselves informed of professional standards relevant to obtaining consent in their practice. Likewise, the employer or service provider has a responsibility to staff to provide access to legal information which may have a bearing on the service provided.

1.5 Age of consent in Irish law

The age of consent in Ireland is outlined in the following Acts:

- The Non-Fatal Offences against the Persons Act, 1997 states that persons over the age of 16 years can give consent for surgical, medical and dental procedures.
- The Child Care Act 1991, the Children Act 2001 and the Mental Health Act 2001 define a "child" as a service user under the age of 18 years, "other than a service user who is or who has been married".

This is discussed further in Part Two of this policy.

[2] For discussion of these exceptional circumstances see chapter one section 6

[3] See Part Three section 3 for provisions relating to medical research involving persons lacking decision-making capacity

[4] Such as if the service user has been made a Ward of Court (see section 5.7) or is the subject of an enduring power of attorney which covers the decision in question

2. What is valid and genuine consent?

Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention. The process of communication begins at the initial contact and continues through to the end of the service user's involvement in the treatment process, provision of social care or research study. Seeking consent is not merely getting a consent form signed; the consent form is just one means of documenting that a process of communication has occurred.

For the consent to be valid, the service user must:

- have received sufficient information in a comprehensible manner about the nature, purpose, benefits and risks of an intervention/service or research project.;
- not be acting under duress; and
- have the capacity to make the particular decision.

These criteria are discussed further in the next section.

3. Providing information and discussing treatment options

The exchange of information between those who provide health and social care and the service user is central to consent. As stated above, for consent to be valid, the service user must have received sufficient information in a manner that is comprehensible to him or her about the nature, purpose, benefits and risks of an intervention. The meaning of sufficient information will depend both on the individual circumstances of the service user and on the nature and extent of the intervention. Ensuring that information is provided in a manner that is comprehensible to the service user requires consideration of the quality of the communication between service provider and service user both in terms of the content of the information to be provided and of how that information should be provided. This will be explained in further detail in Sections 3.1 - 3.3.

Part One—General Principles

3.1 Importance of individual circumstances

How much information service users want and require will vary depending on their individual circumstances. Discussions with service users should as much as possible be tailored according to:

- Their needs, wishes and priorities
- Their level of knowledge about, and understanding of, their condition, prognosis and the treatment options
- Their ability to understand the information provided/language used
- The nature of their condition.

3.2 What information should be provided about interventions?

The amount of information to be provided about an intervention will depend on the urgency, complexity, nature and level of risk associated with the intervention.

Choosing whether to undergo or to forego medical investigation and treatment or whether to agree or not to a major lifestyle change such as admission to residential care often requires the service user to balance the potential risks and benefits of both approaches. In these circumstances, service users need adequate information about:

- Their diagnosis and prognosis including any uncertainties about the diagnosis or prognosis
- Options for treating or managing the condition, including the option not to treat
- The purpose of any proposed intervention and what it will involve
- The potential benefits, risks and the likelihood of success of a proposed intervention, as well as that of any available alternative
- Whether a proposed investigation or treatment is experimental or part of a research project
- If relevant, that costs will have to be paid and how and where information about these costs may be obtained.

By contrast, the nature and effect of some interventions, such as removal of a dressing or provision of assisted personal care in the home, are often self-evident and relatively risk-free. In these circumstances, it is usually enough for staff to seek consent to proceed after a brief description of the intervention.

Refusal of permission, especially if it may be harmful to the service user or a request for additional information should trigger additional discussion.

Although service users may be provided with standardised informational material, they should be told if their particular circumstances might modify the risks or benefits as stated in such material.

Service users should be asked if they have understood the information they have been given, and whether or not they would like more information before making a decision. Questions should be answered honestly and, as far as practical, as fully as the service users wishes.

3.3 What information about risks and side effects of an intervention should be provided?

The amount of information about risk that staff should share with service users will depend on the individual service user and what they want or need to know. Although most service users will be aware that no physical procedure or medication is entirely risk free, they may not be as familiar with the potential risks of common procedures such as the administration of blood products or radiographic procedures. Factors such as service users' occupations or lifestyles may influence those risks that they consider significant or particularly undesirable.

A general rule is to provide information that a reasonable person in the service user's situation would expect to be told. This is in line with ethical and professional standards as well as the legal standard applied by the Irish courts. Such information includes the likelihood of:

- side effects or complications of an intervention;
- failure of an intervention to achieve the desired aim; and
- the risks associated with taking no action or with taking an alternative approach.

A risk may be seen as material/significant if a reasonable person in the patient's position if warned of the risk would attach significance to it. Such risks must be disclosed to the patient.

Thus, common, even if minor, side effects should be disclosed as should rare but serious adverse outcomes. The latter include death, permanent disability (such as paralysis or blindness), permanent disfigurement and chronic pain.

Information about risk should be given in a balanced way. Service users may understand information about risk differently from those providing health and social care. This is particularly true when using descriptive terms such as 'often' or 'uncommon'. Potential biases related to how risks are 'framed' are important: a 1 in a thousand risk of a complication also means that 999 out of a thousand service users will not experience that complication.

In order to best support service users in assessing the risks and benefits of various interventions/ course of action consideration should be given to:

- Designing and employing communications that use plain language
- Avoid explaining risks in purely descriptive terms (such as low risk), try to supplement with numerical data
- Use absolute numbers or percentages; avoid using relative risk or percentage improvements
- Use visual aids e.g. pictographs wherever possible, to maximise understanding.

3.4 How and when information should be provided

The manner in which the health and social care options are discussed with a service user is as important as the information itself. The following measures are often helpful:

- Discussing treatment options in a place and at a time when the service user is best able to understand and retain the information. Sensitive issues should be discussed in an appropriate location to ensure that the service user's privacy is protected to the greatest degree possible in the circumstances.
- Providing adequate time and support, including, if necessary, repeating information

- Use of simple, clear and concise English and avoidance of medical terminology
- Supplementing written or verbal information with visual depictions, e.g. pictures
- Asking the service user if there is anything that would help them remember information, or make it easier to make a decision; such as bringing a relative, partner, friend, carer or advocate to consultations.

Service users should be given the time and support they need to maximise their ability to make decisions for themselves. It is particularly important to ensure this is the case for those with limited literacy skills and those who may have difficulty making decisions including those with communication difficulties, intellectual disability or cognitive impairment.

It must not be assumed that a service user lacks capacity to make a decision solely because of communication difficulties, intellectual disability or cognitive impairment.

For those with communication difficulties, speaking to those close to the service user and to other health and social care staff about the best ways of communicating with the service user, taking account of confidentiality issues, may be helpful.

Additional measures may be required in specific circumstances:

3.4.1 Service users with limited English language proficiency

Except in emergency situations, an interpreter proficient in the service user's language is required to facilitate the service user giving consent for interventions that may have a significant impact on his or her health and well-being. Where practicable, this is best achieved in most cases by using a professional interpreter. The use of family (in particular of minor children) and friends should be avoided if at all possible.

Additional time will always be required for discussions involving an interpreter, and this should be planned for in advance[5].

[5] On Speaking Terms: Good Practice Guidelines for HSE Staff in the Provision of Interpreting Services (2009)

3.4.2 Deaf and hard of hearing service users

Deaf and hard of hearing service users should be asked how they would like information to be provided. Some individuals 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. If required, a sign language interpreter should be obtained. In relation to the use of children, family and friends as interpreters see section above.

3.4.3 Blind and visually impaired service users

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.

3.5 Consent and Pregnancy

Service users who are pregnant must have received sufficient information in a manner that is comprehensible to them about the nature, purpose, benefits and risks of an intervention or lack thereof on their health and life.

Service users who are pregnant will need to receive sufficient information about the benefits and risks of an intervention or lack thereof on the viability and health of a foetus as defined below. They will also need sufficient information on the benefits and risks of an intervention or failure to intervene on the viability and health of the child that will be delivered.

The Health (Regulation of Termination of Pregnancy) Act 2018 defines as follows: *"foetus in relation to pregnancy, means an embryo or a foetus during the period of time commencing after implantation in the uterus of a woman and ending on the complete emergence of the foetus from the body of the woman".*

4. Ensuring consent is voluntary

For consent to be valid the service user must not be acting under duress and their agreement should be given freely, in other words they must understand that they have a choice. Use of threats to induce consent such as withdrawal of any privileges is not acceptable.

Duress refers to pressures or threats imposed by others. However, this is distinct from the pressures that illness itself can impose on service users, who may feel they have little choice regarding treatment as a result. Also, duress should be distinguished from providing the service user, when appropriate, with strong recommendations regarding a particular treatment or lifestyle issue or from pointing out the likely consequences of choices the service user may make on their health or treatment options.

Service users may also be subject to pressure from family and friends to accept or reject a particular intervention, such as, for example, to enter a nursing home if they are perceived to be at risk of harm at home. Staff should take particular care in these circumstances to ensure as far as practical that the service user's decision has not been made under undue pressure and may need to meet the service user alone so that ultimately he or she makes their own decision.

5. Has the service user the capacity to make the decision?

5.1 General principles

Best practice favours a 'functional' or decision-specific approach to defining decision-making capacity: that capacity is to be judged in relation to a particular decision to be made, at the time it is to be made - in other words it should be issue specific and time specific – and depends upon the ability of an individual to comprehend, reason with and express a choice with regard to information about the specific decision. The "functional" approach recognises that there is a hierarchy of complexity in decisions and also that cognitive deficits are only relevant if they actually impact on decision making.

5.2 Duty to maximise capacity

Best practice and international human rights standards favour "supported decision-making" where possible. This requires that efforts must be made to support individuals in making decisions for themselves where this is possible. A service user's ability to make decisions may depend on the nature and severity of their condition, or the difficulty or complexity of the decision. Some service users will always be able to make simple decisions, but may have difficulty if the decision is complex or involves a number of options. Other service users may be able to make decisions at certain times but not at other times, because of fluctuations in their condition or because factors such as confusion, panic, shock, fatigue, pain or medication temporarily affect their ability to understand, retain or weigh up information, or communicate their wishes.

It is important to give those who may have difficulty making decisions the time and support they need to maximise their ability to make decisions for themselves.

Approaches that may be helpful in this regard include:

- Discussing treatment options in a place and at a time when the service user is best able to understand and retain the information
- Asking the service user if there is anything that would help them remember information, or make it easier to make a decision; such as bringing a relative, partner, friend, carer or advocate to consultations, or having written or audio information about their condition
- Speak to those close to the service user and to other health and social care staff about the best ways of communicating with the service user, taking account of confidentiality issues.

5.3 Presumption of capacity

Those who provide health and social care services must work on the presumption that every adult service user has the capacity to make decisions about their care, and to decide whether to agree to, or refuse, an examination, investigation or treatment.

It must not be assumed that a service user 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), their beliefs, their apparent inability to communicate, or the fact that they make a decision that seems unwise to the health and social care professional. Capacity should not be confused with a health and social care professional's assessment of the reasonableness of the service user's decision. The person who has capacity can make their own choices, however foolish, irrational or idiosyncratic others may consider those choices. Similarly, the fact that a service user has been found to lack capacity to make a decision on a particular occasion does not mean that they lack capacity to make any decisions at all, or that they will not be able to make similar or other decisions in the future.

5.4 When to consider incapacity

An important implication of the presumption of capacity is that this presumption should not be challenged unless an adequate "trigger" exists. All service users may experience temporary lack of capacity due to severe illness, loss of consciousness or other similar circumstances.

The possibility of incapacity and the need to assess capacity formally should only be considered, **if, having been given all appropriate help and support**, a service user:

- is unable to communicate a clear and consistent choice or
- is obviously unable to understand and use the information and choices provided.

5.5 Assessing capacity to consent

Capacity to consent should be assessed if there is sufficient reason, as indicated in Section 5.4, to question the presumption of capacity. This involves assessing whether:

- The service user understands in broad terms and believes the reasons for and nature of the decision to be made
- The service user has sufficient understanding of the principal benefits and risks of an intervention and relevant alternative options after these have been explained to them in a manner and in a language appropriate to their individual level of cognitive functioning
- The service user understands the relevance of the decision, appreciates the advantages and disadvantages in relation to the choices open to them and is able to retain this knowledge long enough to make a voluntary choice.

The fact that a person may not, in their current situation have sufficient understanding or appreciation regarding a decision should in the first instance signal a requirement for the provision of supports in order to ensure that the decision-making capacity of the individual is enhanced to the greatest degree possible, rather than an inevitable finding of incapacity to make that decision.

5.6 Making decisions if capacity is absent

There is currently no legislative framework to govern how a decision about treatment and care should be made for those who lack capacity to make that decision themselves.

However, Irish case law, national and international guidelines suggest that in making decisions for those who lack capacity, the health and social care professional should determine what is in their best interests, which is decided by reference to their values and preferences if known.

The health and social care professional should:

- Consider whether the service user's lack of capacity is temporary or permanent. In those with fluctuating cognitive impairment, it may be possible to make use of lucid periods to obtain consent
- Consider which options for treatment would provide overall clinical benefit for the service user
- Consider which option, including the option not to treat, would be least restrictive of the service user's future choices
- Support and encourage service users to be involved, as far as they want to and are able, in decisions about their treatment and care
- Seek any evidence of the service user's previously expressed preferences, such as an advance statement or decision, and of the service user's previous wishes and beliefs
- Consider the views of anyone the service user asks you to consult
- Consider the views of people who have a close, ongoing, personal relationship with the service user such as family or friends
- Consider involving an advocate to support the service user who lacks capacity to participate in the decision making process around consent. This may be particularly helpful in difficult situations such as when service users with no family or friends have to make a complex decision; or when there is significant disagreement regarding the best course of action.

5.6.1 Role of the family

No other person such as a family member, friend or carer and no organisation can give or refuse consent to a health or social care service[6] on behalf of an adult service user who lacks capacity to consent unless they have specific legal authority to do so[7].

However, it may be helpful to include those who have a close, ongoing, personal relationship with the service user, in particular anyone chosen by the service user to be involved in treatment decisions, in the discussion and decision-making process pertaining to health and social care interventions.

Their role in such situations is not to make the final decision, but rather to provide greater insight into his/her previously expressed views and preferences and to outline what they believe the individual would have wanted. In some cases, involvement of those close to the service user will facilitate the service user in reaching a decision in conjunction with health/social care providers.

5.6.2 Emergency situations involving service users who lack capacity

In emergency situations where a service user is deemed to lack capacity[8] consent is not necessary.

The health and social care professional may treat the service user provided the treatment is immediately necessary to save their life or to prevent a serious deterioration of their condition and that there is no valid advance refusal of treatment (discussed in 7.9). The treatment provided should be the least restrictive of the service user's future choices. While it is good practice to inform those close to the service user – and they may be able to provide insight into the service user's likely preferences - nobody else can consent on behalf of the service user in this situation.

[6] See Part Three section 3 for provisions relating to medical research involving persons lacking decision-making capacity

[7] Such as if the service user has been made a Ward of Court (see section 5.7) or is the subject of an enduring power of attorney which covers the decision in question

[8] See section 5.5 for provisions relating to the assessment of capacity

5.6.3 Non-emergency situations involving service users who lack capacity

In non-emergency situations, a distinction can be made between those service users who, depending on the nature of their incapacity, may or may not be able to express an opinion regarding the proposed intervention. Even in the presence of incapacity, the expressed view of the service user carries great weight:

- Cannot express opinion: This includes service users who are in a coma or have severe dementia or have sufficient clouding of consciousness to impair effective communication. Decisions should be made in the best interests of the service user, bearing in mind the principles outlined above. It is good practice to inform those close to the service user of planned interventions and to seek their agreement if possible. However, it is important to remember that the primary duty of the health and social care professional is to the service user.
- Can express opinion: Many service users who lack capacity to make a decision will nevertheless be able to express a preference to receive or forgo an intervention. Such preferences should in general be respected. Most health and social care decisions regarding those who lack capacity arise in the community, and, except in emergencies, it may often be impractical or undesirable to try to impose care, treatment or investigation on someone who refuses it. Legal advice should be sought in respect of refusal of any major intervention including surgery, prolonged detention or other restrictions on liberty.

5.7 Wards of Court

If a ward needs a healthcare intervention for which written consent is required by the service provider, the approval of the President of the High Court should be obtained. In practice a request for consent, for example to carry out an elective surgical procedure or administer an anaesthetic is normally made by the clinician concerned to the Office of Wards of Court. However, emergencies will arise where it is not possible to obtain timely approval and in those circumstances the necessary treatment may be administered in the service user's best interests (see further Section 6.1).

6. Is it always necessary to seek service user consent?

The general principles of consent apply to all decisions about care: from the treatment of minor and self-limiting conditions, to major interventions with significant risks or side effects. However, while the agreement of the service user should always be sought, there are a number of situations where the amount of information provided about an intervention may legitimately be abbreviated. These include:

- Emergency situations
- Where the service user declines information.

6.1 Emergency situations

In an emergency life-threatening situation where the service user lacks capacity to consent or where the urgency of the relevant intervention imposes time limitations on the ability of the service user to appreciate what treatment is required, the necessary treatment may be administered in the absence of the expressed consent of the service user. **The application of this exception is limited to situations where the treatment is immediately necessary to save the life or preserve the health of the service user.**

6.2 Where the service user declines information

Some service users do not want to know in detail about their condition or the treatment. While this should be respected if possible, it is important that some basic information be provided about major interventions in order that consent can be obtained and the service user has been advised of what is involved. If a service user refuses to receive detailed information about their condition, this should be documented[9].

The fact that a service user 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 that they need or are entitled to know.

[9] Further details on the documentation of consent are provided at 7.5

7. Specific Issues relating to consent

7.1 Scope of consent

The need for consent, and the application of the general principles in this policy, extends to all interventions conducted by or on behalf of the HSE on service users in all locations. Thus, it includes social as well as health care interventions and applies to those receiving care and treatment in hospitals, in the community and in residential care settings. How the principles are applied, such as the amount of information provided and the degree of discussion needed to obtain valid consent, will vary with the particular situation. In some situations, permission, as matter of common courtesy and of respect for the service user, rather than consent may be required e.g. to enter a person's home, and should be obtained in keeping with relevant HSE codes of conduct[10].

Provision of health and social care to a service user during a single episode often involves a number of interventions. This is particularly true during acute hospital admissions. A useful approach to consent in this context is to consider what a reasonable person in the service user's situation would consider appropriate.

Thus, for example, it might be judged that someone facing potentially hazardous surgery would more likely prefer to focus on the risks of the surgical procedure than on the much smaller risks associated with the ancillary antibiotic treatment. However, individual preferences remain important in these circumstances: if service users have a strong preference for detailed information and for involvement in all aspects of decision-making, this should be respected as far as possible.

Those who provide health and social care services should discuss with service users the possibility of additional problems arising during an intervention or treatment when they may not be in a position to make a decision about how to proceed.

If there is a significant risk of a particular problem arising, the service user should be asked in advance what they would like the health and social care professional to do if the difficulty occurs.

[10] HSE Doc 2.1: Code of Standards and Behaviour (V3) (2009)

It is important that service users understand the scope of any decisions to be made, especially if:

- Treatment will be provided in stages, with the possibility that changes or adjustments might be needed
- Different professionals will provide particular parts of an investigation or treatment, such as anaesthesia and surgery
- A number of different investigations or treatments are involved.

The service user should be asked if there are any particular procedures they object to in the context of their proposed treatment and this should be clearly documented on their record. If they agree only to parts of the proposed intervention/treatment, there should be a clear process through which they can be involved in making decisions at a later stage. Those who provide health and social care must not exceed the scope of the authority given by a service user, except in an emergency.

7.2 Who should seek consent from a service user?

The person who is providing a particular health and social care service or intervention is ultimately responsible for ensuring that the service user is consenting to what is being done. The task of providing information and seeking consent may be delegated to another professional, as long as that professional is suitably trained and qualified.

In particular, they must have sufficient knowledge of the proposed intervention and of the benefits and risks in order to be able to provide the information the service user requires. Inappropriate delegation (for example where the seeking of consent is assigned to a junior health and social care professional with inadequate knowledge of the procedure) may mean that the "consent" obtained is not valid.

If different aspects of care are to be provided by different professional disciplines, each should usually obtain consent for their particular intervention.

7.3 When should consent be sought?

The provision of information and the seeking and giving of consent should involve a continuing process of keeping service users up to date with any changes in their condition and the interventions proposed. It should not be a once-off, sometimes 'eleventh hour' event, exemplified by getting a hurried signature on a consent form.

While there are no legal provisions relating to the duration of consent, for major interventions it is good practice where possible to seek the service user's consent to the proposed procedure well in advance, when there is time to respond to the service user's questions and provide adequate information. Clinicians should then check, before the procedure starts, that the service user has no questions or concerns and still consents to proceed.

