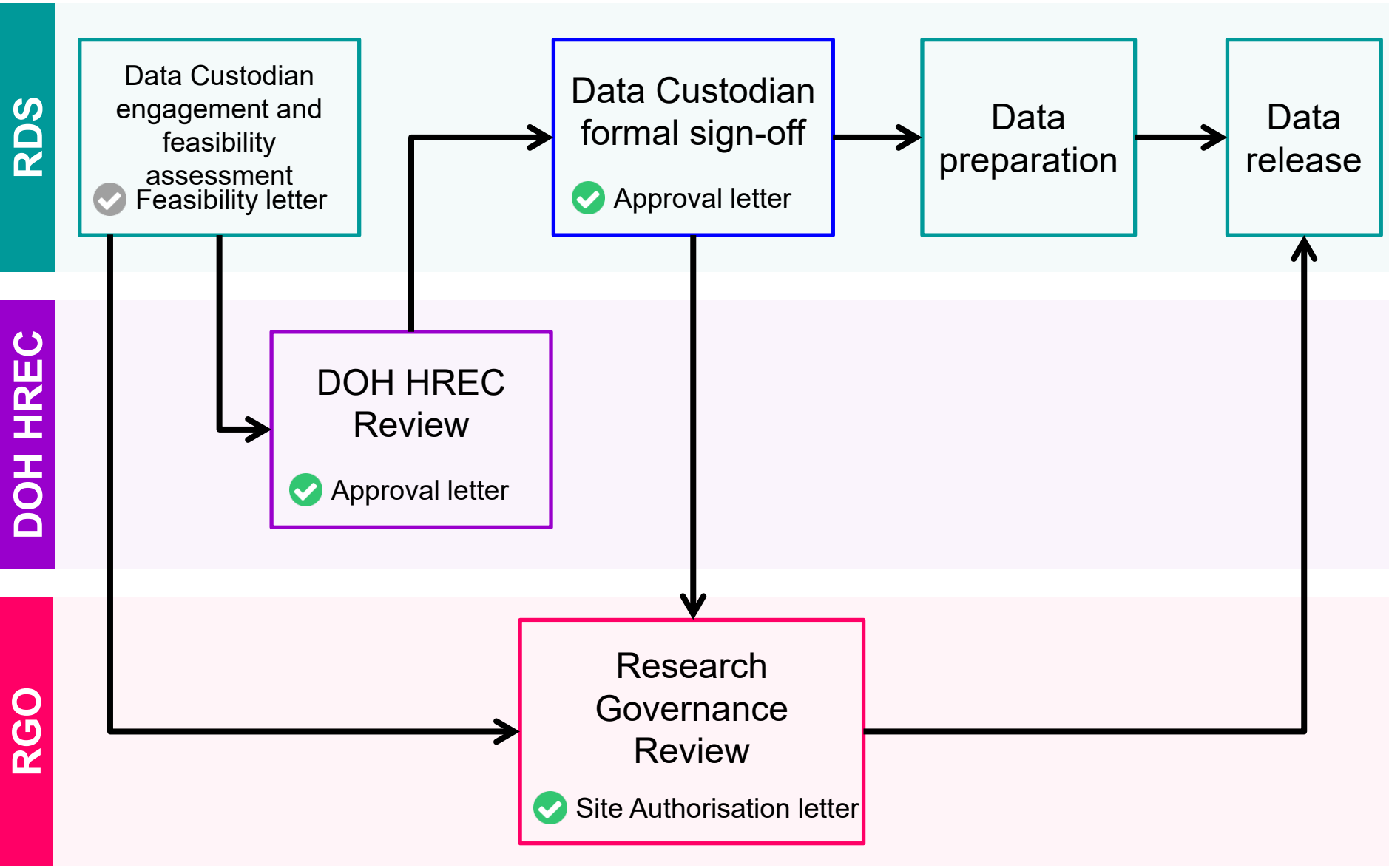
Application for Data Process Overview



PHASE

APPLICANT

RDS

DIS

DATA CUSTODIANS

DOH HREC

RGO

1. DATA CUSTODIAN CONSULTATION AND FEASIBILITY ASSESSMENT

2. DOH HREC REVIEW

3. RESEARCH GOVERNANCE REVIEW

4. DATA CUSTODIAN APPROVAL

5. DATA PREPARATION

START HERE
Applicant creates a user log in and project workspace in RGS system

Applicant submits draft application to RDS via email

Applicant reviews and resubmits revised draft application

Applicant reviews and resubmits revised draft application

Applicant submits ethics application to DOH HREC via RGS

Applicant submits governance application to RGO via RGS

Applicant notifies RDS of DOH HREC approval

Applicant notifies RDS of RGO approval

Applicant receives data via secure online file transfer

RDS reviews application and provides preliminary feedback

If feedback is adequately addressed, project is listed on agenda for next draft application review meeting (fortnightly)

