Providing Services and supports to People with an Intellectual Disability

HUMAN RESOURCES PROCEDURE		
TITLE: Ethics in Research	**NO.:** HRD006.06	**REV:** 1
SECTION 6: HR General	**PAGE:** 1 of 7	
PREPARED BY: Adrian Harney	**DATE:** 18/08/2014	
APPROVED BY: Breda Crehan-Roche	**DATE:** 08/09/2014	

1. PURPOSE:

1.1 The purpose of this procedure is to outline the processes and responsibilities involved in relation to requests to undertake research projects with Ability West.

1.2 To ensure that ethical issues are addressed by the Ethics in Research Committee when considering requests in relation to research.

1.3 To provide guidance and clear expectations in relation to good practice in research and what is expected, with specific reference to ethical considerations.

2. SCOPE:

2.1 This procedure is applicable to all Ability West staff, and other parties making requests in relation to research, and also applies to the processes involved in making such requests.

3. RESPONSIBIILTIES:

3.1 **Ethics in Research Committee** – Consider and make decisions on requests made to undertake research, and respond in a timely manner.

3.2 **Staff Members and other parties** – Make requests to undertake research through the designated method as described in this procedure, and to abide by guidelines if approved.

3.3 **Director of Human Resources** – Request copy of any approved research conducted.

4. REFERENCES (including Policy area):

4.1 Legislation

Data Protection Act (1988) and (2003)
Disability Act (2005)
Employment Equality Act, 1998 & 2004
Equal Status Acts (2000 - 2004)
Freedom of Information Acts (1997) and (2003)
Health Act (1970), (2004), (2007)
Health Act 2004 (Complaints) Regulations
Health and Social Care Professionals Act (2005)
Safety, Health and Welfare at Work Act (2005) and related Regulations
Health Act 2007 (Care and Support of Residents in Designated Centres for persons [Children and Adults] with Disabilities) Regulations S.I. No. 367 of 2013
Health Act 2007 (Registration of Designated Centres for Persons [Children and Adults] with Disabilities S.I. No. 366 of 2013
H.I.Q.A. Standards
I.S. EN ISO 9001:2008
UN Standard Rules on the Equalisation of Opportunities for Persons with Disabilities (1993)
UN Convention on the Rights of Persons with Disabilities (2006)
Universal Declaration of Human Rights (1952)

4.2 Other Policy Framework and Resources

Ability West – Vision Statement
Ability West – Quality Manual
Ability West – Policy on Ethics in Research
Ability West - Complaints Procedures
Ability West - Safety Statement
Ability West – Records Retention Policy and Procedures
National Disability Authority (2005) Ethical Guidelines for Disability Research
National Disability Authority (2009) Ethical Guidelines on Research with People with Disabilities
Federation of Voluntary Bodies – Factsheets on Research

4.3 Other References/Records

Ability West Research Proposal Form – Appendix 1.
Ability West Core Values and Guiding Principles in relation to Research – Appendix 2.

5. DETAILS OF PROCEDURE:

5.1 INTRODUCTION:

As stated by the Federation of Voluntary Bodies (2009), research is an essential element within the intellectual disability sector as in any other branch of human services. It serves a valuable function as it:

- informs practice,
- improves the quality of service,
- creates debate,
- improves understanding between stakeholders,
- validates practice, and
- provides evidence for funding requests.

As Ability West is committed to promoting good practice in all areas of service, this procedure has been developed to ensure that any research is carried out in line with good ethical principles, integrity and in best practice.

5.2 RESEARCH ETHICS COMMITTEE:

In line with this, Ability West has established a Ethics in Research Committee with details outlined hereunder:

Composition of Committee

- Board/Parent Representatives
- Service user Representative
- Frontline Staff member
- Head of Psychology
- Director of Human Resources
- Service Quality Manager
- Eternal e.g. Psychologist, NUI, Galway

Function/Terms of Reference

- To consider the justification and ethical issues involved in conducting proposed research, in order to safeguard the rights, safety and well being of all service users, family members and other parties involved in research.
- Where the committee considers that the proposed research is justified and it is satisfied with those circumstances, approval to the conducting of the proposed research.
- To provide timely reports in relation to decisions on research requests to the Senior Management Team.

5. DETAILS OF PROCEDURE (Contd.):

Responsibilities

- To safeguard the rights, safety and well being of all service users, family members and other parties, such as staff members, involved in research.
- To obtain adequate information from applicants in relation to proposals in order to make an informed decision, taking account of ethical considerations.
- To review and make decisions on research proposals, and inform applicants in a timely manner of decision.
- To provide clear expectations in relations to what is expected for approved research proposals.

Meetings of Committee

- Two meetings of the Research Ethics Committee will be scheduled annually, the dates of which will be posted in Ability West's intranet (internal) system. Further meetings will be convened on a 'once off' basis if needed necessary. All meetings must have at least 50% of a quorum.
- Agendas, previous minutes and research proposals will be circulated to Committee Members at least two weeks prior to the meeting.