If there is a significant time-lapse between the initial seeking and giving of consent and the actual date of an intervention, it is helpful to check if the service user can remember the treatment information given previously and if they have any questions in relation to that information. If the service user isn't satisfied that he or she can remember the earlier information or if he or she has cognitive difficulties that might interfere with his or her recollection of the earlier discussion or there is a change in the service users condition or in the information about the proposed intervention which may result in a change in the nature, purpose or risks associated with the procedure, a fresh consent following provision of appropriate information should be sought.

Asking a service user to provide consent just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, or seeking consent from someone who is sedated, in pain or anxious, creates doubt as to the validity of the consent. In particular, service users should not be given routine pre-operative medication before being asked for their consent to proceed with a treatment.

7.4 Types of consent

The validity of consent does not depend on the form in which it is given. Service users may indicate consent orally, in writing or in certain limited circumstances by implication (such as where a service user holds out their arm for a blood pressure reading). In all situations, common courtesy and respect for the service user is required.

Before accepting a service user's consent, those who provide health and social care services must consider whether the service user has been given the information they want or need, and how well they understand what is proposed.

7.5 How should consent be documented?

It is essential for those who provide health and social care to document clearly both the service users' agreement to the intervention and the discussions that led up to that agreement if:

- the intervention is invasive, complex or involves significant risks;
- there may be significant consequences for the service user's employment, or social or personal life;
- providing clinical care is not the primary purpose of the intervention e.g. clinical photographs or video clip to be used for teaching purposes or blood testing following needle stick injury to staff;
- the intervention is innovative or experimental;
- or in any other situation that the service provider considers appropriate.

This may be done either through the use of a consent form or through documenting in the service user's notes that they have given verbal consent.

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

7.6 Confidentiality and data protection

Service users have a right to expect that information about them will be held in confidence by those who provide health and social care services to them. Confidentiality is central to trust in this relationship. Staff are expected to comply with the provisions of the Data Protection Acts 1988 and 2003 which state that personal information obtained from service users for the purposes of informing care, treatment or service provision should not be disclosed to a third party unless the service user has consented or unless the specific requirements of the legislation are complied with[11]. (The legislation distinguishes between "sensitive" and "non-sensitive" data. For non-sensitive data, information may be shared ("processed") where it is necessary to prevent injury or other damage to the health of the data subject. For sensitive data, information may be shared where it is necessary for medical purposes and is undertaken by a medical professional).

This also applies if a third party, such as a family member, makes a complaint regarding the care of a service user: it is essential in these circumstances to ensure that the service user has consented to their personal information being made available for any internal investigations/ reviews.

Sharing of information on a strict 'need to know' basis between staff involved in a service user's care is essential to the provision of safe and effective care. Similarly, an integral component of modern health and social care is the use of audit and quality assurance programmes to ensure that the care provided is of the highest quality when benchmarked against national and international standards. Consent from the service user is not usually sought in these circumstances except where identifiable data is being made available to a third party. However, it is good practice to make service users aware that such practices occur and that safeguards exist to ensure that their personal information is protected. For example, this could be done in hospitals by providing such information on admission.

[11] See Part Three section 9 for provisions relating to confidentiality and data protection in the context of research

7.7 When consent is refused

If an adult with capacity to make an informed decision makes a voluntary and appropriately informed decision to refuse treatment or service, this decision must be respected, even where the service user's decision may result in his or her death. In such cases it is particularly important to accurately document the discussions with the service user, including the procedure that has been offered, the service user's decision to decline and the fact that the implications of this decision have been fully outlined.

Those who provide health and social care services should also consider and discuss with the service user whether an alternative treatment/measure is acceptable to the service user.

For example in the case of a service user who is refusing a blood transfusion for religious reasons, the service user should be referred for a haematology consultation to ascertain whether any alternative treatment would be acceptable.

In the context of social care, for example, where a frail older person is assessed to require home supports in order to keep them safe refuses these services, alternative measures should be discussed with the service user.

If there is uncertainty about the service user's capacity to make a decision, the guidance in Section 5.5 should be followed.

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

7.7.1 Refusal of isolation for infectious disease

The consent of service users with infectious diseases is required for all health and social care interventions, including treatment of the infection. The refusal of a competent person to receive treatment for an infection, even if medically unwise, should be respected. However, under the provisions of the Health Act 1947 such a person may be isolated in order to prevent the spread of the disease[13].

In practice, detention and isolation is most likely to occur when someone with an infectious disease, such as tuberculosis, refuses treatment that would render them non-infectious and, hence, no longer a risk to others. In these circumstances, while treatment cannot be provided without the consent of the service user, the health and social care professional should explain the possible consequences of the refusal of treatment, including potential detention and isolation.

7.7.2 Refusal of treatment by a service user involuntarily admitted under the Mental Health Act 2001

Where the service user has been involuntarily admitted to an approved centre under the Mental Health Act 2001, the procedures in respect of treatment must comply with the provisions of that Act. In some limited cases, the Act allows mental health treatment to be provided even if the service user is unwilling or unable to consent provided that the requirements of the Act are met. However, this does not remove the ethical imperative to seek the consent of the service user and to make every effort to ensure that the treatment is acceptable to the service user.

Nor does the Mental Health Act 2001 remove the ethical obligation to maximise service user capacity and to involve service users lacking capacity in the decision-making process to the greatest extent possible. All care given to the service user should be explained to him/her once their condition improves.

Where the service user 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.

7.7.3 Refusal of the taking of 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.

[13] Section 38 of the Health Act (1947): 'Where a chief medical officer is of opinion. that such person is a probable source of infection with an infectious disease and that his isolation is necessary as a safeguard against the spread of infection, and that such person cannot be effectively isolated in his home, such medical officer may order in writing the detention and isolation of such person in a specified hospital or other place until such medical officer gives a certificate that such person is no longer a probable source of infection

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. Section 14 of the Road Traffic Act 2010 relates to situations where an "event"[14] has occurred and, as a result, a person is injured and is admitted to or attends at a hospital. In such a situation, where a Garda is of the opinion that, at the time of the event, the person was driving or attempting to drive, the Garda may require the person to permit a doctor or nurse who has been specifically designated by the Garda Siochána to take a sample of blood or (at the person's option) to provide a sample of urine.

The Garda must first consult with the designated doctor or nurse in order to ensure that this requirement would not be prejudicial to the health of the person. Section 12 of the Act relates to testing at a Garda station by a designated doctor or nurse only. The Act does not provide for the forcible taking of a sample without the consent of the person. 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.

7.8 Advance refusal of treatment

Sometimes service users may wish to plan for their medical treatment in the event of future incapacity, including advance refusal of medical treatment. There is no Irish legislation confirming the enforceability of such advance refusals. However, such an advance plan should be respected on condition that:

- The decision was an informed choice, according to the principles discussed in Sections 2-5
- The decision specifically covers the situation that has arisen, and
- There is no evidence that the service user has changed their mind since the advance plan was made.

[14] As specified in the Act

If there is reasonable doubt about the existence of an advance treatment plan, the service user's capacity at the time of making the treatment plan or whether it still applies in the present circumstances, treatment decisions should be made according to the principles discussed in Section 5.6.

7.9 Withdrawal of consent

A service user with capacity is entitled to withdraw consent at any time, including during the performance of a procedure. Where a service user does object during treatment, it is good practice for the practitioner, unless this would genuinely put the life of the service user at risk, to stop the procedure, establish the service user's concerns, and explain the consequences of not completing the procedure and respect the withdrawal of consent.

7.10 Refusal of treatment in pregnancy

The consent of a service user is required for all health and social care interventions in pregnancy in accordance with Section 1.4 of this Policy.

Part Two
Children and Minors

Part Two—Children and Minors

1. Introduction

In any matter relating to children, the child's best interests are of paramount importance. 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. Such an approach involves putting the interests and wellbeing of the child at the centre of all decisions and ensuring that the child's own voice is heard and respected as far as possible.

All service users have the right to participate in decision-making in relation to their care. In the provision of health and social care to children, it is important that respect for their autonomy is integrated into decision-making in the same way as for adults. This does not mean that the interests and views of parents or legal guardians will be displaced, as in most instances the child's interests will be best represented by its parents or legal guardians, 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.

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 and/or 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.

Children with disabilities have the right to express their views freely on all matters affecting them, on an equal basis with other children, with their views being given due weight according to their age and maturity. In order to realize this right, children with disabilities must be provided with disability and age-appropriate assistance (see further Part One Section 3.4).

2. Role of parent(s) and legal guardian(s)

Parents and legal guardians are generally considered best placed to safeguard the health and wellbeing of their children. Parents, legal guardians and health and social care professionals have a responsibility to act in the best interests of children and to care for them in a manner that respects their dignity and wellbeing.

Reference to 'parent' in this policy is intended to mean a parent as defined by Section 2 of the Guardianship of Infants Act 1964 as amended by the Status of Children Act 1987. These provisions mean that only a person who is a legal guardian may give consent in respect of his/ her child. legal guardianship is described below.

2.1 What is legal guardianship**?**

Legal guardianship refers to the right of a parent to be involved in all major decisions affecting the welfare and upbringing of a child including decisions relating to education, health, religious, monetary and moral concerns. Under current Irish law, the following guardianship rules apply:

- Where parents are married, the child's mother and father are the legal guardians.
- Where a child has been jointly adopted, the adoptive parents are the child's legal guardians.
- 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.
- Where the child's parents are not married:
  - ◊ the child's mother is an automatic legal guardian
  - ◊ the child's father is an automatic legal guardian if 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. This provision is not retrospective, so guardianship will only be acquired automatically where the parents live together for at least 12 months after 18 January 2016.

- ◊ 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.
- ◊ the father may apply to court to be appointed legal guardian.

- 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.
  - ◊ 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.
- 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 appoint a person to act as the child's guardian in the event of the guardian's death.

2.2 Who can give consent for a child?

For children below the age of 16, a parent(s) or legal guardian(s) can consent to the treatment of the child (and for a child below the age of 18 being treated for a mental disorder covered by the Mental Health Act, 2001). The age of consent is discussed further at Section 3.

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 and this should be documented in the child's healthcare record. In the event that they indicate that they are not the child's parent and/or legal guardian, contact must be made with the child's parent and/or legal guardian in order to seek appropriate consent.

Consent obtained from parents or legal guardians by telephone, 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. The same standards and principles of informed consent set out in Part One of this policy apply to consent obtained by these means and the consent should be clearly documented in the healthcare records.

Currently, there is some discussion in health and social care practice as to whether one or both parents/legal guardians consent is required prior to commencement of medical treatment and/or social care intervention.

On the one hand, it may be argued that the consent of both parents/legal guardians is required prior to treatment of the child on the basis of the rights of the parents/legal guardians in keeping with Article 41 of the Constitution which recognises the family as the natural primary and fundamental unit group of society and the Guardianship of Infants Act, 1964. However, seeking joint parental consent may cause delays in children receiving services and potential logistical difficulties in ensuring that all forms are co-signed e.g. parents/legal guardians working abroad. In addition the requirement for joint consent may be perceived by those parents/legal guardians not in dispute to be bureaucratic.

Conversely, it may be argued that seeking the consent of only one parent/legal guardian is widely recognised in health and social care practice and is considered to be more practical for safe, timely and effective service provision. It is generally accepted in other jurisdictions from a legal perspective that, in protecting health professionals from an action in battery[15], the consent of one parent or legal guardian (or in their absence, that of the court) is sufficient.

The acceptance of consent of one parent/legal guardian assumes that the child's welfare is paramount, which is in line with the Child Care Acts 1991 and 2001, and that the Health and Social Care professional is proposing a treatment or intervention in the child's best interests. It also assumes that both of the parents/legal guardians are concerned with the child's welfare.

The provisions of the Irish Constitution 1937 acknowledge the important role and responsibility that all parents and legal guardians have to safeguard the welfare of their children in relation to decisions in many different contexts, including health, social development, education and so on.

[15] Battery is a form of trespass to the person resulting from proof of contact with the body without consent

Part Two—Children and Minors

As a corollary to the rights given to parents as legal guardians of their children, there are also duties imposed on them to act in the best interests of their children. In the health and social care context this requires parents and legal guardians to engage with health and social care service providers to ensure that the child receives the best possible care and services. Such involvement by parents and legal guardians should be encouraged and facilitated by service providers as much as possible.

Where both parents/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. This also imposes a responsibility on the parents/legal guardians to be contactable and available at relevant times when decisions may have to be made for the child.

Even where both parents/legal guardians have not clearly indicated their wish to be involved in decision making, if the decision will have profound and irreversible consequences for the child, both parents/legal guardians should be consulted if possible. However if urgent care is required and the second parent/legal guardian cannot be contacted despite reasonable efforts to do so, the service provider has a paramount duty to act in the best interests of the child.

Apart from the circumstances outlined above and in keeping with the prioritisation of the best interests of the child, the consent of one parent/legal guardian will provide sufficient authority in respect of any health or social care intervention in relation to a child.

In emergency circumstances where neither parent/legal guardian is contactable, the general doctrine of necessity applies[16] and the service provider is obliged to act in the best interests of the child.

3. Age of consent

The Child Care Act 1991, the Children Act 2001 and the Mental Health Act 2001 define a child as a service user under the age of 18 years of age, other than a service user who is or has been married.

[16] See Part One section 6.1

Section 23 of the Non-Fatal Offences against the Person Act 1997 provides that a person over the age of 16 years can give consent to surgical, medical or dental treatment and it is not necessary to obtain consent for it from his or her parent(s) or legal guardian(s). The section covers any procedure undertaken for the purposes of diagnosis and any procedure, such as administration of anaesthetic, which is ancillary to treatment[17].

This means that consent to surgical, medical or dental treatment by a 16 and 17 year old has the same status under this Act as if he or she were an 18 year old. While currently there are no legal provisions in Ireland for minors under 16 years to give consent on their own behalf, it is nonetheless good practice to involve the minor in decisions relating to them and listen to their wishes and concerns in terms of their treatment and care.

In many jurisdictions a minor is capable of giving informed consent when he or she achieves a sufficient understanding and intelligence to enable him/her to understand fully what is proposed. For example, in England the 1985 Gillick case[18] established that a doctor had discretion to give contraceptive advice or treatment to a girl under the age of 16 years without her parents' or legal guardians' knowledge or consent provided the girl had reached an age where she had a sufficient understanding to enable her to understand fully what was proposed.

Hence, the concept of a 'mature minor' is dependent on the child's level of maturity, with no lower age limit defined. In addition, the gravity and nature of the treatment are also taken into account when assessing a minor's capacity to fully understand all aspects of the situation and to objectively weigh up treatment options. This concept of the mature minor has been accepted in other jurisdictions including Northern Ireland, Scotland, New Zealand, Australia and some provinces in Canada. However, the Gillick case and other similar cases elsewhere do not have any application in Ireland although they may be of persuasive authority in the event of a judicial determination on this issue.

In Ireland, the courts place great emphasis on the rights of the family and the rights of parent(s)/ legal guardian(s) to decide what is in the best interests of their children. It is possible that the Irish courts may interpret the provisions of the Constitution in such as way as to require parental consent to be obtained before providing a health or social care service to any minor under the age of 16 years.

[17] For detailed information about the assessment of capacity please refer to Part 1: underpinning principles, section 5.5

[18] *Gillick v Western Norfolk and Wisbech Area Health Authority and another* [1985] 3 AER 402

However, as against this, it should be noted that children and minors also have significant personal rights of their own under the Constitution, the European Convention of Human Rights, and the United Nations Convention on the Rights of the Child. These rights include rights to liberty, bodily integrity, the freedom to communicate with others and to follow their own conscience.

This policy acknowledges that in health and social care practice it is usual to involve parent(s)/ legal guardian(s) and seek their consent when providing a service or treatment to a minor under 16. However, the minor may seek to make a decision on their own without parental involvement or consent. In such circumstances it is best practice to encourage and advise the minor to communicate with and involve their parent(s) or legal guardian(s). It is only in exceptional circumstances that, having regard to the need to take account of an objective assessment of both the rights and the best interests of the person under 16, health and social care interventions would be provided for those under 16 without the knowledge or consent of parent(s) or legal guardian(s).

In those circumstances, an assessment must be made as to whether:

- the minor has sufficient maturity to understand the information relevant to making the decision and to appreciate its potential consequences;
- the minor's views are stable and a true reflection of his or her core values and beliefs, taking into account his or her physical and mental health and any other factors that affect his or her ability to exercise independent judgement;
- 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, in respect of which relevant guidance and protocols such as the 2011 Children First: National Guidelines *for the Protection and Welfare of Children* (or any equivalent replacement document) must be applied.

This same assessment of maturity is relevant for all minors under 16 including those who have been diagnosed with intellectual disability.

3.1 Confidentiality and the minor

Prior to giving consent for a health or social care intervention, the minor should be informed by the health or social care provider that confidentiality cannot be assured as his/her parent(s)/legal guardian(s) may have rights to access the minor's medical/other records under the Freedom of Information Act 1997[19].

In certain circumstances there may also be a legal obligation on the health or social care provider to report sexual activity due to the age of the minor (see further Section 10). The minor should be informed of the health and social care provider's intention to report such activity to the HSE or the Garda Siochana.

4. Refusal of health or social care services by children and minors

In the case of young children who are not assessed as falling within the mature minor category described in Section 3 above, consent from the child's parent(s)/ legal guardian(s) is required for every intervention. If the child refuses despite parental consent, the child should be given the opportunity to explain the reasons for their refusal and reasonable attempts should be made to give the child sufficient time, explanation and reassurance to try to address the child's fears or concerns about the intervention.

Where a mature minor refuses a health or social care service the service provider should, as a first step, encourage the minor to involve their parent(s)/legal guardian(s) in the decision. If the minor does not want to involve their parent(s)/legal guardian(s) and the service is deemed to be in best interests of the minor, then the parent(s)/legal guardian(s) must be informed despite the minor's refusal.

Consultation should take place involving the minor and the parent(s)/legal guardian(s), with the assistance of the HSE Advocacy service and/or a third party mediator where appropriate, in order to try to reach a consensus if possible. If this is unsuccessful legal advice should be sought as to whether an application to court is required to resolve the matter, particularly if a physical intervention is envisaged.

[19] Freedom of Information Act, 1997 (Section 28(6)) Regulations 2009

5. Refusal of treatment or social care intervention by a person between 16 and 18 years

The legal position relating to refusal of treatment or social care by a person between the age of 16 and 18 years is unclear. It may be argued that consent and refusal are opposite sides of the same coin and should be regarded in the same way.

This would mean that a young person between the age of 16 and 18 years who is recognised as having the legal capacity to consent must also have the capacity to refuse. However, courts in other jurisdictions have held that there is a clear practical distinction to be made between consent to and refusal of medical treatment in that consent involves acceptance of what is an experienced medical view whereas refusal rejects that experience from a position of comparatively limited knowledge. Consequently, it is argued that the implications of refusal may be more serious and, in extreme cases, may even result in death.

Section 23 of the Non-Fatal Offences Against the Person Act 1997, while it allows the young person aged 16-18 to give consent to medical treatment, does not include an express entitlement to refuse such treatment.

This policy proposes that in cases where an individual between the age of 16 and 18 refuses a treatment or service, in general such refusal should be respected in the same way as for adults. However, if the refusal relates to life sustaining treatment, or other decisions which may have profound, irreversible consequences for him or her, reasonable efforts must be made to discuss the young person's refusal with all the relevant parties, including the involvement of the HSE Advocacy services and/or a third party mediator where appropriate, in an attempt to reach consensus. Failing agreement, an application should be made to the High Court to adjudicate on the refusal.

In such a case, the High Court could intervene to order treatment that is necessary to save life and where this is in the best interests of the young person. In the event of such an application, it would be best practice that the young person would be separately represented.

6. Refusal of health and social care intervention by parent(s)/legal guardian(s)

As noted in Section 2, parent(s)/legal guardian(s) are generally considered best placed to safeguard the health and wellbeing of their children. Service providers should recognise the caring relationship between parent and child in which parent(s)/legal guardian(s) act as advocates and care providers for children and have expertise in the particular needs of their child. Parent(s)/legal guardian(s) are entitled to be treated with courtesy and respect and to be provided with adequate information and support in relation to the provision of health and social care services to their children (see further Part One Section 3).

It is important for service providers to recognise the role of the parent(s)/legal guardian(s) in deciding together with health and social care professionals what is in the best interests of the child. Case conferences involving the parent(s)/legal guardian(s) and all relevant care providers are often a useful way of ensuring that parent(s)/legal guardian(s) and professionals work in partnership in decision-making for the child.

Where a second opinion is sought by parent(s)/legal guardian(s) in order to assist their decision-making, this should be facilitated as far as possible by the service-provider.

In exceptional circumstances where there is disagreement between parent(s)/legal guardian(s) and the health and social care professionals, or where parent(s)/legal guardian(s) refuse medical treatment on behalf of a child, the service provider may consider applying to the court to have such refusal overruled in the best interests of the child. This is provided for by Article 42(5) of the Constitution which states that where a child's parents have failed in their duty to the child the State may intervene to safeguard the welfare of the child. The parent(s)/legal guardian(s) have the right to seek legal representation and to be heard in relation to any such application.

