



Affiliated Health Organisations

What is an Affiliated Health Organisation (AHO)?

AHOs are Organisations that have a legal definition under the [Health Services Act 1997 - section 13](#) but put simply they are Hospitals that are not for profit and treated as part of the public system.

In the context of Research an AHO can be approved as a NSW Health Site by any Lead HREC.

Currently there are two AHO's that are specifically listed in REGIS;

- St Vincent's Hospital Network (Ethics and Sites)
- Calvary Mater Newcastle (Site)

Both of these sites are extremely active in Clinical Trials and Medical Research and have established Research Offices and Governance processes.

Additional AHO's may be added into REGIS in the future.

What does this mean for Ethics?

The St Vincent's Hospital Network is a recognised HREC and can review human research applications under National Mutual Acceptance (NMA)

An AHO can be reviewed by any lead HREC and Ethics approval offered in the same way of any other NSW PHO/SHN and they are listed on the approval letter.

What does this mean for Governance?

The AHOs listed above as active in REGIS must manage their governance applications in REGIS. Any other AHO will manage their governance applications through their own processes.

AHOs not active in REGIS should be treated like any other external to REGIS site, with all Ethics documentation being forwarded from the lead site team to the local team.

How does this work in REGIS?

Project Registration

During the initial submission of a study in REGIS any AHOs participating should be listed in Part C of the Project Registration.

AHOs active in REGIS are selected in the "NSW Health" tab.

Selecting the Project Centre and Project Site in this tab will ensure the STE/SSA is created in REGIS and the PI will receive a system automated email when the application is ready to complete.

The screenshot shows the 'Project Registration' form with three tabs: 'ACT Health', 'NSW Health' (highlighted in red), and 'Other health jurisdictions or organisations'. The 'Project Centre' dropdown is set to 'St Vincent's Health Network'. The 'Project Site' dropdown is open, showing search results for 'St Joseph's Hospital' and 'St Vincent's Health Sydney'. The 'Principal Investigator email (REGIS username)' field is empty. There is a section for 'Other team members' which is partially obscured by a black bar.

AHOs not active in REGIS are selected in the "Other health jurisdictions or organisations" tab. No STE/SSA is created. By adding the site details here a complete listed is prefilled in the Internal Portal for the reviewing Research Office to allow them to track all sites under their review.

The screenshot shows the 'Project Registration' form with three tabs: 'ACT Health', 'NSW Health', and 'Other health jurisdictions or organisations' (highlighted in red). The 'State / Jurisdiction' dropdown is set to 'New South Wales'. The 'Project Site' dropdown is open, showing the text 'Other AHOs listed here'.

The screenshot shows the application details page for '2022/ETH00087 - AHOs in REGIS'. The 'External sites' section is active, showing a table with one entry. The table has columns for 'Order', 'State', 'Site', and 'Principal Investigator'. The entry is: Order 1, State New South Wales, Site Other AHOs listed here, Principal Investigator K/le Becker. There are also '+ Add' and 'Bulk Update' buttons above the table.

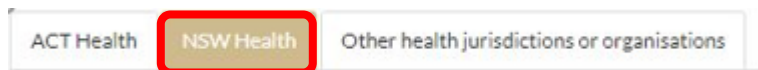
Order	State	Site	Principal Investigator
1	New South Wales	Other AHOs listed here	K/le Becker

Post Approval Activity

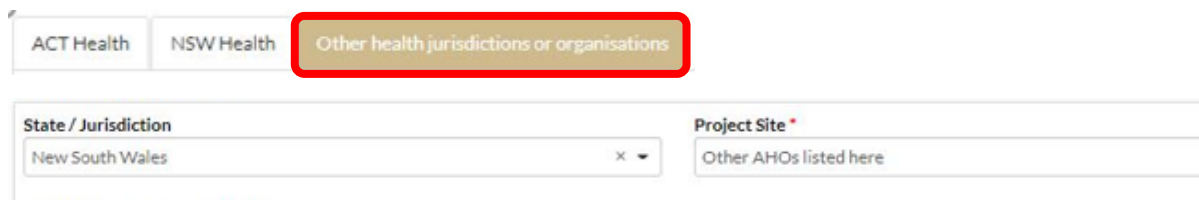
Amendment – Addition of Site

AHOs active in REGIS are selected in the “NSW Health” tab.

