RKE Ethics Policy and Procedures

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UNIVERSITY OF
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Summary
This Policy sets out the principles and procedures to ensure research conducted at the University of Winchester is ethical in design and process, and is carried out with the highest regard of research integrity. It is grounded in the University's three core values: *Compassion*, *Individuals Matter* and *Spirituality*.

This Policy sets out the principles and processes to achieve these ends and should be read alongside the University's other policies, codes, guidance and conduct documents as well as wider guidance to which it is aligned (see appendix 1).

UNVERSITY RESEARCH ETHICS POLICY

UNIVERSITY RESEARCH ETHICS POLICY AND PROCEDURES

Part 1: Principles

Preamble

1.1 This Policy sets out the principles and procedures to ensure research conducted at the University of Winchester is ethical in design and process. It is grounded in the University's three core values of *Compassion*, *Individuals Matter* and *Spirituality* which shape how this is achieved and why. The University believes that academic freedom leads to big ideas which in turn lead to social justice and creativity for a better world. In addition, the University has a commitment to considerations of environmental awareness and sustainable development. Researchers working under the auspices of the University are expected to be mindful of the potential environmental impacts of their research, to take steps to minimise any negative impact on the natural and the built environments.

This Policy enacts the values above in relation to research. It makes explicit the requirements for the ethical conduct of research by staff and students at the University, and the need for integrity in research practice. This Policy sets out the processes to achieve these ends and should be read alongside the University's other policies, codes, guidance and conduct documents as well as wider guidance to which it is aligned (see appendix 1).

This policy and the research ethics review process is intended to facilitate, not inhibit, research; they should be viewed as a way to guide researchers to identify risks and to plan to manage them with integrity.

Research Integrity

1.2 All research conducted at the University of Winchester must be designed and carried out in accordance with relevant legislation and accepted discipline-related ethical and professional standards (see appendix 1). For researchers this means they should act with honesty, integrity and in a transparent manner, respecting the dignity, rights and values of others, guided by relevant legal and regulatory requirements.

This Policy is aligned to UUK's *Concordat to Support Research Integrity* (2012) which sets out five key commitments:

#1: We are committed to maintaining the highest standards of rigour and integrity in all aspects of research.
#2: We are committed to ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards.
#3: We are committed to supporting 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.
#4: We are committed to using transparent, robust and fair processes to deal with allegations of research misconduct should they arise.
#5: We are committed to working together to strengthen the integrity of research and to reviewing progress regularly and openly.

This Policy is written to reflect these commitments.

The University subscribes to an ethic of personal responsibility; this means that those conducting research take primary responsibility for their actions in engaging with the processes set out in this Policy and in undertaking ethically robust research. In doing so, researchers can reflect on the ethical issues raised by their research and give an account of their chosen research procedures and approach. This Policy provides a framework and guiding principles to

help researchers do this. In the case of students, they will also be supported and guided by their supervisor(s) or tutor.

Each Faculty within the University and some Professional Services groups have staff members, researchers, research students, taught postgraduate and undergraduate students undertaking research, therefore processes need to be in place to accommodate this breadth of activity and provide:

- guidance and support on matters of ethics and ethical practice;
- a peer review system to ensure consistency in practice and standards in relation to ethics; and
- teaching to promote awareness of and reflection on ethics throughout the process of research.

Guidance and support

1.3 Within each Faculty, staff engaging in research or supervision of research must read and understand this Policy and abide by it as it relates to their research activity. Any questions about the Policy or ethical issues in general should be directed in the first instance to colleagues in the Faculty who oversee Faculty level ethics scrutiny (supported by the Faculty Head of RKE where required) or the Chair of the University Research Ethics Committee (UREC).

Peer review

1.4 The ethics scrutiny of research is generally undertaken in one of two ways: the first is a Faculty-level process and the second a University-level process. This Policy and ethics forms will guide researchers as to which is the most appropriate one for their project. Typically review should occur at a level as close as appropriately possible to the Department or Faculty where the research will be undertaken. This will help to ensure that review is undertaken by active researchers, for researchers, and promote an open culture of discussion and reflection on ethics and research integrity.

Faculty level ethics scrutiny and review is intended to accommodate studies deemed straightforward and /or low risk. Each Faculty has procedures in place for the review of studies, the nature of which will depend on the volume and character of the research undertaken. Typically, the Faculty Head of RKE (FHoRKE) or other nominated individual will oversee this process, drawing on the expertise of one or more scrutineers, as appropriate.

Where Faculty-level review highlights a project as complex, high risk or the Faculty scrutineers are unsure, then the study will be referred to the University Research Ethics Committee (UREC) by the FHoRKE or nominee.

The University Research Ethics Committee (UREC) carries out full project reviews. The requirement for full committee review can be identified in three ways: 1. the researcher following the ethics process flowchart, reading the policy and completing forms, 2. a recommendation from a supervisor or 3. by referral from a Faculty. The review process is set out in Part 2 of this policy.

