Australian Cystic Fibrosis Data Registry (ACFDR)

Data Access and Publication Policy

Version 3.1

22 MAY, 2020

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Document Version Control

Version	Date	Reason/Comments/Approvals
1.0	23/09/2016	Initial Version Release. Approved by the ACFDR Advisory Group on 23/09/2016
2.0	06/02/2017	Inclusion of role account email for registry contact purposes – administrative change only
2.0a	Insert date	Amended contact details due to error
3.0		Inclusion of DARPC as the representative sub-committee of the ACFDR steering committee to review and approve data access requests. Added section 4 on the use of ACFDR data for publication and presentation Added data fee schedule Amended section 3.1 to include applicants from overseas
3.1	22/05/2020	

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 (CF). 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 HREC.

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 CF data repository to provide valid and reliable cross-sectional and longitudinal data on CF patients in Australia. The primary aim of the registry is to use data from CF centres in Australia to monitor quality of care and disease progress in patients with CF in Australia.

2.2 Project overview

ACFDR collects health information on CF 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 Research Electronic Data Capture (REDCap) server that is managed by Monash University registry staff. 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 by the Data Access and Research Publishing Committee (DARPC), the representative sub-committee of the ACFDR Steering Committee (ACFDR SC). Its purpose is to facilitate the provision of appropriate access to data collected by or information provided by the ACFDR in line with the ACFDR Data Access Policy and protocol, and ethics requirements. The DARPC is expected to receive approximately a dozen or so requests for data access/information per annum.

The DARPC will essentially comprise of: four members from the ACFDR SC, at least two clinicians and two Monash ACFDR team members; two members recruited from the TSANZ membership – one medical and one non-medical; and two consumer representatives, who will be nominated for membership by Cystic Fibrosis Australia.

Membership will be reviewed annually at the direction of the Chair of the ACFDR SC.

Members are encouraged to discuss the data access requests via email before reaching and communicating their decision. Decisions will be final when all members mutually agree. Where there is uncertainty about a request, the DARPC may organise a teleconference to discuss or may refer to the ACFDR SC.

The ACFDR recognises the importance of Indigenous data sovereignty and Aboriginal and Torres Strait Islander Community engagement and governance in research. The ACFDR currently holds approximately 100 records of patients who identify as an Aboriginal or Torres Strait Islander Person. Within the DARPC there must be Aboriginal Representative Members, either from the consumer population and/or a member of staff from the research or clinical community. The Aboriginal Representative Members must be included in all meetings and decisions relating to research and data requests that involve analysis of the Aboriginal Peoples.

The Aboriginal Representative Members of the DARPC will assist in ensuring that research proposals, study design and reporting will reflect no harm to Aboriginal People and research results and conclusions will benefit the Aboriginal People.

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

3.1 Eligible applicants

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

3.2 Access to ACFDR data

1. The ACFDR Data is hosted on a REDCap server that is managed by Monash university.
2. All uses of ACFDR data, in whatever context, must receive prior approval from the DARPC unless a pre-existing funding agreement is in place and has been previously approved by the DARPC. Research

requests using data from multiple sites will require approval by the reviewing HREC (Alfred Health Ethics Committee) or any other HREC that is registered with NHMRC. If the project requires contacting patients or additional medical information through the patient's medical record or linkage with other data sources, HREC approval may be required from each relevant site. Clinicians seeking access to their own hospital data may require their site HREC approval should they wish to publish.

3. Data access may be subject to conditions in agreements and/or research ethics approvals.
4. Other than clinicians seeking access to their own data, under no circumstances will individually identifiable data in respect to patients, contributing clinicians, or hospitals be made available to parties other than the ACFDR SC, authorised ACFDR personnel, and members of any working group directed by and reporting to the SC 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 SC or DARPC 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 DARPC 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 Senior Research Fellow on request form 2 (Appendix 3).
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 on form 2. Such data requests will require DARPC approval.
9. For requests from industry, comparative information i.e. market share will not be provided. In general, for non-research requests data analysis if required will be undertaken by Monash University and may incur a fee.
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 DARPC on behalf of the ACFDR SC in consultation with the ACFDR Senior Research Fellow 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 (Appendix 1) 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 DARPC will occur within two 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 four weeks following DARPC approval, unless the request is referred to the next scheduled SC meeting.
12. Requests must be first made to the Monash University ACFDR study team a who will circulate the request by email to the DARPC for approval. Data cannot be extracted until approval is given and relevant ethics approval from participating institutions are in place (if required).
13. All data must only be used for the purposes outlined in the written request, and approved by the DARPC.
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 DARPC, 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. Requests must be made in accordance with the data access policy and provide full disclosure in the request form for proposed usage of the data. Data usage must comply with all conditions in the approval given for data access.
17. 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.
18. 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.
19. All data requests will be logged, provided to the ACFDR SC for noting at the next scheduled SC meeting.
20. All data requests and research proposals that are specific to the Aboriginal Peoples will need to be reviewed in the presence of the allocated Aboriginal Representative Members of the DARPC.
21. As per Monash University policy, provided data should be kept by the applicant for 7 years in a secure repository, after which it should be destroyed. If the local HREC for the project requires data to be kept for more than 7 years, this will override Monash University policy.

