Ethical Guidance for Research with Disabled People

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# Statement on language

In this report, the terms “people with disabilities” and “disabled people” are used interchangeably. The term ‘disabled people’ is recognised by many within the disability rights movement to align with the social and human rights model of disability, as it is considered to acknowledge the fact that people with an impairment are disabled by barriers in the environment and society. However, others prefer the term “persons with disabilities” because of the inherent understanding in the term that all persons are first and foremost human beings entitled to human rights. This also reflects the language used in the UNCRPD. Many people with an intellectual disability, people with a mental health difficulty or psycho-social disability prefer person-first language. Some people don’t identify with either term. You can find our full statement on language on the NDA website.[[1]](#footnote-1)

# Executive Summary

Disability research understands the social potential that is made possible through material and institutional change. It recognizes how society, by its actions and omissions, can worsen the position of disabled people beyond the level which could be attributed solely to the direct effects of people’s physical, sensory, or mental impairments.

The purpose of this document is to assist researchers and research ethics committees by offering them guidance in relation to good practice in research involving disabled people. The guidance is relevant for disabled research participants and for any research which involves the general population, among which are disabled people. The current 2023 update of the NDA ethical guidance was undertaken to include updates on ethical guidance from the HSE and legislation including the Assisted Decision-Making Capacity Act 2015 and the 2022 amending legislation (ADMCA). With this legislation if a person's capacity to consent to participation in research is questioned, good practice requires a documented assessment of capacity for informed consent, consistent with the standards outlined in the ADMCA 2022 Act. Capacity assessment is used where appropriate information has been provided in an individualised way, but concerns remain about the ability of a person to understand and consent to participation in the research.

The guidance outlines values and principles that should apply to research involving disabled people. It overviews disability research and ethics and addresses understanding and practicing ethical research. Only research that meets both scientific and ethical standards can be called ‘good’ or ‘excellent’ research.

The Convention on the Rights of Persons with Disabilities (CRPD) promotes, protects, and ensures the full and equal enjoyment of human rights and freedom by persons with disabilities, and promotes respect for their inherent dignity. It can be applied to disability research and all research. Article 4.3 of the CRPD contains principles that permeate the CRPD, including the promotion of human rights and fundamental freedoms for all persons with disabilities.Ethical implications for research that emerge from the CRPD include:

* All research should be conducted within the human rights framework although research agendas can overlook the rights and needs of those with the least resources and supports and those who communicate using non-verbal means, etc.
* The research principles of respect, consent, and privacy are core aspects of ethical research involving human subjects but can be neglected when dealing with research subjects who are disabled. Strategies for respectful research practice (including respect for privacy and for seeking consent) require planning. For example, in settings where privacy may be difficult to ensure or where interpreters may need to be used to facilitate communication between researchers and participants.
* Challenges posed by practical operationalization of research ethics in areas such as training of research staff require appropriate resourcing from funding bodies.
* Engagement with DPOs must take place on legislation and policies to implement the CRPD, and in other decision-making processes relating to persons with disabilities such as research projects, developing policy advice, developing strategies, guidelines, standards, and codes of practice.

**Before commencing research**

* Be familiar with the values/principles/standards of ethical research, and with the legal and ethical duties on data protection, confidentiality, capacity to consent and supported decision making.
* Be cognisant that ethical responsibilities apply throughout the research process.
* Reflect on the value of professional integrity and what one needs to do to develop and practice this value.
* Include experts by experience as co-researchers and involve them in planning and designing the research.
* Obtain ethical approval from a Research Ethics Committee with some expertise in the area to be researched.

**Obtaining consent**

* All participants in research must take part voluntarily, free from any coercion or undue influence, and their rights, dignity and autonomy should always be respected and appropriately protected.
* If participants to be included are deemed to lack the capacity to provide informed consent, ensure that a Consent Declaration is received from the HRCDC.
* Do not use other people such as family members or carers as proxies; they can consent to be interviewed as key informants but not to interpret the thoughts and feelings of others.
* Remind potential participants of the purpose and the implications of the research and of their right to decline to take part or withdraw from the research without consequence
* Provide easy-to-understand information and alternative formats, when necessary, for example, Easy to Read documents or video or digital formats for people with an intellectual disability.

**Data collection**

* Ensure that communication methods are adapted to suit everyone.
* Ensure that research venues are physically accessible.
* If the research, for example, interviews or focus groups, are prolonged, ensure that there are accessible sanitary facilities nearby and that breaks are offered as necessary.
* Have procedures in place should a research participant become upset during an interview or focus group discussion or discloses abuse during an interview or focus group discussion.
* Offer research participants the opportunity to review and amend a transcript of their interview.

**Data analysis**

* The inclusion of experts by experience in the analysis of data should be considered as it brings new insights and may challenge researcher biases.
* Take an ethical approach to analysis, and document all decisions made including the rationale for the decisions taken.

**Data dissemination**

* Disseminate research findings in appropriate and accessible formats and make efforts to ensure it reaches the research participants.
* Seek to include co-researchers in data dissemination, for example, through participation including presenting at conferences
* Consider publishing in open access journals to allow universal access to the research.

It is important to assimilate the ethical guidance so that one appreciates ethical problems and behave both ethically and legally.

# Introduction

The purpose of this guidance is to assist researchers and research ethics committees by offering guidance in relation to good practice in research involving disabled people. The guidance applies beyond research targeting disabled research participants and is relevant to any research which involves the general population, among which are disabled people. Unless involving disabled people in a research project is incompatible with the research question, disabled people should not be excluded from the sample of participants. The guidance will be relevant to research sponsors and funders, those involved in research governance, people with disabilities and disability organisations and the public.

The National Disability Authority (NDA) first published guidance for ethical disability research in 2005 following consultation. The NDA updated the 2005 guidance in 2009[[2]](#footnote-2), considering developments such as the UN Convention on the Rights of Persons with Disabilities (CRPD).[[3]](#footnote-3) The 2009 revised guidance was informed by input from an international NDA Disability Research Ethics Committee, set up for the purpose, feedback from consultation with research ethics committees in Ireland and research findings in the international literature.

The current 2023 update of this guidance was done primarily to include recent national developments in terms of legislation such as the Assisted Decision-Making Capacity Act 2015[[4]](#footnote-4) and the 2022 amending legislation (ADMCA)[[5]](#footnote-5), the Health Research Regulations 2018[[6]](#footnote-6), and the General Data Protection Regulation Act 2018[[7]](#footnote-7) and to include updates on ethical guidance from national organisations such as the Health Service Executive. We also reviewed international literature and incorporated where relevant. The NDA consulted Disabled Persons Organisations (DPOs)[[8]](#footnote-8) and other public agencies and disability organisations on the revised document and incorporated pertinent feedback.

The guidance outlines the values and principles that should apply to research involving disabled people and the NDA recommends that research in Ireland involving disabled people should be informed by this guidance.

The remainder of this report is divided into three sections. Section two provides an overview of disability research and ethics. Section three addresses understanding and practicing ethical research. Section four presents a summary of some of the practical guidance on conducting disability research.

# 2.0. Overview of disability research and ethics

## 2.1. Disability Research

The United Nation’s Convention on the Rights of Persons with Disability (CRPD, 2006) underscores the importance of disability research and awareness of the social determinants of health and wellbeing. Medical or rehabilitative research involving disabled people (‘health research’) can be distinguished from disability research, which explores aspects of society that make it difficult for disabled people to attain full societal participation and it investigates how the barriers to participation might be addressed.[[9]](#footnote-9) There is, of course, a great need for health research including disabled people, but it is essential that researchers do not identify disabled people only as subjects to be ‘treated’ medically. Many medical interventions, which appropriately target impairments, may do little to address the non-biological causes of disability.[[10]](#footnote-10) Disability research understands the social potential that is made possible through material and institutional change,[[11]](#footnote-11) and that while people can have impairments, their social and built environments can be disabling.[[12]](#footnote-12) It recognizes how society by its actions and omissions can worsen the position of disabled people beyond the level which could be attributed solely to the direct effects of people’s physical, sensory, or mental impairments.[[13]](#footnote-13)

Disability research redirects focus away from the impaired individual, allows its participants to take on a leadership role in removing social barriers, and can empower disabled researchers and participants. This research acknowledges and validates disability issues, examines biases, encourages enabling rather than disabling attitudes, and fosters respect for the “difference and acceptance of disabled people as part of human diversity and humanity”.[[14]](#footnote-14)

The purpose of the CRPD is to promote, protect and ensure the full and equal enjoyment of human rights and freedom by persons with disabilities, and to promote respect for their inherent dignity. The CRPD offers a framework for recognizing the rights of persons with disabilities and many of its principles can be applied to disability research and, indeed, all research. Good explores how the CRPD is shaping a global disability research agenda, which has implications for ethical research practice.[[15]](#footnote-15) The CRPD’s monitoring and evaluation dimension is set out in Articles 31 to 39 which require states to monitor and demonstrate progress toward human rights for people with disabilities, through regular reporting to the UN, backed by provision of quality evidence from research and from data collection at all levels.[[16]](#footnote-16) Furthermore, it sets out a framework for how ethical practice, which must be a key component of all research involving human subjects, should be effectively applied to disability research. This framework is provided both within the general provisions of the CRPD and in further detail within Article 31. Three sets of ethical implications for disability research emerge from the CRPD as follows[[17]](#footnote-17):

* The overall human rights framework.
* The specific research principles listed as requiring particular attention in disability research which are named as respect, consent, and privacy.
* The challenges posed by practical operationalization of research ethics in areas such as training of research staff, which require appropriate resourcing from funding bodies.

With regards research, Article 4 of the CRPD, which outlines general obligations, lays out the obligation on states parties to undertake or promote research and development in the areas of universally designed goods, services, equipment, and facilities and research and development in relation to new technologies including information and communications technologies, mobility aids, devices and assistive technologies.[[18]](#footnote-18) Article 31 of the CRPD focuses on research and data collection. It obliges State Parties to collect appropriate information including statistical and research data, to enable them to formulate and implement policies to give effect to the present Convention.[[19]](#footnote-19) Article 31 highlights problematic areas in relation to the operationalization of the principles of respect, consent, and privacy. These principles are core aspects of all ethical research involving human subjects but have often been neglected in the treatment of research subjects who are disabled.[[20]](#footnote-20)

Article 31 states explicitly that ethical research practice requires all research participants to be treated with respect. The principle of respect is also addressed in CRPD Articles 3, 17 and 22. The principle includes respect for disabled people’s dignity and for ensuring anonymity, privacy, and confidentiality at all stages of the research, including dissemination of research results and data storage/disposal. To ensure that the principle of respect is upheld, researchers can be trained in disability awareness as a minimum requirement. Strategies for respectful research practice (including respect for privacy and for seeking consent) require planning. For example, in settings where privacy may be difficult to ensure or where interpreters may need to be used to facilitate communication between researchers and participants.

