



Research Governance Requirement for Neonatology Research Projects

All applications for site approval must be submitted via the [Research Governance Service \(RGS\)](#).

When does a neonatology project require site approval from CAHS?

ALL research projects concerning the department of neonatology that involve at least one of the following **MUST** apply to the CAHS Research Governance Office (RGO) for site approval.

- Patients
- Staff
- Data (incl Neobase)
- Facilities

When does a neonatology project require site approval from WNHS and CAHS?

In addition to the application for site authorisation from CAHS, an application **MUST** be made to KEMH RGO when:

- Participants will be recruited prior to or at the birth at KEMH
- An element of the project will occur in KEMH; “outside” of neonatology, for example in the delivery room or outpatient clinics
- The project will involve staff that are employed by WNHS
- The project involves access to data, including medical records (either maternal or child), held by WNHS

How do I choose which forms are to be used to apply for site approval?

Most applications for site approval will require the submission of a **Site Specific Application (SSA) Form and budget**. In certain circumstances (see below) the application for site approval need only involve an **Access Request Form (ARF)** instead of a SSA and Budget.

An ARF can be used to apply for site approval at a particular site when the **ONLY** research activity **AT THAT SITE** will be one or other of the following:

- participant recruitment will occur through posters, leaflets, handouts, letters of invitation (but not recruitment through direct contact with potential participants or enrolment)
- distribution of surveys and questionnaires through personnel of the Health Service (but not collation and analysis of responses at the Health Service); or
- access to data or tissue held at the Health Service (but not processing or analysis at that Health Service)

In all other scenarios a SSA and budget must be completed. If you have any doubts about the appropriate form to use contact:

CAHS.RESEARCSUPPORT@health.wa.gov.au or
ResearchGovernanceOffice.KEMH@health.wa.gov.au

Signatories Required for Site Authorisation Applications

Researchers are responsible for identifying the individual who holds the role listed below*.

Signatories for the Site Specific Application Form

The **Divisional Director** with responsibility for the department where the research is being conducted.

For projects where neonatology is co-ordinating the project it will be the Divisional Director of Neonatology who signs the SSA, and:

- At CAHS, the **Finance Business Officer** with responsibility for research
- At KEMH, the **Finance Business Officer** with responsibility for that Department

Signatories for the Budget

The budget should be signed by the **Head of Department (HoD)** of the department which is conducting the project (the research department) and the HoDs who have agreed to support your project.

Signatories for an Access Request Form

If the project involves accessing a department to put up posters, distribute leaflets or hand out surveys to staff then the **Head of Department** for the department involved should sign the Access Request Form.

If the project involves accessing a data base then the **Data Custodian** for that data base should sign the Access Request Form. This information is available here: [HDWA Data Collections Registry](#).

What to do if the appropriate signatory is a member of the research team?

If the HoD or the Divisional Director of a particular department are members of the research team then the appropriate signatory is the position to which they report.

For example; if the HoD is an investigator on the project then the budget must be authorised by the Divisional Director with responsibility for that particular department. If the Divisional Director is an investigator on the project then the SSA should be authorised by the Executive Director to whom they report. If both the HoD and the Divisional Director are investigators on the project then the appropriate authority to sign the budget and the SSA is the Executive Director.

*People move on and take leave etc. and it is impossible to coordinate and maintain a listing of names centrally. It is therefore prudent to seek advice on the name of the individual required to sign off a particular form directly from the department concerned. If that fails, you can contact CAHS.RESEARCHSUPPORT@health.wa.gov.au for assistance with submissions to CAHS or kemh.rgo@health.wa.gov.au for submissions to WNHS. However, the departments concerned are in a better position to advise who it is that currently holds a particular role than either of the research governance offices.

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Neonatology projects

The project involves patients, staff, data and/or facilities that are part of the Neonatology Dept.

The project involves patients, staff, data and/or facilities that are outside the Neonatology Dept.

Submit to **CAHS** (PCH) Research Governance Office

Submit to **WNHS** (KEMH) Research Governance Office

Submit to both RGOs if appropriate

Which forms should I use?

Research activity at the site involves any of the following:

- Staff
- Recruitment of participants
- Direct contact with patients
- Analysis of data and/or biospecimens
- Use of facilities

Submit an **SSA and Budget form** to that site

Research activity at the site is limited to:

- The distribution of surveys
- The display of posters or leaflets
- Accessing data or biospecimens held at the site

Submit an **Access Request form** to that site – contact relevant RGO