

Research & Development
Taighde & Forbairt

HSE National Policy for Consent in Health and Social Care Research



Citation information:

HSE National Policy for Consent in Health and Social Care Research (2022). Dublin: Health Service Executive

E-version of this policy is available at: <https://hseresearch.ie/publications/>

Published by:

Health Service Executive, Dublin, December 2022

National Research and Development, Strategy and Research Directorate, Health Service Executive

ResearchandDevelopment@hse.ie

<https://hseresearch.ie/>





HSE National Policy for Consent in Health and Social Care Research

Is this document a:

Policy



Procedure



Protocol



Guideline



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

All HSE staff and all its funded organisations

Title of PPPG Development Group:	HSE National Policy for Consent in Health and Social Care Research Steering Group		
Approved by:	HSE National Research and Development, Strategy and Research		
Version Number:	V 1.0		
Publication Date:	December 2022		
Date for revision:	December 2027		
Electronic Location:	https://hseresearch.ie/publications/		
Version	Date Approved	List section numbers changed	Author



Contents

Glossary of Terms	9	1 Preamble	18
Introduction	16	1.1 Purpose	19
		1.2 Scope	19
		1.2.1 In Scope	19
		1.2.2 Out of Scope	19
		1.3 Objectives	20
		1.4 Outcomes	20
		1.5 HSE National Consent for Research Policy Working and Advisory Groups	20
		1.6 HSE Consent for Research Policy Steering Group	20
		1.7 Supporting Evidence	20
		1.7.1 Relevant Legislation	20
		1.7.2 Relevant International guidelines	22
		1.7.3 Relevant Policies, Procedures, Protocols and Guidelines (PPPGs)	22
		1.7.4 List of PPPGs that are being replaced by this PPPG	23
		1.8 Development of PPPG	23
		1.9 Governance and approval	23
		1.10 Communication and dissemination	24
		1.11 Implementation	24
		1.11.1 Education and training	24
		1.11.2 Accountability for the implementation of this policy	24
		1.11.3 Responsibilities of staff and organisations	24
		1.12 Monitoring, Audit and Evaluation	25
		1.13 Revision	25

Contents

2	Consent for research	26	3	Obtaining and recording consent	35
2.1	What is consent?	27	3.1	Who should obtain consent when contacting or recruiting research participants?	36
2.2	Valid consent for research participation and for processing of personal data for health research	28	3.2	Informing prospective research participants	37
	2.2.1 Consent must be informed	29		3.2.1 The Participant Information Leaflet	39
	2.2.2.1 Tiered approach to obtaining consent to facilitate option selection	29	3.3	Recording and documenting consent	42
	2.2.2 Consent should be specific	29		3.3.1 Written consent	42
	2.2.3 Consent for different purposes must be unbundled	30		3.3.2 Digital consent	43
	2.2.4 Consent must be freely given	30		3.3.3 Verbal consent	44
	2.2.5 Consent must be unambiguous	31		3.3.4 Retention of consent-related documentation	44
	2.2.6 The right to withdraw	31		3.3.5 Retention period for consent-related documentation	44
2.3	Consent for storage, maintenance, and secondary research use of identifiable personal data or identifiable biological material	31	3.4	Consent related to incidental findings of health and social care relevance	45
				3.4.1 Disclosure of important incidental findings of a genetic nature	46
2.4	Consent obtained for the processing of personal data secured pre-GDPR	34	3.5	Re-consent	47
			3.6	Withdrawal of consent	47

Contents

4	Capacity to consent in adults	49
4.1	Guiding principles for application in research	50
4.2	Capacity to consent	51
4.2.1	Who should determine capacity to consent?	51
4.3	Obtaining consent for research from adults who may need support with making many decisions	52
4.4	Research involving adults who do not have the capacity to consent	53
4.4.1	Capacity to consent and Ward of Court	53
4.4.2	Capacity to consent and CTIMPs and Clinical Investigations of Medical Devices	54
4.4.3	Capacity to consent and deferred consent in emergency circumstances	55
4.4.4	Capacity to consent and inclusion in health and social care research other than CTIMPs, Clinical Investigations of Medical Devices, or emergency circumstances	55

5	Research involving children and young people aged under 18 years	57
5.1	Age of consent for participation in research	58
5.2	Consent for inclusion of children in research	58
5.2.1	Consent from parent(s)/legal guardian(s)	58
5.2.2	Children in care	59
5.3	Assent by a child	60
5.3.1	Obtaining the assent of a child	61
5.4	Withdrawing consent	62
5.5	Safeguarding children	62
5.6	Valid consent from parent(s)/legal guardian(s)	63
5.6.1	Neonates	63

6	Other consent considerations	65
6.1	Research involving stored biological material and associated personal data from material originally collected for research purposes	66
6.2	Biological material and personal data associated with that material and collected as part of clinical care and treatment	66
6.3	Research involving post mortem biological material	67
6.3.1	Pre-mortem consent	67
6.3.2	Post mortem consent	67
6.3.3	Broad consent for post mortem research	69
6.4	Research involving the personal data of deceased individuals	69
6.5	Consent for research involving the use of personal data and biological material originating from outside Ireland	69
6.6	Research involving the use of anonymous and pseudonymous data	70
6.7	Determining the suitability of prospective participants for inclusion in research (pre-screening)	71
6.8	Research involving the review of existing health records (retrospective chart review)	72
6.9	Deferred consent for research in emergency situations	74
6.10	Research using personal data for research without consent by way of a consent declaration	75
6.11	Covert research	76

ANNEX 1	Differentiating between research and other related activities	79
ANNEX 2	HSE National Policy for Consent for Health Research Working and Advisory Group	82
ANNEX 3	HSE National Policy for Consent for Health Research Steering Group	85
ANNEX 4	Consent declarations and the HRCDC	86

Glossary of terms

The following definitions refer to the meaning given to them within this policy document.

Adult

A person aged 18 years or over.

Anonymous data

Anonymous data are personal data that have been amended in such a way that no individuals can be identified from the data, having regard to all methods reasonably likely to be used by the data controller or any other person to identify the data subject, directly or indirectly. Data that are fully and truly anonymised (i.e. data from which no individuals can be identified) fall outside the scope of both Directive (EU) 2016/680 and the General Data Protection Regulation (GDPR)¹. However, sharing of anonymised data is subject to certain requirements such as a legally binding commitment that the recipients of the anonymised data will not take any steps to re-identify personal data.

Assent

Assent is the expressed agreement of someone not able to give legal consent.

Biological material

Human biological samples such as tissue, blood, saliva, urine, faeces, etc.

Broad informed consent

Broad consent for research refers to consent obtained for additional secondary use of biological material and/or personal data for secondary research that has not yet been specifically defined. The scope of the secondary research is limited to the area of research, or purpose of the research project, specified in

the original consent.² However, when the purpose of the research cannot be fully specified, the researcher must find other ways to ensure that the consent requirements are met, e.g. data anonymisation, dynamic consent, and ensuring transparency. See also 'secondary research'.

Capacity

Capacity is the ability to understand the nature and consequences of a decision a person is being asked to make when provided with relevant information that is presented and communicated to them in a suitable form at the time the decision is to be made, thus enabling the person to express their own personal choice. In the context of this policy, decision-making capacity is defined as: "the person's ability to understand, at the time that a decision is to be made, the nature and consequences of the decision to be made by them in the context of the available choices at that time".³

Child

A person aged under 18 years.

Clinical audit

Clinical audit is the term used to describe a process of assessing clinical practice against established and recognised standards in order to establish if best practice is being adhered to for quality assurance and improvement purposes. The definition adopted by the Health Service Executive (HSE) comes from 2008 Department of Health report and is "a clinically led, quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met".⁴

1 Adoption of the Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and Directive (EU) 2016/680 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data.

2 Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021), <https://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf>

3 Assisted Decision-Making (Capacity) Act 2015, Section 3, page 15, <https://www.irishstatutebook.ie/eli/2015/act/64/section/3/enacted/en/html>

4 Building a Culture of Patient Safety. Report of the Commission on Patient Safety and Quality Assurance. Department of Health and Children, 2008, page 152, <https://assets.gov.ie/18845/59ff088cfaea4c4f8c93b6b04fae9762.pdf>

Glossary of terms

Consent (for research)

Consent is the giving of permission for, or agreement to, a treatment, investigation, receipt or use of a service, or participation in research or teaching, following a process of communication about the proposed intervention. Seeking consent should usually occur as an ongoing process rather than a one-off event.⁵

For the purpose of this policy, the term ‘consent’ refers to the informed and explicit agreement of a prospective research participant to take part in a research study and, when relevant, to the use of their personal data for such research. The agreement for both must be ethically obtained, recorded, and retained; the proposed consent protocol must be approved by an appropriate Research Ethics Committee (REC) and, when applicable, comply with Irish data protection legislation.

Covert research

Covert research is research which is not declared to the research participants and cannot, therefore, involve obtaining consent in advance. Covert research should not involve 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 their intentions to the research participants, which is unethical and is a form of research misconduct.

Data controller

The data controller is normally the organisation(s) of the investigator(s) which determine(s) the purpose and the means by which personal data are processed for a research project. The data controller decides ‘why’ and ‘how’ personal data should be processed and/or determines the methods of processing. Control, rather than possession, of personal data is the key factor in determining who the data controller is. This commonly coincides with the organisation of the researcher who conceives a research idea and generates the project plan. The data controller is ultimately responsible for the data and has the highest level of compliance responsibilities.

Data processing

Data processing is the performance of any operation or set of operations on personal data. It includes, but is not limited to:

- Obtaining, collecting, recording, and storing data obtained
- Aligning, linking, combining, blocking, or erasing, or otherwise destroying, data
- Retrieving, organising, using, consulting, altering, or adapting data
- Pseudonymising, de-identifying, and anonymising data
- Disclosing, transmitting, and disseminating data, or otherwise making data available.

Data processor

A data processor is the legal entity/individual that processes personal data on behalf of and under the instruction of the data controller. The data processor may not carry out processing for its own purpose(s). The existence of a data processor depends on a decision taken by the data controller, which can decide either to process data within its organisation (without the involvement of a data processor), or to delegate all or part of the processing activities to one or more external organisations (data processors). A data processor does not have the same level of obligations under data protection legislation as data controllers. However, the data processor does have some direct obligations.

Data Protection Impact Assessment (DPIA)

A Data Protection Impact Assessment (DPIA) is a risk assessment process designed to identify and minimise the risks associated with the processing of personal data and to help minimise the risks as far, and as early, as possible. A DPIA must be conducted for all research studies where there is a high risk to the data rights of prospective research participants. A Privacy Impact Assessment (PIA) Form is used. Researchers should seek advice from the data protection officer of the data controller when completing the DPIA/PIA Form. For all research studies, it is necessary to carry out an assessment of

5 HSE, National Consent Policy (2022), <https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/documents/hse-national-consent-policy.pdf>

Glossary of terms

the associated data protection implications. Where the assessment indicates a high risk to the rights and freedoms of prospective research participants, a DPIA/PIA Form must be completed.

Data subject

A data subject is a living individual who is the subject of personal data processing, and whose personal data are collected, held, or processed by an organisation. See also 'research participant' and 'special category personal data'.

Dynamic consent

Consent should be a dynamic process of ongoing engagement and communication by the researcher with prospective research participants. Dynamic consent may involve re-consenting a research participant if changes are made to a research study or new information about the research becomes available.

General Data Protection Regulation (GDPR) (and Data Protection Act 2018)

GDPR refers to the European Union's (EU's) Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). The GDPR came into force across all of Europe on 25 May 2018. It replaces the EU's previous data protection legislation, Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. The GDPR governs the data processing of all personal data of living individuals (this includes data collection, use, and storage through to data destruction). The GDPR is law in all EU member states but it allows certain areas of data protection to be given further effect in national law. In Ireland, this falls under the Data Protection Act 2018 (and any subsequent amendments).

Genetics

See also 'genomics'. The World Health Organization (WHO) defines genetics as the study of heredity, and/or the study of the functioning and composition of a particular gene.

Genomics

Genomics refers to the study of the entire genome of an organism. A genome is a complete set of a person or organism's genes (deoxyribonucleic acid (DNA)). The WHO defines genomics as the study of the whole or part of the genetic sequence of an organism. It studies how a person's genes work and interact with each other to affect the growth, development, and functioning of the body.

Higher education institutions (HEIs)

An institution of higher education within the meaning of section 1(1) of the Higher Education Authority Act, 1971 (No. 22 of 1971).

Health practitioner

A health practitioner includes a class of person who provides a health service, such as a registered medical practitioner, dentist, pharmacist, nurse or midwife, optometrist or dispensing optician, health and social care professional, or pre-hospital emergency care practitioner, as defined in section 2 of the Health Identifiers Act 2014 (Number 15 of 2014).

Health Research Consent Declaration Committee (HRCDC)

The Health Research Consent Declaration Committee (HRCDC) is a committee, underpinned by the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018), appointed by and reporting to the Minister for Health. In accordance with the Regulations, the HRCDC considers health research applications seeking a consent declaration to lawfully conduct health research using personal data without the consent of the research participant. The HRCDC may make a consent declaration where

Glossary of terms

the public interest in the health research significantly outweighs the public interest in obtaining explicit consent.⁶

Incidental findings

Incidental findings are findings that arise outside the original purpose for which a test or procedure was originally conducted. They are unavoidable and unanticipated but are clinically or socially relevant. See also ‘secondary findings’.

Legal guardian

A person having the right and duty of protecting the person, property, and rights of another (a child in the context of this document) who does not have full legal capacity or is otherwise incapable of managing their own affairs. A legal guardian is a person who: (a) is a guardian of a child pursuant to the Guardianship of Infants Act, 1964, or (b) is appointed to be a guardian of the child by (i) deed or will, or (ii) order of a court. See also amendments made to the Guardianship of Infants Act, 1964 under Part 4 of the Children and Family Relationships Act 2015.

Legally designated representative

A legally designated representative is an individual who is legally authorised to make a decision on behalf of another person. Examples of a legally designated representative include the parents or legal guardians of a child, a legal representative⁷ in the case of Clinical Trials of Investigational Medicinal Products, or the courts where an individual is a Ward of Court. Note that ‘next of kin’ is not a legally designated representative (see also footnote 62).

Participant Information Leaflet (PIL)

The Participant Information Leaflet (PIL) is usually a written document given to each prospective research participant prior to their enrolment in a research study. It details the purpose of the study, the consent process, the data protection legislation and policies underpinning the research study,

the requirements for participants’ involvement, and study collaborators. It provides information about the study, how long it will last, what is required of the participant, and their right to withdraw consent. It may be presented in a number of formats or media. The PIL is linked to the consent form or assent form. It is designed to facilitate the conversation between the prospective research participants, legally designated representatives, parents or legal guardians of children, individuals providing assent, or other relevant/interested parties, and the study researcher on what the research study will entail.

Pseudonymous data

Pseudonymous data are personal data that can no longer be attributed to a specific data subject without the use of additional information (i.e. a ‘key’/code). Such additional information must be kept separate, and technical and organisational measures for the protection of the data should be in place. Pseudonymised data in the hands of the organisation holding the identification key are to be regarded as personal data because they enable the identification of an individual (albeit via a key). Therefore, they are subject to GDPR requirements. However, provided that the key that enables re-identification of individuals is kept separate and secure (i.e. functionally separated) and technical and organisational measures for the protection of the data are in place, the risks to the data subject associated with pseudonymised data are reduced. When used for research, this type of data is subject to the Data Protection Act 2018 (and its subsequent amendments) as well as the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018)(and their subsequent amendments).

Registries

Registries are systems which collect a defined minimum dataset from patient cohorts with a particular disease, those undergoing a particular procedure or therapy, or those using a healthcare resource.

⁶ See the Health Research Consent Declaration Committee website: <https://hrcdc.ie/about-us/#Overview>

⁷ As defined under Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use.

Glossary of terms

Research

Research refers to many types of scientific investigations that aim to test ideas, answer questions, improve treatment options, and increase knowledge about human health. For the purpose of this policy, the term ‘research’ refers to health and social care research as defined in the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).⁸

Research with the goal of understanding normal and abnormal functioning at molecular, cellular, organ system, and whole body levels

Research that is specifically concerned with innovative strategies, devices, products, or services for the diagnosis, treatment, or prevention of human disease or injury

Research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals

Research with the goal of improving the efficiency and effectiveness of health professionals and the healthcare system

Research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational, and economic factors determine health status.

Health research may also include action taken to establish whether an individual may be suitable for inclusion in the research.

Research Ethics Committee (REC)

A Research Ethics Committee (REC) is a multidisciplinary and independent

committee charged with reviewing research involving human participants, their samples, or their data, in order to ensure that their dignity, rights, and welfare are protected. RECs determine the degree of risk and potential harm that may be tolerable in relation to the potential benefits of the research.

Research participant

A research participant is an individual who is included in a research study after the requirements of this policy have been taken into account. This could include their involvement in a research-related intervention or treatment, or the processing of their biological material and/or personal data. Research participants may be referred to as data subjects in the context of the collecting, holding, or processing of their personal data. See also ‘data subject’.

A prospective research participant is an individual who fulfils the research study criteria and is invited to participate in the study and is identified or engaged as part of the consent process described in this policy, prior to commencement of their involvement in a research study.

Secondary findings

Secondary findings are results that are actively sought in addition to the primary target of a test or procedure.

‘Secondary findings’ in the genetic context refers to the American College of Medical Genetics and Genomics’ list for adults and paediatric patients.⁹

As per the recommendations of de Wert *et al.* (2021),¹⁰ a cautious approach is advocated in this regard (versus ‘incidental findings’; see definition above). Where secondary findings are sought, the involvement of a clinical geneticist from the outset is strongly advised.

⁸ Regulation 3(2) of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).

⁹ Miller, D.T., Lee, K., Chung, W.K. et al. ACMG SF v3.0 list for reporting of secondary findings in clinical exome and genome sequencing: a policy statement of the American College of Medical Genetics and Genomics (ACMG). *Genet Med* 23, 1381–1390 (2021). <https://doi.org/10.1038/s41436-021-01172-3>

¹⁰ Guido de Wert *et al.*, “Opportunistic genomic screening. Recommendations of the European Society of Human Genetics,” *European Journal of Human Genetics*, 29 (2021): 365–377, <https://www.nature.com/articles/s41431-020-00758-w>

Glossary of terms

Secondary research

Secondary research in the context of this policy refers to additional research carried out on the data and/or tissue acquired during a (primary) research process. The scope of secondary research (where a new consent process has not taken place) is limited, as indicated in the definition of 'broad informed consent' above.

Special category personal data

Referred to as 'personal data'¹¹ for the purpose of this document, this refers to any information about a living person; this type of data, also commonly referred to as sensitive data, includes personal data relating to the health of the data subject, or data revealing racial or ethnic origin; political opinions; religious or philosophical beliefs; trade union membership; sex life or sexual orientation; genetic data; or biometric data. Personal data can cover various types of information, such as name, date of birth, email address, phone number, address, physical characteristics, or health data – once it is clear to whom that information relates, or it is reasonably possible to find out. Genetic data, data concerning health and biometric data are defined as follows:

Genetic data: personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question (for example, in some clinical trials, samples are taken from the subjects or patients in order to characterise their genetic profile and to use this information to correlate sub-populations of patients responding to the treatment to a specific genetic profile, which then may be studied and validated as a biomarker); see also 'genetics' and 'genomics'

Data concerning health: personal data related to the past, current, or future physical or mental health of a data subject, which could directly or indirectly allow their identification

Biometric data: personal data resulting from specific technical processing relating to the physical, physiological, or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images, fingerprints, models, similarity scores, behaviour data, and all verification or identification data, excluding the individual's name and demographics.

Therapeutic misconception

Therapeutic misconception arises when research participants have unrealistic expectations of the research and perceive it will have benefits for them personally.

11 While biological material in and of itself is unlikely to be personal data as per Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), associated health, biometric, or genetic data will be personal data. Data derived from a biological sample may also constitute identifiable personal data, particularly the whole genome, which is a unique individual identifier.

