

Disability Research Series

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Ethical Guidance for Research with People with Disabilities

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Introduction to Disability Research and Ethics

1. Introduction to Disability Research and Ethics

Research is undertaken to expand knowledge, discover the truth and provide evidence for practitioners, policy-makers and legislators.¹ Research that involves people with disabilities is important in uncovering issues requiring attention; in informing policy; in evaluating programmes and services; and in tracking how social and economic change affects people with disabilities. The importance of research and data related to disability has been underscored in the *Report of the Commission on the Status of People with Disabilities* (1996), and in the *United Nation's Convention on the Rights of Persons with Disability* (2006), adopted in December 2006.²

Disability research ethics are located within the wider research ethics framework. Ethical principles require that any research involving human subjects is framed and conducted in a way that respects the human rights of the individuals concerned. The UN Convention sets out what recognised human rights principles mean in respect of people with disabilities. Central to the UN Convention's understanding of human rights are respect for the inherent dignity, individual autonomy — including the freedom to make one's own choices — and independence of persons. Other core principles spelled out in Article 3 of the UN Convention and central to the ethical evaluation of research include:

- Equality
- Full and effective participation and inclusion in society
- Respect for difference
- Accessibility.

Examples of applying these principles in a research context include the following:

- Involving people with disabilities in an appropriate way in informing or shaping the research process respects them as active participants in the research and not as passive objects of research.

- Ensuring that deaf participants in the research who so require are provided with sign language interpretation or other communication aids embodies the principle of accessibility.

The extent to which both research and ethical values are embraced influences the quality of research and its outcomes. A core research value for any researcher is an unbiased and objective search for new knowledge, applying an appropriate methodology to derive valid results about the phenomenon being studied, and reporting those results honestly. 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.

The UK Research Governance Framework for Health and Social Care (Department of Health, 2005a) highlights a shift from doing research on and about populations of people to doing research with these populations. That framework requires researchers, wherever possible, to involve relevant service-users and carers or their representative groups in the design, conduct, analysis and reporting of research (Research Governance Framework, s2.2.6).

In research that involves people with disabilities, appropriate engagement with them about the research process can help researchers to frame their research questions better, can test the validity and acceptability of the research methodology, and can assist in interpretation of the findings. In these ways, participatory approaches may enhance the efficacy of the research. However, participatory approaches should never be at the expense of the validity and reliability of the research.

In Ireland, a substantial framework for human participant research ethics governance is emerging, with some initiatives developing locally and others resulting from legal intervention at a national and EU level (Morgan, 2007). While many institutions in Ireland have developed research ethics policies in which disability is dealt with briefly, there is little specific disability-sensitive guidance. No institution or organisation provides tailored guidance with respect to disability (Morgan, 2007). To fill this gap, the NDA, consistent with its obligations to give

advice on disability policy and practice, offers ethical guidance on research with people with disabilities.³

This guidance outlines the core values and central principles that should apply to all research involving people with disabilities. The guidance illustrates, by means of concrete examples, how these values and principles can be applied in the research process. NDA recommends that all research in Ireland involving people with disabilities should be informed by this guidance.

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Ethical Guidance on Research with People with Disabilities

2. Ethical Guidance on Research with People with Disabilities

The purpose of the guidance

The purpose is to assist researchers and Research Ethics Committees by offering guidance in relation to good practice in research involving people with disabilities.⁴ The guidance may also be of interest to research sponsors and funders, those involved in research governance, people with disabilities and disability organisations.

Ethical responsibilities apply throughout the research process. Applying ethical guidance in individual research projects is an ongoing matter of judgment and good research practice. Researchers cannot simply consider their ethical responsibilities as fulfilled once ethical approval for a research project has been obtained. Issues arise during fieldwork that still have ethical implications so that

‘permission from an ethics committee to proceed with the research is just the beginning of a process of constant self-monitoring by the researcher’ (Rolph, 1998, p.135, citing Ristock and Pennell, 1996).

Wiles et al. (2004) state, that, for instance, in relation to issues of informed consent, there are no simple solutions that can be applied universally to resolve all ethical dilemmas. Rather, researchers need at all stages of the research process to be mindful of the various issues that can arise in the context of their individual research projects. Issues can relate to:

1. the needs of participants
2. ensuring ongoing assent or consent
3. handling relationships that develop during the research process
4. unanticipated, distressing emotions
5. unexpected revelations

Tuffrey-Wijne et al. (2008) suggest that, particularly in complex research situations,⁵ clear structures for supervision and ethical advice for the researchers are essential, and they strongly recommend the appointment of a research advisory group, with a named responsibility for ethical standards.

The fact that ‘ethically important moments’⁶ may arise at points during the research process, when they cannot be passed on to a supervisor or manager, places considerable responsibility upon the field researcher. Divided loyalties oblige researchers to balance their responsibilities to sponsor, employer, profession and subject/respondent. A shared understanding of governance, accountability and ethical constraints must run through professional associations, funders and research organisations (Dench and Iphofen, 2003).

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 data are interpreted, communicated and used). Ethics in practice is enhanced by procedural ethics and the underlying values are the same (Guillemin and Gillam, 2004).

Ramcharan and Cutcliffe (2001) propose an ‘ethics as process’ model — the same idea as ‘ethics in practice’ — as particularly suitable for qualitative research where the research design often emerges fully only as the research proceeds. Constant ‘monitoring’ can ensure that the benefit to risk ratio in this kind of research remains on the side of benefit. Ethical considerations in research designs that emerge as the research proceeds include a view of consent and trust not as ‘one-off’ events but as a process that must be renewed and re-established during the course of the research.

This involves, for example:

1. assuring the ongoing assent or consent status of participants
2. reminding participants of their right to withdraw from the study at any time

3. a sensitive and tactful completion of the research process
4. making participants aware of their right to check how they are represented in transcripts/field notes (Cutcliffe and Ramcharan, 2002).

While particularly useful to qualitative research, the 'ethics as process' or 'ethics in practice' model can be applied to all research.⁷

The development of this guidance and its structure

NDA guidelines for ethical disability research were published in 2005 following a large-scale consultation exercise. This guidance builds on those foundations, taking into account developments such as the UN Convention on the Rights of Persons with Disabilities (2006) and the experience of the 2006 National Disability Survey in which 15,000 people with disabilities participated.

The revised guidance has been informed by input from the NDA Disability Research Ethics Committee,⁸ feedback from consultation with research ethics committees in Ireland and research findings in the national⁹ and international literature.

This NDA guidance comprises:

- An introduction to disability research and ethics (Section 1)
- The purpose, development and structure of the guidance (Section 2)
- The core ethical values for research with people with disabilities (Section 3)
- An outline for good practice (Section 4)
- Case studies (Section 5).

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Core Values for Research with People with Disabilities

3. Core Values for Research with People with Disabilities

Promote the wellbeing of those participating, involved in or affected by the research process

Respect the dignity, autonomy, equality and diversity of all those involved in the research process

The wellbeing¹⁰ of research participants must be at the centre of the research process. Promoting wellbeing is attained by upholding the rights of participants and the values and principles that flow from or are a consequence of these rights. The planned or expected benefits of research must never be at the cost of respect for the rights of individual participants in research. The underlying ethical values of dignity, autonomy, equality and diversity underpin human rights and inhere or exist in the person.¹¹ These values should be upheld throughout the research process and should take precedence over any potential benefits of research. How this will be done needs to be consciously considered at the design and planning stages as well as throughout the research process.

This section outlines the underlying values and what they signify. Values and principles are inter-related and it is difficult to separate one from another when weighing them up in practice.

Dignity

Respecting the dignity of the person in research involves upholding the person's multiple and interdependent rights and interests (Canadian Tri-Council Policy Statement, 2005). For people with disabilities, research should respect their freedom to choose to participate or not, their privacy and their confidentiality. It should respect and accommodate their difference as research subjects, for example through choosing accessible venues for focus-group research, or through facilitating alternative forms of communication that may be required.

Autonomy

Respecting the autonomy of a research participant means taking seriously the right every individual has to make their own decisions in the research process. It includes putting mechanisms in place that support autonomy. Autonomy and mental capacity are considered under voluntary and informed consent.

