

Keele University Research Ethics Policy

Purpose:

The purpose of this document is to explain the University's stance in relation to research ethics review and the creation, operation and monitoring of research ethics committees.

Scope:

This document applies to all staff members involved in the design and delivery of research as well as the management and conduct of research ethics committees.

Implementation Plan:

This framework will be implemented directly after its implementation date.

Date of implementation: 12th November 2018 (*University Senate approval pending*)

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Summary

This Framework Document lists Keele University policies and procedure on specific topics relating to Research Ethics:

- University Research Ethics Committees
- Research specific application of Research Ethics
- University Research Ethics Processes
- Appeals against decisions
- Compliance with this document
- Reporting

All staff members within Keele University involved in the design, management or conduct of research and process of ethical review must adhere to these policies.

1. Abbreviations and Definitions

Term	Description
Applicant	Any person who takes responsibility for the content of an application to a relevant research ethics review committee. This is often the research lead.
CV	Curriculum Vitae
ESRC	Economic and Social Research Council
FREC administrator	Faculty Research Ethics Committee Administrator. SEE Research Ethics Officer.
NHS	National Health Service
Researcher	Any person who conducts research, including but not limited to: as an employee; an independent contractor or consultant; research student; visiting or emeritus member of staff; or a member of staff on a joint clinical or honorary contract.
REC(s)	Research Ethics Committee(s)
REO	Research Ethics Officer Any person who takes responsibility for the administration of REC functions, including but not limited to: processing applications, amendments, annual reports, complaints and opinions.
RIE	(Directorate of) Research Innovation and Engagement

2. Introduction

The University is committed to conducting high quality research underpinned by appropriate ethical standards for the benefit of society and in the public's interest.

The University recognises the benefits of a positive culture of ethical reflection, debate and mutual learning particularly against the continuing emergence of new situations and research methodology which require creative approaches to ethics issues.

To promote ethical conduct the University has set up a Quality Management System, of which this policy forms part. The Quality Management System ensures that all researchers consider ethics issues throughout the lifecycle of a research project and seek appropriate review of those issues.

The Policy does not replace the need for researchers to critically and responsibly consider their own activities and issues that arise during the course of their research but does provide a framework to illustrate how to proceed.

3. Policy on Research Ethics

Research conducted by the University covers a wide range of disciplines, requiring an equally diverse set of ethical review processes united by a common set of principles.

Our principles for ethical research are:

- Research ethics should be under continuous consideration, ethical issues can arise in all fields of research and may evolve along with the settings in which it is conducted
- Ethics review should be proportionate to the risk of the research

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- Research should aim to benefit individuals and society while minimising the risk and harm to individuals, society, the environment and cultural objects (i.e. minimising the risk for any given benefit)
- The rights and dignity of individuals and groups should be respected
- Wherever possible, participation should be voluntary and appropriately informed
- Researchers should be aware of, understand and execute their responsibilities in relation to research ethics
- Researchers should understand and observe their obligations regarding the protection of sensitive and confidential information including personal data
- Research should be conducted with integrity and transparency
- Lines of responsibility and accountability should be clearly defined
- Conflicts of interests should be avoided where possible, and where they cannot be avoided they should be disclosed to participants as part of the consent process

The University will call to account any member of staff involved in upheld allegations of research misconduct and breach of compliance with this policy in accordance with the Research Misconduct Policy.

4. Policy on research requiring research ethics committee review

Review by a research ethics committee is required where research involves humans, their data¹ or biomaterial²; risk of damage to the environment; risk of damage to any artefacts of cultural significance; politically or socially sensitive topics with impact on the welfare and interests of local, national or international communities; potential reputational risk to the researchers or University or where a source of funding has the potential to compromise the University's position as a publicly funded charitable body.

Projects including high / substantive risk activity as defined in the [Central Research Ethics Committee Criteria] will be reviewed by the Central Research Ethics Committee (CREC). All other activity may be reviewed by faculty research ethics committees.

5. Policy on University research ethics committees (RECs)

The University has appointed RECs to review research activity conducted by the University, its staff, students and on its premises or property. These RECs are appropriately constituted to provide a competent, timely, proportionate and authoritative review of research. This review is independent of the research team, based on their members' judgement and not subject to managerial direction. Review is divided between Centralised RECs and Faculty RECs according to the level or risk. The REC structure is provided in Figure 1: Organogram of Keele University research ethics committee structure and further described in section 14.

