Specialist Research Ethics Guidance Paper

ETHICAL CONSIDERATIONS IN RESEARCH INVOLVING OLDER PEOPLE

In research, as in wider society, older people are commonly excluded, marginalised or treated as less than fully competent adults. This document identifies the most common examples of unethical research practices involving older people, and suggests some best practice principles for researchers to consider applying to their own work. The most challenging issues are around obtaining informed consent from people who are in some way ‘dependent’, particularly those living in residential institutions and those with cognitive defects.

The representation of older people in research and their inappropriate exclusion

In this document, ‘older people’ are generally taken to be those aged 60 or more years. However, given that some people live for more than 100 years, this makes for a very heterogeneous demographic category, spanning more than 40 years. We expect the physiology, life experience and attitudes of 50 year-olds to differ from those of 20 year-olds: there are equally substantial differences between 60 year-olds and 90 year-olds.

Many clinical and social science studies have inappropriately excluded older people; notoriously, even trials of drugs that will be consumed primarily by older people have done this. Many ‘social care’ studies have sought to establish the wishes and preferences of older people by asking carers or surrogates. Such research designs are unethical.

The following best practice principles are suggested, with respect to the representation and exclusion of older people:

- Studies of the adult population that exclude older people only for convenience’s sake are unscientific and unethical.
- Research that seeks to establish the circumstances, preferences and views of older people by asking carers or surrogates is bad science and unethical.
- Research that seeks to represent the circumstances, attributes and opinions of all older people should address the group’s wide age range; this may require age-stratified sampling or other approaches to ensure a sufficient sample of the oldest age groups.

Care should also be taken not to over-interpret chronological age boundaries (which are no more than pragmatic devices for dividing a population or sample). A useful first assumption in this respect is that older people are no different from other adults, other than being older. Among very disadvantaged people, such as the street homeless, the morbidity and life expectancy of those aged in the fifties is comparable to that of people 20 years older in the general population. In employment or workplace studies, the term ‘older workers’ is commonly applied to those that have turned 50 years-of-age, and raises few objections.

Nomenclature

Some people in their sixties, and of greater age, deny that they are ‘old’, and take the view that the ‘really old’ are those with chronic, irreversible functional limitations (Lund and Engelsrud, 2008). Researchers should be sensitive to people’s denial of old age and their fears of declining capacities, of becoming dependent (or ‘a burden’), and of their own finitude.
The most suitable names to apply to individuals and the collective age group are much debated. A useful two-page overview of some of the options in this respect, and their pros and cons, is available from the U.S. National Academy for Teaching and Learning about Aging (www.cps.unt.edu/natla/rsrclsn_plans/plan_what_call.pdf). In the UK today, the most widely used and acceptable terms for older people are, for an individual, ‘elder’ and ‘older adult’, and for the collective, ‘older people’, ‘elders’ and ‘older adults’. In local authority and public services contexts, ‘senior citizens’ is widely used and raises few objections. ‘Retired’ and ‘pensioner’ are inoffensive euphemistic synonyms for ‘elder’, but are not always correct, particularly for women. ‘Elderly’ is the word that grates most. It is acceptable as an adjective, but the phrase ‘the elderly’ is criticised for its impersonal and stigmatising connotations that align older people with frailty and decline (as has been most evident in health-care settings and research). It is of interest that the two ‘grass-roots’ representative associations of older people in Sheffield call themselves ‘Expert Elders’ (sponsored by the city council) and ‘Sheffield 50+ Older People’s Advisory Group’ (a voluntary association).

**Consultation**

Funding bodies encourage consultation with, or the involvement of, members of the study population. In the past, many researchers erroneously believed that consultation with older people could be achieved by inviting (the staff of) advocacy organisations, such as Age Concern or Help the Aged, to fulfil that role. This is not acceptable. It is basic best practice that consulting older people and involving them in research should not be done through surrogates, except for good and stated – and exceptional – reasons.

