Ethical Guidelines and Policies for Students, Staff, and Research Ethics Committees

Version 2.2 (2022)

Prepared By	Research Ethics and Integrity Subcommittee (REIS) Working Group (Chair/Vice chair/Secretary)
Approved By	REIS 27 April 2022 University Research Committee 18 May 2022 Senate 8 June 2022
Source Location	Edshare - https://edshare.gcu.ac.uk/10152/
Published Location	https://www.gcu.ac.uk/aboutgcu/supportservices/governance/regulationsandpolicies
Other documents referenced	GCU Code of Good Practice for Researchers UKRIO Code of Good Practice in Research RCUK Policy and Code of Conduct on the Governance of Good Research Conduct Concordat to Support Research Integrity Declaration of Helsinki UK Policy Framework for Health and Social Care Research HRA NHS Ethics Decision Tool Joint Service Publication 536 (for MoD related research) GCU Data Protection Guidance for Researchers
Related documents	Regulations for the Award of Research Degrees

Version Number	**Date issued**	**Author**	**Update information**
V 1.0	March 2022	REIS WG	First version presented to REIS for feedback
V 2.0	April 2022	REIS WG	Version approved by REIS
V2.1	May 2022	REIS WG	Version updated following feedback from University Research Committee
V2.2	December 2022	Paul Woods	Amendments made to improve accessibility of document.

Contents

1 Introduction

All projects involving human participants conducted by staff and/or students (undergraduate, postgraduate, or postgraduate research) at Glasgow Caledonian University (GCU) are subject to ethical scrutiny and need ethical approval before commencing. The need for GCU ethical approval applies to all levels of study, (un)funded projects, and all types of methods. GCU ethical approval is required for the duration of the project and before seeking any external approvals.

The ethics guidance and policies contained in this document have been developed by the University Research Ethics and Integrity Subcommittee (REIS), key stakeholders, and with experts in research ethics and integrity. The purpose of the document is to clarify ethical processes and procedures at GCU and set clear expectation about ethical reviews processes and research governance. The document will also outline the role and responsibilities of people involved with the ethical review process and provide guidance about ethically sound practice.

The main aim of this guidance and polices document is to encourage robust, transparent, and auditable ethical review processes at GCU. Robust and transparent ethical review processes are essential for safe and ethically sound projects and to increase the quality of work undertaken at GCU. Is it important everyone (staff and students) is aware of the need for ethical approval and how to secure ethical approval for their project(s). It is also important that ethical approval is seen as an integral and ongoing process that guides the whole project, rather than it being seen as an obstacle or barrier to overcome. It is also acknowledged that ethical approval at GCU does not work in isolation and often projects will require involvement from other departments or services at GCU (e.g. date protection, governance). It is also possible projects will involve working in partnership with external partners (e.g. NHS), so it is important for GCU to be open, honest, and transparent about ethical approval processes.

This document should be read in conjunction with the University's *Code of Good Practice in Research,* UKRIO *Code of Good Practice for Researchers* and the *RCUK*

Policy and Code of Conduct on the Governance of Good Research Conduct. The University supports the principles of the *Concordat to Support Research Integrity*.

2 Ethical Approval

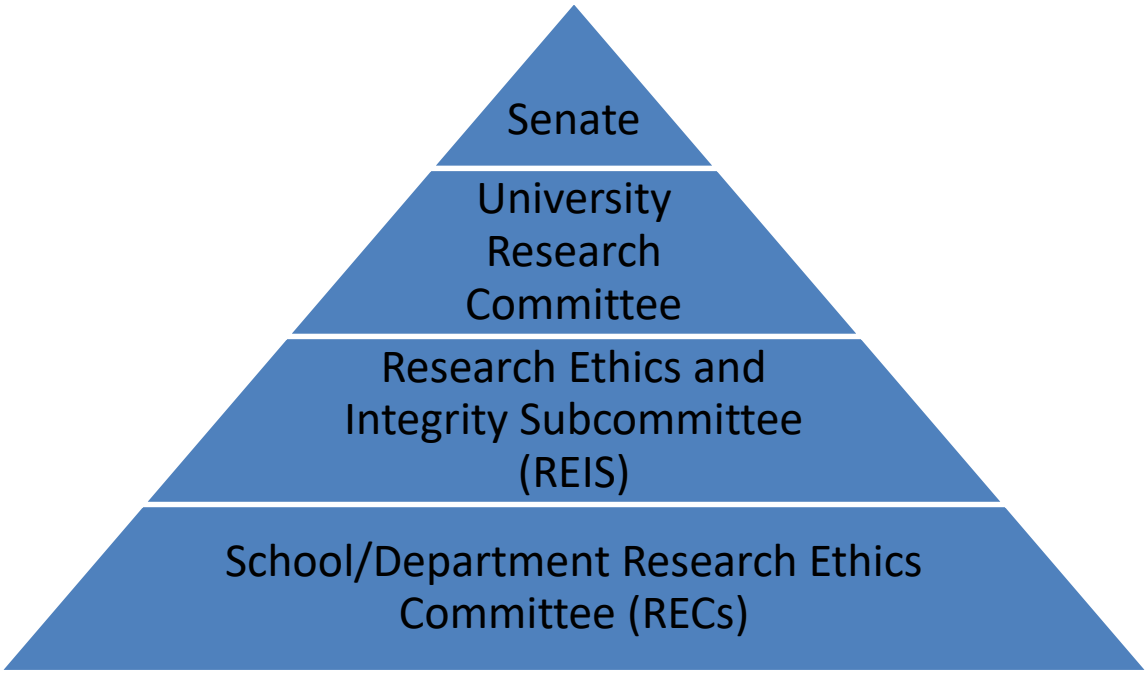
All projects that involve human participants (e.g. personal data, human tissues) require ethical approval from Glasgow Caledonian University (GCU). All projects involving human participants should conform with the Declaration of Helsinki, GCU Research Governance, and all necessary legislative requirements. The type of ethical review required will depend on the type of project and level of ethical concerns. Ethical approval needs to be secured before the project commences (e.g., advertising the study, recruitment) and will need to be renewed (e.g., an amendment) if changes are made to the project after approval has been given. Some projects may also require external ethical approval (e.g., NHS) and/or permissions from a gatekeeper. It is important to secure ethical approval at GCU before seeking external ethical approval from another agency. Securing ethical approval at GCU before applying for external approval ensures the project meets GCU quality and ethical standard before it is reviewed by another organisation. It is the responsibility of the chief investigator (CI) to ensure all necessary approval(s) and permissions are in place before the project commences and that the approvals and permissions are in place for the duration of the project. GCU Departments, Schools, and RECs are advised to align their practice with the guidance contained in this document. This information should be available to all staff and students undertaking projects involving human participants.

2.1 Research ethics committee and governance structure

Research ethics at GCU provides a tiered and proportionate response to ethical scrutiny and approval (Figure 1: GCU Research Ethics Structure). The structure is made up of several different tiers and each of these tiers provides a specific function. Departments and Schools each have their own Research Ethics Committees (RECs), which provide ethical scrutiny and approval within the School or Department. The Research Ethics and Integrity Subcommittee (REIS) is a university-wide REC that deals with research involving major invasive methods or procedures and has an overall monitoring and audit function for ethical approval at GCU. REIS is a subcommittee for the University Research Committee, which provides overall

oversight for research ethics at GCU. All these tiers report and are overseen by GCU Senate.

Figure 1: GCU Research Ethics Structure



2.2 Types of studies and level of approval

GCU is involved with a wide range of varied activities and takes an inclusion approach to ethical oversight. This document will use the term *project* to describe any type of formal activity undertaken to achieve a particular aim or objective. Projects do not include work carried out as part of routine practice (e.g., teaching and learning, module evaluation), but can include original activity being undertaken as part of a service improvement and/or innovation in teaching and learning. Projects include research (e.g., experiments, qualitative research) and non-research (e.g., evaluation, service improvement) activity and can be sub-divided into projects involving humans and projects generating data. Projects involving humans include all activities that gather data through interaction with people (or groups) and/or use identifiable personal information. Projects can either gather/create new data or may use data previously collected/created.

Projects

Involving humans		Not involving humans	
Generating new data	Using existing data	Generating new data	Using existing data
Ethics approval required	Ethical approval required	Ethical approval may be required	Ethical approval may be required

Most ethical approvals will be carried out by School or Departmental RECs. Where any proposed project (staff, postgraduate and undergraduate) involving human participants is deemed to be non-routine, intrusive, or potentially contentious from an ethical perspective, the REC chair may refer these applications to the University Research Ethics and Integrity Subcommittee (REIS) for review, using the REIS referral form.

2.3 Projects involving humans and generating new data

These projects include research and non-research activities that involve gathering new data from human participants or using personal data. These projects involve the highest level of ethical scrutiny and will always require full ethical approval from a REC before commencing. These projects may also need external approval from other organisations (e.g., NHS) and/or gatekeeper approval to access research sites/participants. It will also be necessary for the project to be designed in alignment with current best practice for projects involving human participants (e.g., voluntary participation, anonymity, informed consent, participants/investigator welfare, and with clear societal benefit).

