COVID-19 Register Project Proposal

(last updated November 2023)

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# Version history

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| **Version** | **Description of changes** | **Date** |
| 1.0 | -  | November 2022 |
| 2.0 | New questions and new data sources added. Updated Figure 1 on data access flowchart for clarity. Added an Appendix 2 on the proposal review process and details on additional approvals that may be required. | October 2023 |
| 3.0 | Clarified ethics requirements in Appendix 2 (NSW PHSREC approval as a sub-study)  | November 2023 |

# Instructions

**Complete this form to apply for access to COVID-19 Register for your project**

* Email covid19register@aihw.gov.au for help with your project proposal.
* The AIHW and relevant data custodians will assess your completed project proposal and contact you if we have any questions.
* The AIHW uses the internationally recognised [Five Safes Framework](https://www.aihw.gov.au/about-our-data/data-governance/the-five-safes-framework) for managing the safe release of data. The information provided in this form contributes to this risk assessment. The Five Safes are the basis of the Data Sharing Principles published by the Office of the National Data Commissioner in 2019 to guide safe sharing of Commonwealth data.
* All access to data must be consistent with the requirements of the data custodian and AIHW’s legislative framework, including the [*Australian Institute of Health and Welfare Act 1987 (AIHW Act)*](https://www.legislation.gov.au/Details/C2018C00474) and conditions outlined in the COVID-19 Register terms of use ([Appendix 1)](#_Appendix_1:_National).
* Final project approval rests with the relevant data custodians.
* Any amendments to your approved project proposal (for example, if there are new researchers or new data being requested) must be made on this form as tracked changes, and then recorded in the ‘Document history’ table below. Please forward a copy of the revised proposal to covid19register@aihw.gov.au, after which AIHWwill circulate the revised proposal to the COVID-19 Register Data Advisory Group and facilitate additional ethics approvals where required, before allowing access to the COVID-19 Register.
* Please note that outputs cannot be released from the secure environment without approval. Further details on the approval processes required for output release will be provided to approved researchers during onboarding.

**Consider the following important issues when preparing your project proposal:**

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| Statistical and/or research purpose | The project purpose must be in line with the AIHW Ethics Committee approved themes of research. Refer to [Appendix 1](#_Appendix_1:_National). |
| Public interest value | The proposed research must be in the public interest and benefit. |
| Confidentiality | Research analysis and outputs must not identify an individual person or facility. |
| Data requirements | Researchers must clearly specify the data sets and reference period they require for their project. Each data set requested must be relevant to the project purpose. Other data options including aggregated data sets must have been ruled out as viable for the research purpose, and justification provided for the use of detailed data. |
| Available data must be suitable for the project | Data must be suitable and available for your research purpose. The data must be of sufficient quality for analysis, and the populations of interest / geographic granularity must be high enough, that there is a low risk of identification of individual people or facilities. |
| Ability of the research team | Only researchers listed as ‘analysing unit record data’ in section 7 of this proposal will be allowed access to the de-identified data in the secure remote environment. Researchers must have the ability to use at least one of the statistical analytical languages available in the secure remote environment (e.g., R, Python, SAS, Stata).Experience with analysis of linked data would be beneficial.Where approved researchers have access to personal identifiers and/or content data for cohort members, they must not access personal identifiers and content data at the same time for the duration of their work. |
| Secure remote environment onboarding | Researchers must complete the relevant procedures (for example onboarding procedures) prior to accessing data in the secure environment. We will be in touch with you for onboarding once your project proposal has been approved. |
| Additional approvals | Additional ethics approvals may be required depending on the type of data requested and focus of analysis. Researchers would be required to obtain such ethics approvals and to provide a copy of the approval to AIHW. Please refer to [Appendix 2](#_Appendix_2:_Proposal) for more details. |
| Email your completed project proposal to: covid19register@aihw.gov.au |

**Considerations that may affect access**

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| You should check with us first if: |
| Your research is for commercial gain. |
| The population or geographic granularity you are interested in has low numbers. |

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| Access will not be approved if: |
| Your research is about named people or named facilities. |
| You do not have the support of the organisation you work for. |
| Your research theme is not in line with the AIHW Ethics Committee Approved Uses of Data from the COVID-19 Register as specified in [Appendix 1](#_Appendix_1:_National). |

**Document history**

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| Date of change | Description of changee.g. New data/researchers added | Editor | Organisation |
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**Project ID (AIHW use only)**

