

**Research Collaboration Agreement**

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| **Parties** | Macquarie University ABN 90 952 801 237 of North Ryde, NSW 2109 (**Macquarie**)  Royal Prince Alfred Hospital ABN / ACN 17 520 269 052 of 50 Missenden Rd, Camperdown, NSW (**Collaborating Organisation**) |
| **Agreement** | The parties agree to conduct the Project on the terms set out below and in the attached document headed ‘General Terms’. These General Terms and Annexures form part of this agreement. |

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| **Details** | |
| **Commencement Date** | 1st April 2021 |
| **Agreement End Date** | 1st April 2023 |
| **Project** | Clinical outcomes and adherence to cystic fibrosis standards of care after transitioning to a hybrid model of outpatient care |
| **Address for Notices** | **Macquarie**  Director, Research Services,  Level 3, WW17-17 Wally's Walk, Central Campus  Macquarie University NORTH RYDE NSW 2109  Telephone: +61 2 9850 7737  email: research.postaward@mq.edu.au  **Collaborating Organisations**  **Royal Prince Alfred Hospital**  Sydney Local Health District Research and Governance Office  [maree.larkin@health.nsw.gov.au](mailto:maree.larkin@health.nsw.gov.au)  9515 6111 |
| **Option Period** (clause 6.3) | 30 days from the date of receipt of an Innovation Disclosure |
| **Field** (clause 6.3) |  |
| **Territory** (clause 6.3) |  |
| **Special Terms** | This agreement is subject to the following special terms.  The Project cannot commence until a Human Research Ethics Committee (HREC) application has been approved and site specific applications have been approved at each of the study sites.  Execution of this agreement does not ensure the granting of approval by any Human Research Ethics Committee. |

Signed on behalf of **MACQUARIE UNIVERSITY** by its authorised officer:

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| Signature of authorised officer |
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| Name (please print) |
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| Position |
|  |
| Date of signing |

Signed on behalf of **[insert name of other party]** by its authorised officer:

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| Signature of authorised officer |
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| Name (please print) |
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| Position |
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| Date of signing |

Signed on behalf of **[insert name of other party]** by its authorised officer:

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| Signature of authorised officer |
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| Name (please print) |
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| Position |
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| Date of signing |

By signing this agreement, each signatory warrants that they have authority to enter into this agreement on behalf of the party they are stated to represent.

RECITALS

1. The parties wish to enter into a collaborative research project entitled: “Replacement of multi-disciplinary hospital clinic appointments with telehealth appointments delivered directly to the home for people with cystic fibrosis” (the **Project**), and more particularly described in Annexure 1.
2. The parties agree to conduct the Project on the terms of this agreement.

GENERAL TERMS

# INTERPRETATION

## Definitions

#### The following definitions apply throughout this agreement.

#### **Background Intellectual Property** means Intellectual Property in existence at the date of this agreement or created independently of the Project which a party owns or is licensed to use.

#### **Confidential Information** means information belonging to a party, whether existing prior to the commencement of the Project, or created in the course of the Project, which is disclosed by one party to the other for the purposes of the Project, and includes all technical, proprietary and operational information, drawings, techniques, processes, know-how and other commercially valuable information in any form. Confidential Information does not include information that is in the public domain, is already lawfully known to the Receiving Party or that has been independently developed by the Receiving Party.

#### **Innovation Disclosure** meansa written, confidential and complete disclosure of any Project Intellectual Property that is reported to Macquarie’s Office of Commercialisation and Innovation.

#### **Intellectual Property** means all copyright and neighbouring rights, all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trademarks (including service marks), registered designs, Confidential Information (including trade secrets and knowhow and circuit layouts), and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

#### **Option** means the right to negotiate a Term Sheet to commercialise the Project Intellectual Property disclosed in the Innovation Disclosure in the Field and Territory.

#### **Personal Information** means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about a natural person whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

#### **Project Intellectual Property** means Intellectual Property arising from or developed in the course of the Project by the employees or, in the case of a university party, by Students, of either party.

#### **Project Proposal** means the project proposal which is attached at Annexure 1 to the agreement.

#### **Student** means an individual enrolled as a candidate for a postgraduate research degree at a university that is a party to this agreement.

#### **Term** means the period from and including the Commencement Date to and including the Agreement End Date.

#### **Term Sheet** means a document outlining the material terms and conditions of the commercial agreement contemplated under clause 6.4.

