

**This is a controlled document.
The master document is posted on the RGIT website and any print-off of this
document will be classed as uncontrolled.**

**Researchers and their teams may print off this document for training and reference
purposes but are responsible for regularly checking the RGIT website for more recent
versions**

ICREC & SETREC Ethics Application Process	
SOP Reference: RGIT_SOP_044	
Version Number: 3.0	
Effective Date: 19 Oct 2020	Review by: 19 Oct 2023
Author: Nooreen Shaikh, Ethics and Research Governance Coordinator	
Approved by: Ruth Nicholson, Head of Research Governance and Integrity	Date:

Version	Date	Reason for Change
Version 1.0	21 April 2020	1 st Edition
Version 2.0	28 April 2020	2 nd Edition
Version 3.0	19 Oct 2020	Scheduled Review Administrative changes to SOP. JRCO name change to RGIT

Table of Contents

1. PURPOSE.....	3
2. INTRODUCTION.....	3
2.1. What are ICREC and SETREC?	3
2.3. When and where should applications be made?	3
2.3.1 The definition of research.....	4
2.4. Research which requires full committee review.....	4
2.5. When ethics review is needed but not through ICREC or SETREC	5
2.6. Alternatives to ICREC and SETREC	5
2.6.1. NHS research	5
2.6.2. Educational Ethics Review Process	5
2.7. Tissue bank approvals	5
3. RESPONSIBILITIES.....	5
3.1. Researcher responsibilities	5
3.2. HoD/Appointed Person responsibilities	6
3.3. Ethics and Research Governance Coordinator (ERGC) and Research Governance Facilitators (RGF) responsibilities.....	6
3.4. Head of Research Governance and Integrity/Research Governance Manager responsibilities	6
3.5. Committees responsibilities	7
4. PROCEDURE	7
4.1. Undergraduate Study Proposal Ethics Checklist.....	7
4.2. Complete the application form and supporting documents.....	7
4.3. Submission of documents to the Ethics and Research Governance Coordinator	8
4.4. Review/Notification of Decision	8
4.5. RGIT Approval/Favourable Opinion Letter	8
4.6. After RGIT Approval and /Favourable Opinion	9
5. REFERENCES	9
6. APPENDICES	9
6.1. Appendix 1: A table to differentiate between research, evaluation and audit. 9	

1. PURPOSE

This SOP details how to apply for ethics review via the Research Governance and Integrity Team (RGIT), Imperial College Research Ethics Committee (ICREC) and the Science, Engineering and Technology Research Ethics Committee (SETREC) for health-related and non-health related research projects. It provides general information on the ICREC and SETREC system and outlines each step that should be completed in the application process.

The process for applying for ethics review to ICREC and SETREC is the same. The application form details which committee the application form will be routed to. The application form and supporting document templates for ICREC and SETREC can be obtained from [Human Research Ethics Application Process webpage](#). All research studies must apply through this system.

2. INTRODUCTION

There are 2 routes to ethics review: Low risk studies, which pose minimal ethical issues regarding participant involvement, data management and researcher safety. are reviewed by the Head of Department and the RGIT. High risk studies, which pose more than minimal ethical issues concerning participants, data management and researcher safety are reviewed by ICREC or SETREC.

2.1. What are ICREC and SETREC?

2.1.1. ICREC

Imperial College Research Ethics Committee is the College ethics committee responsible for reviewing the ethical considerations of health-related research involving human participants and /or their data that is undertaken by College staff (including honorary staff) or students. This includes health related studies that present with current and future human impact.

2.1.1. SETREC

Science, Engineering and Technology Research Ethics Committee is the College ethics committee responsible for reviewing the ethical considerations of non-health related research involving human participants and /or their data, or research which could have future human impact that is undertaken by College staff (including honorary staff) or students. This includes non-health related research that presents with future human impact.

2.2. Why do the ICREC and SETREC exist?

ICREC and SETREC review research proposals to ensure that projects are of good quality research and the benefits of the study outweigh the risks. The ethics review process is also about protecting researchers from harm. In addition to this, for proposals that involve human participants, the committees' role is to ensure; the dignity, rights, safety and well-being of all participants. The Committees each consist of 4 College members and 4 Lay members.