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| Project details |
|  Project title *Please limit to 50 characters* |  |
| Lead organisation |  |
|  Partner organisations *If applicable, list organisations that may reasonably require access to unit record data whether for analysis or discussion* |  |
|  Additional stakeholders *If applicable, list stakeholders who only need access to aggregated outputs for analysis or discussion (not unit record data)* |  |
|  Funding source (or grant program) for the project*If the funding source is from more than one organisation, please indicate the value and percentage of funds from each organisation* | Organisation 1:Approximate Value (in AUD):Percentage of contribution:Organisation 2:Approximate Value (in AUD):Percentage of contribution: |
|  Research theme(s)  *Please select one or more*Refer to details in [Appendix 1](#_Appendix_1:_National) |  [ ]  Epidemiological or statistical research [ ]  Service use, medication dispensing and patient journeys  [ ]  Impact on groups or cohorts of interest [ ]  Monitoring, evaluation and data quality improvement [ ]  Other (please specify and contactcovid19register@aihw.gov.au) |

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| Project purpose*Please select accordingly* | Health research projects within the broad acceptable uses of the COVID-19 Register are classified into two broad groups for approval as below. Depending on the type of data requested, projects for non-government purposes may require additional ethics approvals. Researchers would be required to obtain such ethics approvals and to provide a copy of the approval to AIHW. Please refer to [Appendix 2](#_Appendix_2:_Proposal) for more details.[ ]  For **government purposes**, that is projects proposed by government to support government management of the health system (government projects), namely: * statistical analysis leading to the production of official statistics, related insights and reporting
* projects to support government management of the health system such as policy (development and evaluation) and planning
* public health monitoring, analysis, planning and evaluation

[ ]  For **non-government purposes**, that is other health research projects* other health research projects are those within the scope of the agreed purposes for the COVID-19 Register (see [Appendix 1](#_Appendix_1:_National)) that do not meet the above description for government purposes. These are expected to be initiated largely from the academic and research sectors.
 |
| First Nations Data*Please select accordingly* | The COVID-19 Register contains information about whether an individual is a First Nations person[[1]](#footnote-2). If your project has a First Nations focus, details of First Nations engagement and oversight of the project will need to be specified in the project proposal, which includes obtaining approval from a First Nations HREC. This HREC approval will be mutually recognised by jurisdictions and sufficient to cover the project approval. For this purpose, in assessing whether a project has a First Nations focus, regard should be had to ‘What is Aboriginal and Torres Strait Islander research?’, in (page 6) of the [AIATSIS Code of Ethics - for Aboriginal and Torres Strait Islander Research](https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf) (see [Appendix 2](#_Appendix_2:_Proposal) for more details).Is information about First Nations being sought for the purpose of this research project? [ ]  Yes [ ]  NoIf yes, please describe how these data are intended to be used and whether comparisons of First Nations people and other Australians/all Australians will be made in the outputs and reports: |

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| Project timeframes |
| Preferred start date for access to the COVID-19 Register |  |
| Estimated end date for access to the COVID-19 Register |  |
| Planned delivery date(s) for anticipated outputs from your proposed project |  |
| Outline any dependencies or important dates that may affect your project proposal |  |

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| High level project summary |
| Write a short paragraph summarising your proposed project. Include the purpose of the project and the anticipated outcomes.**Note**: this summary may be made available on the project register on the AIHW website. *Please limit to 75 words.* |
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| Research objective and data required |
| **4.1 Project objectives**Elaborate on your project summary, including:* the specific research question/s to be investigated and intended contribution to the field
* how the project purpose is research and/or statistical in nature
* how the project purpose relates to the research themes approved under the COVID-19 Register project (see [Appendix 1](#_Appendix_1:_National)).