¹ Includes primary data originating from human subjects (e.g. anonymous questionnaires or identifiable interview data); and the use of secondary data, which originated from or is about human subjects, which was initially provided for other purposes (e.g. other research projects or organisational datasets).

² Anything that originates from a human subject including: cells; tissues; organs; bodily fluids (e.g. blood, plasma, spinal fluid); secretions and excretions (e.g. breath, urine); outgrowths (e.g. hair, nail, teeth).

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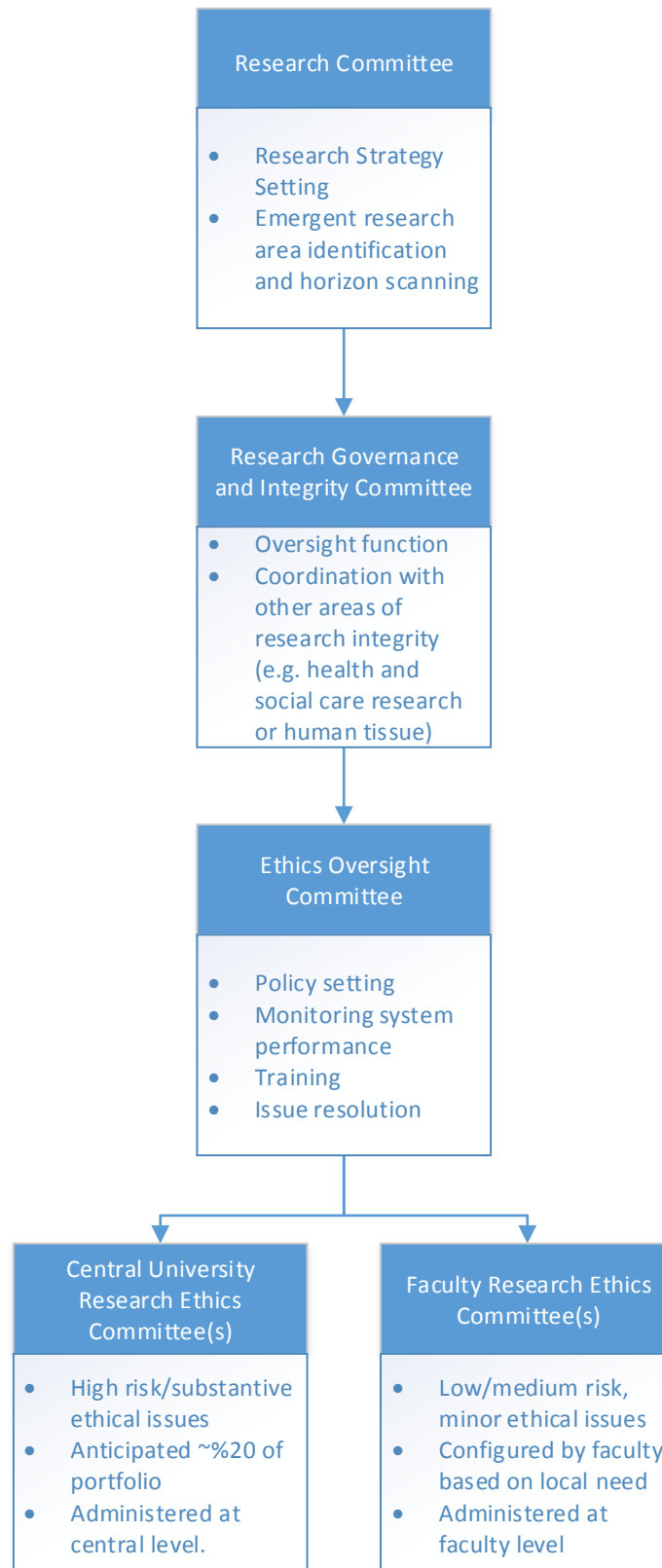


Figure 1: Organogram of Keele University research ethics committee structure

The RECs are able to:

- Confirm that research has received a favourable ethical opinion
- Require clarification or modification of parts of a research submission
- Authorise significant amendments of parts of an approved research proposal
- Defer consideration of a proposal pending expert advice or agreement by the University
- Reject a research proposal as a whole or in part
- Revoke approval of research if dissatisfied with the conduct of the research
- Refer students or staff under the University's research misconduct or disciplinary procedures
- Refer to the Ethics Oversight Committee or other RECs as appropriate
- RECs may appoint sub-committees consisting of its members. These sub committees may exercise any of the RECs functions on its behalf limited to:
 - Research proposals that justify light touch review
 - Research proposals that justify review as part of established protocols/programmes of work
 - Review of information further to earlier review in full committee
 - Amendments
 - Annual progress reports
 - End of study reports

The RECs should receive the following documents:

- Application form
- The protocol or proposal of activity
- Consent forms
- Recruitment materials (e.g. advertisements)
- Written information to be provided to subjects
- Information on substances to be administered where relevant
- Available safety information
- The investigator's CV
- Any other documents which are required to enable the REC to fulfil its responsibilities

5.1. Remit of Review

RECs should review all aspects of research proposals for their ethical integrity. This will involve considerations of the design, management, conduct and proposed outputs of the research.

