



Prifysgol Cymru
Y Drindod Dewi Sant
University of Wales
Trinity Saint David

Research Ethics & Integrity Code of Practice

2017 - 2020

Introduction

The University of Wales Trinity Saint David is committed to the maintenance of high ethical standards in the research undertaken by its staff and students, whether supported directly by the University or funded by external sources. The University recognises its obligations under the Concordat to Support Research Integrity to ensure that research undertaken under its auspices is conducted to appropriate standards, and conforms to generally accepted ethical principles and practices of conduct and governance.

The University believes that research ethics review and approval are important for the following reasons:

- To enhance the quality and integrity of research;
- To protect the rights and welfare of participants and minimise the risk of physical and mental discomfort, harm and danger from research procedures;
- To protect the welfare of researchers and their right to carry out legitimate investigations;
- To minimise the potential for claims of negligence made against the University, its researchers and any collaborating individual or organisation;
- To ensure the reputation of the University for the research it conducts and sponsors;
- To ensure that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards;
- To support a research environment that is underpinned by a culture of integrity and based on good governance, best practice and support for the development of researchers;
- To ensure that transparent, robust and fair processes to deal with allegations of research misconduct should they arise;
- To work together with other institutions as required from time to time to strengthen the integrity of research and to reviewing progress regularly and openly.

The procedures and guidelines outlined in this code of practice apply to all academic and administrative staff, those holding honorary positions at the University, and all students conducting research projects and related activities as part of undergraduate, postgraduate and short courses and research programmes in which students are enrolled/registered at, and/or supervised by staff at the University. The exception shall be cases where the Principal Researcher is registered elsewhere providing that the research project has been approved by an equivalent ethics committee following a comparable level of ethics review.

This code of practice does not refer directly to broader questions of ethical behaviour within the University in areas other than research.

The Terms of Reference for the Committee can be found in Chapter 2 of the Academic Quality Handbook (AQH) 2017-18.

1. Ethics Committee Membership

Membership of the University's Ethics Committee shall be reviewed on an annual basis. In each instance members will act as their respective Faculty's Research Ethics Officer and should seek to ensure that colleagues are aware of the roles and duties of the Ethics Committee and should seek to promote the highest standards of ethics and integrity across the research activities of the University as set out in this Code of Practice.

The membership of the University's Ethics Committee consists of:

The Chair of the Research Degrees Committee or nominee (Chair);

Two named representatives from each Faculty with a minimum of one representative in attendance at a meeting or participating in each e-cycle.

Executive Research Development Officer (RIES)

2. Ethical Principles for the conduct of research

Research conducted in and by the University should be undertaken in accordance with commonly agreed standards of good practice. The Concordat to Support Research Integrity recognises that the core aspects of research integrity include:

- **Honesty** in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.
- **Rigour**, in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.
- **Transparency and open communication** in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.
- **Care and respect** for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations.

These fundamental and widely accepted principles may be broadly operationalised as:

- Beneficence: 'do positive good'
- Non-maleficence: 'do no harm'
- Protect participants' interests and /or rights
- Ensure participant and researcher safety and risk: i.e. the need to avoid harm or potential harm.
- Consider and protect against where necessary the impact of work on others
- Ensure informed consent: i.e. the need to inform participants of the aims and procedures of the research and obtain their agreement to take part on the basis of this information
- Avoid deception: i.e. the need to avoid deception in informing participants about the research, or to justify the need for deception if necessary
- Provide debriefing: i.e. the need to provide participants with additional information to support them after taking part in the research, and/or to provide true information if deception was necessary originally

- Allow withdrawal from Investigation: i.e. the need to inform participants of their right to withdraw from the research at any stage, including during or at the end of their involvement
- Ensure confidentiality: i.e. the need to reassure participants that information they provide will not be disclosed without prior consent to others other than within the context of the research, or at a minimum will be made anonymous
- Data security and archiving: i.e. to ensure that research data is held in a secure manner consonant with the requirements of the Data Protection Act and that it is archived in such a way that it will be accessible for future audit purposes. Special attention should be made with regard to funding body requirements to submit research data to open repositories.

The University recognises that researchers must be able to exercise freedom in their academic choices, and must also accept responsibility for the decisions they make. Thus, the primary responsibility for ensuring that they act according to these principles in all aspects of their research work, including peer review, lies with the individual. However the University, funders of research and other organisations engaged with supporting research and researchers also have important roles to play. The governance process for staff and the University are outlined in this code of practice. In this regard, in line with the Concordat, this Code of Practice seeks to ensure that:

1) Researchers, whether at undergraduate, postgraduate or staff level in the University understand the expected standards of rigour and integrity relevant to their research and maintain the highest standards of rigour and integrity in their work at all times.

