

Note: This form provides a formal notification to the AKTN for a proposal to request and release data associated with AKTN projects.

Overview of process:

1. Complete and return this form to aktn@uq.edu.au
2. The AKTN Data Access Committee will commence the review process.
3. If the request is reviewed favourably, a data sharing agreement may be required prior the release of data.

Section A: Requester Details			
Short title of data request:			
Date of Request:		Date required by:	
AKTN Project of interest:			
Type of data request	<input type="checkbox"/> Aggregate or summary data ONLY <input type="checkbox"/> Data for all participants <input type="checkbox"/> Data for sub-set of participants <input type="checkbox"/> Biological samples of all participants <input type="checkbox"/> Biological samples of sub-set of participants <input type="checkbox"/> Statistical programs used for analysis <input type="checkbox"/> Other, specify		
If the request is for a sub-set of participants, include what sub-set			
Data Requester:		Title:	
Role of the data requestor in the project described in section B:			
Are you a TSC member on the AKTN trial this data request relates to? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Affiliation/Organisation:			

Section A: Requester Details

Address:

Telephone:

Email:

List all other Investigators:

Note: Data Requester to list all researchers who will receive access to the shared data/samples.

Title	Name	Role in the project	Affiliation/Organisation:	Contact

Do you have an affiliation with UQ?

Yes, employed Yes, student No

HREC approval status?
(Attach relevant documentation)

HREC approved * Please attach a copy of your approval letter, a full copy of your application and any other relevant documents such as participant information sheets and consent forms, etc.

HREC approval pending

HREC approval not applicable

Notification of HREC exemption received * Please attach a copy of the notification

Details if HREC approval is not applicable

Section B: Project Details

Please note that approval will only be given for the project described in this application. Use of data/samples for any other purpose will require an **additional** request and approval.



Section B: Project Details

Title of project			
Background and rationale for the project (500 word maximum plus key references)			
Hypothesis and specific research questions			
Outcome measures			
Possible outcomes and clinical significance of this research (250 word maximum)			
Methodology of project (500 word maximum)			
Analysis plan and statistical methods			
Inclusion and Exclusion criteria			
Estimated data analysis start date		Estimated data analysis end/destruction date	
Is this a funded research project?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If YES, who has funded project?			
Was a member of the trial team involved in the funding request?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If YES, who was involved and how?			

Section C: Data fields/Samples required



Note: this section will be completed in Microsoft Excel and attached to the completed Form.

Data fields/sample listing attached

Yes No

If NO, specify the type of data fields/samples requested

Data/sample storage location and security measures

Section D: Conflict of interest declaration

Do you have an actual, perceived or potential conflict of interest?

Yes No

If YES, please state the conflict

Section E: Applicant's signature

- I agree to adhere to all the conditions outlined in any data sharing agreement that will be provided to me prior to data sharing.
- I agree that the information provided by me is true, accurate, complete and without material omission.

Name

Signature

Please return your application to aktn@uq.edu.au

FOR OFFICE USE ONLY:

<p>Trial Steering Committee / Data Access Committee decision</p>	<p><input type="checkbox"/> approved</p> <p><input type="checkbox"/> approved subject to amendment</p> <p><input type="checkbox"/> declined</p>
<p>If approved, subject to approval, list required changes</p>	
<p>Approved by Chair:</p> <p>Signature: _____</p> <p>Name: _____</p> <p>Date of approval: _____</p>	

ACKNOWLEDGEMENT OF RECEIPT:

This must be the same person named in section A Requestor details.

I acknowledge that I have received the requested data/samples:

Signature: _____

Name: _____

Date of approval: _____