**Guidelines for Ethical Approval of Research Involving Human Participants**

**Introduction**

1.1 The objectives of the Ethics Committee are to maintain ethical standards of practice in research, to protect the dignity, rights and welfare of research participants, both subjects and investigators, and to provide reassurance to the public that this is being done. In achieving these objectives, the members of the Ethics Committee should remember that research benefits society and that they should take care not to hinder it without good cause. The Ethics Committee also protects researchers from unjustified criticism.

1.2 All research involving human participants, whether undertaken by the University's staff or students, must undergo an ethics review and ethical approval must be obtained before it commences. 'Human participants' are defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids, and personal data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements)

1.3 It is the responsibility of the person proposing to carry out a research project involving human participants to obtain the approval of the Ethics Committee. If a project is to be undertaken outside the University where a local ethics procedure exists (e.g., within an NHS organisation), the University's Committee need not necessarily be involved. However, approval of the local committee must be sought and obtained before research commences and the Research Governance and Planning Manager must be provided with all documentation relating to the approval.

1.5 Investigators must ensure that there is no undeclared conflict of interest (which may be personal, academic, or commercial) in their proposed work and that the relation between the sources of funding and researchers' control over results is made clear, specifically in relation to the ownership, publication and subsequent use of research data.

**2. Protection of Participants and their Rights**

2.1 All participants have the right not to participate in any investigation and this right must be respected. There must be no attempt to compel research participants to participate in the research. Students and others in a dependent relationship with investigators must be assured that any decision not to participate will not prejudice their academic or other progress in any way.

2.2 Each participant must have the right to withdraw easily from the project whenever and for whatever reason without explanation or penalty.

2.3 All participants and researchers have the right to expect protection from physical, psychological, social, legal and economic harm at all times during the investigation. Where there are significant risks a risk assessment will need to be undertaken. Participants and researcher staff must be fully informed in advance of and protected against any hazardous, stressful or uncomfortable contexts and procedures. In addition, researchers should attempt to avoid harm not only to an immediate population of participants but also to their wider family, kin and community. Please see our risk assessment policy and template.

2.4. Should any adverse event occur, the researcher must report this immediately in writing to the Ethics Committee.

2.5 All participants have the right to expect that the information supplied by them will be treated as confidential and will be protected as such.

2.6 All participants have the right to expect that their identity will be protected. Participants need to be informed about circumstances that might require their identity to be disclosed.

2.7 Researchers must be aware of requirements with respect to personal data laid down in the Data Protection Act 2018. Please see the data protection and research activity policy.

2.8 Participants should be advised how, when and in what form, it is planned to disseminate the findings of the research.

**3. Informed Consent**

3.1 Prospective participants, and their carer, parent or guardian if appropriate, should be provided with as much information as possible about the research to enable them to make an informed decision about their possible involvement. Information should be provided to participants in an accessible manner. If consent is not to be secured a statement justifying this must be provided. The primary objective is to conduct research openly and transparently without deception.

3.2 It should be remembered that research staff are also participants and need to be made fully aware of the proposed research and its potential risks to them.

3.3 Informed consent should be given on a consent form or recorded if oral consent is obtained. It is also good practice to provide participants with a separate participant information sheet in advance.

3.4 Consent forms must be signed by participants before the start of any project indicating that they are giving their informed consent to participate in the project. However, consent should be considered as an on-going process throughout the life of a project and should be reviewed with participants on a regular basis.

3.5 If the participant is not capable of giving informed consent on their own behalf then consent must be obtained from a carer, parent or guardian. A person who is incapable of providing valid consent on their own behalf may nonetheless be capable of expressing their assessment (agreement) or dissent (disagreement) about participation. The assent of the participant should be obtained where possible; if a prospective participant expresses dissent, they should not be involved.

