Ethical Guidance for Undertaking Research with Vulnerable Adults

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Edge Hill University

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Contents

1. Glossary of Terms

MCA – Mental Capacity Act

CTIMPs – Clinical Trials of Investigated Medicinal Products

HRA – Health Research Authority

FoHSCM – Faculty of Health Social Care & Medicine

PPI – Public and Patient Involvement

GMC – General Medical Council

IMCAS – Independent Mental Capacity Advocates

LPA – Lasting Power of Attorney

NHS – National Health Service

Summary

2. Purpose

2.1 This guidance is intended to be used when undertaking research with vulnerable adults. It should be used in conjunction with, and adhere to the Edge Hill University Code of Practice for the Conduct of Research (RO-GOV-01) and the Edge Hill University Research Ethics Policy (RO-GOV-03), Research Ethics Policy Appendix and the Edge Hill University Data Management Policy (RO-GOV-O4) which can be found on the research governance pages website https://www.edgehill.ac.uk/collection/research-governance/ and the Edge Hill University Health, Safety and Environmental Policy https://www.edgehill.ac.uk/documents/health-safety-and-environmental-policy/. The guide outlines the key principles to be considered, and signposts to legal, professional and academic frames of reference for planning a research proposal or conducting research. It also addresses the ethical dilemmas that may emerge from various aspects of the lives and/or nature of including vulnerable adults.

2.2 It is increasingly recognised that the quality of research (research focus, design, management and dissemination) can be improved through meaningful consultation, involvement, and co-production with representatives from the population under investigation. This approach (called Patient and Public Involvement and Engagement within health) is not usually governed by research ethics approval but any work with vulnerable adults should adhere to the core ethical principles outlined below and take a rights-based approach to support engagement with appropriate measures in place. This work requires an appropriate research risk assessment and safeguarding protocol led by the Principal Investigator or a designated senior member of the

research team. Guidance for involvement work with vulnerable adults is available including the Social Care Institute for Excellence (SCIE, 2011; NIHR, 2017, 2019).

3. Introduction

3.1 Vulnerable adults include those adults lacking capacity or having potentially impaired capacity (Mental Capacity Act 2005 [MCA]) for England and Wales). However, vulnerable adults are not just individuals who lack capacity and the Care Act (2014) provides a broader definition which includes: those over the age of 18 years who have need for care or support; those experiencing, or at risk of, abuse, trauma or neglect; and are unable to protect themselves from abuse, trauma, neglect or the risk of it. Participants may not be considered conventionally 'vulnerable' and can be defined in different ways. They therefore possess some property which renders them more susceptible to potential distress or harm arising from their participation in a particular research procedure, than would be the case for the majority of the population. They may include frail older people, people with dementia, those with mind or brain impairments or learning disabilities, (GMC, 2020; GMC, 2010), as well as those with mental health problems, the homeless, travelling communities, asylum seekers, drug users, family carers, the bereaved, victims of abuse or those who have experienced other trauma (Combes & Tan 2010). Neurodiverse research participants may also be more susceptible to potential distress arising from research participation due to nuanced differences in communication and sensory sensitivities which they may experience (Autistica, 2022)

3.2 The MCA 2005 applies to any intrusive research within England and Wales, wherever it takes place, except for clinical trials of investigational medicinal products (CTIMPs). According to the MCA 2005, intrusive research is not confined to trials of clinical interventions and includes non-interventional research where consent is legally required, for example involving the processing of personal data or the administration of questionnaires, interviews or observations. This may include research in healthcare, social care, criminal justice and other settings. It is not limited to research undertaken within NHS organisations or other public bodies. In Scotland, the inclusion of adults lacking capacity in research is governed by the provisions of Section 51 of the Adults with Incapacity (Scotland) Act 2000. In Northern Ireland, it is currently governed by common law. (see HRA).

4. The Research Proposal

4.1 The research proposal should make explicit how the study will adhere to good practice and governance when undertaking research with vulnerable adults, and to professional codes of conduct, Research Councils' guidance and Acts (e.g Human Rights Act 1998; Mental Capacity Act 2005; Equality Act 2010, Care Act (2014) and associated guidance, also see resources below). Public consultation and engagement in the development of the proposal and conduct of the research

should also be made explicit and follow good governance (See INVOLVE; Hayes et al 2012). Advice can also be sought from FoHSCM Public and Patient Involvement (PPI) lead.

5. Considerations for Informed Consent and Conducting Research

5.1 When planning research with any groups who may be considered vulnerable, researchers should consider the participants vulnerability, any potential benefits or negative consequences from participating, consider how information will be provided, consent processes, any limits to confidentiality, legal requirements of working with the specific population such having a Disclosure and Barring Service clearance, and any use of incentives and compensations for participation (UKRI, 2022).

