Lymphoma and Related Diseases Registry (LaRDR)

DATA ACCESS POLICY

VERSION 1.0 DATED 21 MARCH 2016

Lymphoma and related diseases patient data collected and collated by the LaRDR is guided by strict protocols and procedures to ensure that privacy and other ethical principles are maintained at all times. Provision of data to LaRDR is subject to strict data management guidelines and the study project outline as submitted to all participating hospital and Monash University Human Research Ethics Committees. In particular, specific measures have been put in place to maintain the confidentiality of personal identifying information.

This document outlines the LaRDR Data Access policy. Access to data is subject to the approval of the Steering Committee.

Direct access to, and extraction of, data from LaRDR:

The following data access policy has been adopted:

1. Access to the data is subject to the Specific Access Guidelines outlined on page 3 of this document.
2. Only the Project Manager of LaRDR and staff who report directly to the Project Manager of LaRDR have direct access to the LaRDR Registry database.
3. All use of data from LaRDR, in whatever context, must receive prior approval from the Principal Investigator of LaRDR and/or the LaRDR Steering Committee. In all cases, specific hospital ethics committee approval is also required.
4. Any material or manuscript to be published using LaRDR data must contain appropriate acknowledgements of LaRDR. Preferred wording for the acknowledgement will be provided with the data.
5. Any material or manuscript to be published using LaRDR data must be submitted to the LaRDR Steering Committee for information prior to submission for publication. However, the decision to publish remains with the authors of the publication.
6. Under no circumstances will individual unit record data be made available to third parties.
7. Only requests that meet Specific Access Guidelines Categories 1 and 6 (see page 3) will be provided free of charge, unless a large number of such requests are made. This will be reviewed from time to time. The provision of data for all other data requests (Specific Access Guidelines Categories 2-5) will be subject to a fee-for-service. See the 'Fees For Provision of Data' statement (page 4) for an explanation of the fees.
8. All third party requests for access to LaRDR data must take appropriate timelines into account as these requests will need to be scheduled along with routine LaRDR tasks. As a general rule, requests for data under Specific Access Guidelines Categories 1 and 6 will take 2-4 weeks to complete. Data cannot be supplied within 2 weeks of a request. All other requests must first be made to the LaRDR Project Manager, who will then table such request at the next Steering Committee meeting. LaRDR Steering Committee meetings are held at least twice per year and data cannot be extracted until approval is given by the Steering Committee. Under exceptional circumstances, when data is required earlier, the LaRDR Project Manager may request approval by the Steering Committee electronically to consider specific data requests. Once approval has been received, it will take 2-4 weeks to supply the data.
9. All data requests must be formally lodged, using the form on page 6 of this document, via:

Email: SPHPM-Lymphoma@monash.edu

Mail: The Project Manager,
Lymphoma and Related Diseases Registry,
School of Public Health and Preventive Medicine,
Monash University,
Alfred Centre,
99 Commercial Road,
MELBOURNE VICTORIA 3004
AUSTRALIA

LaRDR Specific Access Guidelines

No requests by third parties for direct access to individual records will be approved under any circumstances as this contravenes privacy legislation and ethics approvals for LaRDR granted by Monash University and participating hospitals.

Category 1. Where summary data only is requested, the information can be provided by LaRDR staff. Such provision of data does not require Steering Committee approval but LaRDR will require a formal request in writing and will keep a record of such requests. The LaRDR Steering Committee will be provided with a summary of such requests on a biannual basis. A caveat and conditions of use statement will be provided with the data.

Category 2. All requests for other aggregate data must be in made in writing to the LaRDR Project Manager who will submit the data request to the next LaRDR Steering Committee meeting. A decision on whether to grant access to the data will be made by the LaRDR Steering Committee following advice from the Project Manager. At no stage will data that could identify hospitals or patients be provided. A caveat and conditions of use statement will be provided with the data.

Category 3. Researchers may request LaRDR to undertake specific analyses of data. In all cases, the researchers would subsequently be provided with resulting aggregate data only. A formal written request should be made to LARDR for approval from the Steering Committee. A caveat and conditions of use statement will be provided with the data.

Category 4. If a third party researcher or student requires individual data for linkage, this cannot be provided directly. However, it may be possible for the third party to provide their data to LaRDR for linkage purposes and for LaRDR to provide non-identified data or aggregate data summaries based on the linked data. Individual record data will not be made available to the third party in any circumstance. All such linkage projects will require separate ethics committee approval from each hospital involved. A formal written request should be made to LaRDR for approval from the Steering Committee. This also applies to the comparison of external data sets with data maintained by LaRDR.