2.4 Project involving humans and using existing data

These projects include research and non-research activity and use existing data from human participants. This work includes secondary analysis of participant data and/or using participant data stored in a data sharing repository. These projects will involve ethical considerations and will need ethical approval. These projects may also need external approval from other organisations (e.g., NHS) and/or gatekeeper approval to access research sites/participants. These projects will need to consider whether the data being used was collected ethically, if/when data is anonymous, and

whether consent was given at time of data collection for the data to be shared.

2.5 Projects not involving humans and generating new data

These projects include research and non-research activity, do not involve human participants, and gather new data. This work may include projects involving animals and/or environmental projects. These projects may also need external approval from other organisations and/or gatekeeper approval to access research sites. These projects will involve ethical considerations and may need ethical approval. These projects may need to consider animal welfare, environmental factors, financial matters, legal aspects, conflicts of interest, political allegiances, investigator welfare, and reputational damage.

2.6 Projects not involving humans and using existing data

These projects include research and non-research activity, do not involve human participants, and use existing data (e.g., systematic reviews, anonymous data sets). This work may include projects involving animals, environmental projects and/or anonymous human data. These projects will involve ethical considerations and are unlikely to need ethical approval. These projects may need external approval from other organisations (e.g., NHS) and/or gatekeeper approval to access research sites/anonymous data. These projects may need to consider animal welfare, environmental factors, financial matters, legal aspects, conflicts of interest, political allegiances, investigator welfare, data protection, and possible reputational damage.

2.7 Level of ethical concerns

Projects involving human participants may have different levels of ethical concerns depending on who (e.g. children, vulnerable adults) will be involved with the project and the type of project being undertaken (e.g. clinical trial, deception). GCU takes a proportionate response to ethical scrutiny and approval by ensuring that projects with the highest level of ethical concern receive the most robust ethical scrutiny.

Ethical concern	Description	Approval required
Minimal	Projects involving published materials, secondary analysis of anonymous data, or non-research patient and public involvement.	Peer review or review by academic supervisor.
Low	Low risk anonymous surveys, service evaluations, and low risk research.	Ethical review by REC (one reviewer).
Moderate	Projects involving moderate risk or ethical concerns. May including vulnerable people and/or children.	Ethical review by REC (two reviewers).
Significant	Projects involving significant risk or ethical concerns. May include intrusive procedures, people lacking capacity, and/or high-risk projects.	Ethical review by REC (two reviewers) and referral to REIS (two reviewers).

2.8 Applying for ethical approval

All projects involving human participants completed by staff, students, or partners of GCU will require ethical approval. Ethical approval will be required from GCU and will need to be secured from a designated REC (e.g. School, Department) before the study commences.

To apply for ethical approval, investigators should submit the following documentation to their School REC for consideration:

- A completed EC1 (refer to x)
- A detailed project protocol (refer to x)
- Consent materials (refer to x)
- Participant information sheet (refer to x)
- Materials for recruitment as applicable (e.g., emails, advertisements)
- Materials for data collection as applicable (e.g. interview guide, online survey)
- Evidence of obtained permissions and approvals as applicable (e.g., from partners, collaborators, gatekeepers etc.

2.9 The EC1 form

All submissions for ethical review require an EC1 form. The EC1 is the standard ethics submission form used at GCU. The EC1 form involves providing details about the study and answering questions about the project. The chief investigator is responsible for ensuring the EC1 form is accurate and kept up to date. To ensure a consistent approach to research ethics at GCU it is recommended all RECs use the standard EC1 form (refer to appendix 1).

2.10 The protocol

All submissions for ethical review require a study protocol. The following points are intended to guide completion of the required project protocol, with investigators expected to tailor as appropriate to their proposed project. A template protocol is available to help structure the protocol. The detailed project protocol should include, as appropriate:

- Version control using number and date (e.g. version x, dd/mm/yy)
- Project title
- Background and justification for the project
- Project aims and/or objectives
- Participant selection criteria and planned participant numbers
- Recruitment strategy
- Consent process
- Project design and methods
- Ethical issues identified and how they are being addressed
- Possible harms associated with the project
- Possible benefits associated with the project
- Data collection, handling, storage, access, confidentiality, retention, use and disposal, or permanent preservation
- Implications of working with partners/stakeholders e.g. access
- Consideration of implications of overseas data collection or transfer

2.11 Consent form

Some projects will use a consent form for documenting written consent. The consent form is an important document and will include personal identifiable information (e.g. participants' names). It is important for the consent form to be managed in accordance with data protection requirements and contain the following information:

- Version control using number and date (e.g. version x, dd/mm/yy);
- Project title
- Specific items for consent (see template example)
- Participant signature
- Signature of person securing consent

2.12 General guidance for project documents

It is important to check accuracy, consistency, and presentation of all study documents before submitting for ethical approval. It is also important to ensure participant facing documents (e.g. consent form, adverts, and participant information sheets) are appropriate and accessible enough for the intended audience or the public. Before submitting, investigators should ensure that:

- Page numbering is employed for each required document, respectively.
- The collective documentation is submitted as one PDF file with documents in the order presented on the EC1 checklist and in section 4. Where this is not possible, please ensure documents are submitted with a filename that reflects content and corresponding checklist number e.g., 1. EC1, 2. Protocol etc.
- Version control is followed for the overall documentation (i.e., version x, dd/mm/yy with the date representing the version number).
- Accessibility and use of language/images for the intended audience.
- Where a project involves online participation, investigators should submit their materials (including Participant Information Sheet and Consent Form) as they would appear to participants.

2.13 Post Approval

Where approval of an ethics application has been communicated by the relevant REC, the investigator can commence project work in-line with the proposed protocol of their approved ethics documentation. A copy of the completed application documentation and subsequent versions will be kept on file by the relevant REC. The chief investigator (or designated person) should keep a copy for the approval confirmation for their records. Confirmation of ethical approval should be added to public documentation such as recruitment advertisement or participant materials e.g., 'This project has been reviewed and approved by Glasgow Caledonian University School of Health and Life Sciences Ethics Committee'. Communication of approved application for ethical approval relates only to the submitted and approved version of the documentation submitted for consideration at that time, and the proposed period of time.

2.14 Amendments

Where an investigator plans to change the details of an approved ethics application, the investigator must first notify the relevant REC for request an amendment. The investigator should provide the REC with full details of the proposed/required changes and submit an updated ethics application for review by the REC. Changes to the original/approved project documentation should be made in red or with tracked changes to assist review and version control should be used (see section 4.3). The REC will review the proposed amendment of the approved ethics form and may ask for further information from the investigator where needed

3 Project Roles

3.1 Sponsor

The sponsor is responsible for ensuring the project is appropriately designed and delivered according to an agreed protocol. All projects will need a sponsor and the duties and responsibilities associated with the role are outlined in the UK Policy Framework for Health and Social Care Research. Responsibilities for the sponsor include ensuring the project is conducted ethically and all governance (internal and external) requirements are followed during the project. The sponsor is normally the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research. GCU will normally be the sponsor for projects completed by GCU staff and/or students.

For projects where a university sponsor letter is required, whether for a student or a member of staff, it must be countersigned on behalf of the University by an **appropriate senior member of School *management* staff.** Sponsorship signatories should contact the Finance Office for insurance details and for any further information regarding insurance cover: insurance@gcu.ac.uk.

3.2 Chief Investigator

The Chief Investigator (CI) (sometimes called Principal Investigator) is the person designated as taking overall responsibility within a team of investigators for the design, conduct and reporting of a project. The Chief Investigator is responsible for ensuring that the project has appropriate ethical approval and is conducted in accordance with the University's research governance requirements. It is essential for the Chief Investigator to have completed GCU data protection training and to be familiar with GCU polices around research ethics and integrity (this document). It is desirable for Chief Investigators involved with health-related projects involving human participants to have completed Good Clinical Practice Training.

The Chief Investigator will normally be an experienced member of staff and students will not normally be Chief Investigators (unless the student is also and experienced

member of staff or a Doctoral student with previous research experience). Academic supervisors will normally be the Chief Investigator for student projects or projects being completed by new or inexperience members of staff. All projects will need a Chief Investigator and the duties and responsibilities associated with the role are outlined in the UK Policy Framework for Health and Social Care Research.

3.3 Investigator

The investigator is a person who conducts the study and is responsible for the day-to-day delivery of the study. The investigator will conduct the study as per the protocol and be supervised by the Chief Investigator. The investigator will usually be a student or member of staff. All projects will need Investigator(s) and the duties and responsibilities associated with the role are outlined in the UK Policy Framework for Health and Social Care Research.

3.4 Students

All student projects (undergraduate, postgraduate, or postgraduate research) involving humans must secure ethical approval before they commence and must be supervised by a member of GCU staff. Responsibility for identifying ethical considerations and applying for suitable ethical approvals is shared between the student and staff member supervising the activity. The supervising staff member is responsible for ensuring that the student has secured appropriate ethical approval from the relevant REC and additional/external approvals required for the project.

