

## Ethical approval

The National Records of Scotland (NRS) needs to justify any release of data either under a public interest argument or under legislation. Legislative cover can for example be provided by [The Health Act 1999](#) (for work commissioned by the Secretary of State for Health). Approval by an ethics committee ensures that the study is not against the public interest.

To apply for ethical approval please visit the [National Research Ethics Services](#) web site and follow the instructions. This replaces the previous COREC web page.

A [NHS Research Ethics Committee](#) must approve studies involving the use of NHS data, including:

- patient names, date of birth, etc;
- National Health Service (NHS) numbers;
- cancer registrations; and
- health authority information.

Formal ethical approval is not required for:

- audit studies of a consultant's own patients; and
- research studies that do not use NHS data, e.g. data extracts from registration databases.

However, the Research Ethics committee's opinion on whether the study is ethical is very helpful and may speed up the application process.

A grey area exists for audits including patients other than the researcher's own. Obtaining ethical approval may not be possible for audits of this type. Cases such as these are referred to the Advisory Group for Medical Research for consideration during the Office for National Statistics (ONS) application process.

Any study requesting cancer information must have a medically qualified person, fully registered with the General Medical Council (GMC) on the project team who agrees to take clinical responsibility for the cancer registration and NHS data supplied. This requirement is in order to ensure clinical accountability.