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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)

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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Section 251 of the NHS Act 2006 (originally enacted under Section 60 of the Health and Social Care Act 2001), allows the common law duty of confidentiality to be set aside in specific circumstances where anonymised information is not sufficient and where patient consent is not practicable.

From 31st March 2013, all functions that advise on the use of confidential patient information without consent, according to regulations made under section 251 of the NHS Act 2006 have transferred from the National Information Governance Board (NIGB) to the Health Research Authority (HRA). Responsibility for approving applications will lie with the HRA for research applications; the Secretary of State for Health will retain the approval function for all other non-research applications. As a sub-committee of the NIGB, the Ethics and Confidentiality Committee (ECC) has also been abolished. The function of the ECC is now the responsibility of the Confidentiality Advisory Group (CAG).

The CAG has been established by the HRA to provide recommendations on whether applications made under section 251 of the NHS Act 2006 and the Health Service Regulations (Control of Patient Information) 2002 should be approved and whether any conditions should be attached. 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

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section 251 support. Further information on the CAG can be found at www.hra.nhs.uk/about-the-hra/our-committees/section-251/

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. Formerly this was the responsibility of the National Information Governance Board for Health and Social Care (NIGB).

4. Definitions

4.1 Section 251 Support

Section 251 support permits the common law duty of confidentiality to be set aside so that information which identifies patients can be used without their consent. To obtain section

- 251 supports the following criteria have to be met:

The reason for using the information has to be for the purpose of improving patient care

- OR in the public interest; and

It has to be for a medical purpose; and

- The purpose cannot be achieved using de-identified data; and
- Seeking consent for the use of identifiable data is practical.

4.2 Patient Identifiable Data

Obvious identifiers are name, address, postcode, date of birth, date of death and NHS Number. The combination of data items can sometimes result in the information becoming identifiable. If you are not sure you can contact the CAG for advice.

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5. Responsibilities

This SOP is to be followed by the JREO governance section and the Chief Investigator (CI) of the proposed study.
It is the responsibility of the Head of Research Governance (HRG) 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

Applications to the HRA 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) Applicants should review the pre-application decision tool www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-advice-and-approval-decisions/to identify whether section 251 approvals is necessary. The Advice team should be contacted (via 020 7972 2557 or HRA.CAG@nhs.net) if there are any queries arising from this decision tool.
c) 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.
d) 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.
e) 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.

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f) 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

www.hra.nhs.uk/resources/confidentiality-advisory-group/

www.nigb.nhs.uk

www.myresearchproject.org.uk

8. Appendices

None associated with this SOP.

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