Research Ethics: Definition of key terms

Animals
Anonymity
Children and young people
Confidentiality
Consent
Deception, concealment or covert observation
Incentives
Invasive procedures and intrusive interventions
Risk
Vulnerable groups

Animals

For the purposes of ethical review, a distinction is made between vertebrate animals (including cephalopods) protected under the Animals (Scientific Procedures) Act 1986 (ASPA), and all other vertebrates and invertebrate animals (i.e. all multicellular organisms which are not plants or fungi).

Under the Act, a ‘protected animal’ is defined as ‘any living vertebrate, other than man, and any living cephalopod’. As detailed in the Home Office guidance, ‘embryonic and fetal forms of mammals, birds and reptiles are protected animals once they have reached the last third of their gestation or incubation period’, ‘larval forms of fish and amphibians are protected animals once they are capable of feeding independently’ and ‘cephalopods are protected animals from the point when they hatch’. A protected animal is considered to be ‘living until its circulation stops permanently or its brain is destroyed’. Furthermore, ‘ASPA considers a decerebrate animal to be living, and therefore protected, because its circulation is functioning and its brain is not completely destroyed’. Please refer to the ASPA guidelines. See also Nuffield Council on Bioethics, The Ethics of Research involving Animals (London, 2005).

Anonymity

Unless participants consent to their identity being known, every effort should be taken to ensure that data remains anonymous and cannot be traced back to named individuals. The anonymisation of locations may also be required.

Children and young people

Having ratified the UN Convention of the Rights of the Child (UNCRC), the UK defines a child as ‘every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier’. However, different definitions are in use across the UK depending on the legal context. In Scotland, under the Children (Scotland) Act 1995 a child is generally defined as someone under the age of eighteen, but in relation to matters including children’s hearing and children protection orders a child means someone who has not attained the age of sixteen years. The Children and Young People (Scotland) Act 2014 defines a child as someone who has not attained the age of eighteen. It also contains provisions to ensure that looked after

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2 A detailed overview of the different definition is given in Scottish Government, National Guidance for Child Protection in Scotland (2014), pp.8-9
children (those in the care of a local authority) are entitled to aftercare support up to the age of twenty-six.\(^3\) One of the general principles of the UNCRC is that ‘every child has the right to express their views, feelings and wishes in all matters affecting them, and to have their views considered and taken seriously’ and researchers should ensure that all children are consulted appropriately, with due regard to their age, maturity and circumstances.

**Confidentiality**

Data received from participants in confidence or of a confidential nature, should be kept confidential and should only be accessible to designated or relevant members of staff. Although some information may be disclosed in exceptional circumstances, for instance if there is perceived to be a risk to an individual, extreme caution should be exercised in doing so. Researchers working with children and other vulnerable groups should be clear about their responsibilities in this regard, familiarise themselves with procedures for action and ensure that participants are fully informed prior to the commencement of research. Personal data must be processed in accordance with the provisions of the [Data Protection Act](https://www.gov.uk/government/legislation/data-protection-act) and with reference to the University [Data Classification and Handling Policy](https://www Example.com).

**Consent**

Informed consent is a key principle of research ethics. Participants must be informed fully about the nature, methods, purpose and future use of the research they are being asked to participate in. Researchers must ensure that they have provided participants with sufficient information regarding the nature of the research study and any potential risks so that they are able to make an informed decision regarding whether or not to participate. Participation should be free from coercion or threats. Researchers must not use their relationship or potential position of authority over participants to pressure them into taking part.

Researchers should provide participants with a clearly written information sheet and give them ample time to read, digest the information and ask further questions of the researchers.\(^4\) The information sheet should also provide participants with the researcher’s University contact information so they are able to contact the researcher at a later date if necessary. Personal telephone numbers should not be disclosed. Participants should be informed of their right to withdraw from the study either during or after subject to established deadlines.

