

## Web Version

# PARTICIPANT INFORMATION BOOKLET (Parent/Guardian)

## BEAT CF Platform

Site	
Principal Investigator	

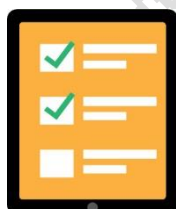
### INTRODUCTION

You are invited to contribute your child's health information to a database of health and treatment information about patients with Cystic Fibrosis (CF). This database is the platform for BEAT CF (Bayesian Evidence-Adaptive Treatment in Cystic Fibrosis) which is a national project aimed at optimising the management of lung exacerbations in patients with CF.

This Participant Information Booklet tells you about the BEAT CF Platform. Knowing what is involved will help you decide if you want your child to take part in BEAT CF. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or your child's doctor. We have also developed an information sheet for children to read to help them understand what their participation involves.

### WHAT IS THE AIM OF BEAT CF?

We want to collect information about patients with CF to find out what treatments are commonly used for lung exacerbations and what outcomes result. We hope that we can then use the information collected to inform the design of the future BEAT CF clinical trial where we will investigate the best treatments to use in managing lung exacerbations or "tune ups".



*Treatments* – we will record what medications your child is prescribed and what physiotherapy they receive.

*Outcomes* – we will record the results of any blood tests or sputum cultures, and any lung function tests your child does. We will also ask you (or your child if they are mature enough to understand) to fill out an electronic symptom survey every 3 months when your child is well and weekly during a lung exacerbation.

## WHAT DOES PARTICIPATION INVOLVE?

If you agree to take part in the study, we would ask you to:

- Give permission to access your child's medical records and collect information about your child such as date of birth, details about your child's CF diagnosis and treatment, results of any blood tests or sputum test your child has done and lung function test results.
- Give permission for delegated research staff to access and record information about the impact of treatment, for example whether your child goes to hospital for a lung exacerbation and what antibiotics or medications they are given.
- Answer 2 types of online surveys from your mobile phone, tablet or computer about how your child is feeling every 3 months when they are well and about their symptoms, weekly during a lung exacerbation. You will receive reminders to complete the survey via SMS or email, whichever you prefer. Mature children who can understand the questions can answer this survey themselves.
- If you consent for your child to be part of BEAT CF, they will not have any extra tests done. We are collecting information from the routine care your child receives.
- When your child turns 18 years of age, we will invite your child to re-consent to the BEAT CF Platform as an adult

## DOES MY CHILD HAVE TO TAKE PART IN BEAT CF?

Participation in BEAT CF is voluntary. If you do not wish for your child to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw consent for your child's participation at any stage.

**Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your child's routine treatment, your relationship with those treating your child or your/your child's relationship with the hospital.**

## WHAT ARE THE BENEFITS TO MY CHILD?

Participation in the BEAT CF Platform is not likely to benefit your child personally, medically or financially. However, participation may help your child and others with CF in the future by increasing the understanding of current management of CF lung exacerbations and informing the design of the BEAT CF clinical trial which, if eligible, your child will be invited to participate in.

When the BEAT CF clinical trial is established, you/your child may be invited to participate and consent in the trial if your child is eligible. You will be informed of the progress of the trial and the likely start date at [insert site name].

## **WHAT ARE THE POSSIBLE RISKS TO MY CHILD TAKING PART IN THE BEAT CF PLATFORM?**

There is minimal risk in taking part in the BEAT CF Platform. There is a possible but unlikely risk of potential breaches in the computer system. In the event there is a breach in the BEAT CF computer system, you will be notified. The University of Sydney has very strict data storage and retention policies to which the BEAT CF research team and data systems must adhere to.

## **I WANT MY CHILD TO BE INVOLVED IN THE BEAT CF CLINICAL TRIAL. IF I ENROL IN THE PLATFORM, IS THIS GUARANTEED?**

Although one of the main goals of the BEAT CF Platform is to inform the design of the BEAT CF clinical trial and to make it easier for patients to participate in research, there is no guarantee that an individual patient will be eligible for the BEAT CF clinical trial or that the hospital where your child receives treatment will be participating in the trial.

