

*Insert Header with institution's name or institution's letterhead*

## Participant Information Sheet/Consent Form

**Interventional Study - Adult providing own consent**

*[Insert site name]*

<b>Title</b>	BCG vaccination to Reduce the impact of COVID-19 in healthcare workers (BRACE) Trial
<b>Short Title</b>	BRACE
<b>Protocol Number</b>	HREC number 62586
<b>Trial Sponsor</b>	Murdoch Children's Research Institute (MCRI)
<b>Chief Principal Investigator/ Principal Investigator</b>	Prof Nigel Curtis / <i>Principal Investigator</i>
<b>Location</b> ( <i>where CPI/PI will recruit</i> )	<i>[Location]</i>

### 1 Introduction

We are inviting you to take part in this trial because you are a healthcare worker. This trial is testing whether the Bacille Calmette-Guerin (BCG) vaccine can help reduce the severity of COVID-19 in healthcare workers.

This Participant Information Sheet/Consent Form tells you about the trial. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the trial.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this trial is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the trial, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read
- consent to take part in the trial
- consent to have the tests and treatments that are described
- consent to the use of your personal and health information as described.

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

**If you want more information or wish to speak to a study team member before providing your consent, please contact:**  
**[study team contact information]**

## 2 What is the purpose of this trial?

The severe acute respiratory syndrome-coronavirus 2 (SARS-Cov-2) is a coronavirus that emerged in China in December 2019. It is predicted that up to 60% of the population could become infected. There have been already over 18,000,000 cases of coronavirus disease (COVID-19) and greater than 690,000 deaths globally (as of 04 Aug 2020). For around 80% of people, the virus causes mild to moderate disease with symptoms similar to common respiratory diseases such as influenza, including fever, cough, and fatigue. In around 14% of people, the disease causes severe disease that requires hospitalisation. The remaining 6% are critical cases that have respiratory failure, septic shock and/or organ failure.

Healthcare workers are at the frontline of the COVID-19 pandemic. Because healthcare workers work closely with patients they have greater exposure and possibly greater risk of contracting the virus. There is currently no vaccine for COVID-19, so protection of healthcare workers relies on the use of personal protective equipment. When healthcare workers are sick and unable to come to work, this puts extra pressure on the healthcare system. All hospital staff, including doctors, nurses, cleaners and administrative staff are vital to ensuring the hospital can function during a pandemic of this scale. It is vital that the hospitals don't lose a significant portion of their workforce due to illness.

The tuberculosis (TB) vaccine, Bacillus Calmette Guérin (BCG), has been shown to protect against non-TB infections by boosting the immune system. Studies show that it can decrease mortality of those infected by half and protects against other infectious diseases and improves the response to other vaccines. The mechanism by which BCG influences immunity is not completely understood

We want to find out whether the BCG vaccine might protect against COVID-19. We are interested to know if the vaccine can reduce the number of cases of COVID-19, and the severity of the illness caused by the virus, compared to a placebo.

The BCG vaccine is approved in [include country] to protect against tuberculosis. However, it is not approved to protect against other infections, such as COVID-19. This study is an experimental use of this vaccine.

The results of this trial will help us find out whether, in future novel disease outbreaks, BCG vaccination could be used as an early intervention to protect healthcare workers and high-risk groups.

You can be in the study whether or not you have had the BCG vaccine in the past.

This research has been initiated by Professor Nigel Curtis, Head of Infectious Diseases at The Royal Children's Hospital Melbourne (RCH), Leader of Infectious Diseases Group at Murdoch Children's Research Institute and Professor of Paediatric Infectious Diseases, Department of Paediatrics, The University of Melbourne.

### Who is involved in this trial?

This trial is being led by the Murdoch Children's Research institute and will take place across multiple centres. There will be multiple sites across Australia, Europe and Latin America.

We hope to have 10078 healthcare workers in total be a part of this trial.

## 3 What does participation in this trial involve?

<site specific inclusion during influenza season> Because of the way this trial is designed, you must have received the current seasonal influenza vaccination to be in the trial (at least 3 days or more prior to your first study visit). We hope receiving the influenza vaccine will reduce the number

of non-COVID-19 respiratory illness, and lessen the risk of being co-infected with COVID-19 and influenza. It also means that any effect of the BCG vaccine will not be changed by participants having the flu vaccine after joining the study.>

You have already answered some screening questions that have determined that you may be eligible to be in this trial.

