1. Tagline Find important information here on [ethical considerations relating to] RESEARCH WITH POTENTIALLY VULNERABLE PEOPLE

2. Brief intro Researchers will need to consider additional ethics concerns or issues arising from working with potentially vulnerable people. Vulnerability may be defined in different ways and will often be influenced by the research context.

For example, vulnerability may arise due to age, as a result of being in an abusive relationship, disability, potential marginalisation, and due to disadvantageous power relationships within personal and professional roles. Participants may not be conventionally 'vulnerable', but may be in a situation that means they can feel coerced or pressured into taking part, for example in prison, the armed forces or a dependent relationship, so extra care is needed to ensure their participation is truly voluntary.

3. High level principles / considerations
Researchers will need to assess potential vulnerability within the context of the research, as well as the potential consequences of participation (immediate and long-term) and potential lack of benefit where this is immediately needed or expected by participants. Vulnerability should be considered on a case-by-case basis; many groups or individuals not traditionally considered as vulnerable could be exposed to issues as a result of participating in research that makes them vulnerable.

Researchers should consider the following:

- Participants' vulnerability
- Potential negative consequences or lack of personal benefits from their involvement in research where these are expected
- Providing appropriate information to elicit freely-given informed consent for participation as well as information regarding data deposit and data re-use (where deposit is possible)
- Limits to confidentiality and occasions where this may occur, such as when child safeguarding issues arise
- Legal requirements of working with the specific population (including Disclosure and Barring Service clearance)
- Incentives and compensation for participation.

Researchers' responsibilities

When working with participants who are considered vulnerable, researchers may find themselves in a position of increased responsibilities or expectations (for example when an interview reveals that a participant is in significant danger and the researcher is obliged to take action), which do not fall within the scope of the research project. Researchers should endeavour to assess the likelihood of additional ethics issues and develop strategies and a framework of clear responsibilities they can refer to should such issues arise. They should also use research ethics committee and, within the health and care setting, local safeguarding teams as valuable resources for advice and guidance. Researchers should be able to justify the approach they take in dealing with unforeseen ethics issues (should these arise) and maintain the integrity of the research.

Consent from potentially vulnerable people

Researchers should make participants aware of the limits to confidentiality when taking consent and decide whether verbal or written consent will be more appropriate to protect participants' interests.

When research involves potentially vulnerable groups, for example children, older persons or adults with learning disabilities, or those who fall under the Mental Capacity Acts, every effort should be made to secure freely given informed consent from participants. Researchers should ensure that they have the time and opportunity to access support in their decision-making, for example by discussing their choice with a trusted adult or relative. Passive assent, including group assent (with consent given by a gatekeeper) should be avoided wherever possible, and every effort should be made to develop methods of seeking consent that are appropriate to the groups studied, using expert advice, support and training where necessary.

Child Protection

Researchers working with children in health and social care settings should have appropriate training in child protection and understand when and how to raise a concern. Researchers have a responsibility to ensure they have procedures in place at the outset of a study to manage any safeguarding concerns that may arise.

Consent from participants who fall under the Mental Capacity Act 2005 / Adults with Incapacity (Scotland) Act 2000 / Mental Capacity Act (Northern Ireland) 2016

Participants who fall under these acts should be adequately and appropriately informed of potential risks arising from their participation in research. When presented with sufficient information individuals will usually be able to use reasoned judgement to decide whether or not to take part. Researchers need to ensure that prospective participants have the capacity to understand the consequences and risks of participating in order to give valid consent. In some cases, where an individual cannot give consent, it is appropriate for a consultee, relative or legal representative to provide consent.

Specific tools provide detailed guidance to researchers about <u>seeking</u> <u>consent from adults lacking capacity.</u>

4. Brief explainer against each document / link

Further information

Key resources

- UKRI Preventing harm in research and innovation
- HRA Decision Tool for research involving adults lacking capacity
- Mental Capacity and the law (Royal College of Psychiatrists)
- Health Research Authority: Mental Capacity Act
- Health Research Authority: Research Involving Children
- NSPCC: Research with children: ethics, safety and avoiding harm
- NSPCC: Child protection system in the UK
- UKCDR Guidance for Safeguarding in International Development
 <u>Research</u>

Mental Capacity Acts

- <u>Adults with Incapacity (Scotland) Act 2000</u>
- Mental Capacity Act 2005
- Mental Capacity Act (Northern Ireland) 2016

5. Case study (or case studies) Case Study: <u>Anonymity and consent in research with asylum seekers</u> Case Study: <u>Researching involving harm to participants</u>

NB. These are the other documents/links provided on the ESRC page (for reference) but probably do not need to be added to the resources list unless a gap is identified

- Access Northern Ireland
- Adults with Incapacity Act 2000: Code of practice
- Adults with Incapacity (Ethics Committee) Scotland Regulations 2002
- Mental Capacity Act and consent for research (PDF) (Gov.Wales website)
- Disclosure and Barring Service
- Disclosure Scotland
- Mental Capacity Act 2005 Questions and Answers (Health Research Authority website)
- Mental Capacity Act 2005
- Mental Capacity Act 2005 Code of practice (Gov.uk website)
- Protecting of Vulnerable Groups (Scotland) Act 2007
- <u>Rehabilitation of Offenders Act 1974</u>
- <u>Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (Amendment) (England and Wales) Order 2013</u>
- <u>Safeguarding Vulnerable Groups Act 2006</u>