2) The University is responsible for maintaining a research environment that develops good research practice and nurtures a culture of research integrity, and supports researchers to understand and act according to expected standards, values and behaviours, and defending them when they live up to these expectations in difficult circumstances.

3. Research which should be considered for ethical approval

General guidance is available in these pages, but in principle careful ethical consideration should be given to any piece of work at any level conducted within the University, or in partnership with it, that implicates the involvement of others (human or animal) or has the capacity to interfere with or make a difference to their lives. 'Others' commonly refers to participants in the research, but could also refer to others affected by it e.g. at risk of physical or mental harm. This is without reference to the length of the piece of work, or the level at which it is undertaken. Researchers in all cases will:

- ensure that all research is subject to active and appropriate consideration of ethical issues;
- comply with ethical, legal and professional frameworks, obligations and standards as required by statutory and regulatory authorities, and by employers, funders and other relevant stakeholders.

It is not possible to provide exhaustive checklists of criteria which determine whether or not a proposed research project concerned with human subjects must or need not receive prior independent ethical review. Appendix A lists the types of research which prima facie should have an independent ethical review but, in general, any research project which has the potential to harm, upset or significantly inconvenience a participant, or seek confidential or sensitive personal information about a participant or where the relationship between the researcher and the participant is unequal, should be reviewed by the Ethics Committee Likewise, research involving any animal, including invertebrates must be submitted for

ethical approval. Note that research involving procedures on live vertebrates and cephalopods must comply with the Animals (Scientific Procedures) Act, 1986, which requires a Home Office Licence for individual researchers, the establishment(s), and the project involved. More guidance can be found at: <https://www.gov.uk/guidance/research-and-testing-using-animals>

4. What happens if I have not applied for or obtained ethical approval?

Failure to follow the University's guidance on ethical review of research may result in disciplinary action. If an individual becomes aware that ethics approval should have been sought then a form should be submitted as soon as possible, with an explanation concerning the reasons for later submission. Where the Ethics Committee become aware that research is being conducted in breach of these policies and procedures or of researchers who are not complying with them, the matter may, in relevant cases be resolved by informal discussion with the researchers and remedial action being taken by them. However, where necessary the matter may be formally presented to the University Ethics Committee. Ultimately non-compliance that cannot be resolved through the channels mentioned previously may become a disciplinary matter.

Refer also to Section 16 below.

Procedures for the Ethical Approval of Research Projects:

The form PG2/E1 should be used by all students and staff undertaking research regardless of level of study or size of research project.

5. Taught Undergraduate, Taught Postgraduate Courses and Undergraduate Dissertations

The Ethics Committee does not, under normal circumstances, review and approve research projects and related research activities conducted as part of taught undergraduate, taught postgraduate, taught short course programmes, or undergraduate dissertations. It does however provide advice, guidance and support to academic staff supervising such teaching, assessment, projects and activities. Each Faculty has its own procedures for ensuring that research conducted in their respective programmes does not breach ethical standards and these are appended to this Code of Practice. These procedures will be reviewed and updated as required and no-less often than is this Code of Practice. Faculty procedures will be reviewed and updated annually and reported to the University Ethics Committee.

6. Taught Postgraduate Dissertation

In the case of dissertations carried out on taught postgraduate courses the responsibility for ethical considerations should be with the research supervisor, and module leader, who should advise the student in line with standard ethical practices and the guidance contained on these pages. For all cases where the School is able to provide ethical approval an annual report shall be forwarded to the Ethics Committee detailing dissertation titles, student names and short statement confirming that no ethical issues have been identified. This will be held by the Academic Office.

In cases where ethical issues are identified by the supervisor, and module leader, then the Ethics form should first be referred to the Faculty Ethics Committee and if necessary these

could subsequently be referred to the University Ethics Committee. Instances needing referral include, but are not limited to, research that implicates the involvement of others (human or animal) or has the capacity to interfere with or make a difference to their lives, that which involves extensive travel abroad to areas associated with safety risks and access to websites or other media which deal with particularly sensitive topics. Due regard shall also be made for the risks identified in Sections H. If any such circumstances are identified the Ethics Committee may refer the application to the University's Health and Safety Officers (care of the Operations Department) for advice or a full risk-assessment.

7. Research Degrees

All prospective research projects, whether at MPhil or Doctoral levels, should be referred to the Ethics Committee by the student and supervisory team for approval after the proposal form (PG1) has been approved by the Research Degrees Committee. The standard PG2/E1 Application for Ethical Approval Form should be completed in these cases and submitted to the Ethics Committee. All research students are required to complete this form. If the research does not include the collection of primary data then some sections do not need to be completed (see guidance notes on form). A copy of the form shall be retained in the Academic Office.