2.3. When and where should applications be made?

Ethics review is a mandatory requirement for the College sponsored research and must be sought before the start of the research project. Conducting research without

ethics approval and/a favourable opinion constitutes misconduct. The College takes no responsibility, financial or otherwise.

Application forms and supporting documents can be found at Imperial College Research Ethics Application documents webpage. All ethics application forms and supporting documents, must be sent to the [ethics and research governance coordinator](#) .

The applicant must meet the application deadlines to be eligible for the next committee meeting date. The dates for the committee meetings and the deadlines can be found on the [ICREC page](#) and on the [SETREC page](#).

2.3.1. The definition of research

Research is defined as: “the attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them”. Studies that come under this definition would require ethics review and approval/ favourable opinion. Whereas audits and evaluations do not.

- An AUDIT - is designed to answer the question "Does this service reach a predetermined standard?"
- An EVALUATION - is designed to answer the question "what standard does this service achieve?"
- Patient and Public Involvement - is the way in which patients, the public, service users and carers can: Influence their own care and treatment. Have a say in the way services are planned and run. Help bring about improvements to the way care is provided.

See appendix 1 for a table that can help to determine if the research proposal is considered research, audit or service evaluation.

2.4. Research which requires full committee review

Low risk research proposals (as determined by Section 2 of the application form – Risk level categorisation and verified by the ERGC) can be reviewed by the HoD and RGIT. Section 2 - risk categorisation in the ICREC and SETREC application form determines the risk level of the study. The ERGC will inform the applicant if the study is high risk and the next committee meeting for review. High risk proposals must be reviewed by full Committee these include but are not limited to:

- Research that involves vulnerable groups; children or adults who are unable to consent, the mentally ill and individuals with learning difficulties.
- Research that involves prisoners and young offenders.
- Research that is invasive.
- Research that takes place overseas and requires local ethical approval (local approval is necessary but not sufficient on its own).
- Research where the subject matter is sensitive.
- Research that involves individuals in an overtly dependent situation (people in care).

- Research taking place in Imperial College laboratories which involves interventionist procedures.
- Research that involves the use of lie detectors.

2.5. When ethics review is needed but not through ICREC or SETREC

ICREC and SETREC do not review research in which a College researcher is a Co-Investigator, unless procedures such as those in section 2.4 will be taking place at Imperial College, where Imperial College is a site i.e. if Interventionist procedures will be carried out by a co-investigator at the College then review is required. However, the Co-Investigator must ensure that the Principal Investigator gains ethics approval from his/her own institution before the research begins.

2.6. Alternatives to ICREC and SETREC

2.6.1. NHS research

If the research involves NHS resources including staff, patients, data or premises the project may be eligible for review by the NHS REC. For more information, use RGIT_SOP_003, this SOP can be found on the [SOP, Associated Documents & Templates page](#).

2.6.2. Educational Ethics Review Process

The [Education Ethics Review Process \(EERP\)](#) is designed for educational projects only.

2.7. Tissue bank approvals

Tissue only studies: For Imperial College studies where the only research being undertaken at Imperial is tissue collection (e.g. collecting biopsies, blood only), ethics review may be obtained from the Tissue Bank, who have been delegated authority from the Research Ethics Committee (REC) to approve this type of project. The applicant is advised to contact the Tissue Bank for advice (tissuebank@imperial.ac.uk). This type of approval can only be considered if tissue collection is the only component of the research being undertaken. If there are other research procedures involved (e.g. questionnaires, scans) then an ICREC/SETREC review will be needed.

3. RESPONSIBILITIES

3.1. Researcher responsibilities

It is the responsibility of the researcher to ensure:

- the application form and supporting documents are accurately completed before submission to the Ethics and Research Governance Coordinator.
- compliance with data protection laws and Good Data Protection Regulation (GDPR).
- the safeguarding, wellbeing and safety of children and adults at risk involved in any Imperial College research activities, whether they are conducted in person or online have been considered. Please see the [safeguarding and](#)

[research website](#), the [child protection and safeguarding code of practice and the child protection and safeguarding policy](#) for more information.