#### Other capitalised terms have the meaning given to them in the Details.

## Rules for interpreting this agreement

#### In this agreement, headings are for guidance only and do not affect the interpretation of the clauses. The following rules apply unless the context requires otherwise:

### words importing the singular include the plural and vice versa;

### words importing one gender include all other genders;

### reference to a person includes a body politic, a body corporate, a partnership, an unincorporated association and a natural person, and the person's executors, administrators, successors, transferees, substitutes (including persons taking by novation) and assigns;

### reference to a statute, ordinance, code or other law includes regulations, directions and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;

### reference to $, dollar or AUD is to Australian currency;

### any agreement, obligation, representation, right or warranty on the part of or in favour of two or more persons binds or is for the benefit of them severally and not jointly or jointly and severally;

### a term or definition incorporated by reference into this document remains in force even if the document from which it was referred may be no longer in force;

### reference to a clause is a reference to a clause of this agreement and includes all sub-clauses, paragraphs and parts of that clause;

### where a word or phrase has a particular meaning, other parts of speech and grammatical forms of that word have corresponding meanings;

### any reference to “insurance”, “insurance policy” or “insurer” in this agreement includes, mutual risk cover held with a mutual risk provider designed to cover similar insurable risks to insurance and the providers of that risk cover; and

### a reference to an office, department or faculty whose functions are assumed by another office, department of faculty includes the office, department of faculty that assumes all or substantially all of those functions.

# RESEARCH AND RELATIONSHIP

## Project Conduct

#### The parties must conduct the Project in accordance with the terms of this agreement and must use reasonable endeavours to carry out the Project within the Term:

### in accordance with the Project Proposal attached at Annexure 1;

### in a collaborative and professional manner;

### ethically and in accordance with the Australian Code for the Responsible Conduct of Research and with the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations as applicable; and

### in compliance with all applicable laws and regulations.

## Ethics/Biosafety Approval

#### If the Project requires approval by a party’s Ethics and/or Biosafety Committees (or equivalent), the relevant party must use reasonable endeavours to obtain that approval. The parties acknowledge that the Project cannot commence until the required approvals are obtained.

## General obligations

#### Each party agrees to:

### provide any other related assistance, information, data, equipment, facilities, resources or materials as may be reasonably required to satisfactorily perform the Project; and

### comply with all safety, security and other procedures notified to it by the other party while on the other party’s site.

## Records

#### Each party must maintain reasonable, up to date and accurate records regarding the conduct and conclusions of the Project.

# PAYMENT AND GST

## Cash Contributions

#### Macquarie must invoice the Collaborating Organisation for its cash contributions in accordance with the Project Proposal. The invoice must be in the form of a tax invoice.

## Payment Terms

#### The Collaborating Organisation must pay Macquarie’s tax invoice within 30 days of the date on which Macquarie submits the invoice.

## GST wording

#### Words defined in *A New Tax System (Goods and Services Tax) Act* 1999 (Cth) have the same meaning in this clause 3.

## Payment of GST

#### If any supply under this agreement is a taxable supply, the party making the supply may, in addition to any payment for the supply, recover the amount of the GST applicable to the supply. Any amount of GST payable is payable at the same time as the payment for the supply to which it relates.

# PUBLICATION

## Publication Request

#### Should a party wish to publish Project material in a scientific journal or academic paper, the party (**Publishing Party**) must send a written request accompanied by the proposed publication material to each other party (**Reviewing Party**) at least 30 days prior to the proposed submission date (the **Approval Period**) asking for permission to publish the material.

## Approval Period

#### If, during the Approval Period, the Reviewing Party reasonably requests that:

### the material be amended to remove any of its Confidential Information, the Publishing Party must remove all such Confidential Information; and

### publication of the material or submission of the material for publication is delayed, the Publishing Party must delay publication or submission of the material for a period not exceeding 60 days to seek appropriate registration of any Project Intellectual Property at the Reviewing Party’s expense.

## Deemed Approval

#### The Reviewing Party is deemed to have approved the publication of material under this clause 4 if the Reviewing Party does not communicate to the Publishing Party its decision regarding approval of the publication with reasons within the Approval Period.

## Student Thesis

#### Despite clauses 4.1-4.3 above, nothing is to delay the submission of a Student thesis, nor require the excision of material from a thesis that represents an essential or significant part of the Student’s work, nor prevent the assessment of a thesis under their university’s usual procedures.  If applicable, public access to a thesis may be restricted for a limited period (not exceeding 12 months) to enable the parties to arrange for protection of any commercial Intellectual Property arising from the results of the Project.