**Vulnerabilities**

The Criminal Records Bureau’s definition of a vulnerable adult includes any resident of a care home, nursing home or sheltered housing, any person receiving statutory social care or health care, and any person who ‘requires assistance in the conduct of his or her own affairs’ (see Appendix One, below). Researchers who have unsupervised contact with, or – as in observational research, for example – proximity to, any such person will require an Enhanced CRB Check.

The vulnerabilities of some sick and frail older people are real but they are not, in all cases, manifest or known. For example, asking apparently innocuous questions about ‘where you came from’ or ‘what you used to do’ (let alone about health, spouses or children) can prompt painful thoughts or memories, and deep distress. Known or possible vulnerabilities will need to be taken into account in some research designs. In some cases, ensuring that support or medical cover is on hand is essential. Exceptionally, risk assessments for each research subject should be undertaken, in collaboration with qualified clinicians. In these respects, the following best practice principles are suggested:

- Care must be taken to ensure that information sheets, consent forms and other documents use font sizes and vocabulary that are appropriate for the study population. As ever, good practice involves direct consultation and pilot trials of materials and data collection methods.
- The vulnerabilities and sensitivities of older people are not always apparent or known. Researchers must be aware that any research contact or intervention with a vulnerable person may cause distress or harm. Advice from relevant qualified clinicians and social care staff should be sought if the research might have such impacts.
Consent
The most testing research ethics issue with regard to older people is how to obtain properly informed, and freely given, consent from those who: (a) in some way are dependent on family carers, professional carers or others, (b) live in institutional settings and, most especially, (c) have diminished cognitive capacity. These issues are confounded because some professional and institutional codes of conduct appear to contradict best research ethics practice. For example, a researcher may wish to treat hospital patients or the residents of care homes as autonomous and fully responsible adults, but the manager of the ward or home will normally expect the researcher to seek permission before speaking to (or observing) any patient or resident. As a second example, it is not uncommon for family carers or relatives to have a different view about the competence and capabilities of the cared-for person from a researcher. In situations such as these, researchers have a dual task: to follow best research ethics practice, and to obtain the co-operation and trust of family or professional carers who have medical or social-care responsibilities. This is not always straightforward, and in exceptional circumstances cannot be achieved.

Until recently, many clinical, health service research and social science studies of older people excluded those with diminished cognitive ability (whether or not established by a diagnosis of dementia or a comparable disorder, or by a threshold score on the Mini-Mental State Examination or similar) on the grounds of their inability to give informed consent. Opinion is changing, however, and an increasing number of researchers believe that most people diagnosed with ‘mild’ or ‘moderate’ dementia are capable of giving informed consent (see Buckles et al. 2003; Terson and Wallin 2003; Warner 2008).

Given the complexities of the issues with respect to consent, the following best practice principles are suggested

- Researchers should not assume unquestionably that the consent to participate in research of an (older) adult who receives any form of treatment, care or support from family carers or professional carers can be obtained from a carer or surrogate.
- Researchers should not assume unquestionably that the consent to participate in research of a (older) adult with any level of cognitive impairment can be obtained from a carer or surrogate.

References
Appendix One: The Criminal Records Bureau's definition of a vulnerable adult

A ‘vulnerable’ adult is a person who is aged 18 years or older and who satisfies any of the following criteria:

- is living in residential accommodation, such as a care home or a residential special school;
- is living in sheltered housing;
- is receiving domiciliary care in his or her own home;
- is receiving any form of health care;
- is detained in a prison, remand centre, young offender institution, secure training centre or attendance centre or under the powers of the Immigration and Asylum Act 1999;
- is in contact with probation services;
- is receiving a welfare service of a description to be prescribed in regulations;
- is receiving a service or participating in an activity which is specifically targeted at people with age-related needs, disabilities or prescribed physical or mental health conditions or expectant or nursing mothers living in residential care (age-related needs includes needs associated with frailty, illness, disability or mental capacity);
- is receiving direct payments from a local authority/HSS body in lieu of social care services;
- requires assistance in the conduct of his or her own affairs.

Source: [www.crb.gov.uk/faqs/definitions.aspx](http://www.crb.gov.uk/faqs/definitions.aspx)