Abbreviations

BRCA2	BReast CAncer 2
CTIMPs	Clinical Trials of Investigational Medicinal Products
DPIA	Data Protection Impact Assessment
DNA	deoxyribonucleic acid
EEA	European Economic Area
EPA	enduring power of attorney
EU	European Union
FREDA	fairness, respect, equality, dignity and autonomy
GDPR	General Data Protection Regulation
GP	general practitioner
GCP	good clinical practice
HRCDC	Health Research Consent Declaration Committee
HSE	Health Service Executive
HEI	higher education institution
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
NALA	National Adult Literacy Agency
NOCA	National Office of Clinical Audit
PPI	patient and public involvement
PIL	Participant Information Leaflet
PPPGs	policies, procedures, protocols, and guidelines
PI	principal investigator
PIA	Privacy Impact Assessment
R&D	research and development
REC	Research Ethics Committee
S.I.	Statutory Instrument
UCD	University College Dublin
WHO	World Health Organization

Introduction

This policy articulates the Health Service Executive (HSE) requirements for obtaining consent for participation in health and social care research from patients, their families, and carers, as well as from the public at large. It aims to ensure that impactful research can be conducted ethically and in compliance with legal requirements, while maintaining the confidence of the participants and keeping them at the centre of the research process.

International evidence has shown that health services where research is formally integrated as part of the organisational structure deliver better care.^{12, 13} Research is a key enabler of best practice in the pursuit of optimal healthcare outcomes, and this policy will provide guidance to facilitate high-quality health research in the context of the *HSE National Framework for Governance, Management and Support of Health Research*.¹⁴

The Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018)¹⁵ (hereinafter referred to as the Health Research Regulations, 2018) govern the processing of personal information for health research purposes and define 'health research' for the first time in Irish legislation.

For the purpose of this policy, the term 'research'¹⁶ refers to health and social care research activity as defined in the Health Research Regulations 2018. See Section 1.2.2 and ANNEX 1 for what is outside the scope of this policy.

Consent is the deliberate, freely given, specific, informed, and unambiguous agreement of a prospective research participant to participate in research, including for the processing of their related personal data (when applicable), after a process of clear communication and exchange of information. Explicit consent refers to informed consent that has been appropriately obtained, recorded, and retained, and it is defined in Irish legislation as a mandatory, suitable, and specific measure to safeguard the fundamental rights and freedoms of data subjects.¹⁷

For the purpose of this policy, the term 'consent'¹⁸ refers to the informed and explicit agreement of a prospective research participant to take part in a research study and, when relevant, to the use of their personal data for such research. The agreement for both must be ethically obtained, recorded, and retained; the proposed consent protocol must be approved by an appropriate Research Ethics Committee (REC)¹⁹ and, when applicable, comply with Irish data protection legislation.

- 12 Stephen Hanney *et al.* "Engagement in research: an innovative three-stage review of the benefits for health-care performance," *Health Service and Delivery Research*, 1, no. 8 (2013).
- 13 Annette Boaz *et al.* "Does the engagement of clinicians and organisations in research improve healthcare performance: a three-stage review," *BMJ Open*, 5, no. 12 (2015): e009415, <https://doi.org/10.1136/bmjopen-2015-009415>
- 14 *HSE National Framework for Governance, Management and Support of Health Research* (2021), HSE: Dublin, <https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf>
- 15 Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018.
- 16 See full definition in the Glossary of terms.
- 17 The term 'data subject' refers to any living individual whose personal data are collected, held, or processed by an organisation (see the Glossary of terms).
- 18 See full definition in the Glossary of terms.
- 19 An appropriate REC is a National REC, a HSE Reference REC, a HSE Hospital REC, or a Section 38 Hospital REC.

Introduction

The process of obtaining consent is a fundamental step in the research process, as it requires that the researcher values the rights, beliefs, and opinions of the prospective participants. Potential participants must have received clear and sufficient information about the proposed research, as well as sufficient time to consider the information, ask questions and receive a response, and come to an informed decision about participation in light of their individual interests and values. For consent to be valid, participants must have freely chosen whether or not to participate in research.

A number of international ethical codes and standards, as well as national and international legal instruments which aim to protect the fundamental human rights of research participants while ensuring high-quality research, have been taken into account in formulating this policy (see Section 1.7).

The process of obtaining valid consent (see Section 2.2) for research is a dynamic process where the ethical requirement for protection of the dignity and rights of prospective research participants is intertwined with the legal requirements to comply with the data protection legislation when the research involves personal data. In practice, those considerations are part of the same engagement process with the prospective research participant and agreement to both has to be clearly documented.

When associated research involves the use of personal data, it must comply not only with ethical requirements, but also with data protection legislation. In these cases, researchers must identify the legal basis for the data processing and, where relevant, the appropriate Article 9 condition before the research commences (see Section 2.1).

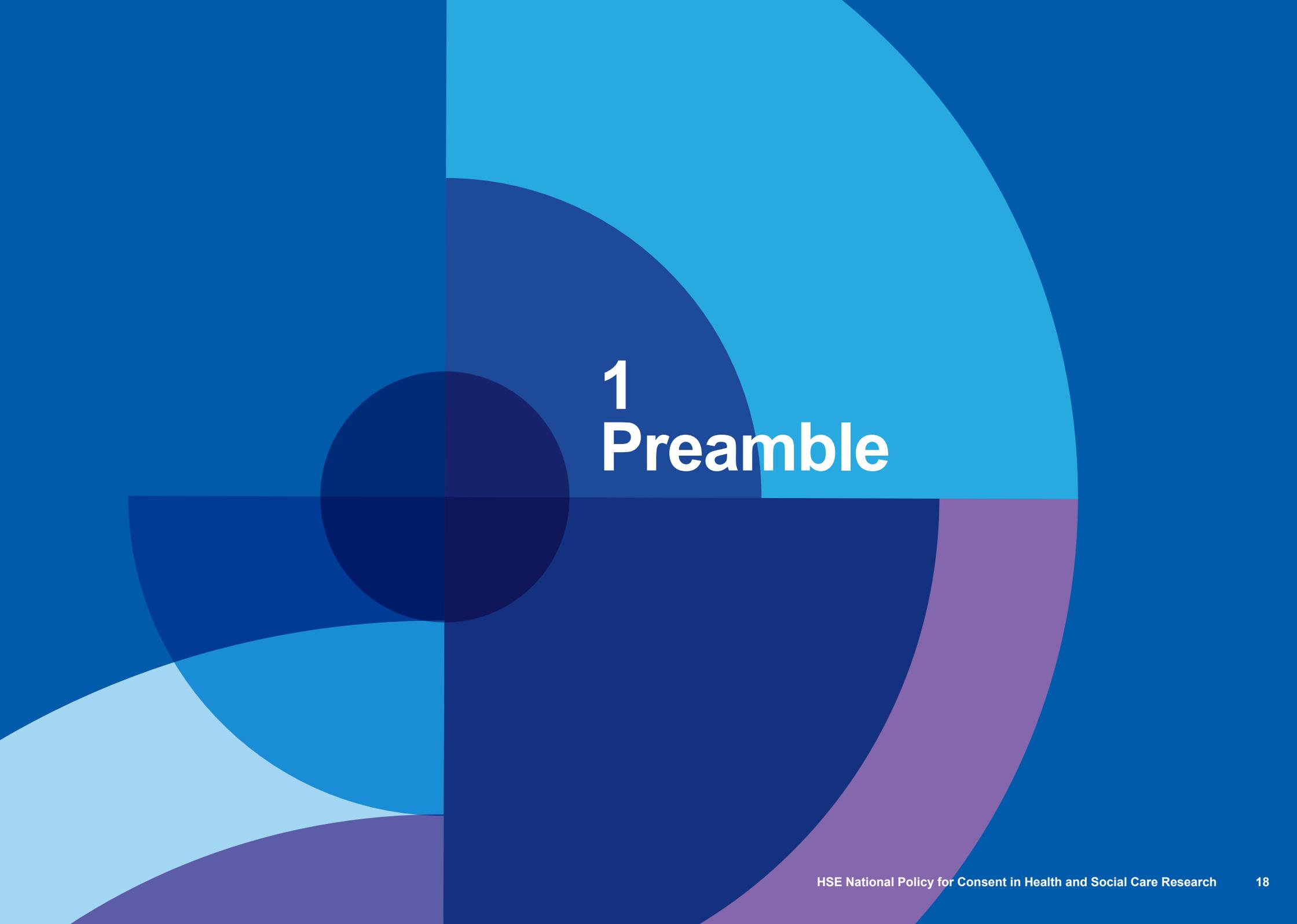
This policy explains what consent for research is and how to validly obtain it while complying with ethical values and data protection legislation. It provides guidance for seeking consent in various situations, including those where legislation for research may not exist or is currently incomplete – for example,

in the case of research involving groups with particular needs, such as adults who lack decision-making capacity. It also highlights the importance of patient and public involvement in the design of the consent material and protocols in order to ensure that the consent process is truly tailored to the needs and requirements of the participants.

The main objective of this policy is to place the prospective research participant at the centre of the research process, and to ensure that when a person gives consent for research, their gift of taking part is based on a person-centred relationship of freedom and trust.

Separate consent, underpinned by the HSE *National Consent Policy*,²⁰ is required for all health and social care interventions which are not part of a research process.

20 HSE, National Consent Policy (2022). Health Service Executive: Dublin, <https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/documents/hse-national-consent-policy.pdf>



1 Preamble

Section 1: Preamble

1.1 Purpose

The purpose of this document is to set out a clear policy position for researchers on all aspects of obtaining consent for health research²¹ purposes.

It aims to ensure that consent obtained for research taking place in the HSE, or in its funded organisations, is underpinned by a commitment to best practice and ethical values, and complies with all relevant legal and regulatory frameworks at national, European, and international levels.

1.2 Scope

1.2.1 In scope

This policy applies to:

- All health research activities taking place in the HSE, or in HSE-funded healthcare organisations involved in the provision of health and social care services, and/or to situations where the research activities involve any of the following factors: health service users (and other members of the public, where appropriate), their personal data and/or their biological material, health and social care staff, or the use of healthcare services, premises, or infrastructure
- Research taking place in HSE collaborative higher education institutions and/or clinical research facilities, etc., when the research activities involve any of the factors above.

Although this is a HSE policy, other entities involved in human research are welcome to reference or adopt this policy.

The target audience for this policy includes:

- The HSE and HSE-funded healthcare providers
- RECs
- All third-party researchers and research-performing organisations, both public and commercial
- Patients and carers, health service users, and other members of the public who are involved in any capacity (hosting, sponsoring, approving, advising, participating, collaborating, etc.) in health research under the remit of the *HSE National Framework for Governance, Management and Support of Health Research*.²²

1.2.1 Out of scope

This policy only relates to health and social care research, the scope of which does not extend to clinical audits, standard service evaluations, or public health or advanced health analytics work carried out by the HSE for the purpose of fulfilling its legal obligations for the planning and delivery of health and social care services (see also ANNEX 1). Health and social care interventions and types of research that are not health research are also outside of the scope of this policy.

²¹ For the purpose of this document, 'health research' is defined as set out in Regulation 3(2) (a) of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018) (<http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf>).

²² HSE National Framework for Governance, Management and Support of Health Research (2021), HSE: Dublin, <https://hseresearch.ie/publications/>

Section 1: Preamble

1.3 Objectives

The specific objectives of this policy are to:

- Explain the meaning of consent for health research purposes
- Set out the essential ethical and legal (including data protection) and best practice requirements when seeking consent
- Articulate how, and by whom, valid consent may be obtained from prospective research participants
- When associated research involves the use of personal data, researchers must identify the legal basis for the data processing and, where relevant, the appropriate Article 9 condition before the research commences (see Section 2.1).

1.4 Outcomes

The expected outcomes of this policy are to ensure that:

- Researchers are aware that prospective research participants have a fundamental legal and ethical right to control their own lives, to make informed decisions on matters that relate to them, and to decide what happens to their own bodies.
- All researchers doing research within the scope of this policy meet their professional, ethical, regulatory, and legal requirements in relation to obtaining consent for research.
- There is a consistent process for obtaining consent for research.
- Consent obtained is documented appropriately.
- Researchers know what to do if consent is withdrawn.

1.5 HSE National Consent for Research Policy Working and Advisory Groups

Content for this policy has been developed by the HSE National Consent in Research Policy Group, including members from HSE National Research and Development and external members, in consultation with the HSE Research Ethics Committee Reform Working Group, members of the HSE Research and Development Patient and Public Involvement Reference Group, and external legal advisors.

Membership details of the Working Group and advisors are provided in ANNEX 2.

1.6 HSE National Consent Policy Steering Group

The HSE National Consent Policy Steering Group has reviewed, edited, and approved the content of this policy.

Membership details of the Steering Group are provided in ANNEX 3.

1.7 Supporting evidence

1.7.1 Relevant legislation

The following legislation has been taken into account for the development of this policy:

- The Constitution of Ireland
- Assisted Decision-Making (Capacity) Act 2015
 - This is the legislative basis for supporting decision-making and maximising a person's capacity to make decisions
 - This Act applies only to adults and is relevant to all health and social care services.

Section 1: Preamble

- The Act was signed into law on 30 December 2015.
- Although certain sections of this Act have been commenced, the essential elements of the Act, including Parts 2–8 inclusive, have not been commenced at the time of the publication of this policy.
- The full Act is due for commencement in 2023.
- Assisted Decision-Making (Capacity) (Amendment) Bill 2021
 - This Bill is sponsored by the Department of Children, Equality, Disability, Integration and Youth and at the time of writing has yet to come into operation.
 - This Bill makes some amendments to the decision-making processes necessary to commence the 2015 Act and improves processes and safeguards for those who will make use of the new decision-making supports
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
- Data Protection Act 2018
 - This gives further effect to the General Data Protection Regulation (GDPR) in the State in areas where the GDPR gives limited flexibility to member states.
- The Health Research Regulations, 2018 made under the Data Protection Act 2018; the two pieces of legislation are collectively referred to as Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018) and subsequent amendments:
 - Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2019 (S.I. No. 188/2019)
 - Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021)
- Child Care Act, 1991 and Child Care (Amendment) Act 2015
- Children First Act 2015
- Health Act 2004
- European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004 (S.I. No. 190/2004) and Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use²³
- Data Sharing and Governance Act 2019
- Non-Fatal Offences Against the Person Act, 1997
- Convention 108+ for the protection of individuals with regard to the processing of personal data (Modernised Convention 108)²⁴
- Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act)²⁵

23 Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

24 Convention 108+: Convention for the protection of individuals with regard to the processing of personal data. Council of Europe, June 2018, https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/LIBE/DV/2018/09-10/Convention_108_EN.pdf

25 Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0868&from=EN>

Section 1: Preamble

1.7.2 Relevant international guidelines

- Belmont Report
- Declaration of Helsinki
- European Data Protection Board (previously the Article 29 Working Party (Art. 29 WP)²⁶
- Global Code of Conduct for Research in Resource-Poor Settings
- The European Code of Conduct for Research Integrity
- Universal Declaration of Human Rights
- European Convention on Human Rights²⁷
- Charter of Fundamental Rights of the European Union
- Convention on Human Rights and Biomedicine (1977)
- Convention on the Rights of Persons with Disabilities
- Convention on the Rights of the Child
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice (ICH GCP)
- International ethical guidelines for health-related research involving humans, Council for International Organizations of Medical Sciences²⁸

1.7.3 Relevant policies, procedures, protocols, and guidelines (PPPGs)

- The HSE's *National Consent Policy* (2022)
- *HSE National Framework for Governance, Management and Support of Health Research* (2021)
- *Health Service Executive Standards and Recommended Practices for Healthcare Records Management*, V3.0
- HSE National Research and Development (R&D), advice on regulatory and ethical requirements for research activities www.hseresearch.ie
- The HSE National Office for Human Rights and Equality Policy has developed guides to accompany the HSE National Consent Policy; 'A Guide for Health and Social care professionals', 'Consent: A guide for patients and service users', 'Consent: A guide for young people' (<https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/advisory-group-documents.html>)
- The Department of Health's *Guidance on Information Principles for informed consent for the processing of personal data for health research*

26 The European Data Protection Board (EDPB) was previously the independent European working party that dealt with issues relating to the protection of privacy and personal data until 25 May 2018 (entry into application of the GDPR) when the working party was replaced by the EDPB. During its first plenary meeting the EDPB endorsed the GDPR related Article 29 Working Party Guidelines. https://edpb.europa.eu/sites/default/files/files/news/endorsement_of_wp29_documents_en_0.pdf

27 Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, ETS No. 164 (1997).

28 International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016, <https://doi.org/10.56759/rgxl7405>

Section 1: Preamble

- Guidance material produced by the Department of Health in collaboration with the HSE, the Health Research Board, and the Health Research Consent Declaration Committee, in consultation with the Data Protection Commission, on amendments to the Health Research Regulations, 2018:
 - *Guidance on Pre-screening: Amendment to the Health Research Regulations – January 2021*
 - *Guidance on Retrospective Chart Review: Amendment to the Health Research Regulations – January 2021*
 - *Guidance on Deferred Consent: Amendment to the Health Research Regulations – January 2021*
 - *Guidance on Informed Consent obtained in the time of EU Directive: Amendment to the Health Research Regulations – January 2021*
 - *Guidance on Explicit Consent: Amendment to the Health Research Regulations – January 2021*
 - *Guidance on Appeals and Technical Amendments to the Health Research Regulations – January 2021.*
- HSE National Clinical Guidelines for Post Mortem Examination Services (in development).

1.7.4 List of PPPGs that are being replaced by this policy

This policy supersedes the research-related content (formerly Part Three (Research)) of the 2013 HSE *National Consent Policy* (revised June 2019). The 2022 HSE *National Consent Policy* should be read in conjunction with this policy when health and social care interventions, including medical care and treatment, are interlinked with research.

1.8 Development of PPPGs

The *HSE National Policy for Consent in Health and Social Care Research* represents an extensive revision of what was Part Three (Research) of the original HSE *National Consent Policy, 2013* (revised 2019).

This policy reflects consideration of important legislative and policy changes since 2013, including the GDPR, the Data Protection Act 2018, the Health Research Regulations, 2018 and amendments, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and the Children First Act 2015.

The Assisted Decision-Making (Capacity) Act 2015 has been enacted and is scheduled to be commenced in early 2023. The language in this policy, in particular an emphasis on the importance of the will and preferences of someone who may lack decision-making capacity, has been changed to align with the 2015 Act in preparation for the commencement of the Act.

1.9 Governance and approval

The development, publication and future review of the *HSE National Policy for Consent in Health and Social Care Research* is coordinated and managed by HSE National Research and Development and reflects the strategic and policy direction established by the HSE Executive Management team, and is consistent with the legislation, regulations, policies, and strategy of the HSE.

This policy is governed by the HSE National Director for Strategy and Research and has been approved by the HSE National Committee for the Governance, Management and Support of Research on behalf of the HSE Executive Management team.

Section 1: Preamble

1.10 Communication and dissemination

This policy will be available, as a minimum, on the HSE National Research and Development website. It will be officially launched and disseminated by way of learning events, including policy briefings, masterclasses, seminars, and webinars for researchers, staff, and services, coordinated by HSE National Research and Development.

Various additional media approaches will also be utilised to circulate key messages in relation to the policy to relevant stakeholders.

1.11 Implementation

1.11.1 Education and training

To support the implementation of this policy and its adoption by researchers, and others, working across the HSE and its funded organisation, the following education and training initiatives will also be rolled-out:

- An education programme including e-learning courses will also be available shortly after the official launch of this policy.
- A supporting summary guidance document in an easy-to-read format will be developed and available online.
- HSE National Research and Development will champion, advance, support, and provide strategic advice on the ongoing implementation of this policy.

1.11.2 Accountability for the implementation of this policy

It is important that this policy is adopted widely across the HSE and its funded organisations. The following are some key stakeholders who are accountable for its implementation:

- HSE national directors, chief officers, and Hospital Group chief executive officers are responsible for ensuring that this policy is implemented throughout their Community Healthcare Organisations, HSE hospitals, and national services.
- Senior management and all line managers have a key role in ensuring that the necessary structures and supports are in place to oversee compliance.

1.11.3 Responsibilities of staff and organisations

All members of staff employed or contracted by the HSE who engage in research activity should familiarise themselves with this policy and with the additional guidance and training material available on the HSE National Research and Development website.²⁹ The following are some of the groups who have responsibility for its implementation:

- RECs have a key role in ensuring that this policy has been applied to the proposals submitted for research ethical approval.
- The HSE, or HSE-funded healthcare organisations involved in research, must facilitate and encourage staff in implementing this policy by providing access to guidance and training material, assistance, and advice if needed.

