Appendix 3 PICF – Families

Project Number:	91117		
Short Name of Project:	Remote symptom monitoring		
Full Name of Project:	Remote symptom monitoring and automated treatment plans in children with Cystic Fibrosis on highly effective modulators		
Principal Investigator:	Jen Corda		
Version Number:	3	**Version Date:**	23/11/2022

Thank you for taking the time to read this **Parent Guardian Information and Consent Form**. We are inviting your child to take part in Remote symptom monitoring and automated treatment plan study.

This form is 8 pages long. Please make sure you have all the pages.

What is an Information and Consent Form?

An Information and Consent Form tells you what the project involves. It helps you decide whether or not you want your child to take part in the project. Please read it carefully.

Before you make a decision, you can ask us questions. You may also want to talk to your family, friends or healthcare worker.

Taking part in the project is up to you

You get to choose whether or not your child takes part in the project.

If you decide you do not want them to take part, this is ok. It will not affect your relationship with The Royal Children's Hospital.

Signing the form

If you want your child to take part in the project, please sign the consent form at the end of this document. By signing this form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received helpful answers
- consent to taking part in the project.

We will give you a copy of this Information and Consent Form to keep.

1. What is the project about?

We are inviting your child to take part in a project called remote symptom monitoring and automated treatment plans. The aim of the project is to test a new model of care aiming to trial remote monitoring of your child's symptoms to help detect and treat pulmonary exacerbations earlier at home.

Currently your child is seen in CF clinic every three months, where the CF team assesses their health since the last clinic appointment, including asking questions about their cough and any antibiotic usage. This relies on families remembering a lot of information to feedback to the team. In periods between clinic appointments families are left to assess their child's health independently and are asked to start antibiotics and increase physiotherapy at any sign of an exacerbation.

We know this is a lot to ask of families therefore we have developed a new way of monitoring and managing when your child is getting unwell at home. A new monitoring system has been created in the RCH patient portal. The system will collect your child's symptoms (cough, sputum, shortness of breath etc.) via a quick survey that you complete twice a week. The system will then compare your child's symptoms to their baseline symptoms i.e., when they're well and at their best. The system assesses the information and has a formula built in to work out if your child is at their best or if their symptoms have worsened. If your child's symptoms have worsened and the system detects your child may have an exacerbation (i.e., increased cough, sputum, change in breathing) it will send you a message with instructions of how to treat this. The information will also be sent to the CF team to review, and you can contact the CF team directly with any questions you may have.

The aim of this study is to compare the new model of care of remote monitoring and automated treatment plans to usual CF care, to see if it is feasible, acceptable and effective.

2. Who is running the project?

The project will take place at the RCH CF clinic. It is a collaborative project between the RCH CF team, the RCH Virtual care team, the RCH Electronic Medical Record team and researchers from the Murdoch Children's Research Institute (MCRI)

3. Why are we asking your child to take part?

We are asking your child to take part in the project because they:

- have cystic fibrosis
- are on either Trikafta or Ivacafor
- have home spirometry
- have access to the RCH patient portal

4. What does your child need to do in this project?

Your child will be in one of two groups: an intervention group and a no-intervention group. The group they end up in will be decided by chance, similar to tossing a coin. Your child has an equal chance of being in either group. This is called randomisation.

You will not get to choose which group your child ends up in. Neither will your doctor. However, once we know what group your child is in, we will give you this information.

As this project aims to compare the new model of care to usual care, those willing to participate in the study will either receive:

- Group one: The new model of care
- Group two: Usual CF care

If your child does take part in the project, they will need to do different things depending on whether they are in the new model of care group or the usual CF care group. This section gives you more information about what they will need to do.

1. **New model of care**

If your child is allocated to the new model of care group, they will continue to attend their routine hospital appointments as normal. Alongside usual CF care they will be asked to:

- Complete a quick online symptom survey via the RCH patient portal **twice a week** for a **12 month period**
- Complete **telehealth lung function each** time an **exacerbation** is detected, and at the start and the end of the trial
- Complete a **series of online surveys**
- Option to participate in voluntary interviews to understand more about your views of the new model of care

Table One on the next page gives you more information about what this project involves.

In this project, we will collect and use information from your child's hospital medical records for research purposes. This includes information such as your child's:

- date of birth
- CF genotype
- Weight
- Height
- Visits to and contacts with the hospital

All communication regarding this project will occur via the RCH patient portal and will be documented in your child's medical record.

2. **Usual CF care**

If your child is allocated to the usual CF care group, they will continue to attend their routine hospital appointments as normal. Alongside this you will be asked to complete a **series of online surveys** and **two additional telehealth lung functions** (at the start and the end of the project) over a **12 month period**. The surveys are described in more detail in this section.

There will be no additional hospital visits required as part of the study.

In this project, we will collect and use information from your child's hospital medical records for research purposes. This includes information such as your child's:

- date of birth
- CF genotype
- Weight
- Height
- Visits to and contacts with the hospital