Consent forms should normally be obtained in a written format, completed, signed and dated by the participant, these forms would then be retained by the researcher. However, it is acknowledged that this is not always possible, for instance if participants have limited literacy skills or if research is being conducted online, and there should be an adapted consent procedure in these instances e.g. checkboxes completed before and after an online questionnaire or oral consent provided in the presence of at least one witness.\(^5\) Consent forms should make explicit reference to the dissemination of outcomes and findings for all types of research, however especially for visual research methods where research may contain identifiable or potentially identifiable individuals.

**Working with potentially vulnerable adults:**

Special care should be taken when seeking consent from participants who may lack the legal capacity to provide this consent. Vulnerable adults should be given time and opportunity to access support in their decision-making. Research issues should be explained to them in ways that they can fully understand, in a language which is appropriate to them, they should also be given the opportunity to provide consent in a way that fits with their communication repertoire. Although it may be necessary to gain consent from a gatekeeper or appropriate adult it is good practice to enable the vulnerable adult to provide consent for themselves. Such

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\(^3\) See current Scottish Government guidance on looked after children and young people.  
\(^4\) Information should be conveyed in simple English and translated into other languages if appropriate.  
\(^5\) The [UK Data Archive](https://www.ukdataservice.ac.uk) provides advice gaining written or oral informed consent - written or oral.
participants should have the opportunity to contradict the decision of their guardian or carer. Every effort should be taken to develop a method of consent that is appropriate for the group of participants.

Guidance recommends that researchers should identify someone who is familiar with the person who lacks capacity but is not a professional or paid care worker. The person giving consent should be someone that the person that lacks capacity trusts to make decisions for them, this should be a family member or a close friend. If no suitable person can be identified a nominated consultee should be proposed by the researcher. This person should be prepared to be consulted by the researcher but has no connection with the research project, in such cases this could be a professional care worker, such as a GP, social worker, school teachers or carers. It should be noted that a person’s ability to give or not give consent may change over the life of the project and that the provision of consent should be regarded as a process not a one off agreement.

Working with Children and young people

Given the particular sensitivities of involving children and young people under the age of eighteen in research, careful consideration needs to be given to the issue of consent. When involving children in research, care should be taken to ensure that the methods for informing and obtaining consent are appropriate to the age and maturity of each child. This applies even if children are very young. In most cases, consent will also be required from parents or guardians, and in some instances it may be necessary to gain the consent of other gatekeepers (e.g. a teacher for research undertaken in a school). Such consent should be sought in addition to the consent of children and parents/guardian rather than in place of it. The specific nature of the research should determine the correct approach to be taken and appropriate guidance should be sought in each case.

Enduring Consent: The ESRC defines enduring consent as consent with no time limit unless consent is withdrawn. Securing enduring consent may be essential in longitudinal studies.

Broad Consent: Involves participants consenting to a framework of future research, not simply to an individual project.

Deception, concealment or covert observation

The deception of participants, concealment of the purposes of research and covert observation is generally discouraged. Guidance from the British recommends that ‘deception or covert collection of data should only take place where it is essential to achieve the research results required, where the research objective has strong scientific merit and where there is an appropriate risk management and harm alleviation strategy’. Research that plans to undertake such methods should be subject to full committee review. Best practice suggests that where possible participants are debriefed at the end of the study on the true aims and objectives of the research and are given the opportunity to withdraw their data from the research.

Incentives

In certain circumstances, it is considered appropriate to provide research participants with a small monetary reimbursement to compensate them for their time and any expenses incurred. However, care should be taken to ensure that payments do not override freely given consent and it should be made clear to participants they are still able to withdraw from the study at any time without losing their reimbursement. To avoid coercion or undue inducement, no incentives should be given for participation in research.