In circumstances where parent(s)/legal guardian(s) disagree between themselves about the provision of a health or social care service to their child, they should be advised that they have a responsibility to discuss the matter and reach an agreement between themselves as quickly as possible, with the assistance of the HSE advocacy services and a third party mediator if required. If agreement is not possible then the service should generally not be provided to the child unless it is deemed by the health and social care professional to be necessary to safeguard the child's best interests. In such circumstances legal advice should be sought as to whether an application to court is required.

Part Two—Children and Minors

7. The minor parent

Parent(s)/legal guardian(s) are presumed to be the best decision-makers for their children and to act in their best interests. This presumption holds even if the parent/legal guardian is under 16 years.

As with all decisions made by parent(s)/legal guardian(s), if the decision is not considered to be in the best interests of the child then the health and social care professional should engage in dialogue with the parent(s)/legal guardian(s) about the decision they are making in relation to their child and carry out an assessment of the minor as outlined in Section 3 above. If appropriate, the maternal grandparents might also be asked to participate in this discussion with the consent of the minor parent/legal guardian. Failing resolution, it is recommended that legal advice is sought.

8. Children in the care of the HSE

It is the responsibility of the HSE to ensure that there is an appropriate care order in place for a child in respect of whom consent is required to be given for the provision of health or social care services. In respect of children who are in voluntary care, consent is required from the child's parent/legal guardian unless a court order has been made dispensing with that person's consent. If there is no parent/legal guardian, or that person is unavailable, the HSE must make an application to the District Court under Section 47 of the Child Care Act 1991 authorising the relevant social worker to give consent. This also applies to children who are in foster care for less than five years or in respect of whom an application has not been made under Section 43A of the 1991 Act described below.

In relation to children who are subject to interim and emergency care orders, an application can be made to the District Court pursuant to the Child Care Act 1991 in regard to medical treatment.

In relation to children who are subject to a full care order, although it is good practice to seek the consent of the parent/legal guardian, the HSE is authorised pursuant to Section 18 of the 1991 Childcare Act to consent to any necessary medical or psychiatric treatment, assessment or examination. However, different procedures apply to admission and treatment under the Mental Health Act 2001 (see Section 9).

For children who are in foster care for five years or more, in accordance with Section 43A of the Child Care Act 1991[20] a foster carer or relative may make an application, and be granted an Order, giving them like control over the child as if they were the child's parent/legal guardian provided that:

- The child has been formally placed in their care for five years or more
- The granting of the Order is in the child's best interest
- The HSE consents to the making of such an Order
- Parental/legal guardian consent is obtained for children in voluntary care or on temporary Orders
- Parent(s)/legal guardian(s) are given notice of the application in the case of children who are subject of full Care Orders
- The wishes of the child have been given due consideration, as appropriate.

The effect of such an Order will be to grant such foster parents/carers the right to do all that is reasonable to safeguard and promote the child's welfare, health and development. This includes the giving of consent to any necessary medical or psychiatric assessment, examination or treatment; and to the issuing of a passport. This Order should be produced by the foster parent to the service provider on request.

In the case of any child in an emergency life-threatening situation, the welfare of the child is the paramount consideration and the doctrine of necessity will apply whereby a medical practitioner may dispense with the requirement for consent.

As with all children and minors, children in care have the right to express their views freely on all matters affecting them with their views being given due weight according to their age and maturity.

[20] As inserted by section 4 of the Child Care (Amendment) Act 2007

Part Two—Children and Minors

9. Mental health services

The provision of mental health services to children follows the same general principles as for other health and social care services. This means that for children below the age of 16 years, consent from the child's parent/legal guardian is required. For minors between 16 and 18 years who access mental health treatment on an outpatient basis through Child and Mental Health Services, general practitioners or other counselling services, the provisions in Section 3 of this policy apply.

The Mental Health Act 2001 sets out some additional provisions in respect of admission and treatment of a child in an approved centre i.e. an inpatient mental health service. The Mental Health Act 2001 defines a child as a person under 18 years of age unless they are or have been married.

Most children are admitted to an approved centre on a 'voluntary basis'. A child is considered a voluntary patient where their parent(s)/legal guardian(s) consent(s) to the admission. Parental/ legal guardian consent is also required to treat the child. Regardless of age, an underlying principle of the 2001 Act (Section 4) is that when it is proposed to give treatment to a person, the person should be consulted and their views listened to and taken into consideration before any treatment is given to them.

It is particularly important that information is provided in a form and language that the child or young person can understand.

Occasionally, a child may need to be detained in an approved centre. This can occur where it appears to the HSE that the child is suffering from a mental disorder and the child requires treatment which he or she is unlikely to receive without formal admission. Such situations may arise, for example, where the parent(s)/legal guardian(s) of a child do not wish to have their child admitted, contrary to the advice of the treating consultant psychiatrist. In such instances, the HSE must make an application to the District Court for a Section 25 order authorising the admission and detention for treatment of the child in a specified approved centre.

Where a young person is the subject of a Statutory Care Order, it is also necessary to seek a Section 25 order for assessment, admission and treatment in an approved centre. It is considered best practice in such situations for the child or young person to have separate legal representation.

The 2001 Act also contains certain provisions in relation to the treatment of a detained child. Section 61 requires the approval of the consultant psychiatrist responsible for the care and treatment of the child and the authorisation of a second consultant psychiatrist before medication which has been prescribed to a child for a continuous period of three months can be continued. Electroconvulsive therapy or psychosurgery cannot be given to a detained child without the approval of the District Court.

There is an uncertain relationship between the 2001 Act and the Non-Fatal Offences against the Person Act 1997. This has created confusion over the capacity of 16 and 17 year olds who have been admitted under the 2001 Act to make mental healthcare decisions and it remains unclear whether 16 and 17 year olds in this situation can consent to treatment without parental/legal guardian consent. Where the young 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.

10. Sexual health services

Under Irish law it is a criminal offence to engage or attempt to engage in a sexual act with a child under 17 years of age[21]. It is not a defence to show that the child consented to the sexual act. The consent of the Director of Public Prosecutions is required for any prosecution of a child under the age of 17 years for this offence. Under the law, a girl under the age of 17 who has sexual intercourse may not be convicted of an offence on that ground alone. This exemption from prosecution does not apply to boys of the same age.

There is no specific provision in law regarding the age at which contraceptive advice and treatment and sexual health services can be provided to a young person and therefore the provision of such advice, treatment or service should follow the same general principles as for any other health and social care service[22]. In keeping with Section 23 of the Non-Fatal Offences against the Person Act 1997, a young person aged over 16 years can give their own consent to contraceptive/ sexual health advice or interventions (see Section 3). However, in light of the fact that the activity may constitute a criminal offence for a person under the age of 17, efforts should be made to involve the parent(s)/legal guardian(s) in this consultation and decision making.

[21] Section 3 of the Criminal Law (Sex Offences) Act 2006 as amended by Section 5 of the Criminal Law (Sexual Offences) (Amendment) Act 2007

[22] Section 3 of the Criminal Law (Sex Offences) as above

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In relation to the Criminal Law (Sexual Offences) Act 2006 and child protection guidelines, it is critical that the heath or social care professional rules out any possibility or suspicion that any aspect of sexual intercourse was abusive, exploitative, or non-consensual. Health professionals need to be mindful of the risks involved in providing medical treatment to this age group. They should therefore:

- document the result of an assessment (to see if there is suspicion or evidence of abuse) and actions taken; and
- document efforts to encourage the minor to involve his/her parent(s)/legal guardian(s).

In addition, the health and social care professional must be aware of any legal requirements to report sexual activity of a minor under 17 years to either the Gardai or to the HSE under the Children First Guidelines (2011)[23].

[23] or any other relevant legislation or national guidelines

Part Three
Research

Part Three—Research

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[24].

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

[24] These documents are referred to in the bibliography

- **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)[25] for a consideration of whether it is adequate to achieve consent.

[25] 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

2.1.1 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 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.

2.1.2 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 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.

2.1.3 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.

2.1.4 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)

Part Three—Research

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).

2.2 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.

2.3 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 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.

Part Three—Research

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[26].

For the purposes of participation in clinical trials, anyone over the age of 16 years can consent on his/her own behalf[27]. 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.

[26] 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

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

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.

Older children, who are more capable of giving assent (i.e. children over the age of 7 years)[28], should be selected before younger children, unless there are valid scientific, age-related reasons for involving younger children first.

[28] 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

Part Three—Research

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 enroll 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.

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.

Part Three—Research

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 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[29,30], 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.

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.

[29] 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

[30] 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

Part Three—Research

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 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 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 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 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 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 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.

Part Three—Research

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 rigorous processes. 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 (DNAR)

Part Four—Do Not Attempt Resuscitation (DNAR)

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 (see also 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 5.6.1).

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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[31]. Decision-making capacity also depends on the ability of 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.

[31] See Part One section 5.5. for further provisions on the assessment of capacity

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.

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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[32].

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. In many cases, a sensitive but open discussion of end-of-life care will be possible in which individuals should be helped to understand the severity of their condition. However, it should be emphasised that this does not necessarily require explicit discussion of CPR or an 'offer' of CPR. 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.

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.

[32] 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

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 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.

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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[33]

- 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.

[33] 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

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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 (see also Section 4.1).

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 (see also 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.

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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[34]. 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.

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

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 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[35].

[35] 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.

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National Consent Advisory Group Membership

Name	Title	Organisation	Role
Deirdre Madden	Senior Lecturer, Faculty of Law	University College Cork	Chair
Angela Hughes	National Quality Lead	HSE, Quality & Patient Safety Division	Programme Lead, Deputy Chair
Ann Duffy	Clinical Risk Advisor Clinical Indemnity Scheme	State Claims Agency	Member
Anne Marie Loftus	Director of Nursing and Midwifery, Sligo General Hospital	Irish Association of Directors of Nursing and Midwifery	Member
Austin Warters	Manager of Older Persons Services	HSE	Member
Bill Ebbitt	General Manager, National Disability Unit	HSE, Integrated Services Division	Member
Caoimhe Gleeson	National Specialist in Accessibility & Equality Officer	HSE, Advocacy Unit, Quality & Patient Safety	Member
Catherine Whelan	Director, Independent Hospitals Association Ireland	Independent Hospitals Association Ireland	Member
Gary Davis	Deputy Data Protection Officer	Office of the Data Protection Commissioner	Member
Kevin Kelleher	Assistant National Director Population Health - Health Protection	HSE	Member
Mary Donnelly	Senior Lecturer, Faculty of Law	University College Cork	Member
Mary Dowling	Clinical Risk Manager	HSE, St. Lukes General Hospital, Kilkenny	Member
Mary O'Meara	Senior Medical Officer	National Immunisation Office	Member
Mary Vasseghi	Service User		Member
Phil Garland	Assistant National Director, Children & Families Services	HSE	Member
Samantha Hughes	Team Lead, Clinical Audit & Research Team	HSE, Dublin Mid Leinster	Member
Shane Brennan	Quality & Clinical Programmes Communications	HSE	
Shaun O'Keeffe	Consultant Geriatrician	HSE, Galway University Hospitals	Member
Siobhan O'Sullivan	Chief Bioethics Officer	Department of Health	Member
Winifred Ryan	Head of Standards and Guidance	HSE, Quality & Patient Safety Division	Deputy Chair until March 2012

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Information Leaflet – Data Protection

Occupational Guidance, Adult Day and Rehabilitative Training Services

Data Protection Legislation requires the HSE to safeguard your privacy rights in relation to the processing of your personal data.

You have a right to know what information is held about you and why that information is held.

The HSE will obtain and share relevant information for the purpose of providing you with an Occupational Guidance Service and/or a HSE Day service.

The HSE will

1. **Obtain relevant information and reports including medical reports that exist within the services listed below**
   - **The Health Service Executive (HSE);**
   - **HSE contracted service providers;**
   - **Education Service Providers;**
   - **The National Educational Psychological Service.**
   - **General Practitioners/Medical Consultants**

2. **Share this information, in strict confidence, for this purpose with third parties including statutory and voluntary organisation such as; the Department of Social Protection, Department of Education and Skills, SOLAS, and any HSE funded disability service providers involved in the provision of services appropriate to you.**

3. **Store and Disclose the information and reports obtained in accordance with Data Protection Legislation.**

Note: If a person is Under 18 then the family or advocate need to be informed.

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CHILDREN'S SERVICES REFERRAL FORM

Date of Referral	**Referrer**

SERVICE YOU WISH TO REFER TO (Please see attached sheet for addresses of local services)

Primary Care Services	**Children's Disability Services**
Children with non-complex needs should be referred to Primary Care. Copies of referral forms will be forwarded to all selected disciplines. Dietetics ☐ Physiotherapy ☐ Speech & Language Therapy ☐ Occupational Therapy ☐ Social Work ☐ Psychology ☐ Community Medicine Service ☐ Nursing ☐ Other ☐ (specify) _____	**Children with complex needs should be referred to Children's Disability Services** A child has complex needs if he or she has a range of significant difficulties that require the services and support of a disability team. **Children's Disability Network Team** ☐

CHILD'S PERSONAL DETAILS

Surname			**First name**		
Gender	**Date of Birth**		**Child's Age Years**	**Months**	
Address				**Eircode**	
Parent/Guardian 1 Name			**Parent/Guardian 2 Name**		
Relationship to child			**Relationship to child**		
Telephone	**Mobile**	**Email**	**Telephone**	**Mobile**	**Email**
Address (If different from the child's)			**Address** (If different from the child's)		

Country of Birth	**First Language** **Other languages spoken at home**	**Interpreter required** YES ☐ NO☐

Number of siblings, their ages and details of any services they are attending

REASONS FOR REFERRAL

What are the main concerns and priorities for the child and their family?	1.
	2.
	3.

GENERAL PRACTITIONER DETAILS

GP Name/Practice	GP Telephone	Email

GP Address

OTHER COMMUNITY HEALTHCARE SERVICES List all other services currently involved or waitlisted

Children's Disability Network Team ☐	**Primary Care:** Speech and language therapy ☐ Occupational therapy ☐ Physiotherapy ☐ Psychology ☐ Other (please give details) ☐
Child & Adolescent Mental Health Service ☐	**Tusla** ☐
Other (Please give details) ☐	

CRECHE, PRE-SCHOOL OR SCHOOL DETAILS (Attach any Preschool or School Reports)

Creche **Preschool** **Address**	**School** Child's Class **Address**
Manager/Contact Person	**Principal's Name**
Telephone **Email**	**Telephone** **Email**

MEDICAL HISTORY (Attach any relevant Medical Reports)

Relevant Medical History & Birth History
Any diagnosis e.g. medical condition, learning disability, developmental disorder, hearing impairment. There may be more than one. Who made the diagnosis and date?
If the child is currently in hospital what date is he/she expected to be discharged?
Current medications
Allergies/Adverse medication events
Current investigations e.g. blood tests, scans, hearing tests

SOCIAL CIRCUMSTANCES

Relevant family and social history
For example family health or housing difficulties, financial or employment problems, bereavement or other stresses.

ANY OTHER RELEVANT INFORMATION

Please indicate whether referrer should be contacted prior to the initial appointment **YES** ☐ **NO** ☐

Are there any relevant risk factors in relation to this referral?

CONSENT: Referrals without signed consent of parent(s) / guardian(s) will not be accepted.

It is required by law that at least one of the child's legal guardians consents to the referral and signs this form. It is advisable that both parents/legal guardians are aware of this referral.

Definition of a Legal Guardian

All mothers, whether they are married or unmarried, have automatic guardianship status in relation to their children, unless they give the child up for adoption. A father who is married to the mother of his child also has automatic guardianship rights in relation to that child. This applies even if the couple married after the birth of the child.

A father who is not married to the mother of his child does not have automatic guardianship rights in relation to that child. If the mother agrees for him to be legally appointed guardian, they must sign a joint statutory declaration. However an unmarried father is automatically a guardian if he has lived with the child's mother for 12 consecutive months after 18/1/2016, including at least 3 months with the mother and child following the child's birth.

Children in Care

For children in voluntary care or on an interim order, the parents must sign the consent. For children on a care order the consent is signed by a Tusla Child and Family Agency social worker.

Child's Name **Date of Birth**

- **I give permission for my child to be referred to Primary Care Services /Children's Disability Services.** YES ☐ NO ☐
- **I give permission for information about my child to be held by Primary Care Services/Children's Disability Services in accordance with obligations under the Data Protection Acts 1988, 2003 and 2018** YES ☐ NO ☐
- **I give permission that in the event that this referral is not appropriate it may be shared with other relevant services to facilitate an onward referral. I will be contacted in advance of this information being forwarded on to another service.** YES ☐ NO ☐
- **I give permission to Primary Care Services/ Children's Disability Services to contact and obtain relevant information in order to understand and address my child's needs from the professionals and services listed below, such as a hospital consultant, psychologist, speech & language therapist, teacher etc. Only those listed below will be contacted.** YES ☐ NO ☐

Name (if available)	Service	Contact Details

Name of Parent 1/Guardian

Signature

Date:

Name of Parent 2/Guardian

Signature

Date

REFERRERS DETAILS

Name: **Role (Parent/ Legal guardian, professional):**	**Date:**
Address:	**Telephone:** **Mobile:** **Email:**
Signature:	

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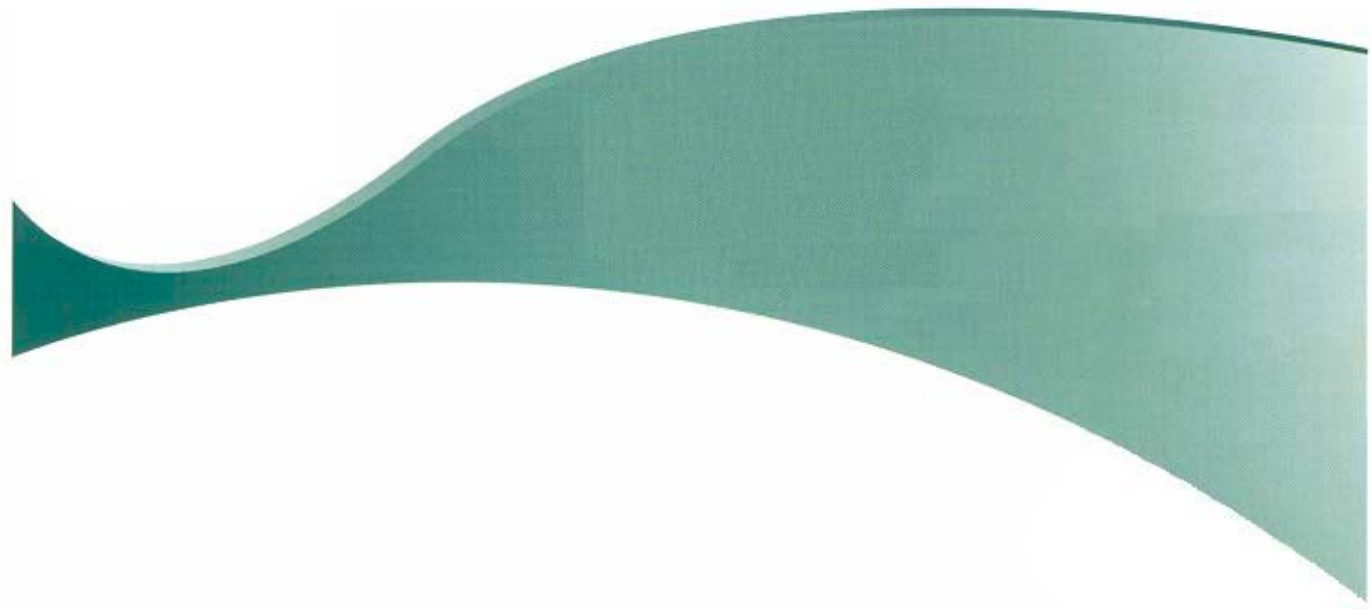
Health Service Executive

Privacy Impact Assessment (PIA) Form

Private & Confidential



This form should be completed with reference to the HSE Privacy Impact Assessment Process Guidance Document

Version2.0

June 2019

Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

Document Information

Title:	HSE Privacy Impact Assessment (PIA) Form
Purpose:	A PIA is a process to help identify and minimise the data privacy risks of a project or activity so as to ensure that patients and service users' rights to privacy and confidentiality are appropriately protected.
Author:	Joe Ryan
Publication date:	August 2018
Review Date:	August 2020

Contact Details

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Document History

Version	Owner	Author	Publish Date
2.0	HSE	Joe Ryan	June 2019

Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

Privacy Impact Assessment Form

Section 1 – Initial Details (Threshold Assessment)

Title of the activity:	Processing of data in Children's Disability Network Teams (CDNTs)
Name of person completing this form:	Dr. Michael Byrne
Title:	National Disability Specialist
Service Area:	Community Operations – Disability Team
Is personal data being collected or used?	Yes ⦸ No ☐
Are special categories of personal data being collected or used? (as listed below)	Yes ⦸ No ☐
If yes, indicate the categories involved:	⦸ Health data ☐ Data revealing racial or ethnic origin ☐ Political opinions ☐ Religious or philosophical beliefs ☐ Trade union membership ☐ Sex life data ☐ Genetic data ☐ Biometric data

If you answered 'No' to both of the questions above you do not need to complete the remainder of the form as a PIA is not required

If you answered 'Yes' to any of the questions above you may need to complete a PIA - answer the questions below to establish if a PIA is required:

Does the processing include the processing on a large scale of special category data?