Other CRPD Articles, while not specifically addressing research ethics, have implications for ethics and practising the principle of respect in disability research. Article 3, for example, addresses the following:

* Respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons
* Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity
* Non-discrimination
* Full and effective participation and inclusion
* Equality of opportunity
* Accessibility
* Equality between men and women

While Article 4.3 of the CRPD does not address research specifically, the content of Article 4.3 is of cross-cutting application, since it contains overarching principles that permeate the text of the CRPD, including the promotion of all human rights and fundamental freedoms for all persons with disabilities. [[21]](#footnote-21) The NDA states in Participation Matters 2022:[[22]](#footnote-22)

Engagement with DPOs must take place on legislation and policies to implement the Convention, and in other decision-making processes relating to persons with disabilities. Other decision-making processes include, for example, research projects, developing policy advice, developing strategies, guidelines, standards, and codes of practice.

Research should always be conducted within the Human Rights model. Research agendas can often overlook the rights and needs of those with the least resources and supports and those who communicate using non-verbal means. It is more difficult to get participants from this part of the population and protecting human rights include learning how to protect the rights of minorities. For example, if a focus group of ten visually impaired people respond that none of them could read braille, and as such, the availability of braille was not a concern for them, this could run the risk of ignoring the fact that access to braille is a human right, regardless of the actual numbers of Braille readers. Closely consulting with DPOs from the start of and during the research process can mitigate against such biases and allow for research which is more accessible for visually impaired people in general, and not just the model minority. Such close consultation from the concept stage can also ensure that there is no unnecessary replication of previous research.

Disability research can track progress in social participation and inclusion and the attainment of human rights as specified in the CRPD; evaluate if the supports and services provided are giving equal opportunities to disabled people to live their lives as fully as possible; and investigate how social and economic change are affecting disabled people. As well as being highlighted by the CRPD and the EU, the importance of research and data related to disability was underscored in Ireland in the Report of the Commission on the Status of People with Disabilities (1996)[[23]](#footnote-23) and, in an ongoing way by the Irish government and various national statutory bodies. A recent initiative by the Government of Ireland called Creating Our Future, facilitated a national conversation on research in Ireland. Over eighteen thousand submissions were received, and these were summarised into 16 themes. Several themes are relevant to the lives of disabled people including enhancing a person-centred approach to health and social care, promoting equality, diversity and inclusion in Ireland, and valuing and connecting community.[[24]](#footnote-24)

How disability research data is reported and disseminated is an important part of the research process and must be conducted under the same ethical principles, i.e., data should be accessible, disaggregated as appropriate and used to address the barriers faced by disabled persons in exercising their rights. Researchers need to be cognisant of the potential harms of reporting and take care in the interpretation and publication of study results.[[25]](#footnote-25) The pending National Data Equality Strategy should be helpful in this regard.

While the development of ethical practice has progressed, there is a documented history of abuse, particularly in health research, where participants’ interests were sacrificed for scientific/state gain.[[26]](#footnote-26) Disability research can present challenges to operationalizing research ethics principles, such as informed consent, confidentiality, privacy, respect, and equality. Ethical requirements are not always met where researchers, alongside research funders and managers, are not well trained or informed in the field. Indeed, some practitioners may avoid ethical requirements because of their resource implications. Indeed, Good contends that when ethical principles are inadequately addressed, the resulting reduced quality research can damage trust in the research process among disabled people. Poor-quality research conducted without careful attention to ethical practice leads to a poor knowledge base underpinning changes in policy and service provision for disabled people. The implementation of the CRPD has the potential to greatly improve ethical practice in disability research.[[27]](#footnote-27)

## 2.2. Research and ethics

Research can be defined as any form of disciplined inquiry that aims to contribute to a body of knowledge.[[28]](#footnote-28) It is undertaken to expand understanding and knowledge and to provide robust evidence for practitioners, policymakers, and legislators. A core value for researchers is rigorous implementation of appropriate research methodologies to derive findings and report the results honestly, attending to relevant quality standards in accordance to the methodology used

Research ethics applies ethical principles that flow from human rights to research activities to ensure that they are conducted ethically. Disability research ethics is located within this wider research ethics framework. Research ethics can be defined as the principles and practices guiding research, from inception through to completion and publication of results and beyond, for example, the curation of data[[29]](#footnote-29) and physical samples, knowledge exchange and impact activities after the research has been published.[[30]](#footnote-30) It clarifies what people ought to do to respect human rights and fulfil their research obligations. It requires that those conducting research respect the human rights of everyone involved, including ongoing considerations by those carrying out research throughout the research process. “It covers those questions about what ought and what not ought to be done by researchers when undertaking social research”.[[31]](#footnote-31) A simple way to think about research ethics in terms of best practices in every aspect of a research programme is to think how to maximise benefits while doing no or minimising any harm.[[32]](#footnote-32)

The extent to which both scientific and ethical values are adhered to influences research quality and its outcomes. Research cannot be ethical unless it meets scientific standards, but research that meets scientific standards may or may not be ethical. Only research that meets both scientific and ethical standards can be called ‘good’ or ‘excellent’ research.

While research ethics has been most developed in medical research, ethical principles apply to all fields of research. Informed consent and confidentiality, for example, are just as important for sociological studies as they are for clinical research.[[33]](#footnote-33) Ethical guidelines for social research cover most of the ethical issues for research with disabled persons. However, in some circumstances, specific strategies are needed to ensure respect for the dignity, equality, autonomy, and difference of disabled people. For example, particular steps may be needed to ensure privacy, confidentiality, and anonymity in settings where advocates and interpreters are used; and in situations where other people, besides the researcher(s) and the participants, are involved in aspects of the data collection. These and other issues should be considered when research is at the design stage. Adhering to ethical principles promotes research aims such as advancing knowledge, representing research data truthfully, avoiding, and minimising errors; practising essential values such as trust, mutual respect, fairness, accountability; social responsibility, human rights, public health, and safety. The requirement to adhere to ethical principles means that researchers can be held accountable to the public and build support for research because of its quality and integrity.[[34]](#footnote-34)

## 2.3. Values/principles/standards of ethical research

Values, principles, and standards are closely inter-related, indeed, often interchangeable, and difficult to separate in practice. While there is diversity nationally and internationally in how principles/values/standards are defined and delimited, they largely cover the same ground because they derive from human rights, which are rooted in the human being, and thus are shared by all people across all cultures, religions, and philosophies. Human rights recognise the dignity, equality, personal freedom, responsibility, and mutual respect that pertain to every human being.

National and international guidelines on the conduct of ethical research involving human participants, outline values/principles/standards that include the following.

* The Nuremberg Code of 1947 lays down standards for carrying out human experimentation, emphasising the subjects’ voluntary consent.[[35]](#footnote-35)
* The Declaration of Helsinki of 1964 (with several revisions) is regarded as a key document presenting ethical principles regarding human experimentation. The fundamental principle is respect for the individual, their right to self-determination, and the right to make informed decisions regarding participation in research. Although the Declaration was initially meant for physicians conducting medical research, it was later applied to all human subject research to ensure that the researchers provide adequate safeguards for protecting the safety, rights, and welfare of research participants.
* The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979).
* EU Clinical Trials Directive (2001/20/EC) central to research governance for clinical trials.
* The 2005 Universal Declaration on Bioethics and Human Rights (UNESCO, 2005).
* The 2016 International Ethical Guidelines for Health-related Research involving Humans crafted by the Council for International Organizations of Medical Sciences (CIOMS, 2016).

The regulations and recommendations contained within these codes are adapted into institutional operational guidance to be used at local level to guide the planning, review, approval, and conduct of human research. For example, the HSE (2021) cite an ethical framework that elucidates seven principles of research ethics review based on these international guidelines, which provides guidance to all clinical research stakeholders in all research settings (pp.53-54, HSE, 2021):

* Value
* Validity
* Respect for the person
* Informed consent
* Favourable risk-benefit ratio
* Fair subject selection
* Independent review

Various organisations and professional research associations have drafted documents that set out the principles and values that should underpin research. Although the values and principles are the same,[[36]](#footnote-36) they are presented in different ways with distinct nuances and different level of detail. Examples of how principles/values are presented in different documents are shown in Appendix 1 (the HSE National Policy for Consent in Health and Social Care Research, the Nursing and Midwifery Board of Ireland, the 2005 Universal Declaration on Bioethics and Human Rights, the National Ethical Research Standards for Health and Disability research in New Zealand (NEAC, 2019).

## 2.4. Research ethics, governance, and legislation

Research governance can be defined as the regulations, principles and standards of good practice that ensure high quality research.[[37]](#footnote-37) Its purpose is to promote good practice, enhance the quality of ethical and scientific research, reduce adverse incidents, and ensure that lessons are learned that prevent inadequate performance and misconduct in the future. It involves setting standards to improve research quality and to safeguard the public. Many countries have legal instruments to govern research with human participants. Research organisations, researchers, professional associations and those commissioning and funding research need to read, comprehend, and comply with the legislation that applies to research and need a shared understanding of the pertinent legislation, governance, accountability, and ethical constraints.[[38]](#footnote-38) They should be familiar with the national legislative framework relating to the rights of people with disabilities and the content and implications of relevant instruments such as the CRPD, 2006. In Ireland the Assisted Decision-Making Capacity Act 2015 as amended by the Assisted Decision-Making Capacity (Amendment) Act 2022 safeguards citizens whose capacity to consent to participation in a particular research project may be called into question (. Each person is at the heart of decision-making in everything that concerns him/her. The ADMCA 2022 legislation assumes mental capacity.[[39]](#footnote-39) If a person's capacity to consent to participation in a specific research project is called into question, good practice requires a documented functional assessment of capacity for informed consent, consistent with the standards outlined in the ADMCA 2022 Act. Capacity assessment is used where appropriate information has been provided in an individualised way but concerns still arise about the ability of a person to understand and consent to participation in the research. Judgement of capacity should not be based on a medical diagnosis. The legal requirement of providing a fully supported process before concluding that a person lacks capacity has the potential to enable many more people to make their own decisions and have them respected.

There are laws to protect data and information through the EUs General Data Protection Regulation (GDPR). This applies to the processing of personal data across the EU, including Ireland, along with the national rules set out in the Irish Data Protection Act, 2018. The Health Research Consent Declaration Committee (HRCDC) was established as part of the Health Research Regulations[[40]](#footnote-40) which were provided for under the Data Protection Act, 2018 (Section 26(2)). The Regulations, originally created in 2018 through a statutory instrument (S.I. No. 314 of 2018 and later amended in 2021) ensure that access to sensitive personal data of participants in health research is valid and lawful.[[41]](#footnote-41)

Many countries have established national bodies to oversee research ethics committees (RECs) with some national bodies serving as ethics review committees themselves. In Ireland, there are ongoing efforts to develop, strengthen and harmonise a robust framework for human participant research ethics governance and address ethical challenges to safeguard the rights of research participants.

