PULMONARY FIBROSIS AUSTRALASIAN CLINICAL TRIALS NETWORK (PACT CTN) TRIAL ENDORSEMENT POLICY

PACT acknowledges the contribution of ACTA to the development of trial endorsement processes within our network (reference: *Trial Endorsement and Review: Guidance for CTNs*).

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 Scientific quality including sufficient preliminary evidence, if appropriate results of systematic reviews, evidence of context such as surveys or observational studies of current practice or equipoise or both, a planned sample size that is sufficient for a plausible effect size, and appropriate statistical methods.

2.5 Feasibility including pilot studies, support from sites, availability of placebo, sufficient funding or a feasible plan to obtain sufficient funding.

2.6 Consumer involvement and/or review.

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

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

3. ELLIGIBLE APPLICANTS

3.1 Applications for PACT CTN endorsements may come from:

- PACT CTN Member/s - A formal member of the PACT CTN who is listed as an investigator on the protocol and/or trial management committee.
- Pulmonary fibrosis investigator - investigator on the protocol and/or trial management committee, not yet a formal member of the PACT CTN (although membership is encouraged).
- Industry representative – PACT accepts endorsement applications from industry-led, commercially-funded trials. Further detail regarding benefits of PACT endorsement for commercial sponsors is provided in Section 10.
- External collaborators - The PACT CTN may support recruitment of participants to a study led by collaborators in another discipline.
- International networks - PACT CTN supports internationally led trials.
- Higher-degree students - The PACT CTN may accept applications from students. Usually their supervisor is listed as an investigator in the protocol or trial management committee.

4. ENDORSEMENT AND GRANT APPLICATIONS

4.1 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.

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

5. APPLICATION PROCESS

5.1 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.

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

5.3 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.

5.4 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.

5.5 The PACT CTN Chair or Chair-delegate will identify at least two individuals to undertake a review of the study. Expert reviewers who are provided with the application and protocol will treat the protocol as confidential and will not forward the protocol to peers. If there are any

concerns about the application, including any conflict of interest, this should be raised with the PACT CTN Chair in the first instance.

5.6 Where required 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.

5.7 In instances where trials have already undergone extensive peer review; for example, by regulators, as part of funding award or ethical approvals; review will focus on overall feasibility and alignment with the PACT CTN goals. Evidence of peer review should be provided (e.g. ethical approval or funding letter).

5.8 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.

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

5.10 Appeals for re-consideration of non-endorsed trials or trials for which endorsement has been withdrawn can be made via the PACT CTN Chair.

6. CONDITIONS OF ENDORSEMENT

6.1 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, if applicable (see Section 10). In general, investigator-led studies will not attract an endorsement fee.
- Trials must be prospectively registered with a recognised trial registry authority, preferably www.clinicaltrials.gov or www.anzctr.org.au.
- Studies must be conducted in compliance with codes of research conduct such as the National Statement on Ethical Conduct in Human Research from the NHMRC.
- Commitment to adhere to trial regulatory requirements including, where appropriate, one or more of Good Clinical Practice, The Australian Clinical Trials Handbook, NHMRC Code of Conduct for Research, SPIRIT guidelines for protocol development, CONSORT and equivalent statements for reporting of trial results.
- 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 upon request (quarterly at most).
- The PACT CTN (usually via the PACT Coordinator) will also request regular study updates (typically quarterly) to ensure that the trial information on the PACT website is up to date.
- Manuscripts arising from the study will comply with the PACT CTN *Publication Policy* (Section 8 below).

6.2 The PACT CTN Executive reserves the right to withdraw endorsement at any stage should the study not progress adequately, if it is not being conducted in accordance with the above conditions, or if irresolvable conflicts of interest arise.

7. MANAGEMENT OF CONFLICTS OF INTEREST DURING THE REVIEW PROCESS

7.1 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.

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

7.3 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.

8. PUBLICATION POLICY FOR ENDORSED STUDIES

8.1 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, require the PACT CTN to be recognised in the acknowledgements section of the final manuscript or thesis.

9. BENEFITS OF PACT CTN ENDORSEMENT

9.1 Paid PACT CTN endorsement can provide the following:

- Facilitated access to a network of trial ready sites across Australia/New Zealand.
- Assistance with collection of site feasibility data
    - PACT has compiled a database of basic site feasibility data for key pulmonary fibrosis trial sites in Australasia.
- Promotion of your trial among the PACT CTN network of health professionals and consumers through listing on the PACT website, inclusion in our quarterly imPACT newsletter and communications to the extensive Lung Foundation Australia clinical and consumer database

- Trials are listed on the PACT website with tailored information for both consumers and clinicians. Details of recruiting trials are summarised on these webpages and linked to individualised trial summaries. The order of listing within the "Recruiting Trials" tables is regularly rotated so all trials feature first in the listings.
- PACT distributes a quarterly newsletter, imPACT, to our growing health professional and consumer membership base. Each issue of imPACT features a "Trials Update" section where new trials are introduced and the latest trial developments summarised.
- Promotion of PACT through Lung Foundation Australia clinical and consumer communications. PACT is regularly featured in Lung Foundation Australia communications including, clinical updates, Inspired Living and bespoke electronic direct messages. The Lung Foundation Australia reach for these communications is over 7,600 health professionals and over 500 PF/IPF/ILD patients and carers.

- Trial recruitment assistance
  - The PACT website facilitates trial enquiries from people living with pulmonary fibrosis through the trial listing pages. Online enquiries are received by the PACT coordinator who assesses them for suitability of current trials and refers them on to potentially suitable trial sites as appropriate.
  - We also help support a streamlined listing of your trials with our patient recruitment partner, HealthMatch, where you can fully optimise trial recruitment.[1]
    - HealthMatch's algorithm screens patients to a high-fidelity are 100% deterministically matched to trials that they are potentially eligible for, while also reducing frictions at your trial sites.
    - Trials on our list that are onboard the HealthMatch platform will have 'next steps' directing patients to the HealthMatch questionnaire.
    - Otherwise, the trial's 'next steps' will default to the PACT coordinator pathway.
- Sponsor presence on the PACT website for the duration of trial endorsement
  - Sponsors will be acknowledged with logo display on the trial listing pages of the PACT website.

10 ENDORSEMENT FEE STRUCTURE

10.1 No fee applies for PACT CTN endorsement of Investigator-led studies.

10.2 Paid PACT CTN endorsement for industry-led, commercially-funded trials attracts a fee of $8,000 per year.

[1] Conditional on an additional contractual arrangement with HealthMatch

10.3 Any questions about the endorsement fee structure should be raised with the PACT CTN Executive.

11. DOCUMENT REVIEW

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

Application for PACT Clinical Trial Network Endorsement

YOUR DETAILS	
Name:	
Position:	
Company/Hospital/University:	
Contact Email:	
Work Telephone:	**Mobile:**
PACT Membership Status: ☐ **Member** ☐ **Non-member**	
Role in Study:	

STUDY DETAILS
Study title:
Sponsor/Lead institution:
Trial Synopsis (200 words; 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	

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	

* 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.