Representative and inclusive

If any piece of research is to be representative, people, regardless of disability or other aspects of human diversity, should be equally eligible to participate as research subjects. As the UK's Research Governance Framework for Health and Social Care states:

The body of research evidence available to policy-makers should reflect the diversity of the population (Department of Health, 2005a, s.2.2.7).

That means taking steps, where possible, to facilitate such participation. These could be simple steps such as:

- Preparing large print materials for participants with visual impairments
- Providing material in easy-to-read format for participants with intellectual disabilities
- Conducting interviews in venues that are accessible and safe
- Providing appropriate disability awareness training for interviewers¹²
- Facilities for hearing-impaired - signage, loops etc.

Standard ethical guidelines for social research cover many of the ethical issues adequately for most research with people with disabilities. Specific strategies, however, may be needed in some circumstances in order to respect the dignity, equality, autonomy and difference of people with disabilities. For example, particular steps may be needed to ensure anonymity, privacy and confidentiality in

care settings; where advocates, interpreters or proxies are used; and in situations where other people, besides the researcher(s) and the participants, are involved in aspects of the data collection. Practical steps would include:

- Choosing a location for interviews to ensure not only accessibility and safety but also confidentiality
- Accommodating participants' physical needs, including access to the venue, comfort, care or refreshment breaks during the interview/focus-group process
- Accommodating any specific information and communication needs related to the disability, including those related to speech, hearing, sight or cognitive impairment.
- These and other disability issues should be considered when the research methods are at the design stage.

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Guidance for Good Practice in Research with People with Disabilities

4. Guidance for Good Practice in Research with People with Disabilities

This section provides specific guidance, which aims to promote good practice in research with people with disabilities. Guidance is provided on six key principles:

- Promoting the inclusion and participation of people with disabilities in research and research dissemination
- Ensuring that research is accessible to people with disabilities
- Avoiding harm to research participants
- Ensuring voluntary and informed consent before participation in research
- Understanding and fulfilling relevant legal responsibilities
- Maintaining the highest professional research standards and competencies.

4.1. Promoting inclusion and participation of people with disabilities in research: understanding and applying the principles

- When research is not specific to particular identifiable groups, researchers should not exclude participants on the basis of attributes such as disability or age. Samples should be drawn from the whole population with the aim of achieving as far as practicable a proportionate representation of all groups within that population. Researchers should be alert to the possibility that people with disabilities are sometimes excluded in research designs intended to cover a 'general' population (Iphofen, 2009).
- It is unethical to place excessively burdensome demands on research subjects with disabilities.
- Consider practical ways in which people with disabilities can be included in a research strategy, for example:

- Consider the sampling strategy, and whether it allows for a diversity of disability to be represented;
 - Disability-proof research methods under consideration at the design stage;
 - Adapt the method, the length and intensity of participation to the needs of research participants;
 - Provide for varied means of communication for research subjects with visual, hearing, speech or cognitive impairments;
 - Consider using large print materials or audio tape for people with vision impairments;
 - Consider easy-to-read materials for people with cognitive impairments or having someone to interpret for them;
 - Consider how interviewers can facilitate lip-reading, provide written material for people who have hearing impairments and consider sign language interpretation if so required;
 - Ensure that physically accessible venues are used.
-
- Ensure that the diversity of research subjects as people is captured, for example diversity in terms of age, gender, social class and other relevant variables, rather than categorised in terms of disability alone.
 - Provide appropriate disability awareness training to researchers and interviewers.¹³ (See Case Study 1 where disability awareness training was provided to all field-staff.)
 - Consult as appropriate with people with disabilities or their representative groups around the research topic, research questions and research design.¹⁴
 - Ensure that research subjects and disability groups are included in the dissemination of the research findings.

Active involvement such as collaboration and consultation with people with disabilities, when carried out to a high standard is more likely to result in ethical research because the research is more likely to be

1. relevant to the people it is trying to help;
2. beneficial in terms of delivering meaningful outcomes for the participants and the population they represent; and
3. conducted in a way that is sensitive to the needs of the research participants (INVOLVE and the National Research Ethics Service, 2009, p.2).

Active involvement can improve the quality of research, promote informed consent, and aid the recruitment of participants, research assistants and co-investigators (Pollard, 2002).

With consultation, participants are usually informed of the research plans after they have been developed and are asked for their opinions and suggestions, which may or may not be accepted. In collaborative processes, by contrast, participants from the target population are a part of the process from the beginning and belong to the planning team, the research steering group and the editing group, and have a say in the production of the final report.

Consultation and collaboration in the research process provide opportunities for shared learning and increased knowledge production and dissemination (McClimens, 2008).

The degree and intensity of participation of people with disabilities in the research process will depend on the purpose of the research and the methodologies used.¹⁵ The diverse nature of research means that the various ways of including people with disabilities need to be considered in order to decide which one is appropriate for a particular study. Different methods may be used at different stages of the research process.¹⁶ The following are some models of inclusion, which researchers, managers and sponsors can consider:

- Establish steering and advisory committees that include people with disabilities, and ensure representation of people with disabilities on research committees and panels, including funding and decision-making panels.
- Set up panels of people with disabilities who can be asked to participate at different stages of the research.¹⁷
- Consult with people with disabilities in the development and design of research.
- Employ researchers with disabilities or employ people with disabilities as research consultants acting in an advisory capacity on research design and implementation.
- Ensure that people with disabilities are represented among research respondents, where appropriate.

Consultation with people with disabilities can be done through organisations such as:

- People with Disabilities in Ireland Ltd
- Disability Federation of Ireland and its member organisations
- Mental Health Ireland and its affiliated organisations
- Inclusion Ireland and its affiliated organisations
- HSE's mental health service users' council
- Centres for Independent Living
- Irish Advocacy Network.

Participation and consultation strategies should be included when working out timeframes and budgets in order to implement them effectively.¹⁸

4.2. Ensuring accessibility: understanding and applying the principle

- The NDA's 2002 'Ask Me': Guidelines for Effective Consultation with people with disabilities is available online¹⁹ and has a useful access checklist (approach to building; interior; communication; lifts; toilets; and staff awareness and training).
- The Code of Practice on Accessible Public Services offers practical guidance on accessibility of premises, services and information (www.nda.ie).
- In order to plan accessibility, including materials, venues and so on, it is necessary to know the characteristics of the population. The following are some figures that can inform planning for participation when conducting large-scale surveys or surveys of particular populations such as older people or people with a particular impairment:

In Ireland, Census 2006 showed that about 9.3 per cent of the population were identified as having a disability. Up to twice as many people may have some form of impairment (National Disability Survey, 2006).²⁰

People with a visual impairment:

There are 51,000 people in Ireland, about 1.2 per cent of the population, who even with glasses or lenses experience significantly impaired vision. About 2,300 cannot see at all. Impaired vision is strongly associated with ageing. Thus, in terms of accessibility, larger-print documents are required especially for older people. Any research website should be accessible to visually impaired potential participants and there should be adequate lighting in any building or part of a building being used to screen potential research participants or conduct research interviews.

People with hearing impairment:

About 58,000 people, or 1.4 per cent of the population, have impaired hearing. About 1,800 cannot hear at all. About 95 per cent of these had onset of hearing impairment in adulthood. In terms of accessibility, provision should be made to allow interviews to be made by text or email; written as well as oral communication should be provided; venues that provide loop systems should be used; lip reading

should be facilitated; and Irish Sign Language interpreters should be provided on request.

People with intellectual disabilities:

There are about 50,000 people who have an intellectual disability — 14,000 with mild intellectual disability, 24,000 moderate and 12,000 with severe intellectual disability. Research designs that are confined to private households may miss those who are living in institutional care (c. 4,000). Ensuring that there is informed consent is a key issue. In terms of accessibility, easy-to-read and easy-to-understand information should be provided and simple instructions and illustrations used.