- all the necessary documentation and contractual agreements on data access, data sharing and collaborative agreements have been obtained.
- The necessary risk assessments have been carried out.
- appropriate insurance in place for the study complete the RGIT Sponsorship and Insurance Request Form or email the [insurance team](#).
- the necessary permissions are in place to identify/recruit study participants.

The applicant may also need to consider:

- having a Disclosure and Barring Service check carried out.
- If the study is taking place abroad, the applicant must obtain local ethics approval.
- If the study is the sub-study of a larger research proposal, evidence of this and any ethics approvals from the larger study must be provided.
- If collecting human tissue or bodily fluids, see RGIT_SOP_003 for tissue bank approval process.
- If using secondary data, consent must be in place for the data to be used for other than its original purpose prior to obtaining ethics review.

Once all documents are in place it is the responsibility of the researcher to send the application form and supporting documents to the Principle Investigator's Head of Department or appointed person for signoff.

3.2. HoD/Appointed Person responsibilities

It is the responsibility of the Principle Investigators HoD/appointed person to highlight any unidentified ethical issues and either designate the proposal for low risk review by RGIT or high-risk review by committee. In signing the ethics application form, they show their support for the research to be conducted within their department.

3.3. Ethics and Research Governance Coordinator (ERGC) and Research Governance Facilitators (RGF) responsibilities

It is the responsibility of the ERGC and the RGFs to:

- confirm submission of the ethics application
- inform the researcher of any missing documentation
- designate the ethics application for either low risk, RGIT review or high risk, committee review within 5 working days of receiving the full set of application documents.

The ERGC and RGF are also responsible for reviewing the research proposal for ethics and governance issues.

3.4. Head of Research Governance and Integrity/Research Governance Manager responsibilities

It is the Research Governance Manager/Head of Research Governance and Integrity responsibility to do a secondary review of all ethics application documents to highlight any further ethics, governance and sponsorship issues not picked up by the ERGC. To ensure the ethical standards and scientific merit of low risk studies.

3.5. Committees responsibilities

It is the committees (ICREC and SETREC) responsibility to ensure; the ethical standards and the scientific merit of research involving human participants, their data or any research with current or future human impact is met. The ethics committee ensure that the rights of research participants are protected. The research ethics committee has an obligation to the researcher to treat the research proposal with respect.

4. PROCEDURE

The procedure for applying for ICREC/SETREC ethics review can be divided into the following steps. More detailed information on each step is given below.

1. For confirmation of the studies requirement for ethics approval consult the ethics application checklist. Undergraduates must complete the Undergraduates Study Proposal Ethics Checklist
2. Complete the Application Form and supporting documents
3. Submit the documents to the Ethics and Research Governance Coordinator
4. Review/Notification of Decision
5. After Approval/ favourable opinion

4.1. Undergraduate Study Proposal Ethics Checklist

ICREC and SETREC do not review undergraduate student research projects for ethics consideration unless their study is considered high-risk. To confirm if undergraduate research proposal requires ethics review via the RGIT, the checklist will determine if it is necessary. The researcher must complete the undergraduate study proposal ethics checklist and send it to the Ethics and Research Governance Coordinator who can advise if the research proposal requires ICREC or SETREC review or not. If certain the study requires ethics review, the researcher complete the application form and supporting documents and submit to the Ethics and Research Governance Coordinator.

4.2. Complete the application form and supporting documents

All researchers must complete the application form. Low risk studies as determined by the checklist in section 2 must complete Parts 1 and 3 of the application form. High risk studies as determined by the checklist in section 2 must complete Parts 1, 2 and 3 of the application form. The application form must be signed by the Principle Investigator (PI) and the HoD/ appointed person prior to submission to the RGIT Ethics and Research Governance Coordinator.

Health related studies collecting primary data in addition to the application form must complete and submit:

- ICREC protocol for primary data studies
- ICREC participant information sheet(s)
- Consent form(s)
- Any advertising material including emails and posters (these must be versioned and dated)

Health related studies using secondary data in addition to the application form must complete and submit:

- ICREC protocol for secondary data studies

Non-health related studies collecting primary data in addition to the application form must also complete and submit:

- SETREC protocol for primary data studies
- SETREC participant information sheet(s)
- Consent form(s)
- Any advertising material including emails and posters (these must be versioned and dated)

Non-health related studies using secondary data in addition to the application form must also complete

- SETREC protocol for secondary studies

4.3. Submission of documents to the Ethics and Research Governance Coordinator

Once all the appropriate ethics application documents have been completed, the applicant must send these to the Ethics and Research Governance Coordinator RGITcoordinator@imperial.ac.uk who will acknowledge receipt of the application prior to review.