This policy should be brought to the attention of any external stakeholders (academic collaborators, contract research organisations, sponsors, charities, etc.) that engage with the HSE or any of its funded health and social care service providers for the purpose of health research.

²⁹ See the HSE National Research and Development website: www.hseresearch.ie

Section 1: Preamble

1.12 Monitoring, audit, and evaluation

Monitoring, audit and evaluation of this policy will assist the HSE with knowing the degree to which it is being implemented.

- RECs have a key role in ensuring that this policy is applied as part of the research ethical approval process.
- The uptake of training will be monitored by HSE National Research and Development.
- Managers are required to monitor local implementation of this policy via their research governance, management, and support functions, as per the *HSE National Framework for Governance, Management and Support of Health Research*.
- Implementation of the policy shall be audited periodically at national level.

1.13 Revision

This policy represents the position of the HSE at the time of publication and will be kept under review. The policy will be reviewed by HSE National Research and Development every five years, unless otherwise required to reflect changes to legislation, regulation, or other relevant policy (e.g. the policy will be reviewed when the Assisted Decision-Making (Capacity) (Amendment) Bill 2022 have been fully commenced).

2 Consent for research



Section 2: Consent for research

2.1 What is consent?

Consent for research is the ethically obtained, informed, explicit agreement of a prospective research participant to take part in a research study, which has been recorded and retained in compliance with Irish data protection legislation. It entails the deliberate, freely given, and unambiguous agreement of a prospective research participant to participate in specific research-related activities and/or for the processing of their related personal data, after a process of clear communication and exchange of information.

Individuals have a fundamental legal and ethical right to control their own lives, to make informed decisions on matters that relate to them, and to decide what happens to their own bodies and personal information. Involving a person in health research without first securing their consent is a violation of their legal and constitutional rights and may result in civil or criminal proceedings. Section 6 of this policy sets out some limited exceptional circumstances where health research can proceed without prior consent.

Consent is a dynamic process rather than a one-off event, with ongoing engagement and communication between researchers and participants. It encompasses the right to withdraw consent at any point (see Section 3.6) and should also involve reconfirmation of consent if changes are made to a research study which affect the participant in a manner to which they have not previously given specific consent (see also Section 3.5).

Consent is required for all health and social care interventions, and separate consent is also required for research. This policy deals specifically with consent for research, while consent considerations for all health and social care interventions and clinical practice are outlined in the HSE *National Consent Policy* (2022). Both policies should be read when health and social care interventions are intertwined with research activities.

Consent for research is underpinned by both ethical and data protection considerations:

- Consent for research is one of the founding principles of research ethics. The ethical principles underpinning the process of consent for health research include those of:
 - **Respect for persons** (respect for individual autonomy and self-determination, in addition to protection of individuals with diminished, or without, decision-making capacity)
 - **Beneficence** (efforts to reduce the risk of harm, and to maximise benefits to the participant, which are usually availed of by members of the larger society)
 - **Justice** (fairness in selection and treatment of research participants)
 - **Solidarity** (empathy, fellowship, and a commitment to work for the good of a research participant from the perspective of partnership), which also applies to participants and the reasons they participate in the first place; solidarity represents a willingness to carry costs in order to assist others with whom a person recognises a sameness, shared situation, or cause.

Section 2: Consent for research

- The core rights of individuals that need to be respected in accordance with these ethical principles while obtaining consent for research include the rights to:
 - Self-determination
 - Be treated in a fair manner
 - Not be harmed or exploited
 - Privacy and confidentiality.³⁰
- When the research involves the processing of personal data, obtaining the explicit consent of prospective research participants prior to starting the research is a mandatory legal requirement in Ireland. In these cases, and in addition to obtaining explicit consent, researchers must also choose the legal grounds for the data processing that underpin the legality of such activity.³¹ This is important because it determines whether or not certain participants' rights apply. It is not possible to change/swap the legal basis for a specific processing activity once it has started (which is, for example, important in relation to participants' right to withdraw their consent). When in doubt, researchers should seek advice and consult with the relevant data protection officer.
- When research also involves an intervention (i.e. rather than solely the processing of data), the participant must consent to **both** the interventional and the data processing elements of the study.

2.2 Valid consent for research participation and for processing of personal data for health research

In order to obtain valid consent from a prospective research participant, a number of important criteria and/or conditions should be met:

- The protocol and materials for obtaining consent, including (among other material) the Participant Information Leaflet (see Section 3.2.1) and the consent form, must be approved by an appropriate REC³² before the research commences for all health research under the remit of the *HSE National Framework for Governance, Management and Support of Health Research*.
- Valid consent must be obtained before the research takes place, with the exception of the specific limited circumstances set out in Section 6 of this policy.
- Where it is not possible to obtain consent for the processing of personal data for research purposes and the research falls outside any exemption to obtain consent, a consent declaration from the Health Research Consent Declaration Committee (HRCDC) will be required (see Section 6.9).
- In situations where prospective research participants have reduced capacity or lack decision-making capacity to provide consent (see Section 4), and in the case of children (see Section 5), particular considerations should be taken into account.

30 Notwithstanding the limits to confidentiality, particularly in relation to *Children First: National Guidance for the Protection and Welfare of Children*, and in relation to mandated persons and to disclosing criminal activity. The right to privacy and patient–doctor confidentiality are additional key considerations which are interlinked with data protection principles.

31 Data processing is lawful under an exhaustive and restrictive list of legal bases provided in the GDPR under Article 6 for non-sensitive personal data, and Article 9 for special categories of data (or 'sensitive data', including health data) which are subject to additional requirements. The legal basis for processing personal data (consent, contract, legal obligation, vital interests and public task) must be identified and decided for each study and category of processing prior to study commencement based on a factual and operational analysis (categories of personal data, purpose of processing, etc.).

32 This can include a National REC, HSE Reference RECs and Hospital RECs, voluntary hospital RECs, RECs with Section 38s/ 39s, and includes the Tusla REC in the case, for example, of children in care.

Section 2: Consent for research

For the consent to be valid, the following apply:

- Consent must be informed (Section 2.2.1)
- Consent should be specific (Section 2.2.2)
- Consent must be unbundled (Section 2.2.3)
- Consent must be freely given (Section 2.2.4)
- Consent must be unambiguous (Section 2.2.5)
- Participants must have the right to withdraw consent (Section 2.2.6).

2.2.1 Consent must be informed

Informed consent means that prospective research participants must be given all of the necessary information in a way that is understandable for them, and with sufficient time to consider it, before exercising their choice. Further details about informed consent are included in Section 3.2.

2.2.2 Consent should be specific

The information provided should be sufficiently specific and detailed and, where possible and appropriate (depending on the nature of the study), participants should be given the option to consent to clearly defined or identified types of research activities within the study (see also Section 2.2.2.1). For consent to be specific the following must apply:

- Consent must be specific about the purpose(s) of the study and the associated data processing.

- While consent for secondary research use of identifiable personal information or identifiable biological material may have to be broader rather than specific, the consent process must include as much detail as possible about the potential secondary use of the personal data or the biological material (see Section 2.3).
- Information and considerations related to the research intervention should be separate from those related to consent for data processing activities (usage, sharing, access, rights, etc.).

2.2.2.1 Tiered approach to obtaining consent to facilitate option selection

It is recommended that, whenever possible and appropriate, a tiered consent format be used in order to allow a prospective participant to select from, and to consent to, a graduated set of consent options. This is particularly useful with respect to the storage and secondary use of biological material or personal data (see Section 2.3). For example, consent options may include the data's secondary use for specified categories of diseases rather than for any disease. The same approach can be used in order to help prospective participants make deliberate choices with regard to the information they do or do not want to receive, whether they want to be contacted in future secondary research, or options regarding future secondary data processing (i.e. including the anonymisation of their data) and secondary use of data. This tiered format is recommended for use with biobanks and genomic databases in particular. When a secondary use for research purposes includes genetic analysis, this should always be specifically indicated as a standalone consent choice. The type of genetic analysis likely to be undertaken must be identified. Whole genome sequencing requires explicit consent, including outlining the risks entailed in such analysis being performed, and the possible ownership of such data by private or commercial interests. The right to withdraw genetic data, and clear information on how to do so, must also be provided.

Section 2: Consent for research

2.2.3 Consent for different purposes must be unbundled

The request for consent for research shall be presented in a manner which is clearly distinguishable from other matters; for example:

- 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 (see the HSE 2022 *National Consent Policy* for guidance) and consent to research participation. This means separate discussions should take place and separate consent documentation should be provided.
- Where possible, the consent process for health and social care interventions and that for research procedures should also each be undertaken by different healthcare professionals who are suitably knowledgeable to do so.

2.2.4 Consent must be freely given

The following should be taken into account when considering whether consent has been freely given or not freely given:

- The consent is “valid only if the prospective participant is able to exercise a real choice and there is no risk of deception, intimidation, coercion or significant negative consequences if he/she does not consent”.³³
- Consent is not considered freely given “if the research participant has no genuine or free choice or is unable to refuse or withdraw consent without detriment”.³⁴ Thus, prospective research participants must be assured that a decision not to consent will not impact on any healthcare and/or medical treatment received. Sometimes access to new therapies may

only be available as part of a research study, and particular care must be taken to ensure that consent is appropriately obtained as per this policy.

- This is especially important where the researcher is also involved in the prospective research participant’s normal healthcare and/or medical treatment. In such circumstances, it is necessary to ensure that the inherent power imbalance (unconsciously or consciously) between the clinician/researcher and the prospective research participant does not interfere with the voluntary nature of the consent process. Power imbalance may be when a participant is not in good health conditions, when participants belong to an economically or socially disadvantaged group or in any situation of institutional or hierarchical dependency.³⁵ There must be no indication of undue influence or pressure on an individual to participate. Consent must be freely given, specific, informed, and unambiguous.
- Researchers should be mindful of the potential for unrealistic or misconstrued expectations from prospective research participants of the benefits of participating in the proposed research (therapeutic misconception) as a result of how information is presented, or of any inherent power imbalance. This may be helped by having different healthcare professionals undertake the consent process for health and social care interventions, and for research procedures, who are suitably knowledgeable to do so.
- It is essential that any conflict of interest that may arise as a result of the original relationship (prior to consent) be acknowledged in writing and that any possibility that the individual might feel obliged to participate be averted. This may be achieved by having the consent either obtained or witnessed by a person who is independent of the research.

33 Guidelines on consent under Regulation 2016/679, Article 29 Working Party, WP259 rev.01, https://ec.europa.eu/newsroom/article29/document.cfm?action=display&doc_id=51030

34 Burden of Proof and Requirements for Consent, Recital 42, GDPR, <https://gdpr-info.eu/recitals/no-42/>

35 Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), adopted on 23 January 2019. European Data Protection Board

Section 2: Consent for research

2.2.5 Consent must be unambiguous

There should be no reasonable doubt that the research participant wants to express their agreement to participate in the study and, when relevant, allow the processing of their data for the research. Consent should be recorded by way of an active choice to opt in (see Section 3.3). Default inclusion, along with the use of opt-out options, cannot be used. Silence, pre-ticked boxes, or inactivity never constitute valid consent, and prospective participants must be offered the opportunity to refuse to consent (e.g. by means of including options to indicate either 'Yes' or 'No' in the consent form). Consent received (by way of either written, verbal, electronic, or other formats) must be recorded and retained, with a copy provided to the participant where they are in a position to receive it (see Section 3.3.3 for details of verbal consent).

2.2.6 The right to withdraw

Participants must have the right to withdraw consent at any time without needing to provide a reason, and this right must be set out in an unambiguous and unconditional manner. Prospective participants and participants must be informed of their right to withdraw consent and given information on how to do so. Participants should be informed at the time of consent that withdrawing of consent will not impact on their current or future clinical care (see also Section 3.6 for further details, including exceptions to being able to withdraw).

2.3 Consent for storage, maintenance, and secondary research use of identifiable personal data or identifiable biological material

When personal data and/or human biological material are collected with the intention of subsequently storing them for secondary research³⁶ purposes, a broader³⁷ (rather than specific) type of consent may be used:

- While this type of consent is broader, it must continue to be as specific, explicit, and informed as possible. The researcher must be open and clear about the subsequent intended uses of the personal data and/or human biological material, insofar as this is foreseeable.
- Blanket consent, or consent to use tissue or data for research in an unrestricted way, is not valid, except in some situations where the donor is deceased (see Section 6.2). For broad consent to be valid, researchers must ensure that secondary use of personal data or biological material continues to be within the area of research specified in the original consent.³⁸
- It is recommended to seek consent in a tiered format in order to give the participant as much choice as possible. For example, choices may include consent to re-contact or not; to receive further information or not; options around secondary data processing (i.e. including the anonymisation of the participant's data); and options regarding specifying categories of research or diseases with respect to future secondary use of data.

36 'Secondary research' in the context of this policy refers to research within the scope of study described as part of the original consent obtained.

37 'Broad informed consent' for research refers to consent obtained for additional secondary use of biological material and/or personal data for secondary research that has not yet been specifically defined but that relates to an identifiable research topic or process for a similar purpose in a particular area, more generally in that area, or in a related area.

38 GDPR Recital 33 and Article 89 shall be considered when determining what constitutes broad consent and the degrees of specification and granularity of consent in the context of the use of personal data for secondary research. In Recital 33, some flexibility is foreseen for situations in which the purposes of data processing in the scientific research project cannot be specified at the time of data collection but can only be described in a high-level way, for instance in terms of (types of) research questions and/or fields of research to be explored. There is a requirement to carefully evaluate the rights of the data subject, the sensitivity of the data, the nature and purpose of the research, and the relevant ethical standards.

Section 2: Consent for research

- This tiered format is recommended for use with biobanks and genomic databases in particular.
- When secondary use for research purposes includes genetic analysis, this should always be specifically indicated as a standalone consent choice. The type of genetic analysis likely to be undertaken must be identified. Whole genome sequencing requires explicit consent, including outlining the risks entailed in such analysis being performed and the possible ownership of such data by private or commercial interests. The right to withdraw genetic data, and clear information on how to do so, must also be provided.
- When research purposes cannot be fully specified, the data controller must seek other ways to ensure that the essence of the consent requirements is best served. These include data anonymisation, dynamic consent, and/or transparency mechanisms.
- Adequate safeguards³⁹ should be in place to enhance the transparency of the processing of the personal data and/or human biological material during the research project, and to ensure that the requirements on specificity of consent are met as thoroughly as possible in order to ensure that the participant's rights are protected.
- At a minimum, information around the scope of secondary research, the storage and sharing of data and/or biological samples, transparency arrangements, the possibility and mechanism of withdrawal of data or samples, and details of the relevant contact person(s) should be included as part of this process.⁴⁰ The following is a non-exhaustive list of issues to be considered and, where relevant, contained in the Participant Information Leaflet (PIL) and Consent Form:
 - A description of the types of secondary research that may be conducted or the potential secondary uses for the personal data or biological material
 - Details about ethical approval requirements for secondary research studies using the participant's personal data and/or human biological material.
 - Permission to re-contact the participant to seek permission for secondary research using their personal data and/or human biological material outside the scope of the original consent.
 - How and when the biological material/personal data will be managed/destroyed once they are no longer required.
 - Details on the process for feedback of information arising from the research study where this could impact the participant's health, such as secondary or incidental findings.
 - The lawful basis for processing personal data and associated rights.
 - Information must be provided regarding whether the biological material will be identifiable, pseudonymised, or irrevocably anonymised, and how personal data will be managed.
 - How the participant's biological material/personal data will be kept confidential.

39 European Data Protection Board, *EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research* (2021), https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnairesearch_final.pdf

40 Maloy, JW, and Bass, PF. "Understanding Broad Consent," *The Ochsner Journal*, 20, no. 1 (2020): 81–86, <https://doi.org/10.31486/toj.19.0088>

Section 2: Consent for research

- Whether data or biological material may be shared with other parties in the future should be provided; this should include the types of institutions or researchers that might conduct research with the participant's personal information or biological material in the future, with the option to indicate that consent is given to the research being undertaken by:
 - Only researchers in the unit to which the biological material was donated
 - Any academic researcher in Ireland, or in the European Union (EU)
 - Any academic researcher globally
 - Industry-funded researchers.
- Information on how long the personal data or biological material may be stored, maintained, and used, including details about locations in third countries not covered by the GDPR.
- If any of the intended research uses will, or may, involve the participation of commercial entities, the prospective research participant must be provided with the option of considering their inclusion or exclusion from this component of the study.
- Participants may be given the choice to opt in or out of receiving information about the research results. If this is not possible, a statement to that effect should be included.
- Participants should be informed about how they can access information about the research that takes place as a result of their broad consent (such as via website updates, a newsletter, etc.).
- Transparency measures should include information about how participants can withdraw their consent and data, or ask for destruction/disposal of banked tissue, if they wish to do so.
- The withdrawal of participants' personal data or human biological materials may not be possible after a certain point in time. For example, their personal data may have been anonymised prior to storage and cannot be separated from the pool of participants' personal data, or their contributions may have been widely disseminated through publications and/or published reports. Researchers must justify any limitations to the withdrawal of personal data or human biological materials to their REC, and these limitations must be explained to participants during the consent process.
- Relevant contact information, and what such contact information may be used for (e.g. who to contact regarding research-related harm).

When seeking broad consent for the use of post mortem tissue (see definition in Section 6.2), the consent process should, in addition to the issues listed above, include options to clearly specify the body parts, organs, or tissues that may be used for research purposes, with the following options:

- Consenting to research on any part of the body
- Excluding particular body parts, organs, or tissues from research studies
- Limiting research to a single body part, organ, or tissue.

Section 2: Consent for research

The type of research that may be carried out, including the options to consent to the post mortem biological material being used, include the following (please see Section 6.2):

- Any type of research
- Excluding specific topics or areas of research to which the individual does not wish to consent
- Specifying that research may only be carried out on specific topics or areas.

Explicit and specific consent must be sought for any genetic or genomic investigations intended to be carried out as part of a research study using post mortem tissue.

An open-ended consent request for permission without any limitations for future unforeseeable secondary research (blanket consent) is not legally valid and cannot be used.

2.4 Consent obtained for the processing of personal data secured pre-GDPR

Explicit consent for the processing of personal data (as defined in the Amendment to the Health Research Regulations January 2021⁴¹ is not required for research that commenced prior to 8 August 2018 where the consent was obtained before 25 May 2018, and was valid consent at the time (in accordance with the European Data Protection Directive (Directive 95/46/EC) on the protection of individuals with regard to the processing of personal data and on the free movement of such data,) with a lawful basis, for specified health research (in accordance with 'broad informed consent'; see also Section 2.3), and where the consent has not been withdrawn.⁴² In these cases, transparency measures and notices should be used where possible and appropriate.

41 "Explicit consent obtained from the data subject, as a suitable and specific measure recorded and retained by the controller, and a copy of which is provided to the data subject prior to the commencement of the health research in accordance with international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight) for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof" Guidance on Explicit Consent Amendment to the Health Research Regulations January 2021, page 12

42 Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021), <https://www.gov.ie/en/publication/b46c2-amendments-to-health-research-regulations/> and <http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf>



3 Obtaining and recording consent

Section 3: Obtaining and recording consent

Obtaining consent may be part of a multi-step process that is generally preceded by the identification of prospective research participants suitable for inclusion in the research study. The research study's principal investigator (PI) is responsible for the consent process, but the various tasks prior to, and as part of, taking consent may be delegated to one or several appropriate team members under the governance of the PI. Actions taken to establish whether a prospective research participant may be suitable or eligible for inclusion in the research are referred to as 'pre-screening'. Potentially suitable research participants may be selected on the basis of specific inclusion/exclusion criteria directly validated by a member of the research team, and which may require access to the participant's personal information (i.e. healthcare records) (see Section 6.6). Prospective research participants may identify themselves, such as by responding to a general announcement or public notice. Such notices should specify what will be required of participants, the personal data that will be required upon making contact, and what data may be required for the study.

3.1 Who should obtain consent when contacting or recruiting research participants?

If a research study is of a clinical nature (i.e. rather than being a social-science-based study), the person who initially contacts each prospective research participant in order to establish their interest in the research study (e.g. where medical records were accessed and a direct phone call made to a person) should be a health practitioner⁴³ employed by the healthcare provider or a person authorised by the healthcare provider to make contact on the provider's behalf. This is distinct from determining interest in a non-specific manner, e.g. posting information in waiting rooms, or via social media. The subsequent and separate process of providing appropriate information about the research study and obtaining consent can then commence.

