

Guide to complete the ADHB Observational Research Review Form

Section A: General Summary

- If the project has been submitted to an Ethics Committee for expedited review, circle which Ethics Committee.
- Complete relevant details for study title and contact details.
- If ongoing communication regarding this application is not with the Principal investigator (i.e. coordinator or co-investigator) include their details.
- If you are not an ADHB employee, you must have enlisted an ADHB person who will act as your contact at the ADHB on your behalf. They must agree to this role and put their contact details and sign in this section.
- If the ADHB contact person is also the clinical director of the department/service where the research is to be undertaken, Section B will require the signature of the person the clinical director reports to, e.g. clinical leader / medical director.
- For student projects (summer, masters and doctoral), please provide name of ADHB clinical supervisor.

Section B: Study Design

- Briefly describe the study aims, purpose, methods. This should be a brief succinct summary from your study proposal. Please ensure a copy of your full proposal/design is attached with your application.
- If there is no budget for this Observational Research or Audit, briefly describe the reason and clearly explain why there will not be any impact on the ADHB resources. For example, patient visits will be incorporated into their standard clinic visit; chart review will be undertaken in non- clinic time, etc.
- Only the Clinical Director (or Nurse Manager or Clinical Leader) is required to sign for Observational Research or Audit with no costs.
- If the Principal Investigator is also the clinical director of the department/service where the research is to be undertaken, signature of the person the clinical director reports to is required, e.g. clinical leader / medical director.
- If research is to be undertaken by more than one department obtain extra signatures as appropriate.

If your study has costs and revenue, i.e. non-standard work or extra consumables are part of the study, complete section C, and a budget must be provided (using the template http://www.adhb.govt.nz/ResearchOffice/Budget/develop_a_budget.htm):

Section C: Financial

- The Clinical Director (or Nurse Manager or Clinical Leader), Service Accountant and Service Manager must sign.

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- The budget must clearly identify all costs and revenue sources. Please use footers/notes if you think an explanation attached to a cost would be advantageous to the budget being clearly understood.
- It is essential that you clearly describe what standard work is and what the research elements are. Failure to do so may mean your study is delayed due to the need for further clarification.
- If you are applying for funding please indicate when you are likely to receive notification. A copy of the funding approval letter is required before formal approval to begin can be issued.
- If your study crosses disciplines or service areas (e.g. Children Oncology and Adult Oncology) then obtain the signatures of all relevant persons for each service.

Acceptable Replacements to Signatures

- E-mails from the relevant people confirming agreement/approval for your project are acceptable pseudo signature formats. It is essential that the study number and title are included on the e-mail to ensure the approval is allocated to the correct project.
- Electronic signatures are acceptable.