Yes ⦸ No ☐

Could the processing likely result in a high risk to the rights and freedoms of data subjects?

Yes ☐ No ⦸

Does the processing include a systematic monitoring of a publicly accessible area on a large scale e.g. CCTV?

Yes ☐ No ⦸

Does the processing involve the automated processing, including profiling, on which decisions are based that produce legal effects concerning the data subjects?

Yes ☐ No ⦸

If you have answered 'Yes' to any of the four questions above then you need to complete the remainder of this form as a PIA is required.

In order to complete this form please note that it is obligatory for you to have completed the HSELanD GDPR/Data Protection Awareness training. Please confirm

that you have completed this training: Yes ⊘ No ☐

Section 2 – Activity Details

Briefly outline the activity (name, purposes, context of use, etc.)

Context
Variable from one geographical area to another, disability services were historically provided by the HSE, or by either Section 38 & 39 (Voluntary or non-HSE) organisations that provided specialist services focused on the type of disability a child had (e.g., intellectual disability; physical & sensory disability). Hence, some catchment populations had access to one type of disability service, yet little, if any, access to another type of disability service.

The HSE is committed to improving children's disability services by implementing the *Progressing Disability Services for Children & Young People (PDSCYP)* programme. The key elements of this programme are to

- Ensure each geographical area is served by a CDNT that provides a service to all children with disabilities regardless of their type of disability;
- Implement the Outcomes for Children & Families Framework (OCFF) in order to provide an outcomes-focused, holistic, & more effective service to children & their families;
- Develop operational efficiencies in service delivery in order to get the best possible value from available resources;
- Make the service, & its management, more responsive through better use of feedback & operational information; &
- Have uniform standards & levels of service across the CDNTs involved in service delivery.

There will be 91 Children's Disability Network Teams (CDNTs; see Appendix A). While some have already reconfigured, those that have yet to will reconfigure in Q2 2021. Serving an estimated 42,000 children and their families, these CDNTs will be staffed by up to 2,000 CDNT members. Each CDNT will be led by a lead agency such as the HSE, or one of a number of Section 38 or 39 (Voluntary) Organisations (e.g., Brothers of Charity, Daughters of Charity, Enable Ireland). Irrespective of who is the lead agency, most CDNTs will be made up of employees from different organisations (e.g., HSE & non-HSE).

Existing data management practices
An estimated 36% of the above mentioned CDNTs will use only a paper-based record system, while the remaining 64% will use a variety of Voluntary Organisation & HSE information management systems (often in combination with a paper-based record system).

In the context of migrating only the data of current service users & CDNT staff, lead agencies will be required to migrate data from existing service provider/HSE data systems to their new CDNT.

CDNT data processing needs to

- Facilitate recording information including service users/families desired outcomes, strategies to achieve these outcomes, related goals & what is deemed to be progress in terms of these goals & subsequent therapy needs/plan. It will allow for the development common systems to measure outcomes (in keeping with the OCFF) being achieved, & to identify what approaches & inputs are most effective with particular groups;
- Facilitate the collection of standardised information on provision, need & outcomes that will help guide a more robust system of forecasting therapy requirements & service planning;
- Support CDNTs in adhering to agreed CDNT work processes (HSE, 2018), & as such, will enable

the development & use of common definitions & understanding of, for example, what constitutes a waiting list.

- Facilitate use of the standardised referral forms from the National Policy on Access to Services for Children & Young People with Disability & Developmental Delay (HSE, 2016) that determines the appropriate pathway for accessing health services for children with disability or developmental delay; &
- Provide data for the National Ability Support System (NASS) that is managed by TEKenable Ltd. on behalf of the Health Research Board.

Describe how the activity generally works (from data collection to data destruction, different processing stages, storage etc.) give a detailed description of each of the processes carried out.
Appendix B profiles the work processes that CDNTs need to adhere to (HSE, 2018). As per above, some CDNTs will use only a paper-based record system; some will use one or more Voluntary Organisation or HSE information management systems; and others will use both a paper-based system as well as one or more Voluntary Organisation or HSE information management systems.

While all members within the same CDNT will have access to all of the files of children attending that CDNT, each child's file will have a red-tab folder that the CDNT's Children's Disability Network Manager (CDNM) & whoever else the CDNM deems appropriate will have access to (e.g., Freedom of Information requests; complaints; select completed test forms).[1]

All paper records related to a child will be kept in hard files in lockable fire / tamper proof filing cabinets in rooms that have either a standard or a coded lock. Access to service buildings will be restricted to staff & to those given access by reception. Discharged hard files will be archived.

Laptops & USB will be used in accordance with HSE Information Technology Acceptable Usage Policy.

Complete hard files that are transferred between the services (e.g., if a family moves from one catchment area to another within a Community Healthcare Organisation [CHO] or between CHOs), will be brought to the new CDNT by a member of the old CDNT or by registered post, & a transfer form will be signed by the new CDNT acknowledging receipt of same.

Restricted Service User data (e.g., Freedom of Information requests; complaints) will be stored in a red-tab folder in each child's file either in a locked filing cabinet in a locked room or on the information management system in use.

Destruction of Files:
Records will be kept in accordance with the HSE policy for Record Retention Periods 2013 HCR10. This notes that "*records in relation to children & young people are retained until the patients 25th birthday or 26th birthday if the young person was 17 at the conclusion of treatment, or 8 years after death. If the illness or death could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain the records for longer periods. Records created under Childcare Acts are to be retained in perpetuity (forever).*" However, this does not apply for people who have a mental disorder as defined in the Mental Health Acts 1945 to 2001. Their data will be kept for 20 years after their last treatment or 8 years after their death. It should be noted that this policy references 'at the conclusion of treatment.' Therefore, if the child is still attending the HSE/agency disability services as an adult, then their records can remain until 8 years after final entry or 8 years after death.

What is the legal basis for processing the data?

☐ Consent from the data subject.

[1] Data minimisation is a principle of data protection. Hence, it is appropriate to restrict access on a necessity & proportionality basis based on clinical advice.

☐ Processing is necessary for the performance of a contract.

☐ Processing is necessary for a legal obligation to which the HSE subject.

☐ Processing is necessary to protect the vital interests of the data subject.

⦸ Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the HSE.

If processing special categories of data what is the legal basis?

☐ Explicit Consent (Service User)

⦸ For the purposes of preventative or occupational medicine, for the assessment of the working capacity of an employee, for medical diagnosis, for the provision of medical care, treatment or social care, for the management of health or social care systems & services. Or pursuant to a contract with a health practitioner.

☐ Other (please state)

If applicable describe the relevant legal obligation (act, regulation, article etc.):

Under EU GDPR Article 6, "Lawfulness of processing", data is processed under section 1(e) processing is necessary for the performance of a task carried out in the **public interest** or in the exercise of official authority vested in the controller

Under EU GDPR Article 9, "Processing of Special Categories of personal data", data is processed under section 2.(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems & services **on the basis of Union or Member State law or pursuant to contract** with a health professional & subject to the conditions & safeguards referred to in paragraph 9.3;

Under the Health Acts of 1947-2019.

Name the Data Controller(s) involved in this activity:

Heads of Disability Services, CHO, HSE.

Describe the Role of the data controller(s) for this activity:

All agencies who have staff on a CDNT will be considered Joint Data Controllers. To be profiled in a Data Sharing Agreement (see Appendix E), the role of the Joint Data Controllers will be to have systems in place to ensure that:

1. Data collected on the IMSs have a lawful basis to process the relevant personal data;
2. All CDNT members are fully informed of the HSE data protection & ICT security policies & procedures;
3. All CDNT members are fully informed of the rights of the service user under GDPR;
4. All will be fully compliant with GDPR legislation;
5. Procedures & audits are in place to ensure the CDNT is meeting its legislative data protection requirements under GDPR;

6. Third-party stakeholders who provide Technical Support for the IMS in use will be fully compliant with GDPR legislation. They will complete, sign & submit to the HSE ICT Security Officer both a standard HSE Data Processing Agreement & a HSE IT Supplier Security Questionnaire;
7. The Joint Data Controllers must approve all new users to the IMS & give access based on role within the service e.g., Health & Social Care Professionals & other staff (e.g., Administrators) will only provide a service to service users in their allocated CDNT catchment area; &
8. Data breaches will be managed promptly & in line with HSE Data Protection policy (https://www.hse.ie/eng/gdpr/hse-data-protection-policy/hse-data-protection-policy.pdf)

Provide details of all data processors involved in this activity:

The Joint Data Controllers must approve all new users to the IMSs & give access based on role within the service e.g., Health & Social Care Professionals & other staff (e.g., Administrators) will only provide a service to service users in their allocated CDNT catchment area.

The Data Processors will be:
1. IMS Project Team;
2. Whoever is providing technical support; & the
3. Health Research Board (who may access data via NASS returns)

Describe the role of data processor(s) as relevant to this activity:

See Table 1 in immediate below section.

For each data processor, describe their responsibilities (duration, scope, purpose, documented processing instructions, prior authorisation, contracts in place) for this activity:

Table 1. Data processors.

Processor	Role /Responsibility	Duration	Supporting documentation/Contracts
IMS Project Team	Identifying requirements, agree work plans, software development, UAT, data migration, risk & issue management, user training, DPIA, & benefit analysis	Life time of project OoCIO staff	
Technical Support Contractor	Deal with technical issues not managed by Superusers or HSE ICT	Annual licence	Service Level Agreement; HSE Data Processing Agreement; HSE IT Supplier Security Questionnaire; HSE Confidentiality Agreement
Health Research Board (HRB)	Research to help plan, develop, organise & budget for further Disability Services	Lifetime of role with CDNT	Joint Data Controller Agreement between HRB & TeKenable
TEKenable Ltd	Deal with technical issues on NASS system used in HRB not managed by Superusers	Annual licence	Confidentiality Agreement with HRB

Provide details of all data sub-processors involved in this activity:

There are no sub-processors of the information management systems.

Does the activity use automated decision making? Yes ☐ No ⊘

If 'Yes' briefly describe the automated decision making

No information management system uses automated decision making. However, some systems will automatically generate metrics or KPIs.

If 'Yes' what are the consequences of the automated decision making for the data subject:

Not applicable.

Explain why all personal data collected is necessary for the purposes of your processing:

In the context of the principle of data minimisation, the personal data collected is required to allow identification of service user records; facilitate communication with service users & their guardians; & to support provision of a service to them (see Appendix C for a list of data fields).

List the data supporting assets (hardware, software, networks, people, paper or paper transmission channels):

Hardware – HSE & non-HSE PCs & laptops utilising networked sites & some with VPN links except where specified below:

- Some staff will use their securely locked PCs to access their information management system. Their policy is that no client data is stored on these PCs. Some use their agency's shared drive before uploading finalised documents to the CDNT's information management system; &

Software – Dependent on what IMS each CDNT uses.

Server – While dependent on what information management system each CDNT uses, where possible, all data within each information management system will be stored on HSE servers in a HSE recommended secure environment.

Shared drive – While dependent on what information management system each CDNT uses, some CDNTs will be on the HSE Network Shared Drive, while some will not be. However, all CDNTs will sign an Information Technology Acceptable Usage Policy (AUP) statement & adhere to the requirements of the HSE Information Technology AUP particularly around secure document storage outside of the information management system used.

Staff – Health & Social Care Professionals; Nurses; Administrative support; Children's Disability Programme Lead & Project Manager; Senior Executive Officer, Disability Services; & Project Team.

Paper – Some CDNTs will use only paper-based records. For other CDNTs, referral forms will be scanned to their information management system. Letters to clients will be generated by their information management system. Reports will be uploaded to their information management system, as will other materials necessary for the provision of services.

Is the personal data going to be shared? Yes ⊘ No ☐

If yes, list the recipients (or categories of recipients) of the personal data and for what purpose it is being shared:

Table 2. Recipients of personal data; & the purpose of sharing it.

Recipient – Includes but not limited to:	**Purpose - Includes but not limited to:**
• Pre-schools • Access Inclusion Model (AIM) staff & Pobal • Schools • Special Education Needs Officer (SENO) • Dept of Education	• To inform resource or support allocation • To inform adaptations necessary to allow child to attend the service • To inform learning goals • Therapy programmes
• Other agencies or professionals (e.g., GP, medical teams, Tusla, etc.)	• To inform of current situation & plan of care to allow them to plan their service for the child • To refer to their services • To seek additional information to inform current service • Information required by law or ordered by a court.
• Emergency services • Gardai	• In the event of emergency • In the event that we feel the child we are dealing with is at immediate risk of abuse; child, parent or guardian being a potential safety risk to themselves or others; identifiable other child(ren) being potentially at risk of harm from others
• Assessment Officers &/or Liaison Officer	• To enable them to plan for & assess child's needs
• Approved volunteers & health & social care students (e.g., nursing; occupational therapy; physiotherapy; social work; speech & language therapy; psychology; early intervention)	• To allow them to provide services to children & young people & their families
• *Technical Support Contractor* who will have a Service Level Agreement (SLA) with the HSE	• *Technical Support Contractor* may have cause to access data when developing the information management system &/or when there is a technical issue unresolved by an information management system Superuser or HSE ICT support
• Health Research Board (HRB)	• Data that is imported automatically to their NASS helps to plan, develop, organise & budget for further disability services • There is a Data Sharing Agreement in place
• TEKenable Ltd (an Irish-based company) that has a SLA with the HRB to provide technical support for the NASS	• Uses a Secure File Transfer Protocol (FTP) to upload the csv files for NASS import

Is the data being sourced from another source? Yes ☐ No ⊘

If yes, please state where the data originates from and if applicable, did it come from a publicly accessible source:

What is the retention period for the different items of personal data:

Records will be kept in accordance with the HSE policy for Record Retention Periods 2013 HCR10. This notes that "*records in relation to children & young people are retained until the patients 25th birthday or 26th birthday if the young person was 17 at the conclusion of treatment, or 8 years after death. If the illness or death could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain the records for longer periods. Records created under Childcare Acts are to be retained in perpetuity (forever).*" However, this does not apply for people who have a mental disorder as defined in the Mental Health Acts 1945 to 2001. Their data will be kept for 20 years after their last treatment or 8 years after their death. It should be noted that this policy references 'at the conclusion of treatment', therefore if the child is still attending the HSE/agency disability services as an adult then the records can remain until 8 years after final entry or 8 years after death.

Describe the steps taken to ensure that the personal data is kept up to date and accurate:

1. 'Good Information Practices' training (www.hse.ie/good-info-practices) will be provided by the HSE to all information management system users. This will include functionality that necessitates clinical note entry within 7 days of an appointment (though addenda can be added, the number of which will be collated for each CDNT to keep track of whether delayed recording entry is problematic); & a process of personal data checking at the beginning of each intervention with each service user; &
2. Annual audit of personal data held by the CDNT will include a review of current practice to ensure service users' data is kept up to date & secure.

How are data subjects informed of the processing?

Referred children / families who either do or do not engage with a CHO's CDNT will be informed of how their data will be processed (see Data Protection Information Leaflet in Appendix D).

How can data subjects exercise their right to access and to data portability under Article 15 and Article 20 of the GDPR?

Service users can apply to for a copy of their records by completing a Subject Access Request form (that is available on www.hse.ie/eng/gdpr). The completed form must then be sent to the relevant Data Protection Decision Maker. A letter requesting access to records will also be accepted. Once the identity of the service user has been verified, the request for data will be processed within one month. This record will be made available in a portable format.

How can data subjects exercise their right to rectification and erasure under Articles 16 & 17 of the GDPR?

Right to Rectification
GDPR Article 16 notes that 'the data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her. Taking into account the purposes of the processing, the data subject shall have the right to have incomplete personal data completed, including by means of providing a supplementary statement.'

In our sample CDNT Data Protection Information Leaflet (see Appendix D), we've included the following:

Rights under GDPR
You have certain legal rights concerning your information/your child's/children's information & the manner in which we process it. This includes:

- A right to request us to correct inaccurate information, or update incomplete information.

Regarding any requests you have to correct inaccurate information, or update incomplete information on

your child's record, you can ask your CDNT Manager.

Right to Erasure
The Right to Erasure, also known as the Right to be Forgotten, is defined via GDPR Article 17. Paragraph 3 of this Article defines the reasons whereby the right to erasure does not apply. Paragraph 3(c) notes that the right to erasure shall not apply to the extent that processing is necessary for reasons of public interest in the area of public health in accordance with point (h) & (i) of Article 9(2).

The legal basis for collection & processing of data, as defined in this document, pertains to the use of Article 9(2)(h), i.e. whereby the information management system will be critical to the management of CDNTs, & in ensuring the HSE understand the quantum of existing service usage & future service demand in order to plan for the provision of services to meet future needs of people with complex disability.

In order to ensure data exists for the management of CDNTs, the right to erasure of data shall not apply to the extent that processing of data is necessary for reasons of public interest in the area of public health, as per Article 17(3)(c).

How can data subjects exercise their right to restriction and object under Article 18 and Article 21 of the GDPR?

In our sample Children's Disability Network Team Data Protection Information Leaflet (see Appendix D), we've included the following:

Rights under GDPR
You have certain legal rights concerning your information/your child's/children's information & the manner in which we process it. This includes:

- A right to request that we restrict the processing of the information in certain circumstances.

Additionally, should a family wish to apply to restrict processing of their data, they can make a request directly to the CDNT manager, noting what data they want restricted & why. While a request can be verbal or in writing, we recommend they follow-up any verbal request in writing because this will allow them to explain their concern, give evidence & note their desired solution.

Service users will be informed that the acquisition & storage of their data is fundamental to their CDNT providing a service to them (i.e. they are not being asked to consent to store their data); but they can request to have processing of their data restricted.

Is the personal data being transferred outside of the Republic of Ireland? Yes ☐ No ⊘

If yes, list the countries where the personal data is to be transferred:

Not applicable.

For each country outside of the EEA (European Economic Area) where data is stored or processed, name it and describe the provisions concerning the transfer:

Not applicable.

Describe the organisational security measures associated with this activity:

Service Building:

- Access to service buildings is restricted to CDNT staff & those given access by reception.

Hard files & local register-based files:

- Hard file copies will be kept in lockable fire / tamper proof filing cabinets in a lockable room in all centres.

Describe the technical security measures associated with this activity:

Infrastructure:
All users will be set up on an Active Directory that ensures authentication of all users. Standard Operation security procedures will be in place as per ICT best practice.

With regard to information management systems (IMSs):

- IMS data will be stored in a secure centrally located site that either the HSE &/or a Section 38/39 agency manages & controls in accordance to industry best practice;
- IMS access will be given only to those providing or supporting the CDNTs. This access will have to be approved by the CDNT managers or senior disability management;
- Access to the data seen by approved personnel will be specific to their role;
- Log-in to the IMSs used will require a unique Username & Password that will have to be updated at a minimum every 90 days;
- Serving as an electronic signature, each CDNT member will have to enter a unique 4-digit Personal Identification Number (PIN) when signing off on entries to their IMS. This PIN will have to be updated at a minimum every 90 days;
- To manage the risk associated with inappropriate activity on the IMS from non-employees (e.g., students & approved volunteers), these individuals will be set up as IMS users (e.g., they will have their own Username, Password & 4-digit PIN for the IMS) & their entries will be counter-signed by their supervisor (i.e. by the supervisor using their own PIN) before such entries will be committed to a child's IMS file.
- While Data Processors outside the HSE such as Section 38 & 39 Organisations will access their IMS through a secure access gateway Citrix Access Gateway CAG, the Technical Support Contractor will access the IMS through a HSE supplied VPN connection;
- Approved users will be added to an active directory security group within the HSE Network;
- Passwords & PINs will adhere to HSE password policies;
- Service User records will be segregated so that Health & Social Care Professionals (HSCPs) & admin staff will only have access to the records within their CDNT;
- Each IMS file will include a red-tab folder for local register-based records such as complaints & FOI; &
- All IMS records will be backed up daily at night.

