Caldicott Guardian & project approval:

1. Caldicott Guardian Role & Register
2. Caldicott Principles
3. Applying to use Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) data
Caldicott guardian

ROLE & REGISTER
Caldicott Guardian:

- A Caldicott Guardian is a senior person responsible for protecting the confidentiality of people's health and care information and making sure it is used properly.
- All NHS organisations and local authorities providing social services must have a Caldicott Guardian.

https://www.gov.uk/government/groups/uk-caldicott-guardian-council#caldicott-guardian-registration
The UK Caldicott Guardian Council (UKCGC) is the national body for Caldicott Guardians.

A Caldicott Guardian is a senior person responsible for protecting the confidentiality of people’s health and care information and making sure it is used properly.

All NHS organisations and local authorities which provide social services must have a Caldicott Guardian.

The UKCGC is a sub-group of the National Data Guardian’s Panel.

When making decisions or giving guidance, Caldicott Guardians will often refer to the Caldicott principles, which can be found in the Information Governance Review. The UKCGC has also produced A Manual for Caldicott Guardians.

Aims of the council

The council aims to:

- be a point of contact for all Caldicott Guardians and for health and care organisations seeking advice on the Caldicott principles
- enable Caldicott Guardians to share information, views and experience
Our services

The Organisation Data Service provides a number of services, including updating and maintaining the registers for Caldicott Guardians, Senior Information Risk Owners, Information Asset Owners and Data Guardians.

Caldicott Guardians

A Caldicott Guardian is a senior person responsible for protecting the confidentiality of people’s health and care information and making sure it is used properly.

All NHS organisations and local authorities providing social services must have a Caldicott Guardian.

Download the Caldicott Guardian register [1.46Mb]

To register your organisation’s Caldicott Guardian, please complete this form [51Kb]

Senior Information Risk Owners

A Senior Information Risk Owner (SiRO) is an Executive Director or member of the Senior Management Board of an organisation with overall responsibility for an organisation’s information risk policy.

The SiRO is accountable and responsible for information risk across the organisation. They ensure that everyone is aware of their personal responsibility to exercise good judgement, and to safeguard and share information appropriately.

Download the SiRO register [2.22Mb]

To register your organisation’s SiRO, please complete this form [81Kb]

Caldicott Guardian register:

• University of Surrey:

• Woodbridge Hill Surgery
Caldicott guardian

HISTORY & PRINCIPLES
Caldicott Review:

• Review was commissioned in 1997 by the Chief Medical Officer of England to address:-
  – Increasing concern about the ways in which patient data is being used in the NHS
  – Ensure that confidentiality is not undermined

• Committee was established under the chairmanship of Dame Fiona Caldicott

• Caldicott Report in 1997 highlighted 6 principles

• These principles were subsumed in the NHS confidentiality Code of Practice 2003

• In 2012, Dame Caldicott produced a follow up report and added a 7th principle to emphasise the importance of data sharing
Caldicott Principles

1. Justify the purpose(s)
   Every single proposed use or transfer of patient identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian, the Caldicott Guardian.

2. Don't use patient identifiable information unless it is necessary

3. Use the minimum necessary patient-identifiable information

4. Access to patient identifiable information should be on a strict need-to-know basis

5. Everyone with access to patient identifiable information should be aware of their responsibilities

6. Understand and comply with the law
   Someone in each organisation handling patient information should be responsible for ensuring that the organisation complies with legal requirements.

7. The duty to share information can be as important as the duty to protect patient confidentiality
   Official policies should support them doing so.

www.surrey.ac.uk
Caldicott Guardian roles

- **Senior person** within a health or social care organisation who makes sure that the personal information about those who use its services is used legally, ethically and appropriately, and that confidentiality is maintained.

- **Provide leadership** and informed guidance on complex matters involving confidentiality and information sharing.

- Play a key role in ensuring that their organisation satisfies the **highest practical standards for handling person-identifiable information** relating to patients, service users and their relatives, staff and others.

- **Apply the seven principles wisely**, using common sense and an understanding of the law - recognising that their decisions will affect real people.

- Acting as “**the conscience of the organisation**” remains central to trusting the impartiality and independence of their advice.
Caldicott Guardian - Responsibilities

• **Strategy & governance** - champion confidentiality issues at board/senior management team level, and act as both the ‘conscience’ of the organisation and as an enabler for appropriate information sharing.

• **Confidentiality & data protection expertise** - develop a strong knowledge of confidentiality and data protection matters, drawing upon support staff working within the organisation’s governance functions, and on external sources of advice and guidance where available.

• **Internal information processing** - ensure that confidentiality issues are appropriately reflected in organisational strategies, policies and working procedures for staff in line with NHS Information Governance Toolkit.

• **Information sharing** - oversee all arrangements, protocols and procedures where confidential personal information may be shared with external bodies.

• **Work closely with the Senior Information Risk Owner**.

