Standard Operating Procedure (SOP)

St George's Research Ethics Committee (SGREC): Study Application and Review Processes

SOP ID number:	JRESGOVSOP0054	**Effective Date:**	10th February 2020
Version number and date:	Version 1.0 20/01/2020	**Review Date:**	10th February 2022
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Approved by:	Professor Paul Heath, (SGREC Chair)	**Date:**	5th February 2020
Signature of Authorisor:			

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The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES website for the most recent version.
They may print off this document for training and reference purposes.

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Georgia Bullock

Contents

1. Background

Ethical approval from a recognised Research Ethics Committee is needed for any research study that involves human participants, their tissue and data. This is to ensure that the dignity, rights, safety and well-being of all participants are the primary consideration of the research project.

Some studies require review and approval by an NHS Research Ethics Committee (REC), for example any study which involves patients/users of the NHS or studies requiring access to data, organs or other bodily material of past and present NHS patients.

Research studies which are being conducted by students or staff of St George's University, London (SGUL) or research studies which involve SGUL students, staff or data, and **which do not require review by a nationally recognised Research Ethics Committee (such as an NHS REC**), must be approved by the St George's Research Ethics Committee (SGREC).

Some studies will require Health Research Authority (HRA) approval, in addition to NHS REC or SGREC approval, including studies which involve NHS patients, NHS staff and NHS data.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP describes the application and review processes for the St George's Research Ethics Committee (SGREC). It includes the processes for research projects and also for projects not considered to be research, such as clinical audits and service evaluations.

This SOP **does not** describe the process for applying for NHS REC and/or HRA approval which can be found here: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

This SOP applies to the JRES Research Development and Governance Manager, the JRES Research Ethics and Integrity Officer and the JRES Governance team. It also applies to all SGUL students, SGUL staff and SGHFT staff needing to obtain SGREC approval for their projects.

4. Definitions

HRA	Health Research Authority
JRES	Joint Research and Enterprise Services
REC	Research Ethics Committee
SGHFT	St George's University Hospitals NHS Foundation Trust
SGREC	St George's Research Ethics Committee
SGUL	St George's, University of London
SOP	Standard Operating Procedure

5. Responsibilities

It is the responsibility of the **SGREC applicant** to:

- Determine whether SGREC approval is appropriate for their study and if so, if any additional approvals are needed.
- Complete the initial review paperwork and submit it to the Research Ethics Officer.

- Respond to any requests from the Research Ethics Officer and provide updated/amended documents in a timely manner.
- Provide additional documentation for the full ethics application, if requested by the Ethics Officer.
- Respond to any SGREC conditions following a review (where applicable).
- Apply for other study approvals where required, ensuring that any additional documents required for that approval are completed.
- Maintain the ethics approval once granted, according to the requirements set out on the SGUL Research Ethics website.

It is the responsibility of the **JRES Research Ethics and Integrity Officer** to:

- Manage the Research Ethics email inbox and respond to queries.
- Ensure that the Research Ethics webpages are up-to-date.
- Provide advice to St George's students and staff on the SGREC procedures.
- Refer applicants to other JRES Governance staff if SGREC approval is not applicable to their project.
- Review and assess the initial SGREC paperwork and request amended documents where relevant.
- Determine what level of review each application requires and inform the applicant.
- Arrange and coordinate the monthly SGREC meetings and write the meeting minutes.
- Issue Favourable Opinion letters and other study-related letters.
- Issue email approval for audits and service evaluations, once reviewed and registered.
- Assign a JRES reference number to each approved SGREC study.
- Enter approved SGREC studies into the EDGE database and onto the SGREC Approvals document in the SGREC folder on the JRES shared drive.
- Ensure that all correspondence is saved in a relevant folder in the Research Ethics inbox and all documents, forms, reports and letters are saved in EDGE under the relevant study.
- Write and distribute the Annual Report for the SGREC when due.

For SGUL students, it is the responsibility of the student's **academic supervisor** to:

- Assist the student with obtaining the necessary approvals for their project.
- Review all documents for accuracy and completeness prior to submission.
- Sign SGREC forms where indicated.

It is the responsibility of the Head of Research Governance and Delivery (HRGD) in the JRES to ensure that this SOP is updated by the review date or as necessary.

6. Procedure

6.1 Applying for SGREC Review

Applicants must apply for SGREC approval by following the procedure set out on the Research Ethics website:

https://www.sgul.ac.uk/research/research-ethics/ethical-review-process/applying-for-ethical-review-of-your-project

Applicants unable to access this should contact the Research Ethics Officer for assistance.

The initial documents (listed in section 1 under '**How to apply for ethical review of your project'**) must be completed in full using the templates provided, signed where requested and then sent to sgulrec@sgul.ac.uk *(It should be noted that incomplete, inaccurate or unsigned documentation may delay SGREC approval which can impact on study start dates).*

Following review of the initial documentation, the Research Ethics Officer may request further documents to be completed and submitted if the study requires full SGREC review (these are listed in section 2 '**Complete and submit full ethics application'**).

All relevant study documents (eg: Protocol, Participant Information Sheet, Informed Consent Form) must be **version-controlled** and **dated**. The Research Ethics Officer will return documents which do not have a version number and date.

6.2 Application Review

When an application is received, the Research Ethics Officer will review the initial documents to check that they are accurate and have been completed correctly. Where forms have not been completed correctly, or where documents are missing, the Research Ethics Officer will email the applicant with guidance on what needs to be amended/added.