3.5 Gatekeeper

The gatekeeper(s) is the person(s) who provides the investigator with permission and/or access to potential participants. The gatekeeper can be internal (e.g. programme leader, Dean) or external (e.g. service manager, group leader) to GCU and must have the necessary authority to give gatekeeper approval. Gatekeeper approval needs to be secured before the study starts inviting people to participate or advertising for participants. Gatekeeper approval would normally be given in writing (e.g., an email) and proof of gatekeeper approval should be submitted when applying

for ethical approval at GCU. Gatekeeper approval should be given voluntarily, without coercion/inducement, and only after they have been given full information (e.g. protocol, participant information sheet) about the study. Gatekeeper approval can be withdrawn at any time, without giving a reason, and should be renewed if amendments are made to the study.

4 Research ethics committees (RECs)

RECs are the backbone of the ethical review process and provide valuable ethical scrutiny and approval for projects completed at GCU.

4.1 REC Chair (and deputy)

The REC Chair (and deputy) is responsible for the smooth operation of the REC review process. The REC Chair will also frequently be expected to provide advice, guidance, training, and feedback on ethical issues. REC Chairs are normally appointed by a department head or Dean and have a leadership role for ethics within the department/School. REC Chairs are normally members of GCU staff who have particular experience or expertise in research ethics and integrity. It is important for REC Chairs to be transparent, have high levels of integrity, and be good role models for research ethics. REC chairs are expected to maintain their own competence with research ethics through continuous professional development, partnership working, peer support, and other related activities (e.g. REC Chairs with external partner).

4.2 REC reviewer

REC reviewers may be a permanent member of a REC or an invited reviewer for a particular study or purpose. It is important for the work, commitment, and expertise of the ethical reviewer to be acknowledged by the REC and wider research community. REC reviewers are people with relevant knowledge, skills, and experience of research ethics. REC reviewers may also have additional subject knowledge and expertise that is relevant for research ethics (e.g., data protection or research integrity). The REC reviewer can have a background in research, education, or professional services. The REC reviewer will often be identified by the REC chair (or designated person) and invited to review a particular study and/or fulfil a particular role in the review process. Interested individuals are also encouraged to contact their REC chair and volunteer to become a REC reviewer.

4.3 Post Graduate Research Students Becoming REC Reviewers

Being involved with ethical reviewing can be a valuable learning opportunity for Post Graduate Research students (PGRs) and can add value to the REC review process. PGRs students interested in becoming involved with REC reviewing should have successfully completed a Masters and/or their RDC 2 (i.e. progression to Doctoral level gateway). It is recommended PGR students do not provide REC reviews for projects submitted by students/researchers from their own research group or School. PGRs students interested in becoming REC reviewers should contact a REC Chair for a different School and express their interest in volunteering to become involved with REC reviewing. It is important for potential PGR students to make the REC Chair aware of any possible conflict of interests (e.g. personal or professional relationships) and disclose if/when conflicts of interest emerge. The REC Chair should provide the PGR students with an induction to the REC and training in ethical reviewing. The induction/training should include familiarity with the roles and responsibilities associated with being a REC reviewer and appropriate Data Protection requirements. The chair should also arrange for the PGR student to 'buddy review' research applications with an experienced REC reviewer. PGRs should not be expected to review applications by themselves and should be properly supported in their role.

4.4 Conflict of interests for ethical reviewers

It is important to consider possible conflict of interests (competing interests) when involved in REC business or undertaking ethical reviews. RECs and ethical reviewers need to disclose when potential conflicts of interest occur and seek to mitigate these potential conflicts of interest. It is important for RECs and ethical reviewers to maintain integrity through being honest and transparent about possible conflicts of interest.

The conflict of interests may result from a number of different factors:

- Financial interests
- Non-financial interests
- Business interests

- Intellectual property rights
- Interpersonal relationships or friendships
- Other roles or responsibilities (e.g. dual roles)
- Political allegiances
- Vested interests
- Status and esteem

This list is not definitive but gives an indication of the possible areas where conflict of interest may occur. When a conflict of interest occurs, it is important to disclose the conflict of interest and for those with the conflict of interest to remove themselves from the review process or other REC business. It will then be necessary for the REC chair (or designated person) to make alternative arrangements and mitigate any possible impact from the conflict of interest.

4.4.1 Dual roles

A commonly encountered conflict of interest is when the REC chair/reviewer has an additional role or responsibility (i.e. dual roles) that may result in them giving favourable treatment to certain ethics applications and/or individuals. An example of this is when an academic supervisor (or module/programme leader) is invited to chair/review an ethics application for one of their students. In this instance, the ethics reviewer has dual roles as an academic supervisor (or module/programme leader) and ethics chair/reviewer and would have to declare a conflict of interest in that particular ethics application. When a dual role and possible conflict of interest is identified then it is necessary for the REC chair (or designated person) to make alternative arrangements and mitigate any possible impact from the dual role.

4.5 Preparation for ethical reviewers

Most ethical reviewers are experienced researchers and/or REC members. Ethical reviewers are encouraged to keep up to date with developments in research ethics through their own continuous professional development. Experienced ethical reviewers are encouraged to participate in some form of research ethics continuous professional development each year (e.g., self-directed study, workshop, or Good

Clinical Practice training). Advice and guidance about suitable development activities will be available from the REC chair.

New and inexperienced ethical reviewers need to be provided with the necessary training and support to fulfil their role. Preparation and training of ethical reviewers will vary from person to person based on their own requirements and preferences. The REC chair (or designated person) will be responsible for supporting new and inexperienced ethical reviewers to become established in their role. Preparation of ethical reviewers may involve training, mentoring, or ‘buddy’ reviewing with more experienced reviewers. There may also be an opportunity for ethics reviews to attend training on ethical review either within GCU or other partner organisations.

4.6 Roles and responsibility for ethical reviewers

- To notify the REC about willingness and availability for ethical reviews.
- Inform REC when unavailable for ethical review.
- To maintain own knowledge, skills, and experience with ethical review through appropriate continuous professional development.
- Respond to invitations from the REC to review ethics applications.
- Declare any conflict of interest that may affect involvement with REC.
- Provide independent ethical review of applications on behalf of the REC.
- Provide ethical review and notify the REC if there are delays in the review.
- To provide evidence of ethical review to the REC (e.g., reviewer checklist).
- To make recommendations and give advice to the REC.
- To provide detailed feedback and recommendations to students, colleagues, and other stakeholders.
- Maintain confidentiality of ethics applications and decisions.
- Contribute to the development of the REC and research ethics at GCU.

4.7 Reviewer checklist

The reviewer checklist is a guide that can be used by reviewers when completing reviews for the REC (appendix). The reviewer checklist covers common factors to consider in all ethics applications and is a useful starting point for ethical reviewers

completing reviews for REC. The reviewer checklist is not supposed to be exhaustive or to replace reviewer judgement but can provide a tool for reviewers to use. Completed reviewer checklists should be returned to the REC when the review is completed and can be used as part of an audit of review activity in the REC. The completed reviewer checklist can also be sent to the person submitting the application to the REC and would provide value feedback/feedforward for future submission and/or revisions.

5 Working with External Partners

GCU often works in collaboration with external partners, and this can raise research ethics and integrity issues. It is important projects involving external partners have proper governance arrangement and clear lines of responsibility and accountability.

5.1 External Sponsorship

In collaborative projects where the Chief Investigator is external to GCU, the external investigator's employer institution or the project funder will be expected to be the project sponsor.

5.2 Externally Awarded Ethical Approval

Where full Ethical Approval for a proposed project involving GCU staff/students has been externally awarded (for example the Chief Investigator is external to GCU), the GCU investigator should complete an EC3 form and submit to the appropriate School Research Ethics Committee (REC) for consideration. The EC3 process helps to minimise replication of effort and ensures that GCU reviews the documentation which has already been granted ethical approval by the external body. The REC will consider the EC3 application in line with the GCU requirements for Research Ethics principles and practices and may request further information if the submitted documentation does not sufficiently meet GCU requirements. Only studies with existing ethical approval from another established Research Ethic Committee will be eligible for the EC3 process.

5.3 International Research

GCU staff and/or students carrying out projects overseas are expected to secure GCU ethical approval and adhere with local practice, legislation, culture, and expectations. It is recommended international projects involving humans be developed in partnership with people familiar with the country where the project will be undertaken. Investigators will be expected to explain how they have involved local people and/or how they have ensured the project is culturally appropriate for the

location where the study will be completed. The investigator should secure GCU ethical approval before identifying and securing ethical approval from the relevant independent overseas body. Where international research involves personal data, it should comply with the relevant data protection and privacy legislation and the international transfer of personal data.

5.4 Research involving the NHS

Research projects that involve recruitment from NHS patients, staff or premises may require ethical approvals from NHS REC. The Health Research Authority (HRA) has set criteria to determine whether projects require NHS REC approvals: HRA NHS Ethics Decision Tool.

NHS Research projects require a variety of external approvals, including approval from the Health Boards/ Health Trusts involved in the research. It is the responsibility of the Chief Investigator to ensure all approvals are in place prior to the commencement of the project. Further guidance has been collated by the HRA.