## Acknowledgment

## Any publication must acknowledge the role of the other party in the Project.

# INTELLECTUAL PROPERTY

## Ownership and Licence

#### The parties agree that:

### any Background Intellectual Property remains the property of the relevant party;

### each party grants to the other party a non-exclusive, royalty-free, non-transferable, worldwide, perpetual licence to use its Background Intellectual Property for the purposes of the conduct of the Project;

### any Project Intellectual Property will be owned by Macquarie and (to the extent necessary) the Collaborating Organisation assigns to Macquarie any Intellectual Property rights in the Project Intellectual Property to Macquarie. If requested by Macquarie, the Collaborating Organisation agrees to draft, sign, execute or otherwise deal with any document which may be necessary or desirable to give effect to this clause 5.1; and

### Macquarie grants the Collaborating Organisation a non-exclusive, non-transferable royalty-free licence to use the Project Intellectual Property for non-commercial, internal business and research purposes.

## Student Intellectual Property

#### Before a Student carries out any part of the Project, the relevant university where the Student is admitted must ensure that the Student has assigned any of their rights in the Project Intellectual Property (other than copyright in their thesis) to that party.

## Copyright in Student Thesis

#### Despite anything to the contrary in this agreement, the parties agree that a Student retains copyright in their thesis.

# COMMERCIALISATION

## Application of Clause 6

#### Subject to the Collaborating Organisation not being in breach of any provision of this agreement, clauses 6.2 – 6.4 of this agreement will apply.

## Disclosure of Project Intellectual Property

#### During the Term and for a period of 90 days following the expiration of the Term, Macquarie must, as soon as practicable, provide the Collaborating Organisation with any Innovation Disclosure(s) it receives.

## Option Notice

#### The Collaborating Organisation must give Macquarie written notice of its decision to exercise the Option (**Option Notice**) before the end of the Option Period, or the Option will lapse.

## Term Sheet

### If the Collaborating Organisation exercises its Option in accordance with clause 6.3, the parties will exclusively negotiate a Term Sheet

### The Term Sheet must include the reservation by Macquarie of the right to use the relevant Project Intellectual Property for research, teaching, education and publication, including research funded by a third party.

### If the parties are unable to agree on a Term Sheet within 90 days from the date of the Option Notice, the negotiations with respect to the Term Sheet will terminate (unless otherwise agreed by the parties in writing) and the Collaborating Organisation’s Option immediately ceases.

## Return of Confidential Information

#### Within 7 days of the:

### lapse or cessation of any Option; or

### termination of the negotiations for a Term Sheet,

#### the Collaborating Organisation must return to Macquarie all Confidential Information relating to the Project Intellectual Property.

# CONFIDENTIAL INFORMATION

## Disclosure and Use of Confidential Information

#### Each party must not during the Term or for five years after the end of the Term, disclose to any third party, or use for any purpose except carrying out the Project, any of the Confidential Information of the other party.

## Obligations on a Receiving Party

#### The party receiving Confidential Information (**Receiving Party**) must:

### take all reasonable steps, and do anything reasonably required by the party disclosing the Confidential Information (Disclosing Party), to keep the Confidential Information under the Receiving Party's control;

### immediately notify the Disclosing Party if the Receiving Party becomes aware of any unauthorised access to, or use or disclosure of, any Confidential Information;

### not use, copy or reproduce, nor cause or allow any other person to use, copy or reproduce, any Confidential Information other than in accordance with this agreement;

### immediately upon completion of the Project or termination of this agreement deliver to the Disclosing Party, or if directed by the Disclosing Party destroy, every copy of Confidential Information in the Receiving Party's possession, except that:

1. they may retain one copy of the Confidential Information to the extent required to comply with applicable law or regulation; and
2. they need not destroy copies of any computer records or files containing the Confidential Information which have been created as a result of automatic archiving or back-up procedures on secured central storage servers and which cannot reasonably be deleted; and

### if any such Confidential Information is retained pursuant to sub-clause 7.2(d), the terms of this agreement remain in full force and effect with respect to such Confidential Information so retained for so long as such Confidential Information is retained.

## Exceptions to Obligations

#### Neither party will be in breach of any obligation to keep any Confidential Information confidential to the extent that it:

### is disclosed to the Receiving Party's employees or agents as necessary for the performance of this agreement and such employees or agents are instructed as to the confidential nature of the information;

### is required to be disclosed by law and the Receiving Party first informs the Disclosing Party of the intended disclosure and cooperates with the Disclosing Party to limit disclosure as reasonably requested;

### is disclosed to the Receiving Party's solicitors, auditors, insurers or accountants; or

### is approved for release in writing by an authorised representative of the Disclosing Party.

# PRIVACY

## Personal Information

#### Where a party has access to Personal Information in order to perform its obligations under this agreement, the party holding the Personal Information must comply with the requirements any privacy legislation applicable to the party, including if applicable, the *Privacy Act 1988* (Cth).

# TERMINATION

## Termination for breach

#### A party may terminate this agreement in writing if the other party breaches a term of this agreement and fails to remedy the breach within 30 days of receiving notice requiring it to do so.