Networked Shared Drive:

- Specific to each CDNT, to be accessed only when permission is granted on the basis of being an active CDNT member. Each CDNT's shared folder or file share will accommodate the drafting of documents (e.g., CDNT-based assessment reports that various CDNT members contribute to), all of which will be backed up daily at night:
    - Some CHO CDNTs will have their file share on a HSE server;
    - For those Voluntary Organisation-led CDNTs that will use their own network file share, these organisations will comply with the various HSE ICT-related policies; &
    - All draft files will be deleted once they are uploaded to the IMS.

Staff PC/Laptop:

- Will be accessed only by username & password. PC passwords will be updated every 90 days;
- Laptops will be used in accordance with the HSE Information Technology Acceptable Usage Policy; &
- CDNTs will phase out the use of HSE-encrypted USBs. In the interim, & as per the HSE Encryption Policy, such USBs will only be used in exceptional circumstances where it is essential

to store or temporarily transfer confidential or restricted information (e.g., when transferring information to a HSE encrypted laptop if there is a need to work off site, or use information for parent training etc.).

Describe the additional measures taken to ensure data security for this activity:

The existing measures outlined above are considered to collectively provide an adequate level of security.

Section 3 – Research

Please complete the following section only if you are completing this PIA as part of a research proposal.

If you are not completing this PIA as part of a research proposal you can go immediately to Section 4.

Please specify what arrangements are in place to ensure that personal data will be processed as is necessary;

(a) to achieve the objective of the health research and;

(b) to ensure that data shall not be processed in such a way as to damage or distress the data subject:

Not applicable.

The provision of training in data protection law and practice to anyone involved in carrying out the health research is a mandatory legal requirement. Please specify the data protection training undertaken by those involved in this research:

Not applicable.

Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased:

Not applicable.

Please specify the arrangements to anonymise, archive or destroy personal data once the health research has been completed and how this will be carried out:

Not applicable.

Please specify other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with process for testing and evaluating the effectiveness of such measures:

Not applicable.

Section 4 – Risks and Risk Mitigation	
Is there a risk of:	a. ⦸ Illegitimate access to personal data b. ⦸ Unwanted modification to personal data c. ⦸ Personal data disappearance d. ☐ Other (please state)

Section 4 (a) – Illegitimate access to personal data

Complete the following questions if you selected a. (Illegitimate access to personal data)

What are the main threats that could lead to the risk?

1. Correspondence &/or printed data left on office desks or, trays not concealed;
2. Correspondence received/sent via email risk being hacked or going to wrong recipient;
3. Business Scanners / photocopiers / fax machines in public waiting area;
4. Hardcopy data being stored for indefinite periods;
5. Personal Data in clients hard copy file, risk when file lost or mislaid;
6. Personal Data in staff diaries if diary lost or mislaid.

What are the potential impacts on data subjects arising from the risk?

Moderate.

What are the risk sources?

1. Staff error / negligence e.g., not clearing desk space; leaving electronic files opened & unattended; send correspondence to an incorrect address or the wrong recipient; mislaying paper-based records & one's diary;
2. External stakeholders breaking into locked filing cabinet in locked office were paper-based records are stored, or hacking into electronic files.

What controls are in place to address the risk and are these controls adequate?

1. A clear desk policy will be put into place in all services where all printed data must be stored securely when staff not at their desks.ge & clear desk policy;
2. All CDNT staff will review & sign HSE IT Acceptable User Policy (4.4, 4.5). All personal data sent via email will be sent from a @hse account or via encrypted email. All attachments to these emails containing personal data will be in a password protected document. Recipient will be contacted by telephone with password;
3. All such equipment should be removed from public waiting areas;
4. The CDNT will review the case & find out from the family if the person continues to avail of HSE services in relation to their disability, & proceed accordingly. If the Section 38 or 39 agency involved has their own record retention policy that states that records must be held longer that this time, the option of transferring the file to them for retention will be considered;

5. Hard copy file will be removed from the service building in exceptional circumstances only, only data absolutely relevant will be taken off site & then returned to the child's file upon return to the service. No personal data will be left unattended in cars & will always be contained in a suitable brief case/bag to avoid any inappropriate viewing & also to secure the record. Staff should not take healthcare records home. However, in exceptional cases, where this cannot be avoided, such records must be stored securely. Healthcare records should not be left in a car overnight but stored securely indoors. When a child is transferring to another CDNT within a CHO, it will be delivered in person by a member of the original CDNT or by registered post, & a form will be signed by the new CDNT accepting the file; &
6. Use of diaries as per HSE data protection policy. Client Name & appointment time in diary only.

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

- ☐ 1 – Rare
- ☐ 2 – Unlikely
- ⦸ 3 – Possible
- ☐ 4 – Likely
- ☐ 5 – Highly Certain

How do you estimate the potential impact of the risk on data subjects?

- ☐ 1 – Negligible
- ☐ 2 – Minor
- ⦸ 3 – Moderate
- ☐ 4 – Major
- ☐ 5 – Critical

What is the overall risk rating (likelihood x impact)?

- ☐ Low
- ⦸ Medium
- ☐ High

Section 4 (b) – Unwanted modification to personal data

Complete the following questions if you selected b. (Unwanted modification to personal data)

What are the main threats that could lead to the risk?

Where IMSs are used:

1. Service user data may be corrupted by a user error;
2. Service user data may be corrupted by a supplier error; &
3. Service user data may be corrupted by a system error.

What are the potential impacts on data subjects arising from the risk?

Minor.

What are the risk sources?

1. CDNT members error / negligence e.g., inputting dated data; inputting data into the wrong child's file;
2. Support contract error e.g., not having a separate test site & inadvertently making technical changes to a live information management system during training provision;
3. Less-than-optimal maintenance of system (e.g., daily back-up), for example, by Office of the Chief Information Officer).

What controls are in place to address the risk and are these controls adequate?

1. Staff training will be provided, as will ongoing support;
2. Ensuring there are separate & training systems;
3. Data will be backed up at night every 24 hours on the IMS &, if available, on a shared file; &
4. There's no evidence of this having happened to date.

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

- ☐ 1 – Rare
- ⦸ 2 – Unlikely
- ☐ 3 – Possible
- ☐ 4 – Likely
- ☐ 5 – Highly Certain

How do you estimate the potential impact of the risk on data subjects?

- ☐ 1 – Negligible
- ⦸ 2 – Minor
- ☐ 3 – Moderate
- ☐ 4 – Major
- ☐ 5 – Critical

What is the overall risk rating (likelihood x impact)?

- ⦸ Low
- ☐ Moderate
- ☐ High

Section 4 (c) – Personal data disappearance

Complete the following questions if you selected c. (Personal data disappearance)

What are the main threats that could lead to the risk?

1. Hardcopy data stored outside service premises between clinics.

What are the potential impacts on data subjects arising from the risk?

Moderate.

What are the risk sources?

1. CDNT members error / negligence e.g., losing or leaving files unattended.

What controls are in place to address the risk and are these controls adequate?

1. Clinics will be held in an area with sufficient network access where possible to allow data to be entered directly into an IMS. Where a venue has no network access (e.g., school), staff will be expected to write their notes & upload the note to their IMS & add to the child's hard file or shred the note on return to the service. Records will always be contained in a suitable brief case/bag to avoid any inappropriate viewing and also to secure the records. All files & portable equipment must be stored securely. If files containing personal information must be transported in a car, they will be locked securely in the boot for the minimum period necessary. Staff will not take healthcare records home. However, in exceptional cases, where this cannot be avoided, the records will be stored securely. Healthcare records will not be left in a car overnight but stored securely indoors. When no network is available, soft copy of notes will be stored on a file share on a password-protected PC. This will be included in GDPR training.

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

- ☐ 1 – Rare
- ☐ 2 – Unlikely
- ⦸ 3 – Possible
- ☐ 4 – Likely
- ☐ 5 – Highly Certain

How do you estimate the potential impact of the risk on data subjects?

- ☐ 1 – Negligible
- ☐ 2 – Minor
- ⦸ 3 – Moderate
- ☐ 4 – Major
- ☐ 5 – Critical

What is the overall risk rating (likelihood x impact)?

- ☐ Low
- ⦸ Moderate
- ☐ High

Section 4 (d) – Other

Complete the following questions if you selected d. (Other)

Describe in detail the risk

Not applicable

What are the main threats that could lead to the risk?

Not applicable

What are the potential impacts on data subjects arising from the risk?

Not applicable

What are the risk sources?

Not applicable

What controls are in place to address the risk and are these controls adequate?

Not applicable

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

- ☐ 1 – Rare
- ☐ 2 – Unlikely
- ☐ 3 – Possible
- ☐ 4 – Likely
- ☐ 5 – Highly Certain

How do you estimate the potential impact of the risk on data subjects?

- ☐ 1 – Negligible
- ☐ 2 – Minor
- ☐ 3 – Moderate
- ☐ 4 – Major
- ☐ 5 – Critical

What is the overall risk rating (likelihood x impact)?

- ☐ Low
- ☐ Medium
- ☐ High

Section 5 – Data Subject Consultation

Were data subjects (or a representative) consulted as a part of the PIA process? ☐ Yes ⦸ No

If Yes, state the number of data subjects consulted, method of consultation and describe the outcome of the consultation:

If No, explain the reasons for not consulting data subjects:

While service users in some areas may have had input into deciding how data is stored & processed, there is a strong culture of consulting service users & parents as to what they require from their CDNTs. For example, parent satisfaction surveys have been consistently undertaken in various CDNTs, with parents also contributing to the formulating measures used in such satisfaction surveys.

Our (national) Progressing Disability Services Steering Group (that includes service users) has also

discussed how CDNTs process data.

Section 6 – DPO/DDPO Consultation
DPO opinion (please ensure the previous questions are completed fully before the DPO can provide an opinion):

Section 7 – Approval ***To be completed by the data controller***
Outcome: ☐ Approved ☐ Denied ☐ DPC Consultation Needed ☐ Further Updates Needed
Signed: _____ **Date:** _____

Appendix A - Children's Disability Network Teams

Table 3. Children's Disability Network Teams.

CHO	WTE's	No. of staff	How data is stored
CHO 1			
1.	• 9 • 9	• 10 • 10	• Goldmine • Microsoft Access
2.	• 12.6 • 8	• 14 • 8	• Goldmine • Microsoft Access
3.	8.1	9	Microsoft Access
4.	18.6	19	Microsoft Access
5.	13	n/a	Microsoft Access
6.	20	n/a	Microsoft Access
7.	6	n/a	Microsoft Access
Total*		**123**	
CHO 2			
1.	22	24	Paper-based
2.	27	38	Paper-based
3.	10 12	16 17	• Paper-based • Paper-based
4.	19	26	Paper-based
5.	11	15	Paper-based
6.	n/a	16 15	• Microsoft Access • Paper-based
7.	15	35	• Electronic • Goldmine • Paper-based
8.	16	36	• Electronic • Goldmine • Paper-based
9.	14	n/a	• Electronic • Goldmine • Paper-based
Total*		**267**	
CHO 3			
1.	19	24	MIS
2.	25	29.5	MIS
3.	19	21	MIS
4.	33	21	MIS
5.	24	26	MIS
6.	33	36	MIS

Total		**158**	
CHO 4			
1.	17	20	Paper-based
2.	19	23	Paper-based & Goldmine
3.	20	25	Paper-based
4.	13	15	Paper-based
5.	22	25	Paper-based & ECRC
6.	15	n/a	Paper-based & ECRC
7.	15	n/a	Paper-based & ECRC
8..	15	n/a	Paper-based & Adest
9.	15	n/a	Paper-based
10.	15	n/a	Paper-based & Adest
11.	15	n/a	Paper-based
12.	15	n/a	Paper-based & Goldmine
13.	15	n/a	Paper-based
14.	15	n/a	Paper-based & Goldmine
15.	15	n/a	Paper-based
Total*		**324**	
CHO 5			
1.	24	n/a	Paper-based
2.	-	n/a	Paper-based
3.	• 24 • 26	n/a	• Goldmine • Paper-based
4.	13	n/a	Paper-based
5.	12	n/a	Paper-based
6.	-	n/a	Paper-based
7.	25	n/a	Citrix IT system
8.	n/a	n/a	Paper-based
9.	n/a	n/a	Paper-based
10.	n/a	n/a	Paper-based
11.	n/a	n/a	Paper-based
12.	n/a	n/a	Paper-based
Total**		**221**	
CHO 6			
1.	18	20	Goldmine
2.	18	22	Goldmine

3.	16	22	Goldmine
4.	16	20	Paper-based
5.	25	28	Goldmine
6.	14	16	Goldmine
7.	14	16	Paper-based
Total		**144**	
CHO 7			
1.	25-30	n/a	Basic Access
2.	25-30	n/a	Goldmine
3.	25-30	n/a	Basic Access
4.	12-20	n/a	Microsoft Access or Excel database
5.	12-20	n/a	Microsoft Access or Excel database
6.	10-15	n/a	Microsoft Access or Excel database
7.	15-25	n/a	Microsoft Access or Excel database
8.	15-25	n/a	Microsoft Access or Excel database
9.	15-25	n/a	Microsoft Access or Excel database
10.	15-20	n/a	Microsoft Access or Excel database
11.	15-25	n/a	Microsoft Access or Excel database
Total**		**221**	
CHO 8			
1.	20	25	Microsoft Access
2.	25.11	26	Microsoft Access
3.	13	9	Goldmine
4.	20	34	Goldmine
5.	15	22	• Goldmine • Paper-based
6.	12	13	Goldmine
7.	23	24	Filemaker
8.	12.5	17	Filemaker
9.	10	11	Filemaker
10.	19.8	26	Filemaker
11.	n/a	n/a	Filemaker
12.	23.45	28	Filemaker
Total*		**257**	
CHO 9			
1.	25	30	Clinical manager

2.	25	30	Clinical manager
3.	14	17	Paper-based
4.	14	17	Paper-based
5.	20	24	Paper-based
6.	17	20	Paper-based
7.	14	17	Paper-based
8.	14	17	ECRS
9.	14	17	Paper-based
10.	17	20	Clinical Manager
11.	25	30	ECRS
12.	25	30	ECRS
Total		**269**	
	TOTAL**	**1,983**	

Notes
*Pro-rated across a particular CHO's CDNTs; **Pro-rated across all CHOs
In many instances, CDNTs will be formed by bringing together an existing 0-5 Early Intervention Team (EIT) & a 6-17-yr-old School Age Team (SAT).

Abbreviations
ECRS=Electronic Client Record System as developed in conjunction with Epic Solutions, Cork; MIS=(HSE-owned) Management Information System.

CHO 2
- Yet to be reconfigured, there are 60 staff working in Galway School Age Services. Hence, as added to the total of each CDNT WTE, an average of 12 will be available to work in each of the five SATs in Galway;
- All the EITs in Galway use paper files for each child given that (1) staff employed by an agency & working in that agency site can use their IT system but that information must be printed & placed in the child's file & other members of that team will not have access to it; & (2) there is a shared drive in some of the EIT's but HSE staff do not have access to it.

CHO 4
- There are 151 WTE's for the 10 yet-to-be-configured CDNTs. Hence, this equates to an average of 15 WTE's per CDNT.

CHO 5
- As the division of staff between Primary Care and Social Care has yet to be finalised, these WTE's are estimates.

CHO 6
- There are 63.97 WTEs due to reconfigure in Dublin South and 52.78 in Wicklow. This gives an average breakdown for each CDNT as 16 and 17.5 respectively, though this will be influenced by other factors (e.g., the child population that a CDNT caters for).

CHO 7
- As the 'Expressions of Interest' process has not been completed, we do not yet know what agencies will be working in what CDNTs.

Appendix B – Children's Disability Teams & Agreed Work Processes (HSE, 2018)

Introduction

Working in partnership with our Disability Voluntary Organisations, the HSE is currently engaged in the implementation of the Progressing Disability Services for Children & Young People (0-18s) Programme. This involves a reconfiguration of existing disability services to geographically-based, 0-18 years Children's Disability Network Teams (CDNTs). The objective of this programme is to provide equity of access & one clear referral pathway for all children (0-18s), irrespective of their disability, where they live or of the school they attend.

The *National Policy on Access to Services for Children & Young People with Disability & Developmental Delay (HSE, 2016)* – hereafter referred to as the 'National Policy on Access' – is currently being rolled out nationally. This policy facilitates all stakeholders in establishing children's complexity of need that in turn will inform what services will be most appropriate for each child.

Supporting the above processes, the National (Disability) Children's Services Team have agreed, & presents here core procedures of service delivery (i.e. the work processes that these services will have to adopt), & some detail as to how the in-development (national) CDNT Information Management System (CDNTIMS) will support these procedures.

1. Core Procedures

Alignment with existing policies / documents

These core procedures are aligned with various policies / documents including

- The National policy on prioritisation of referrals to Children's Disability Network Teams (HSE, 2016);
- The National Policy on Access to Services for Children & Young People with Disability & Developmental Delay (HSE, 2019);
- The National Policy on Discharge/Closure & Transfer from Children's Disability Network Teams (HSE, 2017);
- The Guidance on Individual Family Service Plans (HSE, 2017);
- The Joint Working Protocol Primary Care, Disability & Child & Adolescent Mental Health Services (HSE, 2017); &
- The Assessment of Need (AoN) Standard Operating Procedure (HSE, 2020).

Referral pathways to children's disability teams

- Referrals[2] (from a variety of stakeholders) to children's disability teams will require completion of two forms:
  1. The National Policy on Access 'Children's Services Referral Form'; &
  2. One of the five National Policy on Access age-appropriate 'Additional Information Forms':
     - Birth to 11 months;
     - 12 months to 2 years 11 months;
     - 3 years to 5 years 11 months;
     - 6 years to 11 years 11 months; or
     - 12 years to 17 years 11 months.

If deemed appropriate for children's disability services, a child will be wait-listed for an Initial Contact.

[2] The word 'referral' relates to routine referrals exclusive of applications that come through the Assessment of Need (AoN) process, while 'AoN referrals' relate to those that are received as AoN applications.

Prioritisation

- For referrals, there will be two categories of priority i.e. 'Urgent' & 'Non-urgent'. Referrals will be prioritised at the point of receipt of referral based on referral information. As per the National policy on prioritisation of referrals to Children's Disability Network Teams (HSE, 2016), 'urgent' referrals are those with one or more of the following issues:
    - Equipment/pressure care breakdown;
    - Family in crisis;
    - Critical transition stage where intervention/assessment is essential for continuity of a service;
    - Choking/aspiration Feeding Eating Drinking & Swallowing issue (if this service is available from the team);
    - Critical rehabilitation required post discharge from an acute hospital service following acquired brain or spinal injury;
    - Presentations & behaviours which may lead to
        - Significant risk to health or safety of the child;
        - Significant risk to health or safety of others;
        - Very severe loss in quality of life or daily functioning of child; &/or
        - School placement breakdown;
    - A combination of significant & multiple child & family vulnerabilities likely to lead to severe deterioration in the child's wellbeing & disability related problems; &
    - A child who has been on the waiting list for services for a year.
- Referrals considered to be Urgent will be prioritised for an Initial Contact as soon as possible.

Wait-list

- Teams have a duty of care to children on their waiting list to ensure that the waiting list is monitored & validated.
- All wait-listed referrals (i.e. those that have been accepted) will be offered (yet-to-be-defined) universal low-intensity waitlist initiatives as indicated.
- Children will remain on the waiting list until an Initial Contact has been completed & service provision has commenced.

Taking children off the waiting list

- Wait-listed referrals will be seen (e.g., for an Initial Contact) when (team) capacity permits.
- As determined by a review of existing information, including that derived from the National Policy on Access forms, the child disability team will determine those team members who are the most appropriate to conduct the Initial Contact. If the identified team members are not available, the next most appropriate team members will conduct the Initial Contact.
- If a team is missing, for example, a particular discipline that has been identified to progress an identified goal, children will have to wait for this discipline to become available to progress this goal. However, team-based IFSP development will continue, as will progressing other goals for which the identified disciplines are available.
- While a rare occurrence, when only one discipline has been identified as being necessary to progress specific goals, & that discipline has capacity, the child in question may be seen sooner than a child whose goals require 2 or more disciplines.

Initial Contact

- The aim of the 'Initial contact' is to achieve the following outcomes:
    - Provide an orientation to the service;
    - Profile parental priorities for their child / family;
    - Achieve a better understanding of a child's needs via assessing them through, for example, some of the following (e.g., informal observation; play-based assessment; administration of screening assessment tools / formal or informal assessment tools; discussion with the child);
    - Based on parental priorities & child disability team observations, develop some agreed initial goals;
    - Provide guidance on interventions specific to the agreed initial goals that parents can use immediately;

  - Assign a service co-ordinator[3] to the family; &
  - Facilitate development of initial goals & Individual Family Service Plan (IFSP) within 6 weeks.
- The Initial Contact may be clinic- or home-based depending on both presenting need & available resources within teams;
- Conducted by 2 CDNT members, the Initial Contact may also involve the 2 members working separately with the parent & the presenting child; &
- If children can be seen in less than 8 weeks, for AoN referrals, the Initial Contact will also serve as a Preliminary Team Assessment & will include the necessary completion of a summary report for the purposes of fulfilling the requirements of the Disability Act.