Category 5. If a researcher requires data from a particular hospital or hospitals, a specific ethics application approval from that hospital(s) will be required before data is made available. This ethics approval should be made jointly with LaRDR.

Category 6. If a hospital or its representative makes a specific request for its own performance data, beyond that available on the Hospital Data Report, this will be provided by LaRDR. No data that could specifically identify a patient will be provided. All requests for this category data should be made in writing to the LaRDR Project Manager. Whilst such data requests do not require Steering Committee approval, the Project Manager will notify the Steering Committee of the requests.

LaRDR Fees for Provision of Data

1. Access to data and requests for data from LARDR are subject to strict access guidelines outlined above.

2. All data summaries and analyses provided by LaRDR will incur a fee to cover the costs for staff to undertake this work.

3. The minimum charge per hour of work (or part thereof) is $100. Thus, a data analysis/report requiring 1.5 hours of LARDR Registry staff time will be charged at $200.

4. The fee of $100 per hour (or part thereof) is for basic tabulations and data extractions only. When more detailed analysis of data is required (e.g. statistical comparisons, statistical modelling, etc.), this will be charged at a higher rate (available on application).

5. GST (10%) is also payable and the overall charge per hour (or part thereof) is therefore $110 for a minimum analysis.

6. Upon receipt of a data analysis request, LaRDR will provide a cost estimate for the work. This will normally be within 2 weeks of receipt of the request. Those requesting data must agree to these costs (in writing) before any data request will be met.

7. See also Acknowledgement and Authorship policy (page 5).

Acknowledgement and Authorship Policy

- Any data provided is on the condition that LARDR is acknowledged as the source of the data. The suggested citation is: *The data was provided by the Lymphoma and Related Diseases Registry.*

    - Where the interpretation of LaRDR data is central to the data request, it is expected that at least one member of the LaRDR team is named as a co-author on any publication arising from use of requested data. The actual LaRDR contributor/s to be named would depend on the actual input to the particular data exercise and should conform to the *Australian Code for the Responsible Conduct of Research* (https://www.nhmrc.gov.au/guidelines-publications/r39 or http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf) and Monash University Research Outputs and Authorship Policy (http://policy.monash.edu.au/policy-bank/academic/research/research-outputs-and-authorship-policy.html).

- Powerpoint Slides from LaRDR for presentations are provided on the condition that individual slides are not altered in any way (including background) prior to use.

- LaRDR requires that a copy of any document or presentation using LaRDR data, figures, or powerpoint slides is provided to the LARDR Project Manager at the address below. LaRDR maintains a record of all requests for LaRDR data and its subsequent use as a means of monitoring the value of the project to the wider clinical community.

- Please sign and return this form via:

Email:	SPHPM-Lymphoma@monash.edu
Mail:	The Project Manager, Lymphoma and Related Diseases Registry, Department of Epidemiology and Preventive Medicine, Monash University, Alfred Centre, 99 Commercial Road, MELBOURNE VICTORIA 3004 AUSTRALIA

I agree to acknowledge the Lymphoma and Related Diseases Registry, Department of Epidemiology and Preventive Medicine, Monash University for the provision of data for reports, presentations, publications and documents as appropriate.

SIGNED:_____ DATE:_____

PRINT NAME:_____

POSITION / ORGANISATION:_____

_____

MOBILE NUMBER:_____ E-mail:_____

Request for Data from Lymphoma and Related Diseases Registry (LaRDR)

Date of Request:_____ Date Data is needed:_____

Name:

Affiliation /

Organisation:

Address:

Telephone:_____ Mobile:_____

E-mail:_____

Are you a student? ☐ Yes ☐ No

If YES, what degree are you working towards?

Name and contact details of your supervisor:

Short title of data

request:

Please attach a short description of your project (1-3 paragraphs)

Reason for data request

PLEASE TURN OVER

Actual data requested *(attach separate document if insufficient space)*

Is this for a funded research project? ☐ Yes ☐ No

If YES, who has funded the project?

Was LaRDR formally involved in the grant application? ☐ Yes ☐ No

Have you received Ethics Committee approval to access LaRDR data? ☐ Yes ☐ No

If YES, please attach copy

To what use do you expect to put this information?

Have you read the LaRDR data access policy? ☐ Yes ☐ No

Do you agree to follow it? ☐ Yes ☐ No

Have you read the LaRDR Acknowledgement and Authorship Policy (page 5)? ☐ Yes ☐ No

Do you agree to comply with this? ☐ Yes ☐ No

How did you find out about accessing LaRDR Registry data?

_____

_____

_____

Approved by Project Manager of LaRDR

Signature:_____ Date:_____