# Australian Cystic Fibrosis Data Registry (ACFDR)

## Data Access Policy

Version 2a

06 February, 2017

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# Document Version Control

| Version | Date | Reason/Comments/Approvals |
|---|---|---|
| 1.0 | 23/09/2016 | Initial Version Release.<br>Approved by the ACFDR Advisory Group on 23/09/2106 |
| 2.0 | 06/02/2017 | Inclusion of role account email for registry contact purposes – administrative change only |
| 2.0a | | Amended contact details due to error |

# 1. Preface

The Australian Cystic Fibrosis Data Registry (ACFDR) encourages the use of its data for a variety of purposes such as quality improvement, research, clinical planning and other activities that may lead to an improvement in care to patients with cystic fibrosis. This data access policy defines how data from the ACFDR may be accessed. The policy includes the criteria and conditions for provision of de-identified individual level data, aggregate data, reports or analyses; and procedures for data request applications. It also outlines the cases in which fees for such access might be applicable, and any associated acknowledgement and publishing responsibilities.

Data collected and collated by ACFDR is guided by strict protocols and procedures to ensure the security, privacy and confidentiality of all information collected and stored in the registry. All patient and stakeholder information will be handled in accordance with the *Commonwealth Privacy Act (1988),* the *Privacy and Data Protection Act 2014 (Vic)* and the *Health Records Act 2001 (Vic)*, similar relevant interstate legislation, and any code of practice or guidelines made under these Acts.

All registry activities have been approved by a National Health Medical Research Council (NHMRC) approved Human Research Ethics Committee (HREC) and other participating site and Monash University Human Research Ethics Committees.

The University Privacy Compliance Framework is available at www.privacy.monash.edu.au.

# 2. Project Information

## 2.1 Purpose of ACFDR

The ACFDR has been established as a national cystic fibrosis data repository to provide valid and reliable cross-sectional and longitudinal data on cystic fibrosis patients in Australia. The primary aim of the registry is to use data from Cystic Fibrosis (CF) Centres in Australia to monitor quality of care and disease progress in patients with cystic fibrosis in Australia.

## 2.2 Project overview

ACFDR collects health information on cystic fibrosis patients including data on demographics, diagnosis, health and functioning, treatment, organ transplantation and mortality. As of September 2016, the data is managed in a shared data custodian model between Monash University and Cystic Fibrosis Australia. Data is available to researchers and other interested parties in aggregate/summary form or as a report or analysis, and to researchers as de-identified individual level data. Data from participating sites is held by ACFDR in coded re-identifiable form. Each patient on the registry has a unique registry identifier that is used to re-identify the patient at the site. Access to identifiable data for research purposes, in addition to ethics approvals would require agreement by the site's Centre Directors or Principal Investigator to release patient identifiers.

# 3. Access to Data held by the ACFDR

ACFDR data is hosted on a server that is managed by IS Group Pty Ltd, external IT consultants contracted by Cystic Fibrosis Australia. Access to data is subject to applicable privacy laws and principles, and ethics approvals. Specific measures have been put in place to maintain the confidentiality of personal identifying information at the patient and hospital level.

Data access is generally subject to the approval of the ACFDR Steering Committee. When considering the approval of access to ACFDR data, the ACFDR Steering Committee will consider whether the project satisfies the principles of research merit and integrity.

Access to the data is subject to the Data Access Request Process outlined in this section 3.

## 3.1 Eligible applicants

Researchers, medical professionals and pharmaceutical professionals working at research institutions, hospitals, private entities, government or other health services within Australia and industry are eligible to request access to data held within the registry. All requests for data are noted in the ACFDR Steering Committee minutes and logged.