People who have difficulty in remembering or concentrating:

There are 113,000 people, or 2.7 per cent of the population, who have difficulty in remembering important things; in concentrating for more than ten minutes at a time; and in performing normal daily activities. Of these, 55,000 had moderate difficulties. With these research participants it is important to ensure that there is informed consent. Participants should be reminded of the purpose and the implications of the research and provided with simple easy-to-follow information. Taking short breaks every ten minutes can facilitate their participation.

People with mobility impairments:

160,000 people, or nearly 4 per cent of the population, have difficulty in walking, while 31,000 people use wheelchairs and do not walk. To facilitate participation venues should be used that have level access or ramps, accessible WCs, wide doors and corridors and accessible lifts/elevators. See *'Ask Me' Guidelines* accessibility checklist.²¹

4.3. Avoiding harm: understanding and applying the principle

Research risks should be assessed with respect to their physical, social and psychological effects on participants and all research should conform to legal obligations as outlined in section 4.5. Risks should be commensurate with the expectation of benefit to participants or the importance of the area being explored.

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, which may bring up traumatic memories
- Research methods such as participant observation.

Careful thought should be given to whether a research project can be justified practically and ethically. 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 general society (Roberts et al., 2001).

Confidentiality and data protection

This is both a legal and an ethical duty. Researchers must ensure that they uphold the commitments they make to research participants on confidentiality, including anonymity and data protection. They should be aware of their legal requirements of confidentiality as set out in the Data Protection Acts (1988, 2003). Under these Acts, a person's disability status is regarded as sensitive personal information, which should enjoy higher standards of protection. 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. Researchers should ensure that any electronic storage of material is password-protected. It may be appropriate to retain only records or data that have been made anonymous. 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.

Researchers must protect all confidential forms of written, verbal and electronic communication gained from research. Participants' identities must be sufficiently protected in data presentation. Overlapping relationships between researchers and participants may be allowed for, as these can happen in small communities (see Case Study 2, for example). Researchers should make clear to participants that there are limits to the guarantee of confidentiality.²²

Avoid coercion or undue pressure to participate and safeguard wellbeing

Any form of coercion, manipulation or undue influence to participate in research is unethical and potentially harmful. The researcher must avoid pressurising participants and manage suggestibility and compliance in research participants. It is important not to overstate to research participants what could be the potential benefits of the research (Stineman and Musick, 2001). The issue of making any payments to participants over and above the costs of participation, such as transport costs, must be carefully considered, as excessive incentives to participate can be coercive.²³

Particular care needs to be exercised by researchers in situations where individuals with disabilities might feel pressurised to participate. For example, using carers or service-providers to solicit research participants carries a risk that service-users may feel that there would be negative consequences for their services or care if they declined to participate. Particular care needs to be taken in recruiting research participants living in residential institutions or other residential services. Researchers should take steps to satisfy themselves that there would be no negative consequences for those who choose not to participate, and that that is clearly communicated in a credible way to potential participants.

Every effort should be made not to compromise the physical, social and psychological wellbeing of research participants. Particular care should be exercised when researching in care settings or where advocates, interpreters or proxies are used in data collection or interviews.

Clinical research

There is a well-established system of ethics evaluation of studies involving clinical trials of new treatments. In a disability context, it is important that the issue of informed consent to experimental treatment is one that is carefully considered, particularly where the individuals concerned may potentially have an impaired capacity to consent or to communicate.²⁴

Relationship with a carer

Care should be taken that the research process does not interfere with the relationship between an individual with a disability and their carer. Where possible,

interview subjects should be interviewed in private, with a carer available but not present, to preserve the confidentiality of the research process.

In-depth interviewing

In-depth interviews, particularly on sensitive topics, may bring up traumatic memories. Interviews with people currently experiencing mental health difficulties also carry the risk of harm to the research participant. Appropriate protocols need to be in place as part of the research design, to identify such signs of stress in a research participant and to ensure that there is ready access available to appropriate counselling and support should the need arise. Training in communication and empathy skills may be beneficial to researchers.

The National Centre for Social Research reviewed the literature on empirical studies of ethical requirements and looked at harm and benefits experienced in research participation (Graham et al., 2006). In-depth or semi-structured interviews on difficult personal issues cause adverse emotional reactions in significant numbers of participants. However, some studies highlighted that participants felt that they had benefited from the interviews and were glad to have taken part, even when the interviews were difficult emotionally.²⁵

Newman et al. (2001) analysed reactions to participation, personal benefits, perceived drawbacks and emotional reactions. They 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' (Newman et al., 2001, p.323).

One way to handle difficulties that may arise in particular research methodologies is to establish a research advisory group. This group can then be accessed for support and advice, when required, such as when relationships become too intense (Stalker, 1998), or when relationships that have developed with lonely people in research are withdrawn (Booth, 1998).

Respondent burden

Some people with disabilities may have limited stamina or require frequent breaks during a research process. The individual's wellbeing is the primary concern, and

the research design and protocol should allow for rest or care breaks as required. Over-concern to protect the vulnerable can lead to gate-keepers preventing their inclusion in research studies: 'attempts to protect vulnerable patients from harm through involvement in research can paradoxically be harmful.... A balance is needed between protection and empowerment' (Atkinson, 2007, p. 138). Researchers and funders should look at previous studies and consider the likelihood of over and under-research when formulating their research question. Some people with disabilities consider that they have been 'over-researched' (Mitchell, 2003). There can be a certain lack of respect in approaching the same people repeatedly and asking them the same questions²⁶ (Woods, 2002).

Minimise proxies

Proxies are people who speak on behalf of others or about others and decide whether to consent to their participation in research. To respect the autonomy of individuals, the use of proxy informants should be minimised. There should be clear guidelines and standards in place for proxy involvement, which are clearly communicated to those concerned. In addition to proxy consent, which is required in the case of children and those who lack the mental capacity to consent, it is also necessary to obtain consent from the potential participants themselves.

Covert research

Covert research creates a difficulty, as there is, by definition, no consent by research subjects. The merits of using this methodology need to be carefully considered, together with the potential benefits, and whether there are alternative methodologies available which can validly investigate the phenomenon under study. A justification might be when the research is for the common good, such as a study of behaviour modification techniques or different environments on the behaviour and motivation of people with challenging behaviour. In such cases, the researcher should refer regularly to an advisory group or advisor and should take particular care not to reveal the identities of any of the participants. When deception is used as a part of the research methodology, a debriefing must occur afterwards, with all the research participants being told that deception was used.

Understanding and avoiding stigma and discrimination

Researchers need to appreciate the social, cultural and historical experiences of people with disabilities, including 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 people with disabilities, or linked to any denial of their human rights, would be of ethical concern.

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. They can do this by, for example, adhering to data protection legislation and re-consulting with participants if secondary research is mooted. It is advisable to seek consent for secondary analysis of data at the outset of the research project, when at all practicable. Ethical responsibility to ensure that harm does not result from published research falls on others as well as on the researcher(s), e.g. policy-makers, service-providers, media and other stakeholders. However, the researcher has a responsibility to challenge misuse when it occurs, publicly if necessary. Where research outcomes are not what the researchers and participants expected and could result in negative outcomes, it is important that dissemination is handled sensitively, and support put in place where needed.²⁷

4.4 Ensuring voluntary and informed consent: understanding and applying the principles

Free, informed consent attempts to resolve the ethical tension of involving people in research when they have not actively sought this and when the research often is only indirectly of benefit to them. Obtaining voluntary and informed consent seeks to ensure that individuals are treated as subjects and as participants. Guided by the ethical and legal principle of personal autonomy, research participants should be facilitated to decide freely whether the research is consistent with their interests and preferences.

Information

Obtaining consent involves the provision of comprehensive, accessible information on the research, and discussion with potential participants and parents and advocates about the research before requesting participation. Researchers need to invest time and effort in securing actual informed consent, which entails not only ensuring that potential research participants are fully informed about the research but that they understand 1) its implications; 2) their freedom to choose to participate in the research or not; and 3) their freedom to withdraw from participation in the research at any time.²⁸

Document the consent

Ethics requires documentation of consent. This will usually be a signed document, but a tape/videotape can also be used. While signed consent forms provide evidence that consent has been given, they do not provide evidence of fully informed consent. Consent issues should be reviewed throughout the research process. Participants not wishing to continue with the research should be reminded of their freedom to withdraw from the research if they so wish.

