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: 6.0	
Effective Date: 26 June 2024	Review by: 26 June 2027
Author: Thomas Lewis, Ethics and Research Governance Coordinator	
Approved by: Ruth Nicholson, Head of Research Governance and Integrity	Date: Ruth Nicholson Digitally signed by Ruth Nicholson Date: 2024.07.02 08:49:43 +01'00'

Version	Date	Reason for Change
Version 1.0	21 April 2020	1st Edition
Version 2.0	28 April 2020	2nd Edition
Version 3.0	19 Oct 2020	Scheduled Review Administrative changes to SOP. JRCO name change to RGIT
Version 4.0	25 April 2022	Additional associated templates added to the SOP.
Version 5.0	08 Dec 2023	Schedule review and update for Worktribe processes
Version 6.0	26 June 2023	Clarification for use of publicly available data

Table of Contents

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 *(cited on 08 Dec 2023)*. 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. These are reviewed by the Head of Department and the RGIT. Medium and 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 led by Imperial College London and 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 led by Imperial College London and 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 a minimum 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, and the College takes no responsibility, financial or otherwise.
Access to the online Worktribe system for applications and supporting documents, along with the submission guidance documents, can be found at Imperial College Research Ethics Application documents webpage https://www.imperial.ac.uk/research-ethics-committee/application/ *(cited on 08 Dec 2023)* .
The applicant must meet the application deadlines to be eligible for the next viable Committee meeting date. The dates for the committee meetings and the deadlines can be found on the ICREC page *(cited on 08 Dec 2023)* and on the SETREC page *(cited on 08 Dec 2023)*.

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. More guidance can be found at the Public Involvement Resource Hub *(cited on 08 Dec 2023).*

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, verified by the ERGC, can be reviewed by the HoD and RGIT. For medium or high-risk research proposals, (verified by the ERGC), the ERGC will inform the applicant if the study is medium or high risk and the next committee meeting for review. Medium or 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. 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 HRA/NHS REC. For more information, use RGIT_SOP_003, this SOP can be found on the SOP, Associated Documents & Templates page *(cited on 08 Dec 2023)*.

2.6.2. Educational Ethics Review Process

The Education Ethics Review Process (EERP) *(cited on 08 Dec 2023)* is designed for educational projects only. This includes educational research, an educational review/evaluation, or pedagogic research. Pedagogic research is where the theoretical framing of the research question concerns teaching and learning and the research question itself investigates an aspect of teaching or learning. The EERP would not consider a research proposal as pedagogic simply because it was performed by a student for academic credit or as part of an Imperial College academic programme or module.

2.7. Tissue bank approvals

Studies where the only research being undertaken at Imperial is tissue collection (e.g. collecting biopsies, blood only) from healthy Imperial College staff and students, ethics review may be obtained from the Imperial College Healthcare Tissue Bank, who has been delegated authority from the Research Ethics Committee (REC) to approve this type of project. In this scenario, the project would utilise the Tissue Bank approved consent materials.

If the project involves the above, it is necessary for the researcher to submit a Worktribe application for a low-risk review as a requirement for the Tissue Bank registration process.
More information regarding the Imperial College Healthcare Tissue Bank can be found here Tissue Bank *(cited on 08 Dec 2023).*
Other studies involving tissue collection whereby additional research procedures are involved (e.g. questionnaires) then an ICREC/SETREC review will still be needed.

3. RESPONSIBILITIES

3.1. Researcher responsibilities

It is the responsibility of the researcher to ensure:

- the Worktribe application form is accurately completed, and the supporting documents are uploaded for submission.
- 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 *(cited 08 Dec 2023)*, the child protection and safeguarding code of practice *(cited 08 Dec 2023)*, and the child protection and safeguarding policy (cited 08 Dec 2023) 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.
- insurance in place for the study (via confirmation with the insurance team if necessary) and completing the RGIT Sponsorship and Insurance Request Form if appropriate.
- 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 required.
- 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 that its original purpose prior to obtaining ethics review. It should be noted that the use of anonymous publicly available data does not require ethical review. This also includes data sets which require registration, but not including data sets which require permission.

3.2. HoD/Appointed Person responsibilities

It is the responsibility of the Principal Investigators HoD/delegated person to approve the application to show their support for the research to be conducted within their department. If their review highlights any unidentified ethical issues, they may communicate this to researcher and/or RGIT as appropriate.

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

It is the responsibility of the ERGC to designate the ethics application for low risk RGIT review, or medium/high risk Committee review. In addition, the ERGC will confirm whether the study is deemed under ICREC (health) or SETREC (non-health) classification.

It is the responsibility of the ERGC and the RGFs within 5 working days of allocation to::

- confirm submission of the ethics application
- provide initial feedback to the application, including informing the researcher of any missing documentation

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/RGF.
In addition, it is the Research Governance Manager/Head of Research Governance and Integrity responsibility to confirm when the final approval/favourable opinion letter can be issued.

3.5. Committees responsibilities

It is the Committees (ICREC and SETREC) responsibility to ensure that for medium and high risk studies; 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 documentation requirement for ethics approval consult the ethics application checklist. Undergraduates must complete the Undergraduates Study Proposal Ethics Checklist
2. Complete the Workribe application Form and supporting documents
3. Submit the application into Worktribe

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 medium or high-risk. To confirm if undergraduate research proposal requires ethics review via the RGIT or ICREC/SETREC, he researcher must complete the undergraduate study proposal ethics checklist and send it to the Ethics and Research Governance Coordinator. If the study is significantly low risk then it can be advised to be reviewed and approved at departmental level.. If the study requires RGIT or ICREC/SETREC review then a Worktribe application would need to be submitted.