You will have a chance to consider the information in this form and discuss it with your family, friends or doctor. You can contact us for more information (see Section 20). We will ask you to provide your written consent when you have decided you are happy to participate.

If you agree to be in this trial, we will ask you to fill in some questions about yourself and your health. This will include your date of birth, name and other identifying details. We will ask you to complete a baseline questionnaire on whether you have had other vaccines recently, any other medical conditions you may have, your general health and lifestyle habits, and whether you have had the BCG vaccine before.

Once you have completed the questionnaire, you will come to get your vaccine. You can come at [any time/specified times of day]. [Sites to include information here about bookings, if required].

We will confirm that you have signed the consent form, filled out the baseline questionnaire and will ask you the screening questions again.

**Because of the way this study is designed, even if you have provided consent, we may already have enough people in the trial when you come for your enrolment visit.** If this is the case, we will tell you and you will not be put in the trial.

**Pregnant healthcare workers will not be eligible to participate in this trial.** Although BCG vaccination has not been shown to be harmful during pregnancy, the use of live vaccines (such as BCG) during these times is contra-indicated. Therefore, if you are pregnant, planning to fall pregnant within a month of enrolment in this trial, you will not be allowed to participate in this trial. If you think you could be pregnant we will ask you to do a pregnancy test prior to taking part. We will have pregnancy tests available when you come for enrolment if you would like to check on the day or to take away to self-test before enrolment.

You cannot take part in this trial if you are receiving medical treatment that affects the immune response (or other immunosuppressive therapy), have a serious underlying medical illness, have received any live vaccine in the past month or BCG vaccine in the past year.

Once we have confirmed that you are able to be part of the trial, the study team member will collect a blood sample of up to 30 mL <Brazil: 35ml>. This will be used to check whether you have already been exposed to COVID-19 before being in this trial and to look at the changes the vaccines make to your immune system. We will not have these results until the end of the study.

This is a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

In this trial we will put you into one of two groups:

- Intervention group 1 – You will be given a placebo vaccine. A placebo looks like the real thing but contains no active ingredients.
- Intervention group 2 – You will be given the BCG vaccine.

The chance of being in each group is 1 in 2, or 50%. You will not know which group you are in until the end of the trial. In an emergency, the study staff can find out which group you were in if this information is needed.

**If you consent to being in this trial you are agreeing that you are happy to be in either group and to not knowing which group you are in.**

After we have collected the blood sample, you will be randomly allocated to one of the two intervention groups. If we are unable to collect your blood, you cannot take part in this trial and will not be randomised.

A trial team member will administer your BCG vaccine or placebo in the arm. Once you have had your vaccine, you will need to stay in the hospital or clinic for 20 minutes, as per usual.

We will ask you to complete a questionnaire 2 weeks after your vaccination to tell us about your reaction to the vaccination (BCG or placebo). We will ask you about your vaccination site, and give you the option to send us a photograph of the vaccination site (using your smartphone).

We would like you to complete a survey about any time that you are unwell with a fever (temperature over 38°C) or with any respiratory symptom (sore throat, cough, difficulty breathing). We expect the survey will take no longer than 2-minutes each day you are unwell. <locations using app only: You will be able to access the survey at any time using a phone app. Every week for the 12 months of the trial we will send a reminder, asking if you have had a fever or respiratory symptoms since the last time you responded.> If you haven't been unwell (with fever or respiratory symptom), all you will need to do is respond by saying 'no'. If you have been unwell you will respond with 'yes' and complete the survey.

If you report symptoms of respiratory illness or fever during the 12 months of this trial, we want to confirm whether you have COVID-19 or not. If you have these symptoms you should have a test done through a centralised service, and we will get these results. In rare circumstances, home visits or self-swabbing kits may be required to ensure access to COVID-19 testing. <locations using app only: The app you use to log your symptoms will prompt you to get a test if required.>

At 3, 6, 9 and 12 months after your enrolment, we will send you a longer questionnaire asking about your exposure to COVID-19 and any medical interventions you may have had. To the best of your memory, we will also request you to confirm the main episodes of illness experienced in the prior 3 months. We will also ask for information on the vaccination site of the BCG or placebo, and if you have a wound, how your arm has healed.

