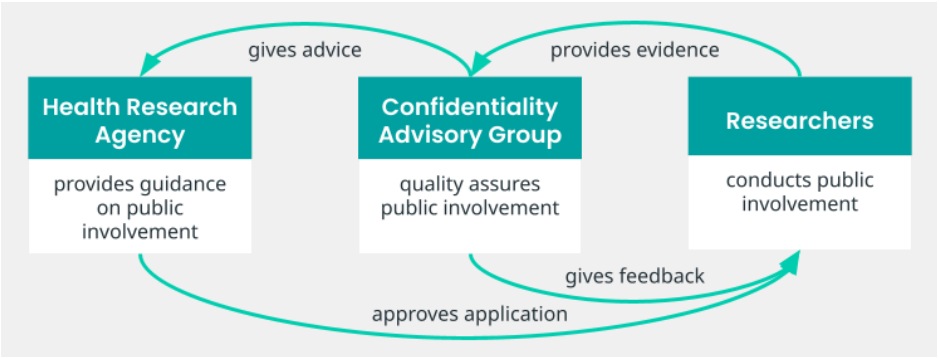
How can we ensure public data is shared in the public interest?

Case study: Confidentiality Advisory Group

The Health Research Authority's Confidentiality Advisory Group (CAG) is an independent body that provides expert advice on the use of confidential patient information in the public interest. The CAG requires researchers proposing to use patient data to involve the public to understand public interest, the acceptability of the data processing, and how patients should be given opportunities to opt-out of the research. The CAG supports accountability by publishing its minutes and registers of requests.

Medical researchers can either ask patients to sign up to a study, or directly access patient data held by NHS bodies. To do the latter, researchers have to get permission from the Health Research Authority (HRA). The HRA gets advice from a Research Ethics Committee (REC), which looks at whether the proposed research is ethical, and the Confidentiality Advisory Group (CAG), which considers whether the public interest of the project is sufficient to justify a breach of confidentiality, and whether the opt-out mechanisms that patients have are sufficient.

Working out whether something is in the public interest (or acceptable to the public) and how to best provide opt-out mechanisms to relevant patients requires public input. There is also evidence that public involvement means research is more relevant and better communicated. While the CAG includes lay members, it cannot provide a sufficient lived experience voice for all types of research. It therefore requires researchers to carry out proportionate, high quality, public involvement. The CAG expects public involvement to be embedded throughout the research, targeted to relevant members of the public and accessible to them. The CAG also looks for evidence that public involvement is meaningful and has helped shape the research.



To build public confidence and promote accountability, the CAG operates in a very transparent way. It publishes future dates and minutes and registers of all applications it has approved. It is responsive, meeting up to twice a month and providing decisions within a maximum of 60 days (or 30 days where an application shares common issues with previous projects). The HRA provides a set of best practice resources for carrying out public involvement, and the CAG provides guidance on what it looks for.

What is the Confidentiality Advisory Group?

'The Confidentiality Advisory Group (CAG) is an independent body which provides expert advice on the use of confidential patient information without up-front consent.

It is part of the Health Research Authority. The HRA is an arms' length body of the Department of Health and Social Care, originally established in 2011, which 'protects and promotes the interests of patients and the public in health and social care research' through ensuring research is ethically reviewed, promoting transparency in research, standardising regulatory practice and providing recommendations on processing identifiable patient information.

The CAG advises the HRA on uses of confidential patient information for research, and the health secretary on non-research uses. It describes its 'key purpose' as protecting and promoting the 'interests of patients and the public' while facilitating 'appropriate use' of their confidential patient information 'for purposes beyond direct patient care'.

CAG covers England and Wales. Scotland has a Public Benefit and Privacy Panel for Health and Social Care and Northern Ireland a Privacy Advisory Committee (with no statutory powers). In England, CAG is part of a wider landscape on advice and assurance around health data which also includes the NHS England Advisory Group for Data and the National Data Guardian.

How does the CAG process work?

If researchers wish to use confidential patient information without consent, then they should apply to CAG for support under section 251 of the National Health Services Act (2006). This allows the common law duty of confidentiality to be set aside for defined purposes. Approval from CAG provides legal means for the data controller to provide access to confidential patient information.

The HRA provides guidance for applicants. Alongside a completed application form, applicants are expected to provide a data flow diagram and a written recommendation from a Caldicott Guardian (or equivalent). Where relevant, they are also expected to include supporting evidence of 'public involvement' and template 'patient notification materials' for telling patients about their activity (more below). Patient notification materials should give them the opportunity to opt out of the specific study and inform them of the National Data Opt Out, an NHS England service which allows patients to opt out of their data being used for purposes beyond their direct care (such as research and planning).

The CAG is made up of professional and lay members – its professional members bring expertise from fields including research, clinical practice and information governance. It meets up to twice a month, publishing future dates and minutes, and publishes registers of all applications it has approved.