## Termination by Macquarie

#### Macquarie may terminate this agreement in writing if:

### the Collaborating Organisation has entered into any form of insolvency, liquidation or external administration, whether voluntary or involuntary, formal or otherwise;

### the Collaborating Organisation is charged with a breach of any law or is the subject of proceedings or investigations commenced or threatened by the Independent Commission Against Corruption, the NSW Police Force or a similar public body whether of a state, territory or the Commonwealth or in any other country; or

### if the Collaborating Organisation is in breach of any other agreement with Macquarie.

## Consequences

#### If this agreement is terminated for any reason, then:

### each party must return all property in their possession belonging to the other party, including Confidential Information and Intellectual Property; and

### the Collaborating Organisation must within 14 days of termination pay Macquarie all cash contributions owing to Macquarie at termination.

## No prejudice

#### Termination of this agreement is without prejudice to the rights of the terminating party to obtain damages for any breach of this agreement.

## Survival

#### Clauses 4 (Publication), 5 (Intellectual Property), 6 (Commercialisation), 7 (Confidential Information), 8 (Privacy), 9 (Termination), 10 (Warranties and Liability), 11 (Insurance) and all other clauses required to give those clauses effect survive the termination or expiration of this agreement.

# WARRANTIES AND LIABILITY

## Due care and skill

#### The parties agree that due to the inherently uncertain nature of research, the actual outcomes and results of the Project cannot be assured. Each party warrants that it will carry out its individual Project obligations with due care and skill and in a professional manner consistent with generally accepted research and academic practice.

## Background Intellectual Property

#### Each party warrants that to its actual knowledge at the date of this agreement use of its Background Intellectual Property will not infringe the Intellectual Property rights of any third party.

## Project Intellectual Property

#### Neither party makes nor have they made any warranties regarding the Project Intellectual Property. All such warranties including those of merchantability or fitness for a particular purpose are excluded to the maximum extent allowed by the law.

## Implied warranties

#### Each party excludes all implied terms, representations and warranties whether statutory or otherwise, relating to the subject matter of this agreement to the extent allowed by the law.

## Consequential loss

#### Neither party is liable to the other party for consequential or incidental damages, or loss of profits, revenue, goodwill or opportunities in contract, tort, under any statute or otherwise (including negligence) arising from or in any way related to this agreement or the Project.

## Contributory negligence

#### Each party’s liability to the other party under this agreement is reduced to the extent that any damages, liability, loss or costs arise from or are attributable to, any negligent act or omission of the other party or its officers, employees, agents or contractors.

# INSURANCE

## Insurance policies

#### Each party must maintain insurances appropriate to its involvement in the Project. On request, a party must provide evidence to the other party of the currency of such insurance policies.

# NOTICES

## Method of giving Notice

#### A notice, request or other communication to a party (**Notice**) under this agreement, must be in writing and be delivered by hand or sent by prepaid post, or email to the notice address, or email address of that party as specified in the Details.

## Effective Service

#### A Notice is given or served:

### if delivered by hand, upon delivery;

### if in the form of a letter sent by prepaid post, three days (eight days if sent from one country to another country) after the date on which it was sent; and

### if by email, when the recipient acknowledges receipt of the Notice by return email to the sender (other than by automatic acknowledgment sent by the recipient's server).

## Notice Serviced Outside Business Hours

#### A Notice that would be given or served on a day which is not a business day in the place to which the Notice is sent, or is later than 5:00 p.m. (local time) it will be taken to have been given or served at the commencement of the next business day in that place. In the case of a university party, that party’s closure days are taken to be not business days for the purposes of this clause 12.3.

## Change of Address for Notices

#### A party may change its Notice address or email address by Notice to the other party.

# FORMAL TERMS

## Jurisdiction

#### This agreement is governed by the laws of New South Wales and any dispute relating to it must only be referred to the courts of New South Wales and the Federal courts of Australia.

## Relationship of Parties

#### Nothing in this agreement constitutes a relationship of employer and employee, principal and agent, or trust, or partnership between the parties. Neither party has authority or power to bind the other party.

## Inconsistency

#### If there is an inconsistency between a provision of the Special Terms, Details, the General Terms or a schedule or annexure then the provisions of the first-mentioned prevail.

## Severability

#### If any clause or any part of this agreement or the Project Proposal are adjudged by a court or other legal authority of competent jurisdiction to be invalid, that judgment does not affect the remainder of this agreement, the terms of which remain in full force and effect.

## Entire Agreement

#### This is the entire agreement between the parties about its subject matter and replaces all oral and written prior communications and agreements between the parties.

## Sub-contracting

#### A party may sub-contract the performance of any part of the Project for which it is responsible only with the prior written consent of the other party, such consent not to be unreasonably withheld. Each party remains responsible and liable for the performance of its individual Project obligations under this agreement and for all costs incurred with respect to its subcontractors.