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

- Understand the research protocol and the potential implications it may have for the prospective participants.
- Understand the alternatives to participation, which may include treatment alternatives.
- Have an ability to communicate effectively with prospective participants, including explaining complex scientific/medical concepts.
- Appreciate how to support the voluntary nature of decision-making and avoid undue influence.
- Know the prospective participants' rights, including data protection rights.
- Have time to dedicate to the process.

In the case of Clinical Trials of Investigational Medicinal Products (CTIMPs), only a registered medical practitioner, a registered dentist, or a registered nurse can obtain the participants' informed consent to participate.⁴⁴ In the case of Clinical Investigations of Medical Devices, only a registered medical practitioner, a registered dentist, a registered nurse or midwife, or a person registered in the Register of Pharmacists, the Register of Optometrists, or another register maintained under the Health and Social Care Professionals Act 2005 may obtain consent.

⁴³ A 'health practitioner' as defined in section 2 of the Health Identifiers Act 2014 (Number 15 of 2014). See also the definition in the Glossary of term.

⁴⁴ ICH, *Good Clinical Practice*, <https://ichgcp.net>

Section 3: Obtaining and recording consent

When the researcher is also providing care or support to the prospective research participant, it is especially important that the voluntary nature of an individual's participation in a research project be emphasised during the consent process (see also Section 2.2.4). This issue needs to be considered on a case-by-case basis, and the REC will also determine if there is any conflict of interest arising from the proposed consent process.

3.2 Informing prospective research participants

Key considerations in informing prospective research participants:

- The consent process should be a dynamic process involving a two-way conversation between one or more members of the research team and the prospective research participant, during which the prospective participant should be encouraged to ask questions, notwithstanding the fact that this may not be possible in certain cases (e.g. in the case of an online survey, or when the prospective participant has no capacity to consent).
- Interactive questioning may aid understanding between the prospective participant and the researcher, highlighting areas that the prospective participant may have misunderstood or that the researcher may have overlooked or used inappropriate language to explain. The prospective research participant should be invited to have a family member, friend, or other support person present for the discussion, and if this option is availed of, that person should act as a witness to the consent process.
- Prospective participants should also be informed how much time will be required for the consent meeting and, if possible, given every support to attend the appointment (including the reimbursement of basic expenses).

- The information provided to invited participants must be accurate and include detailed information about the consent process and relevant information about the study in which they are being asked to participate. This includes:
 - Information related to the clinical or scientific aspects of the study
 - The composition of the research team, the study collaborators, and information on whether such collaborators are commercial entities or academic institutions
 - Information about how the prospective research participant's personal data/biological material are going to be processed
 - The legal basis under which the data will be processed
 - The data protection rights of the study participant.
 - Prospective participants should be made aware of the consequences of not consenting to certain options within the consent form (for example, stating that they do not want their data shared with commercial companies), which might mean that they cannot participate in part or all of the proposed research.
- Prior to the commencement of the study and the invitation to participate in the study process, consultation with patients, carers, patient advocates, or other groups relevant to the prospective research cohort should take place. Such engagement will ensure that the material developed and provided to prospective research participants is understandable and addresses all consent and study issues of importance and relevance to both the participants and those undertaking the research. Embedding patient and public involvement (PPI) from the earliest stages of study design, and building relationships with relevant organisations and individuals, will help to facilitate this important input.

Section 3: Obtaining and recording consent

- Information about the study must be provided in a format that is appropriate for the level of literacy, age, developmental stage, and capacity of understanding of the participant. Information should be provided in a form that most people can understand and be adapted to the type of participant (e.g. according to age, developmental stage, education level, and culture and ethnic background, and depending on whether the research will involve non-English speakers; non-verbal participants; or those with cognitive impairments, memory difficulties, or a disability such as visual impairment, hearing impairment, etc.). Other formats should be used when considered appropriate for the participant group, such as audio, visual aids, video, and online interactive materials, among others. The appropriateness and content of the material must be approved by the relevant REC.
- Densely written PILs are not helpful, and the language and terminology used in PILs should be as simple as possible (e.g. non-technical plain English according to the National Adult Literacy Agency's (NALA's) guidelines).⁴⁵ Researchers must consider balancing the need to provide a lot of important information with not overwhelming potential participants.
- Where the research involves, for example, participants with low levels of literacy, intellectual disabilities, or children, it is particularly important that the vocabulary, tone, and style of the language used are appropriate to the prospective research participants so that they can fully understand the information being presented to them.
- PILs and associated consent and assent⁴⁶ forms should be sufficiently detailed and clear to be standalone. They may be used to support a conversation about consent, but should not be the sole source of information about the research provided to prospective participants. The consent-related discussion should also be documented.
- Prospective research participants cannot give consent under any form of duress and must be given sufficient time to assess the information provided and to ask questions. They should be given adequate time to consider their participation in a study before being expected to make a decision (in other words, a 'cooling-off period'). Providing the information in advance of consenting will enable prospective participants to make an informed choice to participate.
- Complex and technical information, including that related to the processing of personal data or biological material, must be explained in such a way that a participant can understand it in order to ensure that all the information provided will be considered in its entirety.
- Research participants should be able to determine in advance of consenting what the scope and consequences of the processing of their personal data and/or biological material involves, and they should not be surprised at a later point in time about the ways in which their personal data have been used.

⁴⁵ "Plain English writing and design tips," NALA, <https://www.nala.ie/plain-english/plain-english-tips/>

⁴⁶ See the Glossary of terms for PIL, consent and assent

Section 3: Obtaining and recording consent

- Participation in research is not designed to offer benefits to participants, and outcomes can never be guaranteed. Therefore, it is important to ensure that any possible outcomes are never overstated in order to avoid therapeutic misconception or unrealistic expectations by prospective research participants. Research, by its nature, may also include risk, and it is essential that the identified risks of participation in research are reasonable and clear. Where the prospective research participant is a healthy volunteer, it should be clearly stated that participation in the research study will most likely confer little or no benefit to them, and may in fact only carry risk, depending on the nature of the study.

3.2.1 The Participant Information Leaflet

The PIL is a written document which contains all the relevant information about a study. It is provided to prospective participants during the consent process in order to help them understand the implications of participation and to help them make a decision.

It is recommended that the information provided in the PIL be broken down into manageable sections (see also the ICH GCP requirements⁴⁷ and Department of Health guidance)⁴⁸ for example:

a) Introductory section

- A statement stipulating that the study involves research
- The voluntary nature of the participation
- The right to withdraw, and any caveats or conditions to the withdrawal of personal data

- The fact that the prospective participant's decision to participate or not participate will not have an impact on their medical care
- Encouragement to read all information and to ask questions and consult with their general practitioner (GP), family, and friends if they are unsure
- What happens if the participant changes their mind

b) Information about the proposed research study:

- What the study is about and why it is being conducted
- Who the research/study partners are, and their nature (commercial, academics, etc.)
- Why the person is being asked to participate
- Estimated number of participants
- Process of randomisation, if appropriate
- Duration of participation
- How the study will be carried out (when is the study taking place and what is its duration, where is study taking place (where are potential participants being recruited from, and where will the intervention take place), what (what is the nature of the study and what is its purpose and anticipated benefits and side-effects), how (how will it be conducted, e.g., through interventional medical product or placebo)
- What is within and outside of the study scope

47 ICH GCP, Essential documents for the conduct of a clinical trial, <https://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial>

48 Department of Health, *Guidance on Information Principles for informed consent for the processing of personal data for health research* (2018).

Section 3: Obtaining and recording consent

- Benefits and risks of participation in the study
 - What will happen to the participant during the study
 - Any proposed genetic/genomic⁴⁹ testing, and the fact that this would constitute research-related testing, not diagnostic-grade testing⁵⁰
 - What happens if something goes wrong during the study (if applicable)
 - How the participant will receive information on the outcome(s) of the study
 - Whether the participant will receive the results of medical tests or investigations performed as part of the study, or the results of incidental findings (see also Section 3.4)
 - If using human biological material, details of where it will be stored, who will have access to it, how it will be discarded and after what time period, etc.
 - Any potential secondary use of personal data or biological material (see Section 2.3).
- c) Information about data protection and security:**
- What information about the participant will be used for the study, including access to medical records
 - What personal data will be used for any planned secondary research, and how it will be managed
 - GDPR Article 6: lawful basis for the processing of the participant's personal data and associated rights
 - GDPR Article 9: condition relied upon for the processing of the participant's personal health data
 - Method by which it will be ensured that personal data processing is minimised
 - Information about the use (or processing) of personal data required for the research study; this must include, at a minimum:
 - The identity of the organisation(s) (or 'data controller(s)') that is/are determining the 'why' and means by which personal data will be used, and the purposes for which the data are intended
 - The identity of joint data controllers
 - Where possible, the identity of any third-party collaborators or commercial parties that will receive personal data for the purpose of the study
 - The identity of any third party (or processor) that may be acting under the instruction of the data controller(s) specifically for the purpose of the study, such as contractors.
 - How data will be shared
 - How the use and sharing of data will be governed
 - Whether the data will be transferred outside of Ireland (or outside of the EU/European Economic Area (EEA))

⁴⁹ Genetic/genomic research is an interesting and important area of research that can present challenges for consent, particularly in the context of secondary research and incidental findings.

⁵⁰ Further consent is required for further testing to a diagnostic standard in an accredited laboratory, with interpretation confirmed by a clinical geneticist and a clear clinical pathway in place for the return of findings, including access to and the agreement of a clinical geneticist.

Section 3: Obtaining and recording consent

- How data will be stored
 - How long data will be retained, and when they will be destroyed
 - What risks to confidentiality exist, and how confidentiality will be protected
 - Limits of confidentiality and researcher obligations under Children First Act 2015 (see Section 5.5)
 - Security arrangements and who will have access to personal data
 - A statement outlining the rights of the individual with regard to their personal data
 - Planned anonymisation and subsequent sharing/dissemination of personal data:
 - Anonymising personal data constitutes processing in its own right. Where researchers intend to anonymise research participants' personal data, including for further processing or making such anonymised data publicly available, they must seek the consent of the research participants for such processing.
 - Any potential secondary research uses of data.
- d) Costs, funding, and approval:**
- Information about REC approval, including:
 - The name and contact details of the REC that gave ethical approval to the research
 - Whether any of the persons carrying out the research may have any conflict of interest
 - The date ethical approval was given by the REC
 - Reporting arrangements agreed with the REC
 - Any conditions attached to the research by the REC.
- Who is organising and funding the study, including:**
- Who is conducting the research
 - Who is funding the research and if the funder is a commercial sponsor
 - Whether the research is being done as part of an academic qualification
 - Whether the researcher or research team is receiving any compensation, financial or otherwise, to carry out the study
 - Whether the results will be disclosed for commercial purposes
 - Whether there will be any cost or compensation for participating in the study, particularly details regarding if and how expenses will be covered.
- e) Contact information:**
- Contact information in respect of the research project, including who to contact with regard to PIL-related queries, and who to contact in the event of a complaint
 - Contact information for data protection purposes, including who participants can contact directly to enable them to exercise their data protection rights (e.g. the data protection officer, and/or a specific member of the research team)

Section 3: Obtaining and recording consent

- The name of the PI/lead researcher and their contact details
- The institutional affiliations of the members of the research team
- Website/web page details if one has been set up for the study.

f) Other information:

- The potential commercial use of research findings
- The withdrawal of consent process and limitations (i.e. at what point in time personal data may be withdrawn or no longer withdrawn from the study)
- Post-study access to study-related interventions or medication
- Distress protocols
- Training and safeguards that are in place (e.g. Garda Vetting)
- Registration and adherence to associated professional guidelines/ codes of conduct in the case of professionals who have a professional registration body
- Details of how study results will be published and disseminated.

3.3 Recording and documenting consent

Consent may be indicated orally, in writing, or electronically. However, in certain cases, the consent is not considered to be legally valid unless it is in writing or digitally recorded, as is the case for CTIMPs and Clinical Investigations of Medical Devices. Consent must be obtained and recorded so as to leave no doubt about the intention of the research participant. Records must be retained in order to demonstrate what research participants were

told, any concerns/questions that were discussed, and when and how they provided consent.

3.3.1 Written consent

The following must be considered when obtaining written consent:

- Written consent should primarily be captured by way of a consent form, accompanied by a PIL. The function of a consent form is to record the participant's decision and to demonstrate that the consent process was conducted appropriately.
- A person's agreement with each statement contained in the consent form is required in an opt-in manner. Consent cannot be derived from silence, inactivity, pre-ticked boxes, or pre-completed forms, and prospective participants must be offered the means to refuse their consent (e.g. by including the option to indicate either 'Yes' or 'No' in the consent form) (see also Section 2.2.5). A signature alone at the end of the document is not sufficient. Consent can be documented by initialling or ticking boxes labelled 'Yes', or by writing the answer 'Yes' after each statement. Such statements must include sufficient specific detail with regard to both the participation in the study and the processing of the participant's personal data.
- The consent form is signed by the research participant, the member of the research team taking their consent, and a witness (if required). For a prospective participant who cannot read or write and wishes to make their mark, this should be witnessed and recorded by another member of staff independent from the research team. The witness should record the date and time, sign the entry, and provide their details, including their printed full name, employer details (service provider or academic institution), their signature, and their identification number (Irish Medical Council number, Nursing and Midwifery Board of Ireland number, CORU registration number, etc.).

Section 3: Obtaining and recording consent

See also Section 4 – Capacity to consent in adults, and Section 5 – Research involving children and young people aged under 18 years.

- A copy of the signed consent form and PIL must be given to the research participant.

In line with the *Health Service Executive Standards and Recommended Practices for Healthcare Records Management*⁵¹:

- Consent forms should be dated, timed, and signed by the person giving their consent, and should include the participant's printed name.
- Consent forms should also be dated, timed, and signed by the person obtaining the participant's consent, and should include that person's details, including their printed full name, employer details (service provider or academic institution), signature, and identification number (Irish Medical Council number, Nursing and Midwifery Board of Ireland number, CORU registration number, etc.).
- If the services of an interpreter are used to assist the participant when discussing their prospective participation in research and the consent form, the interpreter's name and contact details should also be recorded on the consent form. The interpreter is not authorised to consent on behalf of the research participant.

3.3.2 Digital consent

Electronic (sometimes known as e-consent) methods may also be used for seeking, confirming, and recording consent in research studies, particularly in the context of obtaining consent remotely/off-site. Here are some considerations when using digital consent:

- In the case of the digital/online context, a prospective research participant may be able to issue the required consent statement by filling in an electronic form, by sending an email, by uploading a scanned document carrying their signature, or by using an electronic signature. Individuals without access to the necessary technology equipment or know-how will need additional support or options.
- In the case of an online questionnaire (if this is the only method used to gather data), an option to ask further questions of the researchers could be provided. If the participant has no further questions, then a tick box (or boxes) can be used to confirm consent next to the required statements for consent (particularly if layered consent used).
- An electronic platform can be used to offer choices to research participants and obtain their consent, potentially giving them greater control over the giving, modifying, and/or withdrawal of their consent. It can involve the use of a secure electronic portal that only research participants and authorised research staff can access, so users can be confident that their data are safe. This also gives the research participant the flexibility to change their mind or to be contacted about further uses of their data for secondary research activities. E-consent platforms aimed at facilitating the capture of continuous consent or re-consent may suit certain projects, particularly longer-term projects⁵² (see also Section 3.5).

51 HSE Standards and Recommended Practices for Healthcare Records Management, QPSD-D-006-3 V3.0, 2011, <https://www.hse.ie/eng/about/who/qid/quality-and-patient-safety-documents/v3.pdf>

52 Joint statement on seeking consent by electronic methods. The Health Research Authority and the Medicines and Healthcare products Regulatory Agency, 2018, <https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-mhra-econsent-statement-sept-18.pdf>

Section 3: Obtaining and recording consent

- The process of obtaining digital consent should ensure that the participant is provided with a copy of their consent information.

3.3.3 Verbal consent

An oral statement can be used to express consent; however, records should be available to demonstrate that all conditions were met to validate the consent when it was given such as the following:

- Verbal consent should be witnessed and recorded by, for example, another member of staff independent of the research team, who should date (including the time) and sign the entry and provide their details, including printed name, employer (service provider or academic institution), signature, and identification number (Irish Medical Council number, Nursing and Midwifery Board of Ireland number, CORU registration number, etc.).
- Where possible and feasible, verbal consent expressed over the telephone or via remote technology should have a witness on both sides. If telephone consent is being obtained, the prospective research participant should be provided with a PIL in advance of seeking their consent so that when the consent is being obtained, the prospective participant has already reviewed the information. The researcher will talk the prospective research participant through the information and explain it to them over the telephone or via remote technology.
- Where possible, it is recommended that verbal consent be followed up with written consent. A written record of consent should be provided to the participant in the most suitable manner (e.g. a digital copy of the transcript/record, subsequent written email confirmation to the participant and witness, or the completion of hard copy paperwork if the participant and researcher subsequently meet in person).

3.3.4 Retention of consent-related documentation

Consent for research records are a form of personal data and should be stored in such a way that:

- The potential deterioration or loss of the record is minimised.
- The PIL that provided the information underlying the consent can be linked to the consent record.
- The confidentiality of the research participant is maintained.
- The records are secured and accessible only to those listed in the approved study.
- Participants' consent choices can be kept as part of the same record:
 - The storage strategy should allow researchers to track when consent has been fully or partially withdrawn, and in this case research participants need to be informed that a record of their choice will be kept, why there is a need to retain their data, and of the legal basis for retention.
 - In some instances, participants may withdraw their consent for secondary research-related data processing but may not withdraw their consent for past data processing, and this should be recorded.

3.3.5 Retention period for consent-related documentation

Consent records should be kept for the minimum amount of time required to fulfil the study requirements, but they must be retained for at least 7 years after completion of the research study. The considered provision of personal data and/or biological material from research participants should be respected and their use appropriately maximised, but records should not be held without

Section 3: Obtaining and recording consent

a specified purpose and an appropriate lawful basis. Here are some points to consider for the retention of consent records:

- The length of time for storing a consent record will depend on the requirements of the research itself (e.g. funders' requirements; storage and archiving requirements), and often depends on the level of risk associated with the study and whether the study includes the processing of personal data.
- Where research activities may have an identified risk for participants, it may be necessary to consider potential legal claims for damages arising from participation in the study. Other matters, such as the need to publish a research thesis, academic papers, or longitudinal studies, will all need to be considered when determining how long a consent record needs to be kept.
- Records must be destroyed by the PI once the storage period for legitimate processing lapses, or after legitimate anonymisation has taken place (see also Section 6.5).

3.4 Consent related to incidental findings of health and social care relevance

During the course of a research study, relevant incidental findings may arise which may have a significant implication for the participant, whether health-related, psychological, or social. Where incidental findings are regarded to be of vital and/or immediate clinical significance (such as in the case of tumours, blood clots, aneurysms, etc.), the researcher involved has a responsibility (a duty of care) to take appropriate action to mitigate against any potential risks. As part of the consent process, prospective research participants should be advised that such a duty of care exists, and should be advised of the following:

- The circumstances under which research results would warrant such a disclosure
- The strategy for managing such a disclosure
- The arrangements to provide the participant with appropriate medical or social care advice or referral when such a disclosure is made.

In those cases where the researcher is not the treating healthcare professional, it is not appropriate/ethical for the researcher to disclose such findings to the participant directly. They have a duty of care and responsibility to inform the treating healthcare professional/PI of any findings of note in a timely manner. The treating healthcare professional will then provide the appropriate advice or referral. If, in specific circumstances, it is deemed that the PI is the best person to discuss the findings with the participant, a joint approach by the PI and the treating healthcare professional is recommended.

For incidental findings that are not of vital and immediate clinical significance and/or actionable, but are reasonably possible, during the consent process the prospective participant should be provided with the option of whether or not they wish to have such findings disclosed to them. If the prospective participant chooses the option of having such findings disclosed to them, then the researcher must ensure that appropriate support mechanisms for the participant are in place (i.e. counselling).

