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Department of Respiratory and Sleep Medicine
Women's and Children's Hospital; and

Robinson Research Institute,
The University of Adelaide,
South Australia,

15/2/2019

Prof Andreas Fouras
Australian Lung Health Initiative Pty. Ltd.
169 Fullarton Road
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Letter of Support for the Medical Research Future Fund Frontier Health and Medical Research Program Stage 1:

“4D FUNCTIONAL DIAGNOSIS: A NEW FRONTIER IN LUNG HEALTH FOR CHILDREN”

Dear Professor Fouras,

As members of the Department of Respiratory and Sleep Medicine at the Women's and Children's Hospital, as well as of the Robinson Research Institute at The University of Adelaide, we are pleased to participate as a Project Supporting-Partner in a bid entitled:

“4D FUNCTIONAL DIAGNOSIS: A NEW FRONTIER IN LUNG HEALTH FOR CHILDREN”

for the Stage One component of the Medical Research Future Fund's Frontier Health and Medical Research Program.

We understand that the application is led by a joint venture consortium known as the Australian Lung Health Initiative Pty Ltd (ALHI), sited in Adelaide, and is to comprise of 4Dx Ltd, The University of Adelaide, the South Australian Health and Medical Research Institute, Monash University, The University of Western Australia, and Micro-X Ltd, as the lead Project Partners.

This proposal affords a unique opportunity to undertake world-leading translational research in respiratory medicine. It has the clear potential to transform the health of children with respiratory disease, to achieve substantial economic benefit in the Australian health, business and industrial spheres, and to have a truly global effect on the investigation, detection, treatment and monitoring of respiratory diseases.

In the paediatric setting, this technology will allow structural and functional assessment of children, and be of particular benefit in the neonatal and pre-school years. Currently, in these age groups there is only very limited ability for functional lung measurements and for forced expiratory manoeuvres.

In paediatric medicine there is also significant clinical concern regarding the adverse effects associated with structural measurements using current technology. For example, with CT scans, this would typically involve general anaesthesia (which can possibly affect children's developmental outcomes) and potentially significant radiation exposure (with the long-term risk of secondary

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tumours). 4D analysis would allow clinicians to simultaneously perform both functional and structural analysis in children without either of these significant risks. With this partnership, early respiratory disease could be detected prior to any structural changes, thereby allowing early intervention and clinical benefit. It would also allow for accurate quantification of medication efficacy and safety, both in standard clinical practice and also for medications used in clinical research trials.

As a Supporting Partner, the actual respiratory health and disease studies will be part of the 5-year Stage 2 project period, assuming this Stage 1 application is successful, and the subsequent Stage 2 application is also successful. Within the paediatric context, the aims of the project would be to firstly create a system that is demonstrably a feasible test for children of all ages. Subsequently, testing has to be proven to be both valid and reproducible for these children. Next, normative data would be formulated by repeated measurements in healthy subjects. Once this has been completed, the system will allow for measurements in those with disease.

There are many areas of potential clinical interest including measuring lung structure and function in children with neonatal lung disease, pre-school wheeze, asthma, cystic fibrosis, interstitial lung disease and neuromuscular diseases. Dr Tai (Unit Head, Dept. of Respiratory and Sleep Medicine) and Dr Goddard (Early career clinical researcher and Clinical Fellow, Dept. of Respiratory and Sleep Medicine) will provide oversight of the study in children, including ethics submission, recruitment of subjects, data analyses, conference presentations, and manuscript preparations. There will be opportunities to also formulate new areas of research with pharmaceutical companies to look at the efficacy of new drugs in respiratory disease. Both Dr Tai and Dr Goddard are affiliates of The University of Adelaide and have completed higher degrees in research. Dr Tai has oversight of clinical trials within the department and both Dr Tai and Dr Goddard have strong interests in innovative research projects.

Dr Tai and Dr Goddard will provide paediatric expertise as project Supporting-Partner in:

Stage 1: Providing clinical and research experience, advice, assistance and project document reviews in the planning of Stage 2 respiratory research/clinical activities.

Stage 2: Providing overview of the areas of clinical respiratory medicine and research in the neonatal and paediatric context, understanding of the limitations of current technology to measure structure and function in respiratory disease, and to explore how the XV technique can answer crucial clinical and research questions. Dr Tai and Dr Goddard will offer in-kind support of time, expert advice, special/well-established techniques, access to analytical equipment/skills, and seek further research funding.

In helping to underpin the respiratory health research aspects of the project as a Supporting Partner, during Stage 1, the Respiratory Dept of the Women's and Children's Hospital will contribute significantly to the goals and objectives of the Partnership, through:

- a. collaboration and contributions to the joint development of projects and research programs within Stage 2, with details to be established during Stage 1;
- b. assistance with the design of Stage 2, including proof of concept, validation, and application projects
- c. provision of expert advice on the specific project areas that we have particular interest in (eg. neonatal chronic lung disease, pre-school wheeze, cystic fibrosis, interstitial lung disease)

We understand that the specific commitments for Stage 2 activity are to be determined by agreement during Stage 1, however in Stage 2 we expect to be able to provide the team with significant in-kind support.

Dr Andrew Tai and Dr Thomas Goddard (Women's and Children's Hospital and The University of Adelaide) are committed to working with all collaborating Partners and Supporting Partners of the joint venture submission during Stage 1, to identify ways to assist with the progress of Stage 1, and for the leveraging of funds in Stage Two.

We confirm that we understand Intellectual Property (IP) arrangements, incorporating ownership rights and strategies for protecting Australia's interests as well as the strategies for translation and commercialisation of developed IP, will be put in place by agreement with collaborating partners during Stage 1. These contracts will be in accordance with laws and regulations in Australia. In the event that this application is successful we will execute a formal participant agreement to perform the roles and responsibilities set out in the application.

We are very excited about the prospects of such an innovative technology and its utility in transforming our understanding of early respiratory disease and its potential for global benefit in a wide range of clinical and research areas.

Yours sincerely,



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