Australasian ILD Registry Data access protocol

7th August 2019

One of the main objectives of the Australasian Interstitial Lung Disease Registry is to provide a valuable resource for researchers. This document is a protocol to guide researchers on how to access Registry resources. It gives instructions on the process for applying for access to these resources and outlines the procedure for how a decision on such access will be made.

Applying to use Registry data

Any individual or group of researchers can apply to use the resources and data held by the Australasian ILD Registry, provided that ethical and scientific quality criteria are met.

Registry variables available are detailed in the Registry Data Dictionary.

1. Single site data use

Individual sites may access their own data (subject to ethics approval) for single-site projects without applying to the Steering Committee for data use. However, the Registry authorship and acknowledgement policy remains applicable in this context.

2. Multi site data use

Application process

Researchers and policy makers will request access to Registry data using a two stage process:

Stage 1: At this stage the researcher(s) will be requesting 'in principle agreement' to access Registry data. The researcher should provide:

a) Cover Letter

b) Research Proposal (2 page summary)

c) List of data fields required

Research proposals at Stage 1 will be processed and considered as soon as possible by the Steering Committee members. The research subcommittee will review the proposal out of session and provide a recommendation to the committee.

The steering committee will vote on-line in favour or against approval of projects. Steering Committee members will have the option for their site to be involved or not involved in the project. No project will access data from a site without the approval of the SC member from that site.

The Registry coordinator will collate opinions, finalise decisions and inform the researchers of the outcome to the application (as well as which sites will be involved), together with any recommendations to include in a Stage 2 application, if appropriate.

Stage 2:

A Stage 2 application should be submitted for projects that already have an in principle agreement and subsequently have received funding and/or ethics approval.

The researcher should provide:

a) Cover Letter

b) Evidence of ethics approval

c) Evidence of funding source (if appropriate)

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Stage 2 research proposals are considered in the same manner as Stage I proposals.

It may be that the Steering Committee request that the researcher(s) provide further information and/or details following a Stage 1 application and prior to Stage 2. Depending on the type of application, the Steering Committee is free to waive Stage 2.

All studies will require ethics approval from the Human Research Ethics Committee (HREC) that approved the Registry (approval to release the data for this purpose) and also the researchers` local HREC.

General Considerations

Where an investigator is a member of the Registry Steering Committee or some other conflict of interest exists, a Committee member may participate in discussions about the proposal but will be exempt from the final decision-making process.

Comparable proposal applications

The Registry Steering Committee seeks to ensure that all projects using Registry data are unique and address a specific and sound scientific question. Should a second research group apply to use Registry data for a comparable project already agreed to the second research group will be informed that their proposal will not be considered further, and why. However, if it eventuates that the agreed research does not proceed in a timely way, it is in the discretion of the Registry Steering Committee to withdraw consent and to contact the second team and ask them to resubmit their proposal.

Acknowledgements, authorship and responsibilities of using Registry data

All publications resulting from Registry-related research are subject to the Registry Steering Committee authorship policy.

All conference presentations and publications should acknowledge the Australasian ILD Registry as the data source, and the Lung Foundation Australia as the managing partner, and the Centre of Research Excellence for Pulmonary Fibrosis and include their logos with the title.

Other details of Registry authorship policy are set out in the Australasian ILD Registry authorship policy.

Charges for access to Registry data

The Steering Committee will in general levy to external researchers a fee for the cost of Registry ethics applications, data export and processing, as well as those entailed in data collection, especially where a proposed research study includes access to competitive grant or other funding. Where the Steering Committee considers that a research proposal is of scientific interest and value but has no access to funding this fee may be waived at the discretion of the Steering Committee. The research application will need to indicate resources available to complete the study.

Agreement

Once Stage II assessment and research costs are agreed, external researchers and/or their employing institution will be asked sign an agreement with Lung Foundation Australia that sets out the terms and conditions of the use of Registry data.

The Agreement with the Lung Foundation will be a licence to use Registry data for the specific purpose and research project. The Agreement will include terms of use, storage and access to the Registry data.

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