7.1 Risk Assessment

In addition to requiring the completion of the PG2/E1 Application for Ethical Approval, some researchers may also be required to undertake a full risk assessment and will be referred to the University's Health and Safety Officers for further advice. Where this is the case the Academic Office is required to retain a copy of the Risk Assessment. For guidance applicants should assume that a Risk Assessment Form may be requested by the Ethics Committee if the research process involves any of the following:

- Environmental Risks
- Lone working
- Risk of ill health or injury
- Use of hazardous equipment
- Dealing with the public
- Manual handling
- Chemical / Biological risks
- Working on or near water
- Armed conflict
- Civil unrest
- Other hazards

7.2 Safety and risk in the field

There are a variety of dangers which can face people engaged in research. Researchers have an obligation to themselves, to co-workers and to researchers under their direction to maintain awareness of potential dangers and to take steps to diminish these. The main dimensions of risk to social researchers are:

- Danger of physical intimidation, or actual bodily harm; and also the psychological trauma which could result from these;
- Emotional distress in response to participants' disclosures;
- Being put in compromising situations, such that they risk being accused of misconduct;
- Arousal of suspicion and antagonism from authorities.

Clearly there are arenas in which such dangers are unlikely to arise. Equally there are arenas in which awareness of danger is crucial. For instance, physical danger could be a factor in researching criminal fraternities, addicts or emotionally disturbed people; and emotional distress may be a factor when working with terminally ill people or victims of abuse.

In general, matters of culture, class, race, religion, ethnicity, belief and gender and varied contexts, should be seen as potentially relevant to the safety of researchers. Explicit discussion of risks and identification of appropriate countermeasures is likely to be beneficial in minimising anxiety and thereby freeing the researcher to concentrate on the work. Exercising basic common sense is paramount and each situation should be evaluated separately. Situations can change rapidly in the field; therefore it can be important to keep safety under review, especially where situations have already been identified as dangerous. It should be recognized that in some research scenarios physical dangers may come from people connected with those being researched (e.g. husbands of abused wives, or associates of criminals), rather than from the research participants themselves.

General health and safety issues associated with field research activities should also be considered. Issues could include such things as road accidents, vulnerability to criminal activity (not directly associated with the research) and exposure to infectious diseases. In evaluating the potential dangers of a project, it may be necessary to consider likely impacts on non-field workers, such as transcribers or others engaging with the data.

Staff Research

In principle all researchers should undertake an ethical review of their own research but certain categories of research involving human participants, their tissues or data must be independently reviewed by a properly constituted Research Ethics Committee. Ethics Committee approval must therefore be sought for all research undertaken by members of academic staff within the University that involve human participants in a way that might harm, disturb or upset them (however slight the possibility) or where they can be deemed to be in a vulnerable or disadvantageous situation.

Appendix A lists the types of research which prima facie should have an independent ethical review but, in general, any research project which has the potential to harm, upset or significantly inconvenience a participant, or seek confidential or sensitive personal information about a participant or where the relationship between the researcher and the participant is unequal, should be reviewed by the Ethics Committee.

This is a requirement for both internal /non-funded research and for research where external funding is granted. In instances where the research is dependent upon external funding being secured, it is not normally expected that the Principal Researcher should seek ethical approval at the application stage, although this is recommended in sensitive cases, such as research dealing with medical or health research, any non-CE marked medical device, research working with children, vulnerable adults, or that which take place in hazardous environments (as set out in Paragraph 7.1). In all cases however, externally funded research projects must have ethical approval before the research commences. The Application for Ethical Approval form (PG2/E1) should be completed and submitted to the Ethics Committee.

8.1 Risk Assessment

Refer to section 7.1

In all cases

9.1 Research with the NHS.

NHS Research which involves current or previous NHS service users (or their close relatives or carers) recruited through the NHS (directly or indirectly), must be reviewed by an NHS REC through the NRES (National Research Ethics Service). The NRES system must also be used for Clinical Trials of Investigational Medicinal Products, for any research involving adults who do not have the mental capacity to give informed consent (or might lose that capacity in the course of the research), and any research using human tissue.

9.2 Safeguarding children

Staff undertaking research work which involves one-to-one or other unsupervised contact with children will be required to obtain a current enhanced Disclosure and Barring Service check issued for work conducted through the University. Please see the guidance below.

9.3 Approval

Applications should be submitted for approval as early as possible. All projects must be signed off from an ethics perspective before that part of the work for which approval is being sought begins.

If projects are approved research may proceed. The applicant and supervisor[s] will receive a communication to this effect from the Ethics Committee. Projects will be approved for the duration of the research process subject to resubmission should the nature of the research change or on the identification of unforeseen ethical implications that arise during the research process.