## Variations must be in Writing

This agreement may only be varied by the parties in writing, including by way of e-mail exchange between all the parties to this agreement confirming the variation.

## No Waiver

#### A waiver by a party of any breach or of a failure to comply with any provision of this agreement by the other party has no effect unless it is in writing.

## Disputes

### In the case of a dispute arising under this agreement (the Dispute) a party to this agreement must not commence any court or arbitration proceedings unless the parties have complied with the following paragraphs of this clause except where a party seeks urgent interlocutory relief.

### A party to this agreement claiming that a Dispute has arisen out of or in relation to this agreement must give written notice (the Dispute Notice) to the other party to this agreement specifying the nature of the Dispute.

### Within fourteen (14) days of receipt of the Dispute Notice (or such further period as agreed in writing by them) the parties must agree:

1. the dispute resolution technique (e.g. expert determination) and procedures to be adopted;
2. the timetable for all steps in those procedures; and
3. the selection and compensation of the independent person required for such technique.

### If the parties cannot agree to the matters set out in clause 13.9(c) within fourteen (14) days, the parties must mediate the Dispute in accordance with the Mediation Rules of the Law Society of New South Wales, and, the President of the Law Society of New South Wales or the President’s nominee will select the mediator and determine the mediator’s remuneration.

### If the Dispute has not been resolved within a timeframe agreed under clause 13.9(c)(ii), either party may at their discretion institute legal proceedings.

## Counterparts

This agreement may be signed in counterparts and when taken together constitute the one document. The counter-parts may be exchanged electronically.

**Annexure 1 – Study Budget and Personnel**

There will be no transfer of funds from Macquarie University to Royal Prince Alfred Hospital.

A research assistant (RA) or assistants employed by Macquarie University will attend Royal Prince Alfred Hospital to undertake the research activities outlined in the project proposal for which Human Research Ethics Committee Approval has been obtained (Ref: 2020/ETH03137).

The Macquarie University RA will apply for Contingent Worker Status at Royal Prince Alfred Hospital and they will be supported and supervised on site by staff at Royal Prince Alfred Hospital that have agreed to this supervision as outlined in the site-specific application.

The Macquarie University RA will only attend Royal Prince Alfred Hospital to conduct research activities outlined in the study protocol and only for the period they are granted contingent worker status.

**Annexure 2 - Project Proposal (Ethics Approval Received from Sydney Children’s Hospitals Network HREC, Ref 2020/ETH03137)**

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| **SCHN HREC**  **Low and Negligible Risk (LNR)**  **Protocol Template** |

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| **Important Information** |
| * This protocol template is for all projects that fulfill the criteria of low and negligible risk (LNR) studies as per [SCHN Research Ethics website](https://www.schn.health.nsw.gov.au/research/ethics-governance/ethics/lnr). * Please also read the SCHN HREC: Low and Negligible Risk Submission Guidelines for the submission process. * It is recommended to complete the protocol and then the HREA as you can ‘cut and paste’ thus ensuring the documents are the same. * Please respond to each section. The text in ***blue*** is a guide with some examples – please delete it from your application. * Please use a clear font, minimum size 10 and the whole application must not be in italics |

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| **Protocol Information** | |
| **Title** | Clinical outcomes and adherence to cystic fibrosis standards of care after transitioning to a hybrid model of outpatient care |
| **Version number** | 1.0 |
| **Contact Person** | Michael Doumit |
| **Contact Email Address** | Michael.doumit@mq.edu.au |
| **Contact Phone Number** | 9850 9033 |
| **Study sites requiring SCHN HREC approval** | Sydney Children’s Hospitals Network  Westmead Hospital  Royal Prince Alfred Hospital |

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| 1. **Background Information (maximum two pages)** |

**Background**

Cystic Fibrosis (CF) is a progressive, multi-system disease that requires lifetime treatment. Management of CF incorporates both inpatient and outpatient interventions and reviews on a regular basis to monitor disease progress and provide therapies to optimise respiratory health outcomes. International standards of care recommend that people with cystic fibrosis should be seen by CF specialist teams on a regular basis. The recommended frequency of these reviews ranges from once per month to once every three months, depending on factors such as age and the clinical condition of the patient. 1-4

Traditionally, these reviews occur on a face to face basis in outpatient specialist CF clinics where the patient is seen by multiple members of a multi-disciplinary CF team. It is recommended that these reviews are conducted by specialist CF teams in specialist centres as it has been established that people with CF managed by CF specialist teams have better outcomes, including nutritional status and lung function, compared to those who do not receive their care from CF specialist teams. 5,6. At present in Australia, CF specialist centres are located at tertiary hospitals in major cities.