The Committee comprises academic representatives from each Faculty, RKE centre, lay and student members. The Committee will strive to maintain an equal balance of membership in terms of gender, roles and so forth. Where an imbalance is significant, additional members from the underrepresented group can be co-opted. The Committee convenes face to face three times a year, and electronically otherwise.

The remit of UREC is:

(a) to support the Faculties by developing and promoting policy and guidelines regarding

research integrity and research ethics;

(b) to help sustain a University-wide awareness of ethics-related issues arising from research related activities;
(c) to scrutinise proposals requiring full review – giving or withholding approval;
(d) to propose suitable training where appropriate and to identify and disseminate good practice in research integrity and on ethical issues related to research;
(e) to consider and offer guidance on proposals submitted or referred to the Committee by a Faculty Research & Knowledge Exchange Committee, Research Degrees Quality Committee, the Research & Knowledge Exchange Centre, or individuals;
(f) to report to Senate Research & Knowledge Exchange Committee on a regular basis with any issues relating to the University's ethics procedures and practices relating to research and research integrity;
(g) to advise Deans of Faculties and Professional Services groups in cases of staff failure to comply with ethical guidelines relating to research; and
(h) to seek clarification, when necessary, from the University's solicitors or external expert bodies on matters of ethics procedures and practices in relation to research.

Training

1.5 This Policy should be used to frame any undergraduate or postgraduate training, or documentation concerning research ethics given to students. All degree programmes (undergraduate, master's and research degrees) must include at least one lecture, seminar or support session on research ethics.

All students undertaking research for a dissertation or thesis should have access to advice on ethics from their supervisor. For further information on training, researchers should contact the Secretary of the UREC in the first instance.

All academic members of UREC, as well as Faculty Heads of RKE (FHoRKE) or nominee, Heads of Department and all scrutineers involved in the ethics review of projects are required to have undertaken appropriate training and /or to have had significant relevant research experience before taking up review or scrutiny responsibilities.

Statement of researcher responsibilities

1.6 Those engaged in research have obligations to the participants in their study, to sponsors and stakeholders, employers and colleagues in the development and promotion of knowledge through research. It is the responsibility of the researcher, whether staff or student, to complete the appropriate ethics forms for their research project and identify if ethics review is needed. It is the responsibility of the researcher to ensure that approval has been gained before the proposed research activity starts. Acting otherwise is academic misconduct.

In line with The Data Protection Act 2018 and General Data Protection Regulation (GDPR), researchers are expected to gain explicit, active consent from participants and to inform them about:

- the purpose, nature and scope of data collection;
- the risks and /or benefits of participation to the participants (and be mindful of those to the researcher). Where risk is involved this should be considered carefully and minimised;
- who will have access to the data and how it will be used from analysis through to dissemination;
- how the data will be stored /held securely, especially if it is sensitive or might identify them;
- how data confidentiality will be maintained;
- the right to withdraw from the study;
- the right to request removal of data that identifies them, or if part of the study, when it will

be deleted when it is no longer needed.

Consent therefore should be sought on the basis of 'opting in' rather than 'not opting out' where personal or sensitive data is collected.

If a student or staff member proposes to undertake research into terrorism or radicalisation, they must submit an application for ethical approval to the University Research Ethics Committee for consideration. Faculty level consideration is not appropriate in this case. If the University Research Ethics Committee approves the proposal, a plan will be created for supporting the researcher in accordance with the University's Prevent Duty Implementation Delivery Model in order to safeguard against radicalization, or association with terrorist or otherwise proscribed organisations. Please email the Committee Chair for further guidance on ethics applications for research in this area.

Researchers should consider ethical issues throughout the lifecycle of a research project. The lifecycle includes the planning and research design stage, entering the field and gathering data, analysis, the presentation of findings and follow up knowledge exchange and impact activities – from the short-term dissemination process of reporting and publication through to longer-term archiving, future use, sharing and linking of data.

1.7 This policy and its revisions are subject to oversight by the University's UREC, which is accountable to the Senate Research and Knowledge Exchange Committee and ultimately to the Senior Management Team.

Part 2: Procedures

2.1 When is ethics review required?

2.1.1 *When ethics review is definitely required*

Ethics review will be conducted on projects when: 1. living, human participants or human samples are involved; 2. data is derived from individuals who may be identifiable through that data; 3. where there is the potential of the research to pose a risk of harm and this risk is more than minimal to participants and /or to the researcher; and 4. where the research or investigation(s) is for a medicinal purpose (see appendix 2 for more information).

Research that may have the potential to be deemed 'high risk' will typically have several areas of note: 1. the participants may be particularly vulnerable; 2. the data may be particularly sensitive (in nature or by topic); 3. considerations about the outcome of the research for the wellbeing of the participants or researcher. Depending on the complexity and preponderance of the issues posed (understood in terms of the level of risk for a project), review will occur either at Faculty level or at Committee level. Completing Form 1 will help identify the level of scrutiny needed and signpost the next steps.

