

Royal College of Surgeons in Ireland
Research Ethics Committee

Application Form (online version adapted from Standard Application Form RECSAF)

GUIDANCE NOTES

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Introduction:

The function of the Royal College of Surgeons in Ireland's (RCSI) Research Ethics Committee (REC) is to impartially examine all proposals for research to be carried out by RCSI staff and students which involves human participants or animals. RCSI staff and students have a responsibility to discuss (with the Convenor or Chair of the REC) protocols regarding research projects where the necessity for ethical approval is unclear.

The online application form:

The form is available via login details provided by the REC convenor (Dr Niamh Clarke: nclarke@rcsi.ie) or recadmin@rcsi.ie. Guidance notes, supporting documentation and templates are available on [https://www.rcsi.ie/Research Ethics](https://www.rcsi.ie/Research_Ethics).

The study should be described in lay/non-professional English, so that members of the REC not specialising in scientific study will be able to assess the significance of the research and the associated ethical issues.

The process of completing REC forms is considered an important educational opportunity for those early in a career involving research. Thus student completion is encouraged and where a student completes the application form a supervisor check list and signature sheet is also provided to ensure the REC that the study supervisor has reviewed the application also and is satisfied with the content and associated documentation.

Section A: General Information:

Details of the lead applicant (i.e. individual doing the research study), principal investigator/academic supervisor and/or any other individuals involved should be included here. **If it is a student project being done as part of a course, details of the course should be given. If the study is a multi-centre project, the location of other centres should be indicated.**

- A short title and a full title should be given. The short title is for ease in administration.
- An RCSI (or work) email / postal address should be used for correspondence purposes.
- Contact details for the lead applicant and academic supervisor/principal investigator should be provided
- The lead applicant or study supervisor should sign signature form and provide a hard copy to the REC.

Section B: Study Descriptors: Details regarding study duration, background, references, aims, objectives and methodology should be provided here.

- A research hypothesis (i.e. what the research is expected to answer/intended to test) should be stated.
- A synopsis of the relevant research in this area and a number of key references should be provided.
- Details on statistical methodology used (where applicable) and how the size of the study was determined; this should include (where possible) a formal sample size calculation. (If you are not sure about sample size calculation, contact Prof Ronán Conroy at rconroy@rcsi.ie)

Section C: Study Participants:

C1 Selection and Recruitment: Details should be provided to indicate how participants will be recruited into the study. Other information such as who will administer questionnaires/surveys and whether or not a gatekeeper will be used should be included. If a gatekeeper is used, their details should be provided to the REC

C2 Informed Consent: This should include the following elements:

- A declaration that the participant has read the PIL (i.e.; an explanation of the purposes of the research; the expected duration of the participant’s participation; a description of the procedures to be followed; and identification of any procedures, drugs or devices which are experimental).
- Description of any reasonably foreseeable risks or discomforts to the participant.
- Description of any benefits to the participant or to others that may reasonably be expected from the research, including payment or free treatment.
- A disclosure of appropriate alternative procedures or courses of treatment, if applicable, that might be advantageous to the participant.
- A statement confirming confidentiality of participant records and limits of that confidentiality.
- A statement as to who to contact (an individual) for answers to pertinent questions involving the research and research participant’s rights to contact in the event of a research-related injury to the participant.
- A statement similar to “participation is voluntary” or “you may choose not to participate” and a statement that refusal to participate, or discontinuing participation at any time, will involve no penalty, loss of benefits or denial of treatment or services.

C5 Participants – Checklist for Vulnerable groups:

If there are problems with consent because the study groups falls into the listed categories (details within the online application), the relevant details must be provided.

- **C5.1** If a significant proportion of participants do not speak or read English, special arrangements should be made to inform and include them.
- **C5.3 Women of childbearing potential:** The REC recognises the importance of undertaking research in diverse population groups including women of childbearing potential. However, it notes that there is a need for special care with invasive or other intervention studies in this group because of possible hazards to the potential foetus. If applicable any risks/notes with respect to women of childbearing potential within the proposed study should be outlined and justified in this section.

