Attachment 5: HUB+n project proposal and conditions of use template – health research project

non-government organisations and analysts attached to universities or private research organisations.

Please keep the project proposal brief and delete instructions in blue when complete.

Refer to the National Health Data Hub (NHDH) *Governance protocols* for detailed information about the operation of the NHDH.

Project identifier

Assigned by the NHDH secretariat.

Project title

Auspicing/Funding bodies

If applicable, e.g., The Department of Health etc.

Please list main auspicing body and any other sources of funding for this project. If you are completing this form as part of a quote request for a grant application, please state what grant you are applying for and the submission deadline.

Organisation nominating the project.

E.g., NSW, Vic, Qld, University etc.

Project Type

e.g. Government led or non-government led.

Project leader/Principal Investigator

Include name, organisation, email address and phone number, and brief summary of experience/credentials.

Project Analysts

List intended analysts working on the project.

Include name, organisation, email address and phone number, and brief summary of experience/credentials. These are people who will require access to the secure environment in addition to the project leader.

The AIHW has embedded the *five safes framework* into our approach in making decisions about sharing and releasing data. Researchers will have the knowledge, skills and incentives to act in accordance with required standards of behaviour under the five safes framework.

These people will need to sign a s29 Confidentiality Undertaking (Attachment 2). It is the responsibility of the project leader to ensure the s29 Confidentiality Undertaking are signed.

Members of the research team who will access linked data must be physically located in Australia.

Project analysts and discussants

If applicable, please list other people or organisations (e.g., consultants) who will have access to project outputs and will discuss project outputs during the investigation phase of the project. These people will need to sign a s29 Confidentiality Undertaking (Attachment 2). It is the responsibility of the project leader to ensure the s29 Confidentiality Undertaking are signed.

Include name, organisation, email address.

Project advisors and other contributors

If applicable, please list other advisors or other contributors to the project. This may include peer review groups, committees, and external advisors These people will need to sign a s29 Confidentiality Undertaking (Attachment 2). It is the responsibility of the project leader to ensure the s29 Confidentiality Undertaking are signed.

Include name, Committee or group.

Project objective

What are the main objectives of the project? Please refer to the *Governance protocols* for intended uses of the NHDH.

Please indicate which states/territories hospitals data will be required for the project.

Please provide a headline statement describing the purpose of the linkage of your data set to the NHDH.

Default datasets or by exception datasets.

The NHDH data design uses ***default* data modules** and ***by exception* data modules.** The *by exception* data modules are characterised by containing the more sensitive data items such as exact/full dates for admission, separation, departure, presentation, referral, prescription, and service dates. Please note, the *default* data modules contain month and year of most dates but not the day of the date.

By exception data modules have been created for:

- All hospital content data modules
- MBS, PBS and NDI content data modules
- RAC and HCP aged care content data modules

Do you require access to by exception datasets.

No

Yes

If you have ticked yes. Please provide justification for access to the by exception data modules.

Collections used in the Project

Data modules ☐ ☐	Planned to be included in Analysis Yes/No	Are you requesting access to by exception data modules? Yes/No
Patient Demographics: PATIENTS_DEMOGRAPHY	Yes (all researchers have access to this)	NA
ABS Country Classification Codes for Birth Country: SACC_CODES	Yes (all researchers have access to this)	NA
National Death data modules		
National Death Index: NDI_CONTENT		
Aged Care data modules		
Residential Age Care		N/A
Home Care		N/A
Home Support		N/A
Flexible Care		N/A
Aged Care Eligibility Assessment		N/A
Australian Immunisation Register data modules		
Child data modules: **Natural Immunity Details (Child):** AIR_CONTENT_NTRL_IMMNTY **Medicare Contraindication Vaccines details (child):** AIR_CONTENT_CNTRNDCTN **Vaccination Episodes that Individuals Received (Child):** AIR_CONTENT_VACCNTN_EPSD		
Adult data modules:		

Natural Immunity Details (Adult): AIR_CONTENT_NTRL_IMMNTY **Medicare Contraindication Vaccines details (Adult):** AIR_CONTENT_CNTRNDCTN **Vaccination Episodes that Individuals Received (Adult):** AIR_CONTENT_VACCNTN_EPSD		
Vaccination Supply Details: AIR_DM_SUPPLR_VCCNE	Yes (all users have access to this when requesting AIR modules)	N/A
Antigen Codes and Vaccine Codes: AIR_DM_ANTGN_VCCNE_MP	Yes (all users have access to this when requesting AIR modules)	N/A
File Extract Information: AIR_CONTENT_PERSON_CURRENT	Yes (all users have access to this when requesting AIR modules)	N/A
COVID-19 Vaccination data: AIR_DM_CVD_CMPLNCE_STTS	Yes (all users have access to this when requesting AIR modules)	N/A
Antigen Codes and Antigen Names: AIR_DM_ANTGN	Yes (all users have access to this when requesting AIR modules)	N/A
Medicare Benefits Schedule		
Medicare Benefits Schedule (MBS): MBS_CONTENT		
Supplementary Data Speciality Codes: MBS_REG_SPECIALTY_CODES	Yes (all users have access to this when requesting MBS modules)	N/A
Map of MBS Item Descriptions: MBS_ITEM_MAP	Yes (all users have access to this when	N/A

