****

**COLLEGE OF LAW AND CRIMINOLOGY**

**SWANSEA UNIVERSITY**

**PROCEDURE FOR ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS OR DATASETS**

**November 2015**

This document replaces all previous documents concerning the College’s ethical review procedures and comes into effect from 23 November 2015.

All research in the College of Law and Criminology involving human participants or datasets must comply with the conditions and procedures in this document.

**COLLEGE OF LAW AND CRIMINOLOGY, SWANSEA UNIVERSITY**

**PROCEDURE FOR ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS OR DATASETS**

The College’s procedure for ensuring the probity of research involving human participants and/or datasets has been composed in accordance with the University’s policy on research ethics, and the ethical procedures set out by RCUK and the ESRC, particularly the ESRC’s *Framework* *for* *Research Ethics*. The procedure applies to **all research** involving **human participants** **and/or datasets** undertaken by researchers within the College, including staff, undergraduate and postgraduate students, visiting researchers and honorary researchers. Itapplies to all research, irrespective of the funding source (external or internal). ESRC-funded research **must** comply fully with the ESRC’s *Framework for Research Ethics* in its entirety.

The College requires research to be designed and conducted in such a way that it meets key ethical principles and is subject to proper oversight in terms of ethical research governance to ensure that these principles are met. The intention is to prevent unethical research and unethical research practice from the outset and at any stage during the research.

**The six key ethical principles are:**

1. Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.

2. Research staff and participants must normally be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. Some variation is allowed in very specific research contexts.

3. The confidentiality of information supplied by research participants and the anonymity of respondents must be respected.

4. Research participants must take part voluntarily, free from any coercion.

5. Harm to participants and researchers must be avoided in all instances.

6. The independence of research must be clear and conflicts of interest explicit.

**To implement these principles:**

• The responsibility for the conduct of the research in line with relevant principles rests with the principal investigator.

• The responsibility for ensuring that research is subject to appropriate ethics review, approval and monitoring lies with the College Research Committee.

• Before any research commences involving human participants or datasets, it is the responsibility of the principal investigator to inform the College Research Ethics Committee (CLC-REC) about the intended research, to seek advice and to seek ethical approval.

• The College will have clear, transparent, appropriate and effective procedures for ethics review, approval and governance.

• Risks should be minimised.

• Research should be designed in a way that the dignity and autonomy of research participants is protected and respected at all times.

• Ethics review should always be proportionate to the potential risk, whether this involves primary or secondary data.

• Whilst secondary use of datasets may be relatively uncontroversial, requiring only light-touch ethical review, novel use of existing data (e.g. data linkage) and some uses of administrative and secure data, will raise ethical issues.

• Research involving primary data collection will always raise ethical issues.

**The College has two forms of ethical review:**

**1. Light-touch ethical review**

This will identify those projects where the potential for risk of harm to participants and others affected by the proposed research is minimal. Researchers should complete a *Light-touch Ethical Review Form* for each research project involving human participants or datasets. If the ‘risk evaluation’ reveals no matters of concern, researchers should complete the Declaration and submit the Form to the Research Hub Manager (currently Chris Marshall), along with a copy of the **research proposal**, which should be sufficiently detailed to enable its ethical implications to be assessed should that prove necessary. Research may not commence until approval is given.

* For **academic staff**, the decision will be taken by the Chair of the CLC-REC (or delegate), following consultation with the Committee where appropriate.
* For **postgraduate** research students, the decision will be taken by the Chair of the CLC-REC (or delegate), following consultation with the Committee where appropriate.
* For **PGTM** and **under-graduate** students, by at least two members of staff involved in supervising relevant modules.
* A decision should be communicated within **two weeks** of submission.
* A record of the decision will be retained by the College for audit purposes.

**2. Full ethical review**

Where the ‘risk evaluation’ on the *Light-touch Ethical Review Form* reveals one or more matters of concern, a *Full Ethical Review* is necessary. For academic staff and postgraduate students the Full Review will be undertaken by the College Ethics Committee (CLC-REC). For undergraduate and PGTM students the decision will be taken by the relevant sub-committee.

The ESRC states that “the primary role of a REC is to protect the dignity, rights and welfare of research participants. It should also give due regard to the consequences of the proposed research for others directly affected by it and to the interests of those who do not take part in the research but who might benefit or suffer from its outcomes in the future. RECs also need to consider the safety of researchers, especially where they are working abroad, in covert situations, and/or conducting lone fieldwork in settings that may pose risk to their safety.”

