Research Data Services Roles and Responsibilities

Research Data Applications

June 2023

Version Control and Approval

This document should be considered a 'live document' and will be reviewed regularly and updated as required to:

- Reflect changes to policy and/or procedures
- Incorporate stakeholder feedback
- Determine effectiveness, relevance, and currency

Review and update of this document is coordinated by the Data and Information Systems unit within the Information and System Performance Directorate (ISPD).

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1. Introduction

1.1 Background

The most complex social, health, economic and environmental questions faced by the State can effectively be considered by integrating and analysing data from multiple agencies and jurisdictions. Describes

Data linkage is a method used to integrate information from different sources (e.g., different government agencies) thought to relate to the same person, place, family, or event to provide a complete picture of an individual's experience and service interaction over time.

Population linkage services delivered through the internationally recognised Western Australian Data Linkage System (WADLS) is a core function of WA Health, with the infrastructure having supported significant improvements to health policy and care in WA as well as supporting research projects using linked data for analysis.

The data request, approval and delivery processes are facilitated by several parties both external and internal to the WA Department of Health (the Department), and each stage of the data request pipeline has unique prerequisites or approval requirements that affect the progression of the data application.

A separation principle is consistently maintained between the teams that view demographic data and service level event data to ensure the highest standard of privacy and security. Due to the complexities of the process, it is important to clearly define the roles and responsibilities of stakeholders in data linkage service delivery to develop a systematic, streamlined, consistent and supported approach to accessing data.

1.2 Purpose

This document is an internal and external-facing document, made publicly available on the WA Data Linkage Services website. The purpose of this document is to provide guidance to parties on the research data application process by:

- Outlining the roles and responsibilities of research data service stakeholders in facilitating access to data for research purposes; and
- Describing the activities and interdependent requirements for each stage of research data service applications in line with relevant legislation and policies.

1.3 Scope

This document captures the research data application process, defining each relevant stakeholder's roles and responsibilities in successfully completing the data application process; and outlining interdependent approval requirements in order to progress the application to the data delivery stage.

This document provides guidance to apply for data from the Department to access and/or use the data for research purposes. This model does not apply to applications for aggregate data, or for access to data for non-research purposes.

This document does not extinguish the legal requirements and authorised purposes for which information can be collected, used or disclosed, including requirements prescribed through the *Information Management Policy Framework* and the *Research Policy Framework*. Any

part of this guide considered to be inconsistent with WA Health policies and procedures is not valid.

1.4 Context

This guide has been developed in alignment with the **WA Data Linkage Strategy 2022-2024** (the Strategy), which outlines the vision for growth in the WA's data linkage capabilities in accordance with recommendations from the 2019 *Sustainable Health Review* and the Data Linkage Expert Advisory Group's *2016 Review of Western Australia's data linkage capabilities*.

The end-to-end review of roles of stakeholders within the data request pipeline and implementation of a systematic and consistent approach for access, governance and ethical approvals will satisfy theme 2 of the Strategy, which is **Efficiency and Effectiveness.**

This document will also provide an opportunity for the Department to publicly communicate the various stages and processes involved in accessing health data to improve community engagement and maintain transparency and positive working partnerships with stakeholders as per theme 1 of the Strategy, which is **Engagement and Transparency.**

2. Linear Mapping by Stage

The research data application process is divided into eleven (11) stages as listed below:

1. **Pre-Application**
   - The first point of contact between the applicant and the Department to discuss data application requirements and whether the applicant's request seems viable.

2. **Preliminary Review**
   - Commences after the researcher has submitted their application to the Department.
   - Comprises of an initial review of the data application to validate the application, ensure completeness, and assess the technical viability of the request (linkage and extraction).
   - The Department will utilise the Data Linkage Prioritisation and Costing Framework to support consideration of the viability of a request, ensuring effective allocation of resources for timely progression of projects accepted within the application pipeline.
   - Applicants apply for a login for Research Governance Service (RGS) which is the platform for submission and review of ethics and research governance approvals.
   - As acquiring RGS login is a time consuming process, applicants are advised to apply for RGS login early on in the pipeline to facilitate ethics application without delay upon the receipt of feasibility letter.

3. **Data Custodian Feasibility Assessment**
   - This stage involves a review of the data application by the Data Custodians of requested datasets to consider if data requested aligns with expectations, is permitted within legislation and meets the authorised purposes for which health information can be disclosed.
   - A feasibility letter will be provided to the applicant to inform of Data Custodians' in-principle support as well as provide a cost estimate for the project in accordance with the Prioritisation and Costing Framework (noting a cost estimate can be provided in the preliminary review stage instead if deemed appropriate).

4. **Ethical Approval**
   - Upon receipt of the feasibility letter, the applicant is required to apply for ethical approval(s) through the relevant ethical bodies, including the Department's Human Research Ethics Committee (HREC).

5. **Data Custodian Formal Review**
   - Data Custodian formal review occurs after the application has received the required ethical approval(s).

6. **Research Governance Approvals**
   - Coinciding with data linkage and extraction activities, a governance review is undertaken by the Research Governance Office (RGO) to ensure the research project aligns with legislation and policies.

7. **Data Linkage (if applicable)**

- Coinciding with the research governance approvals stage, this stage involves linking demographic data from the approved datasets to produce linkage keys for merging with content data to produce an integrated and/or linked dataset for analysis.

8. **Data Extraction**

- Coinciding with the research governance approvals stage and occurring after linkage is complete (if applicable), this stage involves the extraction of service level data for delivery to applicants using the linkage keys developed by the data engineers.

9. **Data Delivery**

- After data has been extracted and the relevant research governance approvals are in place, the Department will coordinate the delivery of data via a secure delivery method.

10. **Invoicing**

- Upon delivery of data, the Department determines the final cost of the project with consideration to the cost estimate provided to the applicant in stage three (3).

11. **Project Closure**

- This stage involves the review of outputs produced by the applicant for the project using health data, destruction of data beyond the use of the project and administrative processes performed by the Department to close the project.

Please note that the progression of a project through the eleven stages listed above is dependent on the receipt of necessary approvals.

The below tables provide a linear map to outline the tasks generally involved in completing the above stages, and the stakeholders responsible for undertaking the tasks. This process should be followed for all data applications for research purposes, unless specified otherwise in Section 5 Application Types, noting that each application for data is unique and may therefore require additional considerations and steps.

Stage 1: Pre-Application		
Step	**Party**	**Task**
1.1	Applicant	Contact ISPD Client Services regarding data and application requirements
1.2	ISPD Client Services	Provide advice to applicant (as required); seeking feedback from Data Custodians on data queries and the Data Linkage and Data Engineering teams regarding the technical viability (if needed)
1.3	Applicant	Contact RGO to determine the project's viability and application requirements in terms of governance and ethics
1.3.1	RGO	Provide advice to applicant on ethical and governance requirements

1.4	Applicant	Submit draft data application to ISPD Client Services via email for a preliminary review
1.4.1	MILESTONE	DRAFT APPLICATION SUBMITTED