4.2. Complete the Worktribe application form and supporting documents

All researchers must complete the Worktribe application form and upload the supporting documents

Health related studies collecting primary data in addition to the Worktribe 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 (all versioned and dated)
- Any questionnaires/semi-structured interview guides/focus group topic guides (all versioned and dated)

Health related studies using secondary data only in addition to the Worktribe application form must also submit:

- ICREC protocol for secondary data studies

Non-health related studies collecting primary data in addition to the Worktribe 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 (all versioned and dated)
- Any questionnaires/semi-structured interview guides/focus group topic guides (all versioned and dated)

Non-health related studies using secondary data only in addition to the Worktribe application form must also submit:

- SETREC protocol for secondary studies

4.3. Submission of the application into Worktribe

Once the Worktribe application has been completed and the associated documents uploaded, then the application needs to be submitted into Worktribe. Once the supervisor (if applicable) and the HoD approves the application, it will be transferred to RGIT for 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 in place. The ERGC/RGF will inform the applicant if there is anything missing.

The review process includes:

- Suitability of the PI to the study outlined and the appropriate supervisor (if applicable) and HoD/delegated person approvals 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 medium/high-risk studies and medium/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 (contact the faculty research service)
- DBS checks
- Risk Assessment (contact the departmental administrator for further information).
  The field risk assessment *(cited 08 Dec 2023)* identifies the hazards and risks associated with conducting offsite work, including all fieldwork, in the UK or abroad and conference travel or hosted activities defined as high risk or where local circumstances require a risk assessment.
- Data protection impact assessments. Any activity/project that processes (uses, stores, analyses etc.) personal data requires the completion of a *DART registration (cited 08 Dec 2023).*

4.6. After RGIT Approval/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 Annual Progress Report for studies approved pre-Worktribe must be submitted to the ERGC within 30 days of the anniversary of a project being granted ethics approval. If a study is completed within a year of first obtaining ethical approval, an End of Study Notification must be submitted instead.

Annual progress reports for studies approved via Worktribe, the relevant documentation should also be uploaded to Worktribe and notification made to the ERGC.

- 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. Please refer to the post-approval guidance *(cited 08 Dec 2023).*
- A Declaration for End of Study must be submitted along with a summary report once the study ends.

The PI/research team must notify RGIT when the study has ended; within 90 days of the termination of the study or when the practical research activity ended. The notification must be supported by an end of study summary report.

For studies approved pre-Worktribe the PI/research team must also notify the committee within 15 days if the study has been terminated early. Once completed, this form should be submitted to the ERGC.
For end of study notification/reports for studies approved via Worktribe, they should also be uploaded to Worktribe.

The above will be reviewed within 5 working days of receiving the full set of appropriate documentation.

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

5. REFERENCES

6. APPENDICES

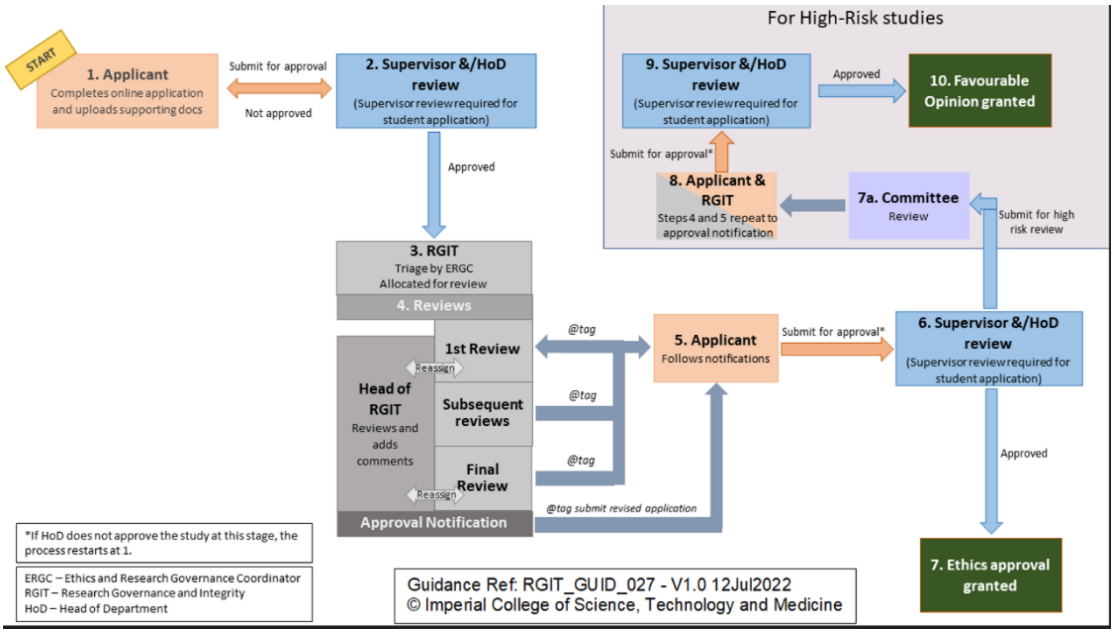
6.1. Appendix 1: A table to differentiate between research, evaluation and audit.

	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	An assessment of if office seat, desk and monitor height match specified standards in an office.

		use and limitations.	
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.



Appendix 3: ICREC Participant Information Sheet – RGIT_TEMP_075
Appendix 4: SETREC Participant Information Sheet - RGIT_TEMP_076
Appendix 5: ICREC Consent Form - RGIT_TEMP_077
Appendix 6: SETREC Consent Form - RGIT_TEMP_078