Health Research Authority

CAG pre-application checklist

Do I need to process identifiable information without consent?

Decisions on whether an application to process patient information without consent should be made locally and ultimately decided by those who hold the requested data. The following sets out some key considerations to assist these local decisions on whether an application to the CAG, to avoid a breach of the common law duty of confidentiality, is advised.

1. Are you processing confidential patient or social care information without patient consent?

Yes → Q2

No → If the local decision by the data controller is that the proposed processing would not involve a breach of confidentiality, an application is not advised.

- Decisions on whether a dataset is identifiable must be taken locally. The CAG can advise you on the considerations it takes into account, based upon its regulatory framework, but will not take this decision on behalf of applicants or other data controllers.
- Processing also includes viewing, but not physically extracting relevant information
- Confidential patient/service user information is considered identifiable based on the context, items requested and other information that is held* or likely to be held by the applicant;
- Contextually driven consideration. Case by case consideration
- Should consider entirety of dataset (s) being requested and interaction with other datasets held by the applicant.
- Obvious identifiers are name, address, postcode, date of birth, and NHS Number. The combination of less obvious data items can sometimes result in the information becoming identifiable, or could involve rare conditions. If you are not sure you must discuss and reach mutual agreement with the person who lawfully holds the information (the data controller)

*If you hold other identifiable datasets you will have to explain in your application the legal basis for holding that information as support will not be retrospectively provided where the legal basis is unknown.

2. Is the information generated within England and Wales?

Yes → Q3

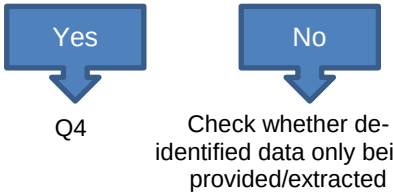
No → Outside remit of CAG

Applications to the CAG only covers relevant information generated in England and Wales. If you intend to access information from Scotland or Northern Ireland you should contact the relevant Group/person below.

Scotland: https://nhsnss.org/how-nss-works/policies-and-statements/privacy-advisory-committee/Northern

Ireland: r.j.mcclelland@qub.ac.uk

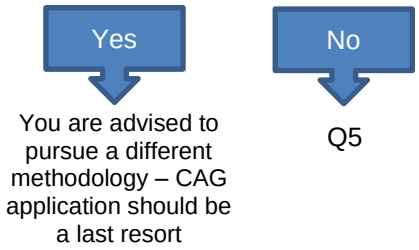
3. Is access requested for someone who would not normally have legitimate access to that information?



The Information Governance Review in 2013 by the National Data Guardian stated that *'direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers...Care teams may also contain members of staff, who are not registered with a regulatory authority, but who may need access to a proportion of someone's personal data to provide care safely'.*

If the person accessing the requested information is not considered to fall within this definition, it is possible that without a legal basis to access identifiable information, disclosure could lead to a breach of confidentiality. A successful application via the CAG would enable a lawful basis to be put in place to avoid this, should the data controller wish to rely upon this legal basis (note support where provided is permissive and does not require data controllers to provide information to the applicant).

4. Can a different methodology be used to prevent the need to seek support?

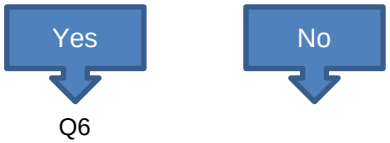


Seeking support via the CAG is considered a measure of last resort where there is no other better way to access and process the information for a specific purpose. Potential applicants should consider whether they are using the least disclosive approach. For example, could those that already legitimately hold the information carry out the linkages and provide the applicant with a de-identified dataset?

Note if you need to send identifiers to a different entity, there must be a legal basis in place to allow them to receive the information.

5. Is the activity research, or non-research?

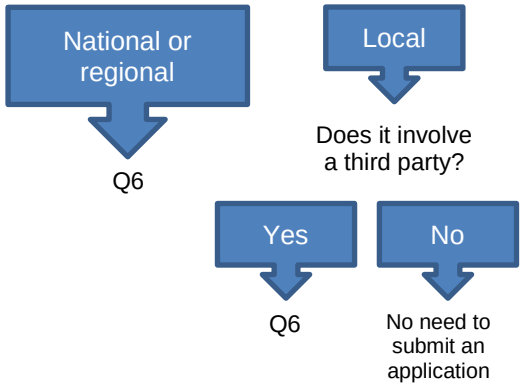
5.1 If research, does it have a favourable opinion from a REC?



Our decision tool that helps you work through whether an activity is research or not. Please remember that non-research applications to the CAG must be submitted on our 's251 form' available on the CAG section of the HRA website.

As part of the regulatory framework all successful applications to the CAG must have a favourable opinion from a recognised REC. You can apply to the REC either before, during or after an application to the CAG, but a final favourable opinion must be evidenced before support to process confidential patient/service user information comes into effect.

5.2 If the audit, is it national, regional or local?



An application to the CAG is not advised for local clinical audit as long as:

- the audit is conducted by one of the organisations that has delivered the patient's care or treatment;
- the audit is carried out in accordance with clinical governance guidelines;
- it has been approved by the NHS Trust's medical director/Caldicott Guardian.