Support to capacity to consent

People with disabilities who have diminished capacity to understand information, such as people with intellectual disabilities, can be provided with support to facilitate their participation in research. Easy-to-read and illustrated information on the purpose and the scope of a research project and taking more time to explain things to them can enable them to understand the research and its implications and to make an informed decision about participation.

‘Most people with learning difficulties need support to lead fulfilling lives, including participation in research. This is fully accepted by people with learning difficulties. They will readily discuss and insightfully critique the nature of the support they need’ (Walmsley, 2004, citing Open University, 1996).²⁹

Ongoing consent

Wiles et al. (2004) describe ways to help researchers check whether they have the ongoing consent of research participants. For example, researchers

- should consider reiterating to participants that they are able to opt out;

- should consider using different coloured cards with children or people with an intellectual disability, so that they can indicate if they want to stop or to pass on a particular question or topic by picking up the appropriate coloured card;
- should be aware that when children are distracted, bored and unengaged, this may be an indication of withdrawing informed consent;
- should be aware that if participants are agitated, want to leave the interview venue or won't sit down, researchers can ask them if they want to stop or postpone the interview to a later time or take it as an indication of withdrawing informed consent.

Proxy consent

Consent of a parent or legal guardian is legally required for children and may also be sought where the potential participant is determined not to have the mental capacity to consent. The ethical need, however, to determine the person's preferences prior to accepting a substituted decision on his/her behalf cannot be eliminated (Stineman and Musick, 2001). As stated earlier, in addition to proxy consent, assent must also be obtained from the individual involved.

Respect refusal to participate

It needs to be highlighted that it would be unethical to proceed with research if a child or adult with an intellectual disability demonstrates that they do not want to engage in the research. The Ethics Guidelines for International Multicenter Research involving people with intellectual disabilities were adopted by the International Association for the Scientific Study of Intellectual Disability (IASSID) Council in Buenos Aires in 2003, and published in the *Journal of Policy and Practice in Intellectual Disabilities* in 2004 (Dalton and McVilly, 2004). These guidelines recommend that the participant consent form should have a clear statement that even where a proxy signs a participant consent form, if the participant does not provide assent to proceed (by protesting or not complying with the procedure), their participation will cease immediately:

The refusal or resistance to participate by a person with intellectual disability must be respected, whatever the view of others involved in the consent

process is.... In some circumstances it might be a legal and/or a cultural imperative to seek informed consent to participate from a proxy (e.g., a person's spouse, parent, legal guardian, family elder or community leader). This could be especially important for participants from cultures that emphasise a collective (e.g., family) identity, as opposed to an autonomous individual identity. However, in such circumstances, genuine assent to participate (which can be either explicit or implicit) must always be obtained from individual participants with intellectual disability. The process by which this is obtained should be documented (Dalton and McVilly, 2004, p. 63).

Appendix 1 of this document contains the IASSID recommended checklist for Participant Information Form and Participant Consent Form, which can also be accessed in one of the appendices of the journal article by Dalton and McVilly (2004) on the IASSID ethical guidelines.

Payment for participation and expenses

While excessive payment could compromise the quality of consent and the answers given to research questions, paying the legitimate expenses of participants in a research project (transport, time lost, etc.) can facilitate participation and be ethical.

In summary, research should:

- Facilitate potential respondents to consider their decision to participate in a full, free and informed manner;
- Document the consent process and review the consent process at all stages of the research;
- Document and review the stages in designing and implementing consent procedures;
- Recognise the implications that obtaining informed consent may have for both timeframes and financial resources and incorporate this into the research design;

- Determine issues around capacity to consent and use methods that may increase a person's capacity to understand the research and its implications and be in a position to give free and informed consent;
- Minimise the use of proxies.

Possible stages in the consent process might be outlined as follows:

1. Provide appropriate, accessible and detailed information on the research in alternative media such as large print, audiotape, videotape, etc.
2. Ensure that research participants understand the nature of the research, what will happen with the data, and that the findings will be reported.
3. Provide written consent forms that are clear, simple and understandable. Ensure that consent covers consent to the research process, to appropriate use and storage of the data and to reporting on the findings. Appendix 1 contains the checklist (IASSID, 2003) for Participant Information Form and Participation Consent Form.
4. Use varied and appropriate methods of communication to cater for those with, for example, visual or hearing impairments or who have intellectual disability.³⁰
5. Build in a number of stages in the research in which consent is required. This will depend on the length and the complexity of the project. Consent must always be given at the initial interview stage, but may also be required for the data protection stage and at pre-report stage.
6. Consider whether the target group is likely to include individuals such as children for whom proxy consent will be required. If required, decide on a strategy for defining who can be a proxy, how they are to be chosen, their role in the research, and the limits to their role, and consider and accommodate their possible biases.³¹ Clarify whether they are to assist with answers or to give answers and whether the proxies will be asked to add observations on the

interviews, if they so wish, as they, too, are participants in the research process.

7. At the final report publication stage (particularly for qualitative research), the researcher may go back to participants with a summary of the findings and look for their feedback, including their agreement that it is a fair portrayal of what they meant. The researchers should consider (together with an advisory committee) what to do if participants withdraw consent from or object to interpretation of data.

4.5. Understanding and fulfilling legal responsibilities

Researchers need to read, comprehend and comply with laws that apply in the area of research. These include laws relating to the protection of data and information and laws regarding child protection and protection of vulnerable adults.³² In terms of developments in research with people with disabilities, researchers should be familiar with the content and implications of current UN instruments, including the UN Convention on the Rights of Persons with Disabilities (2006)³³ and the national legislative framework relating to the rights of people with disabilities.

International research collaborations are on the increase, necessitating work across and between countries. While there are commonalities and overlap around the world, different nations are regulated by different laws. Establishing common ground for ethical research means identifying essential common values that point to a way forward in increasingly complex global collaborations.

Researchers need to be aware of the Irish legislation being introduced and where relevant, International legislation, to safeguard citizens who lack the capacity to consent.³⁴ These include some people with mental illnesses, intellectual disabilities and acquired brain injury and some older people.³⁵

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. Research shows that providing specific legal standards to guide judgments of mental capacity significantly improves the reliability of these

judgments (Church and Jones, 2008, citing Marson et al., 2007). New capacity legislation then should decrease the general judgments that a person, solely because of their diagnosis, lacks capacity.

4.6. Maintaining high professional research standards and competencies

As was stated in the Introduction to this document, research cannot be ethical unless it meets scientific standards but research that meets scientific standards may or may not be ethical; and only research that meets both scientific and ethical standards can be called 'good' or 'excellent' research. Research ethics for researchers, therefore, involves a consideration of their own personal behaviour as well as how they relate and treat others during the research process (Connolly, 2003).

The Australian National Statement on ethical conduct in research involving humans states that the guiding value is integrity, which it defines as a commitment to the search for knowledge and to honest and ethical conduct (Commonwealth of Australia, 1999). The updated 2007 Australian National Statement emphasises that without personal integrity, the involvement of human participants in research cannot be ethically justifiable. Research that is conducted with integrity is research conducted honestly, with upright personal behaviour, and which follows recognised principles of research conduct and disseminates and communicates results whether favourable or unfavourable in ways that permit scrutiny and contribute to public knowledge and understanding.

Connolly (2003), commissioned by the Office of the First Minister and Deputy First Minister in Northern Ireland to draw up ethical principles for research with 'vulnerable' populations, enunciates four guidelines arising from the principle of professional integrity:

1. Researchers should be committed to the unbiased and objective pursuit of knowledge and the comprehensive and accurate reporting of the research

findings. They must avoid selectively reporting their findings or fabricating, falsifying or misrepresenting their findings in any other way.