5.5 Research involving the Ministry of Defence (MOD)

The Ministry of Defence Research Ethics Committee (MODREC) ensures that all research involving human participants either undertaken, funded or sponsored by MOD meets nationally and internationally accepted ethical standards. MODREC operates according to Joint Service Publication 536 (JSP536) which is harmonised with guidelines set out by the HRA. Where the research involves personal data, it should comply with the relevant data protection and privacy legislation and the international transfer of personal data.

5.6 Research involving external partners and personal data

When GCU is working with an external partner and personal data is being shared and/or processed on behalf of GCU by a third party (e.g. external partner) there needs to be a data sharing agreement (see 8 Data Protection) in place which sets out roles and responsibilities for GCU and any other external partner.

6 Projects involving body tissues

Researchers carrying out projects with human tissue should be in touch with the Human Tissue Advisor before the project starts and submit two forms:

- HealthandSafetychecklist2019v2
- Human tissue usage version 2

Both forms are on the RIO and Health and Safety websites (https://www.gcu.ac.uk/healthandsafety/proceduresandarrangements/hazardoussubstancesandbiologicalagents/bloodbodyfluids/).

The human tissue usage v2 form describes how the tissue will be used and stored. Human tissue disposal is regulated under '2022 GCU Disposal of Human Tissue_HTAct_SOP v5 280222'. Researchers using fresh tissue should have their Hepatitis B vaccination complete before they commence a project.

The Human Tissue Act defines "relevant material" as any material from a human body that consists of, or includes, cells. For example, Tissue / Organs, Cells (freshly derived, anything beyond the first passage is exempt), Bone, Blood, and Body fluids (not serum).

Anyone using human tissue in the department should have obtained School Ethical Approval (possibly after NHS ethical approval). Approval for tissue use may also come from the GCU Skin Research Tissue Bank which has its own regulatory process.

7 Research Ethics and Integrity Subcommittee (REIS)

The Research Ethics and Integrity Subcommittee (REIS) is responsible for research ethics and integrity at GCU. REIS also provides expert ethical review and advice for projects involving human participants that are deemed to be non-routine, intrusive, and/or that is likely to be ethically contentious.

7.1 Composition of Research Ethics and Integrity Subcommittee (REIS)

The composition of the Research Ethics and Integrity Subcommittee is as follows:

- Chair
- Deputy or Vice Chair
- Chairs of the School Ethics Committees (or Research Area Ethics Leads, where applicable)
- University Research Integrity Champion Local Research Integrity Champions
- Assistant Head of Governance (Information Compliance)
- Director of Research and Innovation or nominee
- Director of the Graduate School or nominee
- Professional services staff with a role in research governance, ethics and integrity
- Lay member(s)
- PGR Student representative(s)

7.2 Referring applications for ethical approval or advice to REIS

REIS accepts referrals from School Research Ethics Committee Chairs via a designated mailbox: reis@gcu.ac.uk. Referrals are made using the REIS referral and reviewer form (appendix X) and should include all the necessary documentation (e.g. referral form, ethics application, School ethical review). A decision and/or outcome will be provided by REIS in four weeks (20 working days).

7.3 What REIS will consider

REIS provides ethical scrutiny and approval for projects with significant ethical concerns. Studies with significant ethical concerns should be reviewed in the first instance by two reviewers from the School REC. This initial review is important to determine the level of risk involved and decide whether the study has significant ethical concerns. The initial review by the School REC also provides an opportunity for reviewers with subject/methodology expertise to give their opinion on the projects before it is referred to REIS for further scrutiny.

7.4 How REIS reviews ethics applications

Referrals to REIS are reviewed by two reviewers who have no conflict of interest with the referral. At least one of the REIS reviewers should be from a different School from where the referral originated, which will encourage inter-School scrutiny. The REIS review will be completed using the reviewer section (item 4) of the REIS referral form and include a summary of the situation, main concerns, ethical dilemmas, and recommendations. Given the complexity of reviews being completed by REIS the usual timeframe from referral to final decision will be four weeks (20 working days). This time frame may be exceeded if special or external advice is required before making a final decision. The referrer will be notified if there I likely to be delays in the review process.

After review REIS will inform the Chair of the School REC by email about the decision and/or provide recommendations. REIS will provide the referrer with a copy of the completed REIS review and a summary of the situation, main concerns, ethical dilemmas, and recommendations.

REIS decision	Explanation
Approve	The study is approved and can commence
Approved with conditions	The study is approved and can commence of the basis of the condition(s) specified by REIS. REIS and the School Research Ethics Committee do not need to see this study again.

Amend and resubmit to School Research Ethics Committee	Revisions are required before the project can be approved. These revisions can be reviewed and approved by the School Research Ethics Committee. REIS does not need to see this study again.
Amend and resubmit to REIS	Revisions are required before the project can be approved. The revisions need to be reviewed and approved by REIS.
Invitation to attend meeting with the reviewers and/or REIS.	The reviewers and/or REIS would like to meet the applicant or person responsible for the project and ask them questions about the project before reaching a decision.
Not approved	The project has major ethical (or other) concerns and should be discontinued.

7.5 Giving feedback and raising complaints about REIS

REIS welcomes feedback and encourages people to comment and make suggestions about REIS. Feedback can be given informally via the REIS email mailbox (TBC). All informal feedback sent via the REIS mailbox will be responded to by the REIS Chair/Deputy Chair in four weeks (20 working days). Formal complaints can also be made via the GCU complaints procedures (https://www.gcu.ac.uk/gaq/complaintsstudentconduct/complaints/).

8 Data Protection

Guidance has been developed to provide researchers and staff involved in research with support in complying with the Data Protection legislation:

https://www.connected.gcu.ac.uk/sites/InformationMatters/DataProtectionPrivacy/Documents/GuidanceResearchersV14.docx

9 REC Governance

9.1 Terms of Reference for School RECs

This document presents the proposed terms of reference for the School Research Ethics Committees (REC), which are subcommittees for the School Research Committee. The main remit of the School REC is to provide oversight of ethical aspects of research and other project activity by staff and students. These terms of reference are subject to change in line with guidance from the University Ethics and Research Integrity Committee and/or the School Research Committee.

- To consider ethics approval applications for any proposed research and other project activity by staff and/or students, which is deemed to be routine, non-intrusive, and not ethically contentious.
- To refer to the Research Ethics and Integrity Subcommittee (REIS) any proposed research and other project activity that is deemed to be non-routine, intrusive or likely to be ethically contentious.
- To refresh and develop guidance documentation and materials for the process and practice of ethics review and approval by the School REC, in line with the wider Research Ethics and Integrity Subcommittee (REIS) guidance.
- To implement policy in line with the University Ethics and Research Integrity Committee regarding ethical review at departmental level; the GCU Research Integrity Action Plan; matters in relation to the Concordat to Support Research Integrity and any legislation or HE sector guidance or developments which may have ethical implications for research undertaken in the University; and the related review and update of departmental guidance as required.
- To raise the profile of Research Ethics in the School of Computing, Engineering and Built Environment, and to co-ordinate processes and practices with other schools, supporting the University Ethics and Research Integrity Committee to investigate mechanisms to devolve awareness and responsibility of research ethics at Department, Research Centre and Research Group level, supporting local research integrity champions.

- To identify and support the roll-out of any training requirements about research ethics for committee members and wider school staff i.e. those active/interested in research activities as well as those in teaching roles who provide ethical awareness guidance and/or sign off and make recommendations on these requirements to SMG and the University Ethics and Research Integrity Committee.
- To create an annual report for the University Ethics and Research Integrity Committee, which in line with the committee requirements, will include the number of proposals considered from staff, postgraduate and undergraduate students (which cannot be resolved at module/programme leader level), and commentary on any specific research ethics issues facing the School of Computing, Engineering and Built Environment.

To refer to the Associate Dean Research and/or the Dean any proposals that are deemed to hold a reputational risk for the University.

9.2 REC recommended composition

The composition of the School REC will vary depending of local need and arrangements, but the composition will likely include:

- Chair(s)
- Deputy or Vice Chair(s)
- Champion(s) or designated role (e.g. integrity champion)
- School Professional Services Manager (Research Administration) & Clerk
- Reviewer(s) and committee members
- Post graduate research students

9.3 REC reporting requirements

RECs are expected to complete progress reports at the end of each trimester and at the end of every academic session. The progress reports are for use within the School and should be produced by the research administrator or a designated alternative and submitted to the School REC Chair or Associate Dean of Research. The annual summary reports should be completed by the REC ethics chair or a designated alternative and submitted to REIS using the REC Annual Summary Report form in the appendices and emailed to: reis@gcu.ac.uk.

9.4 REC key performance indicators (KPIs)

The performance of the REC will be gauged on the length of time taken to provide a decision on each submission to the REC and the auditability of the review process.