Invasive procedures and intrusive interventions

The University of Stirling determines invasive procedures and intrusive interventions to include research that involves substantial physical contact with or impact on the human body. Procedures which are considered to be invasive include the collection and use of samples such as bodily tissues (e.g. blood, faeces/urine or puncturing the skin for muscle biopsy) and intrusive interventions include the ingestion of food, fluid or

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medicines as well as vigorous physical exercise and hypnosis. Further research which would be considered under the term invasive research include procedures using electromagnetic fields or ionising radiation and may include the use of recording devices such as: Magnetic Resonance Imaging (MRI), Electroencephalogram (EEG), Magnetoencephalography (MEG), Transcranial Magnetic Stimulation (TMS), Electrooculography (EOG – measurement of eye movement), Electromyography (EMG), recording of heart rate or galvanic skin response (GSR), or X-rays. This list is not exhaustive, if in doubt of whether research should be classified as physically invasive or intrusive, seek advice.

Risk

The ESRC FRE guidelines support the principle that ethical scrutiny should be proportionate to the level of risk established in the research proposal and its potential benefits. When considering risk in association with research proposals it is often defined by reference to the potential physical or psychological harm, discomfort, stress or reputational risk to human participants that a research project might generate. Even though the research may pose no physical risk to a participant researchers must consider the wider range of risks to a participant’s social or occupational standing. Researchers should take responsibility for identifying risks to their own well-being and take appropriate action.

Types of research that may be low-risk or require only light-touch review:

- Research involving anonymous, self-completion questionnaires
- Certain research that replicates a previous study that has been granted ethical approval
- Research that uses secondary data without risking the anonymity of the participants.
- Research that has been reviewed by another ethical review body e.g. NHS research, there is no requirement for a further review however the ethics committee should be made aware that the research is being carried out and hold a record of the NHS REC decision.

Research that is considered to be high risk is that involving:

- The use of vertebrate animals (including cephalopods) protected under ASPA (see Error! Reference source not found. definition)
- Potentially vulnerable individuals
  - Children and young people under the age of eighteen
  - those with a learning disability or cognitive impairment
  - individuals who are vulnerable due to a dependent on unequal relationship
  - Individuals who lack capacity to make decisions
- Potentially sensitive topics/areas of research
  - Sexuality
  - Illegal behaviour
  - Political opinion
  - Religious, spiritual or other beliefs
  - Experience of violence, abuse or exploitation
  - Physical or mental health conditions
  - Race or ethnicity
  - Conflict situations
  - Crossing the boundary between public and private spaces
  - Children considered to be at risk of harm.8

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7 These examples of intrusive interventions are given in the ESRC Framework for Research Ethics (2015), p.10.
8 Risk factors are multiple and diverse and can be assessed at various levels (e.g. individual, family, community). Some examples are: experience of abuse or neglect, having a disability or illness, and living in poverty. Children are considered to be at particular risk if protective factors (e.g. those that support safe and supportive families and resilience in children) are absent.
• Individuals that may not be or may not feel able to freely consent to participation in the research
  o Those who depend on the protection of or may be influenced by research gatekeepers – school pupils, members of the armed forces, young offenders, prisoners, asylum seekers, organisational employees
  o Family members of the researcher
  o Those in hierarchical institutional relationships
• Deceased persons, body parts or other human elements – carried out under the relevant legislation
• Deception, concealment or covert observation
• Invasive research methods
• Risk to the safety of the researcher
• Research involving international partners or being undertaken outside of the UK where there may be issues of local practice or political sensitivities
• Internet-mediated research
• Visual or vocal methods where a participant or other individuals may be identifiable in the material used or generated.
• Linking of personal data which may potentially compromise the anonymity of participants.

Vulnerable groups

Vulnerable groups include: children and young people; individuals with learning or communication difficulties; older persons or adults with learning disabilities or those who fall under the remit of the Mental Capacity Act 2005/Adults with Incapacity (Scotland) Act 2000; patients in care; individuals in custody, on probation or under court order; and individuals engaged in illegal activity. Researchers should take extra care when considering undertaking research and therefore seeking valid consent from any participant who is in a dependent or unequal relationship to them. All individuals need to feel able to withdraw from a study e.g. children taken away from their classroom setting should still feel able to withdraw without circumstance.