**FOREWORD**

**CARDIFF UNIVERSITY TEMPLATE PROCEDURES FOR SCHOOL RESEARCH ETHICS COMMITTEES**

In accordance with the Cardiff University Policy on the Ethical Conduct of Research involving Human Participants, Human Material or Human Data (Ethics Policy), School Research Ethics Committees (SRECs) are expected to implement, and act in accordance with, the Procedures for SRECs contained in this template.

**SCHOOL HEALTHCARE SCIENCES RESEARCH ETHICS COMMITTEE PROCEDURES**

Note: Capitalised terms are as defined in the Ethics Policy.

1. **Purpose of the School Research Ethics Committee (SREC)**
	1. The Ethics Policy requires that all Research involving human participants, human material or human data (Human Research) be subject to ethical review **before** the Research commences.
	2. The SREC is primarily responsible for reviewing applications for ethical review for all Human Research proposed by Researchers (staff or students) within the School unless ethical review falls within the remit of an external ethics committee or a specific exemption applies (see the Ethics Policy).
	3. Where another university or research institution has conducted ethical review of a research project involving Researchers at Cardiff University, the SREC is not required to conduct its own ethical review of the research project, but may choose to do so, where appropriate. In all cases where another university or research institution has conducted ethical review of a research project, the SREC must obtain evidence of the review (namely the outcome letter/communication and relevant ethical review policy) from the Researcher. The SREC must keep a record of this.
	4. SRECs are not mandated to review ‘Service Evaluation’ and/or ‘Audit’ Activities, as defined in the Ethics Policy, but may choose to do so.
	5. The SREC is a sub-committee of the University Research Integrity and Ethics Committee (URIEC) and is accountable to URIEC. The role of the SREC is to operate in accordance with its Terms of Reference, the Ethics Policy and these Procedures.

1.6 **Whilst Research falling outside of the definition of ‘Human Research’ does not require formal ethical review, the Research may still raise ethical issues and Researchers are expected to give these issues due consideration.**

1. **Terms of Reference**

The SREC is responsible for:

* 1. considering Human Research proposals (from the School’s staff and students), where responsibility to conduct ethics review does not fall to an external ethics committee (for example an NHS Research Ethics Committee). This includes all Human Research proposals, regardless of whether the Research is funded;
	2. providing an ethical opinion on the proposal, and a written explanation for the opinion (via a response letter), to the Chief/Principal Investigator;
	3. considering research project amendments;
	4. recording all submitted applications, reviews and committee decisions, including the date the ethical approval was given and the anticipated research project completion date;
	5. monitoring all studies that receive a favourable opinion. Ongoing monitoring and support should be proportionate to the nature and degree of risk and harm involved with the research;
	6. referring cases which cannot be satisfactorily resolved, or about which there is uncertainty, to URIEC;
	7. operating procedures no less rigorous than those suggested or required by relevant professional bodies or other organisations in the subject domain (e.g. Sponsoring/funding bodies);
	8. informing URIEC of any changes in the ethical codes of professional bodies in relevant discipline areas, in order that the University’s procedures remain valid;
	9. providing annual reports to the School Board (or equivalent) and to URIEC; and
	10. conducting a review of its procedures at least every three years.
1. **Membership and Quoracy**
	1. The SREC will have sufficient members to deal with the anticipated number of Human Research proposals requiring review. The SREC will comprise of Members who have broad experience and expertise in the areas of Research regularly reviewed by the SREC and will include independent/lay representation.
	2. The SREC will comprise of at least:
		1. a Chair and a vice chair
		2. Academic Members including at least one member from each Allied Health Profession, Midwifery, and each Nursing discipline, a research assistant, early career researcher and professorial representative
		3. one Member from another School; and
		4. one Member from outside of the University (i.e. a lay member).
	3. The School has appointed a School Ethics Officer who will act in accordance with the role description contained in the Ethics Policy and will normally act as Chair of the SREC.
	4. All SREC Members will be appointed by the Head of School, assisted by the School Ethics Officer.
	5. The SREC is quorate when at least one third of the individuals comprising the SREC are ‘in attendance’ (meaning either attending in person, via a live electronic link e.g. Skype or via the issuing of comments prior to the meeting) including the Chair and at least one external/lay Member. Quoracy requirements will remain regardless of meeting format. If the SREC is reviewing an application for ethical review electronically, sufficient Members must respond to ensure quoracy; a nil response will not be considered a favourable opinion.
	6. It is normally expected that the SREC will reach a consensus in its decision-making. Where disagreement remains, decisions of the SREC will be made by a majority vote, with the Chair having a casting vote, and this should be recorded in the minutes of the meeting.
	7. For the avoidance of doubt, the matters stated in paragraphs 3.5 and 3.6 above **do not** apply to applications proceeding by way of the SREC’s proportionate review system. Research projects deemed suitable for proportionate review (as set out in section 7.1) shall be considered by a minimum of two committee members.
	8. Where specific or additional expertise is required to enable the SREC to review an application for ethical review, it may invite individuals with such expertise (an Expert Advisor) to assist with its review. The role of the Expert Advisor will be to provide guidance and assistance to the SREC to enable it to make a decision on the application.
2. **List of current SREC Members**

