Standard Operating Procedure (SOP)

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

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Signature of Authorisor:			

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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
V2.0	Changes in accordance with ARMA-UKRIO guidance	Dr Angelika Kristek
V3.0	Changes in Adverse event	Dr Angelika Kristek
V4.0	Adding notice of Deviation form	Dr Angelika Kristek

Contents

1. Background

A favourable ethics opinion 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 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 of 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 reviewed 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 favourable opinion, 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 and Integrity Officer (REIO).

- Respond to any requests from the REIO and provide updated/amended documents in a timely manner.
- Provide additional documentation for the full ethics application, if requested by the REIO.
- 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 (amendment, annual progress report, end of study notification), according to the requirements set out on the SGUL Research Ethics website.

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

- Manage the Research Ethics email inbox (sgulREC@sgul.ac.uk) and respond to queries.
- Ensure that the Research Ethics webpages (https://www.sgul.ac.uk/research/research-ethics) are up-to-date.
- Provide advice and training 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.
- Conduct a governance review of the project on behalf of the sponsor if necessary.
- 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 Favourable opinion 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.
- Maintain all SGREC documents. (eg: Modus Operandi, Terms of Reference)
- Arrange and coordinate SGREC membership
- Provide training for new Committee members
- 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 REIO for assistance.

The initial documents (listed in section 1 under '**Applying 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 REIO may request further documents to be completed and submitted if the study requires full SGREC review (these are listed in section 1 '**Applying for ethical review of your project**').

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

6.2 Application Review

When an application is received, the REIO will review the initial documents to check that they are accurate and have been completed correctly and give comments within 5-7 working days. Where forms have not been completed correctly, or where documents are missing, the REIO will email the applicant with guidance on what needs to be amended/added.

The REIO 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 REIO, Chair or Deputy 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 REIO 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 REIO will identify a member of the SGREC, other than the Chair/Deputy Chair, and will send the application and the associated documents to them and to the Chair/Deputy Chair for review and for a decision to be made. The reviewer should confirm that they are able to review and send comments within 5 working days to REIO. 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 REIO will issue a Favourable Opinion letter.

For studies requiring full SGREC review, the REIO 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 (https://www.sgul.ac.uk/research/research-ethics/st-georges-research-ethics-committee). The applicant(s) will be invited to attend the meeting to discuss their study with the Committee and answer any queries. Following review, the REIO will issue a decision letter within approximately 5 days of the meeting.

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 or Deputy Chair of the SGREC.

6.3 Post-Approval

Researchers are required to submit the following to the REIO 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 REIO and, where required, the Chair or Deputy Chair of the SGREC. The changes must not be implemented by the study team until approval for the amendment has been received.

The REIO will ensure that all SGREC studies that have been given a favourable opinion 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.

6.4 Data Storage and Retention

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 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 Adverse Events

An adverse event is any untoward medical occurrence in a participant arising during the research, and which does not necessarily have a causal relationship with this research.

For SGREC-approved international Clinical Trials of Investigational Medicinal Products (CTIMPs): Serious adverse events and adverse events (SAEs and AEs) should be reported to the sponsor (sponsor@sgul.ac.uk) within 24 h (SAEs) and every month (AEs).

For SGREC-approved international studies trials that do not involve an Investigational Medicinal Product (non-CTIMPs): Serious adverse events (SAEs) only should be reported to the sponsor (sponsor@sgul.ac.uk) within 24 hours.

For all other SGREC-approved studies: Serious adverse events (SAEs) and any adverse events (AEs) which are considered unexpected and significant by the Chief Investigator should be reported to the REIO (sgulREC@sgul.ac.uk). The events should be reported Adverse Event Log (Appendix 1) within 3 days and a brief summary should be provided on completion of the research by Chief Investigator.

If the SAEs or unexpected AEs have any ethical concerns, the REIO will report to the Chair of SGREC and the Sponsor.

All studies should provide summary on participant safety/adverse events in Annual Progress Reports.

6.6 Notice of Deviation

The Researcher should only conduct the research according to the approved study protocol and documents, unless an urgent safety measure must be taken. Any deviation from the protocol should be reported on the Notice of Deviation form (Appendix 2) within 3 days.

