Is ethical approval required from my Ethics Committee?

(an example flow chart setting out New Zealand ethics requirements)

Does the project involve contacting patients, clients, volunteers or the use of any stored samples/tissue?

if Yes, ethical approval required

Exception: questionnaires or surveys that do not involve the collection or use of confidential or sensitive personal health information (for example, patient satisfaction surveys) [Operational Standard 4.0 134 (i)*]

If No:

Is new information/data being collected only for the purposes of the project?

if Yes, ethical approval required

Exceptions: (i) observational studies in public places in which the identity of the participants remains anonymous. [OS 4.0 134 (iii)]

(ii) research utilising existing publicly available documents or data (for example, analysis of archival records that are publicly available, analysis of any information or data gained by a request under the Official Information Act 1982) [O S 4.0 134(ii)]

If No:

Is identifiable data being collected by people other than those of the team directly responsible for the provision of the service/clinical care or under their supervision?

if Yes, ethical approval required

If No:

Is the purpose of the project <u>more</u> than an investigation into whether an activity meets explicit standards as defined in an auditing document, for the purpose of checking and improving the activity being audited?

if Yes, ethical approval required

If No:

This is an audit as defined by the Operational Standard for Ethics Committees in New Zealand, March 2002 and as such does <u>not</u> require ethical approval.

All information must be recorded in a non-identifiable manner and any report must not identify any individual.

N.B. If the results <u>may be published</u>, a letter from an ethics committee confirming that the project is an audit which does not require ethical approval should be obtained <u>before</u> commencing the project.

If you have any queries, please contact the Administrator of your local Ethics Committee

^{*} The Operational Standard for Ethics Committees in New Zealand was published in March 2002.