*Please limit to 200 words* |
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| **4.2 Research methodology and data analysis plan**Full data specifications are requested in Section 6. To help us evaluate the feasibility of this project, describe the research methodology and design, including: * key variables of interest
* cohort for analysis
* size of the population/s
* geographic area/s of interest
* statistical methods you plan to use
* description of how the project purpose relates to the data sets requested in section 6.
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| Consultation |
| Indicate whether you have undertaken (or plan to undertake) consultation with any relevant organisations or representative groups to seek community views on the proposed project. Please provide a list of the groups (for example, the name of the advisory group) who you plan to consult with. Please note any planned ongoing involvements of these groups throughout the life of the project. If your project has a First Nations focus, please also provide details of all planned engagement and consultations with advisors who can support the appropriate and sensitive reporting of data in relation to the First Nations population.Non-exhaustive list of examples of how community expectations around the project are being considered:* consultation with key stakeholders or client group representatives, for example via working groups or advisory groups
* public engagement such as broad public consultations
* use of focus groups
* engagement with expert groups
* information from engagement events for similar projects
* government initiatives
* public polls
* literature reviews.
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| Data specifications |
| Select the data you need to answer your research question(s). AIHW will be in contact to discuss your data specifications and timing requirements in more detail following submission of this proposal if necessary. |
| Note:* This information is used when seeking advice or approvals from data custodians, where appropriate.
* **Changes to data specifications after a project is approved may require additional approvals and delay access.**
* Each data set requested must be relevant to the project purpose. Ensure the ‘Data required’ section above clearly describes how the project purpose relates to each data set requested below.
 |
| **How to complete this section**Step 1: Use the [data variable list](https://www.aihw.gov.au/reports-data/covid-linked-data-set/resources-for-researchers). This is very important as there are different time periods and geographies available for different datasets.Step 2: Review the files to determine which data items best suit your needs.Step 3: Make your selection from the options below, or if preferred, indicate that a separate spreadsheet has been attached. |
| I have attached a spreadsheet detailing specific data specifications for this project: [ ]  Yes [ ]  No (detail below) |

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| **Data set** | **Reference period** | **Geography** |
| [ ]  All items *(do not fill this table out any further)* | [ ]  **2015**  [ ]  **2016**  [ ]  **2017**  [ ]  **2018**  [ ]  **2019**  [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  Medicare Consumer Directory *(derived fields)* | **N/A** | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  Medicare Benefits Schedule | [ ]  **2015**  [ ]  **2016**  [ ]  **2017**  [ ]  **2018**  [ ]  **2019**  [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  Pharmaceutical Benefits Scheme | [ ]  **2015**  [ ]  **2016**  [ ]  **2017**  [ ]  **2018**  [ ]  **2019**  [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  Australian Immunisation Register  | [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  National Death Index  | [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  National Hospitals Morbidity Database  | [ ]  **2015-16**  [ ]  **2016-17**  [ ]  **2017-18**[ ]  **2018-19**  [ ]  **2019-20**  [ ]  **2020-21**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  National Non-Admitted Patient Emergency Department Care Database  | [ ]  **2015-16**  [ ]  **2016-17**  [ ]  **2017-18**[ ]  **2018-19**  [ ]  **2019-20**  [ ]  **2020-21**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  National Public Hospitals Establishment  | [ ]  **2015-16**  [ ]  **2016-17**  [ ]  **2017-18**[ ]  **2018-19**  [ ]  **2019-20**  [ ]  **2020-21**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  National Aged Care Data Clearinghouse  | [ ]  **2015**  [ ]  **2016**  [ ]  **2017**  [ ]  **2018**  [ ]  **2019**  [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [x]  Specific state/territory (specify which ones):  |
| [ ]  National Notifiable Diseases Surveillance System  | [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  Notifiable Diseases Register *(a file with linked and unlinked case IDs with linkage quality flags- does not contain any information on the infection)*  | **N/A** | [ ]  National [ ]  Specific state/territory (specify which ones):  |
| [ ]  Australian New Zealand Intensive Care Survey (ANZICS) Adult Patient Database (APD) | [ ]  **2015**  [ ]  **2016**  [ ]  **2017**  [ ]  **2018**  [ ]  **2019**  [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones): |
| [ ]  Australian and New Zealand Paediatric Intensive Care Registry (ANZPICR) | [ ]  **2015**  [ ]  **2016**  [ ]  **2017**  [ ]  **2018**  [ ]  **2019**  [ ]  **2020**  [ ]  **2021**  [ ]  **2022**  [ ]  **Most recent available**   | [ ]  National [ ]  Specific state/territory (specify which ones): |