RDS provides consolidated feedback from custodians and relevant teams

RDS provides feasibility letter confirming custodians in principle support for project

RDS schedules linkage (if required) and extraction work (projects are queued)

RDS requests formal approval from all Data Custodians and Data Stewards

RDS confirms site authorisation on AR form in RGS & uploads Custodian approvals

RDS can release the data to the applicant when all required approvals are complete:
- DOH HREC approval
- Data Custodian formal approval
- RGO approval

DIS reviews application and provides preliminary feedback

DIS completes linkage (if required) and extraction work*

<u>Draft Application Review</u>
Custodians review application against data use and disclosure policies, and provide feedback or comment as required

When custodians are satisfied that feedback has been addressed they give their in principle support for the project

Data Custodians and Data Stewards provide formal approval for project

DOH HREC reviews application and requests further information if required

DOH HREC provides approval letter confirming ethical approval

RGO approves user log in and project workspace in RGS.

RGO reviews application and requests further information if required

RGO provides approval letter confirming site authorisation

LEGEND

↔ Indicates iterative process

Indicates process occurs within RGS System

RDS = Research Data Services team

DIS = Data & Information Systems (inc Linkage & Data Outputs teams)

RGO = Research Governance Office

DOH HREC = Department of Health Human Research Ethics Committee

*if DIS does not hold the requested data, RDS will coordinate the extraction with the Custodian directly

Application for data process

There are a number of stakeholders involved in the application process for linked data. The Data Application Flowchart summarises the application process and the interactions of each stakeholder group throughout the process.

The role of each stakeholder group is also summarised below, along with additional definitions of acronyms.

ARF	Access Request Form
DIS	Data and Information Systems; includes the Linkage and Data Outputs teams
DOH	Department of Health
DOH HREC	Department of Health Human Research Ethics Committee
HREA	Human Research Ethics Application
RDS	Research Data Services team
RGO	Research Governance Office
RGS	Research Governance Service
SSA	Site Specific Assessment Form
WAHEAF	WA Health Ethics Application Form
WASM	WA Specific Module

Note that this process applies to applications for unit record level data for research projects only. Certain projects may not be required to complete every stage of the process outlined here. If you are unsure which processes apply to your project, please get in touch with the RDS.

Stakeholder groups

RDS coordinates the application for data process and data delivery for projects, incorporating:

- Data Custodian consultation and feasibility assessment
- Formal Data Custodian approval
- Data linkage and extraction.

Data Custodians have a number of responsibilities related to the access, use and disclosure of data for operational, reporting and research purposes. This includes:

- ensuring the use, disclosure and access to data meets legislative responsibilities and is in accordance with approved protocols, contracts and agreements
- providing advice on the proper use and interpretation of the data to authorised users
- undertaking a risk assessment to ensure the identification of individuals, patients and Health Service Providers have been considered and appropriately managed prior to releasing of information

Department of Health Human Research Ethics Committee (DOH HREC) provides the scientific and ethical review of proposed human research projects requesting information from the DOH data collections, taking into consideration:

- the scientific design and proposed conduct of the project;
- how participants will be recruited, including the means of obtaining consent;
- care and protection from harm of research participants; and
- protection of research participants' confidentiality.

The DOH HREC will ethically assess each application in accordance with:

- the NHMRC National Statement
- the NHMRC Values and Ethics Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research where applicable
- the Department of Health Practice Code for the Use of Personal Health Information
- guidelines approved under the Commonwealth Privacy Act 1988 where applicable and guidelines approved under any other applicable privacy legislation
- any other applicable principles or guidelines required by the NHMRC or by legislation

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Research Governance Office (RGO) conducts research governance review to ensure the DOH remains accountable for the research conducted under its auspices. The research governance review is conducted to assess institutional risk and ensure compliance in line with:

1. Established ethical principles,
2. Guidelines for responsible research conduct,
3. Legislation relevant to both WA Health and the DOH;
4. Nationally recognized research regulations;
5. Institutional policy; and
6. Codes of practice adopted by WA Health, the DOH and those that are nationally and internationally recognized.

The **Research Governance Service (RGS)** supports the research governance framework for all human research conducted within WA Health or accessing WA Health participants, their tissue or data.

The RGS is a centralised IT system for investigators, project members, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices. Enabling the completion, submission, administration, tracking and reporting of ethics and governance applications through the ethics approval and site authorisation processes.

The RGS must be used to process all ethics and governance applications involving WA public health organisations.

Application process

Applications for data must be reviewed and approved by each group before data can be released. There are some aspects of application processes which overlap; this is because there are some aspects of a project that need to be reviewed by multiple parties (e.g. the data requested, methodology and security plan) however it is considered from different perspectives, because each of these groups have different areas of expertise.