## 3.2 Access to ACFDR data

1. Staff who report directly to the ACFDR Data Custodian will have direct access to the database and for operational purposes IS Group PTY.LTD staff, directly involved in supporting registry systems have access for upgrades and break fixes, and are bound by Monash University confidentiality agreements.
2. All uses of ACFDR data, in whatever context, must receive prior approval from the ACFDR Steering Committee unless a pre-existing funding agreement is in place and has been previously approved by the ACFDR Steering Committee. Research related requests may require specific ethics committee approval. Use of data for any other purpose will require an **additional** request.
3. Data access may be subject to conditions in agreements and/or research ethics approvals.
4. Under no circumstances will individually identifiable data in respect to patients, contributing clinicians, or hospitals be made available to parties other than the ACFDR Steering Committee, authorised ACFDR personnel, and members of any working group directed by and reporting to the Steering Committee during the course of incident, complaint or outlier management
5. If a third party research or student project requires individually identifiable data for linkage or further research, this cannot be provided by ACFDR directly. Following ethics approval, sign off by involved Centre Directors or site Principal Investigators and ACFDR steering committee approval, ACFDR will provide the required data to the site/s involved to forward the data and patient identifying keys to the third party or student.
6. Where only basic summary data available through public reports is requested, this can be provided by ACFDR staff without steering committee approval.
7. ACFDR encourages the independent access of clinician data available through the ACFDR web interface however, should a contributing clinician request access to their own patient data ACFDR will provide this. All requests for this category of data should be made in writing to the ACFDR Director on request form 2.
8. If a hospital executive makes a specific request for its own performance data, ACFDR will provide this information. Identification of a clinician will not be provided without the written permission of the Centre Director/Principal Investigator. All requests for this category of data should be made in writing to the ACFDR Director on form 2. Such data requests will require Steering Committee approval.
9. For requests from industry, comparative information i.e. market share will not be provided.
10. The provision of data may be subject to a fee-for-service on a cost recovery basis unless in line with existing funding agreements or MOUs between registry funders/supporters. Fees will be at the discretion of the ACFDR Steering Committee in consultation with the ACFDR Director and will

be based on the complexity and estimated time taken to complete the request as well as current ACFDR routine workload. . Please see the Data Access Fee Schedule for an explanation of these.

11. All requests for access to the ACFDR data are undertaken in addition to routine ACFDR workload. As a general rule, following submission of the request form, review by the ACFDR steering committee will occur within 4 weeks. Requests involving reports or analysis will be provided with a quote and expected time frame for completion. Most data access requests will generally be provided within 2-6 weeks following Steering Committee approval.
12. Requests must be first made to the ACFDR director at Monash University who will either table the request at the next ACFDR Steering Committee meeting or, in some circumstances where the data is required earlier the ACFDR Director, may circulate the request for out of session approval. Data cannot be extracted until approval is given and relevant ethics approval from participating institutions are in place.
13. All data must only be used for the purposes outlined in the written request, and approved by the Steering Committee.
14. No data may be passed onto other researchers, clinicians or any other person/entity not explicitly mentioned in the written data request.
15. Following ethics approval and data access sign off by the ACFDR Steering Committee, de-identified data will be provided by secure file transfer. Following transfer, security and storage of the data provided will be the responsibility of the requester in accordance with good research practice guidelines.
16. Any material or manuscript to be published using ACFDR data must be submitted for review by the ACFDR Steering Committee prior to release for publication. It must contain appropriate acknowledgement of ACFDR. Preferred wording for the acknowledgement will be provided with the data.
17. If the data is the primary source for a report or publication, the source of the data must be acknowledged, along with a statement that the analysis and interpretation are those of the author, not the registry. Where a research collaborator has analysed data, ACFDR, Monash University should be acknowledged as a secondary institution. Where the author is a registry staff member, then the primary attribution should be ACFDR, Monash University. ACFDR reserves the right to dissociate itself from conclusions drawn if it deems necessary.
18. Requests must be made in accordance with the data access policy and provide full disclosure in the request form for proposed access and usage of the data. Data access and usage must comply with all conditions in the approval given for data access.
19. Separate request forms for research and non-research data access should be used. Form 1 should be used for all research related requests and Form 2 should be used for non-research purposes.
20. Patient requests for data access to their information cannot be met by the ACFDR as it is not held in identifiable form. Patients making such requests will be advised to contact their CF centre.

## 3.3 Data Access Request Process

1. All data requests must be formally lodged using the Request Data Application Form via email, post or fax to:

   email – *med-acfdregistry@monash.edu*

   post –*Data Manager, Australian Cystic Fibrosis Data Registry 553 St Kilda Road, Melbourne. 3004*

Upon receipt of the completed and signed form, the ACFDR Director will present the data request to the Steering Committee at the next scheduled meeting if required under Section 3.2. Meetings are held two times per year.