3.3 Data Access Request Process

1. All data requests must be formally lodged using the Request Data Application Form (Appendix 2) via email to:*med-acfdregistry@monash.edu*

   Upon receipt of the completed and signed form, the ACFDR Senior Research Fellow or their appointee will review the request and following confirmation of data requirements with the requester, will email the data request to the DARPC, unless required to be submitted to the SC as required under Section 3.2 at the next scheduled meeting.

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. If approved the ACFDR Senior Research Fellow or their appointee will advise on any fees. Data will be provided accompanied by a statement of the conditions of its following ACFDR receipt of HREC approval if applicable.

4. Use of ACFDR data for presentation or publication

1. If the ACFDR 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. ACFDR reserves the right to dissociate itself from conclusions drawn if it deems necessary. Data published in the ACFDR annual reports is not subject to the data access policy.
2. Where ACFDR data is only a minor portion of the work, it may be more appropriate to acknowledge the ACFDR explicitly in the "Acknowledgements" section.
3. Researchers are welcome to seek a member of the ACFDR SC, to assist with the research and to contribute to the publication. All persons who make substantial contributions to the manuscript should be offered authorship. The actual contributor(s) to be named would depend on the input to the particular data exercise and should conform to the Australian Code for the Responsible Conduct of Research (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).
4. The source and treatment of the data should be made clear in the "Methods" section. Preferably the abstract (and keywords if applicable) should also include "Australian Cystic Fibrosis Data Registry" which would allow for searching Registry publications.
5. For the purposes of reporting of the Registry's publication outputs, once accepted for publication, the ACFDR must be notified by email (med-acfdregistry@monash.edu), advising of the reference details.

APPENDIX 1: DATA ACCESS & REPORTING FEE SCHEDULE

All requests for ACFDR data access (extraction) and reporting must be reviewed by the DARPC.

Data Extraction for Research

Data extraction usually comprises discussions with the applicant, application review, advising and potentially assisting with preparation of the request for the DARPC, extracting data from multiple tables, database manipulation to limit identification risk, providing a summary report as to the methods and processes involved, and responding to follow up queries. This may take from a few hours to multiple days.

In general, **where data access is sought for research purposes** from *participating registry clinicians or hospital staff* (or staff otherwise associated with the registry/hospital e.g. adjunct or honorary appointments undertaking a CF-hospital-based project) the fee for data extraction is waived if the request can be accommodated by registry staff within their usual registry operations.

Where data access is sought for research purposes from *individuals who do not contribute to the registry (or exceeds the capability of normal registry operations*), a fee for data extraction applies and is based on an hourly rate of $200/hour. In these circumstances, a brief data extraction plan and quote is developed by the ACFDR Research Fellow) to be reviewed by the DARP together with the data request, and forwarded to the requester once approved.

Data Analysis for Research

Analysis of registry data **for research purposes** will be undertaken by suitably qualified staff under the supervision of a biostatistician and will incur a fee. This fee may be waived for *participating registry clinicians or hospital staff* depending on the scope of the data analysis, however for all other researchers an hourly rate of $200/hour applies. As for data extraction, a brief data analysis plan and quote (if applicable) will be developed by a Monash biostatistician and reviewed by the DARP.

Commercial (Non-Research) Data Reports

The *ACFDR Data Access Policy* recommends that non-researchers do not have access to identified patient information, and that in general data is provided as aggregated summary reports that comprise data extraction and analysis undertaken by the registry.