An independent office with a statutory function, the National Office for Research Ethics Committees, was established in 2020, as a component of the reform of the research ethics committee framework in Ireland led by the Department of Health.[[42]](#footnote-42) Its role includes creating a cohesive research ethics review system that strengthens the nationalresearch infra-structure, which includes establishing and supporting National Research Ethics Committees in specific areas of health research. To date however, the National Office priorities are clinical trials of medicinal products for human use, clinical investigations of medical devices and performance studies of in vitro diagnostic medical devices. To realise their potential, national bodies need to be adequately staffed and funded to cover all human participant research, rather than clinical trials only.

The HSE (Health Service Executive) set out a ten-year plan in 2019[[43]](#footnote-43) to establish, develop, embed, and consolidate a HSE governance framework for health research. In 2021 they published the HSE National Framework for Governance, Management and Support of Health Research.[[44]](#footnote-44) This framework outlines how both ethical and institutional oversight are necessary for the appropriate governance of health research. In 2022 required reforms were published in the Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees HSE (2022). [[45]](#footnote-45) In addition, in 2023 the HSE published their National Policy for Consent in Health and Social Care Research.[[46]](#footnote-46)

While the objective view of a Research Ethics Committee is important in safeguarding potential participants and highlighting potential ethical issues there can be challenges where research is restricted due to overly zealous committees that fail to adequately balance the necessity and potential benefits of research with potential ethical issues that may arise. Coggon[[47]](#footnote-47) gives practical examples where the process of independent ethical review can be described as weighted against the researchers and the research. “In these examples, ‘devotion to protocol’, without justification, contributes nothing to the ethical conduct of the research and only adds to the intrinsic costs of the research and frustrations of the researcher”: It is important that independent ethical reviews by RECs make an important contribution to the overall research process rather than being identified as an imposed, unnecessary burden.[[48]](#footnote-48)

## 2.5. Participation and collaborative research

In the last decades there has been a shift from doing research on and about populations to doing research **with populations**. Since 2005, Research Governance Framework for Health and Social Care[[49]](#footnote-49) published by the UK Department of Health has required researchers, wherever possible, to involve service-users and carers or their representative groups in the design, conduct, analysis, and reporting of research. With regards disabled people, since the 1970s, co-produced participatory research has been emphasised. This entails disabled people working with researchers to contribute to the production of research that is informed by their input.[[50]](#footnote-50)  The NDA’s 2022 ‘Conducting Collaborative Research with People with Disabilities: A Literature Review’ summarises the many advantages of collaborative research.[[51]](#footnote-51) NDA guidance on conducting collaborative research was published in October 2023.[[52]](#footnote-52)

Disabled people should be eligible to be research participants alongside their non-disabled peers and disabled people and DPOs should be involved in research when the research focus is on a disability issue (collaboration), following the maxim: ‘Nothing about us, without us.’ The 2022 NDA guidelines 'Participation Matters: Guidelines on implementing the obligation to meaningfully engage with disabled people in public decision making'[[53]](#footnote-53) are a practical resource to support the involvement of disabled people and their representative organisations, DPOs, in research as well as in policy development and other processes. The Guidelines take a universal design approach to consultation and participation processes so that disabled people participate on an equal basis with others. The Guidelines are available in Irish Sign Language and Easy-to-Read formats.

Collaboration and consultation with disabled people and DPOs early in the design process, can lead to more effective and ethical research and prevent harmful assumptions. It can foster trust and builds relationships, a fundamental aspect of ethical research. It can help researchers frame research questions, devise appropriate methodology, interpret findings, and avoid an ‘ableist’ bias.[[54]](#footnote-54) It can provide opportunities for shared learning, increased knowledge production and dissemination.[[55]](#footnote-55) Disabled people may also have a more extensive role in the research process and conduct fieldwork, and input into the analysis of data. The contribution of disabled people that play a significant role in the research process should be appropriately recognised. Active participation and engagement of people with disabilities in the research process can promote informed consent because they access more information about the project and can help other persons with disabilities to make more informed decisions.[[56]](#footnote-56) More generally, the more information one has on the project, the more likely one is to make a decision that is informed. In summary, when carried out well participation is more likely to result in ethical research because it will tend to be[[57]](#footnote-57)

* More relevant to the people it is trying to help
* Beneficial in terms of delivering meaningful outcomes for the participants and the population they represent.
* Conducted in a way that is sensitive to the needs of the research participants.

# 3.0. Understanding and practising ethical research

This section, after underlining that ethical responsibilities apply throughout the research and after overviewing the values/principles that underpin ethical research, looks at how to apply the values/principles to practise ethical research.

## 3.1. Continuous ethical responsibilities

Applying ethical guidance in individual research projects is an ongoing process of judgment and good research practice. This means that ‘permission’ from an ethics committee to proceed with the research is only the beginning of a process of self-monitoring by the researcher.[[58]](#footnote-58) Researchers cannot consider their ethical responsibilities as fulfilled once ethical approval for a research project has been obtained. In complex research situations, structures for supervision and access to ethical advice for the researchers are essential[[59]](#footnote-59) such as the appointment of a research advisory group with a named responsibility for ethical standards. At the same time, issues with ethical implications may arise during fieldwork. Indeed, “ethically important moments” can arise at different points during the research process, when they cannot be passed on to managers or a committee. This places responsibility upon the individual researcher. In relation to issues of informed consent throughout the research process, for example, there are no simple solutions that can be applied universally to resolve all ethical dilemmas.[[60]](#footnote-60) Rather, researchers need, at every stage of the research process, to be mindful of the relevant legislation and guidance and be familiar with the issues arising in the context of their individual research projects that relate to:

* The needs of participants
* Ensuring ongoing consent
* Handling relationships that develop during the research process
* Dealing with unanticipated, distressing emotions
* Tackling unexpected revelations
* Dealing with re-traumatisation

Researchers need to understand the challenges that arise and learn to balance their responsibilities to sponsors, employers, professionals, and respondents. It may be helpful to differentiate between procedural ethics (what happens in research design and in research ethics committees) and ethics in practice (what happens in the interactions between researcher and participants and in the way that data are interpreted, communicated, and used). Ethics in practice is enhanced by procedural ethics as the underlying values are the same.[[61]](#footnote-61) However, procedural ethics cannot address all the ethical dilemmas that arise during the research process. Therefore, researchers must be alert to the need to adequately address the ethical issues that arise throughout the research process. Ethical considerations that emerge as the research proceeds include viewing consent and trust, not as ‘one-off’ events, but as a process that is renewed and re-established during the research. This involves, for example:[[62]](#footnote-62)

* Reminding participants of the right to withdraw from the study at any time
* A sensitive and tactful completion of the research process including, e.g., debriefing or having support structures available after their participation if they need them.
* Making participants aware of their right to check how they are represented in transcripts/field notes

The ‘ethics as process’ model has been proposed as particularly suitable for qualitative research where the research design emerges as the research proceeds,[[63]](#footnote-63) but it is applicable to all research. Ongoing consideration of ethical issues is essential as it ensures that the benefit to risk ratio in research remains on the side of benefit for participants.

Each person must be seen as a subject at the centre of decision-making in everything that concerns him or her. How to do this needs to be established at the design and planning stages as well as throughout the research process. Ethical issues in disability research go beyond ensuring that the disabled people participating in one's research do not encounter any risk or harm. It involves being attentive to disabled people's perspectives and their concerns as well as catering for any impairment-related requirements they might have throughout the research process.[[64]](#footnote-64) Their expertise and time should be valued and they should benefit, where possible, from the research they are involved in.

## 3.2. Maximising benefits and minimising harm

### 3.2.1. Beneficence and non-maleficence

Beneficence and non-maleficence are technical terms sometimes used in research ethics. These terms mean respectively to seek to benefit individual participants and society[[65]](#footnote-65) and to promote their welfare[[66]](#footnote-66) and seek to do no harm and never to deceive[[67]](#footnote-67), balancing potential benefits against risks by reducing the possible risks and safeguarding participants.[[68]](#footnote-68) Beneficence can be personal and may differ between individuals. In qualitative research participants may not directly benefit from their involvement in a research study but participants may experience a cathartic effect from telling and having their story heard.[[69]](#footnote-69)

Researchers can consider and articulate potential and perceived benefits and risks and plan how to support research participants before, during and after engaging with them in the research process.[[70]](#footnote-70) Research risks need to be assessed with respect to their physical, social, and psychological effects on participants. Risks should be commensurate with the expectation of benefit to participants, or the importance of the area being explored. All research should conform to legal obligations.

Possible sources of harm include:

* Any breach of confidentiality
* Coercion or manipulation to participate in research
* Drugs or invasive procedures in clinical trials
* Disruption of the relationship between individuals and their carer(s)
* The nature of the interaction between researcher and participants
* In-depth interviewing about intrusive topics, which may bring up traumatic memories
* Research methods such as participant observation.

Research that analysed reactions to research participation, personal benefits, perceived drawbacks, and emotional reactions concluded that: ‘if research is carried out in a respectful and private manner with a clearly communicated and reasonable goal, participants’ expressed emotion or distress may not undermine their assessment of the potential costs and benefits of participation’.[[71]](#footnote-71) Other research on participant experience stressed several elements, which can improve the quality of the research experience and care of participants as well as potentially improving the quality of the research findings: [[72]](#footnote-72)

* Interviewers play a critical role in whether participants are happy with participation, and this has implications for who should carry out interviews and how they should be trained and supported.
* Voluntariness in participation and being mentally prepared for research interviews is particularly important when topics are sensitive ones.
* Having scope for self-expression and being able to withhold information when they do not want to share it.
* Knowing that findings from the research are used and receiving feedback on research results.
* Trust and confidentiality are crucial. Understanding of confidentiality can vary and participants do not often assess what they are told questioningly. The research suggests a need for giving potential participants more information, both before and after the interview. As research is unfamiliar to most potential participants, there is scope to encourage them to learn more about it.