6.7. Clinical Audits and Service Evaluations

In general, these projects do not require ethics opinion. 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 REIO 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 (R&D) 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 REIO 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 REIO will email the applicant to inform them that their audit or service evaluation has been registered.

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 REIO 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 to apply to? https://www.sgul.ac.uk/research/research-ethics

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/

New Research Ethics guide:https://arma.ac.uk/new-research-ethics-guide-from-arma-ukrio/

8. Appendices

1. SERIOUS ADVERSE EVENT (SAES) AND UNEXPECTED ADVERSE EVENTS (AES) LOG

Adverse Events (AEs) Log			
REC reference number:	20xx.xxxx	**Date:**	
Study Title:		**Chief Investigator (CI):**	

Important Notes for Completing of this Log:

Serious adverse events (SAEs) and any adverse events (AEs) which are considered unexpected and significant by the Chief Investigator should be reported to the REIO (sgulREC@sgul.ac.uk). within 3 working days.

Causal Assessment:

1 = Definitely	2 = Probably Related	3 = Possibly related	4 = Unlikely	5 = Not related	6= Not assessable

Severity Grade:

	2 = Moderate	3 = Severe	4 = Potentially life threatening	5 = Fatal

Moderate symptoms cause greater than minimal interference with usual social & functional activities with intervention indicated.
Severe symptoms cause an inability to perform usual social & functional activities with intervention or hospitalisation indicated.
Potentially life-threatening symptoms cause inability to perform basic self-care functions OR Medical or operative intervention indicated to prevent permanent impairment, persistent disability or death.
Fatal symptoms leading to death.
If severity could fall under either one of two grades, select the higher of the two grades.

Subject ID	SAE or AE brief description	Date of Onset (dd/mm/yyyy)	Date of Resolution (dd/mm/yyyy)	Causal Assessment	Severity Grade	Medication given to treat event?	Verified by CI (signature)
						☐Yes ☐No	
						☐Yes ☐No	
						☐Yes ☐No	

2. NOTICE OF DEVIATION

Instructions: Complete this form each time a deviation is identified and send it to St George's Research Ethics Committee (sgulREC@sgul.ac.uk).

Study Short Title	
REC Reference	
Principal Investigator (PI) - staff	
Deviation Code (please tick it)	
A	Informed consent process deviation
B	Inappropriate enrolment: the participant enrolled does not meet the eligibility requirements
C	Failure to follow study randomisation
D	Performing procedures not defined in the Protocol or under local standard of care practices
E	Breach of confidentiality: includes potential and actual cases where participant confidentiality is breached
F	Staff/student performing duties that they are not qualified or trained to perform
G	Failure to follow the Protocol procedures
H	Use of non-approved study materials
I	Other

Deviation Number		Deviation Date	dd/mm/yyyy
Initial or follow up report	☐ Initial ☐ Follow up		
If follow up, date of follow up report (dd/mm/yyyy)			
Description of Deviation (Include how it was identified, who it was reported to)	Study Subject number(s)		

Significance of Deviation (Tick all applicable options as assessed by PI/CI or delegate)	☐ Subject Safety ☐ Integrity of Data
Corrective Action (if applicable)	
Preventative Action	

Reported by:

Name	
Title	
Date (dd/mm/yyyy)	
Staff Signature	
Date (dd/mm/yyyy)	

Please submit completed form to the St George's Research Ethics Committee - Email: sgulREC@sgul.ac.uk

For JRES Office Use only

Report reviewed by

<table>
<tr><td colspan="3">Type of Deviation (JRES classification)

☐ Minor ☐ Major ☐ Critical ☐ Others (comments)</td></tr>
<tr><td colspan="3">Comments</td></tr>
<tr><td colspan="3">Further reporting/escalation required:</td></tr>
<tr><td rowspan="2">Status</td><td>☐ On-going</td><td>Date of review (dd/mm/yyyy)</td></tr>
<tr><td>☐ Closed</td><td>Date for the next review (dd/mm/yyyy)</td></tr>
<tr><td colspan="2">Name</td><td></td></tr>
<tr><td colspan="2">Signature</td><td></td></tr>
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