5.2 Project information sheets and consent forms should be in a variety of formats to suit the individual needs of participants. This may include written text, easy read text, printed materials, Braille, spoken words, audio, DVD or different art forms such as drawings and objects), taking into account of font size, typeface, non-shiny and paper colour. They should also take account of hearing and sight impairment, language needs, with different languages and translation available, use lay language, education grade ease of reading and have an appropriate FLESCH score or follow the NHS accessible information standards (NHS England, 2016). Other considerations are where informed consent takes place, allowing time for potential participants to seek advice, check understanding, have family, friend, carer or advocate present. (See Williams, 1993; Alt-White, 1995; Eggleton, Kearns & Neuwelt 2017; Alzheimer Europe 2011; Health Research Authority ; also Edge Hill University Code of Practice for the Conduct of Research (RO-GOV- and Edge Hill University Research Ethics Policy (RO-GOV-03). Increasingly research studies are incorporating both informed consent and process consent, whereby informed consent is initially obtained and then confirmed at each subsequent contact (Munhall, 2007; Long & Johnson, 2007).

5.3 Where an adult is incapable of giving consent, researchers should, without compromising the rights of that individual, consult with those who have a duty of care towards that person. This may include family members, advocates and/or statutory carers. It is recognised that a potential participant's vulnerability may often be associated with the research topic of interest, for example research exploring issues around alcohol or drug dependency or mental health, and that research frequently needs to address the sensitive issues which can lead to vulnerability in an adult (von Benzon & van Blerk, 2017; Lee 1993). Furthermore, adults who may be deemed vulnerable by the definitions given here have as much right to volunteer to participate in research as any other adult and may be especially motivated to do so when that research is relevant to the source of their vulnerability.

5.4 Where individuals lack the capacity to decide, give their permission or consent to being involved in research, then an attorney or legal proxy (such as a person holding lasting/welfare power of attorney or a court appointed guardian) along with the potential participant can contribute to a decision to participate in research (GMC 2010; Alzheimer Europe 2011). Recommended practice and policy is to take a rights based approach beginning with the presumption that 'every adult has the capacity to make decisions'; the researcher must not assume that a person lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness), beliefs, apparent inability to communicate, or because they make a decision that others disagree with or consider unwise. If a person's capacity to make a decision is impaired, appropriate help and support must be provided to maximise their ability to understand, retain, use or weigh up the information required to make a decision or communicate their wishes. The researcher 'must assess a patient's capacity to make a decision at the time it needs to be made'(MCA, 2005; GMC 2010).

5.5 Independent mental capacity advocates (IMCAS – Department of Health and Social Care, 2007) are available for individuals who lack capacity and do not have friends or family to represent their views. Ordinarily they work with individuals who lack capacity in relation to their care, treatment or protection to ensure statutory principles, requirements and factors are followed when assessing a person's capacity and they follow statutory safeguards to protect vulnerable adults. They *may* support vulnerable adults in relation to research participation, but this is not guaranteed. A vulnerable adult may also have someone who has 'lasting power of attorney (LPA) that is a statutory form of power of attorney created by the Mental Capacity Act (2005). People with capacity can 'choose a person or attorney to make decisions on their behalf if they subsequently lose capacity' (see HRA).

5.6 Researchers also need to be mindful that loss of capacity may be a temporary state (e.g. as a result of road traffic accident, seizure, or medical procedure etc.). Additionally, research participants may lose capacity and become 'vulnerable' after they have consented to take part in research studies, for example as a result of change of circumstances or progression of illness or a condition. The Health Research Authority (HRA) provides guidance for researchers on how to manage such circumstances.

5.7 It should be noted that clinical trials of investigated medical products (CTIMPs) require a researcher to seek consent for a vulnerable adult lacking capacity from a legal representative. The Mental Capacity Act (2005) does not apply to CTIMPs. For non–CTIMP research advice should be sought by a researcher from a consultee (carer or another person). The consultee provides advice but not consent. Their advice can be verbal or written and a researcher

must respect this advice (See HRA). The Research Ethics Service (RES) has identified a number of NHS Research Ethics Committees (RECs) in England and Wales to review applications for approval under the Mental Capacity Act. Members of these RECs have had additional training in relation to the MCA. All intrusive research involving vulnerable adults lacking capacity must be reviewed by an appropriate body. University ethics committees are **not** recognised by the Secretary of State or Welsh Ministers as appropriate bodies under the Act. Applications under the Mental Capacity Act relating to research outside the NHS will be accepted for review by NHS RECs (see HRA).

5.8 An important consideration when involving vulnerable people in research is the clarity of the researcher-participant relationship. Some 'vulnerable' groups can lack social networks, and these sometimes can be made up more of professionals than friends. Researcher should be particularly sensitive to the fact that their relationship could be misconstrued. This risk is heightened when conducting research in participant's homes (Stalker 1998)

6. Managing Risk, Harm, Distress and Accessibility

6.1 Researchers owe a responsibility of care towards any, and all, people involved in, or impacted by, their research (see Edge Hill University Code of Practice for the Conduct of Research (RO-GOV-01) and the Edge Hill University Research Ethics Policy (RO-GOV-03)). This is particularly the case with regard to vulnerable adults where such issues as competency and consent are most pertinent. All researchers should also be cognisant of issues of disparity in relations of power and status involved in research. It is important that power and status issues are considered when working with vulnerable adults.