The list below is illustrative of projects that would be subject to ethics review:

- involves living, human participants;
- gathers data which could potentially identify human subjects;
- gathers data from participants that relates to sensitive personal data or concerns sensitive topics; for example: participants' relationships, emotions, sexual behaviour, experience of violence, mental health, gender, race, ethnicity (status /experience), political or religious affiliations;
- involves tissues under 100 years old that are covered by the Human Tissue Act 2004;
- involves deception, or which is conducted without participants' (or guardians in the case of children) full and informed consent at the time the study is carried out;
- uses complex or contested terms, for example 'capacity', 'vulnerability' which need to be considered in the context of the research proposal (see appendix 2 for FAQs and definitions);
- involves sharing of data or confidential information beyond the initial consent given, or where the anonymity of the participant may be compromised;
- induces psychological stress, anxiety or causes more than minimal pain;
- involving intrusive interventions where there is a high risk of severe physical harm;
- involves children under the age of 18, or involves individuals in a dependent or unequal relationship with the researcher which needs to be considered in the context of the research proposal; or
- research for a medicinal purpose; or
- involves creating, downloading, storing or transmitting material that may be considered to be unlawful, indecent, offensive, defamatory, threatening, discriminatory or extremist.

2.1.2 *When ethics review <u>may</u> not be required*

Ethics review is generally not necessary for research that:

- does not involve living, human or living animal subjects;
- does not concern personal or sensitive data;
- reviews existing literature;
- draws on documentary material, papers, archives or records *EITHER* in the public domain *OR* in a private /closed archive to which the researcher has been granted access. (Note: unless it has the potential to affect living persons - for example collection and use of archive, historical, legal, online or visual materials may raise ethical issues for those vicariously involved with or 'touched by' the research.);

- draws on anonymous records and /or data sets that exist in the public domain, for example, data sets available through the Office for National Statistics or the ESRC Data Archive. (Note: the data provider is likely to specify their own restrictions on access to and use of their data, which must be complied with).

Whilst research falling into the illustrative categories above may not need formal ethics review, the research project needs to be formally recorded. In such cases the researcher completes Forms 1 & 2 and submits them to ethics.declaration@winchester.ac.uk.

Forms submitted in this way will be checked within 10 working days by the Chair of UREC or a nominee and the researcher will receive confirmation of compliance with the University Research Ethics Policy and procedures. The forms are archived centrally on SharePoint. Submissions not suitable for the 'self-declaration' route will be returned to the researcher with guidance on submitting their work for ethics scrutiny.

Outcomes of 'self-declarations' will be reported to the next meeting of the UREC. A list will be included in the UREC Annual Report.

The 'self-declaration' route is intended only for PGR student and staff (academic /professional services) projects. Undergraduate and master's students should follow the ethics scrutiny and approval process in operation at programme /department or faculty level, whichever applies.

2.1.3 *Activities not usually considered research*

The following activities are not typically considered research and therefore do not require ethics review:

- routine audit;
- consultations;
- performance reviews;
- quality assurance studies;
- testing and review within normal education requirements;
- service evaluations;
- polling on current public policy issues; and
- literary or artistic criticism.

Whilst the activities above may be deemed to lie outside the requirements for ethics review, they still need to be recorded via 'self-declaration' as other considerations may apply, for instance those relating to GDPR or Research Integrity.

If such activity is being undertaken as part of a course of study (for example a doctorate or masters), then the student may be required to evidence engagement with ethics processes and should follow the steps in section 2.2 of this document.

2.1.4 *Additional considerations*

Research requiring external ethics review

Some types of research will require external ethics review, for example research involving NHS patients, social care settings, HM Prison and Probation Service (via the HRA), research involving the Ministry of Defence (MoD REC). In such cases, the researcher will complete Forms 1 and 2 (countersigned by the supervisor in the case of undergraduate or postgraduate students) and submit them, along with evidence of external approval to UREC for formal recording.

Research involving documentary material, archives or records: *EITHER* in the public domain *OR* in a private /closed archive to which the researcher has been granted access. In these cases,

the researcher will complete Forms 1 and 2 (countersigned by the supervisor in the case of students) and submit them to UREC for formal recording. Evidence of permissions may be requested, if deemed required.

Research involving animals

If the research involves the use of animals or animal products, the researcher will complete Forms 1 and 5 (countersigned by the supervisor in the case of students) and submit them to UREC for formal recording, along with a copy of the relevant licence (if appropriate).

Research involving environmental interventions

If the research involves altering the environment in any way, the researcher will complete Forms 1 and 2 (countersigned by the supervisor in the case of students) and submit them to UREC for formal recording.

Collaborative projects

For collaborative research projects, the Principal Investigator (PI) is required to manage the ethics scrutiny of the project. Where the PI is employed by another University, the outcome of ethics review by that University should be communicated to UREC to be formally considered and recorded. If the PI is located at Winchester, then the project will undergo scrutiny as per this Policy.

Projects started elsewhere, and the PI has now moved to Winchester

Where a project started when a member of University staff was employed at another institution but has subsequently moved to Winchester, and the project has previously been subjected to ethical scrutiny at the original institution, then it need not go through further ethics review unless there have been significant changes to the original research proposal which have ethical implications. Copies of ethics review from the previous employer must be provided to UREC to be considered and formally recorded.