The following are important considerations for researchers:

* It is always unethical to place weighty physical, emotional, or psychological demands on participants,[[73]](#footnote-73) or to use any form of coercion, manipulation, or undue influence to participate in research. While physical harm is likely to be recognised and therefore avoided or diminished, emotional, social, or economic factors may be less apparent.
* The researcher must avoid pressurising participants and manage suggestibility and compliance in research participants. It is important for researchers not to overstate the potential benefits of the research.[[74]](#footnote-74) Some participants may overestimate the benefits of taking part in experimental treatments seeing it as a chance to gain access to better services and supports.[[75]](#footnote-75)
* All people are at risk of being subject to undue influence[[76]](#footnote-76), but this risk may be exacerbated for those who rely on the support of others to make decisions. Researchers should take steps to satisfy themselves that there would be no negative consequences for those who choose not to participate, and that this fact is communicated in a credible way to potential participants.
* Care needs to be exercised in situations where disabled persons might feel more pressurised to participate, for example, when carers or service-providers are used to recruit research participants. This carries a risk that disabled persons may think that there might be negative consequences in terms of their care or support if they declined to participate. Thus, special caution needs to be taken when recruiting research participants dependant on care related to the research topic and conducting research in such settings or where advocates, interpreters, proxies, or communication assistants contribute to data collection or interviews.
* Safeguards for the exercise of people’s legal capacity include protection against undue influence: however, such safeguards must also respect peoples’ rights, will and preferences, including the right to take risks and make mistakes.
* The issue of making payments to participants above the costs of participation, such as transport and time costs, must be considered, as excessive incentives to participate can be coercive.[[77]](#footnote-77) On the other hand, some researchers pay disabled research participants as routine and consider non-payment as potentially disrespectful.

To apply and practice the principle of maximising benefits and doing no harm, the following considerations on the need and potential benefits of research, methodology, findings etc., may be helpful for researchers and stakeholders including funders to review:

### 3.2.2. Justifying research

Careful thought should be given to whether a research project can be justified practically and ethically. Some of the approaches that can be taken are listed below.

* A collaborative approach will assist in this aspect of the research design. Risk/benefit should be evaluated, first from the perspective of the individual participant and then from that of society.[[78]](#footnote-78)
* Balance respecting a disabled person’s right to access research and the benefits of participation with awareness of the potential for exploitation. Alongside reducing the risk of harm there is need for efforts to maximise benefits to the participant.[[79]](#footnote-79)
* Check previous studies and consider over and under-researched areas when formulating research questions. Some people with disabilities consider that they have been ‘over-researched’.[[80]](#footnote-80)
* Consider whether the methodology chosen tallies with the research objectives and whether the expected benefits outweigh the potential risks.
* Reflect on the social, cultural, and historical experiences of disabled persons, including their experiences of exclusion and stigma. The research process should not perpetrate or endorse, directly or indirectly, any aspect of discrimination, stigma, or exclusion. Any research linked to theories or ideologies around a presumption of inferiority of disabled persons or linked to denial of any of their human rights, would be of great ethical concern.
* Historically, there has been a power imbalance, beyond the asymmetry between researcher and researched, in the relationship between researchers and disabled people. Social inequities maintain this imbalance to varying degrees. Researchers should consider whether a disability advisory group or disability researcher is indicated when reviewing the research design for disabling aspects.
* Approaching the same people repeatedly and asking them the same questions can be a lack of respect.[[81]](#footnote-81)

### 3.2.3. Managing how research is used

Accuracy, honesty, and transparency in reporting research findings are important aspects of high-quality ethical research and of professional integrity. While researchers cannot fully control the use to which their research is put, they can take reasonable steps to ensure that it is used for the purpose stated. This can be done, for example, by adhering to data protection legislation, and re-consulting with participants if secondary research is proposed and by demonstrating how research has been used to inform plan and develop services in the past. It is advisable to seek consent for secondary analysis of personal data at the outset of the research project, when practicable.

For those making use of the research findings, it is important to be accurate about what the findings are. To do this, one needs to know how the research was designed and executed, the decisions that were taken, and the strategies and methods used. Where research outcomes are not what the researchers and participants expected and could result in negative outcomes, they need to handle dissemination sensitively, and put in place support where needed yet remain true to the research findings.

Ethical responsibility to ensure that harm does not result from published research falls on others as well as on the researcher(s), e.g., policymakers, service-providers, media, and other stakeholders. However, the researcher has a responsibility to challenge misuse when it occurs, publicly if necessary.

### 3.2.4. Support and care for researchers

Often overlooked is the risk to researchers, especially where they work alone. Researchers need to be supported by their organisation through relevant policies and procedures.

* Researchers should adhere to any lone worker policy that applies[[82]](#footnote-82). All should be familiar with the policy. Where there are concerns about working alone in particular settings, researchers should check with the ethics review committee, consult with their supervisors and colleagues, and maintain a monitoring visit proforma.[[83]](#footnote-83) [[84]](#footnote-84) Informal debriefs with research colleagues can be very useful.
* A research advisory group can support researchers on how to handle difficulties that can arise with certain methodologies. The advisory group can be accessed for support and advice, such as when relationships become too intense,[[85]](#footnote-85)or when, during the research, relationships that have developed with lonely people are withdrawn.[[86]](#footnote-86)
* Unethical practices of, for example, staff in a residential setting, parents or siblings at home, colleagues, or employers, could be disclosed during the research, and it is important to be familiar with the organisations, ethics review board and governing body’s policy guidelines in such cases. The researcher should have a clear reason for disclosure and seek support from their supervisor, ethics committee and other relevant people, and document the decisions taken.[[87]](#footnote-87)

### 3.2.5. Strategies to deal with the distress of research participants

The potential distress of research participants, for example, due to the topics raised in an interview, should be anticipated where possible and supports put in place in advance. However, it is difficult to anticipate who will become distressed and what will cause that distress so a researcher must be prepared to take relevant action, for example,

* Participants should not be compromised by the demands of the study. If a participant becomes upset, the researcher should offer the participant the opportunity to cease and reconvene at their discretion, and this option should be flagged in advance of participation.
* In-depth interviews, particularly on sensitive topics, may bring up traumatic memories. Interviews with people currently experiencing mental health difficulties carry the risk of harm to the research participant. Appropriate protocols need to be in place to identify signs of stress in a research participant and to ensure that there is access to counselling and support should the need arise. A link to an example of a distress protocol is included in the footnote below.[[88]](#footnote-88)
* Researchers can put support mechanisms in place e.g., counselling, employee assistance programme for participants who become distressed during or after interviews or completion of questionnaires, especially when there is potential to highlight sensitive information, past experiences, etc. Strategies identified in the literature to minimise emotional distress where it is considered a risk include the following: employ interviewers who are trained to handle psychological distress, monitor participants' emotional reactions, provide frequent breaks during stressful data collection procedures, debrief, and provide information on available services.[[89]](#footnote-89)
* Research has shown that interviewers play an important role in whether participants were happy with their experience.[[90]](#footnote-90) This suggests that training in communication and empathy skills may benefit researchers.

### 3.2.6. Attend to wellbeing of participants in practical ways

Researchers have a responsibility to attend to the wellbeing of participants by protecting them from any potential harm arising from the research and addressing their needs during the research process, for example,

* Some people may have limited stamina and the research design and protocol should allow for rest or care breaks during the research process.
* Participants should be afforded a choice of venues to reduce inconvenience and costs such as travel or allowing the researcher into their home.[[91]](#footnote-91)
* While the individual’s wellbeing is of primary concern, excessive concern to protect disabled persons who are seen as vulnerable can lead to gatekeepers preventing their inclusion in research: “A balance is needed between protection and empowerment”.[[92]](#footnote-92)

Gatekeepers are professional or informal supporters who grant or deny researchers access to individuals. A national study in England and Wales showed a widespread lack of understanding that the decision about research participation should be based on what the person’s wishes and what feelings about taking part would be, for those who lack capacity, which can only be determined through consulting with those that know them well.[[93]](#footnote-93) Gatekeepers can deny access to safeguard the “vulnerable”, or to protect themselves. They may be concerned about institutional factors such as policies and relationships or have misconceptions about the nature of the research. Sometimes they pre-select potential participants based on their own conceptions of what the research requires.[[94]](#footnote-94) Denying access avoids having to make decisions regarding the management of organizational, relational, or professional problems linked to results.[[95]](#footnote-95) It can lead to lack of representation of certain populations in research and can violate the rights of individuals to make their own decisions.

The exclusion from research of certain individuals who appear vulnerable, communicate using non-verbal means, or lack decision-making capacity, risks condemning such populations to poor-quality support and care because of a lack of relevant evidence to inform social care and health provision. Such adults e.g., those who lack decision-making capacity must not be unfairly excluded from the benefits of research participation, nor should a lack of capacity to consent be used to inappropriately include them in research.

## Consent to participate in research

### The purpose of informed consent

Free, informed consent is an attempt to resolve the ethical tension of involving people in research when they have not actively sought this and when the research is often only of indirect benefit to them. Obtaining voluntary and informed consent seeks to ensure that individuals are treated and respected as subjects and participants. Guided by the ethical and legal principle of personal autonomy, and protected by legislation, research participants must be facilitated to decide freely whether the research is consistent with their interests and preferences. It is a mechanism to ensure that the rights of individual participants are protected by supporting individual autonomy, protecting participants’ welfare, promoting trust, satisfying regulatory requirements, and contributing to transparency and integrity in research.

Autonomy demands that a person’s right to make decisions, including decisions about participating in research, refusing to participate, or withdrawing consent, is respected by everybody. All prospective participants must be recognised as independent persons able to manage their own concerns and with the right to make and express personal decisions, free of outside interference and to have their decisions honoured. Therefore, researchers must facilitate participants to make free, independent, and informed choices without any coercion when they are deciding whether to become involved in a research study. This means putting in place mechanisms as part of the research design that support each person’s autonomy. To ensure autonomy, prospective research participants must fully understand what is being asked of them, the effect that research participation may have on them and the risks/benefits of participation.

The value of autonomy, which is closely related to self-determination, can be considered from various angles:[[96]](#footnote-96)

* Choice (autonomy of thought) - thinking for oneself
* Capacity (autonomy of will) - freedom to do something based on one’s own deliberations
* Governing oneself/Self-determination (autonomy of action) - freedom to act as one wishes.

The thrust of legislative reform worldwide including in Ireland is to emphasise the capacity of each person. Irish capacity legislation is enabling rather than restrictive, and the legal standard of capacity is decision-specific (functional). Together with GDPR compliance regarding processing personal data, informed, voluntary and fair consent is the cornerstone of ethical research.

Most people, with adequate support, can make informed choices and exercise their right to consent to participate in research or decline to do so. The provision of support should reflect the level of complexity in the research and be sufficient to enable an individual to choose whether to participate. Supported decision-making gives primacy to people’s will and preferences. It provides protection for rights, including those related to autonomy (the right to legal capacity, the right to equal recognition before the law, the right to choose where to live) and those related to freedom from abuse and ill-treatment (the right to life, the right to physical integrity.) Supported decision-making should not overregulate the lives of persons with disabilities in a way that impacts their capacity (CRPD 2006).