- There may be a legal obligation to disclose certain types of other information obtained during the research process to public health officials for important public health purposes (for example, the reporting of infectious diseases) without the consent of the research participant. Prospective participants should be informed of such obligations as part of the consent process, where relevant.
- Prospective participants should also be informed of other disclosure requirements and limitations to confidentiality, particularly in relation

Section 3: Obtaining and recording consent

to *Children First: National Guidance for the Protection and Welfare of Children*, which is underpinned by the Children First Act 2015 (see also Section 5.5), or in relation to any observations of criminality that may be made.⁵³

3.4.1 Disclosure of important incidental findings of a genetic nature

The process of obtaining consent from the prospective participant for the return of incidental findings of a genetic nature is not without its challenges. Researchers should recognise that some of the incidental findings may be outside their specific area of genetic expertise and, as such, it may be difficult to explain to the participant the implications of consenting to the disclosure of important incidental findings of a genetic nature. Where this situation is likely, researchers should make efforts to ensure that the information provided to the participant is as clear as possible in spite of the complexity.

While the principles outlined here in Section 3.4.1 apply to incidental findings of a genetic nature, a cautious approach is recommended in the absence of specific legislation in this regard. Hence, in order for the participant to make an informed decision as to whether or not to participate in the study, it is important to make the participant aware that incidental genetic findings should not be returned to study participants unless the following conditions are met:

- 1) The prospective research participant provided consent for the return of genetic incidental findings at the outset of the study, including consent for further testing to a diagnostic standard in an accredited laboratory.

- 2) Sample(s) can be analysed and interpreted again by an accredited clinical laboratory.
- 3) A clear clinical pathway is in place for the return of findings, including a referral to a clinical geneticist (or geneticists) when relevant.

Where the incidental findings are an integral part of a diagnosis (for example, the presence of the BRCA2 gene in parents of a child diagnosed with Fanconi anaemia), these incidental findings should be returned to the participant.

The capability, or lack thereof, of the research team to meet the three conditions listed here and, therefore, to return incidental findings to the participant must be communicated to the prospective participant during the consent process in order to ensure that the consent is fully informed.

Should the incidental finding be of importance and/or clinically actionable and the three conditions are not met, the researcher should seek the advice of the REC. If researchers are unsure, or where there are any exceptional circumstances, they should consult with a clinical geneticist or a REC.

Secondary findings (as opposed to incidental findings; see definition in the Glossary of terms) in genetics should not be offered unless the three conditions listed above are met, and the research team has followed the latest relevant guidance of the European Society of Human Genetics.⁵⁴

The participant must be made aware of the difference between incidental and secondary findings during the consent process and informed that secondary findings will not, under current guidelines, be sought and reported back to them.

⁵³ Criminal Justice (Withholding of Information on Offences against Children and Vulnerable Persons) Act 2012.

⁵⁴ de Wert G, Dondorp W, Clarke A, Dequeker EMC, Cordier C, Deans Z, van El CG, Fellmann F, Hastings R, Hentze S, Howard H, Macek M, Mendes A, Patch C, Rial-Sebbag E, Stefansdottir V, Cornel MC, Forzano F; European Society of Human Genetics. Opportunistic genomic screening. Recommendations of the European Society of Human Genetics. *Eur J Hum Genet.* 2021 Mar; 29(3):365-377. doi: 10.1038/s41431-020-00758-w. Epub 2020 Nov 22. PMID: 33223530; PMCID: PMC7940405.

Section 3: Obtaining and recording consent

Disclosure should always take place in a sensitive manner with the support of a clinician who, ideally, has a clinical relationship with the participant.

The consent process should also include discussions and agreement about the prospective participant's preference with regard to disclosing incidental genetic findings that may be of relevance to family members (for example, there may be reasons to inform blood relatives of potential genetic risks).

Where secondary findings are sought, the involvement of a clinical geneticist from the outset is strongly advised.

3.5 Re-consent

Re-consent may be required, as the process of obtaining consent is dynamic and should not be a one-off, but should instead involve a continuous exchange of information. This is particularly important when any substantial change occurs in the conditions or the procedures of a research study, or when new information becomes available that might affect the willingness of participants to continue (see also Sections 2.1 and 6.1).

In this case, researchers should seek further REC approval and the re-consent of the participants. The strategy for re-consenting must be approved by an appropriate REC.

Reasons why re-consent may be required can include, but are not limited to, cases where:

- The research protocol has been substantially altered, and the scope of the research is being extended beyond what was originally consented to (see also Section 2).
- New safety information has come to light.
- Alternative treatments have become available (relevant to clinical trials).

- A child participant reaches the age of legal maturity (i.e. 18 years, or 16 years in the case of clinical trials) (see also Section 5.4).
- An adult participant who did not initially have the capacity to consent regains this capacity.

Re-consent may not always be necessary, such as in the case of trivial changes to procedures and conditions or information changes required to meet transparency obligations. Changes to procedures require a submission of the protocol amendment to a REC, which will recommend re-consent if needed. However, when deciding whether a participant's re-consent is required, the reasonable expectations and rights⁵⁵ of the participant should be considered.

It should be noted that, in the event that it is necessary to obtain a participant's re-consent, the updating of a privacy notice or other public transparency notice alone does not meet the requirement for explicit consent under the GDPR or the Health Research Regulations, 2018.

3.6 Withdrawal of consent

Research participants should be able to withdraw their consent to participate in a research study at any time (subject to caveats and limitations listed below in this Section 3.6)

As outlined in Section 2.1, the prospective research participant must be informed of the legal basis underpinning the processing of their personal data for the research study as part of the PIL.

Prospective research participants should be informed of their right to withdraw during the initial consent process, as well as of the fact that they do not

⁵⁵ From a data processing perspective, the GDPR requires that the principles of fairness and accountability be taken into account, as well as the potential effect that the use of a participant's personal data for the research study may have on them and their ability to exercise their rights in relation to the research study.

Section 3: Obtaining and recording consent

need to offer any explanation, and that their decision will not impact on any healthcare services being provided to them (other than those specific to the research study itself).

The process of withdrawing consent should be clear and straightforward. The withdrawing of consent can be verbal and should be recorded and witnessed where appropriate.

Every effort should be made to respect the wishes of a research participant to withdraw from further processing of their biological material or personal data, but it is recognised that this might not always be feasible. In such cases, prospective research participants should be clearly advised of any practical limitations, circumstances, or time points that would prevent their withdrawal of biological materials or personal data from use.

It may not be possible to withdraw from a research study when:

- Personal data and results have been irrevocably anonymised, preventing them from being identified for removal.
- The results from such study have already been published.
- Research results have been disseminated in other ways, such as being deposited in a publicly accessible database, where subsequent usage could not be withdrawn.
- Analysis has been conducted and the data withdrawal may impact on the statistical validity of the result.
- Data have to be retained for safety and regulatory purposes.

The legal basis used for processing personal data will affect the manner in which the personal data of a research participant may, or may not, be processed after they have withdrawn their consent to participate in the study, and researchers or sponsors should seek advice from the relevant data protection officer.

4 Capacity to consent in adults



Section 4: Capacity to consent in adults

The position of this policy with regard to consent for research, in the context of capacity to consent, is in line with the principles of the Assisted Decision-Making (Capacity) Act 2015 (see further details in Section 4.1).

Section 4 of this document focuses on certain issues around adults' capacity to consent to participate in research, relevant content in Parts A and C of this policy also applies; for example:

- Consent must be given in a personal capacity in order for it to be considered both legal and ethical.
- An individual's ability to consent to research participation may be limited as a result of long-term or permanent conditions or disability, or arising from a short-term illness.
- All adults should be considered for inclusion in research and be supported in this regard. Nobody should be either unfairly excluded from the potential benefits of research participation, or inappropriately included in research.
- If a prospective research participant has difficulty providing consent to participate in research, further efforts need to be made to enable and to maximise their capacity to do so, and special measures should be taken to protect their fundamental rights and interests.
- Safeguarding protocols/measures are particularly relevant when conducting research on adults who lack decision-making capacity, including the requirement for Garda Vetting, and registration with and adherence to the associated professional guidelines/codes of conduct in the case of professionals who have a professional registration body.

4.1 Guiding principles for application in research

Here are guiding principles for application in health and social care research:

- A prospective research participant is presumed to have decision-making capacity to provide consent unless the contrary is shown.
- Prospective research participants should be supported, and their capacity maximised, to make their own decisions whenever possible, and information should be presented in a manner to facilitate this.
- A prospective research participant should only be considered unable to provide consent after all practicable steps and efforts to help them to make the decision on their own have failed.
- Decision-making capacity regarding consent can fluctuate over time. It may be necessary, if the circumstances allow it, to provide information and support over a period of time in order to build the individual's decision-making capacity.

These principles are aligned to the principles of the Assisted Decision-Making (Capacity) Act 2015⁵⁶ which provides a statutory framework for individuals who lack, or may lack, the capacity to make decisions unaided to be assisted and supported in making decisions about their welfare, property and affairs. It is important to note in this context that the approach for CTIMPs (see Section 4.4.2) is different to that for other types of research (see Section 4.4.4).

⁵⁶ Assisted Decision-Making (Capacity) Act 2015, <http://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/print#sec8>

The Assisted Decision-Making (Capacity) Act 2015 is relevant to health-related and social care services. In the absence of a robust legislative framework related to capacity to consent for health research, certain key relevant principles from the Assisted Decision-Making (Capacity) Act 2015 have been followed for the development of this policy.

Section 4: Capacity to consent in adults

While the Assisted Decision-Making (Capacity) Act 2015 has not yet been fully commenced, it is a recommendation of this policy that the principles in Section 4.1 should be applied when research involves adults who may lack decision-making capacity, as they are aligned with the Medical Council's *Guide to Professional Conduct and Ethics for Registered Medical Practitioners (Amended)*,⁵⁷ the fairness, respect, equality, dignity and autonomy (FREDA)⁵⁸ principles adopted in the Act, and the ethos of the Convention on the Rights of Persons with Disabilities.

4.2 Capacity to consent

A prospective research participant has the capacity to provide or refuse consent if they are able to:

- Understand the information relevant to the decision.
- Retain that information long enough to make a voluntary choice.
- Use or weigh that information as part of the process of making the decision.
- Communicate their decision (whether by talking, writing, using sign language, using assistive technology, or by any other means).

An assessment that a prospective research participant lacks the capacity to make a particular decision about participating in the research does not imply that they are unable to make other decisions.

Capacity should be assessed using a functional approach on a time-specific and issue-specific basis; a person may not have capacity to make a particular decision at a certain time, but they may have capacity to make that decision at another time.

When determining decision-making capacity, it must be assessed from a functional perspective rather than from a medical perspective.

4.2.1 Who should determine capacity to consent?

The following outline who has responsibility to determine capacity to consent:

- The responsibility to determine capacity to consent lies with the researcher, and they should not include the prospective research participant in the research if they are not satisfied that the consent obtained is valid. If the prospective participant does not have the capacity to consent, the processes described in Section 4.4 should also be considered.
- The researcher has the responsibility to ensure that consent obtained from a prospective participant who may need support in making decisions is valid in accordance with the criteria outlined in Section 2.
- The researcher must be satisfied that the prospective research participant has understood the research-study-related information provided, retained it long enough to reach a decision, used and weighed it as part of making a decision, and is able to communicate their decision to participate (as per Section 4.2).

57 Medical Council, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners (Amended)*, 8th Edition (2019), <https://www.medicalcouncil.ie/news-and-publications/reports/guide-to-professional-conduct-and-ethics-for-registered-medical-practitioners-amended-.pdf>

58 Health Information and Quality Authority, *Guidance on a Human Rights-based Approach in Health and Social Care Services* (Dublin: Health Information and Quality Authority, 2019), <https://www.hiqa.ie/sites/default/files/2019-11/Humn-Rights-Based-Approach-Guide.PDF>

Section 4: Capacity to consent in adults

- While the researcher should engage with treating clinicians and relevant healthcare professionals who are familiar with the prospective research participant's condition in order to ascertain the prospective participant's decision-making capacity, the responsibility for ensuring that valid consent is obtained lies with the researcher.
- When the treating healthcare professional is conducting the research, the researcher should declare this as a potential conflict of interest and how this will be addressed in their application to the REC for their consideration (see also Sections 2.2.4 and 3.1).

4.3 Obtaining consent for research from adults who may need support with making many decisions

Some prospective research participants may have difficulty and need support in making decisions; they may, in some cases, have been previously found to lack capacity to make particular decisions. Nevertheless, with support, they may have the capacity to consent to participate in a particular research study. Hence:

- Researchers should make every effort to maximise a prospective research participant's capacity to consent and enable them to understand the significance, risks, benefits, and requirements of the research, and to make decisions for themselves.
- Extra efforts will be required to do so in addition to conveying the information in a simple and understandable manner; for example, utilising materials and methodologies that may aid the communication process (visual aids, video/ computer-assisted decision aids, plain English printed materials etc.), approaches related to the timing and frequency of the provision of information, and other supports and help that might be suitable to meet the needs of the person.

- The proposed approach and process of consent to be used with those who may have difficulty making decisions must be agreed by a REC.
- A prospective participant's refusal to participate, or a request by the individual to withdraw from a research project, should always be respected.
- The prospective participant should be encouraged to choose and involve someone with whom they have an ongoing close relationship, and who is familiar with their will and preferences, beliefs, and values, in the discussion about the research study. This individual's agreement that the research study is in keeping with the will and preferences of the prospective participant is not a form of legal consent or a validation of the legality of the consent offered by the prospective participant. If the prospective participant wants such a person to be involved in the process, this individual should also act as a witness to the consent process, and this should be documented. This is particularly important when the prospective research participant cannot read or write and/or provides verbal consent.
- The prospective participant should be provided with a record of the decisions taken in the format that would be most useful for them (audio, visual, easy to read, etc.).

Section 4: Capacity to consent in adults

4.4 Research involving adults who do not have the capacity to consent

The exclusion from research of individuals lacking decision-making capacity, due to legislative and regulatory gaps, risks condemning such populations to poor-quality care as a result of a lack of relevant evidence to inform healthcare provision. Hence, adults who lack decision-making capacity must not 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 will need to be taken in order to protect their rights and interests (see Section 4.4.4).

It is important to note that:

- No other person (such as a family member, friend, carer, or organisation) can give or refuse consent to participate in research on behalf of an adult who lacks capacity to consent unless they have specific legal authority⁵⁹ to do so (see Sections 4.4.1 – Ward of Court and 4.4.2 – CTIMPs and Clinical Investigations of Medical Devices).
- Under current law, it is not possible to appoint an enduring power of attorney (EPA) to make healthcare decisions, and an attorney does not have the authority to consent to research participation (with the exception of CTIMPs and Clinical Investigations of Medical Devices – see Section 4.4.2).
- Participants who regain decision-making capacity should be given all the relevant information about the study. Their consent to use their

data and to continue participation in the study should be sought. If they choose to withdraw from the study, their biological material and data collected as part of the study should be destroyed (see further related information on deferred consent in Section 6.8, and withdrawal of consent in Section 3.6).

4.4.1 Capacity to consent and Ward of Court

A Ward of Court⁶⁰ refers to the protection by the court of persons who lack decision-making capacity. If the prospective research participant is a Ward of Court, the court will make determinations on their behalf. The permission of the court is required before the person can participate in research.

A Ward of Court's refusal to participate in, or request to withdraw from, a research project should always be respected. Their assent to participate should also be requested and documented if they are in the position to provide it.

59 The Assisted Decision-Making (Capacity) Act 2015, which is expected to be commenced in 2023, will provide for a new form of legal representative – a Decision-Making Representative – who will be appointed by the courts. This legal representative will only be able to consent to research participation if he or she is specifically authorised to do so in accordance with the Act.

60 A Ward of Court is an individual who the courts have determined that there is adequate evidence that he or she is “of unsound mind and incapable of managing his or her own person and property” and for whom wardship is both necessary and appropriate. Wardship applications are sought in instances where it is determined that a person lacks capacity to make decisions on their own behalf. Persons of unsound mind, Order 47. The Courts Service, 15/24 Phoenix Street North, Smithfield, Dublin 7, <https://www.courts.ie/rules/persons-unsound-mind>. While this is the situation now, it will change when the Assisted Decision-Making (Capacity) Act 2015 is commenced. Wardship will be abolished, and a new support framework will be introduced.

Section 4: Capacity to consent in adults

4.4.2 Capacity to consent and CTIMPs and Clinical Investigations of Medical Devices

When the research requires the enrolment of a prospective participant who lacks the capacity to consent in a CTIMP⁶¹ or a Clinical Investigation of a Medical Device,⁶² the process is as follows:

- A 'legally designated representative' (as defined under European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (S.I. No. 99/2022))⁶³ may provide consent on behalf of that individual to participate in the CTIMP, but not for the processing of their personal data.
- In addition, a consent declaration must be sought from the Health Research Consent Declaration Committee (HRCDC) for the processing of personal data for research.
- The person "shall as far as possible take part in the informed consent procedure"⁶⁴ and the information about the trial must be provided in a way that is adequate in view of their capacity to understand it.
- A prospective participant's refusal to participate, or the individual's request to withdraw from a research project, should always be respected. If possible, their assent to participate should also be requested and documented.
- There are scientific grounds for expecting the trial to produce either direct benefit to the person, which outweighs the risks/burdens, or a benefit for the patient population that "relates directly to the life-threatening or debilitating medical condition from which the subject suffers", and the trial will pose only "minimal risk" and "minimal burden" compared with standard treatment.⁶²
- The participation in a CTIMP by a person who lacks capacity to give informed consent is only permitted if the trial is essential and "data of comparable validity" cannot be obtained in other ways.⁶²
- The trial relates directly to a medical condition of the person.
- There are no incentives or financial inducements beyond compensation for expenses.

61 As defined under Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use.

62 Clinical Investigations of Medical Devices are governed by Regulation (EU) 2017/745 on medical devices

63 "Legally designated representative', for the purposes of these Regulations and Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use only, means (a) in relation to an incapacitated subject who is, or is being considered as, a subject for a clinical trial:

(i) a person, other than a person connected with the conduct of the trial, who by virtue of their family relationship or other personal relationship with the individual:

- can provide the best interpretation of the will and preferences of the individual based on their knowledge of the individual,
- is available and willing to act for that purpose, or

(ii) if there is no such person, the medical practitioner primarily responsible for the medical treatment provided to the individual where he or she:

- can provide the best interpretation of the will and preferences of the individual based on their knowledge of the individual,
- is not involved in the conduct of the trial,
- is of the view that participation in the trial will not prejudice the health and wellbeing of the individual, and
- is available and willing to act for those purposes, and

(b) if there is no such person, a person other than a person connected with the conduct of the trial, who is a solicitor nominated by the relevant health care provider

(c) in relation to a minor who is, or is being considered as, a subject for a clinical trial, a guardian within the meaning of the Guardianship of Infants Act, 1964 (No. 7 of 1964)."

64 European Patients' Forum, *Clinical Trials Regulation: Informed Consent and Information to Patients* (Brussels: European Patients' Forum, 2016) page 6, https://www.eu-patient.eu/globalassets/policy/clinicaltrials/epf_informed_consent_position_statement_may16.pdf

Section 4: Capacity to consent in adults

4.4.3 Capacity to consent and deferred consent in emergency circumstances

Sometimes research may take place in exceptional and specified emergency circumstances where an individual is unable to give consent by reason of physical or mental incapacity and where their vital (health) interests are engaged (see also Section 6.8).

4.4.4 Capacity to consent and inclusion in health and social care research other than CTIMPs, Clinical Investigations of Medical Devices, or emergency circumstances

Section 4.4.4 of this policy will be reviewed and amended when the Assisted Decision-Making (Capacity) (Amendment) Bill 2022 is commenced. This section explains the HSE policy position in this regard in the interim.

For specific situations involving individuals who lack decision-making capacity, such as clinical trials (Section 4.4.2), deferred consent in emergency circumstances (Section 4.4.3), retrospective chart reviews (Section 6.7), and research involving the use of anonymous data (Section 6.5), the indicated sections of this policy apply. For all other situations, the HSE policy position is indicated below.

Adults who lack decision-making capacity must not be unfairly excluded from research participation, but in order to ensure that their rights, interests, and dignity are protected, the following principles should be adhered to:

- a) The research should only be undertaken if the required knowledge cannot be obtained by conducting research involving adults with decision-making capacity.

