Checklist for data linkage project applications

Before beginning a new data linkage research project that requires access to statewide data sets held by the Department for Health and Wellbeing (DHW), HREC review (SA Health or National Mutual Acceptance (NMA) certified), SSA authorisation/s and utilises the services of SA NT DataLink, please consider the following project details. The table below identifies items that are required several times in different forms during the application process. The application forms include:

Population Health Research Network (PHRN) Online Application System - System used by SA NT DataLink for project submissions for data linkage projects.

Research GEMS (GEMS) - System used by SA Health for ethics and governance applications.

Human Research Ethics Application (HREA) - Ethics committees require this form to be completed as part of the ethics application. For SA Health HREC applications, the form is completed in Research GEMS.

Research protocol (Prot) – Document that outlines all project details. A protocol template is available from the DHW HREC website.

Site Specific Assessment (SSA) - Each site requires an SSA to be completed before research can commence. For data linkage studies, the site is defined as where the data set and Custodian are located. Access to DHW held data sets require a DHW SSA, which is completed in Research GEMS. Note that an SSA is required for each project site and is in addition to the ethics application.

Confidentiality Agreement (CA) - Legal agreement required by DHW Data Custodians before data is released.

Aboriginal Health Research Ethics Committee (AHREC) – When the project is in the planning stage, consider if an AHREC review is required in addition to the SA Health or NMA HREC review. Further information can be found on the SA Health and AHREC webpages.

It is recommended to start the process by drafting the study protocol to capture the details required across all applications.

A flowchart demonstrating the submission and review process can be found on the DHW HREC website.

	Project detail	Description
□	**Project title** PHRN GEMS HREA PROT SSA CA AHREC	Ensure the project title is accurate and consistent across all applications. The title will appear in all official communications. GEMS Tip: Include the PHRN OAS identifier in the GEMS project title e.g. Project name (P0000_YYYY).
□	**Project summary and aims** PHRN GEMS HREA PROT SSA CA AHREC	A brief overview of the research purpose and aims. This should be provided in non-technical language. Tip: Do not include references in this section, keep it short and use plain language.
□	**Coordinating Principal Investigator (CPI) + Principal Investigator (PI) information** PHRN GEMS HREA PROT SSA CA AHREC	The CPI has overall responsibility for the research project at all sites and needs to be nominated in the HREA. Students cannot be listed as the CPI; this role must be held by a supervisor. The site PIs have responsibility for the research project at each site (and can be the same person as the nominated CPI). For DHW site applications, the PI does not need to be employed at the site (this is not the case at other sites). The PHRN only uses the term 'PI', so please put the CPI details in the Principal Investigator section in the Summary tab. It is acceptable to add additional PIs in the Researcher tab.
□	**Research team** PHRN GEMS HREA PROT SSA CA AHREC	Identify all team members and their specific roles, particularly who is handling the data and in what format.
□	**Funding and sponsors** PHRN GEMS HREA SSA AHREC	Details of all sponsors and funding bodies are required, including the amount of funding and whether the funding has been confirmed.
□	**HREC details** PHRN GEMS HREA PROT SSA AHREC	Ensure you are aware of which HREC you will be applying to – NMA or one of the SA Health HRECs, and if Aboriginal Health Research Ethics Committee (AHREC) approval is required.
□	**Cohort description** PHRN HREA PROT SSA CA AHREC	Provide a comprehensive description of your study cohort(s) including data sources and date ranges which should be used for selection.
□	**Data sets and variables** PHRN HREA PROT SSA CA AHREC	Identify each required data set for the project, including the official name, the Data Custodian details and requested data variables. Tip: Review the DHW governance webpage and discuss with your SA NT DataLink client services officer for this information. Each organisation involved will review the requested variables and ensure they will answer the research question without providing unnecessary extra information.
□	**Start - End dates** PHRN HREA PROT SSA CA AHREC	Define data set date ranges and anticipated duration of the research project including when you expect to receive linked data for analysis.

□	**Methodology (including details for the data management plan)** **PHRN HREA PROT SSA AHREC**	A detailed explanation of how the project will be conducted is required. See the DHW HREC protocol template for what items should be considered before beginning. Considerations include: How will the research be conducted and how will the data be analysed? What security measures are required to protect the privacy and confidentiality of participants' data? How will any risks of linking databases be managed, including reducing the risks of re-identifiability? How will the data be reported? Are participants or organisations identified? Will the data be published? Tip: Review the ABS Five Safes framework to consider project disclosure risks.
	Data Flow **PHRN HREA PROT SSA AHREC**	Describe the flow of personal identifiers and the flow of content data between Data Custodian(s), linkage unit(s) and researchers taking the separation principle into account (review the *National Statement on Ethics Conduct in Human Research 2023*, section 3.1.40 for an explanation). Tip: The data flow details will be discussed with your SA NT Datalink Client Services Officer