If projects are approved subject to amendments the applicant and supervisor[s] will receive a communication to this effect that indicates the minor points that require clarification. The project should be amended and re-submitted to the Ethics Committee for approval.

If projects are not approved because they contain major flaws the applicant and supervisor[s] will receive a communication from the Ethics Committee, detailing the issues to be addressed. The project must be substantially revised and re-submitted to the Ethics Committee for approval.

10. Continued review of all research projects:

All postgraduate research conducted for research degrees shall be reviewed for on-going and unforeseen ethical issues during the various points of a research degree candidature:

- Progress reviews with the supervisory team
- Submission of full research proposal
- Upgrade from MPhil / PhD (where applicable)
- Successful completion of Probationary Period (where applicable)
- Annual review

Staff research will be continually monitored on a self-regulatory basis.

If projects which have initially been judged not to have ethical implications change and do subsequently have ethical dimensions it is the responsibility of project supervisors for all supervised research, or in other cases the staff responsible for the research, to ensure that ethical scrutiny procedures are invoked and followed through. Such instances must be raised immediately with the Ethics Committee.

11. Unforeseen ethical implications

In all cases any adverse events occurring during the conduct of research projects must be reported to the Ethics Committee. In such cases the researcher, whether staff or student, shall withdraw from the research process with immediate effect until notified by the Ethics Committee that the University is satisfied that the research design has been modified in such a way as to mitigate further harm.

12. Collaborative Research

Research is increasingly conducted on a collaborative basis with a range of public, private and third sector organisations, at national, European and International levels. In such instances the Ethics Committee shall consider the proposed programme of research in its entirety, rather than just those work packages pertaining to UWTSD staff. Consistent with the guidelines in this Code, each organisation shall submit the research proposal to its own governance systems and research shall not commence until each body is satisfied that all ethical issues have been addressed.

13. Research Data Management

Research data must be created, maintained and shared in accordance with contractual, legislative, regulatory, ethical and other relevant requirements. Researchers are expected to maintain awareness of current requirements and obligations set by the University, and where applicable, those of the research sponsor, research partners, the supplier of externally sourced data and any other relevant bodies, and adopt practices that are appropriate and conform to best practice within the subject domain. These should include the application of appropriate measures to protect research participants throughout the research lifecycle and a range of contractual, legislative, regulatory and ethical requirements at local, national, and international level. In general these practices must ensure that research data and records are:

- Accurate, complete, authentic and reliable;
- Identifiable, retrievable, and accessible;
- Retained in a safe and secure manner
- Retained in a manner that is compliant with legal obligations and, where applicable, the requirements of funding bodies and project-specific protocols approved by the University's Research Ethics Committee;
- Available to others in line with appropriate ethical, data sharing and open access principles;
- Commensurate with the legitimate interests and protection of human participants of research data.

13.1 All Staff and Student Research

In order to meet these expectations, the University has established an extensive resource bank which researchers should consult, and against which guidance applications for ethical approval will be screened. The resources are available at the following web address: <http://www.uwtsd.ac.uk/library/research-data-management/>. Additional support is available from Research, Innovation and Enterprise Services.

13.2 Funded Research

All applications for ethical approval for funded research must comply with the Research Data Management Policy. The Policy defines the responsibilities at individual and institutional level which should guide the work of those involved in funded research data collection, curation, storage and maintenance to ensure that research data produced by staff and students will be managed to the highest standards throughout the research data lifecycle. All new research proposals for funded research must include research data management plans that explicitly address data capture, management, integrity, confidentiality, retention, sharing and publication. Research data management plans will, where appropriate, use research funder templates or the Digital Curation Centre's DMPonline tool (<https://dmponline.dcc.ac.uk/>) to ensure that research data are available for access and re-use where appropriate and under the requisite safeguards. Research data management plans must be signed-off by Research, Innovation and Enterprise Services before a grant-funding application is made.

14. Intellectual Property

It is important that researchers consider whether Intellectual Property may be generated by their project and that they are aware of the University policy on Intellectual Property Rights. Provisions for the management of Intellectual Property (IP) are set out in the University's Intellectual Property Policy for Staff and Intellectual Property Policy for Students. Those seeking ethical approval for research are encouraged to contact Research, Innovation and Enterprise Services (RIES) to discuss the management of IP where IP will be generated through the research. This is particularly important where the proposed research is undertaken with collaborative partners, is funded, or has commercial potential. In other instances, issues of confidentiality may arise, in which case RIES will coordinate appropriate Non-Disclosure or Confidentiality Agreements.