Projects conducted in another country

Where a project is conducted in another country, the researcher should consider if it is possible to obtain ethics review by a local research ethics committee or other relevant body (e.g. university, health authority). Where such a committee or body exists, local approval should be sought and formally recorded by UREC. UREC will have regard to (but not be bound by) guidelines or decisions made by other institutions, and may provide further guidance. If this is not possible, the project should be reviewed by the University of Winchester, as per this Policy. No research by staff or students may begin until appropriate approval (either locally or from UREC) has been received.

Researchers traveling abroad to collect data are required to notify University staff responsible for Health and Safety and Insurance of the trip, and a risk assessment will be required. Trips deemed particularly high-risk need to be signed off by SMT. To ensure timely processing of this documentation, researchers should secure the required 'travel abroad' agreement prior to submitting their forms for ethics review.

Research with vulnerable populations

In all cases where research involves collection of data from vulnerable populations, it is the researcher's responsibility to ensure that they have current DBS certification. For research with children and vulnerable adults measures to ensure that potential participants can appropriately access and understand the implications of their involvement should be taken. All staff and PGR researchers must also obtain the explicit, opt-in consent of the parents /carers /guardians where sensitive or personal data is to be collected, before approaching child participants. Where a child participant can understand the nature and purpose of the research, then consent

for participation should also be sought from the child.

2.2 Engaging with research ethics

2.2.1 *Staff*

Staff (both academic and from Professional Services) must complete Form 1 at the start of each project (or, if appropriate, at each project phase if the research design is staged or changes with implications for the ethical aspects of the work), to determine if ethics review and approval is required and what level of review. Research proposals developed by members of Professional Services, which require review, should be referred to the Chair of UREC who will advise on the most appropriate route.

2.2.2 *Postgraduate Research Students (MPhil, PhD)*

PGR students should engage with ethics from the start of their project and will be asked on interview to identify in broad terms the ethical considerations of their work. At the first supervisory meeting the student should discuss ethics with their supervisor(s), identify what level of review will likely be required, if any, and plan when submission of the ethics application should be made. Completing and submitting these forms, countersigned by the Director of Studies /supervisor will meet the requirement to engage with ethics. Confirmation of compliance will be communicated to the submitter and PGR Office.

1. If no review is required, the student should submit Forms 1 and 2 to ethics.declaration@winchester.ac.uk copied to PGRAdmin@winchester.ac.uk.
2. If Faculty level review is required, the student should submit Forms 1 and 3 to the Faculty Head of RKE or their nominee for review.
3. If Committee level review is required, Forms 1 and 4 should be submitted to the University Research Ethics Committee via Ethics1@winchester.ac.uk.

If the research design is staged or changes as the project progresses, this may hold implications for the ethical aspects of the work; therefore engagement with ethics should be considered at the annual progression review and upgrade, and students should demonstrate that they have taken appropriate steps to meet this requirement.

The University Researcher Development Programme will include training in the ethical conduct of research.

2.2.3 *Professional Doctorates ('ProfDocs')*

Students undertaking professional doctorates will typically conduct the initial stage of their training (the 'pre-thesis stage') within an academic department. Should students engage in research activities at this stage, ethics review will be conducted by the Head of Department (or nominee) or Departmental panel, whichever is appropriate.

Once the student has progressed to the 'thesis stage,' the ethical review of their research will be conducted in accordance with the process outlined in this Policy, taking into account the nature of the work.

2.2.4 *Undergraduate and master's student research projects*

Research undertaken as a part of an undergraduate or taught master's programme of study should, if at all possible, not venture into areas requiring more than low risk review. In these circumstances, ethics review will be conducted by the project or dissertation supervisor and countersigned by the Programme Lead, Head of Department, FHoRKE or a nominee, whichever is the most appropriate.

If full review is indicated, Programmes or Departments may – in consultation with the Chair of

UREC - devise appropriate procedures (including alternative discipline-specific forms if they so wish) in order to guide students in framing the necessary ethical safeguards. Such procedures will typically involve the constitution of an Ethics Panel, which may be convened on an ad-hoc basis (where full review is not conducted on a regular basis) or may be formally constituted as a committee. In any case, the full review of students' proposals will be carried out by the Programme Lead, Head of Department (or their nominee) plus two academic members of staff. The outcomes of such panels should be reported to the FHoRKE or nominee for recording.

Failure by a student to comply with the University of Winchester Research Ethics Policy and procedures is considered academic misconduct, and will incur penalties (see the Academic Misconduct policy).

2.2.5 *Taught module (undergraduate or Master's) block ethics review*

Taught modules in which it is routine practice to undertake a practical activity as part of the assessment process may be granted 'block ethics review', provided the activity is always conducted using the same method, approach or protocol, or the activity remains the same each time. Such activity needs to be assessed as posing minimal risk or no risk to participants.

