Report on the research ethics workshop: ‘Doing research with vulnerable people workshop’

The workshop aimed to identify, explore & agree:

1. the meaning of the concept of vulnerability;
2. the key implications of involving potentially vulnerable people in research;
3. how the issue of informed consent should be addressed with potentially vulnerable people;
4. a set of generic principles on the issue of involving potentially vulnerable people in research.

The two presentations from the workshop can be viewed and downloaded from: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/vulnerable-.html

One presentation focuses on the concept of vulnerability whilst the other presentation addresses some of the legal and policy issues around consent, confidentiality and managing information.

Key messages from the workshop:

1. **To be human is to be vulnerable:**
   The Oxford English Dictionary definition of ‘vulnerable’ is:
   i. That may be wounded; susceptible of receiving wounds or physical injury.
   ii. Open to attack or injury of a non-physical nature; especially, offering an opening to the attacks of raillery, criticism, calumny, etc.
   In both of these senses, we are all, as human beings, vulnerable. What’s more, our vulnerability is a routine ongoing characteristic of our human being – to be human is to be vulnerable (should not have preconceptions on who is vulnerable)

   **As well as vulnerability to physical harm and vulnerability to ridicule and criticism there is also vulnerability to psychological and emotional distress. These types of vulnerability may occur in combination.**

2. **Context has an impact on vulnerability:**
   For example, crossing a busy road makes us immediately more vulnerable than staying on the pavement.
   For example, participating in a randomised controlled trial for a new surgical procedure or new drug therapy – e.g. because of the experimental or untried nature of the treatment (it may not work) or due to being allocated to a placebo group (thereby not receiving treatment) or because a conventional treatment might be less effective than an experimental new treatment.
   For example, doing social research in a violent milieu may expose research subjects to risk of physical harm.
   For example, the fact that it is difficult to anonymise participants in small-scale qualitative research may be a source of vulnerability.
   For example, in terms of psychological and emotional distress many kinds of research are inherently risky businesses. In any research dealing with sensitive topics, subjects are at least potentially vulnerable.
3. **Research can increase the potential vulnerability** of human participants but also the potential vulnerability of a participant’s relatives, friends and others with a relationship to the participant and also the potential vulnerability of the researchers themselves. This may be true in both the physical and non-physical senses.

4. **But research may also offer benefits and we should get the balance right:**
   Potential benefits include reciprocity, altruism and providing opportunities to get involved.
   Patients in both arms of a randomised control trial (RCT) may do better than those receiving usual care.
   Prospective human participants should have the right to receive support concerning making the decision on whether or not to participate in a research project.
   Prospective participants should be offered choice in relation to being fully informed about risks and benefits.

5. **In research and research ethics we should not be risk averse.**
   However, we must be **risk aware** & plan & make decisions on this awareness of risk.

**Perspectives of Researchers – The Group Discussion Sessions**

The day involved lively and well informed discussions that could inform ways of supporting ethical research with vulnerable groups. Discussions were enriched as a result of the diverse makeup of the workshop’s participants. Workshop participants included people who had experience as participants in research, researchers from a range of academic disciplines, academic staff, postgraduate researchers, some of whom brought international perspectives, and research support staff. The workshop included two group discussion sessions. Within the first session small groups considered what the key issues were concerning the involvement of vulnerable people in research. The second session, again in small groups, considered what the key issues were concerning informed consent and competency with respect to research involving vulnerable people.

**The key points that arose from the two discussion sessions are presented at Annex 1.**

**Conclusion:**

As researchers we need to consider making judgements in research and research design through adopting ethical principles. To what extent the research design addresses ethical principles could be a measure of quality.

**Ethical principles for researchers might include:**

- being reflective about their research actions and research decisions: This is a common approach in qualitative research, but should be true perhaps for all researchers whatever research design;
- being aware of power relationships in research;
- seeking to minimise the potential risks to prospective participants in their research designs and, where appropriate, offering prospective participants greater choice and options;
- being aware of the risk to researchers themselves, as well as to participants, and minimising the potential risks in their research design;
• showing respect for the potential diversity of prospective participants for diversity in their research designs;
• paying attention to communications within the research process (e.g. considering language and understanding; getting the right balance around the provision of information; issues of translation and meaning);
• considering consent as an ongoing issue, cognisant of the fact that this can also add burden to the research participants.