Applicants can expect decisions on approval within a maximum of 60 days. Applications on a 'precedent set review pathway' take a maximum of 30 days – this is where applications share issues with previous projects (though there are exceptions, including the use of data around potential abuse, social care or prison populations; free text; or where consent is not intended to be sought).

What does CAG expect from public involvement?

'Good public involvement helps the CAG consider the public interest and the acceptability of using confidential patient information without consent.' CAG also recognises that its own panel cannot provide a sufficient lay voice for all types of application, hence the importance of public involvement in each application.

In March 2024, CAG published guidance on public involvement for applicants. It expects public involvement should be 'central' to planning a project and be planned 'at the earliest opportunity', and it should 'specifically test the public acceptability of using confidential patient information without consent for the purpose of your application'. In practice, this means 'providing a public group with a plain language summary of your project that includes the purpose of the project, how confidential patient information is used without consent and the safeguards that will be in place' and seeking views.

Applicants should involve people with lived experience of the condition or situation covered by the research; consider which population data they are using and whether different communities may have different views about the use of their data; and include a proportionate number of people given the size of the cohort. As views can change, CAG says that public involvement is 'not a one-off activity'.

In applications, CAG expects to see:

- 'The demographics of who you have involved, how many and why their involvement is relevant
- 'How you have involved people, such as focus groups or meetings
- 'What questions or topics were used
- 'The number and types of responses you received i.e. both positive and negative and what changed because of this feedback
- 'How you plan to continue this specific public involvement for the duration of CAG support'.

CAG will push back on applications where public involvement has been found wanting. For example, recent minutes include CAG calling public involvement 'insufficient', requiring the applicant to provide all feedback from the project's public involvement group for review, and requiring further information on patient notification strategies; and even requiring that 'further public involvement exercise[s] should be conducted in regions across the country to explore any variations and to collect comparison data'.

An academic analysis of CAG minutes suggests the Group expects patient involvement and engagement work to be embedded (present throughout the research cycle), evidenced (explicit in the application), targeted (specific to the project and discussed with likely data subjects) and accessible (information sensitively provided for all users). Another analysis suggests that the CAG process overcomes traditional problems in framing the 'public interest' in law, which can often be a narrow legal test disconnected from what the public actually thinks, or an ineffective attempt to extrapolate bits of public engagement work into wider policy and law; the CAG's flexible, iterative approach might help reconcile these different approaches.

There is also separate public involvement guidance to help applicants with reviews by Research Ethics Committees (RECs) – in an interview, CAG representatives described the purpose of RECs as looking at

the science of a project and whether what they were doing was ethical, while CAG considers whether the public interest behind the project is sufficient to justify a breach of confidentiality.

The HRA has a section on its website all about public involvement. This includes the benefits of involving the public (more relevant, acceptable and a better experience of research; more understandable information for participants and better communication of results), and four principles for meaningful involvement (the right people, enough people, involving those people enough, and describing how it helps). The HRA also has a set of best practice resources, and supplementary information on the national data opt out.

HRA have also published (with the National Institute for Health and Care Research and a coalition of other organisations) a 'shared commitment' to public involvement in health and social research, with links to evidence of how such involvement improves research and the UK Standards for Public Involvement.

How does CAG define the 'public interest'?

The CAG doesn't have simple boxes to tick as to whether a project is in the public interest. While there are useful resources – including the National Data Guardian on 'public benefit', with a public dialogue – considerations will depend on the application, which is one reason why public involvement is so important. CAG will be interested in whether the research question is one that needs answering, and whether the question is important enough to justify the breach of confidentiality required.

Further reading

- Confidentiality Advisory Group website (Health Research Authority)
- Blog: What is the Confidentiality Advisory Group, and why does it need people like you? (Dr Tony Calland, CAG, for Understanding Patient Data)
    - See also: Who decides how patient data is accessed?; How is data kept safe?; Choices in how your data is used beyond individual care; Single patient records in the NHS: a long-read blog (Understanding Patient Data)
- Guidance for researchers wanting to link NHS data using non-consent approaches: a thematic analysis of feedback from the Health Research Authority Confidentiality Advisory Group (Lauren Cross, Lauren Emma Carson, Amelia Jewell, Margaret Heslin, David Osborn, Johnny Downs, Robert Stewart for Applied Health Sciences)
- Sharing confidential health data for research purposes in the UK: Where are 'publics' in the public interest? (Annie Sorbie for Evidence and Policy)
- To CAG or not to CAG? Difficulties in determining submission to the Confidentiality Advisory Group: a commentary (V Ranieri, H Stynes, and E Kennedy for Research Ethics)
- Using data in the NHS: the implications of the opt-out and GDPR (The King's Fund)
- Case database: NHS Confidentiality Advisory Group (Connected by Data)
- Justice Data Matters 2022: Evaluation Report (Connected by Data)