RECs should not assess the scholarly or scientific standards of proposals. Where the REC requires understanding of peer review to make a judgment about ethical issues the RECs may request evidence of peer review or seek further advice from an independent researcher with expertise in the research methods proposed.

RECs must take into account relevant discipline-specific codes of practice e.g. the Code of Human Research Ethics published by The British Psychological Society and the Declaration of Helsinki published by the [World Medical Association \(2013\)](#).

University RECs will not review research that does not involve Keele University staff, students, premises or property.

The REC may not offer a legal opinion or governance assessment on research proposals, but it may advise the researcher whenever it considers that legal advice might be helpful to them. Researchers retain responsibility for making sure the research is conducted in accordance with the requirements of law, relevant regulators and guidance.

RECs will work collaboratively with applicants to achieve the highest ethical standards in their work.

5.2. Membership

Associate Deans will nominate members for University RECs. REC members may only be selected and appointed to central and faculty RECs by the Ethics Oversight Committee.

REC membership must include a Chair and deputy Chair.

RECs will make decisions following review where membership meets quorum.

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REC membership as a whole should aim to reflect the diversity of the population, taking account of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. The University will take steps to encourage membership from groups who are underrepresented.

REC membership should include a range of experience and expertise to facilitate understanding of the research proposals that it reviews and sensitivity to the dignity, rights, safety and well-being of the likely range of research participants.

REC members must be provided with written terms of appointment including:

- Duration of term of office
- Renewal policy
- Disqualification and resignation procedures
- Policy concerning declaration of interests
- Details of service
- Initial and continual training
- Confidentiality and safeguarding of intellectual property

REC members, including Chairs, are appointed for a fixed term of office not exceeding 5 years. A member may serve a further term of 2 years.

Simultaneous membership of more than one REC is permitted with the approval of the Faculties involved.

RECs may invite non-members with expertise in special areas for assistance. These non-members do not count towards the quorum and may not vote on decisions. They are not involved in any REC business apart from advising on the issues put to them. Their advice is reflected in the record of the relevant REC meeting.

REC members must declare a conflict of interest as soon as the conflict is identified and absent themselves during consideration of research proposals that could be seen to create a conflict of interest including but not limited to personal, academic or financial conflicts.

Representatives of the Ethics Oversight Committee (see Section 14) may attend and observe Faculty or Central Research Ethics Committee meetings at any time, they do not count towards the quorum and may not vote on decisions, but may contribute to discussion if invited by the Chair.

5.3. Review

REC members may be designated as points of contact for applicants to seek advice on the requirement for REC review. REC members may also provide advice on the content, submission or review of an application outside of the RECs deliberations.

Members are required to contribute in full at least two thirds of all scheduled REC business in each year, barring exceptional circumstances. Sub-committee activity should also be taken into account. A REC member unable to contribute may make arrangements with the Chair.

The applicant may provide information during REC discussions but should not participate in the deliberations of the REC or in the vote/opinion of the REC.

REC discussions are not public. Observers may be involved following a written invitation stating the terms and conditions of their attendance. Observer involvement will be agreed by the REC and documented accordingly. Observers do not count towards the quorum and may not vote on decisions. They are not involved in any REC business.

The RECs should conduct continuing review of each ongoing project at intervals appropriate to the degree of risk to human subjects.

Where there are changes to research following initial REC review the REC will review any proposed changes and provide an opinion prior to implementation.

5.4. Decision Making

The RECs will communicate reasons for its decisions to applicants in a documented format, clearly identifying the research, the documents reviewed and the dates of the opinion.

The REC may give an opinion conditional to criteria which must be met by the researcher. This may include but not limited to; annual reporting to the REC, amendments to study instruments, amendments to study power calculations and changes in research team membership.

RECs may delegate the responsibility for determining its final opinion to Chairs or Deputy Chairs, sub committees of specified members.

