

Department of Respiratory Medicine  
PI: A/Prof Paul D Robinson  
Sub I: Dr Katie J Bayfield

Corner Hawkesbury Road  
and Hainsworth Street  
Locked Bag 4001  
Westmead NSW 2145  
Sydney Australia  
DX 8213 Parramatta  
Tel +61 2 9845 0000  
Fax +61 2 9845 3489  
www.chw.edu.au  
ABN 53 188 579 090

4<sup>th</sup> September 2019

Dear ACFRT Board of Trustees,

Please accept this letter as documentation of our six month interim report for the "*Detailed characterisation of Structure-Function Relationships in Mild Cystic Fibrosis Lung Disease and validation of an ultra-low dose high resolution computerised tomography (HRCT) scanning protocol*", for which we received a ACFRT Innovation Grant in 2018. Thank you again for supporting our study.

In brief our study focuses on providing critical information to guide future screening protocols aimed at early detection of CF related lung disease. We aim to use the most sensitive outcome measures for the detection of both structural and functional changes in those with mild disease and to significantly reduce the radiation dose associated with a high resolution CT scan. Importantly this work will be transferable to other CF centers internationally since the tools are widely available.

#### **Aims and Objectives**

- Provide detailed characterisation of structure-function relationships in children with mild CF lung disease in both late preschool and school aged children.
- Describe the functional impact of early changes and relationships to other key CF outcomes (e.g. pulmonary exacerbation rates, progression of MBW since the preschool age range).
- Explore the feasibility and utility of ultra-low dose HRCT scanning protocols in this setting.

From the tables below we hope we are able to provide sufficient feedback that the study is well underway and will not only achieve its recruitment target but will be completed within the budgeted 1 year timeline. We hope that this pilot study will provide a basis for use of these outcome measures in both a larger study but also in some cases clinical practise. We aim to present and disseminate these findings at both national and international conferences as well as publish the results in a relevant high impact journal.

Thank you again for supporting our project.

Yours Sincerely



A/Prof Paul D Robinson & Dr Katie J Bayfield  
Clinical Associate Professor/Staff Specialist & Research  
Officer



## Detailed timeline – Key dates

Date and Activity	Details and output
Grant awarded 2018	Thank you again for accepting our proposed project for your prestigious grant.
25/02/2019 - Post-Doctoral researcher started	<p>Dr Katie J Bayfield is the post-doctoral research officer coordinating the study on behalf of A/Prof Paul D Robinson. Having completed her PhD at Imperial College London in Multiple breath washout testing in those with CF and using some of the advanced techniques also utilised within this study she is well placed to run and perform the study to high quality research standards. Katie also has lots of experience coordinating both academic led as well as commercially sponsored clinical trials, so recruitment, study documentation, budget, analysis and reporting will not only be completed to time but also of clinical excellence.</p> <p>Since Dr Bayfield started, she has organised the study investigator files, pre-screened the 236 children within the Children’s Hospital at Westmead CF clinic, coordinated the logistical aspects of the study i.e. patient or test bookings and developed a good rapport with not only the clinical team but with the patients.</p>
08/05/2019 – First patient recruited	The first patient was consented and recruited in May 2019. There were no issues with the study visit and all data was collected under professional guidelines and as per the research protocol.
3-4/06/2019	Dr Katie J Bayfield visited our collaborators in Heidelberg, Germany. Dr Mark Wielpuetz and Dr Oliver Weinheimer are leading experts in imaging interpretation and have developed automated software to define lung structure from CT Scans (YACTA). Having an established collaboration with this group, Katie visited the site to gain expertise in the YACTA software and provide preliminary data to establish a defined protocol for CT analysis going forwards.
3-6/08/2019 – Australian CF Conference	The project was presented by Dr Katie J Bayfield in the “Celebrating 30 years of the Australian Cystic Fibrosis Research Trust” symposium. The session allowed for presentation of the study design, progress of the study to date, feedback to the research trust supporters as well as valuable collaboration opportunities as per the conference theme “Celebrating Partnerships”.
08/2019 - Interim analysis	Provided evidence that with the new protocol as part of this study for Spirometry gated CT acquisition we have been able to improve the quality of the data i.e. there are tighter limits of agreement with our data compared to previous clinical data and published information on this technique.
08/2019 - Interim analysis	Gained feedback from our collaborators in Heidelberg that the ultra-low dose scans are of a very high quality and show promise in the comparability against the routine CT scans.

## Recruitment

Category	<10years of age Target:20	>10years of age Target:30
Completed	2	13
Booked	0	6
Agreed to take part	11	15
Practicing technique	14	1
<b>Total</b>	<b>27</b>	<b>35</b>

## List of Outcomes

### Oral Presentations

1. Bayfield, K.J., Robinson, P.D., *et al.* Characterisation of Structure Function Relationships in Mild Cystic Fibrosis Lung Disease presented at the Australian CF Conference 2019.

### Abstracts pending

1. Bayfield K.J., Robinson, P.D., *et al.* Characterisation of Structure Function Relationships in Mild Cystic Fibrosis Lung Disease for presentation at the Thoracic Society and Society of Respiratory Science of Australia and New Zealand (TSANZSRS) Conference in March 2020.