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Approved by:	Mark Cranmer, Director of the JREO	**Date:**	
Signature of Authorisor			

This is a controlled document.
The master document is posted on the JREO website and any print-off will be classed as uncontrolled.

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

Standard Operating Procedure (SOP)

Applications to the Health Research Authority under S251

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Kirsti Suomi
V2.0	Updated logo, version number, changes in web addresses, change of title from CRGM to HRG	Mallikarjuna Rao Vemula (Arjun)
V3.0	Update to terminology, referencing and pre-submission requirement.	Subhir Bedi

1. Background

Informed consent is the guiding principle for the use of patient identifiable information by any part of the NHS or research community. Patients provide personal information to healthcare professionals in confidence. UK common law therefore requires informed consent to be in place for the use of this information in a patient identifiable form. Researchers and healthcare professionals also have a duty to comply with the 1998 Data Protection Act, which requires certain information to be provided to patients, and the 1998 Human Rights Act. This SOP is for guidance only and researchers wishing to use patient identifiable information must also refer to the best practice described by the General Medical Council (GMC), Medical Research Council (MRC), British Medical Association (BMA) and standards released by the information Commissioner.

Section 251 refers to the section of the National Health Service Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002 responsible for the common law management of NHS patient health records/information. Under Section 251 approval the Secretary of State for Health (via the Health Research Authority's Confidentiality Advisory Group (CAG)) is allowed to set aside the common law duty of confidentiality in specific circumstances where anonymised information is not sufficient and/or where patient consent is not practicable.

The CAG was established by the Health Research Authority on 01 April 2013 to assess applications against the Health Service (Control of Patient Information) Regulations 2002. It provides independent expert advice to the Health Research Authority and Secretary of State for Health on whether an application to process patient information without consent should or should not be approved

The CAG considers whether certain criteria are met and whether the patient and public interest is sufficiently served by the disclosure of identifiable patient information. It also advises applicants on alternative methods which will not need section 251 support. Further information on the CAG can be found at https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/
CAG review and approval, for the purposes of research, will form part of HRA Approval.

2. Joint Research and Enterprise Office (JREO) Policy

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

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

3. Scope

This SOP provides guidance on applications under S251 of the NHS Act 2006 to the Health Research Authority.

4. Definitions

For general research management related acronyms refer to "Definitions" working practice document (JREOWPD0020).

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5. Responsibilities

This SOP is to be followed by the JREO governance, ethics and regulatory team(s) and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the Head of Research Governance & Delivery (HGD) of the JREO to ensure that this SOP is updated by the review date or as necessary.

It is the responsibility of the Chief Investigator (CI) to ensure that HRA approval is obtained prior to initiating any trial involving the use of identifiable patient information without seeking patient consent.

6. Procedure

The Confidentiality Advice Team offers pre-application assessment prior to formal submission of an application. CI's are strongly encouraged to submit for pre-application advice prior to the submission of a formal application. Details of how to gain pre-application advice can be found on the HRA website, within the CAG webpages https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/

.Applications (for full or pre-submission) to the CAG under section 251 are made via the Integrated Research Application System (IRAS) found at www.myresearchproject.org.uk. ON IRAS, if the correct Project Filter questions are completed, the CAG form appears on the left where the other forms are.**Investigator Procedure**

a) You should apply for section 251 support if you wish to access patient identifiable information without the patient's consent. This also includes situations where you would like to identify a group of patients to seek their consent to take part in a study.
b) Research applications should still be submitted via the CAG form on IRAS. The CAG form and supporting documentation attached to the Checklist should be electronically submitted on IRAS by the specified deadline for the application to be considered.
c) Applications will go through a validation stage where it will be determined if there is sufficient information for the application to be presented to the CAG. This may involve a telephone interview and/or queries being sent. The team may advise on potential alternatives or be asked to revise their application form to ensure the information presented to the CAG is clear.
d) The applicant will be advised whether the application will be submitted for full CAG review or processed via proportionate review, and be given details of the timescales involved.
e) If identifiable data is being sent outside the Trust, please contact the Information Governance Manager (contactable through the Trust's ICT department) for further advice.

7. References

https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/

www.myresearchproject.org.uk

8. Appendices

None associated with this SOP.