Through the consent process, participants should understand clearly what taking part in a specific research programme will mean for them so that they can make an informed choice. This information includes how the researchers intend to use personal data, and the types of data they will use, etc. The consent process aids transparency and fairness for research participants.[[97]](#footnote-97) Project-specific information (the information provided to participants during the consent process) should not be the only information made available to research participants. Who funds the research, etc. is also relevant. For this, researchers, research governance leads, and Data Protection Officers should work together to ensure a joined-up approach to transparency and fairness.[[98]](#footnote-98) Essential components within a valid informed consent process are disclosure of information, comprehension, competency, and voluntariness.[[99]](#footnote-99) The process of obtaining consent begins with a researcher’s first contact with a potential participant and continues until the participant’s involvement in the research ceases. The process requires reciprocal communication between researcher and potential participants. Researchers must provide participants with information in accessible formats about the research they are being asked to participate in, the potential risks and benefits, and the opportunity to ask questions, etc. Essential information elements include the following:[[100]](#footnote-100)

* Title of study
* Researcher(s) name, place of work, qualifications and contact details
* The study population
* The purpose of the study
* The study procedures and steps for data collection
* The potential risks and benefits
* How anonymity or confidentiality will be upheld
* How data will be collected
* Who will collect data?
* How will data be stored?
* Who will have access to data?
* How their participation is voluntary, and they have the right to refuse to participate or withdraw at any time and can choose not to answer any question or cease their involvement at any stage
* The opportunity to ask researchers questions related to the study including timeframes for the study, who else is participating and how the data will be used.
* How participants can obtain the results of the study
* Both parties will receive a dated and signed consent form

It is important to emphasise that obtaining the informed and voluntary consent of participants is a process of ongoing engagement and communication by the researcher rather than a one-off event. And that it may involve re-consenting a research participant if changes are made to a research study or new information about the research becomes available.[[101]](#footnote-101)

### Guiding principles

The HSE’s National Policy on Consent for Research have several guiding principles for application in social care and health research aligned to the principles of the Assisted Decision-Making (Capacity) Act 2015, as amended. These principles provide a statutory framework for individuals who lack, or may lack, the capacity to make decisions unaided or to be assisted and supported in making decisions about their welfare, property, and affairs: [[102]](#footnote-102)

* 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. These steps might include some of the following: amending the information about the project using ‘accessible language’; using an interpreter or reader of written information; providing only essential information about the project; breaking down complicated information into smaller points; conveying information with diagrams and use of colour; providing information in alternative formats, e.g., aurally for people with visual disabilities; encouraging discussion with others, such as family or friends about the project; allowing the person time to reach the decision; providing education about research- would training or discussion about the idea of research help the person to reach a decision about a particular project; being clear about what is required of the participant in conducting the research; consider systems for communicating with the prospective participant such as augmented communication or symbols or ‘talking mats’ and might others assist the person in communicating, whilst at the same time not influencing the person in reaching a decision?[[103]](#footnote-103)

### Legislative basis for including people who cannot consent

The Health Research Consent Declaration Committee (HRCDC) was established on the foot of the Health Research Regulations which were provided for under the Data Protection Act, 2018 (Section 26(2)). The Regulations, originally created in 2018 through a statutory instrument (S.I. No. 314 of 2018 and later amended in 2021) ensure that access to sensitive personal data of participants in health research is valid and lawful. Regarding explicit consent, the Health Research Regulations 2018 maintain that explicit consent is the default position for processing personal data for health research purposes (unless the personal data is wholly anonymised or there is specific legal provision authorising the health research in question). It is important that health researchers engage fully with their Data Protection Officers to understand the law in this area as it affects the processing of personal data for health research in Ireland. However, it is recognised – as it is in other countries – that, in limited situations, obtaining explicit consent from some potential participants, for example some people with severe or profound disabilities, advanced dementia, will not be possible even when using advanced and alternative communication methods and that the public interest of doing the research may outweigh the need for explicit consent.

In order that such applications are carefully considered from a range of perspectives, the Health Research Regulations provide for a statutory consent declaration process through the HRCDC, an independent and representative committee which has a decision-making role on those applications. The legislation enables an organisation as data controller carrying out health research using personal data, to apply for a consent declaration which means that the consent of individuals who are unable to provide consent despite support is not required for the obtaining and use of his or her personal information for the health research concerned. [[104]](#footnote-104) The HRCDC website has detailed guidance on the Consent Declaration Process and amendments to the health research regulations.[[105]](#footnote-105)

If the prospective research participant is a Ward of Court, 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 be sought and documented if they are in the position to provide it.

The process of ending the adult wardship system began in April 2023 with the commencement of the Assisted Decision-Making (Capacity) Act 2015, as amended. All adults who are Wards of Court will exit wardship over a period of three years.[[106]](#footnote-106)

### Legislation to support decision making

The Assisted Decision-Making Capacity Act 2015 as amended by the Assisted Decision-Making Capacity (Amendment) Act 2022 (ADMCA) was commenced in 2023. This legislation brings Ireland into line with Article 12 of the CRPD on equal recognition before the law.[[107]](#footnote-107) The purpose of the legislation is to protect the autonomy of all persons and has implications for consent to participate in research. Amendments to the 2015 Act expanded the definition of ‘personal welfare’ to include participation by persons in social care and healthcare research, except for clinical trials and investigations, which are governed by EU Regulations. The Act applies to adults (18 years and older). It is the legislative basis for supporting decision-making, providing processes and safeguards for those who will make use of decision-making supports.

The ADMCA allows people lacking in or with limited capacity, to make legal agreements on how they can be supported to make decisions about their personal welfare, property, and affairs. As the definition of personal welfare now includes participation in research as noted above, if the decision support agreement extends to personal welfare, the decision supporter can assist the person/decide on behalf of the person re participation.[[108]](#footnote-108) An innovation of the legislation is that it allows for decisions where a person can lack capacity on a certain issue/s but have capacity on other issues. The Act brings four changes:**[[109]](#footnote-109)**

* It gives primacy to the person’s will and preferences rather than the previous ‘best interests’ approach.
* Rather than persons ‘believing’ the information presented to them they must ‘communicate’ their decision for the capacity criteria to be fulfilled. Communication can be by talking, writing, using sign language, assistive technology, or by any other means.
* With the commencement of Part 8 of the ADMCA, advance healthcare directives will have a standing in law.
* The scope of Enduring Power of Attorney will include certain healthcare decisions, but these will not include refusal of life-sustaining treatment or decisions that conflict with advance directives made by the appointer.

Special measures protect the rights and interests of those with diminished capacity:

* 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 authority.
* The ADMCA provides legal authority for decision supporters to help a person participate in research where they have legal authority to support personal welfare decisions. Depending on the tier of decision-making support available, the decision supporter may be able to support the person to give consent, jointly give consent, or consent on behalf of the person.
* Participants who regain decision-making capacity should be given 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, any data and biological material collected as part of the study should be destroyed if this is their wish. A person who withdraws may welcome data collected thus far being processed.

The ADMCA provides for three types of decision-making support where a person is found to

* require decision-making support or lack decision making capacity, even when appropriate supports are provided
* when there is no advance directive regarding the decision to be made
* when there is no Enduring Power of Attorney

The three possible levels of support are as follows:[[110]](#footnote-110)

* A decision-making assistant is the lowest level of supports. The person makes the decision with the assistance of a decision-making assistant who can help to obtain and explain information and help the person decide what he/she wants to do.
* A co-decision-maker is the second level of support and involves a decision made by both the person and a co-decision-maker, who also provides support and information. It is a more formal agreement than the first type, with the need for a document to be registered with the Decision Support Service (DSS)
* A decision-making representative is the highest level of support, is appointed by the Circuit Court, makes certain decisions on the person’s behalf in line with their will and preferences.

Codes of Practice relating to each of these tiers and other Codes of Practice and guidance are available on the website of the Decision Support Service.[[111]](#footnote-111)

### 3.3.5. A functional approach to capacity to consent

Capacity under the ADMCA is assessed using a functional approach on a time-specific and issue-specific basis rather than from a medical perspective. 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. 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.

Researchers should assume that a prospective participant has the capacity to provide informed consent unless their interactions with the person raise doubts about their capacity. If a prospective participant’s capacity to provide informed consent is unclear the researcher must arrive at and document a functional assessment of capacity to provide informed consent.

• When considering their potential involvement in research a prospective participant should be encouraged to obtain support from a person with whom they have a close and trusting relationship. However, unless this person has been appointed as a decision-making supporter their view 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.[[112]](#footnote-112)

A prospective research participant has the capacity to provide or refuse consent if they can:[[113]](#footnote-113)

* 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.

If a participant lacks capacity to provide informed consent researchers should note evidence that indicates assent or dissent. They may also consult with persons that support the prospective participant to ascertain their will and preferences (if known) regarding participation in research. A refusal to participate or a request to withdraw from research should always be complied with.

Researchers should only include persons who lack the capacity to provide informed consent as research participants if they have the appropriate ethical and legal approval. If the research comes within the definition of health research as defined by the Health Research Regulations[[114]](#footnote-114) a Consent Declaration must be sought from the HRCDC in addition to approval from a research ethics committee. Where a decision support agreement extends to personal welfare a decision-making representative will have the legal authority to consent on behalf of a person.

## Confidentiality and data protection

Data protection and confidentiality are legal and ethical duties. Data protection law governs situations where personal data are ‘processed’ by an organisation or person. Processing means using personal data in any way such as collecting, storing, retrieving, consulting, disclosing, or sharing with someone else, erasing, or destroying personal data. Confidentiality is ensuring that only the people who should have access to personal data are processing it.

Data protection is both an integral issue for research ethics and a fundamental human right. It is linked to human dignity and the principle that everyone should be valued and respected. The right to data protection is guaranteed by the EU Charter of Fundamental Rights and the Treaty on the Functioning of the European Union. It gives effect to the right to privacy by providing individuals with autonomy and control over the way information about them is collected and used. This is important as disclosure of identity and insufficient protection of private information are risks faced by research participants. Thus, safeguarding privacy and taking appropriate measures for processing, handling, and storing data are central at all stages of research and beyond.[[115]](#footnote-115)

The ‘General Data Protection Regulation’ (GDPR) is a law which applies to the processing of personal data in Ireland and across the EU, along with national rules set out in the Irish Data Protection Act 2018.[[116]](#footnote-116) GDPR is applicable to all research involving data which can identify an individual (personal data), regardless of the nature of the research. GDPR has an 'integrity and confidentiality' or security principle, which demands that the appropriate security measures are in place to protect any personal data held by an organisation.