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|  | Project team member(s) |
| Provide details of all the researchers on this project and note who will work directly with unit record data for this project. Only researchers listed as ‘analysing unit record data’ in this section will be allowed access to the de-identified data in the secure remote environment. Researchers accessing unit record data agree to adhere to the principles of separation in regard to not accessing personal identifiers and content data at the same time for the duration of their work and complete onboarding requirements. All researchers who will access the de-identified research data are required to submit an *Australian Institute of Health and Welfare Act 1987 s29* [Undertaking of Confidentiality form](https://www.aihw.gov.au/reports-data/covid-linked-data-set/resources-for-researchers). Project team members must not circulate any data from this project outside their project team without discussing this with AIHW project staff. List any organisations that may reasonably require access to data over the course of the project. Note that relevant AIHW business units (for example the COVID-19 Register team, Data linkage team, ICT staff) and AIHW senior executives can discuss and view any data/output generated from the project, for the purpose of reviewing outputs or for providing subject-matter expertise and/or technical support. All staff at AIHW complete an *Australian Institute of Health and Welfare Act 1987 s29* Undertaking of Confidentiality form on appointment at AIHW.Please indicate whether any of the researchers listed below is a student. Please declare any general competing interests, for example if the investigator is employed by an institution that has a financial interest in the results. |
| Name | Relevant qualifications/ experience(1–2 sentences) | Organisation | Email | Phone | Project role(Project lead, analyst, discussant) | Analysing unit recorddata? (Y/N) | Signed s29? (Y/N) | Position title in organisation | Competing interest? (Y/N) |
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| **7.** | **Project team member(s)** *(continued)* |
| Name | Relevant qualifications/ experience(1–2 sentences) | Organisation | Email | Phone | Project role(Project lead, analyst, discussant) | Analysing unit recorddata? (Y/N) | Signed s29? (Y/N) | Position title in organisation | Competing interest? (Y/N) |
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| Anticipated outputs and dissemination methods |
| * Researchers must comply with rules of linked data access and release set out in [Appendix 1](#_Appendix_1:_National).
* Researchers must provide written notice to the AIHW of any pending publication of work from this project, including presentations at academic conferences or journal articles. This must be provided with sufficient time before publication as any publication in the public domain must be reviewed by data custodians prior to release. A citation of your work will be added to the short online description of your project once your work is published in the public domain.
 |
| **Outputs** |
| * Outline anticipated outputs of your proposed project. For example, derived aggregate data items (such as geospatial aggregates), aggregated tables, indexes, new methodology, risk estimates or effect sizes from statistical models.
* Elaborate on the granularity of your results (for example, the level of geography and sub-populations). Note: Unit record data cannot be egressed or taken out from the secure remote environment.
* Please indicate whether jurisdictions or individual entities (for example, hospitals) will be identified in the outputs and reports, if yes, please specify details on what will be presented.
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| **Dissemination methods** |
| Outline how the results of your research will be disseminated and the audience. For example, in-house report, published report or information paper, peer reviewed journal article, and/or presentation (at conferences or other fora). |
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# Appendix 1: COVID-19 Register Terms of Use

The COVID-19 Register has been approved under the AIHW Ethics Committee (EO2021-2-1232), the NSW Population and Health Services Research Ethics Committee - as part of the National Mutual Acceptance Scheme (2021-ETH00412) and the Northern Territory Department of Health and the Menzies School of Health Research (2021-4106). This project is supported by funding from the Australian Government under the Medical Research Future Fund. AIHW and jurisdictional ethics committees have developed strict governance arrangements to ensure that privacy and confidentiality is maintained (see Figure 1). It is therefore pertinent that any researchers accessing the data comply with the terms of use stipulated below.

**Authorised users**

All users wishing to access the COVID-19 Register will need to be approved by the relevant custodians. Users must sign and agree to the AIHW s29 Confidentiality Undertaking form. An appropriate authority in each agency will ensure their researchers sign the Undertaking prior to accessing the de-identified data. Copies of these forms will be forwarded to the AIHW for the COVID-19 Register, and retained as part of our governance responsibilities.

**Approved Research Themes**

The use of the COVID-19 Register is limited to the research themes specified in the ethics application. The specified themes and associated analysis types are shown below.

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| **Research Theme** | **Potential Analysis** |
| **Epidemiological and statistical research** | * Estimates of COVID-19 incidence and prevalence
* Burden of disease analysis
* Cause and timing of death after a COVID-19 diagnosis
* Associations between comorbidities, vaccination status and risk factors

for people who have died from COVID-19* Estimates of COVID-19 severity
* Estimates of re-infection with COVID-19
* Impact of COVID-19 vaccines and treatments
 |
| **Service use and medication dispensing and patient journeys** | * Patterns of health and aged care service use and expenditure before and after COVID-19 diagnosis
* Patterns of medication dispensing before and after COVID-19 diagnosis
* Impact of COVID-19 on long-term service needs
 |
| **Identifying groups or cohorts of interest** | * Impact and extent of infection in key settings of interest, for example in the health and aged care settings
* People with chronic conditions and whether COVID-19 diagnosis is associated with changes in chronic condition outcomes, treatment and management
* Health service use outcomes for particular patient cohorts such as those with long COVID, older Australians, those with comorbidities or who speak a language other than English as their main language at home, those who have received a COVID-19 vaccine
 |
| **Monitoring, evaluation and data quality improvement** | * Monitoring and evaluation of policies and programs designed to reduce

the transmission of COVID-19* Monitoring and evaluation of COVID-19 vaccination and treatments (such as antivirals)
* Verification of information from the NNDSS
 |

