Edge Hill University

Ethical Guidance for Undertaking Research with Vulnerable Adults

Contents

Introduction

- 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 Framework for Research Ethics (RO-GOV-03). 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.
- Vulnerable adults are defined as those adults lacking capacity or having potentially impaired capacity (Mental Capacity Act 2005 for England and Wales). 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, the bereaved or victims of abuse (Combes & Tan 2010).

The Research Proposal

- 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), 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; Hanley et al, 2004; North West People in Research Forum).

Considerations for Informed Consent and Conducting Research Contents →

- 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; National Research Ethics Service, 2007; also Edge Hill University Code of Practice for the Conduct of Research (RO-GOV-01) and Edge Hill University Framework for Research Ethics (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).
- 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 question of interest, and that research frequently needs to address the sensitive issues which can lead to vulnerability in an adult (Lee 1993). Furthermore, adults who may be deemed vulnerable by the definition 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.
- 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 2008). 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 2008).
- Independent mental capacity advocates (IMCAS – Department of Health, 2009) are available and abide by the code of conduct to ensure statutory principles, requirements and factors are followed when assessing a person's capacity and follow statutory safeguards to protect vulnerable adults in relation to research and possible deprivation of liberty. 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 National Research Ethics Service ; Adults lacking capacity to consent to research toolkit 2010)

- It should be noted that clinical trials of investigated medical products (CTIMPs) require a researcher seek consent for a vulnerable adult lacking capacity from a legal representative. For non–CTIMP research advice should be sought by a researcher from a consultee (carer or another person). The consultee provides advice and not consent. Their advice can be verbal or written and a researcher must respect this advice (See National Research Ethics Service). NHS research involving vulnerable adults that lack capacity must be reviewed by a NHS Research Ethics Committee and have 'flagged research ethics committees' that specifically deal with these cases. Non-NHS research involving vulnerable adults lacking capacity must be reviewed by a recognised Research Ethics Committee.

Managing Risk

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- 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 Framework for Research Ethics (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.
- Researching 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. Good practice should be followed to minimise risk to vulnerable adults and researchers. University lone working policies should be adhered to, Criminal Record Bureau 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 Framework for Research Ethics (RO-GOV-03).

References and Resources

Contents →

Professional Organisations Ethical Codes and Forum

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Reports and other Publications

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Links to internal documents updated 27 January 2016