Each School REC should aim to achieve the following expectations and targets:

Performance area	Person(s) responsible	Expectations and target
All submissions to REC should be reviewed by a designated REC reviewer/chair	REC chair and/or Research Administration	Every submission to REC should be allocated a designated REC reviewer/chair who will complete the ethical review **(Target 100%)**
Length of time taken to provide decision on each submission to the REC should not exceed 20 working days	All REC members	Decision on submission should be given within four weeks **(Target 80%)**
REC should maintain accurate and up to date records of submission and approvals for all submissions	REC chair and/or Research Administration	All submission should be recorded on a database with accurate information about submission and decision date and any REC decisions/approvals **(Target 100%)**
REC should maintain accurate and transparent records of the review process	All REC members	Each REC review should have a formal record of review and provide constructive feedback to the student/researcher and a clear decision/outcome **(Target 100%)**
REC decisions should be communicated to the student/researcher formally using email or letter	REC chair and/or Research Administration	All REC decisions communicated formally via email or letter **(Target 100%)**

10 Useful Resources

GCU Data Protection Guidance

Research Ethics Support and Review in Research Organisations

GCU Research Integrity Policy Statement

GCU Code of Good Practice for Researchers

Concordat to Support Research Integrity

UKRIO Code of Practice for Research

UKRIO Code of Good Practice in Authorship

UK Policy Framework for Health and Social Care Research

Good Clinical Practice training https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm

Appendices

11 Appendix: Sample EC1 form

Glasgow Caledonian University
School of Health & Life Sciences
Research Ethics Approval Form
(EC1 form)

All ethics applications should be submitted electronically to the correct email address and marked for the attention of the ethics chair for the committee[1] (see below).			
Committee	**Chair of committee**	**Which committee?**	**Email address**
GSBS	Professor Oonagh Walsh		gsbsethics@gcu.ac.uk
SCEBE	Professor Gianna Cassidy		scebe_ethics@gcu.ac.uk
Nursing and community health	Dr. Ben Parkinson		HLSEthicsNursing@gcu.ac.uk
Psychology, social work and allied health sciences	Dr. Phil Dalgarno		HLSEthicsPSWAH@gcu.ac.uk
Life sciences	Dr. Les Wood		HLSEthicsLifeSciences@gcu.ac.uk
Study overview			
Study title:			
Short title (optional):			

[1] The School of Health and Life Sciences has three departmental ethics committees and each committee uses a separate email address.

Chief investigator (N.B. this should be the academic supervisor in student projects):
Email for the chief investigator:
Other staff involved:
Name of student undertaking the study (if applicable):

Level of study the student is undertaking (if applicable) (e.g. undergraduate, postgraduate, PhD):
GCU email for the student undertaking the study (if applicable):
Study governance
Study sponsor (e.g. GCU for student and/or staff projects):
Study start date:
Study end date:
Is the study research (N.B. use link to decide http://www.hra-decisiontools.org.uk/research/)?
Is the study a clinical trial?
Does the study include any invasive or biological procedures (e.g. taking blood/tissues)?
Does the study involve the NHS (e.g. patients, staff, or both)?
Does the study require NHS REC approval?
Does the project involve using personal data?
Has the chief investigator completed GDPR and data protection training?
Has gatekeeper approval been given (if applicable)?
Has this application been reviewed prior to submission (essential)?
Who has reviewed this application (e.g. study team, peer, academic supervisor)?
Has the study been prospectively registered (essential for clinical trials)?
What is the prospective registration number (if applicable)?
Does the chief investigator have up to date Good Clinical Practice training (desirable)?
Have students involved in the study received teaching on ethical research and consent (if applicable)?
How will results of the study be disseminated?
Study design

Answer all questions in this section by adding an X to either Yes, No, or N/A.	**Yes**	**No**	**N/A**
Is there a robust rationale for the study?			
Is there a clear study question(s)?			
Can the methodology and study design answer the question(s)?			
Are inclusion and exclusion criteria clearly stated?			
Will the study only invite adult participants?			
Does the study exclude potentially vulnerable people (e.g. people without capacity, prisoners, patients, and people with communication or learning difficulties).			
Will participants receive a participant information sheet before starting the study?			
Will participants be able to read and understand the participant information sheet?			
Will the participant information sheet provide full details of the study and any potential risks involved?			
Will participants be given the opportunity to ask questions and/or contact the study team if they want to know more about the study?			
Will participants be told their participation is voluntary?			
Will participants be told they can withdraw from the study at any time and without any penalty?			
Will participants have to opt-in to the study (e.g. by contacting the study team or returning a survey)?			
Will written informed consent be taken for every participant?			

(N.B. anonymous online surveys can use implied consent)			
With questionnaires/interviews, will participants be given the option to skip questions and/or take a break?			
Will data collection methods be tested prior to use with participants (e.g. informal rehearsal with colleague/student)?			
Will steps be taken to reduce the burden on participants (e.g. convenient appointments, expenses, and/or regular breaks)?			
Will permission be secured to use existing/copyrighted data collection tools?			
Will data management adhere to GCU policies (information/data storage policies), data protection legislation, and GDPR?			
Will participants be told their participation is confidential and the situations where confidentially might have to be broken (e.g. disclosure of serious crimes and/or professional misconduct)?			
Will steps be taken to maintain participant anonymity (e.g. pseudonyms)?			
Will participants be told what data will be collected and how their data will be used (e.g. anonymous quotes)?			
Will participants be told about the legal basis for processing data and who to contact if they have concerns about how their data has been handled?			
Will participants be told about what will happen to their data after the study has finished?			
Will participants receive debriefing and/or follow-up support after the study (e.g. links to useful services)?			

Will participants be advised to contact their GP if any serious health concerns are highlighted during the study.			
Will participants be told how to access a summary of the study findings once it is completed?			
Will the study team be able to access emotional support and other assistance during the study to ensure their physical and emotional wellbeing?			
Do the potential benefits of the study outweigh the possible risks associated with the study?			
Will all serious adverse events that are related to the study and unexpected be documented and reported to the sponsor?			
Does the study team and/or student have the necessary knowledge, skills, and competence to undertake the study?			
Have study documents been approved by the study team and/or academic supervisor (e.g. accessibility, presentation, and accuracy)?			
Have all ethical issues been disclosed in this application?			

Review the answers given to the study designs questions (1-33). If you have answered NO to any of the above questions, then please use the space below to give a rationale for your answer and any steps taken to mitigate possible negative consequences.

[write here]

Risk assessment (the risk assessment should consider possible harms to the participant(s), the researcher(s), wider society, GCU, and any risks associated with the use of personal data).

Risk(s)	**Severity** (e.g. low, medium, high)	**Likelihood** (e.g. low, medium, high)	**Mitigation** (e.g. what will you do to minimise harm?)

Does this study have significant ethical concerns (e.g. invasive/harmful procedures, potentially vulnerable participants, child participants, and/or deception of participants)?	
Yes/No (please delete as appropriate)	
Studies with NO significant ethical concerns should include: EC1 form Protocol (2-3 sides of A4) (see separate guidance) Participant information sheet(s) Consent Form(s) Copies of data collection tools/interview guides Adverts and/or recruitment emails Draft letter(s) Proof of gatekeeper approval	**Studies with significant ethical concerns should include:** EC1 form Protocol (4-5 sides of A4) (see separate guidance) Participant information sheet(s) Consent Form(s) Copies of data collection tools/interview guides Adverts and/or recruitment emails Draft letter(s) Proof of gatekeeper approval
Declaration The study team are familiar with the declaration of Helsinki and relevant professional body codes for research ethics (e.g. BPS). I can confirm the study abides with these guidelines. The study team agrees to bring to the attention of the ethics committee any ethical issues not covered by the above document.	
Chief investigator (this will be the supervisor for student projects) Name: Signature: Date:	
Student carrying out the study (if applicable): Name: Signature:	

Date:

12 Appendix: Sample protocol

Glasgow Caledonian University
Study Protocol for Ethics Applications

The protocol must use these headings (if applicable) and contain the information requested. Additional headings can be added if necessary and it is expected all potential ethical issues are disclosed. The protocol should be approximately 2-3 sides of A4 for studies with no significant ethical concerns and approximately 4-5 sides of A4 for studies with significant ethical concerns. The protocol structure aligns with the research ethics toolkit (Li, et al. 2016), which is a framework for protocol writers to use when applying for research ethics. **Reference:** Li R.*, et al.* 2016. Incorporating ethical principles into clinical research protocols: a tool for protocol writers and ethics committees. *Journal of Medical Ethics*, 42(4), pp. 229-234.
Study title:
Short title (optional):
Introduction: Background to the study and relevant literature. What is the scientific and/or theoretical justification for the study.
Study aim(s): Specify the study question(s) or hypothesis(es). The question(s) or hypothesis(es) should link to the scientific and theoretical justification provided in the introduction.