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1. **Data Custodian Consultation & Feasibility Assessment**
   This stage allows for RDS, DIS and Data Custodians to review applications for linked data in detail and provide quality advice in relation to the data requested. Feedback is provided via RDS and must be addressed by the applicant. Once DIS and Data Custodians have provided in-principle support for the request, RDS issues a feasibility letter which allows the application to be progressed formally via submission to DOH HREC.

   Draft applications should be submitted via email to dataservices@health.wa.gov.au and at a minimum should include:
   i. Application for data form
   ii. Data management plan
   iii. Dataset variable lists for any datasets requested
   iv. Applications for linked data must also include Data services forms (linkage form, extraction form etc.)

   This stage is an iterative process where applicants are required to amend their application to address feedback. RDS provides the applicant with the final versions of the application documents to submit with the formal application for ethical review (as attachments in RGS).

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2. **DOH HREC Review**
   The DOH HREC is a Human Research Ethics Committee with special responsibility for oversight of the use and disclosure of personal health information held in the DOH data collections.
   a. All applications for ethical review must be submitted via the RGS, by close of business on the relevant closing date. The closing date for receipt of new applications for the next DOH HREC meeting will be readily available to prospective applicants on the RGS.
   b. Applications must be submitted in the appropriate format and include all documentation as determined by the DOH HREC:
      i. WA Health Ethics Application form (WAHEAF) or Health Research Ethics Application (HREA) form with the Western Australian Specific Module (WASM) attached
      ii. Final versions of Application for Data form, Data Management Plan, Data Services and Variable Lists forms
      iii. Research Protocol
      iv. Feasibility Letter (obtained from RDS)
      v. Copies of any supporting documentation For example, letters to participants, participation information sheets, consent forms,

information about data collections from outside of the Department of Health.

vi. Copies of documentation regarding approval from any other Human Research Ethics Committee.

vii. Declaration of Confidentiality for all researchers involved in the project (completed in the RGS system)

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3. Research Governance review

All human research conducted within WA Health must undergo a governance review which is the mechanism for professional, legal and financial accountability and transparency and is consistent with the NHMRC's Australian Code for the Responsible Conduct of Research 2007 (the Code).

The governance review is a separate process to the ethical and scientific review and should be conducted in parallel to the ethics approval process. It is not necessary to await the ethics outcome before preparing and submitting a governance application to the relevant RG Office.

a. All applications for research governance review must be submitted via the RGS.
b. Applications must include either:
    i. a SSA Form and supporting documentation: for projects conducting an intervention at a site or sites under the jurisdiction of the DOH or if a project will require access to physical resources or staff within the DOH and/or it auspices; or
    ii. an Access Request form and supporting documentation: for projects requiring access to participants, their tissue or their data. The DLB Project Coordinator must be invited to authorise the Access Request form.

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4. Formal Data Custodian approval

Once a project has ethical approval from DOH HREC, RDS will coordinate formal Data Custodian and Data Steward approval. If at this stage Data Custodians identify any issues in the project documentation which they did not support during the feasibility assessment, an amendment to DOH HREC may be required. The feasibility assessment was introduced to avoid this delay.

RDS will then authorise the Access Request form to confirm formal approval from Data Custodians and Data Stewards and upload the Data Custodian approvals. Once the Access Request form is approved, the applicant can then finalise and submit the Research Governance application.

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5. Data preparation

RDS and DIS will coordinate **linkage (if required) and extraction work** for the project

a. If the applicant is providing data for a new linkage, the Team Leader Data Linkage will request this data from the nominated person via a secure online file transfer method.

b. For other linkages and data extractions, RDS and DIS will coordinate the process on the applicant's behalf and get in touch if any action is required from them. Please note that for some datasets external to the DOH, that agency may release the data directly to the applicant.
c. Following data extraction, prior to release to the research team, data will be checked by a DIS Data Engineer to ensure the data files match the request.
d. When data is ready for release, and all approvals are in place, data will be encrypted and sent via a secure online file transfer method to the nominated research team member.