Section D Research Procedures:

Details of the study activities, procedures or interventions (if any) the research participants are asked to undergo or engage in should be stated here. The potential risks and/or benefits associated with any the activities or procedures listed should be included in this section also.

Section E: Data Protection:

- **E2.0 Data Processing - general:** It should be clearly stated if data is confidential, coded or anonymous. This is an important distinction to make and should be made clear within the application and also within the associated documentation such as the consent form and information leaflets.
- **E2.5 Storage:** Study data should be securely stored and encrypted within the applicants unique project folder located within the RCSI V: drive. (Access to this unique folder will be given once approval for the study has been granted) ALL STUDY DATA including any relevant documentation (such as scanned consent forms, participant information leaflets, questionnaires, permission letters, approval letters or documentation from other institutions etc.) must be stored in this location. Please also clarify the duration of data storage (typically 5 – 7 years).
- **E3 Access to Healthcare Records:** The REC application should be clear on how patients charts will be identified or if patients will be consented. Details should be provided on how the applicant will identify which charts. If medical records are to be examined, participants should be reassured that only information directly relevant to the study will be extracted.

Section F: Human Biological Material

If blood and/or tissue samples are taken, consideration must be given to whether they will be destroyed when the study is complete. If they are to be retained participants must be informed. Ethical approval will be needed for any further studies using these samples.

Section G Radiation:

This section must be completed if the study involves the use of ionising or non-ionising radiation, radioactive substances or X-rays.

Section H Medical Devices

This section must be completed if the study involves the use of a new medical device, or the use of an existing device outside the terms of its product licence. Please note that many medical devices are subject to similar regulations to those of new drugs. All medical devices must meet the appropriate safety regulations.

Section I: Medicinal Products / Cosmetics / Food and Foodstuffs

This section must be completed if the study involves the use of a new medicinal product, or the use of an existing product outside the terms of its product licence.

Section J: Indemnity and Insurance

Arrangements must be made to ensure that indemnity is available to cover negligent and non-negligent harm to participants during the course of the research project. This will normally be available for individuals working for RCSI ([insurance for RCSI students](#)). Individuals are also required to maintain membership of their relevant professional defence organisation where applicable.

Section K: Cost and Resource Implications, funding and payments

This section is to ensure a) that potential conflicts of interest, e.g. because of a financial relationship between the investigator(s) and study sponsors, are considered acceptable and b) that research funds obtained will be formally accounted for within the College or elsewhere as appropriate.

Section L: Additional Ethical Issues:

- Careful and realistic consideration must be given to any potential hazards to participants, the likelihood of these occurring and the steps taken to deal with these issues. This will include side effects and adverse effects resulting from treatment or study evaluation.
- Consideration must be given as to the potential discomfort or distress, psychological or physical, caused to participants.
- An information sheet should be given to the participant's general practitioner, if a drug is given, or an invasive procedure is undertaken. Justification must be given if this is not to be done.

Checklist / Uploaded documentation

All relevant documentation should be uploaded within the “**Document List**” section at the end of the application (after section L). Uploaded documents should include:

- **CV** of the lead applicant
- Study **protocol** and full description of the
- **Participant information leaflet (PIL)**: [RCSI Participant Information Leaflet \(PIL\)](#)
- [RCSI template DECLARATION BY THE INVESTIGATOR \(supervisor sign off sheet\)](#)
- **Consent form**: [RCSI consent form template](#).

Consent form Notes:

- Particular care should be taken for participants who are in positions of dependency or vulnerable for other reasons. This includes those who could feel under obligation to participate (e.g. students or patients of the investigator, junior staff, prisoners) as well as those who would have difficulty understanding the research and reaching an independent decision to participate (e.g. children, psychiatric patients, those in distress, those with learning difficulties).
- Special precautions are needed in the case of the use of audio or video recording to ensure confidentiality and anonymity.
- It is the responsibility of the main investigator to ensure that research workers outside the employment of the RCSI are fully aware of the need for confidentiality of information about and from participants.

Further reading:

Guidance notes 1: [Guidance for research with RCSI students](#)

Guidance notes 2: [RCSI Information & Guidelines for Research involving children](#)