Details may be found in **Appendix 1**.

1. **Training for SREC Members**
	1. All SREC Members must have adequate training, to enable them to carry out their duties. The SREC will utilise current Cardiff University training courses, where these are available, including:
		1. Research Integrity Online Training Programme;
		2. Research Ethics 1 – Research Governance (online module);
		3. Research Ethics 2 – Working with Human Subjects (online module);
		4. Human Tissue Act (HTA) (online module);
		5. Managing Research Data – Key Aspects of Legal Compliance and Records Management;
		6. Safeguarding Training for Researchers (Child and Vulnerable Adult Protection); and
		7. Prevent training.
2. **Declaration of Conflicts of Interest**
	1. The SREC will ensure that all applications for ethical review are subject to impartial and independent scrutiny, to the extent possible. As such, all SREC Members are expected to declare any actual, or perceived, conflicts of interest prior to participating in the review of the application. For the purposes of this section, ‘conflicts of interest’ include any direct or indirect pecuniary or other interest in the Research that could be perceived to influence a Member’s judgment.
	2. Any SREC Member directly involved in the Research submitted for review (whether conducting or supervising the Research) must declare a conflict of interest.
	3. Where a SREC Member declares a conflict of interest, the SREC will usually require that the Member withdraws from the discussion/review of the application to which the declaration relates. All conflict of interest declarations must be recorded by the SREC.
3. **SREC Operations**
	1. Type of Review

The SREC requires that all Human Research proposals be subject to full review by the SREC.