In this case, the Module Leader will complete the 'Block ethics review Form' (Form 6) and submit it to the secretary of UREC. Approval can be given by Chair's action, after consulting with members of the UREC, other researchers with relevant expertise or teaching leads.

Once given, the approval will be valid for a period of three years. After this time, the approval must be renewed. If there are modifications to the activity, the Module Leader must submit a new application for block approval.

Any other research activity that is undertaken as part of a taught module, for which block ethics review is deemed unsuitable, instead an ethics checklist must be provided to students to ensure their attention to principles of ethical research practice.

2.3 What type of review?

2.3.1 *Review not required*

Whilst research falling into the categories listed in section 2.1.3 may not need formal ethics review, the research project needs to be formally recorded. In such cases the researcher completes Forms 1 & 2 and submits them to ethics.declaration@winchester.ac.uk.

Forms submitted in this way will be checked within 10 working days by the Chair of UREC or a nominee and the researcher will receive confirmation of compliance with the University Research Ethics Policy and procedures. The forms are archived centrally on SharePoint. Submissions not suitable for the 'self-declaration' route will be returned to the researcher with guidance on submitting their work for ethics scrutiny.

Outcomes of 'self-declarations' will be reported to the next meeting of the UREC. A list will be included in the UREC Annual Report.

2.3.2 *Faculty Review*

Faculty review may be conducted when the potential of the research to cause risk of harm to participants or the researcher is not deemed significant, and data security is straightforward. Typically, Faculty review may be sufficient for research which does not involve deception and where participants (or in the case of children, their parents or guardians in addition to the children's consent) have actively given informed consent to participate and to the use of their data by the researcher(s) in ways which have been clearly defined and communicated.

Members of Faculty will exercise judgement when conducting Faculty review. If necessary, they will seek advice from UREC and /or refer proposals for full review by UREC.

2.3.3 *Committee Review*

Committee review will be conducted when the potential of the research to cause risk of harm to participants or the researcher is deemed significant, and /or data security is complex.

Full review will be conducted by UREC. In some cases, a member of the Senior Management Team may be invited to take part in the review process, for example when the research poses serious risks of reputational damage for the institution.

2.3.4 *Review by Chair's action*

Review by Chair's action may be undertaken in the case of staff project proposals which are being submitted for funding from major funding bodies, where ethics approval is a pre-requisite or an 'opinion' is required as part of the bid submission process. Such opinion may not be sought at Faculty level. In such cases, the researcher should complete the appropriate form (guided by the policy) and submit the form to ethics1@winchester.ac.uk. Where an opinion is given, review is postponed until the outcome of the funding bid is known, but it must then be carried out in line with the requirements of both the University and the funding body, at the most appropriate level (i.e. faculty or committee).

Review by Chair's action may also be conducted for research projects that are eligible for Faculty level review but cannot be reviewed by the Faculty Head of RKE or nominee (for example because there is a conflict of interest). In this case, the review will be carried out by the Chair of the UREC, who may consult one or more members of UREC.

Outcomes of all reviews by Chair's action will be reported to the next meeting of the UREC. A list of all reviews will be included in the UREC Annual Report.

2.4 The ethics review process

2.4.1 The Ethics Policy and review processes are common to staff and students (PGR) research projects, whether undertaken at Faculty or Committee level. The process is as follows:

1. Read this Policy with the scope and nature of the research in mind in order to identify the ethical aspects of the work in need of consideration;
2. Complete Form 1 – this form distinguishes between different types of research and directs the researcher to the next step.
    a. In cases when ethics review is not required, the researcher either completes Form 2 or Form 5 depending on the nature of the project, and submits both forms to ethics.declaration@winchester.ac.uk for acknowledgment and formal recording;
    b. If low risk ethics review is required, the researcher completes Form 3 and submits both Forms 1 and 3 and any supporting documents to the Faculty Head of RKE or nominee for Faculty level review;
    c. If the research presents more complex issues for ethics review, the researcher completes Form 4 and submits both Form 1 and 4 and any supporting documents to the Secretary of the UREC copied to ethics1@winchester.ac.uk for Committee review.
3. There is an additional ethics review process to manage block review for taught modules requested by teaching faculty (Form 6). This needs to be completed and sent to the Chair of the UREC copied to ethics1@winchester.ac.uk for review.
4. The UREC reviews applications once a month. Applications should be received before the 9th of each month in order to be considered in that month. Applications received after that date will be considered the following month. Incomplete applications will be

returned without review for amendment. Please ensure that all relevant information is provided, including participant information sheets and consent forms to avoid delay in the review process.

5. Once a complete application has been received, the turnaround time is four weeks to first outcome; however, it is not unusual for the committee to request further clarifications or amendments, so please allow at least four weeks for ethics clearance. The UREC endeavours to review applications within the turnaround time of a month, though it may take longer during busy periods.

Where an application is submitted for full review, the UREC will make decisions using a majority voting procedure. The possible outcomes of review are:

- Approval with no amendments;
- Approval with recommendations;
- Approval subject to compulsory amendments;
- Not approved;
- No decision.