2. There are three possible outcomes of the data access request. The data access request may be approved, approved subject to amendment or declined. If the application is declined, a major revision and subsequent resubmission will be required. Approval subject to minor revision will not require a full resubmission. An out of session review of the changes will be organised.
3. Upon approval, the ACFDR Director will provide the data accompanied by a statement of the conditions of its use with a cost estimate if applicable.

# APPENDIX 1: Form 1 REQUEST FOR ACCESS TO DATA – RESEARCHER

**Please return your application to the address below:**

| | |
|---|---|
| ***Australian Cystic Fibrosis Data Registry (ACFDR)*** | ***EMAIL:***<br>***med-acfdregistry@monash.edu***<br>***(03) 9903 1656*** |

## Part A: Requester's Details

| | | | |
|---|---|---|---|
| **Date of Request:** | **Date required by:** | | |
| **Organisation** | ☐ Research/Academic Institution<br>☐ Government Department or Agency<br>☐ Hospital<br>Industry: ☐ Pharmaceutical<br>☐ Private Health Insurance<br>☐ Device<br>☐ Other, *specify* …….<br><br>☐ Professional Medical Organisation<br>☐ Other *(please specify)*……. | | |
| **Short title of data request:** | | | |
| **Principal Investigator :** | | **Title:** | |
| **Position:** | | | |
| **Other Investigators:** | | **Titles:** | |
| **Affiliation/Organisation:** | | | |
| **Address:** | | | |
| **Telephone:** | | | |
| **Email:** | | | |
| **Are you a student?** | ☐ Yes ☐ No | | |
| **If YES, what degree are you working towards?** | | | |

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|---|---|
| **Name and contact details of your supervisor** | |
| **Is this a funded research project?** | ☐ Yes ☐ No |
| **If YES, who has funded the project?** | |
| **Was the ACFDR formally involved in the grant application?** | |
| **Does your project require Human Research Ethics committee (HREC) approval?** | ☐ Yes ☐ No * If NO proceed to PART B |
| **If YES have you applied for HREC approval?** | ☐ Yes ☐ No |
| **If YES which organisation's HREC did you apply to?** | |
| **Have you received HREC approval?** | ☐ Yes ☐ No * If YES, please attach a copy of your approval certificate/s, a full copy of your application and any other relevant documents |

## Part B: Project Details

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

| | |
|---|---|
| **Type of data request** | ☐ De-identified patient level data<br>☐ Aggregated/summary data<br>☐ Report/Analysis<br>☐ Data linkage<br>☐ Other, specify …….. |
| **Title of project** | |
| **Background and rationale for the project** (500 word maximum plus key references) | |
| | |

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|---|---|
| **Hypothesis and specific research questions** | |
| **Possible outcomes and clinical significance of this research** (250 word maximum) | |
| **Methodology of project** (500 word maximum) | |
| **Inclusion and Exclusion criteria** | |

## Part C: Data fields required

An ACFDR minimum dataset containing available data fields can be requested. ACFDR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals

| Data item required | Justification |
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## Part D: Requester's signature

*I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ACFDR DATA ACCESS POLICY. I AGREE TO COMPLY WITH THAT POLICY.*
*I AGREE TO UNDERTAKE ALL ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE RESEARCH PROPOSAL, RESEARCH APPROVAL OF THE REVIEWING HUMAN RESEARCH ETHICS COMMITTEE (HREC) AND ALL RELEVANT STATE AND COMMONWEALTH PRIVACY LEGISLATION RELATING TO PATIENT INFORMATION AND HEALTH RECORDS.*
*I AGREE TO ADHERE TO ALL OF THE CONDITIONS PLACED ON USE AND STORAGE OF THE DATA AS OUTLINED IN ANY ACFDR DATA ACCESS APPROVAL THAT WILL BE PROVIDED TO ME PRIOR TO COMMENCEMENT OF ANY RESEARCH ACTIVITY,DATA ANALYSIS OR REPORT.*
*I AGREE THAT THE INFORMATION PROVIDED BY ME TO ACFDR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.*
*I AGREE THAT INFORMATON PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM.*
*I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.*
*I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING AND WILL ACFDR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.*
*I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ACFDR, WHETHER IN THE FORM OF DATA, REPORTS, MODELS, SAMPLES AND REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.*