Stage 2: Preliminary Review		
Step	**Party**	**Task**
2.1	ISPD Client Services	Administrative processing
2.2	Applicant	Apply for a login to the RGS system to commence ethics and research governance process. Complete the New User Sign Up form and submit to the RGS Administrator for approval. If applicant is not a WA Health employee, they will also need to provide a WA Health employee as a referee / Local Contact in the form to verify the user login request (this can be the relevant ISPD Client Services Request Coordinator).
2.2.1	RGS Administrator	If the applicant is not a WA Health employee, the RGS Administrator will contact the WA Health employee who's been nominated as the local contact to verify the applicant's identity and confirm the applicant requires access to the RGS.
2.2.1.1	ISPD Client Services	If applicable, verify the user login request
2.3	RGS Administrator	Approve user (applicant) request for access
2.4	Applicant	Create a project workspace in RGS.
2.5	RGO	Approve the project workspace in RGS.
2.6	ISPD Client Services	Conduct a preliminary review of the draft data application to ensure completeness, and assign a priority to the project in accordance with the Data Linkage Prioritisation and Costing Framework
2.7	ISPD Client Services	Collate feedback and send to applicant
2.8	Applicant	Review feedback, action necessary changes and resubmit draft data application (as required)
2.9	ISPD Client Services	Additional preliminary review of draft data application (as required). If feedback is adequately addressed, project is added to the agenda for the next available draft data application review meeting
2.10	ISPD Client Services	Administrative processing and send the draft data application to Data Custodians for review ahead of the Draft Data Application Review meeting
2.11	ISPD Client Services	Create data flow diagram specific to the project

Stage 3: Data Custodian Feasibility Assessment		
Step	**Party**	**Task**
3.1	Data Custodians	Review draft application against data use and disclosure requirements, including relevant legislation, data sharing agreement and policy frameworks which apply to the data asset in question; provide feedback, recommendations and/or comments for the applicant in preparation for the Draft Data Application Review meeting (as necessary)
3.2	MILESTONE	DRAFT APPLICATION REVIEW MEETING
3.3	ISPD Client Services	Provide the applicant with consolidated feedback from Data Custodians and relevant teams
3.3.1	Applicant	Review feedback provided by ISPD Client Services and resubmit revised draft data application (this is an iterative process which may require multiple reviews)
3.3.2	ISPD Client Services	Process and check revised draft data application, before providing to relevant Data Custodians for additional review (as required)
3.4	MILESTONE	DATA CUSTODIAN IN-PRINCIPLE SUPPORT
3.4.1	Data Custodians	Once satisfied that feedback has been addressed, advise ISPD Client Services of "in-principle support"
3.5	ISPD Client Services	Calculate cost estimate for services in accordance with the Data Linkage Prioritisation and Costing Framework
3.6	ISPD Client Services	Prepare feasibility letter confirming "in-principle support" from Data Custodians to enable applicant to proceed to the Department's HREC review (ethics application)
3.6.1	ISPD Client Services	Provide cost estimate and feasibility letter to the applicant confirming "in-principle support" from Data Custodians for project to proceed ethics application for the relevant HREC review (cc the Department's HREC). Include the latest data application form and data management plan in the email
3.6.2	Applicant	Upload final data application form, data management plan, variable lists, extraction forms and feasibility letter into RGS

Stage 4: Ethical Approval		
Step	**Party**	**Task**
4.1	Applicant	Contact RGO and inquire on all required ethical approvals as well as clarifications on whether a Data Transfer Agreement (DTA), an 'Access Request Form' or 'Site Specific Assessment Form' are required for the project

4.2	Applicant	Submit ethics application and the latest approved data application documents to the Department's HREC for review and approval via RGS
4.3	Ethics Executive Officer	Review ethics application to ensure completeness and validity, requesting further information from applicant if required
4.3.1	Ethics Executive Officer	If feedback is adequately addressed, project is added to the agenda for the Department's next available HREC meeting
4.4	The Department's HREC	Participate in the Department's monthly HREC meeting to discuss and review research ethics application
4.4.1	Applicant	If a significant amendment to the ethics application is required following ethical review, the applicant may have to revert to Stage 3 and resubmit draft data application
4.4.2	Applicant	If application requires minor amendments, the applicant can amend ethics application and resubmit for ethical approval (Step 4.1)
4.5	Other HRECs	If applicable, the applicant must submit an additional ethics application to specialist HRECs for review and approval
4.5.1	Applicant	If a significant amendment to the ethics application is required following ethical review, the applicant may have to revert to Stage 3 and resubmit data application
4.5.2	Applicant	If application requires minor amendments, the applicant can amend ethics application and resubmit for ethical approval (Step 4.4)
4.6	MILESTONE	ETHICS APPROVAL GRANTED
4.6.1	Ethics Executive Officer	Provide letter to the applicant confirming ethical approval via RGS within five (5) working days of the Department's HREC meeting
4.6.2	Other HRECs	If applicable, provide letter to the applicant confirming ethical approval
4.6.3	Applicant	Upload other HREC approval letter(s) (if applicable) via RGS

Stage 5: Data Custodian Formal Review		
Step	**Party**	**Task**
5.1	The Department's HREC	Notify applicant of ethical approval via email with the following attachments: • Data application that was approved by HREC • HREC approval letter
5.1.1	Applicant	Applicant to notify ISPD Client Services of ethical approval

5.2	ISPD Client Services	Cross-reference the HREC-approved data application against the IPS application to identify any significant changes
5.3	ISPD Client Services	Request formal Data Custodian approval of the data application from all Data Custodians/Stewards
5.3.1	ISPD Client Services	Advise the relevant Data Custodians of any significant changes to the application between IPS and HREC approval
5.4	Data Custodians	Provide formal Data Custodian approval of the data application once HREC approval(s) finalised and all relevant criteria satisfied
5.5	MILESTONE	DATA CUSTODIANS' FORMAL APPROVAL GRANTED
5.5.1	ISPD Client Services	Notify applicant that formal approval has been granted, including advice to engage with RGO regarding research governance approval application requirements, and to add ISPD Client Services Request Coordinator as 'Data Custodian' on the Access Request Form or Site Specific Assessment Form and Budget Form as applicable.

Stage 6: Research Governance Approvals		
Step	**Party**	**Task**
6.1	Applicant	Ensure all ethic approval letter(s) (if applicable) have been uploaded into RGS
6.2	Applicant	Liaise with RGO to complete the draft DTA if the applicant is external to WA Health. DTA template can be obtained from RGO
6.3	Applicant	After being advised of Data Custodian formal approval, submit the DTA (if applicable) and relevant site authorisation form via RGS, and add the relevant Request Coordinator as the 'Data Custodian' if applicable
6.3.1	ISPD Client Services	Approve the applicant's Access Request Form submission (if applicable) in order to trigger RGO review, and upload Data Custodian Approval for Research Project document via RGS
6.4	Applicant	Project Principal Investigator to sign the Access Request Form / Site Specific Assessment and Budget form(s), and complete the submission to RGO via RGS.
6.5	RGO	Undertake review of the application made to RGO. Review DTA (if applicable) and request further information from the applicant (as required)
6.5.1	LLS/ICWA	Significant changes to a DTA (if required) are referred to Legal and Legislative Services (LLS) and/or the Insurance Commission of Western Australia (ICWA) for review and/or advice as appropriate

6.6	RGO	If the project requires a DTA, prepare a Briefing Note for approval by the delegated authority.
6.7	Director, Information and Performance Governance (IPG) unit	Reviews and approves the DTA
6.8	RGO & Applicant	Complete site authorisation process within 60 days of receiving request from applicant, notwithstanding time taken for feedback and requests for further information
6.9	RGO	Write a recommendation to the Deputy Director General (DDG) (or delegate, if appropriate) that they consider providing site authorisation for the project and for data to be released
6.10	DDG	Use RGS to indicate if site authorisation is (or is not) granted for the project.
6.11	MILESTONE	GOVERNANCE APPROVED
6.11.1	RGO	Provide finalised DTA (if applicable) and letter to the applicant confirming site authorisation via RGS
6.11.2	RGO	Notify ISPD Client Services of research governance approval and provide a copy of site authorisation via email

