Recommendations and approval decisions	
Why are applications to access confidential patient information without consent assessed in this way via the CAG?	Medical records hold confidential information so any disclosure to a specified person without consent to support activities such as important medical research or healthcare planning must be in the broader public interest and robustly scrutinised to maintain public confidence. The CAG acts as a safeguard through providing reassurance that applications are independently scrutinised by an impartial group before a final decision is taken.
Does the CAG approve applications to access confidential patient information without consent?	No. The CAG provides detailed advice to the approving bodies (the Health Research Authority or Secretary of State for Health) on whether an application should or should not be approved. The CAG dedicates its time to robustly scrutinising applications using the Health Service (Control of Patient Information) Regulations 2002 as the framework to advise whether the activity is in the public interest, if it fulfils a medical purpose, and that there is no other reasonable way in which to carry out the activity (see 'considerations' FAQ below) The CAG can also call upon expert advisors to help inform its recommendations, and has had the benefit of working with the Information Commissioner's Office when seeking advice about likely compliance with the Data Protection Act 1998 on certain applications; this advice is incorporated into the overall CAG recommendation.
What considerations does the CAG take into account?	The CAG considers a number of aspects including, but not limited to: • Is there a practicable alternative to seeking support e.g. is access to all identifiers necessary to achieve the purpose; can the methodology be amended? • Can consent be obtained? This involves looking at the reasons provided for why consent may not be a realistic option at that time. • Can another organisation that legitimately holds the information process and provide the applicant with an anonymised dataset? • Are there any technological developments that mean access to identifiers could be restricted? • Would the public interest in the disclosure and potential benefits, on balance, outweigh the breach of confidentiality?

	• Have patient groups or service users been consulted to test the acceptability of the proposal to help identify the reasonable expectations of a patient on the proposed data use, and subsequently the public interest? • How the applicant intends to manage the activity in such a way so that processing information without consent in future would no longer be necessary? • Is the activity compliant with the provisions of the Data Protection Act 1998? • Are appropriate standards of governance and security in place? Details of considerations can be found in the CAG minutes and also in the paper 'Principles of Advice'.
Who approves applications to access confidential patient information without consent?	The Health Research Authority takes the final approval decision for all research applications where relevant information was generated in England. The Secretary of State for Health (via the Department of Health) takes the final approval decision for all other relevant requests. Both approving bodies use the CAG advice as the basis for their decisions. It has been agreed that where the approver chooses to reach a different approval decision that this will be discussed with the CAG in the first instance to understand the issues, and final outcome is published.
How do I know what has been approved?	The Register of Approved Applications holds summary details of all applications that have received approval and contact details for each applicant. This is updated every two weeks to reflect newly approved applications. Questions on the approval should be initially directed to the applicant listed against each approval. . The CAG publishes its minutes 5 days after they are ratified at the subsequent CAG meeting.
Who can make an application?	Applicants are varied and are listed in our Register of Approved Applications. They can range from academic researchers, the NHS and Local Authorities, government organisations and partnerships. What is important is that the activity must fall within a medical

	purpose. Examples of medical purposes include medical research (that has also been ethically approved by a Research Ethics Committee), and the management of health and social care services
How long has this power been in effect?	Following significant public debate, the Regulations came into effect in 2002. It was noted that it would be key to have an independent body advising on applications, which is why the CAG role is important.