*Name:* _____

*Signature* _____

**FOR OFFICE USE ONLY:**

## REQUEST FOR DATA APPROVAL FORM

***Australian Cystic Fibrosis Data Registry (ACFDR)***

| | |
|---|---|
| **Short Title of Data Request:** | |
| **ACFDR Steering Committee decision (or delegate)** | ☐ approved<br>☐ approved subject to amendment<br>☐ declined |
| If approved, subject to approval, list required changes | |
| Approved by ACFDR Steering Committee Chairperson (or delegate):<br>Signature:_____<br>Date of approval: | |

# APPENDIX 2: Form 2 REQUEST FOR ACCESS TO DATA- NON-RESEARCHER

**Please return your application to the address below**

| | |
|---|---|
| ***Australian Cystic Fibrosis Data Registry (ACFDR)*** | ***EMAIL:***<br>***med-acfdregistry@monash.edu***<br>***PH: (03) 9903 1656*** |

## Part A: Requester Details

| | | | |
|---|---|---|---|
| **Date of Request:** | **Date required by:** | | |
| **Organisation** | ☐ Research/Academic Institution<br>☐ Government Department or Agency<br>☐ Hospital<br>Industry: ☐ Pharmaceutical<br>☐ Private Health Insurance<br>☐ Device<br>☐ Other, *specify* …….<br><br>☐ Professional Medical Organisation<br>☐ Other *(please specify)*……. | | |
| **Authorised requester's name** | | **Title** | |
| **Position** | | | |
| **Organisation:** | | | |
| **Address:** | | | |
| **Telephone:** | | | |
| **Email:** | | | |

## Part B: Project Details

Please note that approval will only be given for the use described in this application. Use of data for any other purpose will require an **additional** request. This information will be reviewed by a committee and may incur a fee depending on the complexity of the request.

| | |
|---|---|
| **Request Title** | |
| **Type of data request** | ☐ Aggregated data/summary data<br>☐ Report/Analysis |
| **Purpose of the request** | |
| **What question/s need to be answered by the information requested** | |
| **Description of the type of information required.** (Please include the subpopulation, and cross tabulation of the variables of interest required) | |
| **Reference period for the data of interest** | |
| **Possible outcomes and potential uses of this request** | |
| **Name all entities that the information requested will be disclosed to** | ☐ Internal use only<br>☐ Government department/agency, specify……<br>☐ Other organisation, specify…….. |
| **If this request is to be used to support an application for regulatory approval and are there potential implications for the registry? E.g. additional data items to be collected etc.** | |

## Part C: Data fields required

An ACFDR minimum dataset containing available data fields can be requested to ensure the information you require is utilised when requesting a summary report. ACFDR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

| Data item required | Justification |
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## Part E: Applicant's signature

*I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ACFDR DATA ACCESS POLICY AND I AGREE TO COMPLY WITH THAT POLICY. I AGREE TO UNDERTAKE THE ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE AGREED USE.*
*I AGREE THAT ANY INFORMATION PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM*
*I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAT THOSE DESCRIBED IN THE REQUEST FORM.*
*I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING IF REQUESTED AND WILL ACKNOWLEDGE ACFDR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSTY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.I AGREE THAT THE INFORMATION PROVIDED BY ME TO ACFDR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ACFDR, REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.*

*Name:* _____

*Signature* _____

**FOR OFFICE USE ONLY:**

## REQUEST FOR DATA APPROVAL FORM

| *Australian Cystic Fibrosis Data Registry (ACFDR)* |
|---|

| | |
|---|---|
| **Data Access Request:** | |
| **ACFDR Steering Committee (or delegate) decision** | ☐ approved<br>☐ approved subject to amendment<br>☐ declined |
| **If approved, subject to approval, list required changes** | |
| **Approved by ACFDR Steering Committee Chairperson (or delegate):**<br><br>Signature:_____<br><br>Date of approval: | |