Selecting the Project Centre and Project Site in this tab will ensure the STE/SSA is created in REGIS and the PI will receive a system automated email when the applicatino is ready to complete.



AHOs not active in REGIS are selected in the “Other heath jurisdictions or ogranisations” tab. No STE/SSA is created.



Milestone – Annual Reports

AHOs active in REGIS will automatically appear on Table 1 or 2, depending on where they are in the lifecycle of the study.

AHOs not active in REGIS are required to be manually entered into Table 3.

HREC Approved Sites

Table 1: REGIS Authorised Sites. This table will pre-fill all NSW site applications that have been authorised in REGIS.

Table 2: Other REGIS Sites. This table will pre-fill all submitted NSW sites applications that are in REGIS but are not yet approved

Table 3: Sites External to REGIS. You will need to manually create this table to list all other HREC approved sites.

If a NSW Site is not appearing table 1 or 2, you may need to submit a Notification of Amendment - addition of site.

If a Principal Investigator is incorrectly listed in table 1 you will need to submit a Notification of Amendment - Change PI/CPI.

REGIS Authorised Sites

Project Identifier	Site	Status	Principal Investigator	Date Authorised
2022/STEO0169	Calvary Mater Newcastle Hospital	Authorised	Kylie Becker	26/09/2022

Other REGIS Sites

Application Identifier	Site	Status	Principal Investigator
2022/STEO0170	St Vincent's Health Sydney	Submitted	Emeritus Professor Kylie Becker

Sites External to REGIS

Sites external to REGIS include any other sites not listed in the above 2 tables. This includes sites from other states/jurisdictions approved under NMA (VIC, SA, QLD, WA), private sites, University sites or NSW sites not included in REGIS. You can add more rows by clicking on the "Add Another" button at the bottom of this table.

Site Identifier	Site	Status	Principal Investigator
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

[+ Add Another](#)

AHO’s that show in Table 1 will have a site specific section appear the “Recruitment/Data/Samples – NSW Site Specific Recruitment” section of the Progress Report form to be completed.

Depending on the study type questions will be shown or hidden. E.g. a clinical trial will have more questions appear.

NSW Site Specific Recruitment

This section relates to **NSW authorised sites only**.

NSW now requires a single, state wide annual report form for Ethics and Governance reporting. **This section must be completed** at the time of completing the form to be submitted to the HREC. Each site identified as a REGIS Authorised site in the Project Details section of the form will pre-fill here.

A lead site can collect this information and entre on behalf of each site OR the ETH project can be shared with site users to allow them to entre their own data. See quick reference guide [Sharing access to an application/project](#)

REGIS Authorised Sites

Project Identifier	Site	Principal Investigator	Planned Recruitment *	Actual Recruitment *
2022/STE00169	Calvary Mater Newcastle Hospital	Kylie Becker	<input type="text"/>	<input type="text"/>

On HREC approval of the Annual Report a copy of the report is automatically forwarded to each of the listed Site RGOs, this includes AHO's active in REGIS.

This form is being submitted to the reviewing HREC. Once the HREC has reviewed and noted this report it will be automatically provided to each authorised site listed in REGIS (see Project Details, HREC approved sites, table 1).

A copy of the annual report should be manually forwarded to any sites not active in REGIS/listed in Table 3.

<https://regis.health.nsw.gov.au/content-resources/>

HEALTH SERVICES ACT 1997 - SECT 13**13 What is an affiliated health organisation?**

(1) An

"**affiliated health organisation**" is an organisation or institution that is an affiliated health organisation under [section 62](#).

(2) An organisation or institution is an affiliated health organisation only in relation to any of its recognised establishments or recognised services.

Note : The Dictionary defines a "**recognised establishment**" of an affiliated health organisation to mean a hospital or health institution of the organisation that is listed in column 2 of Schedule 3 next to its name. It also defines a "**recognised service**" of an affiliated health organisation to mean a health service or health support service of the organisation that is listed in column 2 of Schedule 3 next to its name.