* + 1. The SREC has adopted an approach which allows certain Human Research proposals to receive a proportionate review.
		2. Studies involving any of the following are not suitable for proportionate review and will always require full review:
* where the Researcher is not proposing to obtain the informed consent of participants to take part in the research project, including covert Research (where it is necessary to conceal the Research due to the subject matter, or to test the hypothesis);
* where the Research design includes an element of deception;
* children under the age of 18 or ‘at risk’ (vulnerable) adults or groups[[1]](#footnote-1);
* highly sensitive topics including (but not limited to) sexual behaviour, illegal activities, political, religious or spiritual beliefs, race or ethnicity, experience of violence, abuse or exploitation, and mental health;
* access to records of a sensitive or confidential nature, including Special Category Data for the purposes of the General Data Protection Regulation and Data Protection Act 2018;
* where permission of a gatekeeper is normally required for initial or continued access to participants. This includes participants in custody and care settings, or research in communities where access to research participants is not possible without the permission of another adult, such as another family member or a community leader.
* intrusive/invasive procedures, for example the administration of substances or vigorous physical exercise or where the procedures may involve pain or more than mild discomfort to participants (including the risk of psychological distress, discomfort or anxiety to participants (more than the risks encountered in everyday life);
* visual or audio recordings where participants may be identified;
* the collection or use of human tissue; and
* risks to the safety and wellbeing of the Researchers. [Where a risk assessment has already been performed by an appropriate University body, the SREC should obtain evidence of this. The research project may be considered for proportionate review only where it does not meet any of the other criteria for full review set out in 7.1.2].
	+ 1. If a research proposal is using only common methodologies, which have been previously approved by the SREC, then proportionate review may be applied. At the current time Healthcare SREC does not have any common methodologies.
		2. Studies that do not require full review will follow the proportionate review system.
		3. Studies which present more than a minimal risk of harm will be subject to full review by the SREC.
	1. Submission Process
		1. Human Research proposals should only be submitted to the SREC for ethical review where it is certain that the Research will go ahead (subject to all relevant approvals being obtained). If the Research is dependent on a successful funding application, the proposal should not normally be submitted to the SREC until confirmation of funding is obtained. However, if a funder requires a statement from the SREC prior to making a decision about the success of the funding application, or where the Research must start immediately after the funding has been obtained, the SREC will consider the proposal.
		2. Prior to submission to the SREC, Researchers must ensure that the Human Research proposal has been subject to appropriate scientific/peer review. It is not the role of the SREC to perform this type of review.
		3. The Chief/Principal Investigator must follow the steps below in order to obtain ethical review from the SREC:
* Discuss the Human Research proposal with any co-investigators and/or Supervisors (for student research projects, or where otherwise applicable) including the ethical issues associated with the research project and what action will be proposed to the SREC to address such issues.
* Complete online research integrity module and retain evidence of completion to submit to the SREC.
* Complete the relevant SREC Application Form. For student research projects, the Supervisor will also be required to approve the Form. This form may be obtained from the School of Healthcare Sciences Research ethics webpage <https://www.cardiff.ac.uk/healthcare-sciences/research/research-ethics> .
* Complete, collate and append all necessary supporting documentation as listed in the SREC Application Form. This will usually include the proposal/protocol (or a clear description of the Research), all participant-facing documents (including recruitment documents, information sheets, consent forms, questionnaires) and evidence of training completion where applicable. The Chief/Principal Investigator must pay particular attention to relevant Cardiff University policies, procedures and guidance and any local/discipline specific guidance on research ethics prior to finalising any proposed research project documents. A list of useful resources is contained at **Appendix 2**.
* Submit the SREC Application Form and all supporting documents in electronic format to HCAREethics@Cardiff.ac.uk three weeks before the meeting.
	1. Frequency, Format and Timing of SREC Meetings
		1. The SREC will convene monthly to consider applications submitted for full ethical review. The monthly meetings will be time-tabled in advance and published on School of Healthcare Sciences Research ethics webpage <https://www.cardiff.ac.uk/healthcare-sciences/research/research-ethics>. In order to be considered at the next meeting, applications for full ethical review must be received at least 21 working days in advance of the meeting date.
		2. Whilst the SREC will always aim to meet in person to discuss applications, the SREC may convene to consider and discuss applications electronically (through correspondence) or via a conference call. This will be at the discretion of the Chair of the SREC and may be utilised where the application is deemed unproblematic or where the Chair otherwise considers it appropriate for an application to be considered outside of a meeting.
		3. The SREC does not normally invite the Chief/Principal Investigator to attend/take part in the SREC’s discussion of an application for ethical review. However, the SREC may do so in exceptional cases where it considers that such attendance would assist the SREC.
		4. Where an application for full ethical review is received late (i.e. outside of the timescales indicated above) the application will not be considered until the next meeting of the SREC, save in the most exceptional circumstances. Delay in starting the Research will not normally be accepted as an exceptional circumstance.
	2. Review of Applications
		1. To enable the SREC to reach a decision about a Human Research proposal submitted for ethical review, the SREC will consider relevant policies, procedures and guidance issued by Cardiff University, alongside any guidelines of relevant professional bodies, funders and organisations in the research discipline.

7.4.2 **The SREC will reach a decision about the research proposal based on the information provided by the Chief/Principal Investigator. The Chief/Principal Investigator must ensure that all relevant information is provided to the SREC and that the information provided is accurate.**

7.4.3 For studies requiring full review the SREC Chair will nominate a lead and second reviewer to consider the application in full, prior to the review meeting. The lead and second reviewer will summarise the application for the remaining SREC Members, to enable a collective ethical opinion to be issued. Where full review is conducted by email, all SREC members must receive the application to consider*.*

7.4.4 For studies requiring full review, it is normally expected that the SREC will reach a consensus in its decision-making. Where disagreement remains, decisions of the SREC will be made by a majority vote, with the Chair having a casting vote.