15. Insurance

All research undertaken by the University's staff and students must be adequately covered by the University's Insurance provisions. The University's insurance policy will in most cases provide adequate cover and this will be checked as part of the ethical approval process. Researchers should be aware however that research in the health sector (for instance, working with medical devices, or in clinical settings, or where any medical intervention is undertaken) may require additional insurance to be put in place. In all such cases, research should not commence until ethical approval has been granted. Indemnity issues for research are coordinated by Research, Innovation and Enterprise Services and applicants may wish to discuss indemnity prior to the application for ethical approval.

16. Safeguarding - Disclosure and Barring Service (DBS)

The Disclosure and Barring Service's aim is to help organisations in the public, private and voluntary sectors by identifying candidates who may be unsuitable to work with children or to

hold particular positions. The definition of a child in this context is a person aged under 18 years of age.

Staff and students at whatever level undertaking research work which involves one-to-one or other unsupervised contact with children will be checked. The need for a check should be identified by the researcher and supervisor on the basis of the nature of the activity involved. The Ethics Committees may also make recommendations regarding DBS checks for projects they review.

The Ethics Committee will require confirmation that an enhanced DBS check has been obtained where researchers are working individually or unsupervised with participants who are under 18 years of age. Evidence of the check should be presented alongside all other documentation provided when making an application to the Ethics Committee.

Processing the DBS forms

When it is identified that an individual post will require a DBS check then notification is made on the RS1 form (Permission to Recruit form). DBS checks are administered by the Human Resources Department.

Should the University receive notification of a criminal record that bars an individual from undertaking the proposed regulated activity, the matter will be considered by the Director of HR, the Chair of the Ethics Committee and the Chair of the Research Committee. Matters will proceed in accordance with the relevant Human Resources policy.

There are three different levels of DBS check available, and an enhanced check will be obtained:

- **Standard checks** are suitable for certain financial and security positions. A standard check will show any unspent convictions, cautions, warnings or reprimands along with any spent convictions and cautions that are not eligible for filtering.
- **Enhanced checks** are suitable for eligible roles where the applicant will be working/volunteering with children, young people and/or vulnerable groups. An enhanced check will show any unspent convictions, cautions, warnings or reprimands along with any spent convictions and cautions that are not eligible for filtering. Intelligence held by the police may also be included if the Police reasonably believe it is pertinent to a recruitment decision.
- **Enhanced with DBS Barred List checks** are suitable for roles where the applicant will be working/volunteering in a regulated activity with children and / or vulnerable adults. An enhanced check with DBS Barred list check will show the same information as an enhanced check along with any information held on the barred list(s) being checked.

Regulated Activity

Regulated activity is work that a barred person must not do. The definition of regulated activity (i.e. work that a barred person must not do) in relation to children comprises, in summary:

- unsupervised activities: teach, train, instruct, care for or supervise children, or provide advice/ guidance on well-being, or drive a vehicle only for children;

- work for a limited range of establishments ('specified places'), with opportunity for contact: e.g. schools, children's homes, childcare premises. Not work by supervised volunteers;

DBS Code of Practice

The DBS recognises that the Standard and Enhanced Disclosure information is extremely sensitive and personal, therefore it has published a Code of Practice and employers' guidance for recipients of Disclosures to ensure they are handled fairly and used properly. Organisations that wish to use DBS checks must comply with the DBSs Code of Practice. The University's policy is available from Human Resources.

17. Vulnerable Adults

While the DBS no longer recognises the category of 'vulnerable adult', particular attention must be paid to the research design, research implements, gaining consent and respecting confidentiality regarding research with a vulnerable adult. A vulnerable adult is a person who is aged 18 years or over and:

- 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 offenders 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 include needs associated with frailty, illness, disability or mental capacity);
- is receiving direct payments from local authority/HSS body in lieu of social care services;
- requires assistance in the conduct of his or her own affairs.

18. Research Misconduct

Research misconduct is characterised as behaviour or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. It is a problem because it can cause harm (for example to patients, the public and the environment), damages the credibility of research, undermines the research record, and wastes resources.

The Concordat recognises that academic freedom is fundamental to the production of excellent research. This means that responsibility for ensuring that no misconduct occurs rests primarily with individual researchers. However, the University as an employer of researchers has an active role to play in sustaining research integrity as enshrined in this Code of Practice. Research misconduct can take many forms, including:

- **fabrication:** making up results or other outputs (eg, artefacts) and presenting them as if they were real
- **falsification:** manipulating research processes or changing or omitting data without good cause
- **plagiarism:** using other people's material without giving proper credit
- **failure to meet ethical, legal and professional obligations:** for example failure to declare competing interests; misrepresentation of involvement or authorship; misrepresentation of interests; breach of confidentiality; lack of informed consent; misuse of personal data; and abuse of research subjects or materials
- **improper dealing with allegations of misconduct:** failing to address possible infringements such as attempts to cover up misconduct and reprisals against whistle-blowers

This list is not intended to be exhaustive. Honest errors and differences in, for example, research methodology and interpretations are not examples of research misconduct.