Term of Committee

- The membership of the Committee will be reviewed on a three yearly basis.

5.3 PROCESS FOR SUBMISSION OF RESEARCH PROPOSALS:

There are mainly two situations when Ability West could be requested to become involved in research projects specifically involving service users:

1. **Projects being undertaken nationally or internationally which Ability West could be asked to become involved in.** If such a situation arises the Ethics in Research Committee will consider this as soon as possible at one of their meetings.

2. **Person(s) or groups may wish to undertake research specifically involving service users in Ability West**. In such situations the following is the process

   The dates of Ethics in Research Committee meetings are posted on Ability West's intranet (internal) system and also circulated to all services.

5. DETAILS OF PROCEDURE (Contd.):

Applicants must submit research proposals in a timely manner taking account of the dates of Ethics in Research Committee meetings, i.e. at least three weeks in advance of meetings to allow sufficient time for Committee members to review proposals.

Applicants must submit research proposals on the designed form – 'Ability West Research Proposal Form' (See Appendix 1). This form covers details regarding the proposed study, timeframe, potential benefits, methodology, consent, confidentiality, any risks.

The form can be obtained on Ability West's intranet site (internal) or copy can be forwarded to applicants on request to the Human Resources Directorate. Applicants must also ensure that any necessary documentation required is submitted with the designated form. The proposal should then be submitted to the Chairperson, Ethics in Research, Blackrock House, Salthill, Galway.

The Federation of Voluntary Bodies have developed a number of Factsheets and specific information in relation to research which aim to provide support to individuals who are undertaking or proposing to undertake research. These include - Factsheet No. 1 on Research Definitions, Factsheet No. 2 on Basic Ethical Principles, Factsheet No. 3 – Consent in Research and Using Focus Groups as a Research method in Intellectual Disability Research. Applicants are strongly advised to access these resources.

These resources can be accessed on the website of the Federation of Voluntary Bodies through the following link:

http://www.fedvol.ie/How_To_and_Checklists/Default.1366.html

5.4 CONSIDERATION AND DECISIONS ON REQUESTS BY ETHICS COMMITTEE:

Regardless of whether research proposals emanate from No. 1 or 2 above, the following process is applied.

Ability West acknowledges that applying ethical guidelines in each individual research proposal is a process, and an on-going matter of judgment and good practice.
In some cases, difficult decisions may need to be made, including decisions which involve the balancing of core values against each other.

5. DETAILS OF PROCEDURE (Contd.):

The Committee will consider all proposals taking account of the core values adapted by the organisation in relation to research and also the guiding principles in relation to ethics in research (NDA) which have also been adopted by Ability West. See Ability West Core Values and Guiding Principles in relation to Research (Appendix 2).

The Committee will come to a consensus on individual proposals and decision is communicated to the applicant by the Chairperson, via the 'Ethics in Research Committee Section' of the Proposal Form. The decision will be detailed clearly on this form.

If the decision of the Committee is to request further information, applicant is given a timeframe to submit this information. The committee may invite the applicant to attend a meeting or partake in a conference call to provide additional clarification on occasion.

The Chairperson on the Ethics in Research Committee provides a report to the Chief Executive following each Committee meeting.

5.5 APPEALS TO DECISIONS

Any decisions reached by the Ethics in Research Committee, with which the applicant is not entirely satisfied, can be appealed in writing by the applicant within one ccalendar month to the Chief Executive, who will appoint an independent group to consider the appeal. The appeal should be considered within a timeframe of one calendar month from receipt of the appeal.

5.6 RECORDS MANAGEMENT

The Human Resources Directorate has in place a records management procedure - relevant records pertaining to this procedure are subject to this.

Ability West, and as such, the Human Resources Directorate complies with the Data Protection Act (1988 and 2003) and Freedom of Information Acts (1997) and (2003) and there are procedures in place for their application in the organisation.

6. MONITORING OF PROCEDURE:

BY WHOM	FREQUENCY	METHOD(S)
Director of Human Resources and Service Quality Manager	Every Two Years	Review process for submission and decision making for research proposals in terms of any improvements. Place on agenda for Research Ethics Committee to get feedback from Committee members on any improvements in process.
NEXT REVIEW DUE:		08/09/2016

7. REVISION HISTORY:

REVISION NO	DATE	DESCRIPTION OF CHANGE	NO.
0	10/05/2010	Introduction of new policy and procedure	141
1	24/07/2014	See QARF No. 220 for amendments.	220

APPENDIX 1

Providing Services and supports to People with an Intellectual Disability

RESEARCH PROPOSAL FORM

1. Title of Study:

2. Aim of Study:

(in 200 words describe the purpose of this study and the relevance to people with intellectual disability)

3. Researcher(s):

- Name:
- Position:
- Phone Number:
- Email:
- Please indicate current position and any previous research experience

Blackrock House, Salthill, Galway
Telephone: 091-540900 Fax: 091-528150 Email: ***enquiries@abilitywest.ie*** Website: abilitywest.ie

4. Project Timeframe:

- Proposed Start Date:
- Proposed Finish Date:
- Are there any reasons why either of these dates may be delayed?