Please also be aware that if you/your child consent to the BEAT CF Platform **it does not** mean you/your child consent to any BEAT CF clinical trials. Each BEAT CF clinical trial you/your child enrol in will require that you/your child sign a consent form for that specific trial. Please make sure to discuss any study you/your child are considering carefully with the research staff before signing any consent form.

## **I DON'T WANT MY CHILD TO BE INVOLVED IN THE BEAT CF CLINICAL TRIAL. CAN THEY STILL BE PART OF THE PLATFORM?**

Yes. We hope that you/your child will still be involved in the BEAT CF Platform even if you don't want your child to take part in the BEAT CF clinical trial. Your child's information may be useful to researchers who are trying to learn more about patients with CF.

## **WHAT IF I CHANGE MY MIND ABOUT MY CHILD BEING IN THE BEAT CF PLATFORM?**

If you or your child's doctor do not think it is in your child's best interest to be part of the BEAT CF Platform, **you may withdraw your consent at any time.**

Should you choose to withdraw, the information that you/your child have provided (before withdrawal) will continue to be kept securely and used for BEAT CF. You can withdraw from the BEAT CF Platform at any time by contacting the BEAT CF team at your hospital.

## HOW WILL MY CHILD'S HEALTH INFORMATION BE COLLECTED, USED AND SHARED?

- All information collected for BEAT CF will always be treated confidentially. Only research team members can access your child's data. It will be stored in a secure, password protected database which is hosted on servers located in Sydney Australia.
- Data from the quality of life CFQR (cystic fibrosis questionnaire revised) may be shared with your child's CF Clinical team if it is thought to be in the best interests of the child's wellbeing
- Your child's information collected for the BEAT CF Platform will be identified by a unique study ID, not their name.
- Your child's deidentified data will be used by the BEAT CF Researchers and Investigators to design studies of treatments that will better inform future management of CF. All studies will need to be approved by the BEAT CF Steering Committee and a Human Research Ethics Committee before being implemented.
- This is a perpetual study, meaning it has no end date. Therefore, results from the study analysis will be stored electronically indefinitely.
- Your child's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.
- Information about participation in this research project may be recorded in the participant's health records.
- Information about your child may be obtained from their health records held at this and other health services, for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to participation in this research project.
- Your child's health records and any information obtained during the research project are subject to inspection for the purpose of verifying that all procedures and data collected adhere to relevant regulations. This review may be done by the relevant authorities and authorised representatives of
  - University of Sydney;
  - Child and Adolescent Health Service Human Research Ethics Committee;
  - any other authority required by law.

By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.



- It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your permission.
- In accordance with relevant Australian and/or [name of state/territory] privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about your child. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your child's information.

## WHO IS DOING THE RESEARCH?

Researchers from the University of Sydney and other respiratory doctors and researchers across Australia. Funding for the study has been provided by the Australian Government's Medical Research Future Fund.

## ANY QUESTIONS

If you want to know more about this study, please contact the

- Site Investigator
- Study Team

## WHO HAS REVIEWED THIS RESEARCH PROJECT?

All research in Australia involving people is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Child and Adolescent Health Service HREC. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2018). This statement has been developed to protect the interests of people who agree to participate in human research studies.

We cannot use data or results from the BEAT CF Platform in future research projects without approval. Any new research studies related to the BEAT CF Platform will need approval from the HREC.

## CONCERNS?

If you have any concerns and/or complaints about the study, the way it is being conducted or the rights of your child as a research participant, and would like to speak to someone independent of the study, please contact the:

Executive Director of Medical Services at Perth Children's Hospital – (08) 6456 2222

Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

## WHAT HAPPENS AND WHEN?

If you and your child decide you want to take part in the BEAT CF Platform, you will be asked to sign an electronic consent form. A paper version of the consent form is available should you require this.

By signing the BEAT CF consent you are telling us that you:

- understand what you have read,
- consent for your child to take part in BEAT CF,
- consent to the use of your child's personal and health information as described.

If you believe your child is able to comprehend what their participation in the study involves, then we will ask your child to read the *Child Participant Information Booklet* and provide consent at the same time as you provide consent.

You will be emailed a copy of the Participant Information Booklet and consent form to keep (or we can print you a copy if you prefer).