Stage 7: Data Linkage		
Note this stage only applies to applications for linked data. Applications for unlinked data may progress to Stage 8: Data Extraction.		
Step	**Party**	**Task**
7.1	ISPD Client Services	Prepare for project kick-off, and schedule data linkage and extraction work in project queue
7.2	Data Linkage	Evaluate request and project requirements
7.3	Data Linkage	Request relevant data files
7.4	Data Linkage	Provision of ad-hoc data from datasets for project-specific linkage (if applicable)
7.5	Data Linkage	Validation of ad-hoc data for data linkage (if applicable)
7.6	Data Linkage	Linkage project planning meeting
7.7	Data Linkage	Perform cohort selection (if applicable)
7.8	Data Linkage	Undertake data linkage activities, including quality assurance
7.9	Data Linkage	Provision of linkage keys and/or identifiers for third-party linkage to relevant approved stakeholders

7.10	Data Linkage	Notify ISPD Client Services of linkage completion and progression in pipeline
7.11	ISPD Client Services	Provide a project status update to the applicant via email

Stage 8: Data Extraction		
Step	**Party**	**Task**
8.1	Data Engineering, Data Linkage & ISPD Client Services	Project planning meeting for clarification of data request
8.2	Data Engineering	Data extraction of requested datasets
8.2.1	ISPD Client Services	Request data from external collections (if required)
8.3	Data Engineering	Merging of data
8.4	MILESTONE	LINKAGE AND EXTRACTION COMPLETE
8.4.1	ISPD Client Services	Provide a project status update to the applicant via email
8.5	Data Engineering, Data Linkage & ISPD Client Services	Quality assurance project planning meeting
8.6	Data Engineering	Quality assurance review
8.6.1	ISPD Client Services	Administrative processing

Stage 9: Data Delivery		
Step	**Party**	**Task**
9.1	Data Engineering	Provide data extractions to ISPD Client Services
9.2	ISPD Client Services	Prepare data for delivery to applicant, including encryption of the data
9.3	ISPD Client Services	When all required approvals are complete and the applicant has confirmed contact details, release data to the applicant via MyFT or an e-Research platform
9.3.1	Data Linkage	Release identifiers to the applicant
9.4	MILESTONE	DATA DELIVERED
9.4.1	Applicant	Receive data via secure online file transfer or access data via an e-Research platform once all documents have been approved

Stage 10: Invoicing

Step	Party	Task
10.1	ISPD Client Services	Calculate the final cost to charge the applicant (if applicable)
10.1.1	ISPD Client Services	Investigate any significant changes from the cost estimate
10.2	ISPD Client Services	Send final cost to applicant with explanation for any significant variances from initial cost estimate via email (if applicable)
10.3	Applicant	Review and confirm final cost, and provide Purchase Order (PO) number if relevant
10.4	ISPD Client Services	Prepare S60 Debtor Advice Form for progression to Department's Accounts Receivable team to generate invoice
10.5	Accounts Receivable	Issue invoice to applicant's designated contact
10.6	Applicant	Pay invoice within designated timeframe
10.7	ISPD Client Services	On a quarterly basis, collate a list of all projects awaiting payment confirmation, and provide to Accounts Receivable via email to confirm payment has been received
10.8	Accounts Receivable	Respond to ISPD Client Services, confirming whether payment has been received from each applicant in the list
10.8.1	ISPD Client Services	If payment hasn't been received, follow up with the applicant

Stage 11: Project Closure

Step	Party	Task
11.1	RGO	Site-specific monitoring of the conduct of research projects, to ensure that projects RGO authorise are conducted with integrity and in compliance with relevant procedural requirements
11.2	Applicant	Provide annual progress reports to the Department's HREC via RGS or as per the HREC's conditions of approval
11.2.1	The Department's HREC	Monitor the applicant's research to ensure approved projects are conducted ethically in adherence with relevant conditions
11.3	Applicant	Submit Site Final Report to RGO via RGS after the completion of the project analysis
11.3.1	RGO	Validate, review, and authorise/approve the Site Final Report submitted by the applicant via RGS
11.4	Applicant	Upon approval of Site Final report, submit Project Final Report via RGS

11.4.1	The Department's HREC	Validate, review, and authorise/approve the Project Final Report submitted by the applicant via RGS
11.5	ISPD Client Services	Send Client Feedback Survey to applicant to assess the quality of services provided by the Department
11.6	Applicant	Provide a copy of project draft outputs (study article, etc.) to ISPD Client Services via email for review prior to publication
11.7	ISPD Client Services & Data Custodians (if applicable)	Coordinate review of project draft outputs and complete Draft Output Review Checklist. ISPD Client Services to liaise with Data Custodians (if applicable) to review project draft outputs.
11.7.1	ISPD Client Services	If the applicant has requested to publish small cell counts in their output(s), submit the output(s) to the Department's HREC for review in the monthly meeting.
11.7.2	The Department's HREC	If applicable, review draft output(s) in the monthly HREC meeting and provide outcomes to ISPD Client Services.
11.8	ISPD Client Services	Provide feedback to the applicant regarding publication of project outputs
11.9	Applicant	Provide a copy of project outputs (study article, etc.) to ISPD Client Services after publication
11.10	All (excl. applicant)	Ensure all project records are saved into the Electronic Document and Records Management System (TRIM) in adherence to the *State Records Act 2000*

3. Approval Requirements

The data application pipeline requires particular approvals in order for researchers to access and use health data for research purposes. All data applications for research purposes require approvals for feasibility, ethics, Data Custodians, and research governance. However, some applications may require additional approvals from specialist HRECs or other governing bodies. The approvals outlined below are provided in adherence to legal and regulatory requirements pursuant to relevant legislation, data sharing agreements and policy frameworks.

Feasibility Assessment
Purpose: Consideration of the practical feasibility of requests for access to data for research.   After the preliminary review has been completed, in-principle support is required from WA Health Data Custodians to ensure the requests complies with legal requirements and authorised purposes for which data can be disclosed before the application progresses for ethical approval.   Feasibility reviews are coordinated by the ISPD Client Services team and involve reviews by Data Custodians, ISPD Data Linkage and Data Engineering, and RGO (optional), including participation in a Draft Application Review meeting to raise concerns with the application. ISPD Client Services will then collate the feedback and provide to the applicant. After feedback from the feasibility reviews has been adequately addressed by the applicant (and the data application is deemed feasible), Data Custodians will provide in-principle support.   A feasibility letter confirming Data Custodians' in-principle support is provided to the applicant via email, accompanied by a cost estimate (if applicable) from ISPD Client Services. The applicant is then responsible for providing the feasibility letter to RGO via the RGS workspace in order to progress the application to the ethical approval stage.

Ethical Approval
Purpose: Consideration of ethical scientific standards, welfare and rights, and privacy and confidentiality.   All human research conducted in WA Health must undergo ethical and scientific review, approval and monitoring by a HREC registered with the National Health and Medical Research Council's (NHMRC's) Australian Health Ethics Committee (AHEC) and operating in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The data sought and nature of the research will determine which ethical review body or bodies must be applied for.   Research projects using health data will require specialist ethical approval from the Department's HREC, who has special responsibility for the oversight of the use and linkage of information held by the Department.   To obtain ethical approval, the applicant submits an application to the Department's HREC via RGS upon the receipt of a feasibility letter, which confirms the support from Data Custodians. Once the ethical approval process is complete, a letter confirming the Department's HREC approval is provided to the applicant by the Department's

HREC Office via RGS and includes a caveat that Site Authorisation is required before the release of data.

Formal Data Custodian Approval

Purpose: Ensuring compliance with the legal requirements and authorised purposes for which information can be collected, used or disclosed, including requirements prescribed through the *Information Management Policy Framework* and the *Research Policy Framework*.

Formal Data Custodian approval occurs after the required ethical approvals have been achieved and ISPD Client Services has been notified by either the Department's HREC or the applicant. Formal Data Custodian approval is coordinated by the ISPD Client Services team and granted by the WA Health Data Custodians and/or Data Stewards (if appliable) of the requested data assets.

The finalised Data Custodian Approval for Research Project document signed by all required Data Custodians is uploaded to RGS workspace by ISPD Client Services to assist with RGO approvals.

Research Governance Approval

Purpose: Consideration of professional, legal, and financial accountability and transparency.

It is recommended that the applicant engage with the RGO after formal Data Custodian approval is received to arrange the required research governance approvals (i.e., site authorisation and written agreement such as a DTA), to ensure the correct forms are submitted.

Site authorisations are requested by the applicant in RGS and coordinated by the RGO. The applicant is required to complete either an "Access Request Form" or a "Site Specific Assessment Form and Budget Form" and submit in RGS. The RGO reviews the application and provides recommendations to the authorised delegate to approve the location where the health data will be held, assessed, and destroyed for the purposes of the research. All new applications must be authorised by the Deputy Director General (DDG) of the Department of Health. All post-approval applications (amendments, progress reports, safety reports, final reports) must be authorised by the Director, Office of Medical Research and Innovation (OMRI). In circumstances where the DDG or Director of OMRI hold a conflict of interest, site authorisation must be granted by the Director General or DDG respectively.

Research involving WA health system employees, participants, data or biospecimens and that is undertaken in collaboration with an external entity must be the subject of a written agreement (such as a DTA). The type of the agreement required will be dependent on the nature of the research project. The written agreement lays out the terms and conditions of transferring or receiving health data and is coordinated by the RGO and approved by the authorised delegate. The review may include direct negotiation with the applicant (or the applicants organisations (e.g., a Research Contract Office of an organisation) and/or referral of the research agreement to LLS and/or the ICWA.

The written agreement must be submitted to the RGO via the RGS by the applicant at any time prior to or during submission of the site authorisation application.

RGO approvals will only be granted after evidence of the Department's HREC approval (and approvals from other required HRECs, if applicable) and formal data custodian approval(s) are provided via RGS.

4. Stakeholder Specific Roles and Responsibilities

4.1 Applicant

Specific responsibilities in data applications for research projects:

Pre-Application

☐ Contact ISPD Client Services regarding data application requirements (prior to applying for data)[1]

☐ Contact RGO to determine the project's viability and application requirements in terms of governance and ethics

☐ Submit draft data application to ISPD Client Services via email for a preliminary review

Preliminary Review

☐ Complete the New User Sign Up form and submit to the RGS Administrator for approval. If applicant is not a WA Health employee, they will also need to provide a WA Health employee as a referee / Local Contact in the form to verify the user login request (this can be the relevant ISPD Client Services Request Coordinator).

☐ Review preliminary feedback, action necessary changes and resubmit draft data application (as required)

Custodian Feasibility Assessment

☐ Review feedback provided by ISPD Client Services and resubmit revised draft data application (this is an iterative process which may require multiple reviews)

☐ Upload final data application form, data management plan, variable lists, extraction forms and feasibility letter into RGS

Ethical Approval

☐ Contact RGO and inquire on all required ethical approvals as well as clarifications on whether a DTA, an 'Access Request Form' or 'Site Specific Assessment Form' are required for the project

☐ Submit ethics application and the final approved data application documents to the Department's HREC for review and approval via RGS

☐ Provide additional information to the Department's HREC (as required)

    o If a significant amendment to the ethics application is required following ethical review, the applicant may have to revert to Stage 3 and resubmit data application

    o If the ethics application requires minor amendments, the applicant can amend ethics application and resubmit for ethical approval (Step 4.1)

☐ If applicable, the applicant must submit an additional ethics application to other HRECs for review and approval.

    o If a significant amendment to the ethics application is required following ethical review, the applicant may have to revert to Stage 3 and resubmit data application

    o If the ethics application requires minor amendments, the applicant can amend ethics application and resubmit for ethical approval

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[1] Department of Health Western Australia, *Human Research Ethics Committee Standard Operating Procedure* (July 2018) 10.1.

         ○ Upload other HREC approval letter(s) (if applicable) via RGS

Data Custodian Formal Review

☐ Notify ISPD Client Services when the Department's HREC ethical approval is granted (optional)

Research Governance Approvals

☐ Ensure all ethic approval letter(s) (if applicable) have been uploaded into RGS

☐ Liaise with RGO to complete the draft DTA if the applicant is external to WA Health. DTA template can be obtained from RGO

☐ After being advised of Data Custodian formal approval, submit the DTA (if applicable) and relevant site authorisation form via RGS, and add the relevant Request Coordinator as the 'Data Custodian' if applicable

☐ Project Principal Investigator to sign the Access Request Form / Site Specific Assessment and Budget form(s), and complete the submission to RGO via RGS

☐ Complete site authorisation process with RGO

Data Delivery

☐ Receive data via secure online file transfer or access data via an e-Research platform once all documents have been approved

Invoicing

☐ Review and confirm final cost, and provide PO number if relevant

☐ Pay invoice within designated timeframe

Project Closure

☐ Provide annual progress reports to the Department's HREC via RGS or as per the HREC's conditions of approval

☐ Submit Site Final Report to RGO and the Department's HREC via RGS

☐ Upon approval of Site Final report, submit Project Final Report via RGS

☐ Provide a copy of project draft outputs (study article, etc.) to ISPD Client Services via email for review prior to publication

☐ Provide a copy of project outputs (study article, etc.) to ISPD Client Services after publication

4.2 WA Health Data Custodians & Stewards

Location: Various – please refer to [WA health system Information Register](#)

Details:

- The Data Steward's responsibility for authorising the access, use and disclosure of data from a data collection may be delegated to a Data Custodian, if enabled by legislation.[2] Data Custodians are responsible for the ongoing development, collection, maintenance, and review of their data collection(s); including the quality of the data, its privacy, timeliness, and adherence to standards.

- Data Custodians are the subject matter experts of their data collection. They coordinate the development and maintenance of metadata, data dictionaries (variables) and domain values for their data collection/s.

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[2] Department of Health Western Australia, *Research Governance Procedures* (2021) 3.

- Data Custodians also coordinate and have extensive knowledge of existing legislations, policies, Memorandums of Understanding and DTAs, relevant to their data collection.
- Data Custodians are the decision makers regarding use of their data collection. A data request or project cannot proceed, and data cannot be released without approval from the relevant Data Custodians.
- There are over a thousand separate health data assets throughout the entire WA Health system, each managed by an assigned Data Steward and Data Custodian.
- Data Custodians are required to:
  - Ensure the use, disclosure and access to data meets legal requirements and is in accordance with approved protocols, contracts, and agreements
  - Provide advice on the proper use and interpretation of the data to authorised users
  - Complete risk assessments to ensure the identification of individuals, patients and health service providers have been considered and appropriately managed prior to release of information[3]

Specific responsibilities in data applications for research projects:
- ☐ Provide advice to ISPD Client Services if there are queries from the applicant (as required) in the pre-application stage
- ☐ Review draft application against data use and disclosure requirements, including relevant legislation, data sharing agreement and policy frameworks which apply to the data asset in question; provide feedback, recommendations and/or comments for the applicant in preparation for the Draft Data Application Review meeting (as necessary)
- ☐ Attend Draft Data Application Review meeting and provide feedback to ISPD Client Services
- ☐ Once satisfied that feedback has been addressed, advise ISPD Client Services of "in-principle support"
- ☐ Provide formal Data Custodian approval of the data application once HREC approval(s) have been finalised and all relevant criteria satisfied
- ☐ Ensure all project records have been provided to the ISPD Client Services team to be saved into the Electronic Document and Records Management System (TRIM) per the *State Records Act 2000*
- ☐ Review project draft outputs (when available) and provide feedback to ISPD Client Services (if applicable)

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[3] *Data application process description* – last updated 22/02/2021.

4.3 ISPD Client Services

Location: Information and System Performance Directorate

Details:

- The ISPD Client Services team manage and coordinate queries and requests for WA Health system data for health-related research through the data request pipeline, liaise with clients and WA Health business units to facilitate requests, and track and monitor the progress of open requests.[4]

- ISPD Client Services manage research data applications through the data request pipeline, including receiving, reviewing, logging, and coordinating responses to incoming requests.

- In processing requests, the ISPD Client Services team is responsible for coordinating requests in compliance with policies, procedures, and data governance requirements. As part of its role in coordination and liaison across the Department, the Team works closely with all areas of the Department to ensure services are delivered in a timely and efficient manner.[5]

- Key responsibilities of the ISPD Client Services team include:
  - Request coordination
    - Single coordination point for ad-hoc data requests that require coordination across WA Health
    - Receive, log, and manage all requests in the request register and ISPD Client Services mailbox
    - Assess, prioritise, and allocate requests between relevant teams
    - Facilitate collaboration between WA Health business units
  - Client liaison
    - Initial contact point for ad-hoc data requests to the ISPD Client Services mailbox
    - Liaise between client and WA Health units to facilitate requests
    - Provide advice and status updates to clients regarding requests
    - Provide clear rationale for declined or delayed requests
  - Oversight – tracking, monitoring, reporting
    - Track and monitor the progress status of open requests
    - Seek updates on progress where required
    - Report regularly on the status, scope, and timeliness of requests to Director, Data and Information Systems
    - Escalate unresolved issues to the appropriate management or executive positions.

Specific responsibilities in data applications for research projects:

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[4] Department of Health Western Australia, *01 ISPD and the WA Health System Overview* (2022)
[5] Department of Health Western Australia, *02 ISPD Client Services Function Overview* (2022) pg. 13

Pre-Application

☐ Provide advice to applicant (as required); seeking feedback from Data Custodians on data queries and the Data Linkage and Data Engineering teams regarding the technical viability (if needed)

Preliminary Review

☐ Administrative processing to enter the project into the system

☐ If applicable, verify the user login request

☐ Conduct a preliminary review of the draft data application to ensure completeness, and assign a priority to the project in accordance with the Data Linkage Prioritisation and Costing Framework

☐ Collate preliminary feedback and send to the applicant

☐ Additional preliminary review of draft data application (as required). If feedback is adequately addressed, project is added to the agenda for the next available draft data application review meeting

☐ Administrative processing to progress application to feasibility stage, and send the draft data application to Data Custodians for review ahead of the Draft Data Application Review meeting

☐ Create data flow diagram specific to the project

Custodian Feasibility Assessment

☐ Attend Draft Data Application Review meeting

☐ Provide the applicant with consolidated feedback from Data Custodians and relevant teams

☐ Process and check revised draft data application, before providing to relevant Data Custodians for additional review (as required)

☐ Calculate cost estimate for services after Data Custodian in-principle support is granted, in accordance with the Data Linkage Prioritisation and Costing Framework

☐ Prepare feasibility letter confirming Data Custodians' "in-principle support" from Data Custodians to enable applicant to proceed to the Department's HREC review (ethics application)

☐ Provide cost estimate and feasibility letter to the applicant confirming Data Custodians' "in-principle support" from Data Custodians for project to proceed to ethics application for the relevant HREC review (cc the Department's HREC). Include the latest data application form and data management plan in the email

Data Custodian Formal Review

☐ Once a copy of the HREC-approved data application has been received, cross-reference the HREC-approved data application against the IPS application to identify any significant changes

☐ Request formal Data Custodian approval from all relevant Data Custodians /Stewards after HREC approval is granted

☐ Advise the relevant Data Custodians of any significant changes to the application between IPS and HREC approval

☐ Notify the applicant that formal approval has been granted, including advice to engage with RGO regarding research governance approval application requirements, and to add ISPD Client Services Request Coordinator as 'Data

Custodian' on the Access Request Form or Site Specific Assessment Form and Budget Form if applicable

Research Governance Approvals

☐ Approve the applicant's Access Request Form submission (if applicable) to allow applicants to lodge submission via RGS, and upload Data Custodian Approval for Research Project document via RGS

Data Linkage (note that linkage may not be necessary for unlinked requests or where data is already linked in the Department's Data Warehouse)

☐ Prepare for project kick-off, and schedule data linkage and extraction work in project queue

☐ Provide an update to the applicant on project status when data linkage is complete (if applicable)

Data Extraction

☐ Project planning meeting for clarification of data request

☐ Request data from external collections (if required)

☐ Provide an update to the applicant on project status via email when data extraction is complete

☐ Quality assurance project planning meeting

☐ Administrative processing to progress to data delivery

Data Delivery

☐ Prepare data for delivery to applicant, including encrypting the data

☐ When all required approvals are complete and the applicant has confirmed contact details, release data to the applicant via MyFT or an e-Research platform

Invoicing

☐ Calculate the final cost to charge the applicant (if applicable)

☐ Investigate any significant changes from the cost estimate

☐ Send final cost to applicant with explanation for any significant variances from initial cost estimate via email (if applicable)

☐ Prepare S60 Debtor Advice Form for progression to the Department's Accounts Receivable team to generate invoice

☐ On a quarterly basis, collate a list of all projects awaiting payment confirmation, and provide to Accounts Receivable via email to confirm payment has been received

    ○ If payment hasn't been received, follow up with the applicant

Project Closure

☐ Send Client Feedback Survey to applicant to assess the quality of services provided by the Department

☐ Coordinate review of project draft outputs and complete Draft Output Review Checklist

☐ If the applicant has requested to publish small cell counts in their output(s), submit the output(s) to the Department's HREC for review in the monthly meeting

☐ Provide feedback to the applicant regarding publication of project outputs

☐ Ensure all project records are saved into the Electronic Document and Records Management System (TRIM) in adherence to the *State Records Act 2000*

4.4 Research Governance Office

Location: Office of the Deputy Director General

Details:

- The RGO conducts research governance reviews to ensure the Department is compliant with established ethical principles, legislation, codes of practice and regulations

- RGO also manages RGS to process all ethics and research governance applications and upload necessary approval documentation[6]

- Before research can commence at a nominated site, the RGO must conduct a site review and provide site authorisation[7]

- The RGO is also responsible for site-specific monitoring of the conduct of research projects, to ensure the projects they authorise are conducted with integrity and in compliance with relevant procedural requirements[8]

- The application may also require a DTA to ensure safe and secure release of data for research data requests submitted by researchers external to WA Health

- The RGO review of a valid application for site authorisation must be completed within 60 calendar days of the submission date of the required form (i.e. a 60-day clock commences from the submission date). Time spent waiting for the applicant to provide extra information is excluded from the 60-day clock.[9]

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Specific responsibilities in data applications for research projects:

Pre-Application

☐ Provide advice to applicant on ethical and governance requirements

Preliminary Review

☐ If the applicant is not a WA Health employee, the RGS Administrator will contact the WA Health employee who's been nominated as the local contact to verify the applicant's identity and confirm the applicant requires access to the RGS

☐ Approve user (applicant) request for access (RGS Administrator)

☐ Provide advice to applicant regarding the project's viability

☐ Approve the project workspace in RGS

Custodian Feasibility Assessment

☐ Attend Draft Application Review meeting to provide governance and ethics feedback on draft application (optional

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[6] Department of Health Western Australia, *Research Governance Procedures* (2021) 2.
[7] Department of Health Western Australia, *Research Governance Policy* (2021) 3.1.2.
[8] Department of Health Western Australia, *Research Governance Policy* (2021) 3.2.2.
[9] Department of Health Western Australia, *Research Governance Procedures* (2021) 8.1

Research Governance Approvals

☐ Undertake review of the application made to RGO; review DTA (if applicable) and request further information from the applicant (as required)

☐ If the project requires a DTA, prepare a Briefing Note for approval by the delegated authority

☐ Complete site authorisation process with applicant

☐ Write a recommendation to the DDG (or delegated authority, if appropriate) that they consider providing site authorisation for the project and for data to be released

☐ Provide finalised DTA (if applicable) and letter to the applicant confirming site authorisation via RGS

☐ Notify ISPD Client Services of research governance approval and provide a copy of site authorisation via email

☐ Facilitate execution of relevant confidentiality, indemnity, and conflict of interest forms[10]

Project Closure

☐ Site-specific monitoring of the conduct of research projects, to ensure that projects RGO authorise are conducted with integrity and in compliance with relevant procedural requirements

☐ Validate, review, and authorise/approve the Site Final Report submitted by the applicant after the completion of the project via RGS

☐ Ensure all project records are saved into the Electronic Document and Records Management System (TRIM) in adherence to the *State Records Act 2000*

4.5 Human Research and Ethics Committee

Location: WA Department of Health

Details:

- The Department's HREC is an advisory committee registered with the NHMRC that has special responsibility for oversight of the use and disclosure of personal health information held in the Department's data collections

- All single and multi-site research projects requesting WA Health datasets or projects conducted at WA health system entities must be ethically and scientifically reviewed by the Department's HREC[11]

    o Specialist ethical approval may be required in addition to the Department's HREC ethical approval if the research meets one or more criterion. The two (2) other specialist ethical committees in WA are the Western Australian Aboriginal Health Ethics Committee and Coronial Ethics Committee WA[12]

    o If a project has a clinical or interventional aspect, they will require approval from a public health lead HREC accredited to review and approve the project.

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[10] Department of Health Western Australia, *Research Governance Procedures* (2021) 11.
[11] Department of Health Western Australia, *Research Governance Policy* (2021) 3.1.1; Department of Health Western Australia, *Research Governance Procedures* (2021) 4.1.
[12] Department of Health Western Australia, *Research Governance Procedures* (2021) 4.3.

This could be a WA Health lead HREC (such as South Metropolitan Health Service HREC) or a non-WA ethics committee under National Mutual Acceptance (such as Royal Children's Hospital HREC)

- o For research involving sites across multiple Australian jurisdictions and including at least one WA health system site, the National Mutual Acceptance (NMA) scheme must be used to enable efficient review[13]

- The Department's HREC is responsible for conducting ethical review, monitoring and advice for all linked and unlinked research projects involving personal and non-personal, record-level information from the data collections held by the Department (and aggregate level information requests, at the discretion of the Data Custodian/Steward)[14]

- The Department's HREC meet monthly to review applications for the linkage, release, and usage of health data for research purposes

- The Department's HREC endeavours to complete ethical reviews within 60 days of receiving the application, notwithstanding time taken for feedback and requests for further information[15]

- The Department's HREC has special responsibility for the oversight of the use and linkage of information held by the Department and is accountable to the Department Director General[16]

- The Ethics Executive Officer provides executive support to the Department's HREC.

- A list of other recognised WA Health Ethics Offices and specialist HRECs can be found on RGS website.

Specific responsibilities in data applications for research projects:

Ethical Approval

☐ Ethics Executive Officer review of the ethics application (once received) to ensure completeness and validity, requesting further information from the applicant if required

☐ If feedback is adequately addressed, project is added to the agenda for the Department's next available HREC meeting (Ethics Executive Officer)

☐ Participate in the Department's monthly HREC meeting to discuss and review the research data application, collating feedback for the applicant

☐ Grant ethical approval once feedback has been addressed and application meets ethical standards/requirements

☐ Provide letter to the applicant confirming ethical approval via RGS within five (5) working days of the Department's HREC meeting[17]

Data Custodian Formal Review

☐ Notify ISPD Client Services of ethical approval via email with the following attachments:

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[13] Department of Health Western Australia, *Research Governance Policy* (2021) 4.2.
[14] Department of Health Western Australia, *Human Research Ethics Committee Terms of Reference* (May 2021) 4.1.
[15] Department of Health Western Australia, *Human Research Ethics Committee Standard Operating Procedure* (July 2018) 13.5.
[16] Department of Health Western Australia, *Human Research Ethics Committee Terms of Reference* (May 2021) 1, 5.1-2, 6.1.
[17] Department of Health Western Australia, *Human Research Ethics Committee Standard Operating Procedure* (July 2018) 13.1.

- o Data application that was approved by HREC
- o HREC approval letter attached

Project Closure

☐ Monitor the applicant's research to ensure approved projects are conducted ethically in adherence with relevant conditions[18]

☐ Validate, review, and authorise/approve the Project Final Report submitted by Applicant after the completion of the project analysis via RGS.

☐ If applicable, review draft output(s) in the monthly HREC meeting and provide outcomes to ISPD Client Services.

☐ Ensure all project records are saved into the Electronic Document and Records Management System (TRIM) in adherence to the *State Records Act 2000*

4.6 Data Linkage

Location: Information and System Performance Directorate

Details:

- The Data Linkage team facilitates linkage of data for a large and diverse client base through management of the WADLS. This includes the creation and maintenance of linkages and associated value-adds within and between a wide range of health and other datasets[19]

- The responsibilities of the Linkage team include:

  - o Creation, and maintenance of the WADLS which contains linkage keys for more than forty state-based health and other data collections

  - o Linkage of health and non-health datasets using rigorous, internationally accepted privacy preserving protocols, probabilistic matching, clerical review, and quality control to create a robust, complex system of links (i.e., artificially generated unique person identifiers).

  - o Value adding services, including geocoding, genealogical matching, and derived Aboriginal status

- The Linkage team provides information and advice to the applicants and the ISPD Client Services team on technical feasibility of data applications for research prior to ethical or research governance review

- The Linkage team also facilitates the provision of linked data (through creation of linkage keys) for projects which have received Custodian approval and the Department's HREC approval

- note that linkage may not be necessary for unlinked requests or where data is already linked in the Department's warehouse

Specific responsibilities in data applications for research projects:

Preliminary Review

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[18] Department of Health Western Australia, *Research Governance Policy* (2021) 3.2.1.
[19] Department of Health Western Australia, *Functional Overview: Data Linkage* (2018).

☐ Provide feedback to ISPD Client Services on technical viability of the application (if applicable)

Custodian Feasibility Assessment

☐ Attend Draft Data Application Review meeting and provide feedback to ISPD Client Services

Data Linkage

☐ Evaluate request and project requirements

☐ Request relevant data files

☐ Provision of ad-hoc data from datasets for project-specific linkage (if applicable)

☐ Validation of ad-hoc data received for data linkage (if applicable)

☐ Linkage project planning meeting

☐ Perform cohort selection (if applicable)

☐ Undertake data linkage activities, including quality assurance

☐ Provision of linkage keys and/or identifiers for third-party linkage to relevant approved stakeholders

☐ Notify ISPD Client Services of data linkage completion and progression in pipeline

Data Extraction

☐ Project planning meeting for clarification of data request

☐ Quality assurance project planning meeting

Data Delivery

☐ Release identifiers to the applicant

4.7 Data Engineering

Location: Information and System Performance Directorate

Details:

- The Data Engineering team is responsible for the Department's data warehouse infrastructure utilised to support data extractions in satisfaction of research data requests.

- The Engineering team performs data integration/merging (if applicable) and data quality checking on content/service data to be delivered to Applicants, as well as preparation of metadata and documentation to assist Applicants with their analysis

- The Engineering team also perform extractions of service data by inputting cohort parameters to filter data and extract only what has been requested/permitted for release[20]

- In addition, the team designs and develops data warehousing solutions, to promote data harmonisation, security, and availability via an architecturally managed

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[20] Department of Health Western Australia, *02 ISPD Client Services Function Overview* (2022) pg. 13

environment, and also improve data availability, management, and business support by automating data lifecycles

Specific responsibilities in data applications for research projects:

Preliminary Review

☐ Provide feedback to ISPD Client Services on technical viability of the application (if applicable)

Custodian Feasibility Assessment

☐ Attend Draft Data Application Review meeting and provide feedback to ISPD Client Services

Data Extraction

☐ Project planning meeting for clarification of data request

☐ Data warehouse data extraction of requested datasets

☐ Integration/Merging of data

☐ Quality assurance project planning meeting

☐ Quality assurance review

Data Delivery

☐ Provide data extractions to ISPD Client Services to facilitate data delivery

5. Application Types

5.1 Linked data request

Linked data refers to data that has been interlinked with other datasets to outline a patient's journey through the health system. Applications requesting linked data for research purposes are processed as outlined in this document.

5.2 Unlinked data request

Unlinked data refers to data that remains siloed from other datasets. Therefore, when completing the application process, data linkage is not required. Unlinked data requests are coordinated by the Department, with stages one (1) to six (6) completed as outlined in this document. As data linkage is not required, stage seven (7) is removed from the process. The process then resumes from stage eight (8) until the project is closed in stage 11, as outlined in this document. However, if the application only requests one (1) data collection, the data may be extracted and delivered to the applicant by the relevant Data Custodian, without requiring further Data Engineering support.

5.3 Data repurpose

Repurposing data is the use of data from one approved application for another subsequent application. The secondary application(s) may involve different research questions, aims, methods, personnel and/or organisations. Requests for data repurpose can be categorised into the following attributes, in increasing order of technical complexity:

- The request only uses data previously supplied
- New data variables or record filtering are required on existing datasets
- Additional datasets or data to existing datasets (e.g., years of data) are required

Due to the complexities involved in data repurposing, requests for repurposed data are assessed on a case-by-case basis. As such, the process for executing data repurposing requests has been excluded from this document.

5.4 Data amendment

In circumstances where the applicant has requested an amendment, a refresh or update of data previously provided for an approved project by the Department, the applicant must apply for a data amendment with ISPD Client Services, the Department's HREC (and other HREC bosies, if applicable) and RGO. Data amendment includes request to link new data, change methodology, add variables within a previously requested dataset or make changes to details of a previous application.If the requested data amendment, refresh, or update has not been pre-approved by the Department's HREC, the amendment application is processed as outlined in this document.

5.5 Population Health Research Network

Population Health Research Network (PHRN) projects require cross-jurisdictional data and are therefore coordinated by PHRN on behalf of the applicant. The Department coordinates the delivery of the requested Western Australian health data to PHRN to manage the delivery

of all requested jurisdictions to the applicant. Applications following the PHRN process will exclude the Pre-Application stage, as this is facilitated by PHRN prior to the request being received by the Department. However, all other stages are undertaken as per the processes outlined in this document, with PHRN considered as the applicant for the purposes of this document. The data applicant must facilitate the request for data by contacting PHRN via the online application system.

5.6 Social Investment Data Resource

The Social Investment Data Resource (SIDR) was initially created by the Department of Treasury (Treasury) to support, monitor and evaluate the WA Government's Target 120 program. The SIDR is an enduring linked, administrative database containing de-identified information on individuals who have had contact with key government agencies. Development of the SIDR has been a collaboration between the Department, Curtin University's Centre for Data Linkage and partner agencies, including the Departments of Communities, Justice, Education, the Mental Health Commission and WA Police.

Applications for SIDR data are primarily managed by Treasury, with input from the Department. After the applicant has expressed their interest in using SIDR data via the Application Form, Treasury completes the Pre-Application phase and a preliminary review prior to the Department receiving the draft data application for progression. After receiving the application from Treasury, the Department completes stages two (2) to five (5) as outlined in this document. Once the Data Custodians' formal review is completed, the Department will notify Treasury to complete the application process and deliver the data as required.

The SIDR application process flowchart can be found here.

6. Abbreviations

The following abbreviations are included within this document.

Keyword	Definition
DDG	Deputy Director General, WA Department of Health
The Department	WA Department of Health
DTA	Data Transfer Agreement
HREC	Human Research Ethics Committee
ICWA	Insurance Commission of Western Australia
IPG	Information and Performance Governance
ISPD	Information and System Performance Directorate, WA Department of Health
LLS	Legal and Legislative Services, WA Department of Health
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PHRN	Population Health Research Network
PO	Purchase Order
RGO	Research Governance Office, WA Department of Health
RGS	Research Governance Service
SIDR	Social Investment Data Resource
Treasury	Department of Treasury
TRIM	Electronic recordkeeping system
WA Health	The Western Australian public health system
WA Health system entities	Includes: • All Health Service Providers as established by an order made under section 32(1)(b) of the *Health Services Act 2016;* and • The Department of Health as an administrative division of the State of Western Australia pursuant to section 35 of the *Public Sector Management Act 1994.* Note: Contracted health entities are not considered WA health system entities.
WADLS	WA Data Linkage System

7. Definitions

The following definition(s) are relevant to this model.