Processing personal data for research purposes requires that the data subject has consented to the processing. Researchers must be aware of the legal requirements and uphold the commitment to research participants on confidentiality including anonymity and data protection. 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.[[117]](#footnote-117) Data processing is lawful under Article 9 for special categories of data (or ‘sensitive data’, including health data) which are subject to additional requirements.[[118]](#footnote-118) Data processing is lawful under a list of legal bases provided in the GDPR under Article 6 for non-sensitive personal data. 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 (p.28, HSE, 2023).

The European Commission published ‘Ethics in Social Science and Humanities’ in 2021,[[119]](#footnote-119) which addresses data protection, confidentiality, consent, ethical principles, and the ethical dimensions of research methodology.

Confidentiality should not be confused with anonymity, which refers to people being fully anonymous, and as participants become known to the researchers, true anonymity is not achievable.[[120]](#footnote-120) Therefore, when participants engage in face-to-face contact with the researcher, it is unrealistic to promise anonymity and more appropriate to promise confidentiality. The terms ‘anonymity’ and ‘confidentiality’ are used interchangeably, but they are not synonymous - anonymity is a form of confidentiality, where participants’ identities are kept secret i.e., data do not include any identifiers, codes or unique information that can be used to identify the participant. Participants have the right to exclude themselves, or their information, and thus express themselves selectively. This tendency varies among cultures and individuals. In research, the use of interviews can pose difficulties, as the direction of questions cannot always be anticipated, and probing questions are used to obtain meaningful information about the phenomenon under investigation.[[121]](#footnote-121) Therefore, participants may reveal intimate and personal details, and researchers should reassure participants that the information they disclose is confidential.

The researcher is responsible for ensuring confidentiality of participants and their data. Researchers can ensure that confidentiality is upheld by allocating an identification number or pseudo-name to participants, so that identifiable information is secured, and that identifying information is not entered into a computer system or other potentially accessible database.[[122]](#footnote-122) Researchers must protect all confidential forms of written, verbal, and electronic communication gained from research. Where small samples and/or quotes are used, there is the potential for participants to be identified, so when transcribing, analysing data and writing up findings, researchers should exclude individual expressions or language nuance, and only include information fitting with the findings. Participants’ identities must also be sufficiently protected in data presentation. Overlapping relationships between researchers and participants may be allowed for, as these can happen in small communities. Personal information obtained must never lead to identification of participants and should not be made available to others without participants’ consent and prior knowledge. There are extraordinary circumstances where information may have to be revealed without the permission of participants, thus breaking confidentiality. These situations include public interest and safety, or when the researcher believes that there may be a danger in non-disclosure.[[123]](#footnote-123) The researcher must have a strong reason for the disclosure of information and should seek advice and assistance from the research supervisor, ethics committee and other relevant persons, with all decisions clearly documented.[[124]](#footnote-124)

Raw data should comprise the name and/or identifiers (code, pseudonyms) that can be used to connect the participant’s data to their name. While researchers have access to this information, it should not be contained in the final report, nor should anyone other than those stated in the consent form have access to the data.[[125]](#footnote-125) Data collection and storage practices, whether paper, recordings, or electronic records, should be adequately secured to safeguard confidentiality. For example, research records should be kept separate from clinical records. They should assign each participant an identification code/number that only the researchers have access to. Data should be stored in a locked facility and all electronic data should be password-protected. Participants should be aware of where their data will be stored, for how long and how data will be destroyed after this time.[[126]](#footnote-126) A protocol should be included in the research design on retention of data together with a process for disposal of original records which could identify individuals.

## Professional integrity

The European Code of Conduct specifies four principles that reflect this value of research integrity: reliability (proper use of methods, analyses, and resources), honesty, respect, and accountability. The principles are the same in the global research community.[[127]](#footnote-127)

The National Research Integrity Forum in Ireland comprises 26 universities and other research bodies.[[128]](#footnote-128) It proposes its 2019 Policy Statement on research integrity in Ireland, as a framework that can be adopted by all disciplines, research performing organisations and funders in Ireland.[[129]](#footnote-129) It endorses the European Code of Conduct for Research Integrity,[[130]](#footnote-130) draws on the 2010 Royal Irish Academy Ensuring Integrity in Irish Research discussion document[[131]](#footnote-131) and the “UK Concordat on Research Integrity.[[132]](#footnote-132)

Connolly, when tasked with developing ethical principles for research in Northern Ireland, enunciated four simple guidelines arising from the principle of professional integrity:[[133]](#footnote-133)

* Researchers should be committed to the unbiased and objective pursuit of knowledge and the comprehensive and accurate reporting of research findings. They must avoid selectively reporting findings or fabricating, falsifying, or misrepresenting their findings in any way.
* Researchers should interpret research findings carefully, clearly and report any potential limitations that may relate to these.
* They should make claims or propose recommendations only when these are adequately supported by the data.
* Researchers should recognise the boundaries of their own professional competence, in terms of their ability to use specific research methods as well as their substantive academic knowledge of the subject in hand.
* Researchers should consider the consequences of their behaviour while carrying out research, especially as it affects research participants or, where reasonably foreseeable, those subsequently affected by it. They should avoid conducting themselves in ways that may adversely affect the reputation of researchers generally or make it more difficult for future researchers to gain access to groups or communities.

Upholding ethical values take precedence over planned or expected benefits of research and must be done consciously by researchers at the design and planning stages and throughout the research process. This may not be easy. It requires reflection and effort. The consciousness of being carried away by a new discovery beyond ethical considerations is illustrated in the following quotation:

It was very exciting. This was a breakthrough moment for us in research. Ethically we had to be very careful not to be too excited by the knowledge and science and lose sight of what was best for the child.[[134]](#footnote-134)

According to Roberts et al.,

There is growing sensitivity to the pressures in the research environment that may undermine professional integrity and examples of intentional misconduct and fraud in medical research are unfortunate realities. Consequently, it is imperative that research is fundamentally predicated on a relationship of trust between the researcher and the participant.[[135]](#footnote-135)

Trust in the researcher is a highly significant factor in the decision of people to take part in research[[136]](#footnote-136), and trust in research generally depends on the integrity of the researchers. Integrity requires objectivity, rigour, and diligence. It is important for researchers to practice veracity, a principle grounded in respect for persons. To present clear and logical information about a research project, the researcher should avoid cloaking information in jargon or language that fails to express information in a way that can be understood by the participant. Truth-telling can be dishonoured in at least two ways: first, by the act of lying, or the deliberate exchange of inaccurate information; second, by omission or the deliberate withholding of information.[[137]](#footnote-137) Veracity involves the absence of deception and the responsibility of the researcher to tell the truth about the research.[[138]](#footnote-138) Individuals have the right to be told the truth and not to be deceived about any aspect of the research.[[139]](#footnote-139) All aspects of a research project require description and clarification by the researcher who must make every effort to ensure participants understand all aspects of the study. Participants should be aware of the expected involvement, duration (i.e., time commitment), what happens to their information, and who will have access to the information.

To ensure that researchers develop good research practices, they need to learn to reflect on their practice including their attitudes, behaviour, and knowledge and how they relate to and treat others including research participants during the research process.[[140]](#footnote-140) Reflection on their professional behaviour can form part of the self-regulation of their practice. Access to supervision may be needed to develop reflection on their practice, which can be a key tool for ethical research practice. This ‘reflexivity’ (reflection on practice) is a process whereby they place themselves and their practices under scrutiny, acknowledging the ethical dilemmas that permeate the research process and impinge on the creation of knowledge.[[141]](#footnote-141)

Ethics is more than procedural compliance with a prescribed set of rules or code of conduct that can deliver good or safe research in any given context. While such codes play an important role, there are many ways in which researchers’ own knowledge, beliefs, assumptions, values, attitudes, and experience intersect with ethical decision-making. Thus, critical reflection; cross-cultural, inter-sectoral and cross-disciplinary dialogue is required as is context-specific problem-solving and international collaboration, learning and engagement.[[142]](#footnote-142)

The 2007 Australian National Statement on ethical conduct in research, states that the guiding value for researchers is personal integrity, defined as a commitment to the search for knowledge and honest and ethical conduct.[[143]](#footnote-143) The statement emphasises that without personal integrity, the involvement of human participants in research cannot be ethically justifiable. Research conducted with integrity is conducted honestly, with upright personal behaviour, following recognised principles of research conduct, and disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding. Other professional values for researchers include openness, freedom of thought and independence in the conduct of research, social responsibility and relevance, fairness, and reflection on practice.

Researchers using qualitative and participative research methods need to have the personal capacities that are essential for working well with people over the period of the research. They need a level of personal insight that makes them aware of unintended manipulation and interpersonal dynamics that may arise during a study.

Recommendations for researchers include the following: [[144]](#footnote-144)

* Build self-regulation into the research process and keep notes as proof of self-regulation.
* Demonstrate a critical open-minded approach when conducting research and analysing data.
* Maintain clear accounts of all aspects of the research, including procedures, materials used, statistical techniques used and the contribution of other researchers.
* Build and maintain trusting relationships.
* Assess competence to participate.
* Manage interpersonal and group dynamics.
* Take responsibility for decisions about participation.
* Demonstrate honesty, including observing the rules regarding plagiarism, breach of confidence, falsification of data, and so on, and acknowledge the assistance of others in conducting the research.
* When using participative approaches, develop a level of personal insight and self-awareness through access to supervision which focuses on sources of unintended manipulation and interpersonal dynamics that may arise throughout the course of a study.

# 4.0. Practical guidance for ethical disability research

This section provides some practical guidance for research with disabled people. It follows the research process and focuses on issues related to ethics. Other documents are freely available that provide detailed guidance on accessible digital, virtual and in-person communication,[[145]](#footnote-145) accessible buildings, facilitating meetings (useful for focus groups) and appropriate language relating to disability. [[146]](#footnote-146) Guidance on collaborative research is also available.[[147]](#footnote-147)

## 4.1 Before commencing the research

* Be very familiar with the values/principles/standards of ethical research, and with the legal and ethical duties on data protection, confidentiality, capacity to consent and supported decision making.
* Reflect on the value of professional integrity and what one needs to do to further develop and practice this value.
* Be cognisant that ethical responsibilities apply throughout the research process.
* Consider including experts by experience as co-researchers and involve them in planning and designing the research.
* Obtain ethical approval from a Research Ethics Committee with some expertise in the area to be researched.