* + 1. For studies eligible for proportionate review, the SREC chair will delegate one committee member and another individual to review the application and the outcome will be agreed upon with the SREC chair or nominated representative.
	1. Outcome of Review

Within 7 working days of the review meeting/consideration of the ethical review application, the SREC may:

* + 1. issue an 'Ethical Opinion' to the Chief/Principal Investigator;
		2. defer consideration of the application, where significant further information is required (in such cases, the SREC will confirm to the Chief/Principal Investigator what additional information is required, the deadline for the provision of such information, and a proposed timescale for SREC review (which may be at the next scheduled SREC meeting); or
		3. in exceptional cases, refer the application to URIEC in accordance with paragraph 7.9.

In the majority of cases the SREC will issue one of the following Ethical Opinions to the Chief/Principal Investigator:

* + 1. Favourable Opinion (no conditions). The SREC does not require any changes to the Human Research proposal and the Researcher may proceed, provided no other approvals are outstanding. Authorisation to proceed is granted on the basis that the research project will proceed **exactly** as stated on the application for ethical review and in accordance with the research project documents reviewed by the SREC.
		2. Favourable Opinion (with conditions). The SREC will detail the conditions of the favourable opinion in the response letter. The Researcher may only proceed once all conditions have been met, but is not required to revert to the SREC to obtain a subsequent review (although the Researcher must notify the SREC once all conditions have been met and provide copies of any revised documents).
		3. Provisional Opinion. The SREC will detail the conditions of the provisional opinion in the response letter. The Researcher must revert to the SREC with evidence that all conditions have been met. The SREC will nominate Member(s) to review the evidence submitted. If satisfactory, a favourable opinion letter will be issued by the SREC in order that the Researcher may proceed, provided no other approvals are outstanding.
		4. Unfavourable Opinion. The SREC rejects the application. Detailed feedback will be issued to the Researcher. The Research cannot commence until a favourable opinion has been obtained.
	1. Review of Amendments
		1. Researchers are ultimately responsible for ensuring that all ethical issues arising from their research project are kept under regular review.
		2. Researchers must inform the SREC of any unexpected ethical issues or unexpected adverse events that arise during the research project.
		3. The SREC recognises that Researchers may need to amend their proposal and/or participant-facing documents during the lifecycle of a research project. Dependent on the nature and scale of the amendments (namely whether the amendments are 'substantial' or 'non-substantial'), the SREC may be required to review the proposed amendments before they are implemented. The current review procedure adopted by the SREC is set out below.

**7.7** Substantial Amendments

7.7.1 Any substantial amendments to documents previously reviewed by the SREC must be submitted to the SREC via email to HCAREethics@cardiff.ac.uk for consideration and cannot be implemented until the SREC has confirmed it is satisfied with the proposed amendments.

7.7.2 For the purposes of the above, ‘substantial’ includes (but is not limited to):

* changes to any participant-facing documentation where such changes are likely to have an impact on the safety of participants or the nature of their involvement in the research project;
* changes to the experimental procedures, the procedures undertaken by participants, or uses of the material/data;
* change to the Chief/Principal Investigator;
* a temporary halt of the research project to protect participants from harm, and the planned restart of the research project following the temporary halt;
* other significant changes to research project documentation or the proposal submitted to the SREC.

7.7.3 Proposed substantial amendments will be reviewed by a lead reviewer (nominated by the SREC chair), and then discussed with the chair to agree an outcome. The documents that should be submitted must include a document detailing the proposed amendments and updated documents with changes to the text highlighted within the document. The outcome of the review notified to the Chief/Principal Investigator within [7] working days.

7.8Non-substantial Amendments

7.8.1 Researchers may implement non-substantial amendments to documents previously reviewed by the SREC. However, the SREC must be notified of such changes via an email to HCAREethics@cardiff.ac.uk to enable the SREC to update its records.

7.8.2 The following are examples of non-substantial amendments:

* + - minor changes to the research proposal or other research project documents such as the correction of errors and updating contact details;
		- changes/additions to the wider research team (not including a change to the Chief/Principal Investigator);
		- changes in funding arrangements;
		- changes in documentation used by the research team for recording information about the research project data;
		- changes in any logistical arrangements; or extension of the research project beyond the period specified in the application to the SREC.