Table One: What the project involves

Part of study	In-person or electronic?	How long will this take?	What does this involve?	Will your child complete these tasks? Usual CF care group	Will your child complete these tasks? New model of care group
Survey relating to basic child and family information	Electronic survey	5 minutes	You will be sent a link for a survey via the RCH patient portal The information collected will include: - Childs age - Gender	✓ yes	✓ yes
Lung function at the start and the end of the project	Either in person or via telehealth (at your request)	20 minutes	The lung function lab will get in contact to book a mutually convenient time to perform lung function. Lung function will occur at the start and the end of the project	✓ yes	✓ yes
Lung function at the start and the end of any exacerbation	Either in person or via telehealth (at your request)	20 minutes	The lung function lab will get in contact to book a mutually convenient time to perform lung function. Lung function will occur at the start and the end of any exacerbation	× no	✓ Yes
Surveys relating to quality of life at the start and the end of the project	Electronic survey	15 minutes	You will be sent a link for two surveys relating to quality of life via the RCH patient portal to complete: - Cystic Fibrosis Questionnaire revised (CFQ-R) - EQ-5D-Y This will be collected at the start and the end of the project	✓ Yes	✓ Yes
Follow up survey relating to exacerbations and contact with the hospital	Electronic survey	10 minutes	You will be sent a link at 3, 6 and 12 months to complete a survey asking you about any exacerbations, antibiotic usage, contact with the hospital and general trial satisfaction	✓ Yes	✓ Yes

To be completed at 3, 6 & 12 months					
Symptom survey to be completed twice a week	Electronic survey	3 minutes	You will be sent a reminder via the patient portal twice a week to complete the symptom monitoring survey	✗ no	✓ Yes

Optional consents

Interview at 3 and 12 months – for participants in the new model of care group

We invite you to participate in an interview to understand how this new model of care is changing you and your child's experience in managing their CF. We will ask you questions about your experience using the symptom monitor. We want your opinions about what worked well and what didn't so we can improve this way of delivering health care. The interview will take approximately 30 to 40 minutes and will be via videoconference. To ensure interview responses are collected accurately, interviews will be audio recorded. Audio recordings will be transcribed verbatim and de-identified in preparation for data analysis by a member of the research team and no results will contain any information that could identify you.

You can say no to this if you want to.

5. Can your child withdraw from the project?

Your child can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If your child leaves the project we will keep using any information that we have already collected about them. Please only join this research project if you are happy with this approach. Withdrawal from the study will not affect their care and relationship with The Royal Children's Hospital.

6. What are the possible benefits for your child and other people in the future?

We are doing this study to understand if this new model of care is more effective to our current model. We cannot guarantee that your child will get any benefits from this project. However, there is a chance that your child will be assisted by closer than usual monitoring compared to usual care.

Your participation in this project will provide useful information for assessing and further improving the implementation of the new model of care.

7. What are the possible risks, side effects, and inconveniences?

The study does require time to complete all online surveys which may be an inconvenience to your family.

This is new model of care using the symptom survey has the potential to either overestimate or underestimate exacerbations in your child. If you have concerns about the accuracy of the recommendations, you receive during the study we recommend you get in contact with the CF team.

Participants in the voluntary interviews may experience discomfort, you can pause or stop the interview at anytime. Parents/guardians may be uncomfortable about discussing their clinics, particularly when providing negative details about the intervention, the take up of the intervention, or their relationship with other clinicians involved in the study. To manage these risks, any information from individual interviews will not be shared with the CF team looking after your child.

8. How will we keep your child's information confidential?

Your child's data, such as their name, date of birth, address and UR number, will be de-identified by assigning them a unique participant study number/code during the study; the code will be stored on a secure database called REDCap which has special permission control functionality. Audio recordings from the interview will be destroyed once transcribed. Transcripts generated will be held on password protected computers network computers, with no personal identifiers attached to it, only accessible by the research team involved in this project. Any information collected in the study will be treated as confidential, stored securely and can only be accessed by the research team and The Royal Children's Hospital Human Research Ethics Committee. All information collected will be entered electronically and stored securely on the MCRI hosted REDCap database. All information will be stored securely in the MCRI and kept for at least 5 years. Publications and reports resulting from this study will be presented so that you and your child cannot be identified.

Future funding

We may apply to government organisations or commercial companies for funding for this project. If we get funding, we may need to share your child's deidentified information with the funder. If so, we will do this in a way that protects their privacy. We will also let you know that we have done this.

Storage of information

We may keep the research project data for 15 years. The data may be securely stored at the RCH.

Right to access information

You have the right to access and correct the information we collect and store about your child. This is in line with relevant Australian and/or Victorian privacy and other relevant laws. Please contact us if you would like to access this information.

Publicising results

At the end of the research project, we may present the results at conferences. We may also publish the project results in medical journals. We will do this in a way that does not identify your child.

9. How will you find out the project results?

At the end of the project we will send you a final letter. This letter will explain what we found out in this project – in other words, our project results. The letter will not have any information specifically about your child.

10. Who should you contact for more information?

If you would like more information about the project, please contact:

Name: Jen Corda (Co-ordinating Principal Investigator)

Contact telephone: 9345 9300

Email: Jen.corda@rch.org.au

Name: Dr Shivanthan Shanthikumar

Contact telephone: 9345 6614

Email: shivanthan.shanthikumar@rch.org.au

You can contact the Director of Research Operations at The Royal Children's Hospital if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

You can phone the Director on (03) 9345 5044 or email them at rch.ethics@rch.org.au.

Consent Form

Project Number: 91117

Short Name of Project: Remote monitoring and automated treatment plans

Version Number: 3 **Version Date:** 23/11/2022

- I have read this information statement and I understand its contents.
- I understand what my child and I have to do in this project.
- I understand the risks my child could face because of their involvement in this project.
- I voluntarily consent for my child to take part in this project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Optional consent

Optional consent: Interview I consent to be contacted to participate in an interview relating to the remote monitoring and automated treatment plan model	☐ I consent	☐ I **do not** consent

Child's Name

Parent/Guardian Name | Parent/Guardian Signature | Date

Name of Witness to Parent/Guardian's Signature | Witness Signature | Date

Declaration by researcher: I have explained the project to the parent/guardian who has signed above. I believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

Research Team Member Name | Research Team Member Signature | Date

Note: All parties signing the consent form must date their own signature.