Imperial College London

Research Governance and Integrity Team

Imperial College Healthcare NHS Trust

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# Applications to the Health Research Authority Confidentiality Advisor Group

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| Version 1.0 | 14 Sep 2006 | 1st Edition |
| Version 2.0 | 27 Jun 2007 | Office change of name and annual review |
| Version 3.0 | 25 Jun 2008 | Annual review |
| Version 4.0 | 03 Sep 2009 | Change from PIAG to NIGB |
| Version 5.0 | 08 Feb 2010 | Formation of Joint Research Office |
| Version 6.0 | 14 Jul 2011 | Annual Review |
| Version 7.0 | 30 Nov 2012 | Annual Review |
| Version 8.0 | 18 Feb 2015 | Review and change of NIGB to CAG |
| Version 9.0 | 25 Oct 2017 | Scheduled Review |
| Version 10.0 | 19 Oct 2020 | Scheduled review<br>Templates removed and administrative changes to SOP.<br>JRCO name change to RGIT. |

## Table of Contents

## 1. PURPOSE

This Standard Operating Procedure (SOP) describes the process for applying to the Health Research Authority Confidentiality Advisory Croup (CAG)

## 2. INTRODUCTION

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 Data Protection Act 2018, Human Rights Act 1998 and the Common Law Duty of Confidentiality. 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, Medical Research Council, British Medical Association and standards.

Section 251 of the NHS Act 2006, 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. The Confidentiality Advisory Group has been established to undertake the responsibilities of NIGB under section 251 of the NHS Act 2006 and to consider and advise on ethical issues relating to the processing of health or social care information.

The primary responsibility of the CAG is to ensure data security and confidentiality. CAG seeks assurance that the research team has adequate arrangements in place to ensure the security of patient identifiable data, through obtaining independent assessment of the security arrangements). CAG also considers the mechanisms for ensuring that access to identifiable data is limited to those who require it within the research team, and that the data is retained in identifiable form for the minimum period necessary. ***It is therefore the responsibility of the Chief Investigator (CI) to ensure that CAG approval is obtained prior to initiating any research involving the use of identifiable patient information without seeking patient consent.***

## 3. PROCEDURE

### 3.1. Procedure for obtaining CAG approval

Applications should be made to CAG for approval either by:

i. Data providers when extracting information from medical records to other organisations/ individuals
ii. Organisations/ individuals seeking to gather such information from one or more research organisations

Applications are made via the Integrated Research Application System (IRAS), which combines the ethics application along with forms for CAG (section 251 form) thereby alleviating the need to complete two separate applications. The resulting form from IRAS can be submitted to CAG in the way described below. IRAS is

mandatory and all applications are completed through this system. For further information on IRAS, see RGIT_SOP_003, this SOP which can be found on the SOP, Associated Documents & Templates page.

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On the IRAS checklist the following documents are mandatory for CAG submission:

- Confidentiality policy
- Corporate Level Security Policy (CLSP)
- Data Protection Registration
- System Level Security Policy (SLSP)
- Written recommendation from Caldicott Guardian (or equivalent of applications organisation).

### 3.2. Guidance on how to apply to CAG

The Confidentiality Advice Team (CAT) offers a pre-application assessment service upon request prior to formal submission. This is an assessment of content and will aim to provide you with an indication as to any areas that may be queried further by the CAG, to advise where greater clarity may be required, to highlight key aspects specific to your application and to signpost to specific contacts to address points raised where necessary. Details can be found on the CAG page of the HRA website.

Applications to CAG must be booked for review prior to submission. The process to book an application is:

Review the precedent set criteria prior to booking to determine if any apply to your application.

Check the meeting and cut off dates on the HRA website. The dates advertised specify the date that bookings must be received by to be considered for inclusion onto the scheduled meeting.

Call the Confidentiality Advice Team to book the application into the next available meeting.

Email the fully completed application (for research applications please include pdf and xml versions of the IRAS form) and all supporting documents to the CAT HRA.CAG@nhs.net within 24 hours of booking. If the application is not submitted within this time period it will automatically be removed from the meeting agenda.

If considered valid, the application will be assessed by the CAG administrator and queries will be fed back to the researcher and once any queries have been addressed the submission will be submitted to the CAG Committee. Information and guidance can be found on the CAG page of the HRA website.:

Applications should usually be submitted by those wishing to use patient identifiable information, not by those asked to disclose it. When CAG approval is given, it then extends to all the organisations from which disclosure is required (as identified from the application).

Only those uses of patient identifiable information that fall under Section 251 of the NHS Act 2006 can be approved by the CAG. Such uses are:

- Preventative medicine
- Medical Diagnosis
- Medical Research

- Provision of care and treatment
- Management of health and social care services
- Informing individuals about their physical or mental health or condition, the diagnosis of their condition or their care or treatment.

If there are practical ways of gaining patient consent, or using anonymised information, then the application will be refused. Refer to HRA CAG page for further guidance.

**3.2.1 Types of Support**

**a. Specific Support**

This can relate to any form of information processing – obtaining, holding, recording, using or disclosing.