RECs may only delegate activities to administrative staff where the matters are administrative such as issuing letters confirming the REC's opinion.

5.5. Evidencing and Record Keeping

RECs will maintain written records of its activities, records of decisions made and documentation on which those decisions are based.

REC membership records should be maintained including qualifications/experience of its members.

The University may monitor any of its RECs to demonstrate the RECs integrity and independence in decision making. This monitoring may take the form of reporting on REC activity, membership, procedures and decisions, audit of a sample of reviews and cross-referral between RECs to establish consensus.

University REC operations will be governed by the relevant quality management system, Standard Operating Procedures and associated documents and processes.

5.6. Central REC

The Central REC members may be associated with particular research interests but they are not representatives of those interests. REC members are appointed in their own right to participate in the role of the REC as equal individuals of sound judgement, relevant experience and adequate training.

The Central REC must maintain lay membership as well as people who have relevant qualifications or professional experience that can help the REC understand particular aspects of research proposals.

The Central REC membership shall comprise at least 7 members and shall be multidisciplinary with cross-faculty representation as well as lay representation. Deans shall be responsible for nominating two members to be drawn from each faculty.

5.7. Faculty REC

Faculties are required to have research ethics committee(s) responsible for ensuring that all research is appropriately scrutinised.

Faculties must develop their own terms of reference and procedural guidelines in line with this policy and for approval by the Ethics Oversight Committee.

Faculty REC membership must comprise members from more than one discipline.

Faculty REC membership shall comprise of at least 7 members at least one of which is appointed from outside the Faculty.

6. Policy on expedited review

In exceptional circumstances ethics review may be appropriate where the research is in response to a pressing, time dependent demand. Expedited reviews must be fully justified by the applicant and conducted by full RECs in accordance with the appropriate quality management system.

7. Policy for proportionate or light-touch review

Projects that pose minimal risk of harm to participants or others impacted by the research, as defined in Light-touch Review Criteria may be eligible for light touch review.

Light-touch review may be performed by a Faculty REC sub-committee comprising of a minimum of 2 members.

8. Policy for established protocols of work/programmes of work

Where research involves commonly occurring situations, methodologies, data sets, human samples or interventions an applicant may apply for broad approval of the protocol as an established protocol.

Review of the activity to be classified as an established protocol must be fully justified by the applicant and conducted by a full REC.

9. Policy on ethics committees set up in accordance with applicable laws

All staff and students must comply with national statutory requirements for ethics review by a properly constituted committee set up in accordance with applicable laws (e.g. Medicines for Human Use (Clinical Trials) 2004, Animals (Scientific Procedures) Act 1986). The opinion of these bodies are normally acceptable for University purposes and further ethical review is not required unless specific to the University (e.g. conflicting the interests of the University or otherwise posing a risk to other University activity).

University staff and students must adhere to the relevant standard operating procedures, associated documents and processes when applying to external Research Ethics Committees, e.g. the Standard Operating Procedures for Research Ethics Committees in the UK.

University staff and students must adhere to relevant policy, standard operating procedures, associated documents and processes when applying to the University's Animal Welfare and Ethics Review Body.

10. Policy on external university ethical review

University research ethics review should not seek to duplicate ethical review from another body if set up in accordance with the Economic and Social Research Council framework (e.g. another higher education institution). These ethics approvals must be presented to the appropriate University REC for consideration and approval. The Keele-based REC may wish to consider additional ethical issues that are specific to the University. The Keele-based REC must maintain oversight of external ethical approval and that work is carried out in accordance with it.

11. Policy on research conducted overseas

Research activity conducted by the University overseas should meet, as a minimum, the ethics standard required within the University. Researchers are expected to seek appropriate ethics approval from a properly constituted and independent ethics committee in all states involved in the research. These local ethics approvals must be presented to the appropriate University REC for consideration and approval.

The reviewing REC must maintain oversight of external ethical approval and that work is carried out in accordance with it.

12. Policy on retrospective review

University RECs may not give retrospective opinions on research activity.

13. Policy on non-research related ethical review

The University has a general duty to act ethically in all its activities including but not limited to teaching, fundraising, partnerships, investments and procurement where separate policies and codes apply. Due regard to all ethics policies/codes must be taken where activity is also conducted for non-research purposes and this research ethics policy should be read in conjunction with those broader ethical policies/codes.

14. Roles and responsibilities of individuals and committees

The Applicant

The responsibility for the conduct of ethical research and compliance with the conditions of the favourable ethical opinion ultimately lies with the applicant. Applicants are expected to recognise and operate within the spirit of the principles described in this document and in relevant codes of practice, and to offer specific justifications for research activity that falls outside those principles.