The CLC-REC will:

* Have a Chair, or a designate.
* Have at least three (and up to six) other members, at least one of whom should be drawn from a cognate subject area and at least one of whom should be a **lay member with no affiliation to the University**.
* The ESRC **requires** that:

“*RECs should be multidisciplinary and comprised of both men and women. They must include at least one lay member with no affiliation to the university. There must be members who have broad experience of and expertise in the areas of research regularly reviewed by the REC who have the confidence and esteem of the research community. At least one member must be knowledgeable in ethics. There must be a chairperson. RECs would also benefit from including individuals who reflect ethnic diversity, users of specialist health, education or social services, where these are the focus of research activities, individuals with experience of professional care or counselling, and individuals with specific methodological expertise (e.g. statistics or qualitative methods) relevant to the research they review. Taking all this into account, good practice would suggest that RECs would normally need at least seven members. A REC may seek advice and assistance from experts outside the committee in considering a research proposal. When this happens, the chair should establish that the experts have no conflict of interest in relation to the proposa*l.”

The CLC-REC will require a copy of all appropriate documentation, including a **full research proposal** that is sufficiently detailed to enable its ethical implications to be assessed (e.g. purpose of the research, study design, methods of data collection and analysis, recruitment and role of participants, risks to participants and researchers, securing informed consent, confidentiality and data protection, expected benefits of the research, source of funding, conflicts of interest, etc.). **Research must not commence until approval is given**. If the CLC-REC declines approval, the researcher will be informed what issues will need to be addressed.

* Researchers should expect a decision within **six weeks** of submission.
* A record of the decision will be retained by the College for audit purposes.

The College will follow the ESRC’s guidance on which types of research would normally be considered as involving **more than minimal risk** and therefore most likely to require a **full ethical review**:

* **Research involving potentially** **vulnerable groups**, e.g. with children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Some RECs have facilitated ethics approval by establishing ethics protocols for commonly occurring situations, such as research undertaken with normally developing children in mainstream school settings. Ethics approval may involve light touch review if the researcher can confirm that they are abiding by the established protocol and that this is appropriate for their research.
* **Research involving those who lack capacity** must be approved by an “appropriate body” operating under the Mental Capacity Act, 2005. Apart from a few exceptions, all such research is deemed ‘intrusive’. It is illegal to conduct such research without approval of the ‘appropriate body’ (usually the NRES).
* **Research involving sensitive topics**, for example participants’ sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status. Elite Interviews may fall into this category.
* **Research using administrative data or secure data**. Researchers using these datasets will need to be approved by the body supplying the data and keep data in secure areas. In most cases a light-touch review confirming that researchers have met these requirements will be sufficient. Issues may arise when data are linked and where it may be possible to identify participants.
* **Research involving groups where permission of a gatekeeper is normally required** for initial access to members. This includes research involving gatekeepers such as adult professionals (e.g. those working with children or the elderly), or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, such as a family member (e.g. parent or husband) or a community leader.
* **Research involving deception or which is conducted without participants’ full and informed consent** at the time the study is carried out. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable and consent may need to be managed at a point beyond the completion of research fieldwork.
* **Research involving access to records of personal or sensitive confidential information**, including genetic or other biological information, concerning identifiable individuals.
* **Research which would or might induce psychological stress**, anxiety or humiliation, or cause more than minimal pain.
* **Research involving intrusive interventions or data collection methods** – e.g. the administration of substances, vigorous physical exercise, or techniques such as hypnotism. In particular, where participants are persuaded to reveal information that they would not otherwise disclose in the course of everyday life.
* **Research where the safety of the researcher may be in question**, in particular those working in the field and those locally employed outside the UK.
* **Research involving members of the public in a research capacity** in research data collection e.g. participatory research.
* **Research undertaken outside of the UK** where there may be issues of local practice and political sensitivities. Partnership with a research organisation in the area involved may be helpful. It is necessary to check the requirements for ethics review in the countries included in the research.
* **Research involving respondents through the Internet**, in particular where visual images are used and where sensitive issues are discussed.
* **Other research involving visual/vocal methods** particularly where participants or others may be identifiable in the images used or generated.
* **Research which may involve data sharing of confidential information beyond the initial consent given** – e.g. where the research topic or data gathering involves a risk of information being disclosed that would require researchers to breach confidentiality conditions agreed with participants.