2. Researchers should interpret research findings carefully, clearly reporting any potential limitations that may relate to these. They should make claims or propose recommendations only when these are adequately supported by the data.
3. Researchers should recognise the boundaries of their own professional competence, in terms of their ability to use particular research methods as well as their substantive academic knowledge of the subject in hand.
4. Researchers should consider carefully the consequences of their own behaviour while carrying out research, especially as it affects those participating in the research or, where reasonably foreseeable, those subsequently affected by it. They should avoid conducting themselves in ways that may adversely affect the reputation of researchers more generally or that make it more difficult for future researchers to gain access to particular groups or communities (Connolly, 2003, p. 9).³⁶

According to Roberts et al. (2001),

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 (Roberts et al., 2001, p. 352, citing, among others, Spece et al., 1996; Culliton, 1983; Humphrey, 1992; Dalton, 1997).

Trust depends on the researcher's integrity and trust in the researcher is a highly significant factor in the decision of people to take part in research (Roberts et al., 2001, citing Roberts et al., 2000).

In addition to integrity, which requires, as outlined above, honesty, objectivity, rigour and diligence, other important 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. These professional values are underpinned by the bedrock ethical values of dignity, autonomy, equality and diversity, which underlie the rights of all persons and take precedence over research values.³⁷

Researchers using qualitative and participative research methods need to have the personal capacities essential for working well with people over a period of time. They need a level of personal insight that makes them aware of unintended manipulation and interpersonal dynamics that may arise in the course of a study. 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 researchers place themselves and their practices under scrutiny, acknowledging the ethical dilemmas that permeate the research process and impinge on the creation of knowledge (McGraw et al., 2000, p. 68). Reflection on their professional behaviour can form part of a researcher's self-regulation of their practice.

The Cope Foundation (2005) and Tee and Lathlean (2004) outline recommendations for researchers. These include:

- Building self-regulation into the research process and keeping notes as proof of self-regulation;
- Demonstrating a critical open-minded approach at all times when conducting research and analysing data;
- Maintaining clear accounts of all aspects of the research, including procedures, materials used, statistical techniques used and the contribution of other researchers;
- Building and maintaining trusting relationships;
- Assessing competence to participate;

- Managing interpersonal and group dynamics;
- Taking responsibility for decisions about participation;
- Demonstrating honesty at all times, including observing the rules regarding plagiarism, breach of confidence, falsification of data, and so on, and acknowledging the assistance of others in conducting the research;
- When using participative approaches, developing 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.

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Case Studies

5. Case Studies

Study 1: Research with people with the entire range of disabilities

(Browne et al., 2004; Brady and Good, 2005; CSO, 2006)

The first National Disability Survey in Ireland was conducted by the Central Statistics Office in 2006. A nationally representative sample of more than 17,000 people (adults and children) was chosen, based on responses to the 2006 Census of Population. The sample comprised 15,000 people with disabilities of all types in private households, 2,000 people without disabilities in private households, and 700 people with disabilities of all types in hospitals, nursing homes and children's homes. The survey was conducted by personal interview. The first report on the survey's findings was published in 2008 (www.cso.ie).

A wide range of ethical issues was raised and addressed in the course of planning and conducting this survey. However, difficulties still arose in some areas and lessons have been learned for future surveys.

The NDS was preceded by a pilot exercise conducted during 2002–2004 by the ESRI and UCD on contract to the NDA (see www.nda.ie for a report on the Pilot). Relevant aspects of the pilot included consultation of people with disabilities and their organisations through special seminars, an Advisory Committee with representation from disability organisations and other stakeholders, and a disability equality expert who was contracted to the Pilot study team. The Pilot explored the WHO ICF as the possible framework for the survey; developed interviewer guidelines for use by the survey staff; and addressed concerns raised by the extensive consultation process. One outcome was that the NDA produced its 'Ethical Guidelines for Disability Research', which was used by the CSO as a reference document for the NDS. The report by the Pilot team (Browne et al., 2004) provided the basis for the recommendations from the NDA to government on the NDS.

When the decision was made by government to proceed with the NDS, the Central Statistics Office was asked to undertake that task as a post-censal survey, to be

held after the 2006 census. The CSO took on board the results of the Pilot exercise as well as its own requirements under the statistics legislation, which were applied through the NDS process from the census methodology to options for capturing data from paper questionnaires.

Preparations included careful attention to many aspects of ethical good practice. These included further consultation with stakeholders (including people with disabilities) through the NDS Advisory Board; special training for the NDS field staff, including disability awareness training and distribution of the NDA guidelines for interviewers; establishment of subcommittees of the Advisory Board on aspects of specific disability and questionnaire design, including a subcommittee to advise regarding intellectual and learning disabilities and mental health and another on design of the questionnaire. The NDS field-staff supervisors were trained for five days by CSO staff and disability experts. Interviewers were then trained for five days by supervisors. There was continuous contact between supervisor and interviewers. Debriefings were held for interviewers and supervisors, and a debriefing questionnaire was completed by all staff.

Data from these exercises indicated that the following aspects of the survey went well:

- Training for interviewers and supervisors
- The Interviewer Guidelines which had been produced as part of the NDA Pilot study
- The Advisory Board, including special committees on ID (Intellectual Disability) and MHD (Mental Health Difficulty), and on questionnaires design
- The NDA ethical guidelines
- Normal CSO protections under Statistics Acts, e.g. privacy, confidentiality and reputation of CSO
- Post-censual route and notice given in census
- Information leaflet for all possible respondents

- Provision of supports such as sign-language interpreters
- Use of proxies for children.

During these exercises, several areas for improvement were discussed, with regard to ethical good practice in future surveys. These included the following:³⁸

- Situations where interviewers and respondents knew each other. In some cases, a different interviewer took over;
- Situations where people got upset during the interview; it was felt that there was a need for greater back-up support (some information was available on support services);
- Situations where proxy or assisted interviews took place in nursing homes. Interviewers thought that the residents may have been uncomfortable with this;
- Unease of respondents about the process of their names being taken from the Census form;
- Unwillingness to give a PPS number (allows data linking with other databases);
- Reluctance to participate by some respondents from the 'No' sample who were unsure of the relevance of their involvement (This in a way proves that procedures on consent were adhered to);
- Concerns about allowing interviewers into people's homes;
- Parental concern over the labelling or disclosure of disability where letters went directly to children;
- Cultural issues over interviewer gender: a Muslim man did not wish to be interviewed by a woman.

Study 2: Research involving deaf people

(Pollard, 2002)

Vignette

In a study involving the administration of a general anaesthetic, a physician-researcher warned a deaf woman that participating in the study would entail 'the usual risks associated with anaesthesia'. The sign language interpreter correctly judged that this individual might not be aware of the 'usual risks' of anaesthesia, which include respiratory arrest. The interpreter spoke up, and conveyed to both parties that more specific information was needed or she could not adequately convey what 'usual risks' referred to. When the researcher provided further details, the deaf participant expressed dismay that such critical information was almost withheld from her and she chose to withdraw from the study (Pollard, 2002, p. 164).

Unintended deception

In considering the participation of deaf and hard-of-hearing people in research, there are unique factors that pertain to deception or a perception of deception (Pollard, 2002):

- Researchers should consider the different experiences of hearing versus deaf participants, even if the study involves only deaf people, and rectify any informational differences where necessary.
- Do the communication arrangements for deaf and hard-of-hearing participants give the equivalent amount of information to that which hearing participants would receive? Conveying information through speech and/or writing is frequently inadequate for deaf individuals, especially those who communicate more effectively through sign language.
- Fund of information³⁹ differences between deaf and hearing people are common and arise from differing access to radios, conversations and other auditory information sources, as well as differences in literacy. Researchers should be careful of the assumptions they may make about a participant's background information. Where fund of information is significant to participation

in a study, researchers must take extra precautions to avoid an unintended form of deception (Pollard, pp. 163–4).

Confidentiality and anonymity

Research focused on deaf individuals is quite likely to involve a participant pool with much greater interpersonal familiarity than a comparable pool of hearing participants so additional precautions may be necessary to preserve the anonymity of deaf research participants. The training of researchers must emphasise the heightened risk of confidentiality breaches in such small communities. In addition to the usual methods of preserving anonymity e.g., avoiding documenting names, phone numbers and other information that could lead to disclosure, or confining such information only to the principal investigator, deaf participants should be informed of the names of researchers and research assistants, including interpreters, who may have access to study data. This will afford participants the opportunity to decline participation or discuss anonymity or data security issues, if they are concerned about familiarity with members of the research team (Pollard, 2002, pp. 164–5).

