Research Ethics Policy

Approved by: Academic Board	**Effective date:** June 2020	**Next review:** October 2022

Policy statement (Scope)

For the purposes of this Policy, research is defined as work which involves a systematic investigation to establish understanding, facts, principles or contribution to knowledge and its application.

All research involving human participants[1], sentient animals[2] or data not in the public domain undertaken by all staff, all students or anyone acting on behalf of Canterbury Christ Church University (CCCU) as part of formal University activity is subject to the policy outlined in this document.

Research projects that do not involve human participants or sentient animals and are using publically available/published data do not usually require ethical approval.

Purpose of the Policy

The strategic aims and objectives of the University include actively promoting research, enterprise and knowledge exchange activity that is underpinned by high ethical, social and environmental standards. This Policy provides a framework for ethical research practice and decision making within the University.

Who needs to know about the policy?

- Anyone undertaking research for or on behalf of the University, including:
    - Staff and Associates
    - Postgraduate Research Students
    - Students on Taught Programmes (Undergraduate and Postgraduate)
- Deans of Faculty and Pro Vice-Chancellors
- Heads of School and Department
- Managers, supervisors and others in control of specific areas of work that require ethical review e.g. Programme Leads
- University Ethics Panel
- Faculty Ethics Panels
- Taught Programme Ethics Panels

[1] 'Human participants' incorporates those participating in interviews, surveys, focus groups or experiments (including the use of human tissue) etc.; and also the processing of **any** personal data.
All research that involves human participants, in any way, must comply with this policy and with any relevant University guidance or procedures, legislation or additional codes of ethics that apply in specific areas or organisations within which research is to be undertaken (e.g. NHS procedures, codes within Local Authorities, Research Councils' Research Ethics Frameworks etc.).

[2] The use of sentient animals in research and teaching at CCCU is restricted to observational and behavioural studies only. No research and teaching activities that fall within the scope of the Animals (Scientific Procedures) Act 1986 (Amendment Regulations 2012) are carried out.

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Contacts

The University Research Development team is responsible for:

- Providing advice and guidance on research ethics policy and procedure.
- Maintaining the ethics policy, guidance and templates.

The team can be contacted by emailing: ethics@canterbury.ac.uk

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PART A: GENERAL

1. CORE PRINCIPLES

1.1 No research data collection can commence until ethical approval has been issued.

1.2 Ethical approval cannot be issued retrospectively.

1.3 Researchers are responsible for ensuring that ethical approval is sought and received before commencing any research data collection.

1.4 Relevant legislation, frameworks, policy and official guidance documents must be considered and adhered to in all research and used to inform an ethical approach. This includes, but is not limited to, the documents listed in **Section 5** of this Policy.

1.5 The University operates a proportionate approach to ethical review and as such the level of ethical review required is dependent on the level of risk involved and/or as governed by external legal imperatives.

1.6 An independent/peer review should be applied to all ethics applications. The level of expertise employed should be commensurate with the level and/or complexity of the research Peer/Independent reviewers should use their disciplinary and professional background to assess the potential risks associated with the research and identify any concerns (ethical, methodological, practical or intellectual) they may have about the work under consideration.

1.7 Once ethical approval has been issued any significant change to the original ethics application, research protocol, research materials or other significant change to the research must be agreed through an Ethics Amendment. This must be submitted through the same route as the original application. No changes can be implemented before ethical approval for the amendments has been issued.

1.8 In normal circumstances, only one ethics review application is required per research project i.e. if an external application for ethics review has been submitted (e.g. through IRAS[3]) then an internal CCCU ethics application is not required in addition.

1.8.1 This should not be confused with any management or Research & Development (R&D) department permissions that may be required i.e. if research is taking place in an organisation outside of CCCU then permission from an appropriate person[4] within that organisation will be required for the research to take place - this is not ethical approval it is simply authorisation to undertake your research in a specific location pending ethical approval.