7.9 Referrals and Appeals

7.9.1 Where the SREC is unable to satisfactorily resolve a query/issue that arises during the review of a Human Research proposal, it may refer the matter to URIEC for advice or guidance. Referrals must be made by the SREC via the Head of School. URIEC will expect to receive a summary of the query/issue arising and may invite members of the School to a meeting to discuss the issue. The advice or guidance provided by URIEC will be recorded in writing and issued to the SREC via the Head of School. The SREC remains responsible for making a decision on the Human Research proposal and for notifying the Researchers of the progress of the application and the outcome of the review.

7.9.2 If a Researcher is dissatisfied with a decision made by a SREC, this should be discussed with the Schools Ethics Officer in the first instance. If discussion is unable to resolve the issue satisfactorily, an appeal against the decision of the SREC may be made to URIEC via the SREC and the Head of School. However, it should be noted that URIEC will not normally interfere with a SREC decision. URIEC is concerned only with the general principles of natural justice, reasonableness and fairness of the decision made by the SREC.

1. **Special Category Research**
	1. Human Tissue Studies
		1. All studies that involve the use of human tissue must be submitted to the Human Tissue Act Compliance Team (HTACT) prior to submission to the SREC, including the full application and all supporting documentation.
		2. If a substantial amendment includes changes to the collection or use of human tissue the amendment must be submitted to the HTACT prior to submission to SREC.
		3. The research project will not be considered by the SREC without the accompanying final HTACT report.
		4. The checklist used by the HTACT when performing the review can be found on the HTA pages of the Cardiff University intranet. Applicants are strongly advised to consult this document prior to submission.
	2. Research falling within the UK Policy Framework for Health and Social Care Research
		1. All studies that fall within the above framework require Sponsorship from the University’s Research Governance Team (Research and Innovation Services). Sponsorship should ideally be obtained before a proposal is submitted to the SREC for review. In no circumstances should the research project commence before Sponsorship has been obtained, alongside any relevant external approvals associated with the Sponsorship process.
		2. Chief/Principal Investigators must apply for Sponsorship using the University’s Advanced Project Information Proforma. Further information is available [here](https://intranet.cardiff.ac.uk/staff/research-support/research-projects/conducting-research-in-the-nhs/applying-for-sponsorship)[[2]](#footnote-2).
	3. Security-sensitive Research
		1. Research falling within the scope of the Prevent Duty, namely research involving terrorism, extremism and/or radicalisation (or research involving access to materials of such a nature) must be registered with the University in accordance with the Security-sensitive Research Policy.
	4. Research involving the use of Social Media Data (or similar internet-based data)
		1. The SREC will consider all research proposals falling within this category if the data being accessed, collected or used by researchers comprises Human Data.
		2. The SREC recognises that Human Data obtained through social media or similar platforms can lawfully be used for research purposes without explicit consent, provided certain conditions are met. However, there are still important ethical matters to consider whenever a researcher is proposing to use such data for research purposes.
		3. **The Legal Position**

Personal Data obtained through social media or similar platforms can lawfully be used for research purposes without explicit consent, where:

* + - the data has been ‘manifestly made public by the data subject’, as opposed to being made public by someone else;
		- the data is not being used to make decisions about individuals;
		- the use of the data would not impinge on the rights and freedoms of the individuals;
		- the use of the data would not cause substantial damage/distress to the individuals;
		- data minimisation techniques are employed so that only relevant information necessary for the research is captured and anonymisation takes place prior to publication; and
		- the Researcher complies with the general data protection principles contained within the General Data Protection Regulation. See Cardiff University’s GDPR Guidance for Researchers for further details.

Anonymised Human Data obtained through social media or similar platforms (i.e. where the data being accessed or collected relates to humans (or was obtained from humans) but contains no identifying information) is not subject to data protection legislation, and therefore can be used lawfully for research purposes.

* + 1. **The Ethical Position**

In addition to ensuring the relevant conditions for lawful use are satisfied (as set out above), researchers must consider (and the SREC will consider) the ethical implications of using the data for research purposes. Some relevant ethical questions to consider are:

* + - * + whether the information is truly ‘public’. For example, if a researcher obtains information from a closed social media group/page or from a forum only available to certain users, the individual to which the data relates is unlikely to expect that the information will be used for another purpose. The terms and conditions of the internet provider may provide a useful starting point in terms of what content is considered ‘public’;
				+ the extent to which anonymity can truly be achieved. For example, if a researcher is proposing to use direct quotations in a research publication, the individual from which the quote was obtained may be easily ascertainable; and
				+ whether the information being accessed/used for research purposes is sensitive (which may increase the changes of harm/distress).