- b) The research is either expected to provide a direct benefit to the participants, or to significantly contribute to the generation of 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.
- c) The will and preferences of the prospective participant must be taken into account if ascertainable. A prospective participant's refusal to participate, or a request to withdraw from a research project, should always be respected. Their assent to participate should also be requested and documented if they are deemed to be in a position to assent.
- d) A person or persons (including an advocate) with an ongoing close relationship⁶⁵ with the prospective participant should also be asked about their belief that the research is in accordance with their best interpretation of the will and preferences of the prospective participant, or known as a result of having been previously stated. Their agreement that the research study is in keeping with the will and preferences of the prospective participant is required. This is not a form of legal consent but should be documented by way of an assent form, which should have made clear that the individual is not being asked to give their personal opinion on the study itself, but only their opinion on the will and preferences of the prospective participant, which the researcher has the responsibility to consider. They should be provided with an information leaflet which provides the same information as would be provided to a prospective research participant, and that is tailored appropriately to the situation.

65 There is a common, but inaccurate, belief that next of kin have an important role in providing consent if a person lacks decision-making capacity. However, in Irish law, use of the term 'next of kin' applies only when someone is dead, when laws (for example, governing inheritance) define an order of priority (spouse, children, parents, siblings, nephews and nieces, and so on). However, this order of priority does not apply and does not confer any decision-making authority if a person is alive and has reduced, or lacks, capacity to make a decision. Consideration should, however, be given to the separate situation for CTIMPs and Clinical Investigations of Medical Devices (Section 4.4.2), where a family member, by virtue of their family relationship with another adult and deemed suitable to act as the legal representative for the purposes of that trial, can provide consent.

Section 4: Capacity to consent in adults

- e) In some cases, the prospective participant may be able to identify the person(s) closest to them who is/are familiar with their will and preferences, and who they wish to be involved in the discussion.
- f) If there is nobody who has an ongoing close relationship with the prospective research participant and who is available or willing to be engaged, an independent advocate with the skill set to ascertain the will and preferences of the prospective research participant should be sought.

If the research study involves the processing of personal data, a consent declaration from the HRCDC is required before study start-up, in addition to ethics approval from an appropriate REC.

5 Research involving children and young people aged under 18 years



Section 5: Research involving children and young people aged under 18 years

A child in Ireland is defined by the Child Care Act, 1991 as being aged under 18 years.⁶⁶ It should be noted that research involving children is a complex area, and it has been necessary to take a policy position on certain issues. When in doubt, researchers should seek further advice from a REC, research office, or HSE deputy data protection officer, or seek legal advice as relevant.

While this section focuses on certain research-related, child-specific issues, all of the ethical principles in Sections 2 and 3 and the other issues in Section 6 should also be referred to. Other types of research (e.g. research involving the review of existing health records; see Section 6.7) and the associated processes also apply. The rights of the child must be at the heart of research-related decision-making, including Article 3 of the United Nations Convention on the Rights of the Child to ensure that the best interests of the child are of primary consideration in the determination of matters relating to their welfare, and Article 12 of same, which provides that the child has a right to participate in any such decision-making.

5.1 Age of consent for participation in research

Once they have reached the age of 18 years, a prospective research participant can provide consent in their own right for both their participation in health research⁶⁷ and for the processing of their personal data.⁶⁸

5.2 Consent for inclusion of children in research

5.2.1 Consent from parent(s)/legal guardian(s)

A parent or other legally appointed guardian must provide consent on behalf of the child to participate in research.⁶⁹ However, the type of research being carried out needs to be considered along with the age of consent; for example, for CTIMPs,⁷⁰ a prospective research participant aged 16 years or older can legally consent to their own participation in the clinical trial. For all other research, a participant must be aged 18 years or older in order to consent. However, in all research circumstances, parental/legal guardian consent is required for the processing of the participant's personal data if they are aged under 18 years. Children may present themselves unaccompanied for healthcare treatment or assessment, but they cannot consent to participation in research unless the conditions detailed in Section 5.2.1 are met. Any parent or guardian providing consent for a child's participation in research must be a person who is legally responsible for the child;⁷¹ otherwise, their consent is not valid. Hence, the legal status of the person providing consent for the child needs to be established in all cases. *NOTE: Any further references to 'parent' in this section refer to a person who is legally responsible for the child.*

- It is sufficient for one parent/legal guardian to provide consent for a child's participation in research for lower-risk studies. A REC may require that all parents/legal guardians give consent to the child's participation if it considers the risks associated with the study to warrant this. It is also best practice that all parents/legal guardians

66 Child Care Act, 1991.

67 Department of Children and Youth Affairs, *Guidance for developing ethical research projects involving children* (Dublin: Department of Children and Youth Affairs, 2012).

68 "For the purposes of the application of the Data Protection Regulation in the State, a reference to 'child' in the Regulation shall be taken to be a reference to a person under the age of 18 years" (Data Protection Act 2018, Section 29).

69 Further information with regard to legal guardianship is available in the HSE's *National Consent Policy* (2022).

70 European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (S.I. No. 99/2022).

71 All mothers are legal guardians, and a parent/person who is not a legal guardian cannot give consent on behalf of a child. Further information is available in the Children and Family Relationships Act 2015.

Section 5: Research involving children and young people aged under 18 years

are at least notified and informed of what is proposed. Where both parents/all legal guardians have indicated a wish and willingness to participate fully in decision-making for their child, this should be accommodated as far as possible. However, this also imposes a responsibility on the parents/legal guardians to make this wish known to the service provider in advance, and to be contactable and available at relevant times when decisions may have to be made for their child.

- Should a dispute arise between parents about the participation of a child in a research study then, in general, the child cannot be enrolled. Situations may arise where the participation of the child would clearly be in the child's best interests, or where the child explicitly expresses the view that they wish to participate. In such circumstances, a resolution of the disagreement may be required, either through mediation or through the courts, and it would be up to the relevant parents/legal guardians to initiate this process.
- When one or both parent(s) of a child is/are themselves aged under 18 years and is/are the legal guardian(s) of the child, they have responsibility for providing consent for their child to participate in research. The researcher must ensure that the consent obtained from the underage parent(s) is valid (see Section 2.2). The involvement of the legal guardian of the underage parents in the consent discussion may also be of benefit.

5.2.2 Children in care

For children in care, consent to participate in research may need to be provided by the parents and/or Tusla,⁷² depending on the type of care arrangement that applies to the individual child as follows:

- For children in care, consent protocols to participate in research will be reviewed and approved and/or declined by Tusla's independent REC.⁷³ Researchers may also require ethical approval from other RECs (e.g. hospital-based RECs) when children in care are potential participants in research, or ethical approval from organisations that provide services to children, including children in care. The Tusla National Research Office⁷⁴ can provide advice to researchers who are planning research with children in care.
- When required, Tusla's independent REC can seek legal advice from Tusla's Office of Legal Services and Tusla's Data Protection Unit on a researcher's behalf in order to, for example, seek advice on consent processes and data protection requirements, and where there are legal requirements to consider, such as ongoing and current childcare proceedings.
- The participation of children in care in research may need to be considered on a case-by-case basis through Tusla's independent REC.

⁷² Tusla is the Child and Family Agency in Ireland. On January 01, 2014 Tusla became an independent legal entity, comprising HSE Children and Family Services, the Family Support Agency and the National Educational Welfare Board as well as incorporating some psychological services and a range of services responding to domestic, sexual and gender-based violence, <https://www.tusla.ie/>

⁷³ "Research Ethics Committee," Tusla, <https://www.tusla.ie/research/tusla-research-office/research-ethics-committee/>
Tusla's independent REC was established under the Child and Family Agency Act 2013, Part 2, Section 8 (1)(f).

⁷⁴ "Tusla Research Centre," Tusla, www.tusla.ie/research

Section 5: Research involving children and young people aged under 18 years

There are different legal statuses for children in care (e.g. voluntary care arrangements, in care under an interim care order/care order, or where foster parents have enhanced rights) and, consequently, the consent arrangements will differ. The child's right to assent to the research should always be respected (see Section 5.3). Certain care orders may apply:

- **Care order:** In the case of children in care subject to a Court Order, Tusla will need to be involved in addition to the birth parents. Section 18(3)(a) of the Child Care Act, 1991 authorises Tusla to have control over the child as if it were the child's parent. As parents still retain some rights of guardianship, Tusla continues to have obligations to ensure sufficient consultation with the parents. In practice, researchers will require consent from parents and, generally, the child's social worker for the child to participate in research, as well as the child's assent (see Section 5.3).
- **Interim care order and voluntary care agreement:** In the case of children in care subject to an interim care order or voluntary care agreement, Tusla will need to be involved in addition to the birth parents. However, unlike care orders, under an interim care order or voluntary care agreement, Tusla does not have control over the child as if it were the child's parent. Accordingly, in addition to consultation, the consent of the parent will be required. If a social worker/clinician believes that a child would benefit from participation in a research study, and if parental consent is not forthcoming, it is possible to apply to the District Court for an order under Section 47 of the Child Care Act, 1991.

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/or assent process.

The "*in camera*" rule should also be considered by researchers. Research on files relating to childcare proceedings, or on the proceedings themselves, are subject to strict confidentiality conditions arising from the Child Care Act, 1991, Section 29, which requires that proceedings be held in private (i.e. "*in camera*"). The "*in camera*" rule prevents the publication of material which would allow the identification of parties to childcare proceedings (including the child), and the Child Care Act, 1991 makes it an offence to disclose identities in these circumstances.

Where children are the subject of ongoing and current court proceedings and the research is seeking to examine childcare proceedings and court decisions, the Court should always be told of any intended participation in research and may need to approve the children's participation in the proposed research study. The social worker should be aware of the research, and, in practice, it is a duty of the social worker to inform the judge of the research being planned.

If a researcher wishes to observe childcare proceedings in court, a Statutory Instrument (S.I.) (Child Care Act 1991 (Section 29(7)) Regulations (S.I. No. 467/2012)) is in place whereby, under this regulation, the Minister for Department of Children, Equality, Disability, Integration and Youth can approve the attendance of childcare law researchers in court.

In practice, the REC review will examine the proposed consent protocols and advise on any further legal and data protection requirements and/or ethical considerations before the research can be fully approved.

5.3 Assent by a child

In addition to the parent's/legal guardian's consent for the child's participation in research, the child's assent⁷⁵ to participate, and for the processing of their data for research purposes, should also be obtained as follows:

⁷⁵ Assent is the agreement of someone not able to give legal consent.

Section 5: Research involving children and young people aged under 18 years

- A child must be given the opportunity to provide freely given assent to participate, or to refuse to participate. The principle of obtaining the child's assent is in keeping with legal and international human rights standards and ethical guidance.⁷⁶
- Where a child with the ability to understand the participant information provided to them refuses to participate or requests to withdraw from the study, then, regardless of parental wishes, the child's request should be respected unless the intervention being evaluated offers a 'highly likely', important, direct benefit over standard treatment. However, such circumstances are exceptional, as most research cannot be guaranteed to provide a direct benefit to the prospective child participant. The researcher should discuss this with the parent(s)/legal guardian(s) and the child as part of the going process of seeking assent and consent. In cases of uncertainty, the older and more mature the child is, the more weight should be accorded to their wishes.
- Even in cases where children are not able to formally assent, their opinions and wishes should be considered and respected.
- Older children, who are more capable of giving assent, should be invited to participate in research before younger children, unless there are valid scientific, age-related reasons for involving younger children first, which can be demonstrated as part of the research ethics approval process.

5.3.1 Obtaining the assent of a child

It is important to consider that a child's competence to assent to participation in research should not depend on their age, but rather on an evaluation of the child's individual ability to understand the purpose of the research and the impact of their decision.⁷⁷ Information should be presented to children in a tailored, developmentally appropriate manner in order to maximise their understanding.⁷⁸ The child's assent, or decision not to assent, should be documented.

A child's ability to understand the information presented to them, and to communicate on the topic, may fluctuate depending on the type and complexity of the research being proposed. The maturity of the child, any social or emotional issues, and any acute or chronic health conditions which the child may have may also lead to varying abilities to assent.

In determining the wishes of the child, their understanding of the risks and impacts of the research should be maximised. From the outset, the child should be informed as fully as possible, in keeping with the factors outlined above, about the nature of the study and the methods to be employed.

In general, the information to be provided to children should be prepared in a developmentally appropriate way with a variety of different developmental and literacy levels in mind (e.g. from basic through to more complex, in addition to consideration with regard to vocabulary, tone, and style of the language). After initial engagement, the researcher can determine which set of materials is most appropriate and will have options available in this regard.

⁷⁶ UN General Assembly, *Convention on the Rights of the Child* (United Nations, 20 November 1989), Treaty Series vol. 1577.

Article 3 states that the best interests of the child will be the primary consideration in the determination of matters relating to the welfare of the child.

Article 12 provides the child with the right to participate in any such decisions, with due weight given to their views in accordance with their age and maturity.

⁷⁷ Deirdre Madden, *Medicine, Ethics and the Law*, Third Edition (Bloomsbury Professional, 2016), Section 14.53.

⁷⁸ Pirkko Lepola *et al.*, "Informed consent and assent guide for paediatric clinical trials in Europe," *Archives of Disease in Childhood*, 107, no. 6 (2022): 582–590, <https://adc.bmj.com/content/archdischild/107/6/582.full.pdf>

Section 5: Research involving children and young people aged under 18 years

Information for younger children should be predominantly pictorial and made available in visually attractive and creative ways. For older children, information sheets should be provided that explain briefly and in simple, developmentally appropriate terms the background and aim of the study, and the implications of their participation, the use of their data, and their data rights. The information should be written in clear and simple language and should be read to them. It should also contain an explanation that their parent(s)/legal guardian(s) will be asked for consent, as well as make them aware of the limits of confidentiality (see Section 5.5).

5.4 Withdrawing consent

Parent(s)/legal guardian(s) and the child should be informed that they may choose to withdraw from the research at any stage, and that it will not impact on their clinical care (see also Section 3.6). They should also be appropriately informed that while it would be possible to withdraw the child from secondary research, it may not be possible to delete previously acquired research data (see also Section 3.6). This should be included in the Participant Information Leaflet and explained to the parent(s)/legal guardian(s), as well as to the child, including what data cannot be withdrawn and from what point in time. Children have the same rights as adults under the GDPR with regard to their personal data, but require enhanced protection.

Re-consent is required from the research participant as soon as is practicable if the research participant turns 18 years old (or 16 in the case of a clinical trial) during the course of the research study, and also in respect of the retention of biological material/personal data acquired during studies that have been completed, with the intention of using them in secondary research. Where reasonable efforts to contact participants fail, an application to the HRCDC for ongoing use of the data may be made (see Section 6.9). It is

necessary to ensure that the child knows that they can withdraw the consent given by a parent/legal guardian once they reach the age of 18 years, as well as the processes that are available for this to occur (see also Section 3.6 for limitations to withdrawal of consent). This is particularly relevant in longitudinal studies, and for studies in which the child might have been involved since birth.

5.5 Safeguarding children

Researchers should ensure that their study protocols and procedures are conducted in accordance with statutory requirements and the best practice standards of child protection: *Children First: National Guidance for the Protection and Welfare of Children*, which is underpinned by the Children First Act 2015 and the following should be considered:

- A parent or legal guardian who provides consent on a child's behalf should be given the opportunity, to a reasonable extent, to be present and to observe the research as it proceeds, insofar as it is reasonable and/or appropriate, taking into consideration the child's age and right to privacy.
- Researchers also need to have completed appropriate child protection training (e.g. mandatory Tusla or HSE Children First Training) and need to have evidence of current Garda Vetting before coming in contact with children. Researchers need to be able to produce proof of completion of such training. A Child Safeguarding Statement should also be submitted to the REC.⁷⁹
- In the case of professionals who have a professional regulatory registration body, registration with this body, and adherence to the associated professional guidelines/codes of conduct, is required.

⁷⁹ Research involving children and young people as participants will require evidence of a Child Safeguarding Statement. The REC must make reference to this with guidance for researchers, and the Child Safeguarding Statement must be supplied as part of the application process.

Section 5: Research involving children and young people aged under 18 years

- In certain circumstances, it may not be possible for the researcher to guarantee confidentiality to the child or parent(s)/legal guardian(s) due to regulatory reporting obligations. The child and their parent(s)/legal guardian(s) should be informed of this obligation during the consent and assent process, and it should be highlighted in Participant Information Leaflets (PILs). A disclosure protocol should be submitted to, and approved by, the REC.
 - If a child reveals that they or others are at significant risk of harm, or the researcher observes or receives information leading to concerns of a risk of harm to a child, the researcher must discuss this without delay with their HSE line manager (or relevant line manager and HSE liaison, if they are not working for the HSE) for reporting to Tusla, as per the HSE Child Protection and Welfare Policy, or make a report directly to Tusla if they are a mandated person. In cases of intra-familial abuse, the researcher should consider the risk of harm by both parents. If one is a protective parent, the disclosure should be discussed with that parent unless the risk of serious harm is an immediate one (see the HSE Child Protection and Welfare Policy and HSeLanD training for further information in this area).
 - Where parental/legal guardian refusal to consent is thought to be associated with a domestic-abuse-related situation, concerns of abuse must be reported to Tusla under the Children First Act 2015.
 -
- The research involves vulnerable children, such as those susceptible to social, psychological, legal, economic, and physical harm; those from minority groups; and those who are highly dependent on medical/social care. The researcher is part of the medical team.
 - Then the protocol for obtaining consent must be carefully considered in order to ensure that the consent is freely given, is not given under any duress, and is not given as a result of a perceived imbalance of power or dependency, an unequal relationship with the researcher, or therapeutic misconception (see also Section 2.2.4).
 - Researchers need to ensure that children and their parent(s)/legal guardian(s) do not feel under pressure to participate in a research study, particularly if there is any distress associated with the health of the child, and that refusal to consent or withdrawing consent at any time will not impact on the child's care and treatment in any way.
 - RECs should carefully consider the consent protocols and child assent protocols in the above situations in order to ensure that the protocols are as suitable as possible. It is also good practice to develop a distress protocol (and to have the associated age-appropriate supports in place for the child or their family, should they be required) for submission as part of the REC application.

5.6 Valid consent from parent(s)/legal guardian(s)

In circumstances where:

- The research involves children who may be acutely unwell, and parents are in a heightened situation of distress.

5.6.1 Neonates

For research involving full-term or preterm neonates⁸⁰ or babies, the decision to consent to participate in research rests with their parent(s)/legal guardian(s) and, in general, the same rules apply. Specific consideration should be given to the following:

- Researchers need to be aware that when research involves neonates, particularly after a difficult birth, parental/legal guardian feelings of an increased imbalance of power, perception of

⁸⁰ 'Neonate', or 'newborn', refers to a child in the first 28 days after birth. 'Neonatal' refers to the first 4 weeks of a child's life.

Section 5: Research involving children and young people aged under 18 years

dependency, and therapeutic misconception may be significant factors. Therefore, researchers need to be careful to ensure that the consent obtained is valid.

- As part of the child's medical record, the mother's medical record (or part thereof) may also be required, and this needs to be considered and included as part of the consent process.



6 Other consent considerations

Section 6: Other consent considerations

6.1 Research involving stored biological material and associated personal data from material originally collected for research purposes

The collection of biological material⁸¹ and associated personal data⁸² for the purpose of research should follow the same process of consent outlined in Sections 2 and 3. However, such biological materials are often stored for secondary research uses that may not be specifically known at the time of collection, and care must be taken to ensure that valid consent for secondary research is in place (see Sections 2.3 and 2.4).

The consent requirements for the secondary use of biological material articulated in Section 2.3 of this policy become effective from the date of publication of this policy. The research consent obtained for the processing of personal data associated with historical biological material prior to the enactment of the Health Research Regulations, 2018 should be reviewed in order to ensure that it is still valid. If such consent is deemed not valid, or when in doubt, researchers may consider re-contacting participants if this is a viable, possible, and appropriate option. Otherwise, researchers should apply for a consent declaration from the HRCDC in accordance with Section 6.9.

Where a participant does not want biological material to be used for secondary research purposes, the biological material and/or data should be destroyed on completion of the planned research project, in line with relevant retention requirements or policies.

Research participants whose biological material and personal data are stored for secondary research purposes must be informed of their right to withdraw their biological material and/or data without any negative consequences. Where participants wish to withdraw their biological material, it should be clear and transparent what will happen to their biological samples (see Section 3.6).

