ENDORSEMENT OF STUDIES BY THE PULMONARY FIBROSIS AUSTRALASIAN CLINICAL TRIALS NETWORK (PACT CTN)

1. PURPOSE OF POLICY

1.1 The mission of the PACT CTN is to reduce the morbidity and mortality associated with pulmonary fibrosis and improve the quality of life for people living with pulmonary fibrosis, their carers and families through the facilitation and coordination of high quality clinical research that translates into safe and effective practice and improves patient outcomes.

1.2 The purpose of this Policy is to ensure that PACT CTN endorsement is synonymous with a consistently high standard of study design, conduct, analysis, publication and dissemination, and with optimal research capacity and study feasibility. Maintenance of such high quality will ensure that PACT CTN endorsement of a study and its outputs is considered a 'gold standard'.

1.3 The Policy applies to both applicants and members of the PACT CTN Executive. It outlines the prerequisites, review process, and conditions of endorsement. Endorsement is contingent upon the study steering/management committee fulfilling and maintaining these terms as outlined below.

2. PRECONDITIONS FOR ENDORSEMENT

2.1 A new study proposal is to be developed by a group of individuals who normally form the study steering/management committee.

2.2 The research project must be a clinical research project that is primarily related to an aspect of pulmonary fibrosis.

2.3 Multi-centre collaborative studies are preferred, although single-centre studies may be endorsed.

2.4 Unless exceptional circumstances exist, the PACT CTN Executive will only endorse studies prospectively, that is before they commence recruitment in Australia and New Zealand.

2.5 Applications for endorsement must be made using the 'Application for PACT CTN Endorsement Form' (Appendix).

3. ENDORSEMENT AND GRANT APPLICATIONS

3.1 Investigators may not indicate in a grant application that the study is endorsed by the PACT CTN unless formal endorsement has been approved by the PACT CTN Executive.

3.2 Indication in a grant application of submission (or intention to submit) for PACT CTN endorsement requires the approval of the PACT CTN Executive.

4. ENDORSEMENT PROCESS

4.1 Applications can be built around a grant application or a study protocol (or both) but must provide a detailed rationale and research plan for the study.

4.2 If the study is to be performed in conjunction with a research group or network this must be made clear in the application.

4.3 Proposals will be endorsed on merit, considering whether the study accords with the mission, vision and values, Terms of Reference and research strategy of the PACT CTN.

4.4 The Chair of the PACT CTN Executive or a Chair-delegate will supervise the review of each submitted study. Members of the Executive who have an established conflict of interest (for

example a member of the trial steering committee) will not be involved in either the supervision or the conduct of a review of an endorsement application. If the Chair is conflicted, the Executive will appoint a delegate.

4.5 The PACT CTN Chair or Chair-delegate will identify at least two individuals to undertake a review of the study.

4.6 All reviewers will be asked to comment on the scientific merit, significance and feasibility of the proposed study. Assessment of study feasibility will include the resources required to conduct the study at the site level, and the likelihood of recruiting the required patient numbers.

4.7 The Chair or Chair-delegate will coordinate the reviews. A majority vote of non-conflicted voting members of the PACT CTN Executive will be used to determine the outcome where conflicting reviews exist.

4.8 Applicants will be notified of the outcome in a timely manner.

4.9 Appeals for re-consideration of un-endorsed or dis-endorsed trials can be made via the PACT Chair.

5. CONDITIONS OF ENDORSEMENT

5.1 Once endorsed by the PACT CTN Executive, the following conditions apply for the duration of the study and for all prospectively defined sub-studies. The chair of the trial steering committee will be responsible for ensuring that these conditions are fulfilled.

- Payment of the annual endorsement fee of $2000.00, if applicable. In general, investigator-led studies will not attract an endorsement fee.
- Studies must be conducted in compliance with codes of research conduct such as the Australian Code for the Responsible Conduct of Research produced by the NHMRC.
- Trials must be prospectively registered with a recognised trial registry authority, preferably www.clinicaltrials.gov or www.anzctr.org.au.
- The study steering committee will nominate a member, usually the Chair, who is responsible for liaison with the PACT CTN Executive, and it is the responsibility of the steering committee to update the PACT CTN with respect to any major design or administrative changes that occur after endorsement is conferred.
- The trial steering committee should meet and maintain records of their meetings (for example, minutes or action points) with sufficient frequency to ensure good governance of the study. The records of steering committee meetings will be made available to the PACT CTN Executive if requested.
- A study progress report consisting of, at a minimum, the number of patients screened and randomised globally and in Australasia will be submitted to the PACT CTN Executive quarterly upon request. The PACT Coordinator should also receive study updates that are sent to participating sites.
- The PACT CTN Executive reserves the right to withdraw endorsement at any stage should the trial not progress adequately, or if irresolvable conflicts of interest arise, or for any other reason, without notice.
- Manuscripts arising from the study will comply with the PACT CTN *Publication Policy* (Section 7 below).