Study design and methods: Name the study design being used (e.g. RCT, single-case design, grounded theory).
State the location where study will take place (e.g. online, GCU campus, or NHS). Describe any intervention(s) and/or study procedure(s) (e.g. motivational interviewing, exercise bike). Explain how data will be collected (e.g. online survey, interviews). Attach copies of any data collection tools being used (e.g. PHQ9, MMSE). Specify the length of time participants will be involved in the study (e.g. two half hour appointments in July 2019).
Data management: Will the study collect data (or personal data)? What data (or personal data) will be collected (e.g. names, matric number)? Who will collect data (or personal data)? Who will have access to data (or personal data)? How will data (or personal data) be used? Where and how will data (or personal data) be stored (e.g. on GCU-approved OneDrive with access restricted to authorised staff)? When and by whom will anonymisation occur? When and how will data (or personal data) be destroyed (e.g. confidentially after five years)? Will the study adhere with GCU data security and data protection/GDPR legislation?
Choice of control group and standard care (if applicable): Will the study use a control group? What will participants in the control group receive (e.g. usual care)?
Inclusion and exclusions criteria: List inclusion criteria (e.g. adult, student, living with long-term condition). List exclusions criteria (e.g. child, pregnant, currently on sick leave from work).
Recruitment of participants: Anticipated sample size (e.g. 5 participants). Sampling method (e.g. convenience). Recruitment methods and copies of any advertisements/emails (e.g. social media, posters). Who will make first contact with potential participants (e.g. the gatekeeper)?

How will the first approach to potential participant be made (e.g. email sent by gatekeeper)? Will potential participants be asked more than once to participate (e.g. a reminder email will be sent after four week)?
Consent: When and how will potential participants learn about the study? When and how will potential participants receive the participant information sheet? When and how will potential participants be able to ask questions? Will written consent be used? When and how will consent be secured? Who will be responsible for securing informed consent prior to starting the study? Will participants be told they can withdraw from the study?
What are the possible harms for participants and the study team: What possible harms does the study pose for participants and/or the study team? Could the study have a negative impact on health and/or wellbeing?
What steps will be taken to mitigate possible harms: How are the possible harms being mitigated by the study team? Is debriefing being offered to participants and/or the study team? Are safety procedures in places to support participants and/or the study team?
Possible benefits: What are the possible benefits associated with participating in the study?
Community engagement (if applicable): Does the study include any patient and/or public engagement (e.g. yes/no)? How will patient and/or the public be involved in the study (e.g. dissemination of findings)?

Return of results and incidental findings (if applicable): Will the study team notify participants of any important health related findings (e.g. high blood pressure)? Will the study team signpost the participants to their General Practitioner, if they find any concerning health related information? What steps will the study team take if a participant discloses professional misconduct and/or poor practice during the study? Will participants be able to access the findings from the study they were involved with? How will participants be able to access the findings from the study after it is completed?
Post-trial access (if applicable): Will participants be able to continue using any intervention they received during the study after it is completed?
Payment and/or reimbursement: Will participants receive any payment or reimbursement for their participation? How and when will participants receive payment/reimbursement? How much payment/reimbursement will participants receive?
Study related injury or difficulties: How and when will study related difficulties be reported? Will study related difficulties be reported to chief investigator/sponsor? Will study related difficulties be documented in the final report/dissemination?
Other ethical concerns: What other ethical issues need to be considered?

13 Appendix: Sample Consent form

[Insert title of project]
Consent form

		Please initial box
1	I confirm I have read and understood the information sheet for the above study [insert version number and date], had the opportunity to ask questions, and had these questions answered satisfactorily.	
2	I understand my participation is voluntary and I am free to withdraw at any time without giving a reason and without my medical care and/or legal rights being affected.	
3	(Remove item if not needed) I understand relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [insert company name], from regulatory authorities or from the NHS, where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records.	
4	(Remove item if not needed) I agree to my GP being informed of my participation in the study.	
5	(Remove item if not needed) I understand my participation will be audio-recorded and analysed by the study team.	
6	(Remove item if not needed) I understand results and individual quotes may be published, however, it will not be possible to identify me in future publications.	
7	(Remove item if not needed) I understand information collected about me will be used to support other ethically approved research in the future, and may be shared anonymously with other researchers.	
8	I confirm I am an adult and 18 years or older.	
9	I agree to take part in the above study.	

Name of participant (print)		Signature		Date DD/MM/YYYY
Person taking consent (print)		Signature		Date DD/MM/YYYY

14 Appendix: Sample participant information sheet

[This form can be adapted for your project]

[Title of study] Information Sheet

Introduction
The aim of the study is to [give participants an idea of what the study is about]. The study is being conducted by [name of chief investigator] at Glasgow Caledonian University and [name and affiliation of any other investigators]. The study is being carried out by [name of student] as a part of an educational course for the award of [name of qualification].

Before you decide whether or not to take part, it is important for you to understand what participation in the study will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact us at the address below if you would like more information.

Why is this study important?
This is an important study because [briefly explain why this study is important and what you hope to achieve].

What will I have to do if I take part?
If you are interested in taking part, you will be invited to give consent. Giving consent will involve [explain how, when, where, and by whom]. You will receive a copy of the signed consent form.

Once consent has been completed you will be invited to [explain what the study will involve, making sure you give full details of what will happen, when it will occur, where it will take place, and who will be involved]. Explain the steps taken to reduce the burden of participating in the study [e.g. convenient appointments].

Do I have to take part?
No. You decide whether or not you want to take part. You can stop taking part in the study at any time, without giving a reason. Withdrawing from the study will not affect your medical care or legal rights. [explain what will happen to data if they withdraw].

What are the possible risks with taking part?
All studies involve some level of risk and inconvenience. The possible risks involved with this study are [e.g. data breach or being asked personal questions].

What are the possible benefits of taking part?
We can't promise the study will help you personally. However, the results should help our understanding of the experience of [...]. This, in turn, is expected to be beneficial to [...].

What happens when the study stops?
Written reports of the study findings will be available from [...]. However, a copy of the report can be requested from [name].

What if there is a problem?
If you are concerned about your participation in the study and would like to speak with someone out with the study team, please contact [name, address, phone number, email of independent person].

What will happen to the information given during the study?
This section will explain what happens to the information you given during the study.

Specify what personal data will be collected (e.g. age, name, gender); explain how data will be used/shared (e.g. shared using encrypted/password protected methods); how/when anonymisation will occur (e.g. pseudonyms used after data collection); who will have access to the information and in what form (e.g. immediate study team only); who will carry out data analysis (e.g. by study team); and the storage and destruction of data (e.g. only use encrypted devices; locked cabinet; restricted network drive; stored for 5 years; destroyed confidentially)**.** If the personal data is being processed or shared outside the European Economic Area (EEA) or automated decision takes place you should explain this.

This section should also state that the study complies with the Data Protection Act (2018) and the General Data Protection Regulation (GDPR). GDPR requires the data controller (e.g. this will be GCU when GCU is the study sponsor) and the legal basis for processing personal data to be stated (see below).

The data controller is Glasgow Caledonian University. Information is being processed on the basis of Article 6(1)(e) of the General Data Protection Regulation and to perform a task carried out in the public interest.

Enquiries specifically relating to data protection should be made to the University's Data Protection Officer (DPO). The DPO can be contacted by email: dataprotection@gcu.ac.uk. If you are unhappy with the response from the University, you have the right to lodge a complaint with the Information Commissioner's Office (ICO). The ICO can be contacted by email: casework@ico.org.uk.

GDPR also gives study participants the right to ask for their personal data to be erased. If you would like us to stop using your personal data, then you can contact [insert name and contact details] and ask for your personal data to be erased. However, it will only be possible to erase data that has not been anonymised and/or published. Further information about your rights can be found at: https://www.gcu.ac.uk/dataprotection/rights/

Who is organising and funding the study?
This study is being organised by [name] and funded by [name].

What will happen to the results of the study?
The study results will be available to a range of people including e.g. health professionals, researchers, and the public. It will not be possible to identify any

individual participant from these reports or publications. Some studies may seek permission to share anonymous data with researchers conducting separate ethically approved studies, but this will need to be added to the consent form and included in the consent process for this study.

Who has reviewed the study?
All studies involving human participants carried out at Glasgow Caledonian University are reviewed by an ethics committee. The role of the ethics committee is the protect the safety, rights, wellbeing, and dignity of study participants. This study was reviewed by the School of Health and Life Sciences [e.g. nursing] departmental committee and given ethical approval on [date] under the following approval code: [approval code].

Research undertaken in the National Health Service (NHS) requires additional ethical and/or Research and Development approval. This study was reviewed by [name of NHS REC and/or Research and Development department] and given approval on [date] under the following approval code: [approval code].

What happens next?
If you are interested in participating and would like to know more then please contact [insert name and contact details].

How do I make contact with the study team?
[Provide contact details for study team]

Thank you for taking the time to read this information.

15 Appendix: Sample escalating concerns template

Escalating Concerns Template

The escalating concerns template can be adapted and used is situations where researchers discover something concerning. Escalating concerns normally occurs if data collection discovers a serious health issue, identifies unprofessional behaviour by a health care worker, and/or uncovers serious criminal activity (e.g. people trafficking). Researchers need to be aware of the steps that need to be taken in these situations and need to informed potential participant(s) about the need to escalate these concerns if they occur.
Name of study:
Participant initials/ID:
Date and time of interview:
Researcher/interviewer:
Others involved (if applicable):
Type of interview (e.g. individual telephone interview):
Location of interview (e.g. MS Teams, participant's home):
Did the interview highlight any health, legal, or professional concerns? Yes/No (delete as appropriate)
(If applicable) At what point in the data collection were to concerns identified (e.g. during interview):
(If applicable) What concerns were identified (e.g. disclosed serious criminal activity):
Steps to take when escalating concerns

Tell the person you have concerns and tell them what those concerns are.
Give them time to talk and listen to what they have to say.