Tips on completing your draft application for data

General tips

1. The forms will take some time to complete. To avoid delays in the drafting process, please take the time to ensure that the information captured in the form is as complete, accurate and as up to date as possible. Check you are using the current version of the forms (see Data Linkage WA website or check with the Research Data Services team) and ensure you have answered all questions, including providing justification for sensitive fields in the variable lists.
2. Changes to the forms that have been made as a result of feedback from Research Data Services **must be reflected in other relevant documents**, such as your protocol form(s).
3. Include sufficient detail about your data request in the application forms and ensure they are all consistent. The Application for Data is the main document of reference for the Data Custodians, so if there is important information in the research protocol or the ethics application, make sure it also appears in the Application for Data.
4. If unsure of which variables may be relevant to your study outcomes, contact the relevant Data Custodian or the Research Data Services Team if multiple Custodians need be involved – we can organise a meeting or teleconference to assist with the initial consultation. Data dictionaries may also be downloaded from the Data Linkage WA website (https://www.datalinkage-wa.org.au/resources/dataset-information/).
5. Make sure the ethical review form for submission to the Department of Health Human Research Ethics Committee (DOH HREC) and the Application for Data form are consistent with regards to listed project personnel and assigned roles, project commencement and completion dates, datasets requested, methodology, etc.
6. If you are requesting the Indigenous status variable from any of the datasets or the Indigenous Status flag, please investigate whether Western Australian Aboriginal Health Ethics Committee (WAAHEC) approval is required. More information can be found at the WAAHEC website and the Data Linkage WA website.

Application for Data form – question specific tips

Cover page

- Please ensure the relevant boxes are ticked on the cover page to indicate whether the request is for linked/unlinked data and if the project is research/non-research. The answers to these questions dictate the application process and will impact on delivery timeframes.

Section 3.3

- Please list the locations where the *data for analysis* that is being requested will be stored and analysed. Other data that is part of the research project can also be mentioned here, as long as it is specified whether it is being merged with Department of Health data.

Section 3.5

- Please consider possible conflict of interest in cases where one of the project personnel listed is also Data Custodian of a data collection requested as part of the application (select 'Other' in this case and nominate).
- In case of the above, the next tier or authority above must act as Data Custodian and provide written approval for release of data for the purposes outlined in the application. Note that this does not apply to data that is specifically collected for the research project.
- Include an official email address for all personnel listed in the application. If possible, do not use generic accounts such as gmail or yahoo. Data will not be released to email addresses not tied to the responsible organisation/s.

Section 5.4 Project Outline

- Datasets and data items requested should reflect the research aims. Data Custodians will assess whether data requested is suitable for the intended purpose(s), therefore detailed aims will help guide this assessment and may also result in further suggestions to assist your research.
- Use sub headings if needed.
- If requesting linkage of an external dataset(s), details of how and when each dataset was collected, should be provided.
- If requesting cohort/control selection from one or several data collections, provide details of:
    - which dataset(s) the cohort/controls should be selected from;
    - specified date ranges;
    - where relevant, the definition of the specified diagnosis (principal and/or additional ICD codes, and procedure codes, may be provided in a separate document).

- If requesting a data extract from one or several data collections, provide details of:
    - which datasets you are requesting;
    - specified date ranges;
    - whether you would like all linked records versus only those related to a particular condition (principal and/or additional ICD codes, and procedure codes, may be provided in a separate document);
    - whether you have standard look-back and follow-up time periods (assuming you have a defined index event date, such as date of study enrolment or date of diagnosis or procedure).
- Provide details if requesting genealogical data.
- Provide details and rationale if requesting Indigenous status.
- Provide details if requesting geocoding or SEIFA/ARIA.
- Provide a rationale if requesting identifiable data (personal information variables listed in Section 10.2) or sensitive data items.

Section 8.4

- If you are requesting establishment code (hospital identifier), UMRN and/or patient identifiers as part of the data extract or for patient record review, then additional approvals may be required. If required, a template letter to the relevant Area Health Service (AHS) and private hospital CEOs, seeking approval for the release of hospital identifier, will be provided following in principle approval of the draft application by Data Custodians, prior to submission to the DOH HREC.

Section 9.2

- If you are requesting data from a data collection that is administered by WA Health (e.g. one of the Area Health Services, or an individual hospital), rather than the Department of Health, separate governance and ethical review may be required by the relevant health service.

Section 10.1

- If you are requesting linkage of a cohort of patients (for example) collected previously by your group/department, and have *potential to reidentify* patients, this section should be ticked ‘Reasonably re-identifiable’.

Section 10.3

- Please refer to the Practice Code for the Use of Personal Health Information, to answer this section.

Data Management Plan – specific tips

Section 4

- Please refer to the Practice Code for the Use of Personal Health Information, , to answer this section. A detailed description under each subheading is preferred (2-3 paragraphs), addressing the points outlined in the Practice Code.
- Regarding date of destruction in section 5.1
    - there is no limit set on the time for data retention, however;
    - the generally accepted time period for retention of data is between 5 to 7 years;
    - research guidelines (such as the NHMRC guidelines) should be followed to choose an appropriate retention period;
    - if there are compelling reasons for retention > 7 years, this should be explained;
    - the date of data destruction should add up to the anticipated project end date (section 6.1) plus the data retention period;
    - if the data retention periods needs to be extended in future, you may submit an amendment to extend the retention period.