

SESLHD Guide to Data custodian request Template

REGIS PID Ref.No	The REGIS registration number
CPI	Coordinating Principal Investigator
REGIS SSA Ref.No	Site specific application's REGIS reference number
PI	Principal Investigator
Mobile Contact No	Landline numbers will not be accepted
Email address:	An institutional email address
Study title	State the complete title name
Summary of study	Briefly outline the aim/objective/methodology or design. If HREC approval has been obtained please provide the HREC LHD and date of approval
Sponsor	Please state the name of the SESLHD/tertiary institute or commercial entity etc
Funding	Please state the name of the source providing funding through i.e.: grant/cost centre (including hours in kind) or tertiary/research institute etc
If Collaborative, partners involved	Please clearly list in detail all key policy and practice stakeholders relevant to this request
Data will be accessed and secured by	Please list clearly in detail the person/s name – employment role/ title – dept, that will be accessing the data. Clearly state their role in relation to the said data - both within SESLHD and once it is transferred externally.
Storage duration	Please state how long you expect to retain the files. Please refer to: https://www.records.nsw.gov.au/node/539 8.1.1 Records relating to the conduct of clinical research- including records or documentation relating to: <ul style="list-style-type: none"> • the recruitment and consent of research participants data/records/information access requests • approvals • the collection and analysis of data • preliminary findings • surveys • reporting and results = retain a minimum of 15 years after the date of publication or completion of the research or termination of the study, then destroy. 8.1.2 Records relating to the conduct of: <ul style="list-style-type: none"> • Non clinical research, or • Research not involving humans

	<p>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.</p> <p>= retain minimum of 5 years and after date of publication or completed of research or termination of the study, then destroy.</p>
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 where <i>exactly</i> is the data being transferred from within SESLHD – please clearly state the particular location and database/s or platform/s
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)
Status of data leaving SESLHD	<p>See below for definitions: <i>(if this is incorrect – or not clear, the request will be returned unauthorised, causing delay).</i></p> <p>Unidentifiable (individual identifiers have been <u>permanently removed</u> 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>Re-identifiable (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 who is going to access the master copy and what measures will be taken to ensure its secure storage.</p> <p>Identifiable 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 files	(number of patients' files)
Supporting documents	The protocol will need to be attached. Please ensure that you have the correct version and date in the title and matching footer. For extensive protocols, please include relevant page number/s pertaining to the data export, in the request form.

	Please include the data dictionary of what data will be collected and exported from SESLHD.
Key issues / further information	
*the contact person /author of the brief	Please note the author of the brief should be the PI or CPI.
Letter of confidentiality undertaking	Please ensure that the Principal investigator (who is responsible for the conduct of the study within the SESLHD site) signs the letter. If there are multiple SESLHD sites and PIs – then all must sign the letter,