In addition the applicant is expected to be fully aware of relevant legal requirements and to act accordingly.

The Applicant is responsible for consideration of ethical issues throughout the course of the project, identifying where changes require further ethics review and ensuring reporting is undertaken in line with the requirements of the REC.

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The Applicant is responsible for the design, conduct and reporting of the research. The Applicant is responsible for the content of the submission to the REC.

The Applicant must cooperate with audit and monitoring activity directed by the Ethics Oversight Committee and any investigations resulting from a complaint, concern or accusation of misconduct.

The Research Ethics Officer (REO)

The Associate Dean may appoint a named Research Ethics Officer who is not otherwise involved in research activity who has responsibility for the operation of the faculty RECs.

The Research Integrity Officer (Directorate of Research Innovation and Engagement) is the nominated Research Ethics Officer for the Central Research Ethics Committee

The Research Integrity Officer is responsible for the development and management of the University's Research Ethics Quality Management System and undertaking routine monitoring and audit of REC activity. The Research Integrity Officer is also responsible for the receipt, investigation and escalation of complaints, issues and concerns as they relate to ethical issues.

Associate Dean for Research

The Associate Dean has the responsibility for the creation, operation and oversight of Faculty RECs in accordance with this document.

The Associate Dean will have responsibility for ensuring that applicants fulfil their responsibility in ensuring the ethical conduct of the study and compliance of the conditions of the favourable ethical opinion. The Associate Dean may nominate a Research Ethics Officer to assist with the formation, operation and oversight of Faculty RECs.

The Associate Dean will work with the Research Ethics Officer, Research Integrity Officer and reviewing REC in the event of a complaint, concern or accusation of research misconduct.

Ethics Oversight Committee

The Ethics Oversight Committee is a committee of Senate responsible with developing and maintaining a culture of ethical research at the University. The Committee will:

- Be an overarching committee for all University Research Ethics Committees.
- Develop and review policy and processes for ethical review of research including faculty procedures.
- Have accountability for the formation, operation and oversight of centralised RECs.
- Arrange for appropriate ethics training to be provided for the central and faculty research ethics committee members.
- Monitor and review all research ethics committees.
- Manage appeals and complaints arising through any research ethics committee business.
- Escalate issues with relevant senior authorities within the University.
- Report annually to Research Governance and Integrity Committee on research matters.
- Advise where matters of misconduct arise involving any aspect of Research Ethics.
- Delegate relevant functions to central or faculty sub-committees. Have responsibility to all matters relating to the ethics of conducting University research which are not covered by NHS Research Ethics Committees or by other recognised Ethics Committees.

The Ethics Oversight Committee has overall accountability for the functioning of the RECs in accordance with this document. The Ethics Oversight Committee is responsible for ensuring there are effective mechanisms to make staff and students aware of relevant policies, standard operating procedures, associated documents and processes.

The Ethics Oversight Committee will support and oversee audits, investigations and monitoring activity for research activity that falls within its remit and may involve members of staff with named roles from other areas where research is cross disciplinary.

The Ethics Oversight Committee will consider and advise on non-research ethical issues referred to it by Council, any committee of Council; the Vice-Chancellor; Pro Vice-Chancellors; Faculty Deans; Heads of School; Directorates; Directors of centres or research units and the ethics committees.

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Research Governance and Integrity Committee

The Research Governance and Integrity Committee is coordinated by the Research Integrity Manager based within the Directorate of Research, Innovation and Engagement.

The Research Governance and Integrity Committee is responsible for development and delivery of the University's training to ensure all members of staff are suitably trained in the activities undertaken as part of research.

Research Committee

The Research Committee is one of the Senate committees, and is responsible for all matters concerning the management of, and support for, Keele University research.

Senate

Senate is the academic governing body of Keele University. Its responsibility is to direct academic policy in relation to teaching and research, and to assure itself that the University's academic standards are properly observed.

15. Policy on ongoing review

RECs may require annual reports about the progress of the research they have reviewed. These reports must explain any developments adversely impacting on participants' dignity, rights, safety or well-being and any aspect relating to research ethics, including but not limited to recruitment rate, urgent safety measures and deviations/breaches of protocol. A REC should reconsider its favourable opinion in light of pertinent information that comes to its attention. If the REC, given that information during its initial review, would not have reached a favourable opinion, it must notify the Ethics Oversight Committee and should notify the researcher that its opinion is no longer favourable.