	requesting MBS modules)	
Pharmaceutical Benefits Scheme		
Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS): PBS_CONTENT		
Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) - Map of PBS Item Code Descriptions: PBS_ITEM_MAP	Yes (all users have access to this when requesting PBS)	N/A
Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) - Supplementary Data Speciality Codes: PBS_DERIVED_MAJOR_SPECIALITY	Yes (all users have access to this when requesting PBS)	N/A
Will you be using Repatriation Pharmaceutical Benefits Scheme (RPBS) specifically to analyse the veteran/defence population use of pharmaceuticals Please state: Yes, No		
Hospital Data		
Hospital Data: HOSPITAL_CONTENT_DATA (Public hospital establishment information)	Yes (all users have access to this when requesting hospitals data listed below)	N/A

If the intention is to use all available states/territories then indicate in last row, otherwise place an X for each combination of hospitals collection and state/territory.

State/Territory	**Admitted Patient Care data** (AP_CONTENT)	**Non-Admitted Patient data** (NAP_CONTENT)	**Emergency Department Care data** (ED_CONTENT)	**Are you requesting access to *by exception* hospital data modules?** Yes/No
NSW				
Vic				
Qld				

SA				
Tas				
ACT				
All available				

Project duration, and retention and destruction of data

Planned completion date.

DD/MM/YY

Archiving and Retention of data

As determined by section 2.3 of the Governance Protocols, files will be archived for seven years after the completion of the project unless a Human Research Ethics Approval (HREC) provides another period. Please provide the HREC period if different from section 2.3 of the protocols.

Consideration of community expectations

Please include details of how community expectations around the benefit project are being considered including plans and purpose for consultation with appropriate groups.

Please provide a brief summary description of the benefit of the linkage for the public or cohort.

- non-exhaustive list of examples 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. [1]

Projects with a First Nations people focus.

Will the project have a focus of analysis on the First Nations people population?

Yes No

[1] https://uksa.statisticsauthority.gov.uk/wp-content/uploads/2019/05/2019_Self-assessment_guidance_V2.1.pdf, p. 15

If yes, project proposals should address how external advice from First Nations people is being sought and how appropriate consultation and oversight is provided during the life of the project.

Non-government research proposals where First Nations people are a focus must obtain a First Nations people Human Research Ethics Committee approval (HREC). For guidance in planning, designing, and conducting such research, please consult the NHMRC *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018*, as well as the guidance provided by the First Nations people HRECs.

Outputs and reports

Please provide information on:

- whether jurisdictions will be identified in the outputs and reports
    - please specify jurisdictions and parent data collections being presented.
- whether individual entities (e.g., hospitals) will be identified in outputs and reports.
- whether comparisons of First Nations people and non-Indigenous people/other Australians/all Australians will be made in the outputs and reports
- whether outputs and reports will be distributed to third parties or published
- the audience for the outputs and reports
- where reports are to be published, the name of the publication.
- timeframes for the release of reports.

Please note: Unit record data is not allowed to be transferred outside of the Secure Access Environment

Human Research Ethics Committee (HREC) requirements

Project proposals for health research will require:

- a AIHW Human Research Ethics Committee (HREC) application, researchers must submit their projects to the AIHW Ethics Committee to ensure that their project complies with relevant legislation and requirements under the National Statement on Ethical Conduct in Human Research.
- If Victoria, Queensland, New South Wales, Australian Capital Territory or Tasmania hospitals data is being used, a single HREC application is required which will be mutually recognised across these jurisdictions via the National Mutual Acceptance Scheme. Link to National Mutual Acceptance Single Ethical Review of Multi-centre Research Projects List: https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance
- If Victorian hospital data is being utilised, a Victorian HREC approval is needed. This HREC must report to the Health Complaints Commissioner in Victoria as per the HPP research exemption guidelines 2.2G

- If ACT data is being used AIHW will request a governance approval from ACT Health on your behalf.

Please attach details of these additional approvals.

Data custodian requirements

Approval by all members of the NHDH Advisory Committee and state and territory data custodians for data collections being used.

Commercial Gain

Please provide information on whether this project could be used for commercial gain.

Disclosure agreement

A description of your project may be included on the AIHW website.

Is there a non-discloser agreement on this project?

Yes No

Information on the data set to be linked to the NHDH.

Provide a description of the data set.

Will any content or cohort files to be supplied to AIHW include free-text fields?

Are there any time-critical aspects of the research project you would like us to be aware of? (e.g. funding expiry)

Expected date/s of supply of data to AIHW

Expected date/s of supply of linked data from AIHW

As defined in section 2.9 datasets that have less than 100,000 records will be assigned a data manager who will scope and cut the data manually. Please include information on how many records your dataset holds. Please provide information on who the data manager will be for this project (if required).