The Research Ethics Officer will determine what level of review is required, once the documents/forms have been assessed as acceptable. There are 3 options:

1. No further review is required as the study is low risk.
2. Proportionate Review – low risk but requires further review (by the Research Ethics Officer, Chair of the SGREC and one other member of the SGREC).

3. High risk – requires review by the full Committee at the next SGREC meeting.

Where the study is low risk and does not require any further review, the Research Ethics Officer will issue a Favourable Opinion letter to the applicant and their academic supervisor (where applicable) using the appropriate letter template, which must list all of the documents received and reviewed with their date and version number.

For studies requiring Proportionate Review, the Research Ethics Officer will identify a member of the SGREC, other than the Chair, and will send the application and the associated documents to them and to the Chair for review and for a decision to be made. This can be done via email rather than in a face-to-face meeting. Once any conditions have been met and the study has been approved, the Research Ethics Officer will issue a Favourable Opinion letter.

For studies requiring full SGREC review, the Research Ethics Officer will send the documents to the SGREC members in time for the next SGREC meeting. Dates and times for the monthly meetings are available on the Research Ethics webpage. The applicant(s) will be invited to attend the meeting to discuss their study with the Committee and answer any queries. Following review, the Research Ethics Officer will issue a decision letter within approximately 5 days of the meeting.

More information on the review process and review options can be found here:

https://www.sgul.ac.uk/research/research-ethics/documents/SGREC-Processing-October-2019.pptx

Applicants will be requested to re-submit their study if conditions have been issued after the review and these will be reviewed by the Chair of the SGREC.

6.3 Post-Approval

Researchers are required to submit the following to the Research Ethics Officer when they have received full approval for their project:

1. An Annual Progress Report for every year that the study runs.

2. An End of Study notification when the study ends.

3. An amendment application if changes to the study are needed, eg: amended participant documents, changes to the study design, study dates or study team.

More information on this can be found here:

https://www.sgul.ac.uk/research/research-ethics/ethical-review-process/running-and-amending-your-project

Amendments will be reviewed by the Research Ethics Officer and, where required, the Chair of the SGREC. The changes must not be implemented by the study team until approval for the amendment has been received.

The Research Ethics Officer will ensure that all approved SGREC studies are assigned a JRES reference number (using the R&D number generator) and are entered into the EDGE database. All relevant documentation must be uploaded to EDGE, including the study documents, approval letters, study reports and any amendment documentation. When the study ends, EDGE must be updated to reflect this. All email correspondence will be saved in the relevant folder in the Research Ethics inbox. The SGREC Approvals document in the SGREC folder in the JRES shared drive must also be updated with all approved research projects.

6.4 Data Storage and Retention for Student Studies

It is essential that research data is stored securely and according to the SGUL Research Data Management Policy and related policies. Students have two options for storing data for their research projects. More information on this can be found here under 'Advice and Resources': https://www.sgul.ac.uk/research/research-ethics/ethical-review-process/applying-for-ethical-review-of-your-project

Data from student studies should be retained for at least 5 years following the End of Study notification. Some studies may require a longer retention period. The student's supervisor will assume responsibility for the data once the student leaves and will destroy it at the end of the retention period.

6.5 Clinical Audits and Service Evaluations

In general, these projects do not require ethical approval. However SGUL students and staff must submit the same paperwork as for a research project (SAFE and Protocol) to the SGREC, in order for the project to be reviewed by the Research Ethics Officer to confirm that it is not considered to be research.

This tool can be used to determine if a project is research or not:

http://www.hra-decisiontools.org.uk/research/

Applicants should also seek approval from the department and/or organisation where they are conducting the service evaluation or audit.

All audits and service evaluations conducted by SGUL students/staff will be registered by the SGREC once all of the documents have been reviewed. The Research Ethics Officer will register

them on the Service Evaluations and Audits Register, located in the SGREC folder on the JRES shared drive. This will generate a reference number (SE*** or AU***) which can be provided to the applicant for any future correspondence. The Research Ethics Officer will email the applicant to inform them that their audit or service evaluation has been registered and thus has SGREC approval.

SGHFT staff: St George's Hospital staff who are conducting service evaluations or clinical audits do not need to apply to the SGREC but must register their audit/evaluation with the clinical audit team in the NHS Trust where they are conducting the audit/evaluation. They may also need approval from the department lead or organisation where the audit/evaluation is taking place.

The Research Ethics Officer will save all email correspondence and documents for each service evaluation/audit in the Audits and Service Evaluations folder in the Research Ethics inbox under the reference number/name of applicant.

7. References / Useful Links

Is my project research?
http://www.hra-decisiontools.org.uk/research/

Do I need NHS REC approval?
http://www.hra-decisiontools.org.uk/ethics/

Which Ethics Committee?
https://www.sgul.ac.uk/research/research-ethics/documents/Which-Ethics-Committees-to-Apply-to.docx

SGREC: https://www.sgul.ac.uk/research/research-ethics

Research Ethics email (for SGREC applications and queries): sgulrec@sgul.ac.uk

SGUL Research Data Management:
https://www.sgul.ac.uk/about/governance/policies/research-data-management

Joint Research and Enterprise Services (JRES):
https://www.sgul.ac.uk/about/our-professional-services/joint-research-and-enterprise-services/research-support/about-us

NHS REC and HRA Approval:
https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

8. Appendices

None associated with this SOP.