In recent years, there has been success in moving some aspects of CF care away from the hospital setting to the home environment. This includes delivery of intravenous antibiotics through various models of ‘Hospital in the home (HITH)’ as a replacement for inpatient hospital admissions. 7-8 In addition, various aspects of outpatient assessment and care have been trialled in the home environment, including home spirometry 9, exercise testing 10, adherence support 11 and enhanced disease monitoring using lung function and symptom diaries to detect pulmonary exacerbations 12. The aforementioned literature has focussed on using telehealth as a method to provide enhanced monitoring of patient progress in addition to usual face to face care, as opposed to replacement of outpatient visits with telehealth appointments. To date, there is only one study which evaluated the replacement of a visit to the multi-disciplinary CF clinic with a telehealth consultation 13.

Telehealth was rapidly rolled-out internationally as a replacement for hospital outpatient attendance in early 2020 as a necessary response to the COVID19 pandemic. For the vast majority of people with chronic health conditions, including CF, this meant going from a model of care where all visits were face to face to a hybrid model which involved the majority of appointments being delivered by telehealth14-16. It is likely that this increased utilistion of telehealth will continue post the COVID19 pandemic in Australia and worldwide17-21, with the current Australian Health Minister stating in a media release; “I hope and intend for telehealth to be a positive legacy of this crisis and am already engaged with the medical community in planning a long-term future for telehealth”22 Despite the sudden and ongoing increase in utilisation of telehealth, there remains a lack of information regarding the best models of care for outpatient care delivered using a hybrid model of care which incorporates multi-disciplinary outpatient telehealth appointments.

Another potential impact of moving from a traditional face to face model of care to a hybrid model incorporating telehealth and face to face care is adherence to recommended standards of care. Cystic fibrosis specialist centres aim to adhere to the Australasian CF Standards of Care (2008 – update in press). These standards of care are national recommendations regarding the necessary components of care delivery and set out based on literature, local and international guidelines and expert opinion. Adherence to standards of care is considered a key component of CF Centre accreditation conducted by Cystic Fibrosis Australia annually.

References

1. Lahiri T, Hempstead SE, Brady C, et al. Clinical practice guidelines from the cystic fibrosis foundation for preschoolers with cystic fibrosis. *Pediatrics.* 2016;137(4):e20151784.
2. Conway S, Balfour-Lynn IM, De Rijcke K, et al. European Cystic Fibrosis Society Standards of Care: Framework for the Cystic Fibrosis Centre. *Journal of cystic fibrosis : official journal of the European Cystic Fibrosis Society.* 2014;13 Suppl 1:S3-22.
3. Cystic Fibrosis F, Borowitz D, Robinson KA, et al. Cystic Fibrosis Foundation evidence-based guidelines for management of infants with cystic fibrosis. *The Journal of pediatrics.* 2009;155(6 Suppl):S73-93.
4. Yankaskas JR, Marshall BC, Sufian B, Simon RH, Rodman D. Cystic fibrosis adult care: consensus conference report. *Chest.* 2004;125(1 Suppl):1S-39S.
5. Mahadeva R, Dodge J, Webb K, et al. Clinical outcome in relation to care in centres specialising in cystic fibrosis: cross sectional studyCommentary: management in paediatric and adult cystic fibrosis centres improves clinical outcome. *Bmj.* 1998;316(7147):1771-1775.
6. Doull I, Evans H, South, Mid Wales Paediatric Cystic Fibrosis N. Full, shared and hybrid paediatric care for cystic fibrosis in South and Mid Wales. *Archives of disease in childhood.* 2012;97(1):17-20.
7. Balaguer A, de Dios JG. Home versus hospital intravenous antibiotic therapy for cystic fibrosis. *Cochrane Database of Systematic Reviews.* 2015(12).
8. Collaco JM, Green DM, Cutting GR, Naughton KM, Mogayzel Jr PJ. Location and duration of treatment of cystic fibrosis respiratory exacerbations do not affect outcomes. *American journal of respiratory and critical care medicine.* 2010;182(9):1137-1143.
9. Logie K, Welsh L, Ranganathan SC. Telehealth spirometry for children with cystic fibrosis. *Archives of disease in childhood.* 2019.
10. Cox NS, Alison JA, Button BM, Wilson JW, Holland AE. Assessing exercise capacity using telehealth: a feasibility study in adults with cystic fibrosis. *Respiratory care.* 2013;58(2):286-290.
11. Gur M, Nir V, Teleshov A, et al. The use of telehealth (text messaging and video communications) in patients with cystic fibrosis: A pilot study. *J Telemed Telecare.* 2017;23(4):489-493.
12. Lechtzin N, Mayer-Hamblett N, West NE, et al. Home Monitoring of Patients with Cystic Fibrosis to Identify and Treat Acute Pulmonary Exacerbations. eICE Study Results. *American journal of respiratory and critical care medicine.* 2017;196(9):1144-1151.
13. Wood J, Mulrennan S, Hill K, Cecins N, Morey S, Jenkins S. Telehealth clinics increase access to care for adults with cystic fibrosis living in rural and remote Western Australia. *J Telemed Telecare.* 2017;23(7):673-679.
14. Baum A, Kaboli PJ, Schwartz MD. Reduced in-person and increased telehealth outpatient visits during the COVID-19 pandemic. *Annals of Internal Medicine.* 2020.
15. Wosik J, Fudim M, Cameron B, et al. Telehealth Transformation: COVID-19 and the rise of Virtual Care. *Journal of the American Medical Informatics Association.* 2020;27(6):957-962.
16. Compton M, Soper M, Reilly B, et al. A Feasibility Study of Urgent Implementation of Cystic Fibrosis Multidisciplinary Telemedicine Clinic in the Face of COVID-19 Pandemic: Single-Center Experience. *Telemedicine and e-Health.* 2020.
17. Maese JR, Seminara D, Shah Z, Szerszen A. What a Difference a Disaster Makes: The Telehealth Revolution in the Age of COVID-19 Pandemic. *American Journal of Medical Quality.* 2020.
18. Najafi B. Post the Pandemic: How will COVID-19 Transform Diabetic Foot Disease Management? *Journal of Diabetes Science and Technology.* 2020:1932296820930290.
19. Fryer K, Delgado A, Foti T, Reid CN, Marshall J. Implementation of obstetric telehealth during COVID-19 and beyond. *Maternal and child health journal.* 2020;24(9):1104-1110.
20. Novara G, Checcucci E, Crestani A, et al. Telehealth in Urology: A Systematic Review of the Literature. How Much Can Telemedicine Be Useful During and After the COVID-19 Pandemic? *European urology.* 2020.
21. Thomas EE, Haydon HM, Mehrotra A, et al. Building on the momentum: Sustaining telehealth beyond COVID-19. *Journal of telemedicine and telecare.* 2020:1357633X20960638.
22. Continuous care with telehealth stage seven (Press Release, 20 July 2020) [press release]. 2020.