There are various frameworks available that address the ethical considerations of using social media/internet data in further detail. Whilst many of these were drafted prior to the introduction of the General Data Protection Regulation, they still provide a useful starting point for researchers and SRECs. Examples include:

* + - * + ‘Social Media Research: A Guide to Ethics’, ESRC and the University of Aberdeen
				+ ‘Internet-mediated research’, UK Research Integrity Office
				+ ‘Internet-Based Research’, University of Oxford
1. **SREC Governance**
	1. Record keeping
		1. The School Ethics Officer (or a delegated nominee) will keep an accurate record of every SREC meeting/deliberation. This must include details of:
			* + the names of those in attendance (where a meeting);
				+ any conflicts of interest declared;
				+ a summary of the matters discussed; and
				+ a report of the decisions made.
		2. The School Ethics Officer (or a delegated nominee) will maintain a record of all applications submitted to the SREC and the associated outcomes. The record will include details of (this list is not exhaustive):
* The research project (including title, start date, anticipated and actual end date)
* The Chief/Principal Investigator
* Whether the proposal was subject to full or proportionate review
* The application review date, the identity of the reviewers, and the outcome
* Any substantial amendments considered (including the review date, the identity of the reviewers, and the outcome)
* Any non-substantial amendments notified to the SREC
	+ 1. The SREC will ensure that all records are stored securely and that access is granted to the individuals responsible for maintaining the records.
	1. Monitoring
		1. The School Ethics Officer is responsible for ensuring that appropriate measures are in place to monitor the progress of studies that have received a favourable opinion.
		2. When considering an application for ethical review, the SREC will determine what form of monitoring is required for the research project and will confirm this to the Chief/Principal Investigator within the ethical opinion response letter. The form of monitoring required will depend on the type of research project and the risk involved. Consideration will be given to the use of:
* End of project reports;
* Annual reports;
* Periodic reports from and/or visits to the Chief/Principal Investigator;
* Oral updates to the SREC (by the Chief/Principal Investigator);
* Establishing a project-specific monitoring provision.
	1. Audit

In order to assess its performance against the standards contained in these Procedures and the Ethics Policy, the SREC may audit its activity from time to time. This may include conducting a review of a sample of applications previously reviewed by the Committee and may include auditing the evidence provided by Researchers where ethical review was conducted by another university or institution.

* 1. Closure/reporting

For all studies reviewed by the SREC, the SREC requires notification from the Chief/Principal Investigator when the research project has ended. This notification should be made within three months of research project completion.

1. **Contact/Queries**

All queries regarding the procedures or operation of the SREC should be directed to Dr Kate Button, School of Healthcare Sciences Ethics Officer at buttonk@cardiff.ac.uk or 02920687734.

**Appendix 1**

Chair – [Kate Button]

Vice chair - Paul Brown

Academic Members –

Jane Davies, Children and young people,

Rebecca Hemming, Physiotherapy

Dikaios Sakellariou, Occupational Therapy

Una Jones, Physiotherapy

Tim Sharp, Physiotherapy

Amy Bendall, Physiotherapy

Anna Sydor, Midwifery

Jessica Baile

Anna Jones

Dominic Roche

External – [INSERT NAME of the member from another School]

Lay Members – [Stuart Nixon, Alan Meudell]

Professional Support – Marie Nation (Administrator), Liz Harmer-Griebel

**Appendix 2**

**Useful resources for School of Healthcare Sciences Researchers**

General/Central Cardiff University policies and guidance

* Cardiff University Policy on the Ethical Conduct of Research involving Human Participants, Human Material or Human Data
* [Research Integrity and Governance Code of Practice](https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/research-integrity-and-governance)

**NOTE: Both of the above documents refer Researchers to a range of other relevant policies, procedures and guidance relating to Research Ethics and Integrity.**

1. As defined in the University’s Safeguarding Policy [↑](#footnote-ref-1)
2. Student link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/conducting-research-in-the-nhs/applying-for-sponsorship> [↑](#footnote-ref-2)