It must be remembered that interpreters may also be familiar to research participants.

Study 3: Research with people recovering from acute mental health problems

(*Research Ethics Review*, 2007, 3(3), p. 91 and 3(4), pp. 127–9)

Obtaining consent

This case study concerns how informed consent was obtained in a qualitative research study in the UK in which participants were recovering from acute mental health problems (Research Ethics Review, 2007, 3(3), p. 91).

The Research Ethics Committee (REC) involved was concerned that a prompting approach by one of the person's care team could be interpreted by the participant as coercive. It was acknowledged that this interpretation was in keeping with Royal College of Psychiatrists' research guidance (2001). However, the same guidance also recommended that vulnerable groups should have the opportunity to

participate in research and have their needs investigated. This is also the recommendation of other organisations such as INVOLVE (Steel, 2004).

The research team proposed that the potential participants should be asked for their decision on participation by a staff member who did not belong to their care team, and the REC agreed to this modification.

Difficulties with presuming vulnerability

The World Medical Association's Declaration of Helsinki (1964 and last revised 2008) states that some research populations are vulnerable and need special attention. However, vulnerability is never defined. It should not be assumed that vulnerability is a universal characteristic of everyone with a mental health problem.

In the same journal edition (Research Ethics Review, 2007, 3(4)), Atkinson (2007) argues that over-concern to protect the vulnerable can lead to gate-keepers preventing their inclusion in research studies at various stages of the research. This denies such groups a voice in the research process. Atkinson points out that 'ethical scrutiny of research is not only to prevent harm to the vulnerable, but also to provide a framework to empower such people to take part in research. To do otherwise is to further stigmatise and marginalise them' (Atkinson, 2007, p. 134).

He argues that,

attempts to protect vulnerable patients from harm through involvement in research can paradoxically be harmful. They may stigmatise individuals by always using a category descriptor e.g., mental illness, as inclusive vulnerability, rather than individual factors, or they may be disempowering by over-stringent gate-keeping through access channels or capacity criteria, so that they are automatically excluded or researchers find the barriers to their inclusion insurmountable.

Study 4: Research with people with learning disabilities

(Tuffrey-Wijne et al., 2008)

Anonymity, confidentiality versus participant's autonomy

Tuffrey-Wijne et al. (2008) undertook research on people with learning disabilities who had cancer.⁴⁰ Participants shared personal stories. While some sought assurances that the researcher would keep their situation confidential, two participants wanted to own their stories. Assuring confidentiality is done to protect the person from harm but what happens when participants want to own and publicise their story? The need to make data anonymous was difficult to explain. Some argue that because participants' autonomy should be respected, their choice to waive confidentiality should be seriously considered, with examination of the reasons for refusing the participant such a choice, as well as the implications for following it (Tuffrey-Wijne et al., citing Giordano et al., 2007). Lack of anonymity could affect the rigour of the study. Researchers may feel less free to construct theory from stories that are clearly owned. Accommodating participants' right to refuse anonymity could therefore undermine research objectives. In this case, the researchers decided that it was ethically justified to give the participants an opportunity to leave the legacy they wanted. However, there were unexpected ethical complications.

Capacity to consent

Some persons lacked capacity to consent and also did not know that they had cancer. The researchers adopted the principle of 'process consent' (Department of Health, UK, 2001). In 'process consent', the researchers give continuous attention to the question of whether the participant seems happy to engage with the researcher. If not, the planned data collection visit is cut short. The questions that this approach raises include: is it ever ethical to allow researchers access to persons' lives if they cannot give their consent? In this case, the researchers argued that:

1. This particular group of people with learning disabilities had indicated that they wanted to be included and listened to. Where possible, and if it is methodologically appropriate, where people with learning disabilities

indicate that they want to be included, they should be included as participants.

2. The importance of understanding the experiences of those who lacked capacity to understand the reason for the researcher's presence or who were unaware of their diagnosis justified their inclusion.
3. It could be unethical to exclude people with more severe learning disabilities from studies that could provide insight into their experience and help to shape more sensitive care in the future.

In this case, the Research Ethics Committee agreed to process consent, but wanted to be explicitly reassured that they would not reveal any information to the participants about their diagnosis or prognosis. Carers, too, wanted to be reassured. This case study illustrates issues around consent but also around the fact that while the concept of people with learning disabilities as partners in research is gaining ground, there is the danger of omission in research of those with the greatest disabilities because they are perceived to be too difficult to include.⁴¹ Some of the members of the Research Ethics Committee set up by the NDA considered that while reason 1) above is a strong reason for adopting the principle of process consent, in a situation where one might try to argue the case on the basis of reasons 2) and 3) alone, which are weaker reasons, it might be more ethical to consider the use of proxy decision-makers.

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Appendix 1

Appendix 1

Participant Information Form and Consent Form Checklist

IASSID (2003) proposed that a participant information form and consent form checklist should be on institutional/organisational letterhead and should include the following: (Both of these forms can be found in the *Journal of Policy and Practice in Intellectual Disabilities*— see Dalton and McVilly, 2004):

1. The short, plain-language title of the project.
2. A brief, plain-language statement of the project aims and potential benefits. The statement should acknowledge if the project is being conducted to meet the requirement of a qualification, e.g. a university degree. Also, any sponsorship of the project by government or non-government organisations should be acknowledged.
3. The names and contact details of those responsible for the project, including those with overall administrative responsibility and those with local responsibility.
4. The name(s) and contact details of the authority(s) who has/have approved the project.
5. A description of what the participants are expected to do, where they should be expected to participate and over what period of time. This description should include acknowledgement of any audio or video recording that could be involved in either research activities or data collection.
6. A clear statement of any potential risks or discomfort for participants or those with whom they live, work or socialise. Information about how any adverse events will be addressed.
7. A clear statement of any potential benefits to participants and any possible limitations to these benefits (e.g. for the duration of the project), including any

compensation for their participation or costs they might incur as a consequence of their involvement in the research.

8. Details of how data is to be collected, stored and later destroyed or preserved. Details of how the privacy and confidentiality/anonymity of participants are to be maintained. Also, any limitations on the maintenance of confidentiality and/or circumstances where information might need to be disclosed to a third party (e.g. reporting any disclosure of abuse).
9. Details of how the findings are to be disseminated, including how the confidentiality of individual participants is to be maintained. Also, a statement of how participants will be advised and/or can find out about the findings other than through the peer-reviewed literature. Information about whether and how individuals can gain access to data to assist with their usual support or treatment.
10. A statement guaranteeing the participants' right to withdraw at any time, without having to give a reason or in any way having an adverse consequence for them personally (e.g. the cancellation or alteration of any support service and/or treatment they would ordinarily receive).
11. A statement that the person has been given a signed copy of the Participant Consent Form.
12. Contact details of an independent authority to whom participants can direct any inquiries or concerns that they may have about their involvement in the project. The independent authority should be readily accessible at a local level. However, contact details for the principal ethics committee should also be included.
13. A signed statement (by the person or legal guardian) that the participant has read, or had read to them, the Participant Information Sheet (which they can keep for their own records), that they understand what participation in the project involves and that they agree to participate on the understanding that they can withdraw their consent at any time without prejudice to their usual services and/or treatment.

14. The Participant Consent Form should also provide for the consent of a 'Legal Guardian' or 'Person Responsible', where the person is unable independently to provide informed consent — for example, in the case of a person whose disabilities limit their decision-making capacity, or a minor (Note: the age of consent varies between jurisdictions and across cultures). The reason why someone other than the participant is signing the form should be documented (e.g. the person did not understand the consent process or was not deemed legally competent). In such circumstances, the relationship between the participant and the person providing the consent should be detailed. There should be a clear statement that the person providing the consent on behalf of the participant does so without any inducement or likelihood of personal gain as a consequence of providing consent. Also, there should be a clear statement that even though someone else signed the Participant Consent Form, if the participant does not provide assent to proceed (i.e., they protest or choose not to comply with the procedure), their participation will cease immediately.
15. Pages on any Participant Information Sheet or Participation Consent Form should be clearly numbered in the format '*Page 1 of 2*', etc.