For national and regional clinical audits or where third party organisations are used to conduct a clinical audit the use of de-identified data should be considered. If it is not possible to use de-identified data then patient consent should be sought, or if this is not feasible, an application to the CAG will be advised.

If your responses to questions above indicate that you should possibly apply for support to avoid a breach of confidentiality, you will have to satisfy the legal requirements established under section 251 of the NHS Act 2006. Questions 6 to 11 reflect the minimum legal criteria set out in legislation.

6. Is it for a medical purpose?

Yes → Q7

No → Outside remit of s.251

The activity must be a medical purpose as stated within the Act, and are listed as: Preventative medicine, medical diagnosis, medical research, the provision of care and treatment, management of health and social care services.

It is the applicant's responsibility to clearly demonstrate that an activity falls within the relevant medical purpose; legal advice must be sought locally if this is unclear prior to submission.

7. Can consent be reasonably sought? Is it possible and practicable to seek consent/re-consent?

Yes → You are advised to seek consent

No → Q8

Applicant must demonstrate that it is not possible to carry out the activity another way, taking into account cost and available technologies (s.251(4)).

The CAG will have to be satisfied, based on the circumstances, that seeking consent is neither possible nor practical.

8. Is the purpose to improve patient care or in the public interest?

Yes → Q9

No → Outside remit of s.251

Public Interest Overarching purpose of the activity has to focus on improving patient care, or to be in the public interest (s251(1)(a-b)).

The application must clearly demonstrate how there will be a clear public or clinical benefit arising from the use of information without consent.

9. Can de-identified information be used?

Yes → You are advised to use de-identified data

No → Q10

Applicants must demonstrate that it is not possible to carry out the activity another way, taking into account cost and available technologies (s251(4)).

The CAG will have to be satisfied, based on evidence, that the use of de-identified data information cannot satisfy the purpose of the activity. Applicants will be expected to justify why, for example, full postcode is necessary rather than partial postcode.

10. What is the purpose of the activity – is it other than direct patient care?

Yes → Q11

No → Outside of remit

Primary purpose of application cannot be for care and treatment in relation to specific individuals (s.251(6)).

Applicants should map out the data flow and be aware what elements cannot be considered to fall within a direct care purpose.

11. Is the activity compliant with the Data Protection Act 1998?

Yes → Q12

No → Advised to address this before submit an application

- Regulations under section 251 cannot make provisions for or in connection with the processing of patient identifiable information in a manner inconsistent with any provision under the Data Protection Act 1998.
- Applicants must demonstrate compliance with the Data Protection Act 1998 as this is a mandatory requirement of any support.
- If you are planning to process deceased patient identifiable information please note that it is generally accepted by the Department of Health and the GMC that the duty of confidentiality extends after death. Remember that the processing of deceased persons information requires a legal basis, such as through obtaining support.

If your activity satisfies the legal requirements above, please consider questions 12 to 14

12. Is applicant linking to other, non-NHS data sources?

Yes → Applicant to establish legal basis for accessing non-NHS data before submitting application

No → Q13

The CAG cannot advise support if the legal basis for onward linkages is unknown. The application should make clear under what basis other data sources will be obtained.

Applicants are also advised that they should make very clear what elements of the application they are seeking support for.

13. Is there evidence of proportionate patient and public involvement in the development of the study?

Yes → Q14

No → You are advised to address this before submit an application, or clearly set out concrete plans

Patient and Public Involvement:

Accessing confidential patient/service user information is a privilege. Whatever the purpose of your application, you should be able to demonstrate that you have specifically tested the views of patients or public on the use of their health information without consent, where this is feasible.

In particular, the CAG will look to see what changes have been made as a result of this involvement. If no involvement has yet taken place, the applicant should set out their plans, and note that if approved, they will typically be expected to provide clear details in their annual review to avoid jeopardising the status of the support

14. Is there a mechanism in place to ensure the relevant population are informed of the activity, and opportunity given for patients to register an objection

Q15

You are advised to address this before submit an application, or clearly set out concrete plans

Principle of patient notification:

The CAG follows the National Data Guardian approach to no surprises'. Where support is provided, this means information can be processed without consent. However, applicants will be asked to address how will they make these patients/service users aware that the activity is taking place, and how they can make an objection if they wish.

Applicants should consider what opportunities may exist to inform these patients where possible.

15. Support is intended to be a temporary measure where feasible. Have you considered an exit strategy when you will no longer need support?

You are advised to consider exit strategy before submitting an application.

Exit Strategy:

You will have to consider measures which will allow you to carry out your activity not using identifiable information without consent. For example, seeking consent from patients or using de-identified data. You will need to explain in your application how you have considered an exit strategy.

If you are now eligible to proceed, you should now consider which route your application should take, either to a full CAG meeting or via precedent-set review. Please review the precedent set criteria document on the website, and follow the booking process in order to complete your submission. You may also wish to use our pre-application assessment service – further details are available on the website. Queries on this document should be sent directly to HRA.CAG@nhs.net