Individual Family Service Plan (IFSP)

- An IFSP will be a combination of a dynamic, rolling plan, with continuous progress & updating of goals, & additional internal referrals where necessary, will be used to determine & define the service provided to the child for the duration of the particular episode of care; &
- Children will be added to waiting lists for any support when it is relevant to achievement of a goal identified in their IFSP. A 'Team Support' is, for example, Occupational Therapy will provide family with a visual dressing sequence, whereas 'Team Action' is, for example, the scheduled appointment to provide same.

AoN referrals

- Where requested, the AoN process will be a sub-process of the core process. It will not drive the core process. The AoN will be governed by a three-month legislative timeline.
- The referral pathway for AoN referrals[1] will differ slightly whereby
  1. The applicant (e.g., a parent) will complete the AoN application form & send this to the Assessment Officer for review;
  2. To facilitate determination of eligibility & to identify the appropriate pathway, the Assessment Officer will then request the applicant to complete both of the required National Policy on Access forms; &
  3. If deemed appropriate for children's disability services, a child will be wait-listed for a Preliminary Team Assessment, or in cases where a child can receive an Initial Contact within 8 weeks, this meeting will also serve as a Preliminary Team Assessment after which a summary report will also need to be completed & returned to the Assessment Officer.
- As per the *AoN SOP (HSE, 2020)*, a Preliminary Team Assessment will be the basis for AoN referrals.
- AoN referrals will be treated like other referrals provided the waiting list for an Initial Contact for AoN referrals is less than 8 weeks. If greater than 8 weeks, AoN referrals will get a Preliminary Team Assessment (ahead of other referrals) so as to satisfy the requirements of the Disability Act.
- Children will receive their AoN from a team where the referral information clearly shows that the child meets the criteria for acceptance to the team. Therefore when an AoN referral is accepted, the child is put on the core pathway for the Children's Disability Network Team.
- The Preliminary Team Assessment will answer the questions as per a summary report within the timelines of the Disability Act. These four questions are:
  1. Does the child have a disability?
  2. What is the nature & extent of the disability?
  3. What are the health needs occasioned to the person by the disability?
  4. What intervention services are required?
- If, based on the Preliminary Team Assessment, the child / young person is deemed to have 'no disability,'
  - The summary report form will be returned to the Assessment Officer;
  - The child will be discharged from the children's disability team; &
  - The Assessment Officer will refer the child to the appropriate alternative service.
- If, based on the Preliminary Team Assessment, the child / young person is deemed to require further input from the Children's Disability Service, then they will remain on the core process for an Initial

[3] Previously noted as a 'care co-ordinator,' a 'service co-ordinator' is a named CDNT member who helps families co-ordinate the care of their child(ren).

Contact; & will be offered same as per standard waiting times from date of referral i.e. the AoN Preliminary Team Assessment will not impact on the child's place on the waiting list for an Initial Contact.

Goal attainment

- While a goal attainment scale & process have yet to be developed, goal attainment will be captured in a word-based drop down (i.e. Achieved, Not Achieved, Partially Achieved, etc.) & a scoring system will be developed.
- Note: It is recognised that goal setting will require definition & standards, & related instruction & training, so that the level & nature of goals can be consistently applied across all teams. This level of detail will be addressed separately.

Other

- To maximise access to services, it is the responsibility of each Children's Disability Team Manager to monitor waitlists & caseloads, & to utilise resources to best effect.

2. Process

Table 1 presents some details of how teams go about their day-to-day activity.

Table 1. CDNT work processes.

Process
Referral received & reviewed by team to determine if appropriate & if priority. Note: Until the National Policy on Access is implemented in full, existing care pathways will remain in place. Note: While incorporated in the National Policy on Access referral forms, existing referral forms require same for a child to be accepted into a child disability service.
Referral will go on a waiting list for an Initial Contact. There will be two categories of referral; 'Non-urgent' & 'Urgent', see note in the procedures section above. Referrals considered to be 'Urgent' will be prioritised for contact as soon as possible
Referrals while on the Initial Contact waiting list will receive information, literature, invitations to group information sessions etc.
Teams will have a duty of care to children on their waiting lists to ensure that their waiting list is continually monitored & validated.
AoN requests will be received from the Assessment Officer. AoNs will be completed in accordance with the new AoN SOP.
Initial Contact scheduled (see outline in procedures section above)
The initial IFSP will be prepared & agreed with parents as part of the initial Contact process. It will consist of parental priorities, goals, strategies & team actions. Each goal area will have a baseline to put the goal itself in context. The strategies will describe what the parents or guardians will do & the

team actions will describe what the service will provide.

It is intended that the plan will be described in a way that is clear & easily understood by both parents & CDNT. The parental concerns will be the overarching issues & wishes as described by the parents e.g., "We would like Sean to be able to prepare himself for school in the mornings as much as possible."

The goals, strategies & actions will then break that down into a plan.

Examples of the various elements are as follows:

- Parental Priority: We would like Sean to be able to prepare himself for school in the mornings as much as possible
- Baseline: Sean is unable to put on his coat without assistance
- Goal: Sean will put on his coat without assistance when leaving the house
- Strategy: Parents will use a visual dressing sequence to teach Sean how to put on his coat
- Team Supports: OT will support parents in learning visual dressing sequence
- Team Actions: OT sessions to target dressing skills.

Team actions will be any combination of individual or group sessions, parent only sessions, information sessions etc. These will be noted as part of the plan to begin with & then will be specifically scheduled at an appropriate time.

The actions will be assumed to be part of the (generic) discipline waiting list once they are noted as a requirement, & will become part of the (named) therapist waiting list once they are scheduled or associated with a therapist or therapists. The original referral date will be used to calculate the waiting list duration for requirements identified as part of the Initial Contact.

The specific scheduling will be recorded for the child, therapist, & room & will be confirmed by letter.

Group sessions will be controlled differently to individual one-to-one sessions:

- Groups will be created with a name, type, provisional number of places, number of sessions & a potential start date, & a group owner;
- The group will then be able to be confirmed subsequently with dates, therapists, & rooms for each session. This can be changed as the need arises;
- Children will be placed on a waiting list for the group as part of the Team Supports; &
- The person organising the group will be able to review it from time to time, review the waiting places & available places & allocate the child to the group from that point.

Intra-team referrals

- In addition to the team actions contained in the initial plan, & to ensure that no identified need is lost within the system, intra-team referrals will be able to be raised at any stage once the engagement with the child has commenced;
- Intra-team referrals will be able to be raised by any therapist but will have to be confirmed with the therapist on whom they are raised before the referral is considered valid;
- This will become part of the team actions & will be scheduled in the same way;
- The date of intra-team referrals will be used to calculate the duration on waiting lists for these goals arising subsequent to the initial contact process.

Duration of appointments

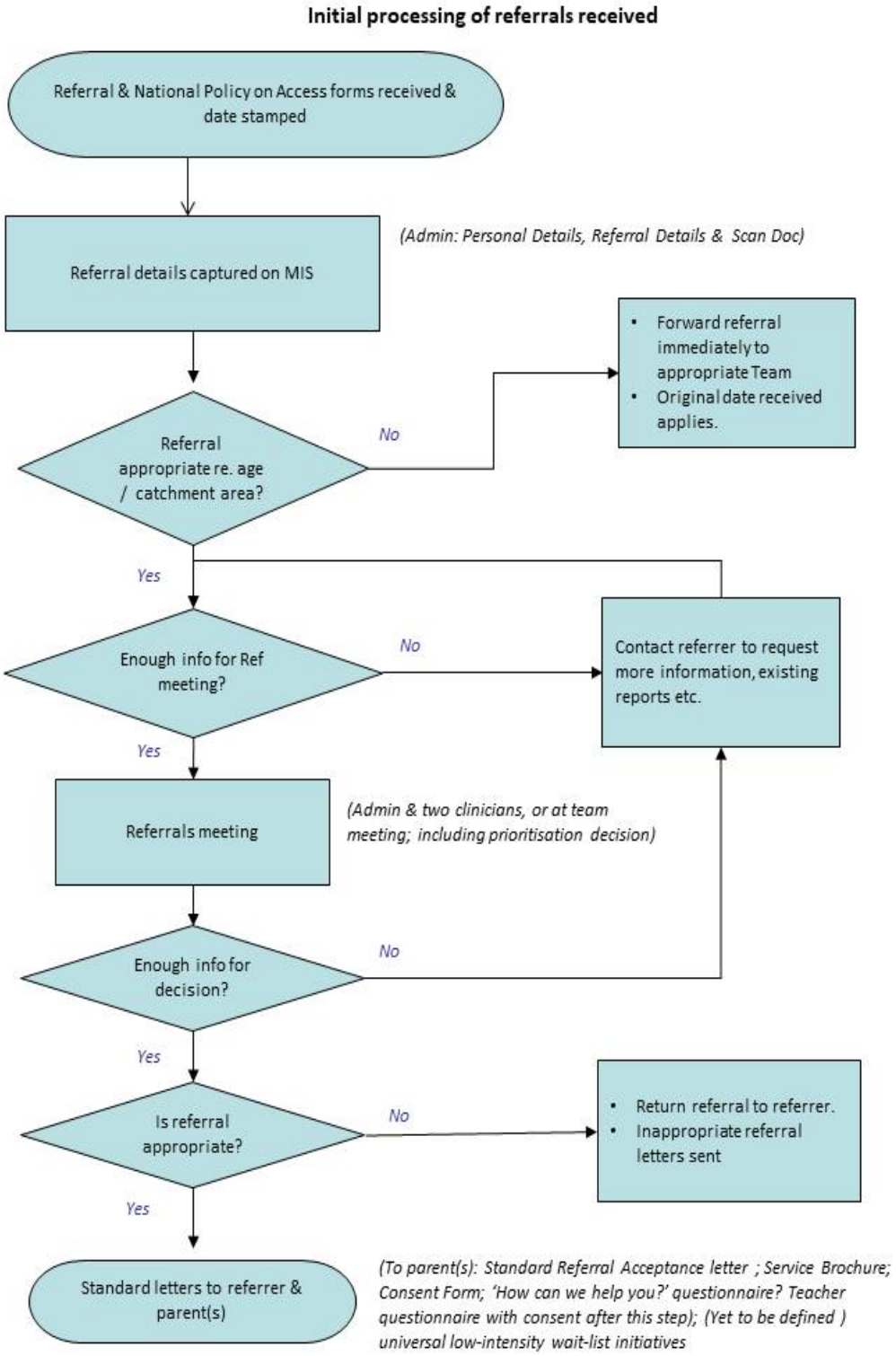
Appointments will be confirmed in writing at the time the appointment is made & a text reminder will automatically sent on the day before the appointment.

Appointments can be deemed completed where the child in question has attended the session or they

can be incomplete by nominating one of three categories: • DNA where the child does not attend & does not advise in advance that they will fail to do so; • CNA where the child cannot attend but parents make contact in advance & provide a valid reason; & • TNA where the child is told not to attend, in effect where the session is cancelled by the service. Note: In summary, where session is a DNA, the team will try to make contact & then send a letter giving the parents / guardians 14 days to make contact. If the appointment is a first appointment & no contact is made, the child will be discharged. If the child is already established with the service & no contact is made, the issue will be discussed by the team & a risk assessment may be recommended. Where sessions are completed normally, Contact Notes will be completed for each appointment. They will include the clinical notes from the appointment, identification of the goals focused on during the appointment, acknowledgement of any changes to the goals, or new goals established, as part of the contact. Relevant documents can also be uploaded as part of that process.
All relevant contact with parents or guardians will be summarised & recorded over the course of the episode.
The combination of a dynamic, rolling plan, with continuous progress & updating of goals, & additional internal referrals where necessary, will be used to determine & define the service provided to the child for the duration of the particular episode of care. The child will be discharged, from either a discipline or the team as a whole.
Continuous Review
Standard & quality of plans: An Audit Process will be put in place to ensure that an agreed number of randomly selected plans are reviewed each quarter to ensure consistency of approach & adherence to a defined standard.
Delivery of plan goals: A simplified goal attainment scale will be used to measure goal attainment.
Review all contact with child / parents as necessary
Workload will be viewed as necessary to see past or future appointments.
Waiting lists/caseload management processes
Reporting
A variety of standard reports will analyse & monitor performance.

Some parts of the process have been represented graphically in Figures 1 & 2.

Figure 1. The proposed initial clinical pathway.



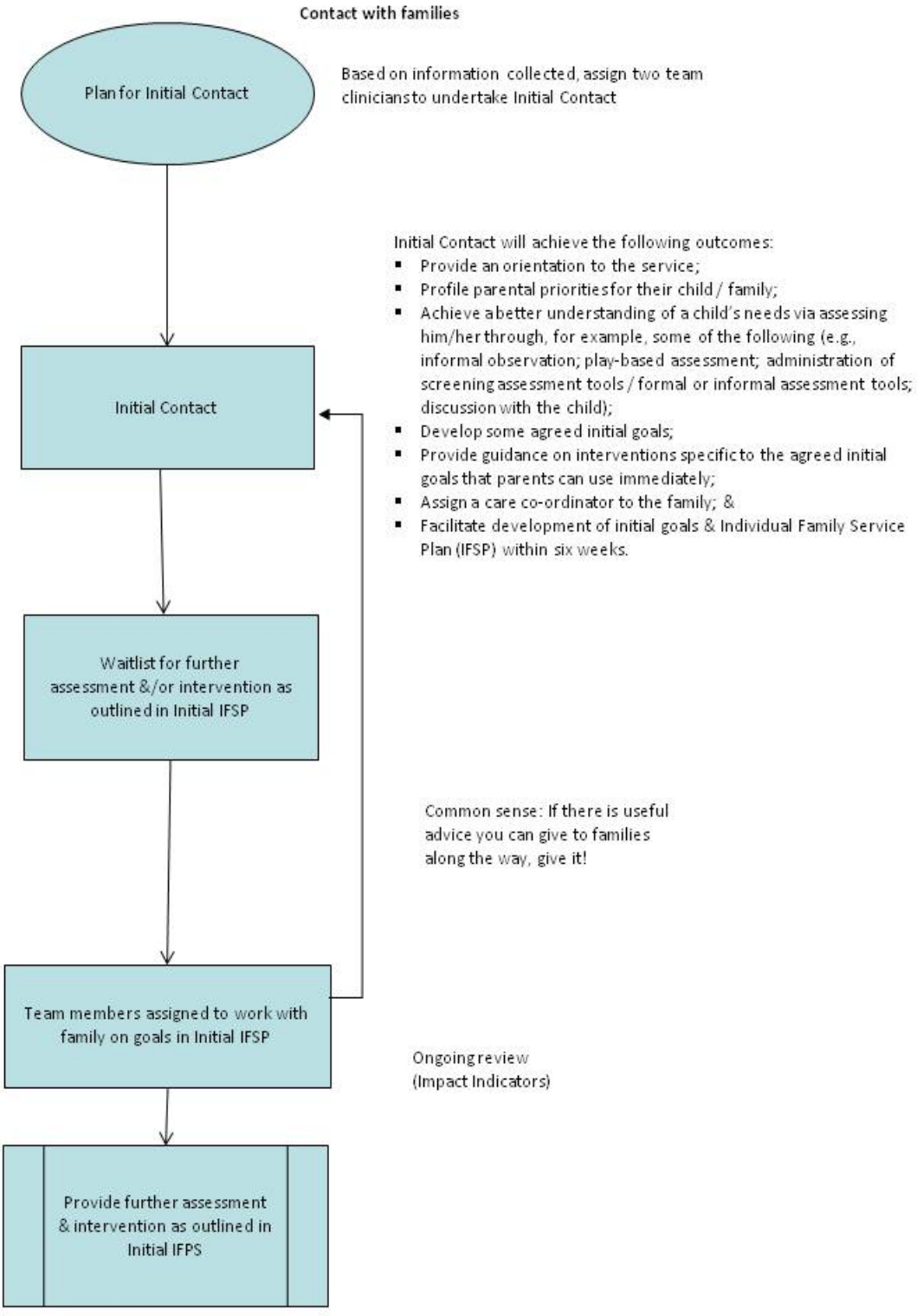
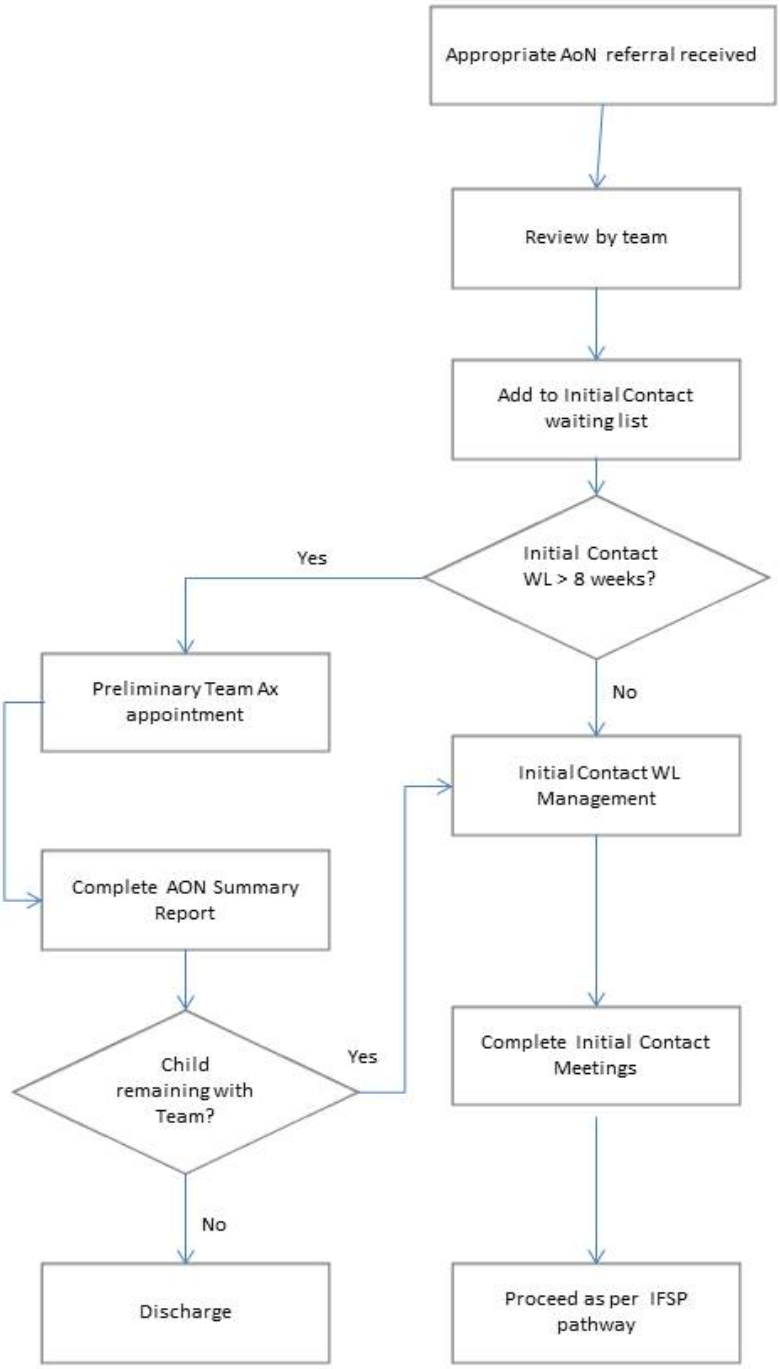

Contact with families
Plan for Initial Contact
Based on information collected, assign two team clinicians to undertake Initial Contact
Initial Contact will achieve the following outcomes:
Provide an orientation to the service;
Profile parental priorities for their child / family;
Achieve a better understanding of a child's needs via assessing him/her through, for example, some of the following (e.g., informal observation; play-based assessment; administration of screening assessment tools / formal or informal assessment tools; discussion with the child);
Develop some agreed initial goals;
Provide guidance on interventions specific to the agreed initial goals that parents can use immediately;
Assign a care co-ordinator to the family; &
Facilitate development of initial goals & Individual Family Service Plan (IFSP) within six weeks.
Initial Contact
Waitlist for further assessment &/or intervention as outlined in Initial IFSP
Common sense: If there is useful advice you can give to families along the way, give it!
Team members assigned to work with family on goals in Initial IFSP
Ongoing review (Impact Indicators)
Provide further assessment & intervention as outlined in Initial IFPS

Figure 2. The proposed AoN pathway.



Appendix C – Data Collection Fields

Data is held in relation to the following

- Child's personal & demographic details
- Referral details
- Details of contacts with the family, guardians or relevant service providers.
- Relevant notes service providers may deem necessary or appropriate over the course of service provision
- Lists of all appointments including attendance history
- Clinicians notes following each appointment
- Uploaded relevant documents such as letters from doctors, forms completed etc.