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Endnotes

ENDNOTES

1 The ESRC (2005) defines research as any form of disciplined inquiry that aims to contribute to a body of knowledge or theory. Research ethics is defined as the moral principles guiding research from its inception through to completion of results and beyond (ESRC, Research Ethics Framework, 2005).

2 See Articles 4 and 31 of the Convention. Ireland has signed the Convention. As a signatory to the Convention, Ireland is obliged to refrain from actions that would defeat the aims and purposes of the treaty. The adoption by the UN General Assembly in 2006 of the UN Convention on the rights of people with disabilities was the result of five years of negotiation with unprecedented participation of persons with disabilities and their representative organisations. One of the unique characteristics within the process of drafting and negotiating the Convention was the involvement of civil society institutions.

3 Disability research commissioned, undertaken or supported by the National Disability Authority (NDA) includes national surveys on attitudes to disability; research on health, education and transport services; research on standards and on person-centred planning; studies on conducting research with children and how to include people with disabilities in research; a research promotion scheme to build capacity in the disability sector; literature reviews on a wide range of disability issues including women and disability, physical activity and sport and poverty; a pilot survey commissioned prior to the carrying out of the first national disability survey by the Central Statistics Office (CSO) in 2006. In addition to the routine use of data from the National Disability Survey, the Census Data and other existing datasets with a disability indicator, the NDA has commissioned or conducted statistical analyses on existing datasets e.g. research on disability and social inclusion. The NDA promotes the addition of a census-type disability question to existing mainstream data collections. It collaborates with other bodies e.g. currently with the Health Service Executive (HSE) on its census of congregated settings and with the Broadcasting Commission of Ireland (BCI) on the representation in the media of people with disabilities. The NDA supports the development of a diverse range of research methodologies, recognising that qualitative and quantitative methodologies are complementary, while stressing the need to maintain the essential standards of validity and relevance in all methodologies.

4 The NDA has a statutory role in relation to research. Section 8 (2) (b) of the National Disability Authority Act 1999 outlines that role: 'to undertake, commission or collaborate in research projects and activities on issues relating to disability and to assist in the development of statistical information appropriate for the planning, delivering and monitoring of programmes and services for persons with disabilities'.

5 They conducted research with persons with learning disabilities who were seriously ill or dying with cancer. Some of their research with persons with learning disabilities is used in case study 4 to illustrate situations that can arise during a research project .

6 Expression used by Guillemin and Gillam (2004)

7 Ramcharan and Cutcliffe (2001) and Guillemin and Gillam (2004) propose reflection on practice — 'reflexivity' — as a tool that is useful for both research rigour and ethical research practice.

8 The NDA Disability Ethics Research committee was set up in 2007 in response to a growing number of requests for advice in relation to research ethics and/or ethical approval for proposed disability research, with a remit to give guidance through the National Disability Authority on the ethics of proposed disability research. Members of the committee were Professor Jerome Bickenbach from Canada, Dr Ron Iphofen from England, Dr Tim Jackson, Selina Bonnie, Máiríde Woods

from Ireland, and NDA staff Mary Van Lieshout and Dr Anne Good. NDA staff wrote the guidelines with input from the committee.

9 There is an NDA unpublished report entitled 'Disability and Research Ethics Governance in Ireland' (Morgan, 2007) which identifies disability research ethics governance structures within the country. This research was commissioned by the NDA to support the NDA Disability Research Ethics Committee in its work and planning.

10 Summer (1996) makes a distinction between objective and subjective definitions of wellbeing. Objective definitions assume that wellbeing can be defined without reference to the individual while subjective definitions require that individuals' preferences, interests, ideals, values and attitudes be included (Schimmack, 2008). The inclusion of the subjective dimension fits in with the rights approach to disability in which the person has to be the locus of control, evaluation and measure.

11 Upholding the dignity of research participants requires that every person is seen as a subject. As subjects, they are at the centre of decision-making. Respecting equality and diversity in research are interlinked. In order to understand equality, Sen (1992) suggests that appreciating the heterogeneity of persons is essential. The notion of equality and diversity in research involves accommodating personal and circumstantial variations and eliminating avoidable differences in opportunity, to facilitate participation. Often, simple steps will allow participation.

12 Disability Awareness Training was provided for all field-workers prior to conducting the Central Statistics Office's National Disability Survey in 2006.

13 For detailed recommendations on training interviewers see Browne et al., 2003.

14 The 2002 NDA publication, *Guidelines for Including People with Disabilities in Research*, is available on the NDA website, <http://www.nda.ie>

15 Participatory research is part of a methodological progression in social research where the role of the researcher has adapted to new methodological demands and the researcher works in partnership with people with learning difficulties and other groups of research participants, and participants have greater influence over the research process than hitherto (Chapell, 2000). The term 'inclusive research' was coined to shorthand the various strands of research in which people with learning difficulties, in particular, have been involved as active research participants (Walmsley, 2001). Inclusive research includes participatory and emancipatory research. In the UK, emancipatory methodologies have been promoted by Oliver (1992), Zarb (1992), Barnes and Mercer (1997), Barnes (2003), Priestley (1999) and others. Emancipatory research is a tool to achieve the transformation of the social relations of research production, and its purpose is to improve the lives of disabled people. These research methods have not been used extensively.

16 See NDA (2003): Using emancipatory methodologies in disability research and two 2002 NDA publications: Guidelines for including people with disabilities in research and The ask me guidelines for effective participation.

17 The idea of panels of service-users or panels representing different populations is gathering momentum. For example, in 2001, the Service User Research Enterprise (SURE) Unit was set up at the Institute of Psychiatry, King's College in London, to ensure that mental health research is informed and guided by service-users. Most members of staff in the unit have received or are receiving services. Network 1000 is a longitudinal panel survey of 1,000 people in the UK who are visually impaired. Those on this panel, as with those on SURE panels, are involved in all stages of survey design and in the dissemination of research findings; they also play a key role in generating themes for the survey instruments.

18 See guidelines on research governance from UK Department of Health (DH) for a comprehensive discussion of the various roles and responsibilities of managers, researchers, sponsors etc <http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en>

19 Access at www.nda.ie/resourceNew.nsf/askme.pdf

20 The prevalence of disability in the Census (2006) was 9.3 per cent while the prevalence of disability in the National Disability Survey (2006) was 18.5 per cent. Both of these figures are correct because different questions were asked and different realities measured. The Census is a multi-purpose survey with a yes or no response on disability (do you have any of the following long-lasting conditions and if yes do you have difficulties with the following) while the NDS was a specific survey with a 5-point scale (seeing, hearing, speech, mobility and dexterity, remembering and concentrating, pain, breathing, intellectual and learning and emotional, psychological and mental health. The Census is self-completed at household level while in the NDS, personal interviews of named individuals were conducted. In the Census, the head of the household was asked about long-lasting conditions, while in the NDS, individuals were asked about conditions lasting six months or more or regularly recurring conditions.

21 www.nda.ie/resourceNew.nsf/askme.pdf

22 Breaching confidentiality means the disclosure of participant information to others. Researchers should explain to anyone taking part in research the limitations on confidentiality, that is, the material will remain confidential unless there is a serious danger to the person or to a third party, or the researcher is compelled to disclose by a court of law. Data offered in confidence do not always enjoy legal privilege and researchers should be aware that they could be liable to subpoena by a court (Wiles et al., 2007, cited by Prosser et al., 2008). There are three examples of this in the United States but perhaps none in Europe to date (Prosser et al., 2008). The ethical duty of confidentiality may also be legally overridden e.g., when a person threatens to harm themselves or a specified individual or where there is suspected abuse or neglect of a child. When a disclosure or allegation, e.g. of abuse or harm, emerges during an interview, the researcher can inform the interviewee of their rights in relation to reporting the matter to the appropriate authorities. While there are differing views on this, where the interviewee is a competent consenting adult, some consider that, after they have been given the information about how to make a complaint, it should be their choice whether to do so or not (Australian Government, National Health and Medical Research Council, 2006). In a different but related issue, what should happen where researchers observe that harm is being done to research participants? The National Centre for Social Research in the UK, in an internal policy statement on disclosure of harm, outlines the decision-making process where researchers, in the course of their work, observe or suspect risk of harm to research participants. Examples include physical or psychological abuse, neglect, unsafe or unsanitary conditions, lack of support or adequate supervision or restriction of freedom. Researchers discuss with the principal investigator or head of research project what they have observed and the possible consequences of a report, to the participants. If necessary, they refer the case to the Disclosure Board of the National Centre for Social Research. The Board decides what and how much information is to be passed on, by whom and to whom (NatCen Internal Policy Statement, Jan 2008).