1.8.2 This does not apply if material changes are made to the design and methodology of the research, in which case a new application for ethical approval or an amendment may be required.

1.9 Research Development and the relevant Faculty and/or Programme will retain all ethics applications for a period of no less than five years after the research has completed for audit and reference purposes. Records should be kept updated with any dissemination materials or follow on research projects as applicable.

[3] The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care / community care research in the UK.

[4] This should be someone with the authority to make decisions on behalf of an organisation e.g. a CEO, HR Manager, Team Manager, NHS research and development office. Exactly who this is will be dependent on the organisation but the person providing the approval should always have the authority to do so.

2. RIGHT TO APPEAL

2.1 Appeal requests that amount to an expression of dissatisfaction with the original decision will not be considered.

2.2 All applicants have the right to appeal the outcome of their CCCU ethical review, however, to do so at least one of the following grounds for appeal must be met:

2.2.1 procedural irregularities occurred in the review process, which were sufficient enough to cause reasonable doubt as to whether the Panel would have reached the same conclusion had the irregularities not occurred; or

2.2.2 there is demonstrable evidence of prejudice, bias, or inadequate review.

2.3 If an appeal does not fall within any of the grounds specified above, it shall be dismissed and the appellant will be informed accordingly.

2.4 Legitimate appeals must be submitted within 1 month of the date of the outcome letter/email. Requests received after this time will not be considered.

2.5 It is the responsibility of the appellant when submitting the appeal to ensure that all necessary evidence is provided.

3. REPORTING ADVERSE EVENTS

3.1 The safety of staff, students and research participants is a priority for the University. The reporting of all incidents, however minor, allows the risks to staff, students and research participants to be identified and used to create a safer research environment and develop good practice.

3.2 An Adverse Event is an event that occurs during the course of a research project that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a researcher, research participant or others (such as family members or the general public).

3.3 Adverse Events include, but are not limited to, breaches of security, violence, physical injury and psychological distress. It includes 'near misses', where an incident had the potential to cause injury, harm or disruption had intervention or evasive action not been taken. Examples of adverse events that may occur within research include but are not limited to:

3.3.1 An incident involving violence or intimidation during a research interview.

3.3.2 Theft or damage to property during a research activity.

3.3.3 Accidental injury to a research participant or to a student or member of staff during a research activity.

3.3.4 Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

3.4 If the research has been approved by an NHS Research Ethics Committee (or other external ethics approval body) the Principal Investigator is responsible for ensuring that an incident report is sent to the approving committee.

4. FAILURE TO COMPLY

4.1 Failure to comply with this policy will be taken very seriously and may constitute research misconduct. This includes but is not limited to:

4.1.1 Failure to undertake an appropriate ethical review and/or failure to seek ethical approval.

4.1.2 Beginning data collection without ethical approval where this is required.

4.1.3 Failure to accurately represent the research project within the ethics application and/or deliberately misrepresenting the project within the ethics application.

4.1.4 Failure to apply reasonable care and diligence in determining the likely ethical implications of a research project.

4.1.5 Failure to comply with any conditions detailed with ethical approval.

4.1.6 Changing the research project and proceeding with alternative data collection without approval of amendment.

4.1.7 Failure to comply with this policy, the University Research and Enterprise Integrity Framework, relevant legal requirements and ethical codes of practice.

5. RELEVANT LINKS

5.1 University policy and guidance

Research and Enterprise Integrity Framework
Business Travel Policy
Health and Safety Policy

5.2 External policy and guidance

UK Policy Framework for Health and Social Care Research

General Data Protection Regulation (GDPR)

Data Protection Act (2018)

Children Act (2004)

Mental Capacity Act (2005)

Human Tissue Act 2004

Home Office Guidance for Research involving animals www.gov.uk/research-and-testing-using-animals

Understanding Animal Research www.understandinganimalresearch.org.uk

PART B: STAFF AND POSTGRADUATE RESEARCH STUDENTS

6. RESEARCH ETHICS APPLICATIONS

6.1 It is the Principal Investigator's[5] responsibility to ensure that the level of ethical review undertaken is proportionate to the level of risk involved.

