Ethical Guidance for Undertaking Research with Vulnerable Adults

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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

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), and Research Ethics Policy Appendix. 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 vulnerable adults.

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 or neglect and are unable to protect themselves from abuse, neglect or the risk of it. 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, 2008; GMC, 2010), as well as those with mental health problems, the homeless, travelling communities, asylum seekers, drug users, family carers and the bereaved or victims of abuse (Combes & Tan 2010).
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).

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.

Considerations for Informed Consent and Conducting Research
5.1 Project information sheets and consent forms should be in a variety of formats (text, Braille, spoken, audio, DVD), take 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. 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).

5.2 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 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.

5.3 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 states that the principle is 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’ (GMC 2010).

5.4 Independent mental capacity advocates (IMCAS – Department of Health, 2009) 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 Health Research Authority).

5.5 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 developing dementia. The Health Research Authority (HRA) provides guidance for researchers on how to manage such circumstances.
5.6 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).

Managing Risk
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 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 EPRC safe fieldwork protocol and 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).
Reference and Resources

Professional Organisations Ethical Codes and Forum


7.6 People in Research https://www.peopleinresearch.org/ (Accessed 19/11/18)


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


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

7.14 BACP: British Association for Counselling and Psychotherapy https://www.bacp.co.uk/
7.15 UKAHP: UK Association of Humanistic Psychology Practitioners https://ahpp.org.uk/
7.16 ADMP UK: Association of Dance Movement Psychotherapy UK https://admp.org.uk/
7.17 BAAT: British Association of Art Therapy https://www.baat.org/
7.18 BAMT: British Association of Music Therapy https://www.bamt.org/
7.19 BADth: British Association of Dramatherapy http://badth.org.uk/
7.21 General Dental Council, https://www.gdc-uk.org/
7.22 Nursing & Midwifery Council https://www.nmc.org.uk/standards/code/
7.23 Royal College of Psychiatrists https://www.rcpsych.ac.uk/usefulresources/publications/collegereports/cr/cr186.aspx
7.24 Royal College of Nursing https://www.rcn.org.uk/professional-development/publications/pub-003138
7.25 British Association of Social Workers https://www.basw.co.uk/
7.26 Health Research Authority https://www.hra.nhs.uk/
7.27 Higher Education Academy https://www.heacademy.ac.uk/
7.28 The Oral History Society http://www.ohs.org.uk/
7.29 NAWE National Association of Writers in Education https://www.nawe.co.uk/

Reports, other Publications and references


8.25 Williams SG (1993) How do the elderly and their families feel about research participation? Nurses conducting research among the elderly should know what concerns the patient and the family. Geriatric Nursing 14, 11-14.
## Ethical Guidance for Undertaking Research with Vulnerable Adults

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