The specific data held across these topics includes the following

- Child's name & address
- Country of birth, first & other languages
- Date of birth
- GP & other relevant professionals
- Details of schools attended including whether resource help is available
- Any diagnosed conditions
- Details of medical, GP Visit, Long Term Illness & other relevant cards held
- Siblings name, age & whether they are in the service
- Any relevant school & background general notes
- Parent / Carer names, addresses, contact details & relationship to the child.
- Current parenting status of parents / guardians
- Whether currently in hospital
- General notes in relation to Current Medication, Relevant Family Social History, Any Other Relevant Information
- Names of clinicians or other relevant individuals available for contact.
- Dates of appointments, history of attendance, list of those in attendance.
- General notes or observations arising from each appointment
- Details of every contact, other than appointments, with the family. Summaries of the content of such phone calls or discussions. Observations arising from the phone calls or discussions
- Service plans showing parental concerns, goals, actions agreed by the parents & actions agreed by the CDNTs;
- Notes in relation to the performance in achieving such goals;
- Relevant documents that are uploaded & held on the IMS server. These can include doctors or consultants' reports, referral forms, relevant correspondence etc.; &
- Child Protection concerns.

Appendix D – Sample Disability Services Data Protection Information Leaflet

We respect your rights to privacy & to the protection of your personal information. The purpose of this leaflet is to explain how we collect & use personal information for the provision of our services & the day-to-day running of our Children's Disability Network Teams (CDNTs). Our CDNTs are made up of a mix of staff from the Health Service Executive (HSE) & Contracted Service Providers funded by the HSE (e.g., depending on the local CDNT, *Brothers of Charity; Daughters of Charity; Enable Ireland*).

Personal information is collected & stored by our CDNT staff when your child/children attend a CDNT. This information is used to give your child/children quality care & to improve the services we provide. It includes your child/children's contact details & date of birth; parent/carer names, postal addresses, mobile phone numbers & relationship to the child; & siblings; names, ages & whether they are in the service. We will store your records in our *paper-based records and/or other (electronic information management systems)*.

What the law says

Our CDNTs need a legal basis to process personal information. There are 6 provided for under the EU General Data Protection Regulation (GDPR); & we must make sure that one or more of these apply when we process your information. The 6 provided for are:

1. The consent of the individual;
2. For the performance of a contract;
3. Compliance with a legal obligation;
4. Necessary to protect the vital interests of a person;
5. Necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Data Controller; &
6. Legitimate interest.

In general, we process personal information in the exercise of our official authority (i.e. number 5 above). For the HSE & Contracted Service Providers, this official authority is vested in us through the Health Act 2004 (as amended). However, we may rely on some of the other above legal basis depending on circumstances that may arise.

In addition, under GDPR, the processing of special categories of personal data (which includes health data) shall be lawful where it is necessary:

(a) for the purposes of preventative or occupational medicine;
(b) for the assessment of the working capacity of an employee;
(c) for medical diagnosis;
(d) for the provision of medical care, treatment or social care;
(e) for the management of health or social care systems & services; or
(f) pursuant to a contract with a health practitioner (Health Identifiers Act 2014).

Processing is lawful where it is undertaken by or under the responsibility of:

(a) a health practitioner; or
(b) a person who in the circumstances owes a duty of confidentiality to the data subject that is equivalent to that which would exist if that person were a health practitioner. For example, the CDNT administrator.

If the processing of special categories of data is not covered by the categories above, the HSE may use another lawful basis such as:

- explicit consent; or
- the processing is necessary for reasons of substantial public interest; or
- the processing is necessary for reasons of public interest in the area of public health; or
- the processing is necessary to protect the vital interests of the data subject or another natural person.

This means that the law allows us to process personal data to:

- Provide the most appropriate service for your child/children & family;
- Help us to develop better services in the future; &
- Manage our health systems & services.

Type of data we collect
Under Irish Data Protection law, this data has two parts: 'personal data' & 'special categories of personal data.' You can read about these categories below:

1. **Personal data (or information)** includes contact details & date of birth; parent/carer names, addresses, mobile phone numbers & relationship to the child; & sibling's names & ages, & whether they too attend our services; &
2. **Special Categories of data** includes health data like your child/children's service notes & notes or reports about their health needs (https://gdpr-info.eu/art-9-gdpr/).

How we obtain data
Along with the information you provide us, we may obtain your information from a variety of sources including, for example, third parties like your GP, your Social Worker or your Public Health Nurse (PHN).

What we do with the data that we collect
The data we collect are used to give a record to your child's/children's CDNT. They use this to work out the best way to give your child/children the high quality support your child/children need. Your child's/children's data allows your CDNT to see what has worked to help your child/children in the past & helps them to work out how best to help your child/children now & in future.

We also use the data we collect to:

- Review the care we provide for your child/children & family to ensure it is of the highest standard;
- Provide you with information, literature, & invitations to group information sessions;
- Send reminders of appointments by post or text to the mobile number provided;
- Investigate complaints, legal claims or adverse incidents;
- Protect wider public health interests;
- Provide information for planning so we can meet future needs for children's disability services;
- Provide information to prepare statistics on health service performance, for example, how many people use the service;
- Carry out health service audit; & to
- Provide training & development.

Any information that we use in our reports is anonymised. In other words, the information is not filed with your child/children's name or any means of identifying your child/children. This means that your child/children's identity is never made public. Fully anonymised information may also be used as part of our training or service development of CDNTs.

We do not transfer your child's information overseas.

Who has access to your child/children's information?

- HSE or Contracted Service Provider staff who work with your CDNT;
- A small number of HSE support & administration staff;
- Staff from the Health Research Board (HRB) via the National Abilities Support System (NASS). You can find out more about the data that the NASS collects at: https://www.hrb.ie/fileadmin/2._Plugin_related_files/Publications/2019_Publication_files/2019_HIE/NASS/NASS_Plain_English_information_leaflet.pdf; &
- Staff from two Information Technology (IT) companies called EBCS & TEKenable Ltd. who provide technical & IT development support to our CDNTs. Both are bound by confidentiality agreements with the HSE & by data protection laws.

How do we keep your record secure & confidential?

We are committed to ensuring that your information is secure with us. We have a number of security precautions in place to prevent the loss, misuse or alteration of your information:

- All CDNT members have a legal duty to keep information about you confidential;
- All CDNT members are trained in information security and confidentiality;
- Our services have strict information security policies and procedures in place to ensure that information about you is stored safely;
- *Our paper-based records are kept in locked filing cabinets in locked rooms;*
- *Our 'name of electronic information management systems' (where your information is stored) has full traceability on all changes to your information i.e. it provides full details of who accessed your information, when they did so; and what changes they made; and*
- *To ensure that entries to your record are completed and saved by the appropriate CDNT member, a unique Personal Identification Number (PIN) needs to be entered by the logged-in user. This serves as each CDNT member's electronic signature on notes and reports*.

Who else might we share your information with?

By consenting to the provision of services from a CDNT, the CDNT will, as part of this service provision:

- When using our service, we may share your child's & family's information with the other services (e.g., Primary Care, Mental Health or other HSE Services; HSE-funded or Contracted Service Providers or Voluntary Organisations), when, for example, your child's referral is more appropriate to other services, or when there is a need for shared care or care that requires input from more than one service;
- Where necessary, share your information with other agencies such as the Department of Education; Tusla, Child and Family Service; Emergence Services; and the Gardai; &
- Contact other services (e.g., Primary Care or Mental Health Services; non-HSE services) to obtain (& share) relevant information in order to understand & address your child's needs as might be addressed by input from a variety of other professionals including Hospital Consultants (e.g., Paediatricians); Health & Social Care Professionals [HSCP's] such as Psychologists, & Speech & Language Therapists; Teachers; Assessment Officers; Liaison Officers; & approved volunteers & students (e.g., Nurses; HSCP's) who might work with your child under the clinical supervision of a more senior & qualified clinician.

Therefore, for example, if you consent to receiving services from our CDNT, we may link & share your information with other professionals who are or have been involved in your child's health or education.

Where will my information be kept?

We will store your *paper-based records in locked filing cabinets in locked rooms.*

We will store your record in our *'names of electronic information management systems'*, whose records are backed up daily at night. Your child's data on this system is stored on a secure, central computer system that the HSE manages and controls. It is stored in line with HSE information Security Policies that are aligned to industry good practice.

How long is my information kept?

Historical paper records & current electronic records are kept in accordance with the HSE policy for Record Retention Periods 2013 HCR10 (https://www.hse.ie/eng/services/list/3/acutehospitals/hospitals/ulh/staff/resources/pppgs/rm/recret2013.pdf). This notes that records in relation to children & young people are retained 'until the patients 25th birthday or 26th birthday if the young person was 17 at the conclusion of treatment, or 8 years after death. If the illness or death could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain the records for longer periods'; & records created under Childcare Acts are 'to be retained in perpetuity (forever)' (p.8). However, this does not apply for people who have a mental disorder as defined in the Mental Health Acts 1945 to 2001. Their data is kept for 20 years after their last treatment or 8 years after their death. It should be noted that this policy references 'at the conclusion of treatment' (p.8); therefore if the child is still attending the

HSE/agency disability services as an adult, then the records can remain until 8 years after final entry or 8 years after death.

Can I see a copy of my information?
Yes. You can

1. Apply to the *'name of the Lead Agency'* for a copy of your child/children's records under the Data Protection law. If you do this, it is called a Subject Access Request (SAR). *If the Lead Agency is the HSE,… You can get a SAR form at www.hse.ie/eng/gdpr.* Complete this form and send or give it to your child's/children's CDNT; or
2. You can write a letter asking for a copy of your child/children's records. To assist with your application, you will need to provide a clear description of the information you are seeking, and evidence of your identity and your relationship to the child; or
3. You can apply for a copy of your child's/children's record under the Freedom of Information (FOI) Act 2014. To do this, you must write to the *'name of the relevant Lead Agency'* that holds the records you are seeking and state that you are requesting a copy of the records under the FOI Act. A copy of government-issued photographic identification along with evidence of your relationship to the child will be required.

Rights under GDPR
You have certain legal rights concerning your information/your child's/children's information & the manner in which we process it. This includes:

1. A right to ask for access to the personal information;
2. A right to request us to correct inaccurate information, or update incomplete information;
3. A right to request that we restrict the processing of the information in certain circumstances;
4. A right to data portability in certain circumstances; &
5. A right to object to us processing the personal information in certain circumstances.

Regarding any requests you have regarding any or all of the above rights, you can ask your CDNT Manager.

You also have the right to complain to the Data Protection Commissioner if you feel your rights are not being respected.

If you have questions about how your child/children's data is stored
Ask a member of your CDNT (e.g., Administrator; Health & Social Care Professional). They may not have an answer for you straightaway but will get back to you as soon as they can.

You can get more information about your child/children's privacy rights from *https://www.hse.ie/eng/privacy-statement/*

You can contact the *'name of Lead Agency'* Data Protection Officer or the relevant member of his/her team (see Table 1 below).

Table 1. Contact details for *'name of Lead Agency'* Data Protection Officer (DPO) and his/her team.

Data Protection Officer (DPO)	**Contact details**
DPO, *'name of Lead Agency'*	*Email address* *Telephone number*
Deputy DPO West, HSE (excluding Contracted Service Providers) • *CHO 1 – Cavan, Donegal, Leitrim, Monaghan, Sligo* • *CHO 2 – Galway, Mayo, Roscommon* • *Mid-West Community Healthcare* • *Saolta Hospital Group*	*Deputy DPO West* *ddpo.west@hse.ie* *T 091 775 373*

Deputy Data Protection Officer Dublin North-East (excluding voluntary hospitals and agencies) *Consumer Affairs, HSE DNE, Bective St., Kells, Co. Meath.* • *Midlands, Louth, Meath Community Health Organisation* • *Community Health Organisation Dublin North City & County* • *CHO 6 – Dublin South East, Dublin South & Wicklow* • *RCSI Hospital Group* • *National Children's Hospital*	*Deputy DPO Dublin North East* *ddpo.dne@hse.ie* *T 046 925 1265* *T 049 437 7343*
Deputy Data Protection Officer Dublin mid-Leinster (excluding voluntary hospitals and agencies) *Consumer Affairs, HSE, Third Floor Scott Building, Midland Regional Hospital Campus, Arden Road, Tullamore, Co. Offaly.* • *Dublin Midlands Hospital Group* • *Ireland East Hospital Group* • *Community Healthcare Dublin South, Kildare & West Wicklow*	*Deputy DPO Dublin Mid-Leinster* *ddpo.dml@hse.ie* *T 057 935 7876* *T 045 920 105*
Deputy Data Protection Officer South (excluding voluntary hospitals and agencies) *Consumer Affairs, HSE South, Ground Floor East, Model Business Park, Model Farm Road, Cork. Eircode: T12 HT02* • *Cork & Kerry Community Healthcare* • *CHO 5 – Carlow, Kilkenny, South Tipperary, Waterford & Wexford* • *UL Hospital Group* • *South South-West Hospital Group*	*Deputy DPO South* *ddpo.south@hse.ie* *T 021 492 8538*

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Data Sharing Agreement

between

Health Service Executive CHO *X*

&

Service Provider #1

&

Service Provider #2

&

etc.

1. Introduction

This agreement sets out the framework for the sharing of data, including personal data & special categories of personal data, between the parties as Joint Data Controllers. It defines the principles & procedures that the parties shall adhere to & the responsibilities the Parties owe to each other.

2. Definitions[4]

In this Agreement, unless the context otherwise requires:

Aggregate data: Data collected from individual or multiple sources & compiled into data summaries or summary reports.

Anonymised data: Data that has been manipulated so as to irreversibly remove all personal identifiers from the data so that it is impossible to identify an individual whom the data relates to.

[4] As informed by Article 4 of the GDPR: https://gdpr-info.eu/art-4-gdpr/

Anti-Malware Software: Any software program designed to prevent, detect & remediate malicious programming (e.g., viruses, spyware, adware, keyloggers, & ransonware) on individual computing devices & IT systems.

Children's Disability Network Team (CDNT): The multi-agency team of Health & Social Care Professionals who provide services for the families of children with, or at risk of disability, who present with complex needs.

Cloud Computing: The delivery of computing service, servers, storage, databases, networking, software, analytics, intelligence & more over the Internet ("the cloud") to offer faster innovation, flexible resources & economies of scale.

Consent: Any freely given, specific, informed & unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

Contracted Service Providers: Section 38 & 39 organisations whose staff work on CDNTs in CHO *X (e.g., the Brothers of Charity, the Daughters of Charity, & Enable Ireland)*.

Computer Device: Any fixed, mobile or handheld device that is capable of accepting, processing & storing data, including but not limited to desktop computers, mobile computer devices, & smart devices.

Computer Media: Any removable or portable storage devices used to store data on, including but not limited to CD's, DVD's, Portable hard drives, USB sticks, flash drives, Zip disks, & floppy disks.

Cyber Security Incident: Any malicious act or suspicious event that compromises, or was an attempt to compromise, IT systems & networks or the security controls used to protect the IT systems & networks.

Data: Any information, in any format, by whatever means is shared by the Parties under this Agreement. For the avoidance of doubt, Data shall include all Personal Data & Special Categories of Personal Data, shared by the Parties under this Agreement.

Data Controller or **Controller:** The natural or legal person, public authority, agency or other body that, alone or jointly with others, determines the purposes & means of the processing of personal data.

Data Protection Legislation: All applicable laws & regulations relating to the processing of personal data & privacy including the Data Protection Act 2018); the EU General Data Protection Regulation 2016/679 (or the 'GDPR'; https://gdpr-info.eu/); the European Communities (Electronic Communications, Networks & Services) (Privacy & Electronic Communications) Regulations 2011 (S.I. 336/2011); & any statutory instrument, order, rule or regulation made there under, as from time to time amended, extended, re-enacted or consolidated.

Data Subject: An identified or identifiable natural person i.e. one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Degaussed: The process of totally erasing data by reducing or eliminating an unwanted magnetic field (information) stored on tape & disk media.

European Economic Area (EEA): The free trade area agreed between the 28 EU member states & the three EFTA States (Iceland, Liechtenstein, & Norway).

Encryption: The process of converting (or encoding) information from a readable form (e.g., plain text) that can be read by everyone into an unreadable form (e.g., cipher text) that can only be read by the information owner & other authorised persons. Related word is **Encrypt.**

Freedom of Information Act: The Freedom of Information Act 2014 & any amendments to or replacements thereof, including by means of directly effective EU Regulation.

GDPR: The EU General Data Protection Regulation, Regulation (EU) 2016/679 (https://gdpr-info.eu/), the effective date of which is 25th May 2018.

Mobile Computer Device: Any mobile or handheld, computer device, including but not limited to laptops, tablets, notebooks, & personal digital assistants (PDAs).

Party / Parties: Any organisation that has signed up to this Agreement i.e. the HSE & the specified organisation(s).

Personal data: Any information relating to an identified or identifiable natural (living) person (or data subject).

Personal Data Breach: A breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.

Privacy Notice / Privacy Statement: The public statement or notice published by an organisation that describes what data they collect about individuals, how & why this data is processed, & what other organisations they share this data with.

Process: Any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction. Related words are **Processed / Processing**.

Pseudonymisation: The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately & is subject to technical & organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. Related word is **Pseudonymised**.

Service user: Child & his/her family who receives children's disability services from the various Community Healthcare Organisations.

Smart Device: Any handheld mobile computer device which is capable of wireless connection (via WiFi, 3G, 4G etc), voice & video communication &, internet browsing. These include, for example: Apple IOS enabled devices (i.e. iPhone & iPad); Google Android enabled devices (i.e. Samsung Galaxy tablet); Windows Mobile enabled devices; & Blackberry RIM enabled devices.

Special Category Data: Personal data that reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation (https://gdpr-info.eu/art-9-gdpr/).

Third Party: A natural or legal person, public authority, agency or body other than the data subject, controller, processor & persons who, under the direct authority of the controller or processor, are authorised to process personal data i.e. any person or organisation not party to this Agreement.

3. Parties to the Agreement

3.1 The following organisations are party to this Agreement [The **Parties**]:

a) The Health Service Executive [hereafter the HSE], a body corporate with perpetual succession established by the Health Act 2004 as the single body with statutory responsibility for the management & delivery of health & personal social services in the Republic of Ireland, which has its principle administrative offices at Dr. Steevens' Hospital, Steevens' Lane, Dublin 8, D08 W2A8;

b) *Service Provider #1*

c) *Service Provider #2*

d) *Etc.*

3.2 The HSE, *Service Provider #1, Service Provider #2 etc.* may be individually referred to as a "Party" or collectively as the "Parties" hereunder.

3.3 This Agreement shall be managed by the following authorised officers from each of the participating organisations:

a) The Health Service Executive

Mr / Mrs. ……
Location: ……
Ph: ……
Mobile: ……
Email: ……

b) Service Provider #1

Mr / Mrs. ……
Location: ……
Ph: ……
Mobile: ……
Email: ……

c) Service Provider #2

Mr / Mrs. ……
Location: ……
Ph: ……
Mobile: ……
Email: ……

d) etc.

4. Description of data shared

4.1 Data relating to service users

Data collected by the service, which will be shared between staff working on the CDNT in respect of providing health & personal social services, includes:

- Personal data;
- Special category data (including health data); &
- Anonymised data.

Data are received from numerous sources, including but not limited to:

- Families of children referred to the CDNT;
- Pre-schools;

- Access Inclusion Model (AIM) staff & Pobal;
- Schools;
- Special Education Needs Officer (SENO);
- Department of Education;
- Other agencies or professionals (e.g., GP, medical teams, TUSLA, etc.);
- Gardai;
- Assessment Officers &/or Liaison Officer; &
- Approved volunteers & health & social care students (e.g., nursing, occupational therapy, physiotherapy, social work, speech & language therapy, psychology, & early intervention).

Data held by the CDNT & available to staff include, but are not limited to:

- Child's personal & demographic details;
- Referral details;
- Details of contacts with the family, guardians or relevant service providers;
- Relevant notes service providers may deem necessary or appropriate over the course of service provision;
- Lists of all appointments including attendance history;
- Clinicians notes following each appointment; &
- Uploaded relevant documents such as letters from doctors, forms completed etc.