**UK Data Protection Act 1998 (DPA)**

It is important that researchers are aware that most of the Data Protection Principles embodied in the DPA apply to their work. Researchers should be aware that the processing of any information relating to an **identifiable living individual** constitutes ‘personal data processing’ and is subject to the provisions of the DPA, including the eight data-protection principles, summarized as follows. Data:

* must be obtained for a specified and lawful purpose.
* shall not be processed in any manner incompatible with that purpose.
* shall be adequate, relevant and not excessive for those purposes.
* shall be kept up to date.
* shall be kept for no longer than is necessary for that purpose.
* must be processed in accordance with the data subject's rights.
* must be kept safe from unauthorized access, accidental loss or destruction.
* shall not be transferred to a country outside the European Economic Area unless that country has equivalent levels of protection for personal data.

For further information see: <http://the-sra.org.uk/wp-content/uploads/MRS-SRA-DP-Guidelines-updated-April-2013.pdf>

And: <http://www.jisclegal.ac.uk/ManageContent/ViewDetail/ID/3648/Data-Protection-and-Research-Data-Questions-and-Answers-21-August-2014.aspx>

**Data requirements**

Researchers should ensure that appropriate practical arrangements are in place to maintain the integrity and security of research data. Researchers should be mindful of the threat to data integrity and security presented by routinely used collection and storage methods, such as computer files on hard drives and similar devices, portable computing equipment and memory, email, and databases. Researchers should also be mindful of the limits of the original consent given by participants. Transferring personal data and sensitive personal data to others in which the original participants are identifiable may violate the original consent.

Further guidance on data management can be found at: <http://www.swansea.ac.uk/iss/researchsupport/rdm/>

**Secondary data sources**

Secondary use of datasets needs to be given careful consideration by both the researcher and the REC, especially with regard to presumed consent and the potential risk of disclosure of sensitive personal information. A data provider (such as Economic and Social Data Service (ESDS) or the Office for National Statistics (ONS)) may also have stringent requirements and restrictions relating to access and use of secondary data that must be followed.

**Limits to confidentiality**

Researchers working with children, families and vulnerable populations should, when eliciting consent, make clear the limits to confidentiality. If, for example, an interview reveals that a participant or another person identified in the interview is in significant and immediate danger, the researcher will be obliged to take action in response to that disclosure. Before starting a project involving children, families or vulnerable populations, the principal researcher should have established a procedure and the necessary systems and identified contacts to activate help and support in the event of a disclosure. If the researcher feels it is necessary to break confidentiality, the participant will normally be informed what action is being taken by the researcher unless to do so would increase risk to those concerned. In projects collecting data on criminal behaviour, it may be necessary to explain to participants that confidentiality will be preserved as far as the law permits.

**Work with potentially vulnerable populations**

Independent Safeguarding Authority (ISA) and Criminal Records Bureau (CRB) have merged to become the Disclosure and Barring Service (DBS). DBS checks are required for researchers conducting any research with potentially vulnerable populations. See: <https://www.gov.uk/disclosure-barring-service-check/overview>

**Research conducted outside the UK**

Where research is to be conducted outside the UK, researchers should establish whether local ethical review is required by the host country and, if not, how the principles of the FRE can be followed in developing and undertaking the research.

**Supervisors of students**

Supervisors of students must keep good records of their ethics procedures in case they are called to account or required for audit. As a minimum, supervisors need to retain such things as consent documents, other special permissions and relevant paperwork, information on data storage and data sharing, as well as a note of changes that have been made, highlighting specific problems.

**Avoiding duplication of ethical review**

Researchers should avoid duplication of ethical review, especially in respect of research that may fall under other frameworks. The appropriate body will be determined by the issues to be raised by the research, the nature of the data to be obtained, the population to be included in the study and the requirements of those funding and/or sponsoring the research. **The Chair of the CLC-REC must be provided with a copy of the outcome of all such ethical reviews**.

**Reporting changes to the research after approval has been given**

Any changes or amendments to the approved research proposal **must** be reported to the Chair of the CLC-REC for further review. The Chair will decide whether these are ‘minor’ or ‘substantial.’ The former will be approved by the Chair. The latter will be considered by the CLC-REC and may necessitate a new ‘full’ ethical review.

**Further guidance**

All researchers are encouraged to consult the ESRC’s *Framework for Research Ethics*, which provides helpful advice about research ethics, including a fuller explanation of many of the points mentioned above:

<*http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx*>

**Complaints and concerns**

Anyone with reason to believe that a research project is being undertaken without ethical approval or without due regard for ethical integrity should inform either the Chair of the CLC-REC or the College’s Director of Research as soon as possible.