18.1 Dealing with Allegations of Research Misconduct

The procedures for dealing with unfair practice in research programmes are set out in Chapter 8 of the University's AQH 2017/18.

19. A Brief Summary of Guiding Principles

The following is a summary of the guiding principles which Schools, Faculties and the University's Ethics Committee will refer to in making their decisions. It is not intended to be exhaustive, and of necessity, individual School's will need to reference the norms and conventions of their own disciplines in reaching any decision.

Above all it should be remembered that the integrity of any research depends not only on its scientific rigour, but also on its ethical adequacy. Ethical issues are many and varied, and may be quite complex. Research involving human participants is undertaken by many different disciplines and conducted in a broad range of settings and institutions. While some issues are specific to professional groups, all research should be guided by a set of fundamental ethical principles to ensure the protection of human participants. Underpinning the standards are the ethical imperatives of 'do no harm' (non-maleficence) and 'do good' (beneficence). Consideration of risks versus benefits need to be weighed up by researchers. In medical research, physically invasive procedures are easily defined, but what constitutes risk in social research is sometimes less clear cut. Questionnaires, observation and interviews can all be potentially intrusive and provoke anxiety in participants, or worse, involve psychological risk. It is important to think through carefully the likely impact on participants of any data collection methods. Certain groups are particularly vulnerable and may succumb to pressure, for example students, children or people with learning disabilities. Some participants are unable to give informed consent and are therefore less able to protect themselves, for example people with dementia. Research activities may be so unobtrusive that individual consent is not warranted, such as in the case of some community-based studies.

The following standards have been developed to guide staff and students undertaking research involving human participants. They are intended to cover general principles, but they may not address all situations and the researcher should seek further advice from their School's Research Ethics Officer, the University's Research Ethics Committee and their profession's code of practice for research ethics as appropriate.

19.1 Responsibilities to research participants

Researchers enter into a personal and moral relationship with those they study and should strive to protect their rights. Researchers have a responsibility to ensure that the physical, social and psychological well-being of the participant is not adversely affected by the research. So, while researchers are committed to the advancement of knowledge, the goal of the research does not provide a right to override the rights of others. Wherever possible, researchers should seek to:

- Minimise disturbance to both those participating in the research and to their relationships with their environment and those gatekeepers who may control access to participants - since these relationships will continue long after the researcher has left;
- Anticipate and guard against consequences for research participants which can be predicted to be harmful and try to anticipate the long-term effects on individuals or groups as a result of the research;
- Take special care where research participants are particularly vulnerable by virtue of age, social status and powerlessness;
- Resort to covert research only where it is impossible to use other methods to obtain essential data (in such studies it is important to safeguard the anonymity of research participants);
- Take care to avoid falsification or misrepresentation of evidence, data, findings or conclusions;
- Clarify with participants the extent to which they are allowed to see transcripts of any interviews and field notes and to alter the content or interpretation of the data.

19.2 Beneficence and Non-Maleficence

Terms such as risk, harm and hazards include emotional and mental distress, and possible damage to financial and social standing, as well as to physical harm. In principle:

- The research should be methodologically sound and the purpose should be to contribute to knowledge;
- The research should be undertaken and supervised by those who are appropriately qualified and experienced;
- The importance of the objective should be in proportion to the inherent risk to the subject. Concern for the interests of the subject must always prevail over the interests of science and society;
- The research should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others;
- Research should not be undertaken where the hazards involved are not believed to be predictable;
- Adequate facilities and procedures should be in place to deal with any potential hazards.

19.3 Informed Consent (Adults)

It is generally held that sane competent adults should be free to make their own decisions. Consequently, respect for the individual right to choose is at the core of ethical research. Gaining informed consent is an essential element of ethically valid social research. Thus three basic principles apply. Consent needs to be:

- Informed - given in possession and understanding of the principal, relevant information;
- Voluntary - given freely and not as a result of coercive pressure (real or perceived);
- Competent - given by somebody able, in virtue of their age, maturity and mental stability, of making a free, considered choice.

More specifically, it is necessary to ensure that the potential research participant is fully aware of, and fully understands,

- What the research is about;
- Why it is being conducted;
- Who it is being conducted for and who is funding it;
- What the purpose of the study is and what will happen to the results;
- Where the results will appear and who is likely to have access to them;
- What will be expected of them if they agree to participate and how long their participation will take;,
- What anonymity and confidentiality mean in practice and an understanding that the participant does not *have* to participate; and having agreed to participate can withdraw any time without detriment.