Where **commercial organisations** (such as pharmaceutical or device organisations, private hospitals, private insurers etc.) seek a **specific report** from the ACFDR, they will receive a quote that will include (exclusive of GST):

- Costs of application review
- Data extraction
- Data analysis
- Data interpretation if required
- Production of a report with graphical displays or other features as required

The minimum cost of such a report will be approximately $5,000-$10,000 and will depend on the size of the request. Again, this will be reviewed and approved by the ACFDR Steering Committee.

Funding Agreements

For commercial organisations that request regular specific reports from the ACFDR these may form part of a specific *funding agreement*. In such an agreement, as a benefit to a significant financial contributor (e.g. minimum value of $20,000 per annum), CFA on behalf of the ACFDR would agree to provide data reports to a specified value per year. See Appendix 1A for draft Funding Agreement letter.

Individual Centre Reports

The ACFDR system has the capability of individual centre real-time data reporting. Centre practitioners are encouraged to undertake the brief training provided by Monash so that they can prepare individual centre reports themselves rather than seeking Monash staff to do these on their behalf.

APPENDIX 1A: DRAFT FUNDING AGREEMENT LETTER

To xxx
Pharmaceutical Company or other

Dear XXX

Re: Australian Cystic Fibrosis Data Registry Funding Request

It was a pleasure to meet you and xxx on [date] to discuss xx's support of the Australian Cystic Fibrosis Data Registry (ACFDR). Your support of the ACFDR is important to the ongoing operation and development of Australia's most comprehensive national clinical data collection for patients with cystic fibrosis (CF). The ACFDR is a vital source of information for clinicians and their patients, hospitals, governments and policy makers regarding best practice care for patients with CF as well as being a valuable repository for clinical researchers.

As per our discussion today, as a financial contributor to the ACFDR to the value of [e.g. $20-$100K p.a] this provides for:

- A copy of the ACFDR Annual Report when released
- Subscription to the ACFDR quarterly newsletter
- Invitation to an annual ACFDR Contributor's Liaison meeting where we showcase up to date analyses and findings from the ACFDR
- Requests for specific ACFDR data analysis reports according to the ACFDR Data Access Policy (which requires Data Access and Research Publishing Committee approval) to the value of [e.g. 50% of value of funding]; and
- Permission to advertise your support of and association with the ACFDR

We also acknowledge our contributors in our publications and at events that we run.

Thank you again for your support of the ACFDR. If you have any queries, please don't hesitate to contact me.

Yours sincerely,

Nettie Burke
CEO, Cystic Fibrosis Australia

APPENDIX 2: Form 1 REQUEST FOR ACCESS TO DATA – RESEARCHER

Please return your application to the address below:

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

Part A: Requester's Details

Date of Request	Date required by		
Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital ☐ Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* …… ☐ Professional Medical Organisation ☐ 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?	
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 ☐ Aggregated/summary data ☐ Report/Analysis ☐ Data linkage ☐ Other, specify ……
Title of project	
Background and rationale for the project (500 word maximum plus key references)	

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

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 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 ACCEPTED REPORT FOR REVIEW PRIOR TO PUBLISHING AND WILL ACKNOWLEDGE 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 ☐ Approved subject to amendment ☐ Declined
If approved, subject to approval, list required changes	
Approved by ACFDR Steering Committee Chairperson (or delegate): Signature _____ Date of approval:_____	

APPENDIX 3: Form 2 REQUEST FOR ACCESS TO DATA- NON-RESEARCHER

Please return your application to the address below

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

Part A: Requester Details

Date of Request:	Date required by:		
Organisation	☐ Research/Academic Institution ☐ Government Department or Agency ☐ Hospital Industry: ☐ Pharmaceutical ☐ Private Health Insurance ☐ Device ☐ Other, *specify* …… ☐ Professional Medical Organisation ☐ 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 ☐ 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 ☐ Government department/agency, specify…… ☐ 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

Part E: Applicant'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 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 ACCEPTED REPORT FOR REVIEW PRIOR TO PUBLISHING AND WILL ACKNOWLEDGE 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)	
Data Access Request:	
ACFDR Steering Committee (or delegate) decision	☐ approved ☐ approved subject to amendment ☐ declined
If approved, subject to approval, list required changes	
Approved by ACFDR Steering Committee Chairperson (or delegate): Signature:_____ Date of approval:	