(3) The principal reason for recognising affiliated health organisations is to enable certain non-profit, religious, charitable or other non-government organisations and institutions to be treated as part of the public health system where they control hospitals, health institutions, health services or health support services that significantly contribute to the operation of that system.

Note : Affiliated health organisations are intended to replace the system of separate institutions and associated organisations recognised under Part 5AA and section 29B(1)(a) of the *Public Hospitals Act 1929*, respectively.

HEALTH SERVICES ACT 1997 - SECT 62**62 Recognition of affiliated health organisations**

(cf PH Act s 29B)

(1) An organisation or institution whose name is included in column 1 of Schedule 3 is an affiliated health organisation in respect of any of its recognised establishments and recognised services.

(2) The Governor may, by order published on the NSW legislation website--

(a) amend column 1 of Schedule 3 by inserting the name of any organisation or institution (other than a local health district or statutory health corporation) that controls any hospital, health institution, health service or health support service, or

(b) amend column 2 of Schedule 3 by inserting a description of any hospital, health institution, health service or health support service under the control of the organisation or institution, or

(c) amend Schedule 3 by omitting or altering any such name or description, or

(d) omit Schedule 3 and insert instead a Schedule containing the names of any organisations or institutions (other than local health districts or statutory health corporations) and descriptions of any hospital, health institution, health service or health support service under their control.

(3) An order made under subsection (2) may amend column 2 of Schedule 3 to describe an organisation or institution by reference to some or all of the hospitals, health institutions, health services or health support services it controls.

(4) An order cannot be made under this section--

(a) inserting or altering the name of an organisation or institution in column 1 of Schedule 3 unless the organisation or institution (or its governing body) consents to it, or

(b) inserting or altering a description of any hospital, health institution, health service or health support service under the control of an organisation or institution in column 2 of Schedule 3 unless the organisation or institution (or its governing body) consents to it.

(5) In this section, "**governing body**" of an organisation or institution means the person or the board or other body that is responsible for the management of the organisation or institution.

HEALTH SERVICES ACT 1997 - SCHEDULE 3

Column 1	Column 2
Name of organisation	Recognised establishment or recognised service
Benevolent Society of New South Wales	Central Sydney Scarba Services. Early Intervention Program. Eastern Sydney Scarba Services. South West Sydney Scarba Services.
Calvary Health Care (Newcastle) Limited	Calvary Mater Newcastle
Calvary Health Care Sydney Limited	Calvary Health Care Sydney.
Catholic Healthcare Limited	St Vincent's Health Service, Bathurst. Lourdes Hospital and Community Health Service (other than Holy Spirit Dubbo).
Hammondcare Health and Hospitals Limited	Braeside Hospital, Prairiewood. Greenwich Hospital, Greenwich. Neringah Hospital, Wahrenonga. Northern Beaches Palliative Care Service.
Karitane	Child and Family health services at Carramar, Fairfield, Liverpool and Randwick.
Mercy Hospitals NSW Ltd	Mercy Care Centre: Young, excluding Mount St Joseph's Nursing Home. Mercy Health Service Albury.
NSW Service for the Treatment and Rehabilitation of Torture and Trauma Survivors (STARTTS)	NSW Service for the Treatment and Rehabilitation of Torture and Trauma Survivors (STARTTS)
Royal Rehab	General rehabilitation services. Brain injury rehabilitation services. Spinal injury rehabilitation services. Extended care services.
Royal Society for the Welfare of Mothers and Babies	Tresillian Family Care Centres at Belmore, Broken Hill, Coffs Harbour, Dubbo, Lismore, Penrith, Queanbeyan, Taree, Willoughby and Wollstonecraft.
St Vincent's Hospital Sydney Limited	Sacred Heart Health Service. St Joseph's Hospital (Auburn). St Vincent's Hospital, Darlinghurst.
Stewart House	Child health screening services at Stewart House Preventorium, Curl Curl.
The College of Nursing	Nursing Education Programs conducted under agreement with the NSW Ministry of Health.
Uniting Church in Australia	War Memorial Hospital (Waverley).

This legislation information was correct at the time of publishing (Nov 22)

<https://legislation.nsw.gov.au/view/html/inforce/current/act-1997-154>