Cohort Specifications

Study cohort/s	
Did the cohort give consent to be part of your study?	EXPRESSED CONSENT ☐

Please attach consent forms/PIS when you return this form to AIHW DISC.	OPT-OUT CONSENT ☐ NO CONSENT ☐
Did the cohort give consent to have their data/information linked? *Please attach consent forms/PIS when you return this form to AIHW DISC.*	EXPRESSED CONSENT ☐ OPT-OUT CONSENT ☐ NO CONSENT ☐
If unconsented, how are you proposing to satisfy the Australian Privacy Principles? *Please make specific references of how you will satisfy the requirements as detailed in the NHMRC National Statement.* *If you are requesting a waiver of consent pursuant to s.95 of the Privacy Act, please do not list what HRECs have already granted a waiver. You need to provide justification as to why the AIHW Ethics Committee should grant a waiver.*	

Please list the data collection/s or source(s) from which the study cohort will be derived.
•
Please describe the inclusion/exclusion criteria for the study cohort/s (including variables, dates)

Estimated number of individuals	N =

Other information about the study cohort/s

Personal identifiers for cohorts provided <u>to</u> the AIHW for linkage	
For studies where the cohort/s are not created by the AIHW, please list the personal identifiers (e.g. names, date of birth, sex, full address) or Statistical Linkage Key (SLK) information that will be provided to AIHW DISC either from you or another third party. *Best practice for probabilistic linkage is first name, last name, DOB, sex, address, postcode.*	
☐ Full name (including middle names if available)	☐ Death status and/or date of death
☐ Date of birth	☐ Date of diagnosis
☐ Sex	☐ Date of last contact
☐ Address	☐ Multiple births flag

☐ Postcode	☐ SLK-581
☐ Other (please specify):	

Control/comparator group/s		
Handy tip: When completing this section, please review the 'Comparator group advice' researcher resource on our website		
Is a control/comparator group part of your study?	YES ☐	NO ☐
Did the control/comparator give consent to be part of your study?	EXPRESSED CONSENT ☐ OPTOUT ☐ NO ☐	
Did the control/comparator give consent to have their data/information linked?	EXPRESSED CONSENT ☐ OPTOUT ☐ NO ☐	
If 'YES', who will create this group – e.g. AIHW, researchers, other linkage unit, other?		
Please list the data collection/s or source(s) from which the study control group/s will be derived.		
•		
Please describe the inclusion/exclusion criteria for the control group/s (including variables, dates)		
Estimated number of individuals	N =	
Other information about the control/comparator group/s		
Personal identifiers for controls/comparators provided to the AIHW for linkage		
Please list only if these identifiers differ to those listed above for the study cohort		

Data Specifications

Data flow

Please outline the flow of 1) personal identifiers and 2) content data between data custodians, linkage unit/s and researchers.
Your AIHW linkage contact will help you format this section to align with AIHW standards.

Researcher/data provider/state linkage team will provide:

- e.g. Study content file and personal identifier file with project specific keys.

AIHW will:

- e.g. Receive study content file and personal identifier file with project specific keys under a by-law exemption to the Privacy Act 1988.
- e.g. Study cohort linked to MBS/PBS data uploaded into SURE.
- e.g. NDI file with project specific key to Researcher.

Researcher will receive:

- e.g. NDI file and save to access controlled directory on secure file server.

Data storage sites

Please list all the sites where any project-related data will be stored and a summary of security arrangements.

Where a project requires Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, Centrelink, or certain other data, it is a data custodian requirement that the linked data set must be stored and analysed within an AIHW approved secure access environment (SAE)

Data sets specifications

Data sets to be linked

Please list the data sets to be linked to the National Health Data Hub and the data provider. Please delete the rows for any data sets you are not requesting.

If known, please indicate the legal mechanism you intend to utilise to authorise transfer of data to AIHW. If not, DISC will work with you to clarify this.

Data set	Data provider	Linkage or Content Data?	Legal Mechanism			
			Consent	Authorised by law	Waiver	De-identified
AIHW Health Spine or AIHW Health & Welfare Spine (Required)	AIHW	Linkage		x		
e.g. Cohort Personal Identifiers		Linkage				

When completed for AIHW analysts or analysts using the RON please attach this form to your IT request. For EDW analysts please email this form to NHDH@aihw.gov.au

e.g. Cohort Content Data		Linkage				
e.g. State/territory data sets						

Invoice details

Invoice details for feasibility questionnaire review fee	
As per our website, due to the effort involved in reviewing a feasibility questionnaire and preparing a quote, this service is subject to cost recovery. Please provide the requested details below. These details will only be used to invoice for the feasibility questionnaire review.	
Invoice recipient name:	
Invoice recipient position title:	
Invoice recipient postal address:	
Invoice recipient email:	

Data Integration Services Centre

Name	**Date**

Project leader

Name **Signature**	 **Date**

AIHW Head of Ethics, Privacy and Legal Unit

I support the project noting the following, **Name** **Signature**	 **Date**

NHDH Data Custodian

I support the project noting the following, **Name** **Signature**	 **Date**

NHDH Advisory Committee member

Approved ☐ **Approved with conditions (please specify)** ☐ **Not approved** ☐ **Name** **Signature**	 **Date**

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