The UREC may at its discretion request advice and guidance from colleagues with particular expertise, consult SMT and in addition may call upon outside experts to assist with advice and review as required. Where an application is not approved, the Chair will discuss the reasons with the applicant (or the supervisor in the case of PGR students) with a view to identifying a solution that is acceptable to UREC. Where a decision cannot be reached by the Committee, the Chair will refer the matter to SMT.

Decisions made by the UREC for each proposal will be documented and provided to the relevant researcher(s). The decision will be kept securely for a period of at least seven years. Both Faculty and Committee documents and outcomes will be stored on the Ethics Sharepoint Workspaces.

2.5 Appeals

2.5.1 Where the UREC does not approve an application, the researcher has the right to request that the decision is considered by a Research Ethics Appeals Panel. All members of the Panel must be fully apprised of and familiar with the University Research Ethics Policy.

The Research Ethics Appeals Panel will consist of the following:

a. Director for RKE as Chair (the Director has the right to appoint another senior member of academic staff in his or her absence);
b. Two senior academic appointed by the Chair; and
c. If additional expertise is required, the Chair may invite up to two further members of academic staff with relevant expertise but who have not been involved in the initial decision to join the panel.

Appeals should be made in writing to the Chair of the Research Ethics Appeals Panel supplying all the documentation considered by UREC and a covering letter clearly setting out the grounds for appeal and any supporting evidence.

Unless the Panel decides to uphold the appeal as a result of its deliberations, hearings must provide the researcher with the opportunity of presenting a case in person. Following the withdrawal of the researcher from the meeting, the Panel will determine its decision and provide clear justification, whether the appeal has been successful or unsuccessful.

2.6 Amendments

2.6.1 If, after obtaining ethics approval, a research project changes substantially in such a way that

new ethical considerations arise, these changes need to be communicated to the Committee that granted the original approval (in the case of staff and research students this will be either Faculty level or UREC). The researcher should amend the original form (Form 3 – section 5; Form 4 – section 4; Form 5 – section 6) and provide a narrative detailing the changes and any ethical issues associated with these changes that have not been considered in the original application. In some cases, a new application may be required, depending on the nature of the changes and the complexity of the research project.

Taught students would not normally be expected to make significant changes to their research proposals, given the short time to final submission. However, where such changes are necessary, then a narrative should be submitted to their Programme or Module Lead or nominee, countersigned by their supervisor, detailing the changes and any ethical issues associated with these changes. Approval of the changes will be given by the Programme or Module Lead or nominee, by the Departmental or faculty, whichever granted the original approval. In some cases, a new application may be required, depending on the nature of the changes and the complexity of the research.

2.7 Institutional monitoring

2.7.1 In the first instance, it will be the responsibility of the researcher to monitor the conduct of research that has received ethics approval (for students, in consultation with supervisors). The researcher must ensure that there is an appropriate continuing review of the research, taking into account any possible changes that may occur over the duration of the research project. It is the responsibility of the researcher to alert the Chair of the UREC, Faculty Head of RKE or nominee or Supervisor (whoever is the most relevant) if any further ethical implications arise.

The UREC may periodically conduct a selective audit of current, approved research projects and faculty /programme processes.

Faculty RKE Committees will be accountable to UREC for the Faculty level decisions and provide an audit of review activity for each academic year plus any recommendations for the development of the ethics policy and processes.

Approval given at module, programme, or department level should be recorded and retained. From time to time the Chair of UREC may request an overview of applications /approvals, information about typical issues encountered and the ethics scrutiny process in place.

UREC will provide an annual report to the Senate RKE Committee and will comment on the development of research ethics within the University.

2.8 Complaints and research misconduct

2.8.1 The University takes all allegations of misconduct relating to research ethics seriously, by both staff and students. The University will handle such allegations using existing appropriate policies and disciplinary procedures.

Types of research misconduct are outlined in UUK's *Concordat to Support Research Integrity* (2012: 17) and may include:

- **fabrication**: making up results or other outputs (e.g. 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; or

- **improper dealing with allegations of misconduct**: failing to address possible infringements such as attempts to cover up misconduct and reprisals against whistle-blowers.

Concerns about the conduct of research carried out under the auspices of the University should be made in the first instance in writing to the Director of Research and Knowledge Exchange of the University of Winchester. The Director of RKE will liaise with the Chair of UREC and the relevant Dean of Faculty, as appropriate, in recommending further action which may invoke the University complaints procedure.

Where significant concerns have been raised about the ethical conduct of a study, UREC can request a full and detailed account of the research for a further ethical review. Where UREC considers that a study is being conducted in a way which is not in accord with the conditions of its original approval, consideration will be given to approval withdrawal and require that the research be suspended or discontinued. It is the duty of UREC to inform the Director of Research and Knowledge Exchange in writing and the appropriate funding body (if an externally funded project) that ethics approval has been withdrawn.

2.9 Failure to comply with this policy

2.9.1 Failure to undertake a review of the ethical implications of research, or to comply with any other aspect of this Policy, or failure to apply reasonable care in assessing the likely ethical implications of a research project, may be deemed to constitute academic and /or research misconduct.