6.2 Researchers should also ensure that there is appropriate access to buildings or sites being used for research and that the participants are supported throughout with any accessibility needs.

6.3 Researchers who work directly with participants must undergo security screening through enhanced Disclosure and Barring Service (DBS) clearance. The DBS certificate for any staff who will have contact with participants should be submitted as part of the ethical review of the study.

6.3 All concerned in the process of the research need to identify what they understand as 'risks' that are involved for the person because of their participation in the research project. Risk assessments should clearly identify potential risks to participants and researcher and include an action plan detailing what steps will be taken to mitigate risks and a safeguarding protocol, led by the Principal Investigator or a senior member of the team.

6.4 Research involving vulnerable adult populations can make the researcher vulnerable too. This may be due to the locations where the research is undertaken, its sensitive nature (Lee, 1993) or that a researcher is working alone (Lee, 1993; von Benzon & van Blerk 2017). Good practice should be followed to minimise risk to vulnerable adults and researchers. University/faculty lone working policies should be adhered to (see the EHU lone working policy), Disclosure and Barring Service (DBS) checks undertaken and the researcher should be mindful of these and other safety issues. The latter includes a researcher having a plan, an identified exit route, ability to call for help, a before and after contact if undertaking data collection, as well as access to supervision or debriefing sessions. They should also adhere to the Edge Hill University Code of Practice for the Conduct of Research (RO-GOV-01) and the Edge Hill University Research Ethics Policy (RO-GOV-03).

6.5 The following are some questions that may help guide the researcher in the assessment of harm and distress:

- How severe may the harms associated with the research process and procedures be?
- How likely are the harms to occur?
- How invasive or intrusive is the research? (Note that these concepts would be applied just as much to the possibility of social/psychological invasion and intrusion as physical)
- How will the researcher manage the situation if the participant becomes distressed?
- Might adverse effects be brief or long-lasting, immediate, or not evident until years later?

7. Reference and Resources

HRA Decision tool. http://www.hra-decisiontools.org.uk/consent/principles-children.html

7.1 Professional Organisations Ethical Codes and Guidance

ADMP UK: Association of Dance Movement Psychotherapy UK https://admp.org.uk/

Alzheimer Europe (2011) Ethics of Dementia Research; Informed consent to dementia research. Available from https://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2011-Ethics-of-dementia-research/Informed-consent-to-dementia-research

BAAT: British Association of Art Therapy https://www.baat.org/

BACP: British Association for Counselling and Psychotherapy https://www.bacp.co.uk/

BADth: British Association of Dramatherapy http://badth.org.uk/

British Association of Social Workers https://www.basw.co.uk/

British Society of Gerontology (2012) 'BSG Ethical Guidelines', (March). Available at: http://www.britishgerontology.org/about-bsg/bsg-ethical-guidelines.html.

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British Medical Association (2018) Consent toolkit: Research https://www.bma.org.uk/advice/employment/ethics/consent/consent-tool-kit/10-research

British Sociological Association https://www.britsoc.co.uk/publications/ethics/

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General Medical Council 2020. Guidance on professional standards and ethics for doctors. Decision making and consent. General Medical Council. https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf

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Medical Research Council (2007) *MRC ETHICS GUIDE 2007 Medical research involving adults who cannot consent*. Available at: https://mrc.ukri.org/documents/pdf/medical-research-involving-adults-who-cannot-consent/

NIHR (2019). UK Standards for Public Involvement. Available at https://sites.google.com/nihr.ac.uk/pi-standards/home

Health Research Authority https://www.hra.nhs.uk/

HCPC Standards of Conduct, Performance and Ethics. https://www.hcpc-uk.org/aboutregistration/standards/standardsofconductperformanceandethics/

Higher Education Academy https://www.heacademy.ac.uk/

NAWE National Association of Writers in Education https://www.nawe.co.uk/

NHS England 2016. Accessible Information Standard. Making health and social care information accessible. Available at https://www.england.nhs.uk/about/equality/equality-hub/patient-equalities-programme/equality-frameworks-and-information-standards/accessibleinfo/

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People in Research https://www.peopleinresearch.org/

Royal College of Nursing (2011) Informed consent in health and social care research. Available at: https://www.rcn.org.uk/professional-development/publications/pub-002267

Royal College of Psychiatrists https://www.rcpsych.ac.uk/usefulresources/publications/collegereports/cr/cr186.aspx

Royal College of Nursing https://www.rcn.org.uk/professional-development/publications/pub-003138

Social Research Association Ethical Guidelines, SRA: London, available *at* :http://the-sra.org.uk/research-ethics/ethics-guidelines/

The Association for Nutrition 'Standards of Ethics, Conduct and Performance' Standards: http://www.associationfornutrition.org/Portals/0/Public/Registration/AfN%20Standards%20Ethics%20Conduct%20Performance.pdf

The Association of Internet Researchers Ethics Guidelines 2012. https://aoir.org/reports/ethics2.pdf

The Oral History Society http://www.ohs.org.uk/

UKCP: UK Council for Psychotherapy https://www.psychotherapy.org.uk/

https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/research-with-potentially-vulnerable-people/

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End matter

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