End note: The workshop focused on the needs of researchers engaged in health-related research. Ethical issues and rules will vary between disciplines. For example ‘covert’ research may have different parameters around ethical principles. The workshop did not cover the implications of the Research Governance Framework for Health and Social Care, which applies to all UK-based health and social care research.
Doing research with vulnerable people
Annex 1: Perspectives of researchers: points from discussion

1. Some key issues concerning the involvement of vulnerable people in research

All humans are vulnerable, but some may be more vulnerable than others. Who could these be?
Examples: - People who are ill and/or in pain;
- People who are desperate not to be ill
- People on very low incomes or the unemployed (people with capital may feel more able to resist participating in a project)
- Children showing a willingness to please
- People who suffer from Munchausen syndrome (fake disease, illness, or psychological trauma in order to draw attention/sympathy to themselves)
- People in developing countries who by participating in a clinical trial can access drugs which otherwise they would not
- The example of Bangladesh was given to illustrate the point that its citizens are vulnerable to flooding, they are very resilient when faced with the danger

Those who actually have no real choice on whether or not to participate. Who could these be?
Examples: - People with terminal illnesses
- Incapacitated adults - People with dementia
- People who lack the competence to make an informed decision
- People to whom access via a 'gatekeeper' is required – gatekeepers can make choices or prevent choices on behalf of people over whom they control access to. Research ethics reviewers/committees should avoid being too paternalistic and should not abuse their gatekeeping power over enabling or preventing researchers' access to people. Examples of gatekeepers – people in positions of power over others: Directors of care homes, prison wardens, army officers, village tribal elders.
- The example of care homes in Hong Kong was given, wherein perhaps relatively less educated care home residents feel they need to participate in studies in order to receive better treatment
People may participate due to living in cultural norms in which participation is expected
People being observed by researchers undertaking observational research

Those who may not understand what is being asked of them. Who could these be?
Examples: - People lacking linguistic competence (cultural, proficiency (limited vocabulary etc.), receiving information overload, poor communication methods)
- People lacking intellectual competence (people with Alzheimer's, strokes, learning disabilities)
- Children
- People unfamiliar with research (cultural, background/experience
- People who are suspicious (image problem of science)
- People who have a little knowledge about the research but do not understand it (‘little knowledge can be a dangerous thing’)
- Kind of research may make it hard for participants to understand – e.g. covert research methods, research that evolves over lifetime of a project, observational research

The well-intentioned who simply want to help. Who could these be?
Examples: - Doctors who have sense of obligation towards patients
- People who are altruistic (e.g. those involved in service evaluation projects)
- People who feel they want to give something back
2. Some key issues concerning informed consent and competency with respect to research involving vulnerable people

How do you know that someone has understood the information that you have given them and that they appreciate what participation will involve?
- The researcher should check that a prospective participant has understood information and should remain aware for signs of potential misunderstanding
- Ask the prospective participant to describe the research process and what involvement will mean
- Where the prospective participant’s first language is not English employ a translator to accurately translate information
- Jargon should be avoided and any terms defined
- Users themselves could be involved from the outset to some degree- e.g. from the design stage onwards
- In terms of how much information to convey to a prospective participant, where a research project is very complex lay language may not enable an informed decision to be made on whether or not to participate. However, it should be made clear to prospective participants that if, after receiving information and an explanation, they have further questions that the researcher will provide further information and explanation.

How can you judge when someone wants to withdraw from a study?
- Be alert for physical signs/body language conveying reluctance to participate
- Be alert for signs of lack of cooperation and concordance
- Be alert for behaviors that are inconsistent with 'normal' behavior
- Be alert for the potential influence of a gatekeeper applying pressure on a person to participate
- Be alert to deteriorations of physical / mental capacity

How long do they have to withdraw?
The length of time in which to withdraw depends very much on nature of the research and it should be made clear at the point of consent

Further question raised: Is there a point at which withdrawing becomes no longer an option? – Three examples: samples/tissues are now being used in experiments or original data collected has been processed or the research has already been published

Further question raised: Where a research project involves collecting data at several points (multiple data collection), if a participant withdraws far into the research project should the researcher remove all their data?

Who owns the data? – participant?, researcher?, grant holder?, research funder?, gatekeeper? public?
Further questions raised: Is a simple principle possible? – can you own everything?
Ownership in a material sense? in a psychological sense? in a political sense?
Who has ownership over raw data? over processed data? over a publication?
There is an argument in favour of each potentially owning the intellectual property
The decision on data ownership can have an impact on an individual’s career and on institutional mobility: student, supervisor, research assistant, PI
There may be commercial issues and research exploitation issues
There may be political issues – a belief that the research should be in the public domain (intellectual democracy)