## 4.2 Obtaining consent

* If participants to be included lack the capacity to provide informed consent, ensure that a Consent Declaration is received from the HRCDC.
* Do not use other people such as family members or carers as proxies; they can consent to be interviewed as key informants but not to interpret the thoughts and feelings of others.
* Remind potential participants of the purpose and the implications of the research.
* Remind potential participants of their right to decline to take part or withdraw from the research without consequence
* Provide easy-to-understand information and alternative formats, when necessary, for example, Easy to Read documents or video or digital formats for people with an intellectual disability.

## 4.3 Data collection

* Ensure that communication methods are adapted to suit everyone.
* Ensure that research venues are physically accessible.
* If the research, for example, interviews or focus groups, are prolonged, ensure that there are accessible sanitary facilities nearby and that breaks are offered as necessary.
* Have procedures in place should a research participant become upset during an interview or focus group discussion.
* Have a procedure in place should a research participant disclose abuse or similar during an interview or focus group discussion.
* Offer research participants the opportunity to review and amend a transcript of their interview.

## 4.4 Data analysis

* The inclusion of experts by experience in the analysis of data should be considered as it brings new insights and may challenge researcher biases. Article 29b) states that States Parties shall “promote actively an environment in which persons with disabilities can effectively and fully participate in the conduct of public affairs, without discrimination and on an equal basis with others, and encourage their participation in public affairs”.
* Take an ethical approach to analysis, and document all decisions made including the rationale for the decisions taken.

## 4.5 Data dissemination

* Disseminate research findings in appropriate and accessible formats and make efforts to ensure it reaches the research participants.
* Seek to include co-researchers in data dissemination, for example, through participation including presenting at conferences.
* Consider publishing in open access journals to allow universal access to the research.

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# Appendix 1

The below codes and standards show how principles and values are presented in different ways, but the core content recurs: beneficence, non-maleficence, justice, respect, solidarity, autonomy, professional integrity, consent, confidentiality, equality, etc.

The 2005 Universal Declaration on Bioethics and Human Rights contains 28 articles addressing fundamental principles and their application:

* Respect for human dignity, human rights, fundamental freedoms (Article 3)
* Benefit and harm (Article 4)
* Autonomy and individual responsibility (Article 5)
* Consent (Article 6)
* Persons without the capacity to consent (Article 7)
* Respect for human vulnerability and personal integrity (Article 8)
* Privacy and confidentiality (Article 9)
* Equality, justice, and equity (Article 10)
* Non-discrimination and non-stigmatization (Article 11)
* Respect for cultural diversity and pluralism (Article 12)
* Solidarity and cooperation (Article 13)
* Social responsibility and health (Article 14)
* Sharing of benefits (Article 15)

The National Ethical Research Standards for Health and Disability research in New Zealand (NEAC, 2019), which apply to all research with human participants living in New Zealand, are rooted in two sets of principles - four bioethical principles and four Māori ethical principles

**Four bioethical principles**

* Beneficence and non-maleficence
* Justice
* Respect for people

**Four** **Māori ethical principles**

These Māori ethical principles draw on a Māori foundation of ‘Te Ara Tika’ (to follow the right path) practices are taken as a generic set of principles that apply to all human persons in New Zealand:

1) *Tika*, that is, doing what is right and good in concrete situations e.g., research design, respectful relationships, engagement with group on which research questions are the important ones.

2) *Manaakitanga* is caring for others, being careful in the way one treats them.

3) *Whakapapa* is the quality of relationships, the reasons for their formation and the processes established to support them.

4) *Mana* refers to power, prestige, leadership, or authority bestowed, gained or inherited individually or collectively. It infers that everyone has the right to determine their destiny themselves (autonomy). It relates to distributive justice and equity in terms of risks, benefits, and outcomes of research.

The 2023 HSE National Policy for Consent in Health and Social Care Research Consent Policy states that the ethical principles underpinning the process of consent for health research include:[[148]](#footnote-148)

* Beneficence
* Justice
* Respect for persons
* Solidarity

The Nursing and Midwifery Board of Ireland (NMBI) identify seven principles for ethical research:[[149]](#footnote-149)

* Beneficence and non-maleficence
* Justice,
* Veracity
* Fidelity
* Autonomy
* Confidentiality

1. NDA, 2022 [↑](#footnote-ref-1)
2. NDA, 2009 [↑](#footnote-ref-2)
3. United Nations, 2006 [↑](#footnote-ref-3)
4. Assisted Decision-Making (Capacity) Act 2015 [↑](#footnote-ref-4)
5. Assisted Decision-Making (Capacity) (Amendment) Act 2022 [↑](#footnote-ref-5)
6. Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018). [↑](#footnote-ref-6)
7. Data Protection Act 2018 [↑](#footnote-ref-7)
8. DPOs are civil society organisations of persons with disabilities. They are led, directed, and governed by disabled people for disabled people. The CRPD states in Article 4.3: “In the development and implementation of legislation and policies to implement the present Convention, and in other decision-making processes concerning issues relating to persons with disabilities, States Parties shall closely consult with and actively involve persons with disabilities, including children with disabilities, through their representative organizations”. For more information see the 2021 NDA paper ‘[A review of Disabled Persons Organisations and their participation in implementing and monitoring the UNCRPD](https://nda.ie/publications/a-review-of-disabled-persons-organisations-and-their-participation-in-implementing-and-monitoring-uncrpd). [↑](#footnote-ref-8)
9. The National Ethics Advisory Committee (NEAC) – Kāhui Matatika o te Motu (NEAC) - is an independent advisor to the Minister of Health in New Zealand on ethical issues related to health and disability research and services. [↑](#footnote-ref-9)
10. A social approach to disability has been indispensable to overcome the medicalisation of disability, which has been an obstacle to analysis and policy. A social approach focuses on social-political issues, but more sophisticated and complex approaches will further explain and address the social exclusion that disabled people face and the complexity of their needs ( Shakespeare and Watson 2001; Shakespeare 2010). [↑](#footnote-ref-10)
11. Williamson 2015 cited by National Ethics Advisory Committee (NEAC), 2019. [↑](#footnote-ref-11)
12. NEAC, 2019 [↑](#footnote-ref-12)
13. Leonardi et al, 2006 cited by Good, 2020 [↑](#footnote-ref-13)
14. NEAC, 2019, p. 51-52 [↑](#footnote-ref-14)
15. Good, 2020 [↑](#footnote-ref-15)
16. Good, 2020 [↑](#footnote-ref-16)
17. Good, 2020 [↑](#footnote-ref-17)
18. [Article 4 – General obligations | United Nations Enable](https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-4-general-obligations.html) [↑](#footnote-ref-18)
19. [Article 31 – Statistics and data collection | United Nations Enable](https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-31-statistics-and-data-collection.html) [↑](#footnote-ref-19)
20. Good, 2020 [↑](#footnote-ref-20)
21. Article 4.1. CRPD states that “States Parties undertake to ensure and promote the full realization of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability”.

    Article 4.2. CRPD states that “With regard to economic, social, and cultural rights, each State Party undertakes to take measures to the maximum of its available resources and, where needed, within the framework of international cooperation, with a view to achieving progressively the full realization of these rights, without prejudice to those obligations contained in the present Convention that are immediately applicable according to international law.

    Article 33 addresses national implementation and monitoring.

    Article 4.3. CRPD states that “In the development and implementation of legislation and policies to implement the present Convention, and in other decision-making processes concerning issues relating to persons with disabilities, States Parties shall closely consult with and actively involve persons with disabilities, including children with disabilities, through their representative organizations.