5. How will this Study Benefit:

- People with intellectual disabilities or their families?
- Staff and service providers?
- How will it improve services?

6. Methodology:

• Quantitative or	• Qualitative research	• Mixed methods

Who will you gather data from?

• parents / family	• Service Users	• Staff

Proposed Number in sample:

How will sample be drawn?

7. How will Participants be Selected and Subsequently Approached?

(Please describe fully)

Selection process

Proposed method for inviting people to take part in this research including and

Inclusion /exclusion criteria:

8. How much Time will the Data Collection require of each Respondent?

(Please be as accurate as possible e.g. number of minutes)

9. Instruments/Questionnaires used to Collect Data:

(Include copy of all instruments)

- Own questionnaire
- Existing questionnaire
- Data form
- Other

10. How will the data be recorded? Analysed?

(e.g., audio, video tapes, transcripts etc.)

11. How will Consent be sought?

(Describe fully your procedures for obtaining the following)

a) Informed Consent

b) Proxy Consent or

c) Assent

Include copy of information being provided and copy of Consent Form (see Federation of Voluntary Bodies Factsheet No. 3 on Consent for information on this area)

12. How will Confidentiality be assured?

13. What risks or adverse conditions could arise from this study?

(e.g. distress to respondents, families becoming upset, raising expectations which may not be met, etc.)

How will you deal with those risks?

14. What benefits may arise from this study?

How will these benefits be maximised?

15. What is your proposed Timescale?

- Literature review completed by:
- Data collection completed by:
- Analysis completed by:
- Findings written up by:
- Deadline for completion (if any):

16. How will the data be analysed?

Please describe clearly statistical analysis and qualitative analysis and rationale for using methods of analysis.

17. In what form will the data be stored?

Describe how data will be kept secure including procedures for destroying written records etc.

18. What will be the Outcomes of this Study:

Thesis	Report	Article	Other Publication	Conference Presentation

Will you provide feedback to participants?

Will you provide a copy of your report to the CEO?

Will you make a short presentation to staff, if asked?

Will you acknowledge the agency in your report?

19. What costs (materials, expenses) will the project incur and how will they be met?

(Budget for the project must accompany this proposal)

20. Whom should we contact regarding any queries about this proposal?	
Name:	
Full Postal address:	
e-mail address:	
Phone Numbers: Work	Mobile:

21. Is there any other information you think would help us consider your proposal?

- Any ethical issues arising from your proposal?

- Any issues relating to your methodology?

- Any practical issues (demands on staff, contact with families, …)?

Signed:

Date:

Checklist:

- All sections of this form completed in detail?
- Copy of consent information and consent form attached?
- Copy of any questionnaires, forms etc. to be used attached?

ABILITY WEST – RESEARCH ETHICS COMMITTEE

Blackrock House, Salthill, Galway
Telephone: 091-540900 Fax: 091-528150 Email: ***enquiries@abilitywest.ie*** Website: abilitywest.ie

CONSIDERATION OF PROPOSAL

FOR RESEARCH ETHICS COMMITTEE USE ONLY:	
Title of Research Proposal:	
Submitted by:	
Date received by Research Ethics Committee:	
Date considered by Research Ethics Committee:	
DECISION BY ETHICS COMMITTEE:	
Approval Given: ☐ Further Information Requested: ☐ Approval Denied: ☐	
Provide Reason for decision:	
Signed (on behalf of Research Ethics Committee):	
Date:	
Notification to Research Applicant Provided: ☐ Date:	

APPENDIX 2

Blackrock House, Salthill, Galway
Telephone: 091-540900 Fax: 091-528150 Email: ***enquiries@abilitywest.ie*** Website: abilitywest.ie

CORE VALUES AND GUIDING PRINCIPLES IN RELATION TO RESEARCH

CORE VALUES:

Ability West has adopted the National Disability Authority (2005, 2009) **core values** in relation to ethics in research and must be considered by the Research Ethics Committee when considering proposals:

- **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 wellbeing[i] 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.[ii] 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 interviewers[iii]
- 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.

Blackrock House, Salthill, Galway
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As noted in its policy on Ethics in Research, Ability West has adopted the National Disability Authority guidance on ethics in disability research as its **guiding principles in relation to ethics in research**. As such, when considering research proposals the Committee will take the following (or elements of) to assist in decision making:

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.

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.

- Consult as appropriate with people with disabilities or their representative groups around the research topic, research questions and research design.

- 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.[iv] 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.[v] 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.
- 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.

2. Ensuring accessibility: understanding and applying the principle

- The NDA's 2002 'Ask Me': Guidelines for Effective Consultation with people with disabilities is available online[vi] 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).

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.

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.

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.

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.

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.

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 questions[vii] (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.

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.

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).

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.

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.[viii] 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.

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.[ix] 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), 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.[x] These include some people with mental illnesses, intellectual disabilities and acquired brain injury and some older people.[xi]

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.

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).

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.

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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