In practice researchers should therefore ensure that:

- Each potential subject is adequately informed of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort it may entail;
- Any documentation given to potential participants must be comprehensible and there should be an opportunity for them to raise any issues of concern;
- Consent should be acquired in writing and records of consent should be maintained;
- Potential participants must be informed that they are free to withdraw consent to participation at any time;
- There should be a procedure for making complaints and participants should be made aware of this;
- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, students must be assured that any decision not to participate will not prejudice in any way their academic progress;
- Any inducement offered to participants should be declared.
- Consent must be obtained from a legal guardian in the case of minors or any others who do not have the legal competence to give informed consent.
- Asking participants to sign a written consent form is a widely accepted method of obtaining informed consent. In addition to ensuring that participants agree to participate of their own free will and understand what they are getting involved in, the existence of signed documentation protects the researcher from subsequent accusations by participants.

19.4 Informed Consent (Children)

- Young people aged 16-18 with sufficient understanding are able to give their full consent to participate in research independently of their parents and guardians.
- Where research involves children under the age of 16 assent should be obtained from parents or those in *loco parentis*. However, it is highly desirable that children themselves should be actively engaged in the consent process. It is arguable that children are

capable of being partners in research and that they have rights to receive information, to be listened to, have their wishes and feelings taken into account and to give or withhold consent if judged competent to do so. From this perspective, assumptions about lack of competence to give informed consent can function to deny children valuable opportunities for involvement, thereby eroding their rights and excluding them from processes of developing shared understanding of social relationships. It may, therefore, be appropriate to seek consent from the parents of participating children *and* from the children themselves. However, if consent is gained from the relevant adult but the child clearly withholds consent or shows distress, the wishes of the child should prevail. Enabling children to engage in a meaningful way requires careful attention to practical considerations, including the use of information sheets and consent forms written in a child-friendly way

- One parent can give assent but it is preferable to have both.
- Further guidance should be sought from the BERA Guidelines.

19.5 Exceptions

There are occasions when informed consent may be impracticable or meaningless in social research, for example:

- Research on 'public behaviour', e.g. street or crowd settings
- Where it would compromise the subjects of research (e.g. when studying those engaged in illicit or illegal behaviour, such as drug-taking), or
- Where written consent could put them at unnecessary risk.

Retrospective consent

In some contexts consent can be gained retrospectively (and in this case informed consent refers more to consent to use the data gained and an understanding of how the data is to be used) e.g. as in the example of observational psychological experimentation, or where covert research is necessary and warranted – such as work in the field of deviance where it involves immoral or illegal behaviour.

When consent forms are not appropriate

It should be recognised that seeking written consent is not under all circumstances appropriate. For instance, illiteracy may be an issue, such that imposing written consent forms would not be a meaningful or legitimate means of establishing consent. In overseas research there may be circumstances where translation is not feasible; or it may be that asking for written agreement is culturally inappropriate. In such cases the researchers should seek informed verbal consent. In the case of children however informed consent must always be obtained as set out in 16.4.

Covert Research

Covert research cannot, by definition, involve informed consent, because informing the subject would render the research overt. If informed consent is ethically required for research, then covert research is not permissible.

If any member of staff or student is seeking to use research methods and designs covered in these exceptions they should in the first instance seek the advice of their Research Ethics Committee.

19.6 Anonymity and Confidentiality

The right of the individual to privacy is a pre-eminent ethical driver in western societies. In the social researcher's relationship to participants this translates into two imperatives: anonymity and confidentiality. Anonymity and confidentiality may be defined as follows:

- Anonymity refers to concealing the identities of participants in all documents resulting from the research;
- Confidentiality is concerned with who has the right of access to the data provided by the participants.

In practice the obligation of the researcher to the researched may be summarised thus:

- Anonymity and privacy should be respected. This means that care should be taken in deciding whether or not sensitive information should be recorded;
- Identities and research records should be kept confidential whether or not an explicit pledge has been given;

The right to remain anonymous should be respected unless a clear understanding to the contrary has been reached. Researchers have the responsibility to ensure appropriate precautions to protect the confidentiality of participants' data. For instance, names and any information from which identities could be inferred (e.g. locations) should be removed.

Anonymity, confidentiality and the greater good

Whilst respecting anonymity and confidentiality are core principles of social research they are not absolutes. There may be situations when the researcher has a duty of care to reveal information that has been provided in confidence, or which the researcher has discovered through interactions with the participant. For example, if a researcher were to become aware of abuse in a care home, it would be necessary to act on this knowledge and inform the relevant authority. Who constitutes the relevant authority in any given case would depend on a variety of factors, including whether the abuse is isolated or systemic within the organisation. In any case, researchers would be well advised to consult confidentially with their own colleagues and inform their own institution.