6.2 All research must undergo a proportionate independent/peer review and be approved by the relevant Faculty/Research Ethics Panel/Committee (internal or external).

6.3 Any project submitted for CCCU ethical review must include:

- 6.3.1 A completed application submitted through Research Space
- 6.3.2 A satisfactory independent/peer review
- 6.3.3 A completed, approved and signed Research Health & Safety Risk Assessment form
- 6.3.4 In addition, where relevant to the ethical substance of the application the following must be included: a copy of any questionnaires, interview schedules or other research materials/ tools to be used in the collection of data; Participant information material(s); and Participant consent material(s)

6.4 It is the Principal Investigator's responsibility to ensure that the application is complete and of sufficient quality to enable review. Failure to submit all the necessary material or follow instructions will inevitably result in a delay in the processing of applications.

7. EXTERNAL ETHICS REVIEW

7.1 For external review find the appropriate review body and proceed according to the instructions given. The instructions for applicants and any guidance notes should be read carefully and fully complied with. For example, for research involving the NHS use the Health Research Authority (HRA) decision making tool.

- 7.1.1 All external ethics applications must be logged with the relevant Faculty Ethics Panel.

8. INTERNATIONAL RESEARCH

8.1 Staff and postgraduate students may be involved in international research collaborations, or wish to carry out their research or data gathering in countries outside of the United Kingdom. Depending on circumstances, ethical review of such research may be carried out in the countries concerned e.g. where CCCU is not the lead organisation. Where this is the case the appropriate Faculty Ethics Panel must be notified and will make a decision about whether CCCU ethical approval is required.

8.2 Adherence to the General Data Protection Regulation (GDPR) must be ensured.

8.3 In all cases where staff or students intend to carry out their research or data gathering in countries outside the United Kingdom they will be required to complete a declaration of compliance with any laws, ethical procedures and protocols in effect in the country concerned and this must be lodged with the appropriate Ethics Panel.

[5] Postgraduate Research students must work closely with their supervisor on all ethical elements of their research

8.4 The University Business Travel Policy must be adhered to when undertaking **any** business travel related to research.

9. UNIVERSITY ETHICS PANEL

9.1 The University Ethics Panel (UEP) operates as part of the University's research governance obligations, and exists to protect research participants, researchers and the University itself.

9.2 Deriving authority from the Research and Enterprise Integrity Committee (REIC) of the Academic Board, the UEP shall, with due regard to the University's Research and Enterprise Integrity Framework, act as both a University wide review panel and a working group for the development and implementation of ethics and governance related policies, processes and guidance. The UEP is responsible for the review of any appeals (see Section?) and the ongoing quality assurance and improvement of ethical review procedures and practices.

9.3 The UEP will comprise members drawn from a range of professional disciplines, of whom:

- 9.3.1 There is at least one member from each Faculty Ethics Panel, at least one of which must be the Faculty Ethics Panel Chair.
- 9.3.2 All members are knowledgeable in ethics and related University policies and procedures.
- 9.3.3 The Chair must be independent of any Faculty.
- 9.3.4 At least one member will be a representative from Research Development.
- 9.3.5 All members must have undertaken the University Health and Safety Risk Assessment training.

9.4 The UEP is bound by the terms and conditions set out in the Research and Enterprise Integrity Framework, associated key documents and the REIC.

10. FACULTY ETHICS PANELS

10.1 The role of a Faculty Ethics Panel (FEP) is to ensure that all relevant research performed within a Faculty by Staff and Postgraduate Research students has undergone ethical review; they operate as part of the University's research governance obligations, and exist to protect research participants, researchers and the University itself. They are responsible for independent, multidisciplinary review of the ethics of research to determine whether research should be permitted to start or to continue.

