

St George's Research Ethics Committee (SGREC)

Modus Operandi

a. Quorum

A meeting shall be considered quorate if at least 5 members of the Committee are present (including two lay members or one lay member and a student representative, and also three Institute members, one of whom must be either the Chair or Deputy Chair).

If the Chair is not present, the Deputy Chair shall take the role and powers of the Chair for the duration of that meeting.

If quorum is not reached, the meeting shall go ahead as planned, but any decisions reached will be subject to subsequent ratification by other members of the Committee.

b. Student Representation

The Committee shall have at least 2 SGUL students as active members of the Committee. Student representatives will take part in the project discussions and decision making in line with other members.

Students or staff wishing to observe the Committee as part of their course requirements or for personal development must make a request to the Research Ethics and Integrity Officer (REIO). The Committee should provide their agreement for observers to attend meetings. They will not form part of the quorum or discussion for the meeting.

c. Committee Representation

The Committee will make every effort to ensure membership is representative of the London communities, where St George's, University of London is situated. In line with our values, it is essential that diverse perspectives are included in considerations and decision-making regarding research projects undertaken by the University.

d. Term of Office

The Term of Office for Committee members is 3 years, renewable once. The Term of Office shall begin on the date of the first meeting attended. The Research Ethics and Integrity Officer will seek renewed terms of office from members two months in advance of the 3rd anniversary of the member's start of office.

Committee members should attend at least 60% of meetings scheduled in a given year. The Research Ethics and Integrity Officer will register the attendance for each meeting.

If a Committee member wishes to resign from the Committee before their Term is completed or due for renewal, they should give at least 2 meetings' notice in writing to the Chair of the SGREC and the Research Ethics and Integrity Officer.

e. Chair's Action

Chair's Action is defined as a decision taken by the Chair and one other Committee member (subject to any conflicts of interest that may arise) and the Research Ethics and Integrity Officer.

The Chair can only take action if:

- A SGREC meeting is cancelled and, following email consultation with members, it is felt that a project can be given favourable ethics opinion before the next meeting.
- It is a medium risk study in accordance with the Self-Assessment Form for Ethics (SAFE) and study protocol and requires a proportionate review only.
- In any other circumstances deemed appropriate by the Committee, such as where a project is suitable for Fast Track process.
- Resubmissions following Conditions and Amendments which are best served by this level of review. It can be agreed by the Chair on behalf of the SGREC.
- In an event of the Chair unavailable to act (within 5 working days) the Deputy Chair can take the decision.

f. Research Ethics and Integrity Officer's Action (REIO)

Research Ethics and Integrity Officer's Action is defined as a decision taken by the Research Ethics and Integrity Officer. The REIO can only take action if it is a low risk study in accordance with the Self-Assessment Form for Ethics (SAFE) and study protocol.

g. Monitoring of Projects

Chief Investigators (CIs) once favourable ethics opinion has been given, are obliged to report to the Committee:

- Any serious adverse (non -international SGREC approved studies) or any adverse events (AEs) which are considered unexpected and significant by the Chief Investigator Any material changes to the protocol or study personnel;
- Any external information likely to have a bearing on the research in question.

- An Annual Progress Report (APR) within 30 days of the anniversary of the date ethical and governance approval was originally given, where the duration of the project is at least 12 months.
- The declaration of the end of study within 90 days of the termination of the study and within 15 days if the study terminates early.