20. Professional Bodies – Ethical Codes of Practice

Various professional groups have their own ethical guidelines and many of these are easily available on the internet and can be consulted by following the links below. In all cases the onus is placed on the researcher to meet the highest ethical thresholds set by the relevant professional body.

British Association for Counselling & Psychotherapy

http://www.bacp.co.uk/ethical_framework/

Economic and Social Research Council

<http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/>

British Educational Research Association

<https://www.bera.ac.uk/researchers-resources/resources-for-researchers>

Association of Social Anthropologists

<https://www.theasa.org/ethics.shtml>

Social Research Association

<http://the-sra.org.uk/research-ethics/ethics-guidelines/>

British Sociological Association

<https://www.britisoc.co.uk/equality-diversity/statement-of-ethical-practice/>

Royal Anthropological Institute

<http://www.therai.org.uk/about-the-rai/governance/ethical-policy/>

The British Psychological Society

http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf

RCUK

Policy and Code of Conduct on the Governance of Good Research Conduct

<http://www.rcuk.ac.uk/documents/reviews/grc/rcukpolicyandguidelinesongovernanceofgoodresearchpracticefebruary2013-pdf/>

Singapore Statement on Research Integrity

<http://www.singaporestatement.org/>

European Code of Conduct for Research Integrity

<http://archives.esf.org/coordinating-research/mo-fora/research-integrity.html>

Government Office for Science (www.bis.gov.uk/go-science)

Rigour, Respect, Responsibility: a Universal Ethical Code for Scientists

<http://www.bis.gov.uk/assets/goscience/docs/u/universal-ethical-code-scientists.pdf>

Improving Dispute Resolution Advisory Service for Further and Higher Education (www.idras.ac.uk)**UK Research Integrity Office (www.ukrio.org)**

Code of Practice for Research: Promoting good practice and preventing misconduct

<http://www.ukrio.org/what-we-do/code-of-practice-for-research/>

Procedure for the Investigation of Misconduct in Research

<http://ukrio.org/publications/misconduct-investigation-procedure/>

21. Appendix A: Types of research requiring ethical review by a committee

In the following cases proposed research should always be referred to a Research Ethics Committee for approval. The list, however, is not exhaustive:

- a. Research involving the ingestion (by whatever means of delivery) of any substance by participants. This might be a drug but also food or drink if consumed for research purposes.
- b. Research involving any invasive procedure, such as a biopsy.
- c. Research involving the use of human tissue, including foetal and placental material (in compliance with the terms of the Human Tissue Act 2004).
- d. Research involving the cadavers of or tissue from the deceased (in compliance with the terms of the Human Tissue Act 2004), other than bequeathed cadavers and tissue obtained in the normal course of necropsy;
- e. Research involving *any* animal, including invertebrates. Note that research involving live vertebrates and cephalopods must comply with the Animals (Scientific Procedures) Act, 1986, which requires a Home Office Licence for individual

researchers, the establishment(s), and the project involved. More guidance can be found at: <https://www.gov.uk/guidance/research-and-testing-using-animals>;

- f. Research involving privileged access to clinical or personal records, or access to potential participants on the basis of their being or having been patients, or the invitation to participants to divulge facts about themselves which they would not wish the investigator to allow to become known to other persons.
- g. Research involving any form of risk or inconvenience to the participant; this might include but not be limited to interviews, observations and focus groups
- h. Research involving any risk of psychological damage or distress to the participants or their family.
- i. The use of novel techniques, technologies or devices even where apparently non-invasive, whose safety may be open to question
- j. The collection of person-identifiable data requiring consent under the Data Protection Act.
- k. The participation of vulnerable individuals
 - l. NHS patients, their data or tissues;
- m. NHS staff where the research is not limited to non-sensitive questions about their personal role
- n. Participants who are users of any of the services for which UK Health Departments are responsible. This includes adult social care in England under certain circumstances; a full list of circumstances that require approval by the National Social Care Research Ethics Committee can be found at <http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/>.
- o. Prisoners in the custody of the National Offender Management Service, the Scottish Prison Service or the Northern Ireland Prison Service, where the research is health-related.
- p. Adult participants who, under the Mental Capacity Act, may lack the capacity to provide informed consent
- q. A non-CE marked medical device
- r. Exposure to ionising radiation
- s. Processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers without consent
- t. A clinical trial involving the participation of practising midwives

In all cases of doubt, appropriate advice should always be sought.