Tell them you will have to inform the chief investigators and/or your academic supervisor.
Explain the concerns might also have to be raised with other services (e.g. GP, police).
Ask if they would like to take a break or discontinue the interview.
Ask them if they would like you to contact someone for them.
Ask them if they would like signposting to relevant services or supports(have a list of useful resources available).
Report the incident to the chief investigator/academic supervisor.
Avoid giving advice or your opninion.
Consider whether changes need to be made to prevent it from happening in other interviews.

16 Appendix: Sample EC3 from (process to be taken to REIS)

Glasgow Caledonian University Application for externally approved research projects
(Sample EC3 form)

Project overview
Project title:
Short title (optional):
Chief investigator (N.B. this should be the academic supervisor in student projects):
Email for the chief investigator:
Other staff involved:
Name of student undertaking the Project (if applicable) (N.B. student projects should secure ethical approval at GCU before seeking ethical approval externally):
Level of Project the student is undertaking (if applicable) (e.g. undergraduate, postgraduate, PhD):
GCU email for the student undertaking the Project (if applicable):
Project details
Project sponsor (e.g. GCU for student and/or staff projects):
Project start date:
Project end date:

Is the Project research (N.B. use link to decide: http://www.hra-decisiontools.org.uk/research/)?
Is the Project a clinical trial?
Does the Project include any invasive or biological procedures (e.g. taking blood/tissues)?
Does the Project involve the NHS?
Does the Project require NHS REC approval?
Does the project involve using personal data?
Has the chief investigator completed GDPR and data protection training?
Anticipated number of participants?
Has gatekeeper approval been given (if applicable)?
Ethical approval
What is the name of the ethics committee that approved this Project?
When was ethical approval given?
What is the reference number for the ethical approval?
Who is the contact person for the ethical approval?
Are any other approvals necessary for this Project (e.g. Caldicott)?
When were these other approvals secured (if applicable)?
Checklist of items to submit with completed EC3 form.

Please check box for those items attached	**Yes**	**No**	**N/A**
Completed EC3 form			
Research protocol			
All Project documents (e.g. participant information sheet, data collections tools, and consent forms).			
Proof of ethical approval			
Proof of gatekeeper approval (or other necessary approvals)			

Declaration
The project team are familiar with the declaration of Helsinki and relevant professional body codes for research ethics (e.g. BPS). I can confirm the Project abides with these guidelines.

The project team agrees to bring to the attention of the ethics committee any ethical issues not covered by the above document.

Chief investigator (this will be the supervisor for student projects)
Name:

Signature:

Date:

Student (if applicable):
Name:

Signature:

Date:

17 Appendix: School Research Ethics Committee Review Form

Research Ethics Committee (REC) Review Form

This form should be completed by REC reviewer(s) and returned to the REC Chair (or designated person) via email. The form provides a guide for the reviewer(s) and is not intended to be prescriptive or to replace reviewer judgement. This form does not cover all possible ethical issues and it is possible the reviewer(s) may identify ethical issues not included in this form. REC reviewer(s) are encouraged to use this form and their judgement to reach a balanced decision about the ethical issues associated with a particular study.	
Name of applicant:	
Name of the study:	
Study ID:	**School REC:**
Date review received:	**Date completed review sent to REC:**

Reviewer Checklist
1. Is the application complete and ready for REC review? [Applications should include high quality and clearly presented study documentation. Consider whether the application contains all the necessary documents (e.g. EC1 form, protocol, information sheet), whether the application is complete (e.g. does the protocol tell you everything you need to know), and whether the application is of sufficient quality for approval (e.g. spelling, presentation). The ethical reviewer is not expected to proof read ethics applications and can decline to review the application if it is not of an acceptable standard. Incomplete and/or low quality application will be returned to the applicant without a decision and will delay the approval process]
Reviewer comments …
2. Is it clear who is involved in the study and their roles (e.g. chief investigator, collaborators, students)? [The application should include the names and roles for all members of the study team. This may include students and/or people from other organisations]

Reviewer comments …
3. Are the aims of the study clearly stated? [It is unethical to recruit participants without clear study aims. The study aims should be clearly stated in the protocol and participant information sheet]
Reviewer comments …
4. Is it clear where the study will take place (e.g. on campus, community venue, online)? [It should be clear where the study will take place. Will participants/researchers have to travel and what are the risks associated with location?]
Reviewer comments …
5. Does the study need internal/external approval and will this be secured before starting the study (e.g. gatekeeper, NHS ethics)? [The chief investigator or academic supervisor is responsible for ensuring all necessary approvals are in place for the duration of the study. The application should explain what approvals are needed and provide evidence that these have or will be secured before the study starts]
Reviewer comments …
6. Are the inclusion/exclusion criteria appropriate (NB: consider possible vulnerability and age of participants)? [Are inclusion/exclusion criteria provided? Does the study specifically seek to recruit vulnerable participants (e.g. people without capacity, children, prisoners)? Studies specifically seeking to recruit vulnerable participants may need additional ethical scrutiny from a School or University REC]
Reviewer comments …
7. Does the study have an appropriate recruitment plan? [The study should clearly state how and where participants will be invited to participate in the study. Recruitment should be voluntary, without coercion, and on an opt-in basis]
Reviewer comments …
8. Are study documents (e.g. participant information sheet, consent form) accessible enough for the intended audience (e.g. plain English)? [Applications should include high quality documentation. Public facing documents (e.g. adverts, participant information sheets, and consent forms) should be accessible enough for the intended audience and provide all the information necessary for participants to make informed choices about the study]
Reviewer comments …
9. Does the participant information sheet include enough information about the study (e.g. consent, risk-benefits, commitment, complaints, information security)? [The participant information sheet should be given to potential participants before they give consent. Potential participants should be given the opportunity to ask questions (e.g. invited to email the researcher) and/or time to decide whether they wish to participate. The

participant information sheet needs to provide enough information about the study for potential participants to know what is involved with the study, what will be expected of them, and what their rights are (e.g. data protection, complaints)]

Reviewer comments …

10. **Does the study have appropriate informed consent arrangements (e.g. fully informed, voluntary, and reversible)?** [Gaining informed consent is a complex process involving the potential participant, the researcher, and potentially other people. The consent process does have to be indicated in some way, but can be proportionate and may vary between different studies (i.e. implied, verbal, and written consent). All consent processes should consider the nature of the study, capacity of the person, the information provided, the voluntary nature of consent, and be reversibility of the consent process]

Reviewer comments …

11. **Has a risk assessment been completed for the study and is there an acceptable risk-benefit ratio (i.e. the risks do not exceed the potential benefits)?** [All studies include some risk and there needs to be evidence of a risk assessment and what steps will be taken to mitigate the possible risks involved. The risk should not exceed the possible benefit from the study]

Reviewer comments …

12. **Does the application demonstrate how it meets data protection legislation and GCU information security requirements (e.g. password protection, data encryption, information security training, information/data management and storage)?** [Ethics applications should include detailed and comprehensive information about how data will be collected, handled, analysed, stored, reported, and destroyed. Data should be stored in authorised University storage and access available to and restricted to authorised individuals. All studies should comply with the relevant data protection legislation and GCU policies and procedures for data management]

Reviewer comments …

13. **Is it clear how the researcher(s) will respond to a participant who experiences deterioration in health and/or acute distress during the study (e.g. loss of capacity, suicidal ideation)?** [Researchers should anticipate and plan for situations where a participant may become unwell and/or distressed during the study and have a management plan in place to support the participant(s)]

Reviewer comments …

14. **Is it clear how the researcher(s) will escalate concerns if/when they are discovered during the study (e.g. unprofessional/criminal activity, identification of previously unknown health conditions)?** [Researchers should anticipate and plan for incidental findings or situations they discover information that needs to be shared with the participants and/or the authorities]

Reviewer comments …

15. Is the level of ethical concern in this study acceptable for approval by the School Research Ethics Committee? [The reviewer(s) need to consider whether the application can be approved by the school REC. School RECs can approve most studies, but should additional scrutiny by REIS may be required for studies involving major ethical concerns/dilemmas]
Reviewer comments …
16. Additional comments (Use this space for ethical concerns not covered in the checklist) [This form provides a guide for the reviewer(s) and is not intended to be prescriptive or to replace reviewer judgement. This form does not cover all possible ethical issues and it is possible the reviewer(s) may identify ethical issues not included in this form. This section can be used by the reviewer(s) to identify additional ethical issues that are not covered elsewhere on the form]
Reviewer comments …

Reviewer decision (Delete as appropriate)	
• Approve (study able to start) • Approve with conditions (provide conditions) • Amend and resubmit (provide list of revisions in reviewer comments below) • Not approved (study not appropriate in current format) • Significant ethical concerns (refer to REIS)	
Reviewers comments and/or conditions for approval [This space should be used to provide clarification or conditions for the approval]	
Reviewer	
Name:	Conflict of interest declared with this review? Yes/No (delete as appropriate)

18 Appendix: Research Ethics and Integrity Subcommittee

The Research Ethics and Integrity Subcommittee (REIS) is a subcommittee of the University Research Committee and provide ethical review and guidance for projects involving major ethical concerns or issues.