The Committee has the power to initiate a review of the favourable ethics opinion at any time it sees fit. Committee opinion lasts for five years; projects that wish to last longer than this may do so as long as satisfactory Annual Progress Reports and other reporting requirements (e.g. protocol deviations) are reported to the Committee.

h. Specialist Advice

If necessary, the Committee can invite a specialist to give information on a project. Any such individuals will be invited for that project only and shall not participate in the final decision of the Committee.

i. Presence of Chief Investigators

All CI's whose projects are being discussed shall be invited to attend the meeting, to give explanations/clarification as necessary. **The named CI should make every effort to attend, although they can bring any other relevant people (including students) as appropriate. This also stands with student projects where the named CI is the supervisor.**

The CIs shall be present in the room only for the question/answer session and shall not participate in the final decision of the Committee.

j. Declaration of Interest

Committee members must provide details of their interests for a SGREC members' register, which will be held by the Research Ethics and Integrity Officer and updated at least on an annual basis. If any member has a financial or personal interest in any project, they must declare this before discussion of the project commences. Member conflicts of interest with respect to specific projects will be considered on a case-by-case basis. If an individual declares a conflict of interest, they may contribute to the discussion of that project but must not participate in the final decision.

k. Confidentiality

The University seeks to undertake an agreement of confidentiality with Committee members who are not currently employed by the University. Where applicable, members will be asked to complete the Confidentiality Undertaking Form. This will be held by the Research Ethics and Integrity Officer for the term of the members' office.

l. Equal Opportunities Monitoring Form

The Equal Opportunities Monitoring Form will be used for monitoring the diversity of the membership.

m. Frequency of Meetings

At present, the Committee shall meet a minimum of seven times a year according to a published schedule. Papers for the meeting must be circulated to the members no less than 7 days before the meeting and must be received by the Research Ethics and Integrity Officer from the applicant no less than 14 days before the meeting.

In normal circumstances, all projects will be discussed at the next available meeting. However, in any situation deemed extraordinary, projects can be dealt with in one of the following ways:

- An email correspondence or teleconference to discuss the specific project. At least 4 members, including 2 lay members/ student representative and 2 members (one of whom must be either the Chair or Deputy Chair), must contribute to the discussion; or
- Chair's Action can be recommended by the Committee, or
- The decision can be devolved to an extraordinary sub-committee of no less than 2 people approved of by a quorum of the Committee.

n. Process of Appeal

If a CI feels the decision of the SGREC is unjustified, they have the right to a single appeal at the University's Research Committee (RC). SGREC shall provide an explanation of its decision, and the CI must provide evidence to counteract that.

The CI and a representative of the SGREC and Research Ethics and Integrity Officer shall be invited to attend the next meeting of the RC to discuss and answer questions on the papers and the case. The decision of the RC is final.

o. Reports

The REIO will present the low risk cases to the SGREC monthly (part of the Agenda).

The Chair will present the SGREC`s meeting minutes to the Committee as soon as approved by SGREC.

The SGREC will produce an Annual Report and submit it to the RC (by academic year, period of 1st of Aug to 31st of July) by 31st of Aug. This report will outline issues such as the work of the Committee, the names of the members of the Committee, the number of meetings, any protocol deviations and the number of applications submitted and given favourable opinion by SGREC.

p. Indemnity for Members

The University will indemnify members of the SGREC against legal liability claims made against them which arise in respect of their membership of SGREC, provided that members have acted in good faith.

q. Validation of applications

The applicant will be informed within 5 working days of whether their application is valid or not. If the application is valid, it will either go through the fast track process if appropriate or go to the next Committee meeting if the submission deadline has been met. If the application is not valid, the CI will be invited to correct the application and resubmit.

r. Decision-Making

The decision of the SGREC is final, subject to a single appeal by a CI as detailed above. The Committee shall inform the CI of its decision, with explanations where appropriate, normally within 10 working days following the meeting.

s. Research Conducted Overseas

Studies where the research takes place only at sites overseas are required to apply for two-fold review:

1. St George's Research ethics Committee (SGREC) review
2. Country-specific, local ethics review and any other local/national approvals required in the relevant country or countries

In the circumstance where there is no local ethics committee, proof of evidence that this is the case must be provided to the SGREC Committee. In the circumstance of no local ethics available, site-specific approval to conduct research should be sought and demonstrated to the Committee as part of the application process before favourable review can be given. Evidence of local ethics review must be submitted as part of the SGREC application.

The Modus Operandi was updated and approved by the SGREC at the meeting of 19th of May 2021.