Department for Health and Wellbeing (DHW) Human Research Ethics Committee (HREC) application process

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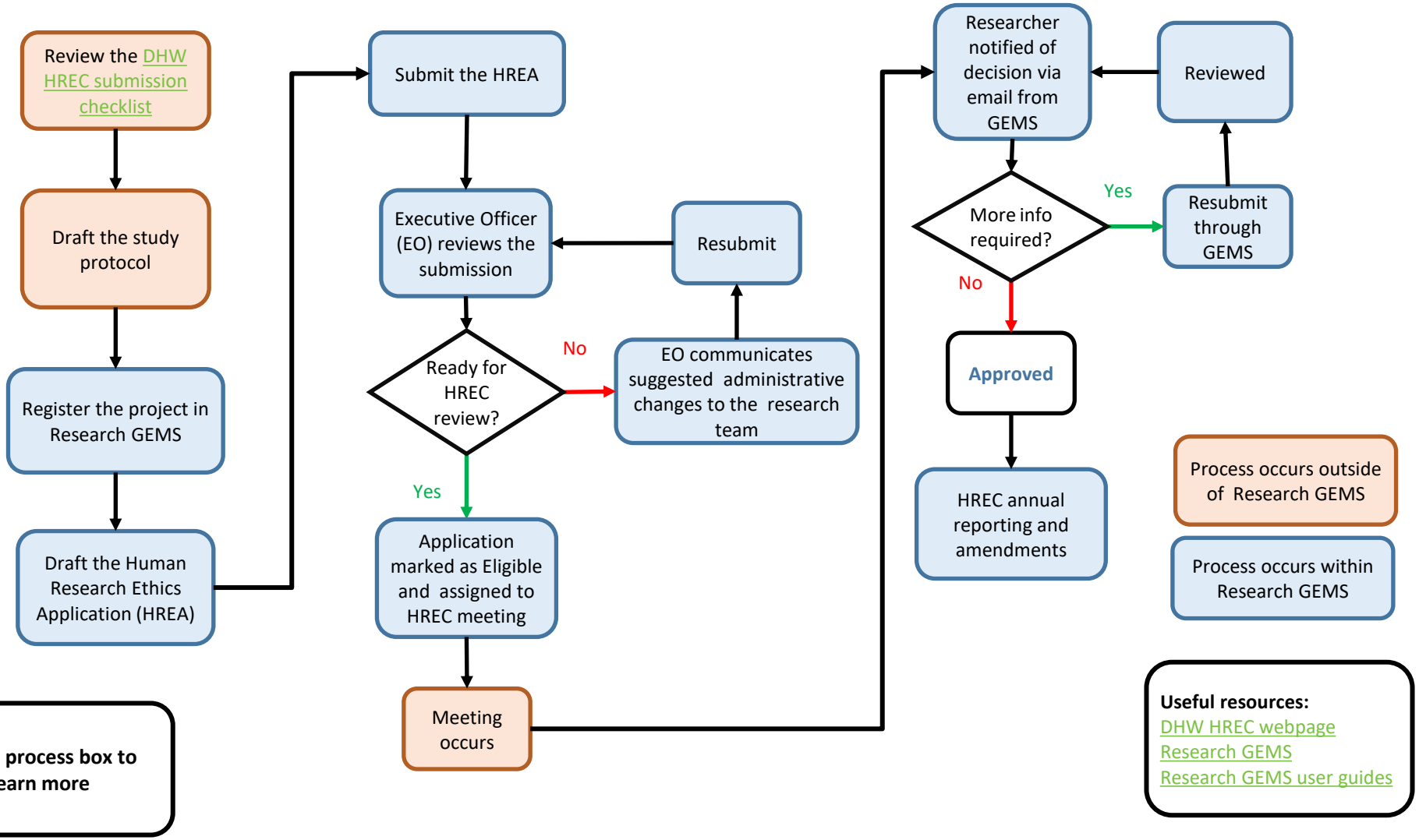
Government of South Australia

SA Health

DHW ethics process



SA Health

Checklist for data linkage studies

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

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. 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.

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

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.

Checklist for data linkage studies

	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.

Checklist for data linkage studies

☐	**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 (review the *National Statement on Ethics Conduct in Human Research 2023*, section 3.1.40 for an explanation) into account.

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Draft the study protocol

The DHW HREC study protocol template is provided for assistance.

Existing protocols will also be reviewed by the HREC, provided that all relevant sections from the DHW template are present.

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Register the project in Research GEMS

See Research GEMS user guide Completing project registration.

If the research project has already received ethics approval via the National mutual acceptance scheme, see user guide Completing project registration - NMA projects.

Before you begin this step, know:

- the key research team members and their roles: Coordinating Principal Investigator (CPI); Principal Investigators (PI); administrators and people delegated by the CPI to be able to submit the application.

- the project's sites (both internal and external to SA Health). A site specific assessment (SSA) is required for all research sites within SA Health relevant to the project. SSAs can be completed concurrently with the ethics application, but will not be authorised until the HREC grants ethical approval.

A site can be added after the project registration has been submitted by following the user guide Adding a new site application – Existing applications.

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Draft the Human Research Ethics Application (HREA)

See Research GEMS user guide Completing an ethics application.

Draft versions of the HREA can be saved in progress, to be continued later.

The DHW HREC is committed to reducing duplication between the protocol and the HREA. Please include all project details within the protocol, and when completing the HREA online, respond with 'Refer to section xxx in the protocol'.

Upload all ethics application attachments to HREA.

Label documents as 'Description—v1.0– dd.mm.yyyy' e.g Protocol—v1.0—01.01.2023

See user guide File naming convention

Ensure each document's footer contains the version control and date that match the file name. This version control is used in the ethics approval letter, so it must be updated with each version.

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Submit the HREA

Meeting cutoff date is 2 weeks before the meeting

Only the CPI or person with ‘submitter’ access can submit the HREA.

If you are an editor, ask the CPI to log in to their GEMS account and submit the application. Once this step is completed, the application status will change to ‘**submitted**’.

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Executive Officer (EO) reviews the submission

The Executive Officer reviews the submission to ensure:

-All relevant documents are provided, as per the submission checklist.

-The footer in each document contains version control and date

- Correct SA Health sites are identified

- Common HREC concerns are addressed (e.g. waiver of consent details, data variable lists are provided)

If changes are required, the EO will contact the researchers with advice and return the application to the research team in Research GEMS.

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Application marked as Eligible and assigned to HREC meeting

Submission cut-off and meeting dates can be found here.

The Executive Officer will send an email from GEMS stating that the application is eligible, and has been assigned to the upcoming meeting.

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Meeting occurs

The HREC assigns two lead reviewers to each application. They are selected for their research experience and methodological knowledge to lead the review of the application and then the HREC has a robust conversation to discuss each application.

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HREC requests more information

The HREC is required to send notice within 5 business days

Depending on the scope of the changes the application will either be reviewed by the Chair or sub-committee out of session, or the full committee during a monthly meeting.

The review pathway will be specified in the response letter.

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Approved

Congratulations! Please note that the project cannot commence until the required SSA(s) are also authorised.

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HREC annual reporting and amendments

In order to maintain ethics approval, progress reports need to be submitted to GEMS annually on the anniversary date of approval, and a final report must be submitted once the project is complete.

Amendments also need to be submitted via a GEMS amendment form when any changes are made to the project (e.g. a change to the research team, methodology, data requested or extensions).

See Research GEMS user guide: Ethics amendment - completing and submitting

See Research GEMS user guide: Submitting a progress report or final report

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