Dr Samantha Scallan
Chair, University Research Ethics Committee

Revised: August 2019

References

UNIVERSITY OF WINCHESTER (2015) *Strategic Plan 2015-2020*. Winchester: University of Winchester. Available at: https://intranet.winchester.ac.uk/information-bank/annual-operating-statements/Documents/UOW-Strategic%20Plan.pdf

UNIVERSITIES UK (UUK) (2012) *The Concordat to Support Research Integrity*. London: UUK. Available at: https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf

Appendix 1

Resources

1. **Legal and statutory frameworks informing this policy**

Disclosure and Barring Service (DBS) checks: please see this link

Legislation.gov.uk: Data Protection Act 2018

Legislation.gov.uk: Mental Capacity Act 2005

The Information Commissioner's Office (ICO): Guide to the General Data Protection Regulation (GDPR)

2. **Helpful external guides and resources**

ALLEA - All European Academies: *The European Code of Conduct for Research Integrity* [PDF]

ESRC: Principles and guidance on ethics [web resource]

Government Office for Science (www.bis.gov.uk/go-science): *Rigour, Respect, Responsibility: a Universal Ethical Code for Scientists* [PDF]

Improving Dispute Resolution Advisory Service for Further and Higher Education (www.idras.ac.uk) for students, academics and managers: *Standards Matter: A review of best practice in promoting good behaviour in public life* [PDF]

Montreal Statement: *Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations* [PDF]

NHS Health Research Authority: *UK Policy Framework for Health and Social Care Research* [PDF]

Nuffield Council on Bioethics: The ethics of research involving animals [web resource]

Singapore Statement on Research Integrity: *Singapore Statement on Research Integrity* [PDF]

Social Research Association (SRA): Research ethics guidelines [web resource]

The Information Commissioner's Office (ICO) code of practice for anonymisation and managing data protection risk: *Anonymisation: managing data protection risk code of practice* [PDF]

The Information Commissioner's Office (ICO) guidance on the risks organisations must consider when allowing personal devices to be used to process work-related personal information and how this approach can be adopted safely in a manner that complies with the Data Protection Act: *Bring your own device (BYOD)* [PDF]

The Research Ethics Guidebook: An online guide for social science researchers [web resource]

UK Research and Innovation (www.ukri.org): *RCUK Policy and Guidelines on Governance of Good Research Conduct* (2013, updated 2015 & 2017) [PDF]

UK Research and Innovation guidance: research integrity [web resource]

UK Research Integrity Office (UKRIO): Code of Practice for Research [web resource]

UK Research Integrity Office (UKRIO): Procedure for the Investigation of Misconduct in Research [web resource]

Universities UK (UUK): *The Concordat to Support Research Integrity* [PDF]

Vitae: *Concordat to Support the Career Development of Researchers* [PDF]

3.	**University of Winchester policies and resources linked to this policy** Strategic Plan Data Protection Policy Equal Opportunities Policy Data Storage and Management Policy Freedom and Information obligations Research Misconduct Complaints Policy Grievance and Disciplinary procedures Health and Safety Policy Intellectual Property Insurance

Appendix 2

FAQs and definitions

1.	**What is research?** Following Research England's (2018) definition of research: 1. For the purposes of the REF, research is defined as a process of investigation leading to new insights, effectively shared. 2. It **includes** work of direct relevance to the needs of commerce, industry, culture, society, and to the public and voluntary sectors; scholarship21; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It **excludes** routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also **excludes** the development of teaching materials that do not embody original research. 3. It **includes** research that is published, disseminated or made publicly available in the form of assessable research outputs, and confidential reports (as defined at paragraph 251). Draft Guidance on Submissions (2018, Annex C, p. 107) Available online: https://www.ref.ac.uk/media/1016/draft-guidance-on-submissions-ref-2018_1.pdf
2.	**What is personal data?** The General Data Protection Regulation (GDPR) gives the following definition of personal data: "'personal data' means any information relating to an identified or identifiable natural (living) person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person." Link
3.	**What is sensitive data?** Some personal data is viewed as more sensitive in nature and is referred to as 'special categories of personal data.' This type of data requires a higher level of protection and concerns information about an individual's: • race; • ethnic origin; • political opinions; • religious or philosophical beliefs; • trade union membership; • genetic data; • biometric data (where this is used for identification purposes); • health data;