6.2 Biological material and personal data associated with that material and collected as part of clinical care and treatment

Biological material, and the personal data associated with the material, gathered for clinical purposes (diagnosis, treatment, etc.), without additional and appropriate consent for research, cannot generally be used for research purposes (see also Sections 6.2, 6.5, 6.6, and 6.7).

In circumstances where there is a requirement for such biological material to be used for research purposes, the following applies:

- Consent should be obtained for the use of the biological material and the associated personal data for research purposes.
- Only in exceptional and rare circumstances, in the case of historical collections, when it is believed that the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the participant, and obtaining that participant's consent is not possible, the researcher should apply for a consent declaration from the HRCDC. The HRCDC will assess whether the public interest in carrying out the health research significantly outweighs that of the data privacy rights of the individuals. In addition, approval from a health REC⁸³ will be required. The researcher must adhere to any additional conditions imposed by the HRCDC and ensure that sufficient transparency and communication is in place to inform the public of the intended research.

81 'Biological material' refers to any material from a human body, including, but not limited to, blood, saliva, urine, or biopsies.

82 See definition in the Glossary of terms for special category personal data.

83 An appropriate REC is a National REC, a HSE Reference REC, a HSE Hospital REC, or a Section 38 Hospital REC.

Section 6: Other consent considerations

6.3 Research involving post mortem biological material

'Post mortem biological material' refers to a person's whole body, individual organs, tissues, cells, cellular contents, genetic material, or bodily fluids which are proposed to be used for research purposes following the death of that person (see also Sections 6.1 and 6.1.1). It includes organs or tissues removed and retained following post mortem examination (PME), bodies (and their tissues) donated to medical schools for the purposes of anatomical teaching and research, and biological material from procedures undertaken in a healthcare facility before death that have been retained.

Consent for the use of post mortem biological material for research purposes is required regardless of the biological material's origin, and approval for each research study using this material must be provided by an appropriate REC (see Sections 6.1 and 6.1.1).

6.3.1 Pre-mortem consent

A person agreeing to the post mortem donation of their biological material before death (pre mortem), where the purpose of the research is known,

should be provided with PILs, consent forms, and any other relevant information required (such as a distress protocol) and approved by a REC.

In the case of an objection from the family, the designated healthcare professional may meet with them to share the wishes of the deceased. However, if the family continue to object the PME should not take place.

6.3.2 Post mortem consent

In most instances, the deceased person will not have given consent in advance for a PME for the use of post mortem tissue for research purposes, so any required decisions are made by people who had a close ongoing personal relationship with the person, such as family or friends, or by anybody chosen by the person in advance. The knowledge that these people may have of the deceased, will be helpful in eliciting the person's values, beliefs, and goals in life. This approach is in keeping with the principles of the HSE National Consent Policy (2022).

The third party who provides consent for the use of post mortem tissue for research purposes should be the same person who provides consent for the PME after death.⁸⁴ For further advice related to consent for research sought

84 The HSE National Guidelines for Post Mortem Examination (to be published) refer to the person who gives consent as the 'designated person'. The 'designated person' must be 16 years of age or more immediately before the person's death. The list below includes, in order of priority, persons who may be contacted during the consent process and are, or at the time of the deceased persons death were:

- A spouse or civil partner of the deceased person
- A cohabitant of the deceased person
- A child of the deceased person
- A parent of the deceased person or their guardian before they reached the age of 18 years
- A brother or sister (full or half) of the deceased person
- A grandparent of the deceased person
- A grandchild of the deceased person
- An uncle or aunt of the deceased person
- A niece or nephew of the deceased person
- A close friend who can demonstrate to the person seeking consent that they can accurately convey the wishes of the deceased person

Although this represents the order in which people should usually be contacted to provide consent, a number of exceptions may arise. Further advice is provided in the HSE National Clinical Guidelines for Post Mortem Examination Services (to be published).

Section 6: Other consent considerations

from a parent or legal guardian⁸⁵ of a deceased child, including a still born child or foetus, please refer to Sections 4 and 5 of this policy.

Where consent for the removal, retention, and use of biological materials for research purposes is being sought from a third party prior to a post mortem examination⁸⁶ taking place, it must be recognised that consent for a post mortem examination and consent for research are two different processes and that, in respect of consent for research, the period immediately following death may not be the most appropriate time to seek such consent. While consideration must be given to the individual circumstances of the bereaved as to when might be the most suitable time, as a general principle, a two-stage process of consent for research is recommended:

- Stage one would generally take place at the same time as the consent for the PME and involves seeking consent for the retention of the biological material for future use. It is also to obtain permission to contact the person giving consent after a period of approximately 12 weeks to seek their consent to use the deceased person's biological material for research purposes.
- Stage two, taking place approximately 12 weeks after the post mortem examination, is to seek formal and valid consent for the biological material retained at stage one to be used for research purposes.

The precise gap between stages one and two will depend on the wishes and needs of the bereaved. The following should also be taken into account when seeking consent:

- The principles of valid consent apply to first- and third-person consent for the use of biological material in research (see Section 2.2).

- The processes for recording and documenting consent apply to pre-mortem and post mortem consent for the use of biological material in research (see Section 2.3). The record of consent must also be kept as part of anatomy department, mortuary, and pathology records.
- In the event that a person declines consent following the discussion during stage 2, the HSE Clinical Guidelines for Post Mortem Examination Services outlines the process to be followed for the management of organs.
- If the person giving consent for the retention of the biological material does not wish to be contacted after 12 weeks, they may give broad consent for the use of the biological material, or refuse consent for research purposes, at stage one. Each research study proposed under such broad consent must be assessed by the REC for its adherence to the principles of broad consent as specified in Section 2.3.
- Those being asked to give consent must not feel under pressure to give consent to the biological material being retained or used in a research study.

Note that a Coroner does not have the legal authority to give consent for the retention of organs for research purposes.

The use of biological material (removed as part of the post mortem process) by commercial companies must first be approved at hospital level by the Chief Executive Officer or suitably nominated equivalent. Where approval has been given, a registered medical practitioner can seek consent from a designated family member, parent, or guardian of a child following the two-stage process described above.⁸⁷

⁸⁵ For a list of those who qualify as legal guardians, see Appendix 5 of the HSE National Consent Policy (2022)

⁸⁶ HSE National Clinical Guidelines for Post Mortem Examination Services (to be published).

⁸⁷ General Scheme of a Human Tissue (Transplantation, Post-Mortem, Anatomical Examination, and Public Display) Bill 2018.

Section 6: Other consent considerations

6.3.3 Broad consent for post mortem research

Where the purpose of the research has not been fully determined at the time that consent is sought for the use of biological material, those giving consent (whether pre mortem or post mortem) should be provided with as much information about the potential research as possible under the principles of broad consent outlined in Section 2.3.

6.4 Research involving the personal data of deceased individuals

Under the remit of the GDPR, consent is not required for research involving the processing of the personal data of deceased individuals.⁸⁸ However, the following should be considered:

- The Common Law duty of confidentiality still applies to any individual who is deceased, and researchers have ethical responsibilities in respect of conducting any health research involving the personal data of a deceased person.
- Researchers should also be cognisant of the potential of the research to identify members of the deceased individual's family and any data protection issues that would arise as a result, falling within the remit of the GDPR and the Health Research Regulations, 2018.

6.5 Consent for research involving the use of personal data and biological material originating from outside Ireland

The collection and processing of biological material and personal data for health research are subject to the legislation of the country in which the consent was collected, but the researcher is responsible for satisfying themselves that the consent obtained is valid. If they are not satisfied, the data/biological material should not be used. Consideration should also be given to the following:

- If consent is obtained by an international third party in line with its country's data protection requirements and international ethical standards in health research, then there should generally be no need for the Irish researcher to obtain additional consent for further processing if the international third party is located in the European Economic Area (EEA), and as long as the processing of the personal data falls within the scope of the original consent.
- If consent is obtained by third parties located outside the EEA, researchers should always seek the advice of a REC, and then the relevant data protection officer, if required.
- For international collaborations, where the data controller or data processor conducting the data collection and processing is not based in the EU, data processing is subject to the GDPR and to the Health Research Regulations, 2018 when research participants are based in Ireland.

⁸⁸ The GDPR and the Health Research Regulations 2018 only apply to the processing of the personal data of living individuals. Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018)

Section 6: Other consent considerations

- In the case of international research studies which seek to recruit Irish prospective research participants, the research study must be reviewed by a REC in Ireland. Prospective research participants must be fully informed and brought through the full consent process prior to enrolment in the study and prior to any requirement for them to travel to take part.
- Where consent cannot be obtained for the processing of personal data for international studies led by international data controllers, they may apply for a consent declaration from the HRCDC to process the personal data of research participants in Ireland.

6.6 Research involving the use of anonymous and pseudonymous data

Anonymisation is a data processing technique that removes or modifies personally identifiable information in an irreversible way. Data can be considered anonymised from a data protection perspective when an individual is not identified or identifiable, having regard for all methods reasonably likely to be used to identify them, either directly or indirectly.⁸⁹

The potential for data linking and recognition (personal knowledge of any participants allowing the identification of data subjects) should be considered when determining whether the data are fully anonymised.

Consent is not required to conduct research using data that have previously been anonymised (i.e. for a previous and separate purpose other than the specific research for which they are to be used) and that have been fairly accessed in circumstances where sufficient transparency measures are in place.⁹⁰

If access to the personal data was originally obtained with the consent of the individual, then consent is also required to anonymise the data for research purposes. In this case, individuals should be informed at the time of consent that one of the purposes of the data collection will be to anonymise the data for secondary research use. If such consent for anonymisation was not sought at the time, researchers may consider applying for a consent declaration from the HRCDC (see also Section 6.9). Further guidance on previously collected data is available in Section 6.1. If access to personal data was obtained during the normal course of clinical care or regular HSE business, (i.e. the legal basis used for processing the data in the first instance was not consent), then consent for anonymisation is not required if the purpose of the anonymisation is to continue to fulfil the statutory duties of the HSE; this may include the completion of clinical audits (see ANNEX 1), quality improvement initiatives, health service planning, etc. Datasets anonymised in this fashion can have a secondary use for research if all of the following mandatory requirements are met:

- The sole purpose for the anonymisation of the dataset in the first place was to fulfil a clinical function or other statutory duty of the HSE.⁹¹

89 Data Protection Commission, *Guidance Note: Guidance on Anonymisation and Pseudonymisation* (Data Protection Commission, 2019), <https://www.dataprotection.ie/sites/default/files/uploads/2019-06/190614%20Anonymisation%20and%20Pseudonymisation.pdf>

See also Recital 26 of the GDPR.

90 These data fall outside the scope of the GDPR, the Data Protection Act 2018, and the Health Research Regulations. However, processing is required in order to anonymise data, and therefore the safeguards required by the GDPR and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018) still apply.

91 It is not acceptable to use a clinical audit or similar activities as a means to avoid consent or REC requirements.

Section 6: Other consent considerations

- Secondary use of such anonymised datasets for research must receive REC approval (which cannot be obtained retrospectively for studies already undertaken).⁹²
- **Transparency measures** are in place informing patients of the fact that their personal data may be anonymised and of the purpose for which the data are being anonymised.
- **Relevant data-sharing agreements** are in place between the HSE and the organisation receiving the data, with the agreements including all required safeguards.
- **Appropriate internal data transfer protocols** are in place where the anonymised data are to be transferred and used within the HSE.

Anonymisation should not be confused with pseudonymisation.

Pseudonymisation⁹³ is a reversible method of de-identifying data (i.e. where identifiable information is substituted with a code to which only the data controller would have the 'key'). Pseudonymised data in the hands of the organisation holding the identification key are regarded as personal data because this enables the identification of an individual (albeit via a key), and therefore the requirements for explicit consent do apply if these data are to be used for research.

6.7 Determining the suitability of prospective participants for inclusion in research (pre-screening)

Actions taken to establish the eligibility or suitability of prospective research participants for inclusion in a particular health research study are known as pre-screening. This includes, for example, reviewing the medical records of patients who have received health services through the HSE.

Pre-screening is permitted without the consent of participants or REC approval, subject to mandatory safeguards and specified governance mechanisms.⁹⁴ When performing pre-screening activities, personal data can only be accessed and used for the purpose of establishing eligibility or suitability for research study inclusion.

Once eligible prospective research participants are identified, the consent considerations articulated in this policy, and ethics approval requirements, apply to the subsequent recruitment of research participants and the substantive part of the research.

The individuals permitted to conduct pre-screening activities without consent and REC approval include:

- Health practitioners employed by the data controller of the medical records, e.g. the HSE or healthcare provider (i.e. voluntary hospitals, GPs)⁹⁵

92 If anonymised data produced from a clinical audit are subsequently required for research purposes (e.g. to produce a research article), REC approval is required before the research commences. Alternatively, proof of REC approval prior to conducting the clinical audit will also be required by most peer-reviewed research journals. Requirements for a HRCDC consent declaration may also need to be met.

93 Pseudonymisation is a data security measure that is strongly encouraged and should be performed by the researcher as early as possible on datasets that are not being fully anonymised as a way of safeguarding privacy rights. Provided that the 'key' enabling reidentification of individuals is kept separate and secure, the risks to the data subject associated with pseudonymised data are reduced. For more information on pseudonymisation for the purposes of data protection, please see: <https://www.dataprotection.ie/en/dpc-guidance/anonymisation-and-pseudonymisation>

94 Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021), <https://www.gov.ie/en/publication/b46c2-amendments-to-health-research-regulations/>

95 'Health practitioners' as defined in section 2 of the Health Identifiers Act 2014 (Number 15 of 2014).

Section 6: Other consent considerations

- Health students under the direction and control of such health practitioners
- Employees of the healthcare provider who ordinarily access the data (e.g. medical records clerks), and who may act as gatekeepers⁹⁶
- Persons authorised by the healthcare provider (i.e. the data controller of the medical records) to perform pre-screening activities (authorised persons); such authorised persons must be employees of one of the following:
- A higher education institution⁹⁷
 - A registered charity which supports research and education⁹⁸
 - A body or person that has as its principal activity the provision, management, or development of health practitioners.

The authorised person must be Garda Vetted prior to their appointment, and a legal agreement between the HSE and the employer of the authorised person is required to regulate the appointment and activities of the authorised person. Any access or use of personal data outside the purpose of establishing suitability or eligibility for inclusion in a specific health research study would be a breach of the agreement and result in sanctions.⁹⁹

Healthcare providers must use transparency measures to make patients aware that pre-screening actions are taking place and of the associated process of appointing an authorised person. These measures include notices and posters displayed in healthcare provider/HSE public areas where individuals attend for the provision of healthcare and on the healthcare provider/HSE website (as appropriate).

It should be noted that pre-screening can also be conducted based on explicit consent and REC approval, or a successful application for a consent declaration to the HRCDC.

6.8 Research involving the review of existing health records (retrospective chart review)

A retrospective chart review (also called a medical records review) involves the examination of existing patient records (including, but not limited to charts, medical images, clinical safety data, healthcare resource utilisation data, case records, case files, and administrative records), which were collected for the provision of healthcare (for the avoidance of doubt, the term does not include the retrospective review of stored biological material associated to a patient record). Such reviews can be carried out for a variety of purposes, including research.

A retrospective chart review carried out *for research purposes* can be done without the consent of participants, subject to mandatory safeguards and specified governance mechanisms,¹⁰⁰ including the following:

96 A gatekeeper is someone at a research site who provides access to the site and to the research participants. The *HSE National Framework for Governance, Management and Support of Health Research* refers to such a person responsible for the coordination of access to data for research purposes, in an appropriate and legally compliant manner, as the research site responsible officer. See <https://hseresearch.ie/publications/>.

97 'Higher education institution' as defined in section 1(1) of the Higher Education Authority Act, 1971 (Number 22 of 1971).

98 'Registered charity' as defined in the Charities Act 2009 (Number 6 of 2009).

99 The authorised person must agree in writing to be bound by the terms and conditions of the agreement, including, but not limited to: access, processing, and use of data only as specified in the agreement; being granted permission only for a specified health research study (rather than a 'blanket permission'); being under the control and direction of a health practitioner employed by the HSE when conducting pre-screening activities; and being subject to sanctions, including by their employers, in the event of a breach.

100 "Amendments to Health Research Regulations," gov.ie, <https://www.gov.ie/en/publication/b46c2-amendments-to-health-research-regulations/>

Section 6: Other consent considerations

- The proposed research must be low risk (i.e. the study does not put the privacy and rights of participants at risk). A risk assessment of the data protection implications of the health research must be carried out by the researcher and, if required, reviewed by the relevant data protection officer before applying to the relevant REC. If the study is not deemed to be low risk, consent from the individual is required or an application seeking a consent declaration must be submitted to the HRCDC.
- The research study must be approved by a REC before it commences. As part of this approval, the REC must state in writing that it is satisfied with the classification of the study as low risk from a data protection perspective. A REC always has the discretion, should it consider it appropriate, to require that consent be obtained for the study for reasons other than that of data protection.
- Appropriate transparency requirements must be met¹⁰¹ i.e. patients should be made aware that retrospective chart review studies for research purposes are taking place by way of notices and posters¹⁰² on display in public areas within the healthcare setting where individuals attend for the provision of their healthcare.
- Only the following categories of individuals can conduct retrospective chart reviews for research purposes without the explicit consent of the participant:
 - Health practitioners¹⁰³ employed by the HSE or the healthcare provider
 - A person studying to become a health practitioner under the direction and control of an abovementioned healthcare provider
 - Employees of the healthcare provider who ordinarily access the data (e.g. medical records clerks).
- The personal data accessed under these conditions and used for a research retrospective chart review cannot be used for other purposes. The data used for a research retrospective chart review by the above authorised individuals cannot be shared with others (third parties) unless it is fully anonymised. Any published results must not be identifiable.
- If the retrospective chart review is not considered to be low risk, then consent from the individual is required or an application seeking a consent declaration must be submitted to the HRCDC.

101 Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021), <http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf>

102 The posters must state, at a minimum, the following in plain English:

(a) Personal data, collected by the controller for the provision of healthcare to an individual, may be used by the controller for a retrospective chart review study but not disclosed to another person (a third party) by the controller for a retrospective chart review unless such data are anonymised.

(b) Any findings from the study that are published must not identify an individual whose personal data were used in the study.

(c) The study will be reviewed and approved by a REC prior to commencement of the study.

103 A 'health practitioner' as defined in section 2 of the Health Identifiers Act 2014 (Number 15 of 2014).

Section 6: Other consent considerations

6.9 Deferred consent for research in emergency situations

Deferred consent for research refers to consent that is obtained after (rather than before) an individual has been enrolled in a research study. The use of deferred consent can only apply in exceptional circumstances, where the principal purpose is the provision of healthcare in the vital interests of the individual.¹⁰⁴ Additionally, where personal data are being processed, a consent declaration from the HRDC may be required. Deferred consent is acceptable in circumstances when:

- A REC has approved the proposed research.
- The prospective participant is unable to give consent by reason of physical or mental incapacity (traumatic brain injury, they are unconscious in an intensive care unit, etc.), and their vital (health) interests are engaged, requiring urgent intervention (for which available treatments are unproven or unsatisfactory) in order to save their life or prevent serious detriment.
- The type of medical situation/emergency involved creates an urgency for a decision to be made on treatment and it falls, in the circumstances, to the clinician to make a decision that they feel will benefit the patient's care.

In these circumstances, the research may proceed until the participating individual has the capacity to give consent. Once the individual regains this capacity:

- They must be told how they became enrolled in the study, what has happened to date, and their options going forward.
- They must be given all the relevant information in a tailored manner, specific to them, including a specific 'consent to continue' information leaflet and deferred consent form.
- Their consent to continue their participation should be obtained as soon as is reasonably possible after they regain capacity.
- 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.

If the participant declines to give consent:

- Their inclusion in the health research must stop.
- Any personal data already processed for the health research only must be erased, except when exceptions outlined in Section 3.6 apply.
- Any personal data processed that are necessary for the care and treatment of the individual are not affected by a decision not to give deferred consent to the research, hence protecting the integrity and accuracy of the patient's healthcare records.