Where a research design is emergent the REC may agree procedures for reporting to the REC or sub-committee to enable ongoing ethics review. Triggering events or situations which might provide grounds for further review or discontinuation of the research should be agreed with the researchers before the REC's initial decision is granted.

16. Policy on training

REC members should receive training and guidance about the issues they should consider, both in general and specific cases. The training and guidance should reflect general standards for ethical research, such as the European Textbook on Ethics in Research, Economic and Social Research Council's Framework for Research Ethics, and take into account relevant legislation and discipline-specific ethical standards.

All REC members must agree to take part in any initial and continual training appropriate for their role. Attendance at meetings of other RECs is encouraged in the interests of training and consistency.

17. Policy on appeals and complaints

Appeals against decisions made by Faculty RECs or Central REC may be addressed to the Research Integrity Officer. The Chair of EOC will decide whether to allow the appeal. In the event that the appeal is allowed, EOC will consider the substantive and procedural soundness of the REC's decision and may ask the REC to reconsider its decision, or may substitute its own decision.

The Ethics Oversight Committee will not hear appeals against decisions of RECs external to Keele University.

REC members should treat applicants with courtesy and professionalism. If an applicant feels they have been treated unfairly or discourtesy they may raise a complaint with the Chair of the REC in the first instance. Applicants may also contact the secretary of the Ethics Oversight Committee with their complaint who will initiate the appeal and complaints procedure

Disputes, appeals and complaints must be dealt with in a confidential manner by those involved in investigation and resolution of the issue.

18. Policy on safety issues

One of the aims of robust ethical review is to safeguard the health and wellbeing of individuals and groups of individuals with whom research is being conducted. Any unanticipated or serious harms must be reported to the reviewing REC, including a description of the event and any immediate remedial actions taken.

The REC may, at the discretion of the Chair after consultation with no fewer than two members of the Committee, one of whom must be a lay member, re-review the proposal in light of any safety events.

19. Policy on monitoring

RECs adhere to the principle of openness, transparency and accountability. The Ethics Oversight Committee will maintain a schedule of audit of REC procedures, ensuring robustness and assuring the University of the independence and rigor of the review. The monitoring carried out must respect the independence of the University's RECs and are not intended to make a judgement on the accuracy or correctness of REC decisions.

Monitoring may take the form of desk based review of a sample of reviews. Any monitoring reports may be made available to Research Councils UK funders should they wish to see them.

The Ethics Oversight Committee may direct audit and monitoring of individual research projects and request access to study documentation, records and activities.

20. Policy on suspension and withdrawal of favourable ethical opinion

Where the reviewing REC considers that a study is being conducted in a way which breaches the conditions of the ethical opinion or otherwise fails to protect the rights, dignity and wellbeing of participants it will arrange a meeting with all researchers involved in the research with a view to resolving the matter.

Where the issue is not resolved the REC may suspend or withdraw its favourable ethical opinion on the grounds of:

- a) Scientific validity of the study, for example in the light of new research findings, which may affect consequent research ethics issues
- b) Risks to the safety or physical or mental integrity of participants
- c) The competence or conduct of the researchers
- d) The feasibility of the study
- e) The adequacy of the locations or facilities
- f) Legal non-compliance

Before suspending or withdrawing its opinion the REC will consider whether to consult with the applicant's Faculty to give them an opportunity to address concerns within a specified timeframe.

Where RECs feel that risks to participants warrant it they may immediately suspend approval.

Withdrawal of favourable opinion must only be done following a quorate meeting of a full committee and must be notified to the Applicant and Ethics Oversight Committee.

21. Reporting to external bodies

Where breaches of ethical approval are identified, the Ethics Oversight Committee will ensure that any resultant suspension or discontinuation is notified to external bodies as required, e.g.

suspensions or withdrawal of favourable ethical opinion on any ESRC funded research will be reported to the ESRC by the Ethics Oversight Committee.

22.Related procedures/checklists:

- Glossary of Terms
- Criteria for Research that must go to the University's Central Research Ethics Committee or an NHS specialist REC

23.References:

- Keele University, Regulation 17, Research Committee Terms of Reference,
<https://www.keele.ac.uk/regulations/regulation17/researchcommittee/>
- European Textbook on Ethics in Research. Available at:
<https://publications.europa.eu/en/publication-detail/-/publication/0f37f142-c333-40a8-90a7-bba25c314720/language-en>
- ESRC Framework for research ethics [Online] Available at:
<http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/>