**Figure 1: Governance of data access flowchart for the COVID-19 Register**



**Data Access and Usage**

**Principles of Separation**

In accordance with the principles of separation, where researchers have access to personal identifiers and/or content data for cohort members, they will not access personal identifiers and content data at the same time for the duration of the project. Where additional content data or the personal identifiers of study participants are held outside the secure research access environment, researchers will have their access to this information suspended while they are working in the secure environment. This applies to both AIHW Data Integration Services Centre (DISC) staff and any Commonwealth Department of Health and state and territory health department staff working on the project.

**Data Access Environment**

The de-identified research data will be held in an AIHW ethics committee approved, secure research access environment. Access is strictly controlled within the environment, with no access allowed to other project workspaces. To gain access to data held by the AIHW requires multiple levels of approval. A person is provided with approved access to the level necessary. Access is audited and logged and permissions removed from those who no longer require access.

**Data Output**

All analysis outputs will be reviewed by the data custodian of the linked research data prior to release. Only aggregated, or modelled, outputs will be approved for release by the data custodian of the linked data from the secure environment. Data custodian approval will be sought to identify organisations in research outputs, and no outputs identifying organisations will be output without such approval.

**Dissemination of results**

AIHW will ensure that:

* privacy and confidentiality requirements are met (no risk of re-identification of participants)
* appropriate acknowledgment of the released data is met and
* relevant data custodians are informed of the release.

AIHW will send a draft copy of the report to relevant custodians who will have responsibility for ensuring that approval conditions are met.

# Appendix 2: Proposal review process and additional ethics approvals

Figures 2 and 3 provides an overview of the approval process for projects classified into government and non-government purposes. Following project approval, for both government and non-government projects, jurisdictional ethics approvals to add researchers is facilitated by AIHW. Details of the proposal (including how it relates to the approved themes of the COVID-19 Register) need to be submitted to NSW PHSREC as part of their ethical approval process starting from September 2023. This process will be facilitated by AIHW. NSW PHSREC is a full HREC which provides ethics oversight for jurisdictions participating in National Mutual Acceptance.

Any additional approvals required due to the type of data requested will need to be obtained by the researcher as detailed in Figure 2 and 3 below.

**Figure 2: Approval process overview if proposal is for government purposes**



**Figure 3: Approval process overview if proposal is for non-government purposes**



**Additional approvals to be obtained by researcher**

**First Nations person focus**

For any government research projects with a First Nations focus, details of First Nations engagement and oversight of the project will need to be specified in the project proposal, and this may include obtaining approval from a First Nations HREC (see Figure 2).

For any non-government research projects with a First Nations focus, details of First Nations engagement and oversight of the project will need to be specified in the project proposal, and this includes obtaining approval from a First Nations HREC (see Figure 3).

This First Nations HREC approval will be mutually recognised by jurisdictions and sufficient to cover the project approval. For this purpose, in assessing whether a project has a First Nations focus, regard should be had to ‘What is Aboriginal and Torres Strait Islander research?’, in (page 6) of the [AIATSIS Code of Ethics - for Aboriginal and Torres Strait Islander Research](https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf).

*For internal AIHW researchers, please also seek advice from AIHW First Nations Health and Welfare Group Head for potential sensitivities.*

**Hospitals data**

If the project is for non-government purposes and includes hospitals data, the researcher will need to obtain additional approvals (see below and Figure 3):

* If ACT hospitals data is accessed, researcher to provide the HREC letter of approval, together with the project proposal, to ACT Health to enable a site-specific assessment to be conducted and request a governance approval through ACT Health.
* If Victorian hospitals data is being utilised, the HREC must report to the Health Complaints Commissioner in Victoria as per [the HPP research exemption guidelines 2.2G](https://hcc.vic.gov.au/sites/default/files/2021-04/guidelines_research_vic_gazette.pdf).
1. The AIHW uses First Nations people to refer to Aboriginal and/or Torres Strait Islander people. [↑](#footnote-ref-2)