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| 1. **Research Plan** |

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| **Study Design** | Retrospective Medical Record Review |
| **Study Sites** | Sydney Children’s Hospitals Network  Westmead Hospital  Royal Prince Alfred Hospital |
| **Purpose of the Study** | The aims of this medical record review are:   1. Compare the clinical outcomes of people with CF managed with a hybrid model of multi-disciplinary outpatient care to the outcomes of the same participants managed with traditional face to face care prior to the transition to the hybrid model during the COVID19 pandemic 2. Compare adherence to CF Standards of Care since implementation of a hybrid model of care with adherence to the standards prior to transition to this model |
| **Participants** | Review of the Electronic Medical Record (eMR) of children who attend the CF clinic at Sydney Children’s Hospitals Network (SCHN) and adults who attend the CF clinics at Westmead and RPA Hospitals.  Approximately 400 children aged 0-18 attend the CF clinics at SCHN  Approximately 350 adults with CF attend the adult CF clinics  **Inclusion criteria**  All people with CF that attended the CF specialist services at Sydney Children’s Hospital and Westmead Hospital in the 12 months prior to the COVID 19 pandemic and for 12 months post the pandemic will be eligible.  **Exclusion Criteria**  Any person who has not continues attendance at the CF specialist centre for the period under review. For example, if a young adult has transitioned their care to a different facility during the review period. |

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| 1. **Recruitment Methods** |

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| **Identify and invite participants:** |
| Not applicable – retrospective medical record review |
| **Consent** |
| Please see attached waiver of consent application |
| **Reimbursements** |
| Not applicable |

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| 1. **Data Management Plan** |