10.2 Each FEP is chaired by a nominated staff member who has the responsibility for independent, multidisciplinary reviews of proportionate ethics applications to determine whether the research should be permitted to start or to continue.

10.3 Each FEP will comprise at least five representative members drawn from a range of academic disciplines and perspective, of whom:

- 10.3.1 At least two members have broad expertise in the methods or in the areas of research that are covered by that Panel.
- 10.3.2 At least one member is knowledgeable in ethics.
- 10.3.3 At least one member has no affiliation with the relevant academic/subject discipline(s) and is independent of the Faculty.
- 10.3.4 All internal members must have undertaken/seek to undertake at the earliest opportunity the University Health and Safety Risk Assessment training.

10.4 Review must, in all cases and regardless of the level of the research, be consistent with the principles outlined within this Policy statement.

10.5 FEPs are responsible for identifying and fulfilling their own training needs.

10.6 Each FEP will be responsible for implementing and overseeing the approval mechanisms and for maintaining appropriate records which will be open to scrutiny. Records include all internal and external ethics applications. Sufficient Faculty administrative support should be allocated for this purpose.

10.7 FEPs are bound by the terms and conditions set out in the CCCU Research and Enterprise Integrity Framework, associated key documents and the Research & Enterprise Integrity Committee.

PART C: STUDENTS ON TAUGHT PROGRAMMES (POSTGRADUATE AND UNDERGRADUATE)

11. BACKGROUND

11.1 Students on taught programmes that carry out research as part of their academic journey should adhere to the policies within the Research and Enterprise Integrity Framework.

11.2 The success of the Research & Knowledge Exchange Internship Programme over recent years has shown that undergraduate and postgraduate taught students can carry out highly successful research when managed and monitored by experienced research staff.

11.3 The current University templates should be used for all ethics applications.

11.4 Schools/Programmes are responsible for determining the ethics procedures and level of sign off required based on this Policy.

11.5 No student should be permitted to commence their research data collection until and unless an appropriate ethics review has been completed and approved.

12. PROCEDURE FOR ETHICAL REVIEW

12.1 The ethics review process for students on taught programmes should be kept as simple as possible whilst maintaining an appropriate degree of rigour, high quality and uniformity across the University.

12.2 The **Ethics Review Application Form for Students on Taught Programmes** is the standard document for taught student ethical review applications. Programmes may add questions to the form to seek additional information but to ensure uniformity should not remove any of the existing questions.

12.3 The project must receive ethical approval before the student is permitted to commence any research data collection.

12.4 In cases where completion of the **Ethics Review Application Form for Students on Taught Programmes** indicates that the ethical issues involved demand further scrutiny, or at the supervisors discretion, the proposed research project must be undergo additional review. The form of this additional review may include, but is not limited to:

12.4.1 a colleague independent of the research

12.4.2 a panel established or convened by the School or Programme.

12.5 To ensure quality and support students the Academic Supervisor should oversee all ethically relevant aspects of the research project, including the preparation of the ethics application and related materials such as participant information, consent materials, Research Health & Safety Risk

Assessment and research tools (e.g. interview and/or survey questions, focus group outline etc.). However, the Academic Supervisor should not act as Principal Investigator unless the project is embedded in a pre-existing staff project with prior ethical approval from the relevant Faculty Ethics Panel (or other designated external ethics review body).

12.6 A supervisor and/or those involved in additional review as per local processes can approve projects, impose conditions, or decide that a project is inherently unsuitable for the student applicant's level of experience and expertise and reject the application.

12.7 Where an application is rejected suitable feedback and support should be provided to allow the student the opportunity to either amend their research proposal or to identify a more suitable research project.

13. UNSUITABLE TAUGHT PROGRAMME RESEARCH PROJECTS

13.1 In general research to be carried out by taught students is unsuitable if it has more than minimal risk to cause harm, detriment or disadvantage to participants, the researcher or the general public beyond the risks encountered in normal daily life/the usual context of daily activity.