    General Comment No. 7 on the participation of persons with disabilities, issued in 2018, to provide States Parties with guidance on how to implement Article 4(3) and Article 33. General Comment 7 states that the rights under these Articles are civil and political rights and therefore of immediate application. General Comments are the interpretation of the Committee on a particular Article and while not legally binding countries are encouraged to apply them [↑](#footnote-ref-21)
22. NDA, 2022b [↑](#footnote-ref-22)
23. Commission on the Status of People with Disabilities, 1996 [↑](#footnote-ref-23)
24. [Government](https://creatingourfuture.ie/wp-content/uploads/2022/07/Creating-Our-Future-EXPERT-Report.pdf) of Ireland, 2022 [↑](#footnote-ref-24)
25. NEAC, 2019 [↑](#footnote-ref-25)
26. Doody and Noonan, 2016 in table 1 give examples of research where there were human rights violations. The 11 studies they listed include the Tuskegee syphilis study (1932-1972) where treatment was withheld from 399 African American syphilis sufferers to study the long-term effects of the disease; the Willowbrook Study (1963-1966) where children with disability were infected with hepatitis to investigate the course of the disease and to test a potential vaccine. The Bristol Royal Infirmary Inquiry (2001) investigated 30-35 children who had heart surgery between 1991-1995 as experimental subjects and died unnecessarily as the surgeon operated to introduce new techniques despite poor survival. [↑](#footnote-ref-26)
27. Good, 2020 [↑](#footnote-ref-27)
28. UK Economic and Social Research Council, 2023 [↑](#footnote-ref-28)
29. Curation of data is the process of creating, organizing, and maintaining data sets so they can be accessed and used by people looking for information.  [↑](#footnote-ref-29)
30. UK Economic and Social Research Council, 2023 [↑](#footnote-ref-30)
31. Barnes, 2008 [↑](#footnote-ref-31)
32. Stewart et al, 2011 [↑](#footnote-ref-32)
33. European Commission, 2013 [↑](#footnote-ref-33)
34. Resnik,, 2020 [↑](#footnote-ref-34)
35. US Department of Health and Human Services, 2022 [↑](#footnote-ref-35)
36. Because the values/principles/standards for ethical research flow from human rights that inhere in all human beings, they are fundamentally the same even though expressed or summarised in various ways. [↑](#footnote-ref-36)
37. National Institute of Health and Care Excellence (NICE), 2018 [↑](#footnote-ref-37)
38. Dench et al, 2003 [↑](#footnote-ref-38)
39. Detailed references to capacity are found at Sections 3.3. and 3.4. [↑](#footnote-ref-39)
40. Health Research Regulation, 2018 [↑](#footnote-ref-40)
41. More information on Irish legislation in provided in section 3.3. [↑](#footnote-ref-41)
42. [National Office for Research Ethics Committees - NREC (nrecoffice.ie)](https://www.nrecoffice.ie/about/national-office/) [↑](#footnote-ref-42)
43. HSE, 2019 [↑](#footnote-ref-43)
44. HSE, 2021 [↑](#footnote-ref-44)
45. HSE, 2022 [↑](#footnote-ref-45)
46. HSE, 2023 [↑](#footnote-ref-46)
47. Coggon, 2007 [↑](#footnote-ref-47)
48. Rawbone, 2007 P. 110 [↑](#footnote-ref-48)
49. Department of Health, 2005, s2.2.6 [↑](#footnote-ref-49)
50. Montgomery et al*,* 2022 [↑](#footnote-ref-50)
51. NDA, 2022a [↑](#footnote-ref-51)
52. NDA, 2023 [↑](#footnote-ref-52)
53. NDA, 2022b [↑](#footnote-ref-53)
54. Ableism is a set of beliefs or practices that devalue and discriminate against people with physical, intellectual, or psychiatric disabilities and often rests on the assumption that disabled people need to be ‘fixed’ in one form or the other – Center for Disability Rights, the USA <https://cdrnys.org/blog/uncategorized/ableism/> (Accessed June 2023) [↑](#footnote-ref-54)
55. McClimens, 2008 [↑](#footnote-ref-55)
56. Pollard (2002) gave the example of a physician researcher who informed a Deaf woman that participating in the study would entail ‘the usual risks associated with anaesthesia’. The sign language interpreter conveyed to both parties that more specific information was needed before she could convey what usual risks referred to. When the researcher provided further details, the Deaf participant expressed dismay that critical information had been withheld from her and chose to withdraw from the study. Fund of information differences between Deaf and hearing people are common and arise from differing access to auditory information sources and differences in written literacy. (Fund of information is the accumulated pool of facts one knows and is a separate matter to intelligence). Where fund of information is significant to participation in research, researchers must take extra precautions to avoid an unintended form of deception. [↑](#footnote-ref-56)
57. INVOLVE and the National Research Ethics Service, 2009, p.2 [↑](#footnote-ref-57)
58. Rolph, 1998 p.135, citing Ristock et al, 1996 [↑](#footnote-ref-58)
59. Tuffrey-Wijne et al, 2008 [↑](#footnote-ref-59)
60. Wiles et al, 2004 [↑](#footnote-ref-60)
61. Guillemin et al, 2004 [↑](#footnote-ref-61)
62. Cutcliffe et al, 2002 [↑](#footnote-ref-62)
63. Ramcharan et al, 2001 [↑](#footnote-ref-63)
64. L- Universitata Malta, 2018 [↑](#footnote-ref-64)
65. Beauchamp and Childress, 2012 and Parahoo, 2014 cited by Doody and Noonan, 2016 [↑](#footnote-ref-65)
66. Butts and Rich, 2013 as cited by Doody and Noonan, 2016 [↑](#footnote-ref-66)
67. London School of Hygiene & Tropical Medicine, 2020 [↑](#footnote-ref-67)
68. Parahoo, 2014 [↑](#footnote-ref-68)
69. Davies and Gannon, 2006; Elmir et al, 2011; Rossetto 2014 cited by Doody and Noonan, 2016 [↑](#footnote-ref-69)
70. Doody and Noonan, 2016 [↑](#footnote-ref-70)
71. Newman et al, 2001 p.323 [↑](#footnote-ref-71)
72. Graham et al, 2007 The study design included 50 in-depth main interviews with follow up interviews at two weeks - 10 participants from five qualitative and five quantitative research studies. [↑](#footnote-ref-72)
73. Polit and Beck, 2013 [↑](#footnote-ref-73)
74. Stineman et al, 2001 [↑](#footnote-ref-74)
75. Wertheimer, 2013 [↑](#footnote-ref-75)
76. Undue influence is influence by which a person is induced to act otherwise than by their own free will or without adequate attention to the consequences. [↑](#footnote-ref-76)
77. Payment can also compromise the validity of the research. [↑](#footnote-ref-77)
78. Roberts et al., 2001 [↑](#footnote-ref-78)
79. HSE, 2022 [↑](#footnote-ref-79)
80. Mitchell, 2003 [↑](#footnote-ref-80)
81. Woods, 2002 [↑](#footnote-ref-81)
82. For example, see Health Safety Authority on lone workers <https://www.hsa.ie/eng/topics/hazards/lone_workers/> and the 2022 HSE Policy and Guidance on Lone Working <https://assets.hse.ie/media/documents/Lone_Working_policy.pdf> [↑](#footnote-ref-82)
83. Doody and Noonan, 2016 [↑](#footnote-ref-83)
84. A key issue in Lone Worker Procedures for Researchers is the appointment of a contact person with clearly delineated responsibilities should a researcher fail to make contact according to an agreed schedule. [↑](#footnote-ref-84)
85. Stalker, 1998 [↑](#footnote-ref-85)
86. Booth, 1998 [↑](#footnote-ref-86)
87. NMBI, 2015 [↑](#footnote-ref-87)
88. Haigh et al, 2009 [↑](#footnote-ref-88)
89. Draucker et al, 2009 [↑](#footnote-ref-89)
90. Graham et al, 2007 [↑](#footnote-ref-90)
91. Burns et al, 2013 [↑](#footnote-ref-91)
92. Atkinson, 2007, p. 138 [↑](#footnote-ref-92)
93. Shepherd et al, 2018 [↑](#footnote-ref-93)
94. Williams, 2019 (a) [↑](#footnote-ref-94)
95. Williams, 2019 (b) [↑](#footnote-ref-95)
96. Gillon, 1985 cited by Doody and Noonan, 2016 [↑](#footnote-ref-96)
97. UKRI, Medical Research Council [↑](#footnote-ref-97)
98. ibid [↑](#footnote-ref-98)
99. Beauchamp and Childress, 2012 cited by Doody, and Noonan, , 2016 [↑](#footnote-ref-99)
100. Doody and Noonan 2016 [↑](#footnote-ref-100)
101. HSE, 2022 [↑](#footnote-ref-101)
102. P.19, HSE, 2023 [↑](#footnote-ref-102)
103. British Psychological Society, 2008, Section 3 [↑](#footnote-ref-103)
104. <https://hrcdc.ie/> / [↑](#footnote-ref-104)
105. https://hrcdc.ie/guidance/ / [↑](#footnote-ref-105)
106. P. 54, HSE 2023 [↑](#footnote-ref-106)
107. Oireachtas Library and Research Service, 2017, as cited by Murphy et al, 2023 [↑](#footnote-ref-107)
108. P.20-23, HSE, 2023 [↑](#footnote-ref-108)
109. Murphy et al, 2023 [↑](#footnote-ref-109)
110. Murphy et al, 2023 and Decision Support Service

     <https://www.decisionsupportservice.ie/services/decision-support-arrangements>

     <https://www.decisionsupportservice.ie/services/decision-supporters> [↑](#footnote-ref-110)
111. <https://decisionsupportservice.ie> [↑](#footnote-ref-111)
112. HSE, 2023 [↑](#footnote-ref-112)
113. Ibid, P.51 [↑](#footnote-ref-113)
114. Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 [↑](#footnote-ref-114)
115. Rauhala and Kalokairinou (European Commission), 2021 [↑](#footnote-ref-115)
116. Data Protection Act 2018. See also : <https://www.dataprotection.ie/sites/default/files/uploads/2019-07/190710%20Data%20Protection%20Basics.pdf> [↑](#footnote-ref-116)
117. P.20, HSE, 2023 [↑](#footnote-ref-117)
118. Ibid, P.28 [↑](#footnote-ref-118)
119. Rauhala and Kalokairinou (European Commission), 2021. The document is available online to support researchers in social sciences and humanities to identify and address ethical dimensions and ensure that research ethics is integrated into their research design when involved in research financed by the EU. It is also designed to help the wider research community deal with the ethical issues that may arise in interdisciplinary research using social sciences and humanities methodology. [↑](#footnote-ref-119)
120. Scott, 2005 [↑](#footnote-ref-120)
121. Richards and Schwartz, 2002; Parahoo, 2014 [↑](#footnote-ref-121)
122. Polit and Beck, 2013 [↑](#footnote-ref-122)
123. NMBI, 2015 [↑](#footnote-ref-123)
124. NMBI, 2015 [↑](#footnote-ref-124)
125. Dempsey and Dempsey, 2000 [↑](#footnote-ref-125)
126. Doody and Noonan, 2016 [↑](#footnote-ref-126)
127. Marusic, 2023 [↑](#footnote-ref-127)
128. The list of organisations which comprise the forum can be accessed in Appendix 1 of the National Policy Statement <https://www.iua.ie/wp-content/uploads/2021/04/National-Policy-Statement-on-Ensuring-Research-Integrity-in-Ireland.pdf> [↑](#footnote-ref-128)
129. <https://www.iua.ie/wp-content/uploads/2021/04/National-Policy-Statement-on-Ensuring-Research-Integrity-in-Ireland.pdf> [↑](#footnote-ref-129)
130. ALLEA, 2023 [↑](#footnote-ref-130)
131. Royal Irish Academy, 2010 [↑](#footnote-ref-131)
132. Universities UK, 2019 [↑](#footnote-ref-132)
133. Connolly 2003, p. 9 [↑](#footnote-ref-133)
134. Australian Government, 2006, p. 45 - comment from Ethics Committee member [↑](#footnote-ref-134)
135. Roberts et al., 2001, p. 352, citing, among others, Spece et al., 1996; Culliton, 1983; Humphrey, 1992; Dalton, 1997 [↑](#footnote-ref-135)
136. Roberts et al., 2001 citing Roberts et al., 2000 [↑](#footnote-ref-136)
137. Doody and Noonan, 2016 [↑](#footnote-ref-137)
138. It may be ethical in some circumstances to conceal the true research question. The European Commission addresses methodologies that involve deception (Rauhala and Kalokairinou , 2021, for the European Commission -DG Research and Innovation). Covert research, for example, is done without informing those that are the focus of the research that they are being researched. Such research requires strong justification and a demonstration of the clear benefits of the chosen method over any other approach. Covert research should be avoided unless it is the only method by which information can be gathered. Circumstances that may lend support to using covert methods include settings where research participants change behaviour because they know they are being studied. Covert research must be conducted with respect for privacy. Data should be fully anonymised at the point and time of collection and data are collected unobtrusively and in accordance with local cultural values. [↑](#footnote-ref-138)
139. Parahoo, 2014 [↑](#footnote-ref-139)
140. Connolly, 2003 [↑](#footnote-ref-140)
141. McGraw et al., 2000, p. 68 [↑](#footnote-ref-141)
142. ERIC (Ethical Research involving Children) citing <https://childethics.com/philosophy/> [↑](#footnote-ref-142)
143. Commonwealth of Australia, 1999. This statement was replaced by the Australian Government’s 2007 statement. [↑](#footnote-ref-143)
144. Cope Foundation, 2005 and Tee and Lathlean, 2004 [↑](#footnote-ref-144)
145. Department of Public Expenditure and Reform and NDA, 2023 [↑](#footnote-ref-145)
146. NDA, 2022b [↑](#footnote-ref-146)
147. NDA, 2023 [↑](#footnote-ref-147)
148. P.27, HSE, 2023 [↑](#footnote-ref-148)
149. NMBI, 2015 [↑](#footnote-ref-149)