Am I advised to apply to the NIGB ECC?

Please go through the questions below which will help you to find out whether or not you are advised to submit an application to the NIGB ECC.

1. Do you require ***Patient Identifiable Information***?

YES → Q2

NO → No need to submit application

Patient Identifiable Information:

- Confidential patient information is identifiable based on required information and other information that is held* or likely to be held by the applicant;
- Contextually driven consideration. Case by case consideration.
- Need to see entirety of dataset being requested and interaction with other datasets held by you.
- Obvious identifiers are name, address, postcode, date of birth, date of death and NHS Number. The combination of data items can sometimes result in the information becoming identifiable. If you are not sure you can contact the NIGB Office for advice.

*If you hold patient identifiable information you will have to explain in your application the legal basis which provide you with a legitimate legal right to hold this information.

2. Is it within England and Wales?

YES → Q3

NO → Outside remit of NIGB

If you intend to use patient identifiable information from Scotland or Northern Ireland then you should contact the relevant privacy advisory committee.

Scotland:
http://www.nhsnss.org/pages/corporate privacy_advisory_committee.php

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

3. Who is accessing/processing the data – are they outside the ***Care Team***?

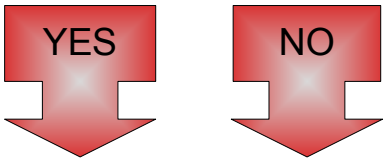
YES → Q4

NO → Check whether de-identified data only being provided/ extracted

Care Team:

The care team refers to health professionals involved in the diagnosis, treatment or care of a patient. This includes pathology and radiology staff whose activities directly support the care of the patient even though usually they have no contact with the patient. A staff member, who is not involved in the direct delivery of care, who is brought in just to carry out a research activity is not considered a member of the care team and so a recommendation of support under the Health Service (Control of Patient Information) Regulations 2002 would be required for this person to access identifiable information. Members of a care team accessing the records of a patient under the care of another care team, who they are not directly treating, would also require a recommendation of support.

4. Can a different methodology be used to prevent the need for ECC recommendation of support?

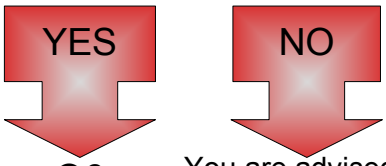


You are advised to pursue different methodology as an application to the NIGB ECC should be your last resort

Q5

5. Is the activity research, audit, service evaluation, surveillance or screening?

5.1 If research, does it have ***REC Approval***?

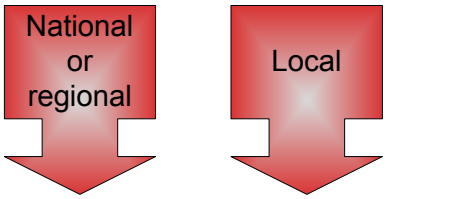


Q6

You are advised to apply for a REC and progress with ECC, however final ECC recommendation is subject to REC favourable opinion

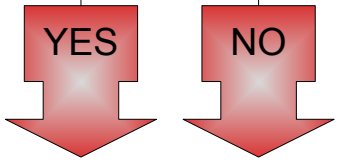
For more information about REC approval please visit the National Research Ethics Service (NRES) website, http://www.nres.nhs.uk/

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



Q6

Does it involve a third party?



Q6

No need to submit an application

An application to the ECC 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 and 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 ECC will be advised. The ECC expects to see national audits make reasonable attempts to seek consent and involve patients and service users, where identifiable data is needed.

If your responses to questions above indicate that you still need to apply to NIGB, you will have to satisfy the legal requirements established in section 251 of the NHS Act 2006.
Questions 6 to 11 reflect the minimum legal criteria set out in legislation ('legal showstoppers'):

6. Is it for a medical purpose?

YES → Q7

NO → Outside remit of s.251

- Must be a medical purpose as stated within s.251(1)
- Specified categories s.251(12)(a)): Preventative medicine, medical diagnosis, medical research, the provision of care and treatment, management of health and social care services.

7. Can consent be reasonably sought? Is it possible and practicable in resource terms 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 Committee will have to be satisfied, based on evidence, that seeking consent is not possible and 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))

9. Can ***pseudonymised/ anonymised data be used***?

YES → You are advised to use pseudo/ anonymised data

NO → Q10

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

The Committee will have to be satisfied, based on evidence, that the use of de-identified data (anonymised or pseudonymised data) cannot satisfy the purpose of the activity.

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

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

YES → Q11

NO → No need to submit application

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

- 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***.
- Minimum threshold to be met in s.251(7) of the NHS Act 2006.
- If you are planning to process deceased patient identifiable information please note that the duty of confidentiality extends after death (Bluck v Information Commissioner and Epsom and St Helier University NHS Trust). Whilst the DPA only applies to personal information of living individuals, the Committee would expect that the DPA principles are applied and respected when processing deceased patient identifiable information.

YES → Q12

NO → Advised to address this before submit an application

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

12. Is applicant linking to non-NHS data?

ECC cannot advise support if legal basis for onward linkages is unknown.

YES → Applicant to establish legal basis for accessing non-NHS data before making application to ECC

NO → Q13

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

Patient and Public Involvement:

Whatever the purpose of your application, you must be able to demonstrate that you have specifically tested the views of patients or public on the use of their health information without consent. You are required to include as part of this participation: the justification of each data item, the impracticality of seeking consent and how the public interest is served. Please then summarise in your application what patients' views were on not seeking this consent.

The ECC will be unable to provide a favourable recommendation of support without this.

14. An ECC favourable recommendation of support is a temporary measure to access patient identifiable information without consent. Have you considered an ***exit strategy*** when you will no longer need ECC support?

YES → Q15

NO → 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 patient 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 need to consider which route your application should take, either to full Committee or proportionate review. The route the application will take will be determined by the NIGB Office during validation 1 (see high level process). Question 15 is designed to make you familiar with the criteria.

15. Does the application satisfy **proportionate review criteria**?

YES → Following Validation 1, you will likely take the proportionate review route

NO → Following Validation 1, you will likely take the full Committee route

If after this self-assessment you conclude that you are advised to submit an application to the NIGB ECC please complete an application on the Integrated Research Application System – IRAS (https://www.myresearchproject.org.uk/) if your activity is research.

For non – research applications (audit or service evaluation) please complete a section 251 form available on http://www.nigb.nhs.uk/s251/howtoapply

If you are not sure whether or not you are advised to submit an application to the NIGB ECC please contact the NIGB Office by email, eccapplications@nhs.net or by telephone 0207 004 1539.