13.2 In addition, where interaction with external bodies and/or organisations is proposed (e.g. schools or hospitals) consideration should be given to the potential burden, inconvenience or added responsibility on that outside body/organisation and whether the potential research outcomes justify requests being made to these bodies.

13.3 The student's and staff experience, capabilities and training as well as the subject of study should be taken into account when deciding whether or not a research project is suitable. Due consideration should also be given to the level of study. For ethical approval to be granted the reviewer(s) must be confident that the research will be carried out with minimal risk to cause harm, detriment or disadvantage to participants, the researcher or the general public beyond the risks encountered in normal daily life/the usual context of daily life.

13.4 If the reviewer(s)is/are unsure, cannot agree, or do not feel confident to assess the suitability of a project, or if the project will place undue burden on the supervisor, in relation to either time or expertise, then the project should be rejected as unsuitable.

13.5 In cases of doubt, the Chair of the relevant Faculty Ethics Panel may be available for consultation on what might be considered unsuitable, but will not be responsible for review of taught programme ethics applications nor will they make or arbitrate decisions.

13.6 Subject to 14.3 and 14.4, examples of types of research that are likely to be unsuitable include, but are not limited to:

13.6.1 activities that may induce physiological stress, pain, or more than mild physical discomfort to humans or animals, beyond the risks encountered in normal life/the usual context of daily activity;

13.6.2 activities that may induce psychological stress or anxiety or cause harm or negative consequences in humans (including the researcher) or animals beyond the risks encountered in normal life/ the usual context of daily activity;

13.6.3 invasive or intrusive procedures such as blood taking or muscle biopsy;

13.6.4 activities that involve harmful or potentially harmful substances or stimuli;

13.6.5 interference with medical or psychological treatment;

13.6.6 traumatising and/or disadvantaging experiences;

13.6.7 security-sensitive topics including but not limited to terrorism or child sexual abuse;

13.6.8 activities that are illegal under applicable laws;

13.6.9 activities involving criminal activity or that have the potential to raise disclosures of criminal activity;

13.6.10 activities involving or that have the potential to raise safeguarding issues;

13.6.11 activities involving deliberate deception and/or covert observation;

13.6.12 activities that involve prolonged or repetitive testing;

13.6.13 offering financial inducements including reasonable expenses and compensation for time;

13.6.14 involve participants who may lack capacity to consent or are at risk of losing capacity to consent as defined by the Mental Capacity Act 2005;

13.6.15 recruitment of participants (patients and/or carers[6]) through the NHS;

13.6.16 participants (Children or Adults) who are currently users of social services including those in care settings who are funded by social services or staff of social services departments[7]; and

13.6.17 activities involving interaction with animals beyond observing them within their natural habitat or zoo with no contact at all.

13.7 Particular Programmes will have their own legitimate approaches to questions of ethical suitability. However, exceptions made to the indicative list of exclusions in 14.7 should require explicit and careful justification if they are to receive approval.

14. QUALITY ASSURANCE AND OVERSIGHT

14.1 Quality assurance and oversight of the processes for ethical review of students on taught programmes sits with Boards of Study.

[6] A carer is anyone, including children and adults who looks after a family member, partner or friend who needs help because of their illness, frailty, disability, a mental health problem or an addiction and cannot cope without their support. The care they give is unpaid.

[7] This does not include incidental users of social services where they happen to be part of a random sample.

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Responsible Officer	Research Integrity & Contracts Manager
Related University Policies and Procedures	Research and Enterprise Integrity Framework
Approved by	Academic Board
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Date of Commencement	Parts A&B: June 2020 Part C: From September 2020. No ethics applications from students on taught programmes will be reviewed by Faculty Ethics Panels from August 2021
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Website Address	https://www.canterbury.ac.uk/research-and-consultancy/governance-and-ethics/governance-and-ethics.aspx