Confidentiality Advisory Group - CAG

The CAG is an independent body which provides expert advice on the use of confidential patient information. Researchers wanting access to NHS patient identifiable data for their study, without going through the route of patient consent, can make an application to CAG, who act as a gateway to gaining access to NHS patient identifiable data by enacting section 251 of the NHS Act 2006.

In England and Wales, section 251 of the NHS Act 2006 provides statutory power to allow NHS patient identifiable data needed to support essential research activity to be used without individual consent. CAG has the ability to pass section 251, establishing a lawful basis in the absence of patient consent.

The key purpose of CAG is to protect and promote the interests of patients and the public, whilst at the same time facilitating appropriate use of confidential patient information for purposes beyond direct patient care. Further information about CAG and the use of confidential patient information for research can be found here.

When is CAG approval needed?

If a researcher intends to access confidential patient information (such as names, addresses, dates of birth) without consent, outside of the direct care team in England and Wales, they will need to apply for CAG approval. For guidance on whether CAG approval is needed for your project, explore the NHS HRA decision tool. The CAG pre-application checklist is also useful in highlighting key considerations when deciding whether there is a need to apply to CAG.

Note: Applications made to CAG will only be considered when the data being requested cannot be collected using informed consent, or if other means of data collection are not viable. Those asking for approval must not normally have legitimate access to this information already.

How to apply for CAG approval:

The CAG application process, gaining section 251 support, and achieving the necessary legal and governance approvals, is complex and lengthy. This section will help make things clearer regarding next steps and also signpost to relevant guidance and information.

CAG applications are completed on the Integrated Research Application System (IRAS). Guidance on using the IRAS system can be found here. The online application form is made up of many different sections and parts, not all will be applicable, this will depend on the researcher's data needs. The application must be clear and very detailed, to allow the CAG committee to fully understand the reason for the application and the intended impact and use of such sensitive, confidential data.

The CAG approval process involves a wide range of people reviewing the application and assessing the study's feasibility, with a mixture of expert members (with backgrounds in medicine, research, statistics, and information governance) as well as lay members of the public. It might be useful to see what projects have received CAG approval in the past. Details of applications CAG has supported to use confidential patient information can be found on the CAG registers.

One of the main things the CAG will be looking for in an application is a justification that patients or end-users would support the proposal, even if they are not being asked for consent. This can be evidenced by reporting on patient and public consultations about the

proposed project. Applicants must evidence how they discussed the proposed project with patient and public contributors, their feedback, and any changes made to the project as a result of the consultation. It is important applicants plan these consultations into their preparation time.

Further guidance for researchers applying to CAG can be found here. Information on supporting documentation researchers will need to include in their CAG application can be found on this page.

The CAG application pathway:

Step 1: Complete CAG application form via IRAS

Step 2: Submit all mandatory documents and any relevant supporting documentation

Step 3: A confidentiality advisor will be the first to review the application, to check it meets the validation criteria to be considered for CAG approval

Step 4: If validation criteria has been met and the application is considered suitable, it will be passed on to the CAG committee for review

Step 5: The researcher will be invited to a review meeting to answer any questions the committee may have. A time slot of 20 minutes will be allocated and the applicant is expected to join the meeting on Zoom. Details of which will be sent to the applicant

Step 6: After the meeting, the applicant will be informed of the outcome and next steps. Notice of the outcome will usually be within 10 working days of the review meeting

Step 7: Depending on the outcome of the review, the application may:

a. Gain approval
b. Action required – to be resubmitted with amendments
c. Rejected

Even if approval for section 251 support has been granted through CAG, this is only part of a process and other approval may need to be requested. The CAG support team will make clear what other approvals are needed.

The approval process is expected to take 1-2 months from the submission of an application, but in practice may take up to 6 months.

Guidance on completing a successful CAG application:

Useful guidance on completing a successful CAG application can be found here.

Listed below are some top tips curated from feedback received and experiences shared by previous CAG applicants.

- Write in plain English and avoid the use of overly technical language or terms without prior explanation
- Be transparent and clear
- Be consistent
- Remember to submit supporting documentation
- Learn from others

Detailed feedback from previous CAG applicants has primarily focused on four themes: PPIE, establishing rationale, data maintenance, and further permissions.

PPIE: One of the most common themes from the feedback received.

- CAG encourages PPIE work to be embedded, evidenced, targeted and accessible.
- PPIE is considered essential. For patients and the public to make informed opinions and decisions they need the information and knowledge to do so.
- Applicants will need to prepare PPIE documentation and communication materials for submission, as supporting evidence, as part of their CAG application.
- A variety of communication methods with the public are recommended in order to maximise information pathway, promotion and response.
- Information must be accessible, and content should be written in a digestible format for non-expert readers.
- CAG encourages the involvement of under-represented groups to achieve a rounded view, whilst also expecting involvement with a representative sample of the patient population.
- CAG requires clear detailing of what PPIE has taken place, on what scale, and how it is representative of the population.
- The PPIE report should include questions asked and discussion points raised, as well as an overview of the views collected, both positives and any concerns. The PPIE report should outline ongoing engagement activities so that CAG can see and be assured of the continued involvement of patients and the public.
- Details of how PPIE will continue should be addressed clearly.

Here is a useful resource outlining the importance of PPIE and how to demonstrate, evidence and explain this work successfully in a CAG application.

It is also important to note that applications without clear opt-out/dissent mechanisms will be asked to be amended. Therefore, this must be implemented in the project and addressed clearly in the application.

Establishing rationale: Identifying need and demonstrating a clear project pathway and framework. Applicants should be able to justify the following in their application:

- Purpose of the project is for medical research and in the public interest
- The methodology is appropriate and proportionate to the study objectives

CAG will require clear and concise detail on exact data requested.

Data maintenance: This refers to legacy planning for the future of the data once used. Applicants will need to demonstrate a clear understanding of what will happen next and detail explicitly when confidential data will be destroyed and by whom.

Further permissions: It is important to know that gaining section 251 approval from CAG is only part of the process and there will be additional permissions required to complete approval and gain access to the data. These will usually be made clear in the correspondence with the CAG support team.

Additional Information

Additional information about CAG can be found here.

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