The specific data held & available to staff, across these topics includes the following

- Child's name & address;
- Country of birth, first & other languages;
- Date of birth;
- GP & other relevant professionals;
- Details of schools attended including whether resource help is available;
- Any diagnosed conditions;
- Details of medical, GP Visit, Long-Term Illness & other relevant cards held;
- Siblings name, age & whether they are in the service;
- Any relevant school & background general notes;
- Parent / Carer names, addresses, contact details & relationship to the child;
- Current parenting status of parents / guardians;
- Whether currently in hospital;
- General notes in relation to Current Medication, Relevant Family Social History, & Any Other Relevant Information;
- Names of clinicians or other relevant individuals available for contact;
- Dates of appointments, history of attendance, list of those in attendance;
- General notes or observations arising from each appointment;
- Details of every contact, other than appointments, with the family. Summaries of the content of such phone calls or discussions. Observations arising from the phone calls or discussions;
- Service plans showing parental concerns, goals, actions agreed by the parents & actions agreed by the CDNTs;
- Notes in relation to the performance in achieving such goals;
- Relevant documents that are uploaded & held on the child's file. These can include doctors or consultants reports, referral forms, relevant correspondence etc.; &
- Child protection concerns.

4.2 Data relating to employees

Data collected by the employing organisation during the recruitment process may include the following:

- Personal data; &
- Special category data (including health data).

Data is received from numerous sources including but not limited to:

- Application form of employee;
- Previous Employers;
- Occupational Health; &
- Garda Clearance Department.

Data is held by the employing organisation & shared on a need-to-know basis with the service provider (if different) managing the service the employee works as part of. Information shared may include the following:

- Employee's name & address;
- Date of birth;
- Garda Vetting status;
- Any occupational health issues relevant to the position;
- Details of next-of-kin;
- Details of previous employment.
- Qualifications/ relevant training / Registration details;
- Role & WTE;
- Any ongoing commitments to the employee from employer specific to the individual (e.g., training, working arrangements etc.);
- Summary / handover report from current supervisor to new supervisor;
- Leave entitlements & annual leave record for defined period;
- Details re. parental leave entitlement & time taken to date where applicable;
- Sick leave records for a defined period; &
- Details of any current / open performance management or disciplinary issues (as previously written up & seen by employee).

5. Purpose of sharing data

'In healthcare organisations the word 'communication' takes many forms, from a formal written document to an informal chat among colleagues. This communication involves the exchange of service user information among healthcare professionals. Structuring & organising service user information in the healthcare record is the responsibility of all users & can result in improved service user safety & quality of care' (*HSE Standards & Recommended Practices for Healthcare Records Management, 2011*, p.9).

Following the implementation of the national Progressing Children's Services for Children & Young People (PDS) programme, multi-agency CDNT's were established within each CHO, each of which employ a mixture of HSE & Agency 38/39 staff.

The Programme's overall vision is the achievement of best possible outcomes for children & their families through a combination of:

- One clear pathway to services for all children according to need;
- Effective teams working in partnership with parents & service users;
- Resources used to the greatest benefit for all children & families; &
- Partnership between health & education to support children to achieve their potential.

In line with the principle of data minimisation, it is appropriate to share both service user & CDNT staff data on a necessity & proportionality basis so as to provide children and their families with the required supports they need, & CDNMs with the data they need to manage their CDNT staff.

6. Legal basis for data sharing

The legal basis on which the service user's data is shared amongst the Parties is covered in section 7 of the Health Act 2004 & section 52 of the Data Protection Act 2018 (see Appendix A).

The Principles of Data Protection found in Article 5 GDPR (https://gdpr-info.eu/chapter-2/) must be kept in mind at all times:

- Lawfulness, fairness, & transparency
- Purpose limitation;
- Data minimisation (e.g., necessity, proportionality & pseudonymisation);
- Accuracy;
- Storage limitation;
- Integrity & confidentiality; &
- Accountability.

7. Methods Used for Sharing Data

7.1 Data relating to service users:

The lawful basis for the transfer of service user files is underpinned by the Health Acts 1947-2020 & under GDPR 6.1(e) [public interest] & 9.2 (h) [provision of care].[5]

Data is shared by several methods:

1. Direct discussion with other CDNT staff (e.g., CDNT meetings, discussions between staff members, & joint working);
2. Telephone or text messaging (in the context of service provision);
3. Email (in the context of service provision);
4. Paper-based files;
5. Electronic files;
6. Networked shared drive;
7. Regional service meetings, including Clinical Managers' meetings, case management meetings & service planning meetings; &
8. Through the Assessment of Need Process.

Data will be shared on a daily basis, & with electronic files, will be backed up daily at night.

Data will be held in the following places:

- Paper-based records in locked filing cabinets; or information management system(s) either owned by the HSE (e.g., *Management Information System*) or a Section 38 or 39 organisation;
- HSE network shared drive;
- Section 38/39 information management systems;
- Local register-based records (e.g., complaints, FOI); &
- Laptops / PCs (e.g., for temporary storage).

Security Controls:

- As part of the Service Level Agreement within Community Healthcare Organisation *X*, all staff must read & sign a privacy & confidentiality agreement;
- A region-wide Record Management Policies, Procedures, Protocols & Guidelines (PPPG) has being developed, with annual audit of same;
- 'Good Information Practices' training (www.hse.ie/good-info-practices) will be provided to all staff.
- Staff/students/volunteers are required to get CDNM approval for access to the information management system & local networked shared drive. CDNMs are responsible for ensuring that access is withdrawn when an employee leaves the service;
- PC's are password protected, & passwords are changed at least every 90 days.

[5] In light of an open legal case, it would be prudent to keep a copy of the child's file at the original location with all records up to the point of transfer. The original can then be passed to the new location where they can continue to add to the file.

- Any information management systems used will be password protected, & held on the HSE server, or connected to the HSE server by a VPN link;
- All staff must adhere to the HSE Information Technology Acceptable Usage Policy (https://www.hse.ie/eng/services/publications/pp/ict/i-t-acceptable-use-policy.pdf) & the HSE Electronic Communications Policy (https://www.hse.ie/eng/services/publications/pp/ict/electronic-communications-policy.pdf) in relation to the information management system; &
- All email between organisations containing service user & staff data must be encrypted.

7.2 Data relating to staff

The lawful basis for sharing CDNT staff personal data is underpinned by GDPR 6.1(b) [contract] & 9.2 (b) [employment]. While all other data will be shared across all the Joint Data Controllers, employee data will be shared only between the employer and the Lead Agency. These data will be shared by:

1. Direct discussion between the employer of each CDNT staff member & their CDNM;
2. Email; &
3. Post.

Data is shared on a need-to-know basis, based on the requirements of the position involved. For those CDNT staff who work on a CDNT that is managed by a CDNM from a different agency, their CDNM will have access to their HR details that pertain to the day-to-day management of the CDNT (e.g., annual / sick / study leave) but not to other non-routine HR data (e.g., Garda Vetting; disciplinary proceedings). Hence, a CDNM will hold a confidential HR file on each CDNT member, while each Agency will hold a confidential HR file on each of its employees.

Security Controls:

- The Service Level Agreements within each CHO require that all staff & managers must read & sign a privacy & confidentiality agreement within their organisation relating to data;
- 'Good Information Practices' training (www.hse.ie/good-info-practices) will be provided to all staff & managers;
- PCs are password protected & passwords are changed at least every 90 days; &
- All emails between organisations containing employee-related data must be encrypted.

7.3 Data subject rights

Both service users & staff have a right to data access; rectification; & portability (Articles 15, 16 & 20 respectively of the GDPR) but not to data erasure (Article 17). If, for example, data rectification is agreed with the data subject, all Joint Data Controllers must consent to rectifying the data subject's record.

8. Data Protection Impact Assessment (DPIA)

A DPIA has been submitted in relation to the information management system.

9. Data Quality

9.1 Each Party to this Agreement shall be responsible for the quality & accuracy of the Data they share with the other Parties; &

9.2 Data discovered to be inaccurate or inadequate for the specified purposes outlined in Section 5 of this Agreement will be brought to the notice of the Party that supplied the Data. The Party that supplied the Data will be responsible for correcting the Data & notifying all other Parties of the corrections.

10. Joint Data Controllers

10.1 All agencies in a CDNT are considered the Joint Data Controller for any Personal Data & Special Categories of Personal Data shared under this Agreement;
10.2 When a Party shares Personal Data &/or Special Categories of Personal Data with another Party, the Party receiving such Data shall be considered the Data Controller for that copy of these Data that they have received from the other Party; &
10.3 Each Party is responsible for complying with their obligations as Data Controllers under the Data Protection Legislation.

11. Privacy Notes

11.1 Each party shall ensure, where applicable, that they update their individual Privacy Notice / Privacy Statement to take into accounts the sharing of any Personal Data & Special Categories of Personal Data under this Agreement.

12. Disclosure of Data Shared Under This Agreement

12.1 Each Party shall ensure that any Personal &/or Special Categories of Personal Data shared under this Agreement are only disclosed to Third Parties in accordance with the relevant legislation or as required pursuant to an enactment, rule of law or by order of a court;
12.2 Each Party shall ensure that any Personal &/or Special Categories of Personal Data shared under this Agreement are only disclosed to the general public in accordance with the relevant legislation or as required pursuant to an enactment, rule of law or by order of a court;
12.3 Each Party shall take appropriate measures to notify & provide individuals with any information referred to in Articles 13 (https://gdpr-info.eu/art-13-gdpr/) & 14 (https://gdpr-info.eu/art-14-gdpr/) of the GDPR; &
12.4 Each Party is individually responsible for managing & complying with requests from individuals exercising their rights under the Freedom of Information Acts, the Data Protection Acts & the GDPR (https://gdpr-info.eu/).

13. Restrictions on the use of data shared

13.1 All Parties shall ensure that Personal Data & Special Categories of Personal Data shared as part of this Agreement must only be used for the purpose(s) specified at the time of disclosure(s) & as defined in Section 5 of this Agreement. Such Data must not be used for any other reason(s) without the written permission of the Party who supplied the data, unless an exemption applies within the Data Protection Legislation or the data is required to be provided under the terms of the Freedom of Information Acts or under the instructions of a court of law.

14. Security

In consideration of the Parties sharing Data with each other, each Party agrees that it shall:
14.1 Maintain the security & confidentiality of all Personal Data & Special Categories of Personal Data shared under this Agreement;
14.2 Process all such data shared under this Agreement in accordance with the Data Protection Legislation;
14.3 Ensure that access to any Personal Data &/or Special Categories of Personal Data that they receive from the other Parties is limited to those of their employees & contractors who need to have access to it, & that they are informed of the confidential nature of such Data, are under an obligation to keep such Data confidential, & comply with the obligations set out in this Agreement;
14.4 Ensure all their relevant employees & contractors with access to the Personal Data &/or Special Categories of Personal Data have been provided with appropriate Data Protection & IT security training;
14.5 Implement appropriate technical & organisational measures (TOM's) within their own organisation to protect against the unauthorised or unlawful processing & the accidental loss, destruction, damage, alteration & disclosure of any Personal Data &/or Special Categories of Personal Data

that is shared under this Agreement. As a minimum, the following TOM's shall be implemented by each of the Parties:

14.5.1 Strong & robust Access controls are in place to manage & protect access to Personal Data & Special Categories of Personal Data;

14.5.2 Access to such electronically stored data is controlled by strong unique passwords;

14.5.3 All Mobile Computer Devices that are used to Process &/or store Personal Data & Special Categories of Personal Data have strong Encryption facilities available that allow for the encryption of the Mobile Computer Device &/or the Encryption of such Data at a file or folder level;

14.5.4 All Computer Devices that are used to Process or store Personal Data Special Categories of Personal Data have real-time protection Anti-Malware Software installed that is updated on a regular basis;

14.5.5 All Personal Data & Special Categories of Personal Data which is Processed or stored off-site or within a Cloud Computing solution by a Third Party on behalf of a Party is Encrypted at rest using strong Encryption protocols;

14.5.6 All Personal Data &/or Special Categories of Personal Data transmitted via electronic means outside their organisation is sent via secure channels (e.g., VPN, Secure FTP, TLS) or Encrypted email using strong Encryption protocols;

14.5.7 All Personal Data &/or Special Categories of Personal Data is backed up on a daily basis & backup copies of the data are tested on a frequent basis to ensure the data can be restored in the event of a hardware or software crash or a Cyber-Security Incident;

14.5.8 Appropriate processes are in place that allow the Party to regularly test, assess & evaluate the effectiveness of the technical & organisational measures they have implemented within their organisation; &

14.5.9 Each Party have documented IT & information security policies that define how the Party's employees, contractors & Third Parties are to manage, process & secure the Party's data.

15. Data Retention

15.1 No Party shall retain Personal Data or Special Categories of Personal Data shared under this Agreement longer than is necessary;

15.2 All Data shared under this Agreement shall be retained in accordance with each Parties data retention policies; &

15.3 Data shared under this Agreement which has reached the end of its legal retention period & is no longer required shall be disposed of securely in accordance with Section 16 of this Agreement.

16. Data Disposal

The Parties agrees that all Data shared under this Agreement which is no longer required, shall be destroyed as follows:

16.1 All paper records containing Personal Data &/or Special Categories of Personal Data shall be shredded &/or incinerated;

16.2 All old & obsolete magnetic hard drives containing Personal Data &/or Special Categories of Personal Data are Degaussed or physically destroyed by shredding, pulverising, crushing or incineration;

16.3 All old & obsolete solid state hard drives containing Personal Data &/or Special Categories of Personal Data are physically destroyed by shredding, pulverising, crushing or incineration;

16.4 All old & obsolete PDA's, mobile phones & Smart Phones containing Personal Data &/or Special Categories of Personal Data are physically destroyed by shredding, pulverising, crushing or incineration;

16.5 All old & obsolete Computer Media containing Personal Data &/or Special Categories of Personal Data is physically destroyed by shredding, pulverising, crushing or incineration; &

16.6 All Computer Devices containing Personal Data &/or Special Categories of Personal Data shall be overwritten using data sanitised software before being re-used with the organisation, sold or donated to staff, charities or others.

17. International Data Transfers

17.1 Each Party shall ensure that Personal Data & Special Categories of Personal Data shared under this Agreement will not be transferred or processed outside the European Economic Area (EEA) without first ensuring the appropriate safeguards are in place, as set out in Chapter 5 of the GDPR (https://gdpr-info.eu/chapter-5/).

18. Security Breach

18.1 In the event that any Party becomes aware of a Personal Data Breach, that Party shall fulfil its obligation to notify the CDNT Lead Agency of the Personal Data Breach in accordance with Articles 33 (https://gdpr-info.eu/art-33-gdpr/) & 34 (https://gdpr-info.eu/art-34-gdpr/) of the GDPR.

18.2 While the Parties agree to provide reasonable assistance as is necessary to each other to facilitate the handling of any Personal Data Breach in an expeditious and compliant manner, the CDNT Lead Agency will manage any such data incidents.

18.3 Should the CDNT Lead Agency conclude that a data breach has occurred that requires reporting to the Data Protection Commission (DPC), then they will make the report using the DPC process on its website.

18.4 Regarding notifying the HSE (and other agencies involved) of any data breach, sufficient information will be provided to enable the HSE to understand the breach, its potential consequences and how it is being managed.

19. Monitoring & Review

19.1 If a new organisation joins the Agreement a new version of the Agreement will be issued as soon as is possible & within one month at the latest, & circulated to all the Parties;

19.2 If an organisation leaves the Agreement, a new version of the Agreement will be issued as soon as is possible & within one month at the latest, & circulated to all the Parties;

19.3 If any organisation is replaced by a successor body or have their relevant powers & responsibilities transferred to another body, a new version of this Agreement shall be issued as soon as is practical, & within one month at the latest, & circulated to all the Parties;

19.4 This Agreement may not be supplemented, amended, varied or modified in any manner except by an instrument in writing signed by a duly authorised officer or representative of each of the Parties hereto; &

19.5 This Agreement will be formally reviewed on an annual basis by the Parties, unless legislative changes necessitate an earlier review.

20. Dispute Resolution

20.1 In the event of a dispute arising under this Agreement, the authorised officers from each of the Parties will discuss & meet as appropriate to try & resolve the dispute within seven calendar days of being requested in writing by any Party to do so. If the dispute remains unsolved, it will then be referred to a senior manager from each of the Parties, who will use all reasonable endeavours to resolve the dispute within a further fourteen calendar days; &

20.2 In the event of failure to resolve the dispute through the steps set out in clause 20.1, the Parties agree to attempt to settle it by mediation.

20.3 In the event of a dispute or claim brought by a Data Subject or the Data Protection Commission concerning the processing of shared Personal Data against any Party, the Parties will inform each other about any such disputes or claims, and will cooperate with a view to settling them amicably in a timely fashion.

20.4 The Parties agree to respond to any generally available non-binding mediation procedure initiated by a Data Subject or by the Data Protection Commission. If they do participate in the proceedings, the

Parties may elect to do so remotely (such as by telephone or other electronic means). The Parties also agree to consider participating in any other arbitration, mediation or other dispute resolution proceedings developed for data protection disputes.

21. Severance & Unenforceability

21.1 If any provision, or part thereof, of this Agreement shall be, or is found by any authority, administrative body or court of competent jurisdiction to be, invalid, unenforceable or illegal, such invalidity, unenforceability or illegality shall not affect the other provisions, or parts thereof of this Agreement, & of which shall remain in full force & effect; &

21.2 If any invalid, unenforceable or illegal provision, or part thereof, would be valid, enforceable or legal if some part were deleted, the provision, or part thereof, will apply with whatever modification is necessary to give effect to the intention of the Parties as appears from the terms of this Agreement.

22. Indemnity

22.1 The Party's, agree to indemnify each other, from & against any loss (including `legal costs & expenses on a solicitor/own client basis), or liability, arising from any claim, suit, demand, action or proceeding by any person against any of those indemnified Parties where such loss or liability was caused by any wilful, unlawful or negligent act or omission of a Party, its employees, agents or subcontractors in connection with a Party's performance of its obligations under this Agreement & in particular relating to Processing of Personal Data & Special Categories of Personal shared under this Agreement.

22.2 Neither Party shall be liable to the other whether in contract, tort (including negligence) or otherwise for any indirect, consequential or economic loss, loss of business or similar head of loss, howsoever arising.

22.3 Nothing in this Agreement shall limit a Party's liability in respect of death or personal injury caused by its negligence or for any fraudulent misrepresentation, or for any other liability which cannot be excluded under applicable law.

22.4 The indemnity in clause 22.1 shall survive the expiration or termination of this Agreement.

23. Further Assistance

23.1 The Parties agree to cooperate with & provide assistance to the other Parties consistent with the terms & conditions of this Agreement.

24. Further Assurance

24.1 Each Party undertakes to do all acts & execute all documents which may be necessary to give full effect to this Agreement.

25. Governing Law

26.1 This Agreement will be governed by & construed in accordance with the laws of Ireland, & the Parties submit to the exclusive jurisdiction of the Irish courts for all purposes connected with this Agreement, including the enforcement of any award or judgement made under or in connection with it.

26. Termination

27.1 Any Party may terminate this Agreement by providing the other Parties with thirty calendar day's written notice of their intention to terminate the Agreement.

Appendix A – Processing of special categories of personal data for purposes of Article 9(2)(h) of Data Protection Act 2018 (pp.42-43; https://gdpr-info.eu/art-6-gdpr/).

Section 52

(1) Subject to *subsection (2)* & to suitable & specific measures being taken to safeguard the fundamental rights & freedoms of data subjects, the processing of special categories of personal data shall be lawful where it is necessary
   (a) for the purposes of preventative or occupational medicine
   (b) for the assessment of the working capacity of an employee
   (c) for medical diagnosis
   (d) for the provision of medical care, treatment or social care
   (e) for the management of health or social care systems & services, or 42 PT.3 S.52 [No. 7.] Data Protection Act 2018. [2018.]
   (f) pursuant to a contract with a health practitioner

(2) Processing shall be lawful in accordance with *subsection (1)* where it is undertaken by or under the responsibility of
   (a) a health practitioner, or
   (b) a person who in the circumstances owes a duty of confidentiality to the data subject that is equivalent to that which would exist if that person were a health practitioner.

(3) In this section, “health practitioner” has the same meaning as it has in the Health Identifiers Act 2014.

IN WITNESS where of this *Agreement* has been entered into the day & year first herein written.

SIGNED on behalf of the **Health Service Executive**	**In the presence of**
..... Signature	..... Signature
..... Name (printed)	..... Name (printed)
..... Title	..... Title
SIGNED on behalf of the [the **Specified Organisation**]	**In the presence of**
..... Signature	..... Signature
..... Name (printed)	..... Name (printed)
..... Title	..... Title
Date:	Date: .....
SIGNED on behalf of the **Health Service Executive**	**In the presence of**
..... Signature	..... Signature
..... Name (printed)	..... Name (printed)
.....	.....

Title

Title

SIGNED on behalf of the
[the **Specified Organisation**]

…….
Signature

…….
Name (printed)

…….
Title

Date: ……..

In the presence of

…….
Signature

…….
Name (printed)

…….
Title

Date: ……..

SIGNED on behalf of the
Health Service Executive

…….
Signature

…….
Name (printed)

…….
Title

In the presence of

…….
Signature

…….
Name (printed)

…….
Title