



Murdoch Children's Research Institute (MCRI)

Data Sharing Plan

Notes
<ul style="list-style-type: none"> • <i>Data Sharing Plans must be prepared in accordance with all relevant MCRI policies and procedures.</i> • <i>Data Sharing Plans must also be consistent with the Protocol, Patient Information and Consent Form (PICF) and the terms of any funding, collaboration agreements or other legal agreements governing the project.</i> • <i>Data Sharing advice should be obtained from the the Melbourne Children's Trial Centre by contacting: MCTC@mcri.edu.au</i> • <i>Legal and Intellectual Property advice should be obtained from the Business Development and Legal Office by contacting: legal@mcri.edu.au</i>

PROJECT DETAILS	
Protocol Title	
Protocol Number	
Sponsor-Investigator Name	
HREC Approval Number	
DATA SHARING PLAN DETAILS	
Do you plan to share any data?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If no, provide justification. <i>**Remainder of form does not require completion**</i>	

If you DO intend on sharing data, please complete the remaining questions below:		
Will individual participant data be available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If Yes, will this include data dictionaries?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
What data will be shared? <i>(Tick which applies)</i>	Individual participant data that underlie the results reported in the <u>primary publication</u> (text, tables, figures, and appendices), after deidentification.	<input type="checkbox"/>
	Individual participant data that underlie the results reported in subsequent publications (text, tables, figures, and appendices), after deidentification.	<input type="checkbox"/>
	All of the available individual participant data collected during the trial, after deidentification.	<input type="checkbox"/>
What other study documents will be made available?	Study Protocol	<input type="checkbox"/>
	Statistical Analysis Plan (SAP)	<input type="checkbox"/>
	Informed Consent Form	<input type="checkbox"/>
	Clinical Study Report / Statistical Report	<input type="checkbox"/>
	Analytic Code	<input type="checkbox"/>
	Other, specify:	<input type="checkbox"/>
When will the data be made available? <i>Enter event that triggers availability: e.g. 6 months after publication of the primary endpoint results/analysis</i>		
With whom will data be shared? <i>(select one)</i> <i>Enter any restrictions if applicable.</i>	Investigators whose proposed use of the data has been approved by an independent review committee (learned intermediary) identified for this purpose.	<input type="checkbox"/>
	Researchers who provide a methodologically sound proposal to the trial team.	<input type="checkbox"/>
	Anyone who wishes to access the data.	<input type="checkbox"/>

For what types of analyses? <i>(select one)</i>	For individual participant data meta-analysis	<input type="checkbox"/>
	To achieve aims in approved Data Access Applications	<input type="checkbox"/>
	Any purpose	<input type="checkbox"/>
By what mechanism will data be made available? <i>(select one)</i> <i>Enter information of person to contact / request process (this may be an email or link to a website if appropriate)</i>	Data requests should be directed to MCTC@mcri.edu.au . To gain access, data requestors will need to sign a Data Transfer Agreement.	<input type="checkbox"/>
	Data are available at the following third-party data repository website: specify:	<input type="checkbox"/>
	Other, specify:	<input type="checkbox"/>

DATA SHARING STATEMENT

<p>What is your “Data Sharing Statement” to be included in clinical trial registries or forwarded to publications?</p>	
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SPONSOR-INVESTIGATOR DECLARATION

I confirm that the Data Access and Sharing Plan is appropriate for the research study and complies with all relevant MCRI policies and procedures and is consistent with the Protocol, PICF and the terms of any funding, collaboration agreements or other legal agreements governing the project.

Sponsor-Investigator Name

Sponsor-Investigator Signature

Date