4.4. Review/Notification of Decision

For the application to be reviewed for ethics approval and/or favourable opinion it must be successfully completed with all necessary documents and signatures in place. The ERGC will inform the applicant if there is anything missing.

The review process includes:

- Suitability of the PI to the study outlined and the appropriate HoD/appointed person signatures are in place.
- Identification of ethics and governance issues.
- Ensuring consistency between all documents
- All relevant processes from recruitment to data collection have been adequately stated.
- If participants have been recruited, it is safe for them to participate and they are fully informed about their participation.

4.5. RGIT Approval/Favourable Opinion Letter

For low-risk studies and low-risk amendments to studies the applicant will receive a RGIT approval letter. For high-risk studies and high-risk amendments to studies the applicant will receive RGIT approval and a favourable opinion letter from ICREC/SETREC. Once the RGIT approval and/ favourable opinion letter is received research may only commence if the following, if needed are in place:

- Contractual agreements (For further information, please contact your [faculty research service](#))

- DBS checks
- Risk Assessment (Please contact your departmental administrator for further information)
- Faculty of Medicine studies using identifiable data must be registered on the [Faculty of Medicine Asset register](#). Queries to the [Faculty of Medicine GDPR team](#).
- [Data protection impact assessments](#) (for non-Faculty of Medicine).

4.6. After RGIT Approval and /Favourable Opinion

RGIT approval and /favourable opinion letter is on the condition that the PI/ a member of the research team submit an Annual Progress Report if the study goes beyond a year from the original ethics approval/ favourable opinion date. The PI/ a member of the research team must submit a Notice of Amendment for any changes to the study such as the protocol, research team or study duration. A Declaration for End of Study must be submitted along with a summary report once the study ends. These will be reviewed within 5 working days of receiving the full set of application documents.

A flow chart detailing the ethics review process can be found in appendix 2.

5. REFERENCES

6. APPENDICES

6.1. Appendix 1: A table to differentiate between research, evaluation and audit.

	Research	Evaluation	Audit
Purpose	Derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care systems or policy implementation.	Designed and conducted to produce information to inform delivery of best care or policy implementation
Approach	Quantitative Research – designed to test a hypothesis Qualitative research – identifies or explores themes following established methodology	Designed to understand the current state of a given situation	Designed to understand if a specific standard is being met in a situation

Outcome	Addresses clearly defined questions, aims and objectives	Measures the current state of a given context without reference to a standard	Measures against a standard
Research Activity	Quantitative Research – may involve evaluating or comparing various interventions, solutions, or prototypes. Qualitative Research – usually involves studying how interventions, solutions, prototypes and relationships are experienced.	Involves examining the world as it already exists and does not involve implementing and measuring new interventions.	Involves examining the world as it already exists and does not involve implementing and measuring new interventions.
Data Source	May involve the use of existing or routine data but typically will involve collecting additional data to answer a specific question.	Often involves observation, questionnaire or interview in addition to the use of existing data.	May involve observations, questionnaires or interviews in addition to the use of existing data.
Study Design	Quantitative research may involve allocating participants to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	Participants are not asked to change what they would normally be doing. Instead, the researcher examines what is being done.	Participants are not asked to change what they would normally be doing. Instead, the researcher examines what is being done.
Example	Quantitative – measuring the effect of one design tool/technique over another Qualitative – exploring attitudes towards a product or prototype	Contextual observations and questions of a surgeon using a medical device to understand current use and limitations.	An assessment of if office seat, desk and monitor height match specified standards in an office.
Ethics Approval Required?	These studies will typically require approval from ICREC or SETREC or through appropriate means for student work.	Does not require ethical approval.	Does not require ethical approval.

Appendix 2: Ethics process flow diagram.