¹⁰⁴ Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18/2021), <https://www.gov.ie/en/publication/b46c2-amendments-to-health-research-regulations/>

Section 6: Other consent considerations

If, in the circumstances outlined above, the participant does not regain capacity to consent and subsequently dies, the data collected for research can be retained.¹⁰⁵

Note that in public health emergencies, consent and ethical approval are still required.

Where deferred consent is being relied on for a study which is not necessary to protect the vital interests of the individual, an application seeking a consent declaration for the processing of the personal data of the participant must be submitted to the HRCDC.

6.10 Research using personal data for research without consent by way of a consent declaration

Although explicit consent is required for the processing of personal data for health research, it is recognised that, in certain circumstances, obtaining consent from research participants may not always be possible. In such circumstances, a researcher may apply to the HRCDC for a consent declaration and the following applies:

- Applying for a consent declaration from the HRCDC is not an alternative to seeking consent. The HRCDC requires strong evidence to support a claim that obtaining consent is not possible and that the public interest in carrying out the proposed research significantly outweighs the public interest in requiring the explicit consent of the participant.
- A consent declaration allows the processing of personal data of research participants without explicit consent for the health research

concerned, subject to suitable technical and organisational data protection measures being in place, including that:

- A Data Protection Impact Assessment (DPIA) has been carried out.
- Research ethics approval has been granted for the research study.
- The public interest in carrying out the health research significantly outweighs the requirement for consent for the processing of personal data.¹⁰⁶ This may be the case where certain collections of biological material and associated personal data are a unique resource.
- There are suitable and specific measures¹⁰⁷ in place prior to the commencement of the research to ensure the fundamental rights and freedoms of the research participants are safeguarded.
- Patient and public involvement (PPI) activity is being carried out in order to ensure a patient- and public-centred approach regarding the development and implementation of the study, and to ensure that the perspective of the participant is always considered.

¹⁰⁵ Data protection legislation does not apply to deceased individuals.

¹⁰⁶ Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).

¹⁰⁷ All suitable and specific measures set out in the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).

Section 6: Other consent considerations

- Appropriate transparency measures have been implemented¹⁰⁸ such as: effective public display of information notices about the study; providing individuals from whom biological material and associated data may have been originally sourced the opportunity to opt out; and the use of websites and other techniques to inform individuals about further intended research and of how to make contact with the research team. However, it should be noted that transparency measures do not remove fundamental requirements for consent if such is possible.

6.11 Covert research

“Covert research”¹⁰⁹ is research which is not declared to the research participants and cannot, therefore, involve obtaining consent in advance. While there are many contexts in which covert research may take place, this section of the policy refers only to health research under the remit of the *HSE National Framework for Governance, Management and Support of Health Research* (2021).¹¹⁰

In this context, covert research:

- Is a type of social research which involves the observation¹¹¹ of participants or groups from a distance
- Must always be underpinned by ethical principles and approved by an appropriate REC that would assess the merits of the research in the context of the public interest. Covert observation should only proceed if researchers can demonstrate clear benefits of the research, when no other research approach seems possible (e.g. if informing potential participants may change the outcome of the research) and when it is reasonably certain that no one will be harmed or suffer as a result of the observation.

Covert research should not be undertaken lightly and is only justified if important issues and matters of social significance are being addressed, or are likely to be discovered, which cannot be uncovered in other ways. Even though consent is not obtained prior to the research, it should, where feasible, be obtained at a later time. In cases where participants who are asked to give deferred consent express concerns about their inclusion in a project, the researcher should give them the option of withdrawing their data from the study. Covert research should not involve:

108 In accordance with data protection legislation and best practice.

109 Please see Glossary for “covert research”

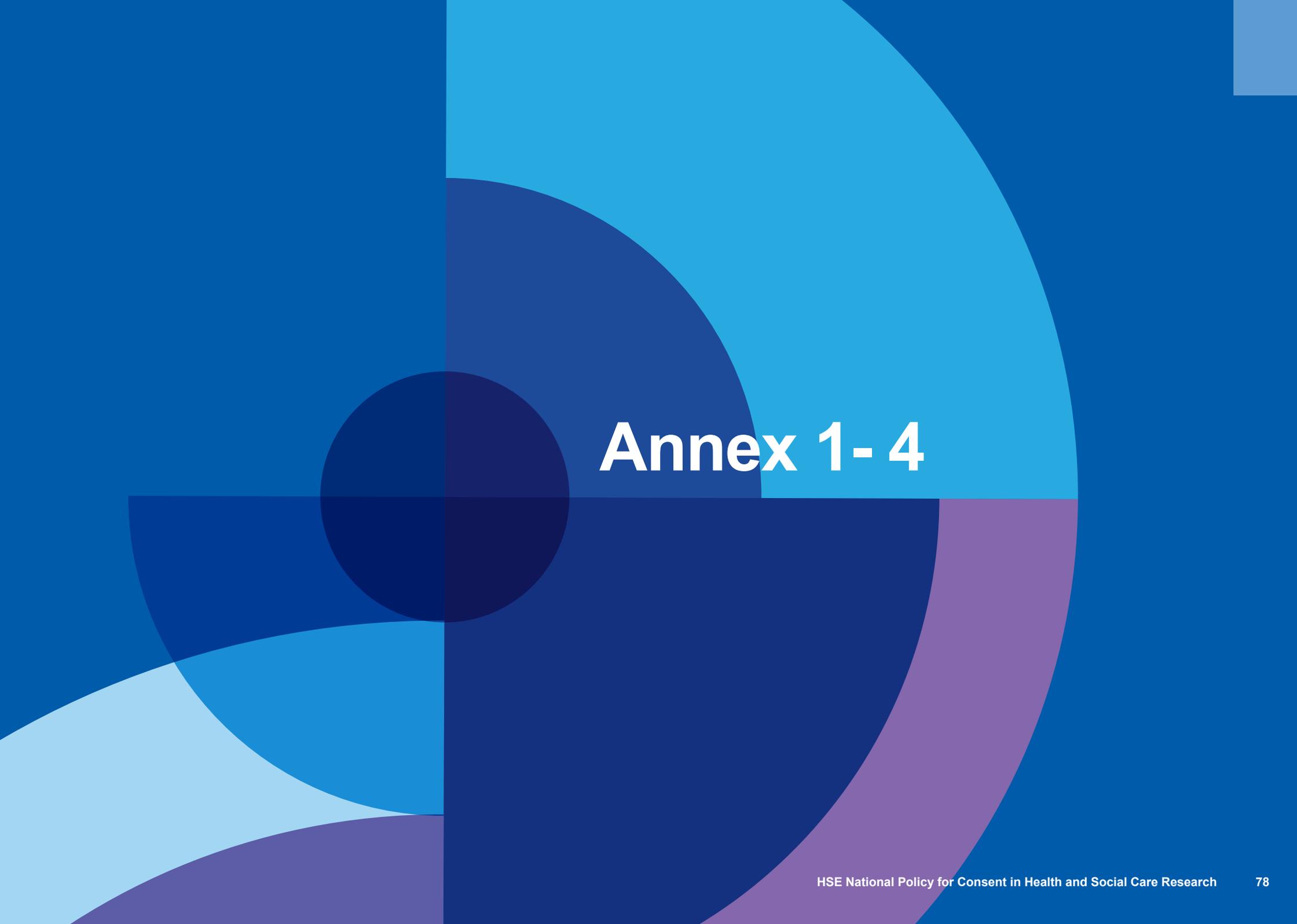
110 The *HSE National Framework for Governance, Management and Support of Health Research* (2021) applies to all health research activities taking place in the HSE and its funded organisations involved in the provision of health and social care services, when the research activities involve any of the following factors: health service users, their personal data, and/or their biological samples; health and social care staff; or the use of healthcare services, premises, or infrastructure. It also applies to health research taking place in third-level collaborative institutions and/or clinical research facilities when the research activities involve any of the aforementioned factors.

111 While covert research involves observation of participants, it is distinct from observational research in the context of health research. The term ‘observational research’ can be used in a clinical context as well as in social sciences. In a clinical context it is generally used to distinguish such research from intervention or experimental studies, as no intervention other than the recording, classifying, counting, and analysis of data takes place, and the investigator has no control over study variables and merely observes outcomes. Studies involving covert research are distinct from observational studies in social science research, which may include the observation of participants during an intervention. In both cases, consent from the participants would be sought at the outset.

Section 6: Other consent considerations

- Deception (i.e. where the researcher deliberately misrepresents their intentions to the research participants); this is unethical and is a form of research misconduct.
- The processing of personal data. If it were to involve the processing of personal data, it would fall outside the scope of covert research as per this policy, and a consent declaration from the HRDCD would be required.

If a pre-screening process is required to identify or select potential participants in accordance with inclusion or exclusion criteria, the guidance in Section 6.6 applies.



Annex 1-4

Differentiating between research and other related activities

Determining whether a project needs ethical approval often depends on whether it is a form of research, or something else, such as a clinical audit or service evaluation.

Sometimes healthcare professionals undertake what they mistakenly think is clinical audit, when what they are really doing is research, or including elements of research. Calling research by any other name does not remove the research-related approval requirements.

The *HSE National Centre for Clinical Audit: Nomenclature – Glossary of Terms for Clinical Audit*¹¹² distinguishes between clinical audit, clinical registry, service evaluation, and research as follows:

What is clinical audit?

“Clinical audit is a clinically led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements”.¹¹¹

Clinically led includes the breadth of clinical professionals working in health and social care services.¹¹³

What is service evaluation?

“Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service”.¹¹⁴

Unlike clinical audit, it does not compare the service to a predefined standard.¹¹²

What is a registry?

“A clinical registry is described as a system which collects a defined minimum data set from patients undergoing a particular procedure or therapy, diagnosed with a disease or using a healthcare resource”.¹¹⁵

What is research?

“Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses”.¹¹⁶

112 HSE, *HSE National Centre for Clinical Audit: Nomenclature – Glossary of Terms for Clinical Audit* (2022), <https://www.hse.ie/eng/about/who/nqpsd/ncca/nomenclature-a-glossary-of-terms-for-clinical-audit.pdf>

113 Building a Culture of Patient Safety. Report of the Commission on Patient Safety and Quality Assurance. Department of Health and Children, 2008, page 152, <https://assets.gov.ie/18845/59ff088cfaea4c4f8c93b6b04fae9762.pdf>

114 Twycross A, Shorten A. Service evaluation, audit and research: what is the difference? *Evid Based Nurs*. 2014 Jul; 17(3):65-6. doi: 10.1136/eb-2014-101871. Epub 2014 May 14. PMID: 24829302.

115 Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM. Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. *PLoS One*. 2017 Sep 8; 12(9):e0183667. doi: 10.1371/journal.pone.0183667. PMID: 28886607; PMCID: PMC5591016.

116 What is research? Health Research Board, 2019, <https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/>

Table 1: Definitions, purpose, contexts and methods for clinical audit, service evaluation, research, and registry

Theme	Clinical audit	Service evaluation	Research	Registry
Definition	“Clinical audit is a clinically led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met”	“Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service”	“Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses”	Registries are systems which collect a defined minimum dataset from patients with a particular disease, undergoing a particular procedure or therapy, or using a healthcare resource
Answers question	Clinical audit demonstrates whether a predetermined standard is being met	Service evaluation tells how well a service is working	Research demonstrates what should be done	Registries show the details of certain patient groups. They can be used to answer both clinical audit and research questions
Purpose	To find out if best practice is being practised for quality assurance and improvement purposes	To evaluate current practices for information purposes. The information can inform management decisions	To generate new knowledge and find out what treatments, interventions, or practices are the most effective	To monitor a patient population or healthcare process. A registry may have an improvement aim, a cost focus, or form an epidemiological database used for research
Context	Carried out at local or national level	Carried out at local level only	Carried out at local or national level	Carried out at national level only
Methods	Measures practice against evidence-based clinical standards	Measures current service without comparison against standards	Has a systematic, quantitative, or qualitative approach to investigation	Carries out data collection and analysis
REC review and approval	No, but ethical considerations should still be considered	No, but ethical considerations should still be considered	Yes	<ul style="list-style-type: none"> • Yes, if for research • No, if for others listed (e.g. audit, evaluation)

Research projects require ethical approval. If a project contains an element of both clinical audit and research, research ethical approval for the research component of the project is required from an appropriate REC.

Other useful sources of information/references include:

- GDPR Assessment Table, National Office of Clinical Audit, https://s3-eu-west-1.amazonaws.com/noca-uploads/general/GDPR_Assessment_Table_-_Clinical_Audit.pdf
- Backhouse A, Ogunlayi F. Quality improvement into practice BMJ 2020; 368 :m865 doi:10.1136/bmj.m865, <https://www.bmj.com/content/bmj/368/bmj.m865.full.pdf>

HSE National Policy for Consent for Health Research Working and Advisory Groups

Policy content has been developed by the HSE National Consent for Research Policy Working Group, including members from HSE National Research and Development and external members, in consultation with advisory groups such as the HSE Research Ethics Committee Reform Working Group, members of the HSE Research and Development Patient and Public Involvement Reference Group, and external legal advisors. The membership of these groups is as follows:

Working Group

- Dr Ana Terrés, Head of Research and Evidence, HSE (Chair)
- Dr Declan O’Hanlon, General Manager, HSE National Research and Development (R&D)
- Dr Natalie Cole, Senior Research Manager, HSE National R&D
- Dr Ruth Davis, Barrister, The Law Library, Four Courts
- Laura Méchineau-Phelan, Senior Manager, Contracts and Data Governance, HSE National R&D
- Máiréad Murray, Senior Research Manager, HSE National R&D
- Dr Jean Saunders, Deputy Chair of Limerick University Hospital Research Ethics Committee and Director of Claddagh Statistical Consultancy Services and Centre for Support Training Analysis Research (CSTAR) at the University of Limerick
- Dr Emily Vereker, Programme Manager, Secretariat of the Health Research Consent Declaration Committee

Advisors

Members of the HSE Research Ethics Committee Reform Working Group:

- Dr Claire Collins, Chair, Irish College of General Practitioners REC
- Dr Rachel Crowley, Chair, St Vincent's University Hospital REC
- Prof. Patrick Dillon, Chair, Limerick University Hospital REC
- Dr Jean Saunders, Deputy Chair of Limerick University Hospital Research Ethics Committee
- Dr Úna Fallon, Chair HSE Reference REC for Regional Health Area B and HSE Corporate
- Prof. David Kerins, Chair, REC of the Cork Teaching Hospitals
- Caroline Lamb, REC Manager, HSE South East REC
- Prof. Gerard Loftus, Chair, Galway University Hospital REC
- Dr Barry Lyons, Chair, Children's Health Ireland REC
- Prof. Brendan McClean, Chair, St. Luke's Oncology Network REC
- Lynne McGlynn, REC Office, Beaumont Hospital
- Dr Gemma Moore, Qualitative Evaluation and Research for Quality Improvement, HSE
- Chita Murray, REC Office Manager, Tallaght Hospital
- Joanne O'Connor, REC Office Manager, Limerick University Hospital
- Dr Sadhbh O'Neill, REC Office Manager, Tallaght Hospital
- Dr Lucia Prihodova, Programme Manager at National Office for Research Ethics Committees
- Dr Jennifer Ralph James, Director, National Office for Research Ethics Committees
- Aileen Sheehy, Programme Manager at National Office for Research Ethics Committees
- Rosalie Smith-Lynch, Manager HSE North East REC
- Dr Oonagh Ward, Head of Research and Innovation Infrastructures at Health Research Board

HSE Research and Development Patient and Public Involvement Reference Group:

- Dr Virginia Minogue, Senior Research Manager, HSE National R&D
- Raymond Cregan
- Ann Cullen
- Carmel Geoghegan
- Robert Joyce
- Kerry Lawless
- Anne Lawlor
- Kara Madden
- Ciara O'Reilly
- Patrick Power
- Nuala Ryan
- Hannah Stephenson

Members of the National Consent Policy Working Group:

- Prof. Mary Donnelly, Professor of Law, UCC
- Caoimhe Gleeson, National Programme Manager for the National Office for Human Rights and Equality Policy
- Prof. Shaun O'Keeffe, Consultant Geriatrician and Honorary Personal Professor, University of Galway
- Marie Tighe, HSE National Quality Improvement Team, Project Manager, National Office for Human Rights and Equality Policy

HSE National Guidance for the Post Mortem Examination Services Working Group, including

- Prof. Linda X. Mulligan, State Pathologist
- Juanita Guidera, Senior Manager and QI Facilitator, National Quality and Patient Safety Directorate, HSE

Other advisors:

- Prof. Peter Doran, University College Dublin (UCD) School of Medicine and Medical Science, Scientific Director of the UCD Clinical Research Centre
- Dr Avril Kennan, Chief Executive Officer, Health Research Charities Ireland
- Dr Lydia O’Sullivan, School of Medicine, UCD
- Dr David Smyth, Associate Professor of Health Care Ethics, Royal College of Surgeons in Ireland
- Department of Health Officials, including Peter Lennon and Siobhan O’Sullivan among others

HSE National Policy for Consent in Health Research Steering Group

The Steering Group has reviewed, edited, and approved the content of this policy:

- Dr Ana Terrés, HSE R&D (Chair)
- Dr Myles Balfe, University College Cork
- Prof. Gianpiero Cavalleri, Royal College of Surgeons in Ireland
- Dr Carly Cheevers, National Disability Authority
- Prof. Conal Cunningham, St James's Hospital
- Prof. Philip Dodd, HSE National Office for Suicide Prevention/St Michael's House
- Dr Clare Farrell, Department of Children, Equality, Disability, Integration and Youth
- Sinéad Fitzpatrick, HSE National Health and Social Care Professions Office
- Dr Maureen Flynn, HSE Director of Nursing, Office of the Nursing and Midwifery Services Director and National Quality and Patient Safety Directorate
- Dr Anna-Marie Greaney, Munster Technological University
- Susan Kennefick, National Disability Authority
- Peter Lennon, Department of Health
- Dr Barry Lyons, Consultant, Department of Anaesthesia & Critical Care Medicine & Chair of the REC in Children's Health Ireland, Crumlin and Associate Professor in Medical Law & Ethics, TCD
- Grainne McGettrick, Research and Policy Manager, Acquired Brain Injury Ireland
- Dr Laura Méchineau-Phelan, Senior Manager, Contracts and Data Governance, HSE R&D
- Cliona O'Donovan, Quality Assurance and Operations Manager, National Office of Clinical Audit (NOCA)
- Dr Declan O'Hanlon, HSE Consent for Research Policy Project Manager, HSE R&D
- Dr Edel Tierney, National Research Officer, Tusla – Child and Family Agency
- Marie Tighe, HSE National Quality Improvement Team, Project Manager, National Office for Human Rights and Equality Policy
- Collette Tully, Executive Director, NOCA
- Dr Anna Visser, Principal Officer, Research and Evaluation Unit, Department of Children, Equality, Disability, Integration and Youth

Consent declarations and the Health Research Consent Declaration Committee

The consent declaration process is a statutory process governed by the Health Research Regulations 2018–2020. A researcher must apply for a consent declaration where explicit consent cannot be obtained from the research participant.

In order to ensure that consent declaration applications are carefully considered from a range of perspectives, the Health Research Regulations 2018–2020 provide for an independent and representative committee – the Health Research Consent Declaration Committee (HRCDC) – to make decisions on those applications. A consent declaration can only be made by the HRCDC where it is satisfied that the public’s interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the participant.

A consent declaration is made to the data controller to allow the researcher to process personal data for specified health research. A consent declaration may be for a defined part of a project, not necessarily the entire project. The HRCDC can only make a declaration once research ethical approval has been received. Therefore, applications to the HRCDC must show that ethical approval or provisional ethical approval is in place.

Where provisional ethical approval has been granted, the HRCDC may make a conditional declaration, where the condition attached is the requirement to ensure that full ethical approval is obtained prior to the effective date of the declaration.

A consent declaration does not extend to cover the use of personal data by third-party data controllers for separate projects. A third-party data controller wishing to further use personal data for its own purpose must seek the explicit consent of the individual concerned or, alternatively, it may need to seek a separate consent declaration.

A consent declaration cannot be made where consent has been withdrawn by a participant – in other words, a consent declaration cannot override the decision of an individual not to take part in a research study.

The HRCDC is not empowered to consider consent declaration applications from researchers where health research commenced prior to 8 August 2018.

Information on how to apply for a consent declaration may be obtained on the HRCDC website at www.hrcdc.ie.