19 Terms of reference for REIS

Research Ethics and Integrity Subcommittee (REIS)

Terms of Reference

To consider applications referred by School Ethics Committees for any proposed research (staff, postgraduate and undergraduate) involving human participants that is deemed to be non-routine, intrusive or any research that is likely to be ethically contentious.

To oversee the GCU Research Integrity Action Plan and matters in relation to the Concordat to Support Research Integrity and any legislation or HE sector guidance which may have ethical implications for research undertaken in the University and to review and update University Guidance as required.

To identify any training requirements for researchers identified in relation to research ethics and integrity and make recommendations on these requirements to the DARE Group and URC, as appropriate.

To consider an annual report from School Ethics Committees, to include the numbers of proposals considered by School Ethics Committees and those submitted externally, and commentary on any specific ethical issues facing the School.

To prepare an annual report on the Committee's operation for the University Research Committee and consider the initial draft of Research Integrity Annual Statement and Report for recommendation to the URC.

Procedural Note:

Conflicts of interest must be declared before reviewing any ethics application referred to the subcommittee.

Any ethics application referred to the subcommittee will normally be reviewed by two committee members, as first and second reviewer.

20 Composition of REIS

- Chair
- Vice Chair
- Chair of the School Ethics Committees (or Research Area Ethics Leads, where applicable)
- University Research Integrity Champion Local Research Integrity Champions
- Assistant Head of Governance (Information Compliance)
- Director of Research and Innovation or nominee
- Director of the Graduate School or nominee
- Professional services staff with a role in research governance, ethics and integrity
- Two lay members
- One PGR Student representative

Nominated by the University Research Committee for a term of 3 years.

The vice chair will be from a different School to the Chair and will be expected to assume the Chair after their 3-year term of office. A new vice Chair will be selected at that time from another School (on a rotation basis).

Where the local chair is the chair/vice chair of REIS, they may nominate another member of the local committee.

21 Appendix: REIS Conflict of Interest Guidance

Background
This paper documents the process for identifying and reducing the possible impact of conflict of interest in the Research Ethics and Integrity Subcommittee (REIS) at Glasgow Caledonian University. The paper covers conflict of interests (and competing interests) for members of REIS involved in committee business. The paper acknowledges every member of REIS will have potential conflicts of interest and seeks to identify and mitigate these potential conflicts of interest. It is important for REIS to maintain rigour and show care and respect to others. The aim of this paper is to demonstrate how REIS is being honest and transparent about possible conflicts of interest.
Examples of possible conflict of interests
The conflict of interests may result from a number of different factors: Financial interests Non-financial interests Business interests Intellectual property rights Interpersonal relationships or friendships Others roles and responsibilities Political allegiances Vested interests Status and esteem This list is not definitive, but gives an indication about the possible areas where conflict of interest may occur. Further guidance is available in the GCU Register of Interests Policy (https://www.gcu.ac.uk/media/gcalwebv2/theuniversity/supportservices/peopleservices/Register%20of%20Interests%20Policy.pdf).
Recommendations
Align REIS with GCU Register of Interest Policy REIS members will complete GCU Register of Interest Policy

REIS members should declare possible conflicts of interests and update the GCU register of interests when necessary

REIS members should exclude themselves from ethical review and other committee business when conflicts of interest arise

Ethical review and approval should involve more than one person

Applications for ethical review and approval should be assigned a designated lead reviewer and second reviewer (plus additional named experts, if necessary). The lead and second reviewer should complete their review and report their findings and their recommendations to REIS.

The lead and second reviewer with make recommendation, but the final decision for ethical approval will provided by REIS.

Ethical review and approval should involve people from more than one school and encourage cross school scrutiny

Ethical reviews should not be completed by people who are involved in the study or are likely to benefit (directly or indirectly) from the study being approved (e.g. dissertation supervisor, co-author)

Ethical review and approval should not be completed by someone who has provided school level scrutiny or review (e.g. departmental ethics chair)

Ethical review and approval should be transparently documented and available for external audit

22 Appendix: REIS Referral and Reviewer form

REIS Referral and Reviewer Form (This section is completed by referrer)
This form is used to request ethical review or advice from the Research Ethics and Integrity Subcommittee (REIS). The form is also used by REIS for their reviews. Referrals should be completed by the Chair (or their deputy) of the School Research Ethics Committee and emailed to: REIS email address: REIS@gcu.ac.uk
1) Referral details (section completed by referrer)
Name of referrer
Email of referrer
Date of referral
School/department making the referral
Reason for referral (e.g., ethical review, advice)
2) Study details (section completed by referrer)
Name of study
Study identification number
What are the main ethical issues or concerns with this study?
3) School REC Review
Has the study been reviewed by the School Research Ethics Committee?
How many people were involved in the review?
What recommendations were made by the reviewer(s)?

Has the protocol, study documentation, and School ethical review been attached?	
REIS Review (This section is completed by REIS reviewers)	
This section of the form will be completed by a lead and second reviewer before being submitted to the wider committee. The REIS review will be completed after school level ethical review and provide recommendations for the School Research Ethics Committee (see below).	
Situation	
Main concerns	
Ethical dilemmas	
Recommendations	
REIS reviewers	
Lead reviewer: Conflict of interest: yes/no Date:	Second reviewer: Conflict of interest: yes/no Date:

23 Appendix: Recording Research ethics and integrity activity on Pure

Research ethics and integrity work is an essential aspect of research and promotes quality. GCU is keen to recognise the valuable contribution made by academics and professional services involved with research ethics and integrity. It is now possible to use Pure to record involvement with research ethics and integrity.

The instructions on how to record research ethics and integrity activity on Pure is provided below:

- Activity -> Other -> Types of Internal academic engagement - Membership of peer review panel or committee
- To create a complete record, we would suggest adding the following fields at a minimum:
- Title – e.g., Reviewer for SHLS Research Ethics Committee
- Organisational Unit – the associated school e.g., School of Health and Life Sciences Description – e.g., number of reviews completed
- Period – a start date and end date (if applicable)
- Degree of recognition – local
- Person – the reviewer in question. Here you can also add their specific role e.g., reviewer
- Visibility – ensure this is set to “public” so that when activities are eventually published to the portal the record will be visible
- You can also add additional keywords and link the activity to the associated project in Pure (if applicable).

24 Appendix: Sample Sponsorship Letters

SPONSORSHIP LETTER - STUDENT

Dear Sir or Madam

Title of Research Study:

Name of Researcher:

Location of Research:

I am writing to confirm that Glasgow Caledonian University is aware of the above student research proposal and has agreed to undertake the role of Sponsor as outlined in the UK Policy Framework for Health and Social Care Research. I am the student's supervisor for the study. I understand that the University may delegate the responsibilities of the sponsor to me and I agree to undertake them accordingly. I confirm that Glasgow Caledonian University has appropriate insurance cover under the terms of its Professional Negligence Insurance Policy.

I understand that we must have approval letters from an appropriate Ethics Committee and NHS **NAME OF HEALTH BOARD** Research & Development Office before we can commence the proposed research.

Yours faithfully

To be signed by an NHS passport holder or supervisor.

Counter signatory – Associate Dean for Research

.....

SPONSORSHIP LETTER - STAFF

Dear Sir or Madam

Title of Research Study:

Name of Researcher:

Location of Research:

I am writing to confirm that Glasgow Caledonian University is aware of the above research proposal and has agreed to undertake the role of Sponsor as outlined in the UK Policy Framework for Health and Social Care Research. I am the Dean of the School of [add name of School] and am responsible for the conduct of the study. I understand that the University may delegate the responsibilities of the sponsor to me and agree to undertake them accordingly. I, in turn may delegate sponsorship duties to the Principal Investigator of the study. I confirm that Glasgow Caledonian University has appropriate insurance cover under the terms of its Professional Negligence Insurance Policy.

I understand that we must have approval letters from an appropriate Ethics Committee and NHS (Name of Health Board) Research and Development Office before we can commence the proposed research.

Yours faithfully

To be signed by Dean of School

Counter signatory – Associate Dean for Research

25 REC Reporting (trimester and annual reports form)

Research Ethics Committee Report Form (To be completed every trimester and at the end of every academic session)
Name of the REC (e.g. Nursing REC)
Comments:
Academic Session and/or Trimester(s) (e.g., 2022/2023 trimester A)
Comments:
Number of Projects submitted (how many applications has the REC received?)
Comments:
Number of reviews completed (including reviews of resubmissions and amendments)
Comments:
Average review time (Time from submission to decision e.g. processing and review)
Comments: (NB include mean and standard deviation)
Number of reviews exceeding 20 working days (Clock starts at zero for each review)
Comments:
Number of reviewers in the Research Ethics Committee
Comments:
Review
What has worked well this trimester/year?
Comments:
What has not worked so well this trimester/year?
Comments:
What (if any) problems or difficulties has the REC experienced this trimester/year?
Comments:
Recommendations or possible enhancements?
Comments: