

# SESLHD Guide to Data custodian request Template

Blanks on the form may render the application ineligible for review and will be returned to the applicant causing delays.

REGIS PID Ref No.	The REGIS registration number
CPI	Coordinating Principal Investigator's name
REGIS SSA Ref No	Site specific application REGIS number
PI	Principal Investigator's name
Mobile Contact number	Landline numbers will not be accepted
Email address	Non-Institutional email addresses will not be accepted
Study title	State the complete study name
Summary of study (regarding data)	Briefly outline the design/method regarding data collection and analysis
Ethics submitted to HREC (LHD/organisation name)	The name of the HREC that the ethics application was submitted to
Sponsor	Name of the LHD/Tertiary Institute or commercial sponsor
Funding	The name of the source/s providing/ managing funding (both in-kind and financial) i.e.: grant/SESLHD cost centre/tertiary or research institute or commercial entity
If collaborative, name partnering organisation/s	Name of all participating partners
Data at destination will be accessed and secured by:	List clearly in detail the person/s name – employment role/title – dept, that will be accessing the data at the destination. Clearly state the recipient's role in relation to the said data and once it is transferred externally. The person/s must be listed as study site members
Storage duration	<p>State how long you expect to retain the files. Please refer to: <a href="https://www.records.nsw.gov.au/node/539">https://www.records.nsw.gov.au/node/539</a></p> <p>8.1.1 Records relating to the conduct of clinical research including records or documentation relating to:</p> <ul style="list-style-type: none"> <li>-the recruitment and consent of research participants data/records/information access requests</li> <li>- Approvals</li> <li>- the collection and analysis of data</li> <li>- preliminary findings</li> <li>- surveys</li> <li>- reporting and results</li> <li>- retain a minimum of 15 years after the date of publication or completion of the research or termination of the study, then destroy.</li> </ul> <p>8.1.2 Records relating to the conduct of:</p> <ul style="list-style-type: none"> <li>- Nonclinical research, or</li> <li>- Research not involving humans Including records of associated consents or data/information access requests and approvals, the collection and analysis of data, conduct of surveys, reports of findings or results.</li> </ul>

	= retain minimum of 5 years and after date of publication or completed of research or termination of the study, then destroy.
Storage platform	State concisely the storage platform from which the data being exported will be held for the duration of the study.
Data being transferred from	From what location or service precisely is the data being transferred from within SESLHD – please clearly state the particular location and name of database/s or platform/s
Name of SESLHD staff member and role title, responsible for the data preparation and transfer	
Data being transferred to	State exactly the name and detail of the destination of the data being exported to – (not just the platform they will utilise to store the data) and who will be responsible for the data once exported from SESLHD
Status of data leaving SESLHD	<p>See below for definitions: <u>(if this is incorrect – or not clear, the request will be returned unauthorised, causing delay).</u></p> <p><b>Unidentifiable</b> (individual identifiers have been permanently removed and by no means of which specific individual can be identified). If it is Unidentifiable data – please state the process of de identification. Clearly provide the name of person/s who will be holding the key to the codes and how that will be secured.</p> <p><b>Re-identifiable</b> (All identifiers are removed from the dataset e.g. name, postcode, date of birth), replaced with a code, or are aggregated. Re-identification may be possible if a master copy of data that contains identifiers or master copy of study participants is kept. Please ensure you are clearly identifying <u>who is going to access and manage the master copy (or code key)</u> and what measures will be taken to ensure its secure storage.</p> <p><b>Identifiable</b> The identity of an individual information, or other sensitive information, can be reasonably discerned. Please ensure that the risk and potential considerations such as sensitivity of the information is declared within the request.</p>
Number of patient files that data will be extracted from	Please state what records from each file and how many patient files in total
Supporting documents <b>The protocol</b> will need to be attached (with reference to pages relevant to data) <b>The data dictionary, survey questions</b> or list of what data will be collected and exported from SESLHD.	Ensuring that you have the correct protocol version and date in the title and matching footer.

Key issues / further information	Please use this if further contextual content will help in providing transparency and clarification
Contact person (author of the brief)	Please note the author of the brief should be the Principal Investigator who is responsible for the conduct of the study within the SESLHD site.
Letter of confidentiality undertaking	The Principal investigator (who is responsible for the conduct of the study within the SESLHD site) must sign the confidentiality letter. If there are multiple SESLHD sites and PIs – then all PIs must sign the letter.