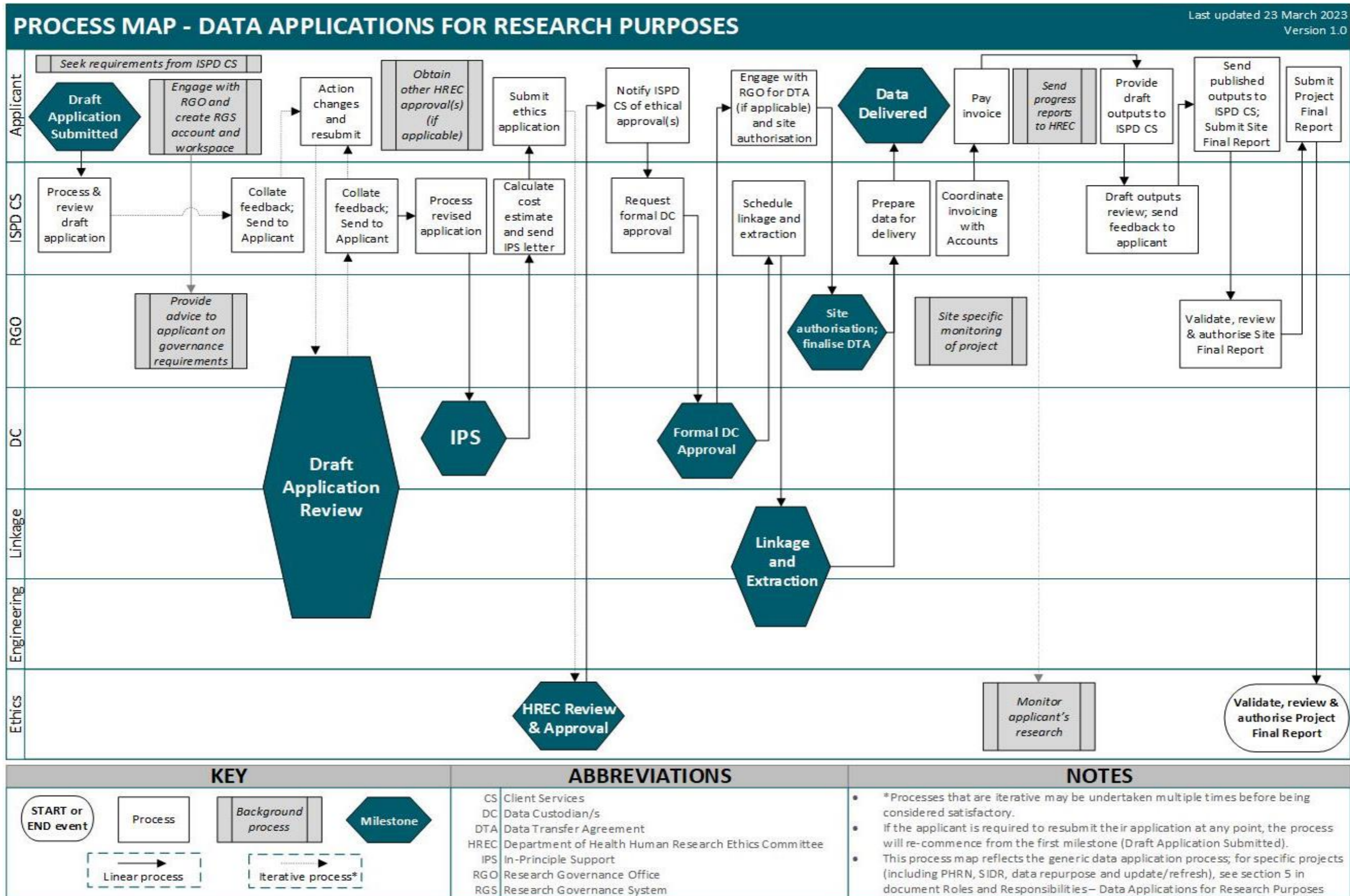| Keyword	Definition
Approved user	An approved user, in the context of data linkage and integration, is the person utilising an integrated dataset having been granted all relevant mandatory legal and ethical approvals.
Content data	Data which includes non-personal information, such as service or clinical information including details of diagnosis or treatment in hospital and related metadata.
	The content data is used as an analysis variable once merged using data linkage keys (via data integration).
Data	The term 'data' generally refers to unprocessed numbers, facts or statistics, while the term 'information' refers to data that has been processed in such a way as to be meaningful to the person who receives it.
	The terms 'data' and 'information' are often used interchangeably and should be taken to mean both data and information.
Data integration	A technical process of merging or combining content data which exists in different sources to provide approved users with a unified view of it. A data linkage key (generated via the data linkage process) is used to integrate the content data of the records, without releasing the person's name or other reasonably identifiable information.
	The terms 'merging' and 'combining' are often used interchangeably and should be taken to mean both merging and combining.
Data linkage	A complex technique connecting data records within and between datasets thought to relate to the same person, place, family, or event. Data linkage typically uses a combination of demographic data (for example: name, date of birth, address, sex, medical record number) and facilitates analysis of linked information in a way that protects individual privacy through the generation of a data linkage key (based on the degree of similarity between records) to enable data integration.
	This is also referred to as 'probabilistic matching' and includes software-driven probabilistic record matching and clerical or manual checking in accordance with the best practice linkage process described by Kelman, Bass and Holman (1999).
Data linkage key	A special unique identifier generated via data linkage for each group of records that is thought to relate to one person. The data linkage key enables data integration without releasing the person's name or other reasonably identifiable information.
Demographic data	Data which includes personal information (or reasonably identifiable information) such as name, date of birth, address,

	contact details, and other uniquely identifying numbers, e.g., a passport or unique medical record number. The demographic data is used as a variable for data linkage and/or matching processes.
HREC	A Human Research Ethics Committee registered with the NHMRC to conduct the ethical and scientific review of a human research project. Within this document, the term HREC has been used generally to refer to the WA Department of Health's HREC; some projects will require further ethical approval by additional specialty HRECs.
Information	The term 'information' generally refers to data that has been processed in such a way as to be meaningful to the person who receives it. Information can be personal or non-personal in nature. The terms 'data' and 'information' are often used interchangeably and should be taken to mean both data and information in this policy.
NHMRC	The National Health and Medical Research Council is a statutory authority and the primary agency of the Australian Government responsible for medical and public health research and the certification of committees under the NHMRC National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-Centre Research.
Personal information	Defined in the *Freedom of Information Act 1992* (FOI Act) as information or opinion about an identified individual.
Reasonably identifiable information	Reasonably identifiable information is personal information. It includes information connected with an individual's name, image, date of birth or address; information that contains a unique personal identifier when the holder of the information also has the master list linking the identifiers to individuals; and information that the holder can merge or link to other information they already hold, enabling them to identify individuals.
RGO	Research Governance Office oversees the governance aspects of research projects, to ensure projects are conducted with integrity and in compliance with relevant procedural requirements. Within this document, the term RGO has been used generally to refer to the WA Department of Health's RGO; some projects will require further research governance approval(s) by RGO(s) external to the Department.
Separation principle	The separation principle is a mechanism to protect the identities of individuals and organisations in datasets, applied as part of the data linkage and data integration process used to form the integrated dataset. Visit Data Linkage WA for more information.

WA Health system entities	Pursuant to section 19(1) of the *Health Services Act 2016* and section 35 of the *Public Sector Management Act 1994*, the WA health system includes:
	• All Health Service Providers as established by an order made under section 32(1)(b) of the *Health Services Act 2016;* and • The Department of Health as an administrative division of the State of Western Australia pursuant to section 35 of the *Public Sector Management Act 1994*.

8. Appendices

8.1 Process Map – Research Data Applications

PROCESS MAP - DATA APPLICATIONS FOR RESEARCH PURPOSES

Last updated 23 March 2023
Version 1.0

KEY

START or END event • Process • Background process • Milestone • Linear process • Iterative process*

ABBREVIATIONS

CS	Client Services
DC	Data Custodian/s
DTA	Data Transfer Agreement
HREC	Department of Health Human Research Ethics Committee
IPS	In-Principle Support
RGO	Research Governance Office
RGS	Research Governance System

NOTES

- *Processes that are iterative may be undertaken multiple times before being considered satisfactory.
- If the applicant is required to resubmit their application at any point, the process will re-commence from the first milestone (Draft Application Submitted).
- This process map reflects the generic data application process; for specific projects (including PHRN, SIDR, data repurpose and update/refresh), see section 5 in document Roles and Responsibilities – Data Applications for Research Purposes

Department of Health Data Linkage Roles and Responsibilities: Data Applications for Research Purposes v1
08/07/2023