23 Payment can also compromise the validity of the research.

24 The Scheme of a Mental Capacity Bill, published by the Department of Justice, Equality and Law Reform in 2008, provides a legal framework for determining capacity to consent to any treatment.

25 Similar conclusions were drawn in other studies where talking about painful experiences provided participants with the opportunity to talk, a chance to reflect, to get a better grasp of an event or to reassess experiences, attitudes and their impact, e.g. Dyregov (2004); Scott et al. (2002); Ruzek and Zatzick (2000); Hiller and DiLuzio (2004) and McGrath (2003).

26 People with disabilities should be involved, as members of the community, in all research done in the population, and the problems associated with under-research can compromise the advancement of people with disabilities. At the same time, ethical challenges may arise in small populations, including the overuse of parents and people with disabilities as research participants (Bjarnason, 2007). Ethical issues may also arise because of poor research processes. Parents in Iceland had students doing research not only from universities but also from upper secondary schools. Bjarnason quotes a mother: 'It is OK. You can come because I know who you are. But I am getting a little tired of telling our story. Only this year I have

contributed to at least nine or ten essays. I have never seen any of the essays. Students just come with their questions about difficult aspects to our lives, tape my answers and then leave. I never know what they do with the stuff. I want to help and I do it because I want students to understand. But sometimes it is very difficult'.

27 If research among people with disabilities on specific services or on their accommodation or housing, for example, were to find a high rate of satisfaction when objectively the housing or service might be considered of a very low standard, care would have to be taken with the presentation of the results, which may indicate not good quality of housing or service but low-expectation results on the part of the research participants.

28 Bucinni et al. (2009) report that the comprehension requirement of informed consent is not always consistently fulfilled. In a systematic review of studies, which examined the relationship between informed consent and research participant comprehension of the clinical trials they were participating in, they found that few participants knew the purpose of the study or specific aspects of the procedure.

29 A major shift is taking place towards always gaining consent from the potential participants themselves, be they persons with mental health problems or people with intellectual disabilities. Conditions such as schizophrenia or intellectual disability in themselves are no longer assumed to be a barrier to individual consent or research participation. If consent is obtained from a proxy, the assent of the participant is still always required. There is a growing body of evidence demonstrating the value of various approaches for supporting valid decision-making capacity. One review found that in twenty-five out of thirty-four studies, subjects' understanding and recall were improved by a variety of methods of support (Church and Jones, 2008, citing Dunn and Jeste, 2001). Some adults with moderate learning disabilities who have a research project explained to them twice understand what the research is about (Arscott et al., 1998). Education, learning trials with corrected feedback, simpler written materials such as consent forms, etc. can all significantly increase capacity to make an informed decision (Church and Jones, 2008). In real life, a researcher will not be able to engage in such long-term training — though they should be prepared to explain several times what they are doing.

30 Approximately five weeks was built into the timeframe to allow for the collection of consent from people with intellectual disabilities In the NDA piloting of an audit tool for the National Standards for Disability Services in 2003.

31 In the NDA piloting of an audit tool for the National Standards for Disability Services in 2003, it was stated that, in terms of the role of the proxy in interviews with people with intellectual disabilities, proxies must be reminded not to interject their own views or opinions and to answer 'don't know' whenever they are unsure of how the respondent would answer a particular question; they should also be reminded that they are representing the views and responses of the service-user, and should be asked to respond at all times from the perspective of the service-user; they should be asked to try to answer as objectively as they can based on their knowledge of the respondent. In terms of who can be a proxy, the draft pilot audit tool specified that any person whom the service-user chooses could be a proxy. This includes a sibling, a parent, a family member, a carer, a friend, a neighbour or a staff member. Conditions were specified re choosing a proxy: the service-user should have a proxy of their choice; the proxy must be empathetic with the service-user and have known them for a significant period of time; the person who is chosen as proxy should be offered opportunities to spend time with the service-user in advance of the external assessments, fine-tuning their communication with and understanding of the service-user; the preparation should focus on proxies ensuring that they feel that they can represent the service users' views. Again, it must be noted here that the trend is increasingly against the use of proxies in most every instance.

32 For example, the Data Protection Act, 1988, 2003; The Freedom of Information Acts, 1997 and 2003, and the Equal Status Act, 2000 and 2004.

33 Commitment to the ratification of the UN Convention on the Rights of Persons with Disabilities requires the enactment of legislation which will ensure compliance with Article 12 of the Convention, particularly the requirements of equal recognition before the law, regular review, adequate procedural safeguards and access to the support required to exercise legal capacity. The Convention is the first legally binding instrument with comprehensive protection of the rights of persons with

disabilities. Disability research is addressed in two principal areas in the convention – in Article 4 General Obligations, and in Article 31 Statistics and Data Collection. Article 4 is in Part II of the Convention. It requires that states promote research that furthers the participation of persons with disabilities in every aspect of society, specifying that state parties will do this by undertaking to promote research and development of universally designed goods, services, equipment and facilities, and undertaking to promote research and development of, and promoting the availability and use of new technologies, including information and communications technologies, mobility aides, devices and assistive technologies, suitable for persons with disabilities, giving priority to technologies at an affordable cost. Article 31 of the Convention on Statistics and Data-Collection requires statistics and data collection methods to be based in an ethical framework that respects human rights and fundamental freedoms of persons with disability, including their right to privacy. The article declares that states must mandate disability research and data collection that is directed towards the realisation and monitoring of the human rights and fundamental freedoms of persons with disability set out in the convention.

34 Ireland's proposed legislation (see Scheme of Mental Capacity Bill 2008) sets out a presumption of capacity to consent, and core principles to be applied in exercising substitute decision-making where capacity to consent is absent (Head 3): is capacity likely to return; support the person's ability to exercise capacity; consider the person's past and present wishes, beliefs and values; consult with relevant people concerned with the person's welfare. It requires 1) that capacity be determined in respect of individual functions or decisions rather than a determination of overall incapacity based on diagnosis; 2) that any substitute decision-making be in the best interests of the individual and that there be guidelines on support to exercise capacity.

35 The thrust of legislative reform worldwide emphasises capacity; it is enabling rather than restrictive and the legal standard of capacity is decision-specific (functional). In most cases, the reform of legislation brings laws into line with the human rights model of inclusion and full participation in all aspects of life. In the mental health area, there are extra safeguards for involuntary detention. There is a move away from treating the person who lacks capacity or is assumed to lack capacity with models of care based on a medical diagnosis.

36 Upholding the ethical values that underpin human rights and inhere in the person and take precedence over planned or expected benefits of research must be done consciously at the design and planning stages, as well as throughout the research process, and 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' (Australian Government, 2006, p. 45 — comment from Ethics Committee member).

37 Research and ethical values hold, whatever the methodologies used. Differences between research methodologies have, at times, been overstated. Increasingly, the complementary nature of different research methods is recognised, as is the overlap between them. Different methods are used depending on the purpose or stage of the research.

38 The issues listed below would not all carry the same weight but are listed to give an idea of the range of issues that arise and must be dealt with during the research fieldwork.

39 Fund of information is the accumulated pool of facts one knows and is a separate matter to intelligence.

40 This case study is taken from Tuffrey-Wijne et al. (2008), pp. 171–184.

41 Kellett and Nind (2001) explores some of the ethical concerns raised with models proposed for involving people with profound learning disabilities as real partners in research.