6. MANAGEMENT OF CONFLICTS OF INTEREST DURING THE REVIEW PROCESS

6.1 The PACT CTN Executive is committed to providing a fair and transparent process of review for all endorsement applications. A member of the PACT CTN Executive is regarded as conflicted with respect to an endorsement application if that person is a member of the steering committee or a proposed or confirmed site principal investigator for that study.

6.2 Members of the PACT CTN Executive who are conflicted will not participate in the assessment and evaluation of endorsement applications.

6.3 Individuals who are invited to review studies and manuscripts on behalf of the PACT CTN Executive must not be involved in the design or conduct of the study.

7. PUBLICATION POLICY FOR ENDORSED STUDIES

7.1 For investigator-driven studies, all manuscripts and theses that report processes of, or results obtained from PACT CTN-endorsed studies, or from post-hoc analyses of a PACT CTN-endorsed study, must be submitted for review and endorsed by the PACT CTN Executive prior to submission for publication or examination.

7.2 The default authorship for all PACT CTN-endorsed investigator-led study manuscripts must include 'on behalf of the Centre of Research Excellence in Pulmonary Fibrosis - Pulmonary Fibrosis Australasian Clinical Trials Network (PACT CTN)' as part of the author (if appropriate) or acknowledgement line.

7.3 Manuscripts submitted to the PACT CTN for publication endorsement will be reviewed in a timely manner by at least two persons.

7.4 Publication of all studies where PACT is acknowledged must follow Consolidated Standards of Reporting Trials (www.consort-statement.org) guidelines.

8. DOCUMENT REVIEW

Timeframe for review: Every year, or earlier if required.

Application for PACT Clinical Trial Network Endorsement

YOUR DETAILS	
Title:	**Surname:**
First name/s:	
Contact email:	
Work Telephone:	**Mobile:**

STUDY DETAILS
Study title:
Sponsor/Lead institution:
Trial Synopsis (please also attach trial protocol if requested):
Disease target:
Duration:
Investigational medicinal product information:
Comparator and randomisation:
Trial status in Australasia: Recruiting ☐ Not recruiting ☐ If already recruiting, please explain why an application for retrospective endorsement is being made: **Trial status global:** Recruiting ☐ Not recruiting ☐

Trial phase: Phase I ☐ Phase III ☐ Phase II ☐ Phase IV ☐	
Key inclusion criteria:	
Key exclusion criteria:	
Primary endpoint:	
Target number of participants:	**ClinicalTrials.gov Identifier:**
Lead site in Australia: **Lead site in New Zealand:**	
Additional sites:	
Lead HREC (if applicable):	**HREC approval date: (Please attach approval)**

I have read and agree to the PACT CTN Endorsement policy. I understand that Endorsement may be withdrawn at any time without notice. I acknowledge that the Clinical Trials Summaries for clinicians and patients will be made publicly available on the PACT website.

Applicant signature: _____

Applicant name: _____

Date: _____

Clinical Trial Summary for Patients*

Trial title	
Trial synopsis	[Lay language]
Investigational medicinal product	
Disease target	
Sponsor	
Duration	
Trial Status	
Lead site(s) in Australia	
Lead site(s) in New Zealand	
Additional sites	
Contact	Pactcoordinator@cre-pf.org.au

Centre of Research Excellence in Pulmonary Fibrosis

Lung Foundation Australia PACT Network

Clinical Trial Summary for Clinicians*

Trial title	
Trial synopsis	
Investigational medicinal product, comparator and randomisation	[eg Active / oral; Matching placebo / oral; 1:1]
Disease target	
Sponsor	
Duration	[weeks]
Trial Status	[Recruiting / Not yet recruiting]
Trial phase	
Key inclusion criteria	
Key exclusion criteria	
Primary endpoint	
Number of participants sought	
Lead site(s) in Australia	
Lead site(s) in New Zealand	
Additional sites	
Contact	Pactcoordinator@cre-pf.org.au

* The patient information should be written in lay language. These summary forms will appear verbatim as publicly available PDFs on the PACT website. Completion of the PACT endorsement application form is taken as confirmation that the information is approved to be made publicly available by the study sponsor.