> 3.5.1. Consent and children: Minors (under the age of 18) with sufficient understanding of the nature, purpose and potential risks of the research are able to give their consent to participate in research. The ability to understand will be heavily influenced by how the information is presented to the minor. As a matter of good practice, parental consent should also be sought, unless the minor objects to this. The researcher should think carefully about whether to include the minor as a participant should this be the case. Consent from a carer, parent or guardian must be obtained if the minor lacks the necessary understanding to provide valid consent.
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> 3.5.2 Adults lacking capacity: The law in England and Wales does not recognise proxy consent by a relative if an adult lacks capacity to provide informed consent. Such persons can only be included in research projects under the conditions laid out in sections 30 to 34 of the Mental Capacity Act 2005. Consulting the person's carer is required and the person cannot

be included as a participant if they object or appear to object, if it contradicts an advance decision made by them which has effect, or any other previous statement that was not subsequently withdrawn.

3.6 Consent should also be obtained for the sharing of research data as appropriate and for the publication of findings. Many funding bodies require that data obtained from a funded project are made available for research undertaken by others at a later date. Participants should be advised how the data that they provide will be stored, used and accessed including details of how confidentiality will be maintained. Consent for this needs to be obtained from participants before the start of the original project.

3.7 Participants should be provided with a copy of their signed consent form.

**4. Recruitment of and Payments to Participants**

4.1 Advertisements or other recruiting materials seeking human participants for a research project require ethical approval. Such material should also include the name of the Voice Study Centre unless you are acting as an independent researcher.

4.2 Participants must be clearly advised, in advance, of any arrangements to reimburse them for expenses incurred or for loss of earnings.

4.3 Incentives, additional payments and rewards paid to participants require approval by the Departmental Director of Research / Ethics Officer, Faculty Ethics Sub-Committee or the Full Ethics Committee as appropriate.

**5. Ethics Standards of External Bodies**

5.1 In addition to University guidelines, researchers should be aware of ethics codes of the relevant professional or regulatory bodies related to their research. Such codes should be followed.

5.2 If research is to be conducted in an institutional setting other than the University, eg NHS organisations, schools, prisons, etc, researchers must follow any ethics standards, procedures and regulatory guidelines of that institution. This will include obtaining approval from the local ethics committee, if required, and may necessitate obtaining a Disclosure and Barring Service (DBS) check.

5.3 The following documents and websites may be useful:

British Psychological Society: Code of Conduct and Ethical Guidelines

(https://www.bps.org.uk/news-and-policy/bps-code-ethics-and-conduct)

British Sociological Association: “Statement of Ethical Practice for the British

Sociological Association” (https://www.britsoc.co.uk/publications/ethics/)

Economic and Social Research Council: “Framework for research ethics

(FRE)” (https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/)

Government Office for Science: “Rigour, Respect, Responsibility: A

Universal Ethical Code for Scientists”

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads

/attachment_data/file/283157/universal-ethical-code-scientists.pdf)

Human Tissue Act 2004

(http://www.legislation.gov.uk/ukpga/2004/30/contents)

Medical Research Council: Good research practice: Principles and

guidelines (https://mrc.ukri.org/publications/browse/good-research-practiceprinciples-and-guidelines/)

Mental Capacity Act 2005

(http://www.legislation.gov.uk/ukpga/2005/9/contents)

NERC: Ethics Policy (https://nerc.ukri.org/about/policy/policies/)

NHS Health Research Authority: https://www.hra.nhs.uk/

Ofcom Broadcasting Code (https://www.ofcom.org.uk/tv-radio-and-ondemand/broadcast-codes/broadcast-code)

RESPECT project funded by the EC's IST programme to draw up

professional and ethical guidelines for the conduct of socio-economic

research (www.respectproject.org/main/index.php)

RESPECT Code of Practice for Socio-Economic Research

(www.respectproject.org/code/respect_code.pdf)

Royal College of Physicians of London (www.rcplondon.ac.uk/): "Guidelines on the Practice of Ethics Committees in Medical Research involving Human Subjects" (Fourth edition) published in September 2007 and "Ethics in practice – Background and recommendations for enhanced support: A report of the Working Party on Clinical Ethics"

Social Research Association: "Ethics Guidelines" (https://thesra.org.uk/SRA/Ethics/Research-ethics-guidance/SRA/Ethics/ResearchEthics-Guidance.aspx?hkey=5e809828-fb49-42be-a17e-c95d6cc72da1)

Society of Editors' Code of Practice (https://www.societyofeditors.org/resources/editors-code-of-practice/)

UK Research Integrity Office (https://ukrio.org/research-ethics-support-andreview/)