• **Staff should be advised to seek assistance** from the Caldicott Guardian where necessary.
Accessing RCGP RSC data

APPROVAL PROCESS

www.surrey.ac.uk
Approval to access RCGP RSC data:

- University of Surrey is the data and analytics hub for the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC)

- We hold routine data for
  - National surveillance – supporting the role of Public Health England (PHE)
  - Our data are available for audit, research & quality improvement

- Steps to gain access to our data:
  1. Define the use – Is it research? MRC HRA form
  2. (a) Write a protocol (2) Complete a data application form to seek RCGP approval – delegated approval process
  3. Finally, your project/research may need approval through the IRAS process – a study may require approval by HRA Confidentiality Advisory Group (CAG)
Approval to access RCGP RSC data:
1. Define the use – Is it research?

- Health Research Authority (HRA leaflet)

- HRA / Medical Research Council (MRC) online tool
  http://www.hra-decisiontools.org.uk/research/
<table>
<thead>
<tr>
<th>RESEARCH</th>
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<tbody>
<tr>
<td>The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.</td>
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<tr>
<td>Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.</td>
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<tr>
<td>Addresses clearly defined questions, aims and objectives.</td>
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<tr>
<td>Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.</td>
</tr>
<tr>
<td>Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.</td>
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<tr>
<td>May involve randomisation.</td>
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<tr>
<th>SERVICE EVALUATION*</th>
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<tr>
<td>Designed and conducted solely to define or judge current care.</td>
</tr>
<tr>
<td>Designed to answer: “What standard does this service achieve?”</td>
</tr>
<tr>
<td>Measures current service without reference to a standard.</td>
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<tr>
<td>Usually involves analysis of existing data but may include administration of interview or questionnaire.</td>
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<tr>
<td>Usually involves allocation of patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.</td>
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<tr>
<td>May involve randomisation.</td>
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<td>Does not require REC review.</td>
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<th>CLINICAL AUDIT</th>
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<tr>
<td>Designed and conducted to produce information to inform delivery of best care.</td>
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<tr>
<td>Designed to answer: “Does this service reach a predetermined standard?”</td>
</tr>
<tr>
<td>Measures against a standard.</td>
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<tr>
<td>Usually involves analysis of existing data but may include administration of interview or questionnaire.</td>
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<tr>
<td>No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.</td>
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<td>No randomisation.</td>
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<td>Does not require REC review.</td>
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<th>SURVEILLANCE</th>
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<tr>
<td>Designed to manage outbreak and help the public by identifying and understanding risks associated.</td>
</tr>
<tr>
<td>Designed to answer: “Was this the cause of this outbreak?”</td>
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<tr>
<td>Systematic, statistical methods to allow timely public health action.</td>
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<tr>
<td>May involve analysis of existing data or administration of interview or questionnaire to those exposed.</td>
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<tr>
<td>Does not involve an intervention.</td>
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<tr>
<td>No randomisation.</td>
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<tr>
<td>Does not require REC review.</td>
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<th>USUAL PRACTICE (in public health)</th>
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<tr>
<td>Designed to investigate outbreak or incident to help in disease control and prevention.</td>
</tr>
<tr>
<td>Designed to answer: “Was this the cause of this outbreak?” and treat.</td>
</tr>
<tr>
<td>Systematic, statistical methods may be used.</td>
</tr>
<tr>
<td>May involve administering interview or questionnaire to those exposed.</td>
</tr>
<tr>
<td>Does not involve administration of interview or questionnaire.</td>
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<tr>
<td>Does not require REC review.</td>
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Approval to access RCGP RSC data:
2. (a) Protocol (b) Data application form

- **Protocol**
- Set out *a priori* your aim - STROBE
- [www.equator-network.org/](http://www.equator-network.org/)
- **Data application form**
Approval to access RCGP RSC data:

3. IRAS process

- Integrated Research Application System (IRAS)
- https://www.myresearchproject.org.uk/
Approval to access RCGP RSC data:
3. IRAS process – may require CAG approval
(Section 251)
www.hra.nhs.uk/about-the-hra/our-committees/section-251/

The Integrated Research Application System (IRAS):

- is a single system for applying for the permissions and approvals for health and social care / community care research in the UK
- enables you to enter the information about your project once instead of duplicating information in separate application forms
- uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required
- helps you to meet regulatory and governance requirements

IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / NHSRC Research Ethics Committees
- NHS / HSC Research Ethics Committees
- National Offender Management Service (NOMS)
- Social Care Research Ethics Committee

Please help us to improve IRAS by sending your feedback to iras.queries@nhs.net. Your comments and suggestions will be included in the next review of the system.
Summary:

1. Explained my role as Caldicott Guardian Role & Register

2. Described the Caldicott Principles

3. Provided information how to apply to use Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) data
Some references/resources

- Information Governance Review: To Share or Not to Share". Department of Health. 2013
- Manual for Caldicott Guardians