	• sex life; • sexual orientation; • criminal convictions and offences. Link By extension if these areas are the subject matter of the research then this would raise the risk level of the research and would be a consideration in review. Other topic areas might include: physical or mental health, abuse, nudity, violence, terrorism, extremism etc.
4.	**What research needs external ethics review?** Research involving NHS patients or individuals covered by the Mental Capacity Act (2005) requires NHS REC approval. Under the MCA, research involving adults aged 16 or over with learning difficulties or who otherwise 'lack capacity' will be subject to NHS approval if that research is deemed to be 'intrusive'. For guidance see link. Similarly, social care research involving adults, intergenerational social care studies involving adults and children or families and some proposals for social science studies situated in the NHS will fall under the remit of the Social Care Research Ethics Committee. For further guidance see link. http://www.hra-decisiontools.org.uk/research/
5.	**What is audit?** Audit is a way of finding out whether we are doing what we should be doing. It is defined as assessing the level of service being provided against a set of predetermined standards. This generally involves analysing existing data with results usually being used/distributed locally in order to effect change to improve /change the level of service currently being provided. It does not require ethics approval.
6.	**What is service evaluation?** "Service evaluation is designed and conducted solely to define or judge current care and should answer the question: "What standard does this service achieve?" It should measure current service without reference to a standard and involve an intervention in use only. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference and this should happen before service evaluation). Service evaluation usually involves analysis of existing data but may include administration of interview or questionnaire. There should be no randomisation and service evaluation does not require NHS REC review." Taken from: http://www.hra-decisiontools.org.uk/research/glossary.html#C
7.	**What is research for a medicinal purpose?** 'Medicinal purpose' means: • treating or preventing disease or diagnosing disease; or • ascertaining the existence degree of or extent of a physiological condition; or • assisting with or altering in any way the process of conception; or • investigating or participating in methods of contraception; or • inducing anaesthesia; or

	• otherwise preventing or interfering with the normal operation of a physiological function; or • the use of drugs; or • the use of surgery (other than biopsy); or • genetic engineering; or • pharmaceutical product /appliance designed or manufactured by the University; or • such work outside of the United Kingdom. If you think your research comes under the definition of 'for a medicinal purpose' there are further considerations regarding University insurance coverage which need to be clarified. Please note however where the research activity is taking place within the UK and is limited to the following, insurance cover is automatic: I. Questionnaires, interviews, psychological activity including CBT; II. Venepuncture (withdrawal of blood); III. Muscle biopsy; IV. Measurements or monitoring of physiological processes including scanning; V. Collections of body secretions by non-invasive methods; VI. Intake of foods or nutrients or variation of diet (other than administration of drugs). Please email the Committee Chair (ethics1@winchester.ac.uk) for further guidance if your project falls within the definition of 'for a medicinal purpose' as it is likely it will need to be scrutinised by the Committee.
8.	**Note on vulnerability** In the context or research ethics, vulnerability is defined as an impaired capacity to provide fully informed consent to participate in research. Whether a person is considered to be 'vulnerable', and therefore unable to provide consent will depend on a range of factors and circumstances. These will include some linked to the individual (age, mental capacity, disability, susceptibility to coercion), the type of research being undertaken, how and where the research is being undertaken and so forth. Vulnerability may arise as a result of being in an abusive relationship, potential marginalisation due to disadvantageous power relationships within personal and /or professional roles. Participants may not be conventionally 'vulnerable' but may be in a dependent relationship which means they can feel coerced or pressured into participating in research, an example being students. Researchers must consider additional ethics concerns arising from working with potentially vulnerable people and ensure their participation is truly voluntary. Researchers must therefore consider the presence and weight of such factors when assessing whether individuals identified as potential research participants should be deemed to be 'vulnerable' or 'particularly vulnerable' and their capability to give informed consent.
9.	**Note on deception** Deception can occur at a variety of levels: for example, at one level, experimental methods may depend on participants being deliberately misled as to the true nature or purpose of the research in which they are taking part; at another, covert participant observation may entail an implicit deception as to the true identity and role of the researcher. Deception may be a legitimate and necessary feature of social scientific research, but its use must always be properly justified.
10.	**Note on child participants**

	Guidance can vary on the capacity of children to give consent to participate in research based on age. If working with children in schools, researchers should bear in mind the following: • for children under 16, informed consent to participate must be given by a parent /guardian; • in addition, good practice encourages researchers to seek informed consent from the young person before they participate in the research where they can understand the research aim and participation requirements; • the gatekeeper, for example the head teacher of a school, can only make a decision as to whether a researcher should be allowed to provide information on the research to young people and their families, and seek their informed consent for participation. If accepted practice in relation to consent and children is set out in guidelines from a professional association or specific, agreed standards of practice exist, then these should be cited in making a case for the approach proposed if it differs to the general guidance above.
11.	**Note on data protection considerations** Changes in data protection regulation generally requires that consent be informed and given openly, explicitly and freely. If sensitive or personal data (see FAQ 3) is to be collected, participants should be given the opportunity to cease participation without giving a reason and be able to request that their data be withdrawn from the study up to a practical point () e.g. before it has been fully anonymised). Researchers should ensure the information sheet and consent forms are explicit about the nature and scope of the data to be collected, how it will be stored securely, what it will be used for (e.g. a paper, report, teaching), how long it will be held for and how it will be destroyed. The names and contact details of the data protection officer and ethics approval point of contact should be included. Where consent is indicated, good practice is to request potential participants to initial boxes and then sign the form.

Appendix 3: Decision flowchart for University Research Ethics Committee (UREC) Scrutiny