**b. Class Support**

This allows the processing of patient identifiable information without consent for one or more of the following purposes:

i. To obtain anonymised data from individual identifiable patient records to support medical purposes i.e. the process of extracting and anonymising the information
ii. To look at patient identifiable information in order to:
    a. Select patients who are to be invited to participate in medical research
    b. Contact patients to obtain their consent for their information to be used
    c. Contact patients to obtain their consent for use of tissue and other biological samples
iii. To obtain and use information about past or present geographical location from patient records
iv. To link patient identifiable information obtained from more than one source in order to validate the completeness or quality of the information or to avoid including the same information more than once
v. To process patient identifiable information for the purpose of auditing, monitoring and analysing patient care and treatment

An additional measure is also supported to allow the authorised user for one or more of the above purposes:

vi. To process patient identifiable information to provide access to an authorised user for one or more of the purposes outlined above

**c. Additional Requirements**

When you have approval from CAG to process patient-identifiable information you must also comply with the requirements set out in the NHS Act 2006. As well as the above limitations on the medical purposes that are in the interest of patients or the wider public, and the test of whether a reasonably practicable alternative to use of the data exists, requirements include:

i. Ensuring that all staff with access to the information have contractual obligations of confidentiality, enforceable via disciplinary procedures;
ii. Limiting access to the information whilst it is in a form that might identify individual patients to the minimum necessary to satisfy the purposes for which the information was made available;
iii. Be contractually bound or otherwise undertake not to disclose identifiable patient information except:
    a. To the data controller that made the information available
    b. To other data controllers similarly supported in law for limited use of data;
    c. To others on a need to know basis where there is a significant public health interest justification for doing so;
    d. Where there is a specific statutory requirement to do so;
    e. Only hold patient information in a form that might identify individual patients for the minimum time period necessary;
    f. Only process patient identifiers that are needed to satisfy the purpose;
    g. Document and make available to any who request, details of how the conditions set out in Section 251 are being met;
    h. Facilitate and support reasonable audit of data processing by designated agents of the Secretary of State

**3.3. The Application**

i. The first step is to obtain a Research Sponsor. In the case of Imperial College AHSC, the RGIT will advise you on whether the Trust or College will act as sponsor. Sponsorship should be arranged by contacting the Research Governance and Integrity Team.

ii. Studies that fall under the UK Policy Framework for Health and Social Care Research must have Research Ethics Committee approval, please refer to RGIT_SOP_003 for guidance on process.

iii. IRAS applications are made via IRAS - My Research Project
- Complete documents required for CAG application are detailed on the checklist on IRAS: The following are mandatory:
    - CAG Application form (signed and authorised), this is generated through IRAS
    - Research proposal or Project proposal
    - Data Protection Registration
    - Written recommendation from Caldicott Guardian (or equivalent of applicants' organisation

iv. Each application is reviewed by the CAG Administrator. If the Administrator has concerns with the application, they will contact the Chief Investigator for clarification and will return applications that are clearly inappropriate.

v. In circumstances where an application for specific support has to be considered by Parliament and requires both public consultation and the drafting of regulations, a decision and the provision of support in law may take between 3 to 6 months from the date of the CAG meeting.

vi. CAG assessment forms part of the ethics and HRA review process administered through IRAS and standard review timelines will apply.

### 3.4. Amendments

Amendments should be submitted using the CAG amendment template: They should also go through the HRA process. In order to obtain the amendment template, when access the above web site scroll to Guidance\amendment form. This is Microsoft Word documents template.

### 3.5. Annual Review

CAG approved research projects must submit annual reports as part of the ethics approval process to ensure approved projects are progressing as planned, and that the use of patient identifiable information is consistent with what was agreed and that security is maintained. An annual review report should be submitted no later than 11 months following the final approval and will be assessed by the CAT in the first instance. The CAG annual review template should be used.

### 3.6. Information Governance Toolkit Requirements

Any research involving the use of NHS data being submitted to CAG requires Information Governance (IG) registration as a condition of approval.

It is Department of Health (DH) policy that all organisations that have access to NHS patient information must provide assurances that they are practising good information governance and use the Department of Health's Information Governance (IG) Toolkit to evidence this by the publication of annual IG Toolkit assessments.

For research conducted at Imperial College Healthcare NHS Trust, the project must be registered with the Trust Information Governance Office. Advice can be sought by emailing: InformationGovernanceAdvice@nhs.net

For research being conducted at Imperial College London the department or project team is classed as a Hosted Secondary Use Team/Project under the Toolkit definition.

At present each project occurring on College premises is required to submit to the Information Governance Team (Professor Paul Elliot email: p.elliott@imperial.ac.uk Tel: 0207 594 3328) for review, they will then advise regarding submission to the IG toolkit.

The Toolkit asks a number of questions regarding data security policies and information security policies can be found on the Information on College policy site.

The IRAS application asks for details of 'Corporate Level Security Policy' (CLSP). Imperial College Information Systems Security Policy and its associated Codes of Practice, whilst not accredited to any formal methodology, has been developed using ISO 17799:2005 - for guidance.

## 4. REFERENCES

Information Governance Toolkit website

HRA CAG Guidance

HRA CAG application Guidance

Human Fertilisation and Embryology Act 1990

Data Protection Act 2018

Data Protection Act 1998

Human Rights Act 1998

National Health Service Act 2006 cited 24 August 2020