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| **Data Collection** |
| * Retrospective Medical Record Review * Databases – SCHN eMR, RPA and Westmead Hospital eMR   Variables/Outcome Measures  Aim 1:   * Spirometry – Forced Expiratory Volume in One Second (FEV1), * number of hospitalisations * number of days on Intravenous antibiotics (IVAB), * number of presentations to the Emergency Department * Number of ICU admissions * number of deaths * lower airway microbiological results and * nutritional outcomes – BMI z score and weight for length z score dependent on age   Aim 2:  Medical record review will take place for the 12 months prior to initiation of the hybrid method of care to measure adherence to the following standards of care as defined in the Australian CF Standards of Care Document. This list is subject to update with the release of more current standards of care. Each standard of care will be categorised into either a yes/no response for each participant depending on whether or not the standard was met in the 12 months prior to and 12 months post initiation of hybrid care.   * 4 reviews per year by CF Specialist Centre * Sputum / Oropharyngeal sample collection for culture of common CF pathogens four times per year * Sputum microbiology including AFB (Acid fast bacilli) once per year * CXR and or/CT scan * Abdominal ultrasound * Comprehensive nutritional assessment by CF dietitian * Fat soluble vitamins levels (A, E, D), full blood count, urea, electrolytes and creatinine, liver function tests, random or fasting blood glucose level (BSL), total IgE. * Assessment for presence of CF related diabetes either by a formal oral glucose tolerance test or fasting and random blood glucose testing on a regular basis. * Spirometry measurements at each visit’ * Growth measurements * Bone mineral density assessment using DEXA scanning every 1-2 years depending on previous results * Comprehensive physiotherapy assessment including review of musculoskeletal system, urinary and faecal incontinence * Review of airway clearance treatments including check of equipment, technique and cleaning/maintenance of equipment. |
| **Analysis of Data plan** |
| * Analysis for Aim 1:   The primary outcome will be change in % predicted FEV1. A two-way (centre and patient) random intercept linear mixed model will be used to compare changes in % predicted FEV1 for the period before and after introduction of hybrid outpatient care. Potential confounding factors such as BMI z-score, lung transplantation, mutation status, age of visit, pseudomonas infection, comorbidities and pancreatic insufficiency will be accounted for in the analysis. Secondary analysis will involve differences in the remaining clinical outcomes measures in the pre and post telehealth periods and will be compared using paired t-tests with each participant serving as their own control.   * Analysis for Aim 2:   Each standard of care will be converted to a categorical variable with a yes/no for the standard being met or not in the 12 months prior to hybrid model of care delivery and the 12 months following initiation of telehealth. Percentage of participants meeting each standard will be calculated for the year prior to the hybrid model of care and the year following initiation of the hybrid model of care. Categorical variables will be compared using the chi square test and presented as a percentage of response. P-values of 0.05 will be considered to be statistically significant. |
| **Reporting of Results** |
| The researchers will submit their results for presentation at relevant conferences and will consider submitting the research finding to a journal for peer review and publication. Any results will be de-identified and presented as group data only.  The respiratory medicine team hosts annual parent information evenings and results of research activities completed are presented to the parent group at that time. |
| **Data storage** |
| All data will be collected from online NSW health electronic medical record. There will be no paper records of clinical data used in this project.  Each participant will be given an ID number. The password protected *identifiable* spreadsheet containing the ID number, name, MRN and DOB will be kept on the secure Respiratory Medicine Department servers for the participants at each individual site. A *re-identifiable* (containing participant ID and no other identifiable information) password protected spreadsheet will be kept on Macquarie University’s Microsoft SharePoint/OneDrive drive, and will be accessible to the research team only through Microsoft Teams. Data in Microsoft OneDrive, SharePoint and Teams is kept securely at industry-standard levels as per the details in the footnote below. Data will be stored for 15 years after project completion and then deleted, by assigning those expiry requirements on the Microsoft Team for this project.  FOOTNOTE: Microsoft Teams is built on the same Office 365 environment used by Macquarie University. It delivers enterprise-grade security and compliance standards including being Tier C-compliant\*. This includes the following standards: ISO 27001, ISO 27018, SSAE16 SOC 1 and SOC 2, HIPAA, and EU Model Clauses (EUMC). Teams also supports Cloud Security Alliance compliance. (\*Services in compliance categories C and D have industry-leading compliance commitments and are enabled by default.)Users use the same OneID/password to authenticate via a secure federated identity authentication mechanism with MQ Active directory in order to gain access to Microsoft Teams. |
| **Access to data** |
| Access to data is limited to study investigators listed on the ethics application and approved in each site-specific approval. |
| **Research data storage time** |
| The study data will be stored for 15 years post completion / termination of the study |
| **Sharing and re-use of data** |
| There are no plans to share data in the future and no secondary uses are foreseen |
| **Disposal of Data** |
| Electronic data will be deleted – for more detail please see data storage section. |

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| 1. **Study Risks and Benefits** |

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| **Risks and Benefits** |
| There is a risk to patient privacy and confidentiality during the retrospective data collection from the electronic medical record. This risk is mitigated by de-identifying the data and storing the data files securely as outlined in the data section of this protocol. |

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| **Links to other Resources and Templates** |
| <https://www.schn.health.nsw.gov.au/research/ethics-governance/ethics/lnr>  <https://www.schn.health.nsw.gov.au/research/ethics-governance/ethics/resources-templates> |