Approximately 3, 6, 9 and 12 months after your enrolment in the trial, you will attend a study visit and the trial staff will collect a blood sample of up to 30mL. This will be tested to see if you had a COVID-19 infection without having symptoms and to look at the changes the vaccines made to your immune system. <country/site specific: The blood collections at 6 months and 9 months may be done by self-administered finger prick blood spots with kits provided to you by the study team. This means you could collect the sample at home yourself instead of at a site study visit. If this is your preferred way of providing your sample we will also ask you for your home address so that we can mail the in-home collection kits to you.>

<Locations using third party providers for messages/booking system> Mobile messages and managing study appointment

<Locations using message> As a participant in the study you will receive messages from the study team. You may receive these messages via a third party communications platform used by the study team.

You may need to use an online appointment scheduling platform to book study visit appointments. You may be required to login to book and manage your appointment time for your clinic visit.

To enable you to <location using message> receive messages and to manage your study appointments, some limited personal information (such as your name, mobile phone number and email) may be transferred to the vendors of the third party platforms. The vendor may be located

locally or in another country. The platforms used by the study team have been carefully chosen so that your personal information will be stored securely and processed only in accordance with applicable data protection and privacy laws and regulations. The vendors of the relevant platforms are not permitted to share your personal information with any third parties, and may use your personal information solely to communicate with you regarding the study.

#### Collection of Hospital data

In addition, we will obtain details about your health from <insert name of government body who holds the hospital level data> who collects information about presentations to hospitals and emergency departments for medical care in <insert state name>.

Collecting this information will help us to determine if the BCG reduces the likelihood of getting admitted to hospital, whether it is cost effective and will help us measure the outcomes at the end of the study.

For us to obtain details from <insert name of government body who holds the hospital level data>, we will require you to complete the consent form authorising the study to access your complete hospital records.

The specific health data we would like to obtain from <insert name of government body who holds the hospital level data> is for 12 months from the time you consent to the study. It will include details of your hospitalisations and emergency department visits such as diagnosis, length of stay and its costs.

This data collection within the trial has been approved by the Human Research Ethics Committee at the Royal Children's Hospital. With your consent, we will provide your identifying information (your name, address, date of birth, country of birth and <country specific detail ie. Medicare care number>) to <insert name of government body who holds the data>. Based on only this identifying information, these organisations will identify the health related data they hold about you and release to the trial researchers only information that is consistent with the aims of this research project.

Information about how your data will be protected is in section 16 of this form.

#### Collection of data on herpes simplex recurrences (exploratory objective)

As BCG could also help to prevent other viral infection, we will ask you whether you have recurrent herpetic infection (such as cold sores on the lips). This will be asked at enrolment and in the questionnaires at 3, 6, 9 and 12 months after your enrolment.

#### OPTIONAL CONSENT – Contact for future research

Because you have been involved in this trial, there may be future studies for which you are eligible. Should this occur, we would like to contact you to find out if you are interested in participating. If you agree to this, please tick the box on the final page of this form.

#### OPTIONAL CONSENT – Biobanking of Samples

We are asking you to consider allowing us to store any remaining samples and data at the end of this trial for use in future research relating to immunology, vaccines or infectious diseases.

Samples would be stored, labelled with a code, at MCRI laboratories (Infectious Diseases Group) in Melbourne.

For tests that require equipment or technical expertise not available in Melbourne, select specimens may be sent to collaborating laboratories outside of Melbourne (interstate and/or overseas) for further testing.

Any research conducted with your samples will be approved by a Human Research Ethics Committee. We do not plan to contact you for your permission to conduct this future research.

If you agree to this, please tick the box on the final page of this form.

#### OPTIONAL CONSENT – Genetic analysis

Our bodies are made up of different types of cells. Inside these cells you find genes. Genes are passed down in families from parents to children: you get half your genes from your mother and half from your father. Our genes contain all the information that makes us what we are, including our eye colour, blood type, and height and whether we are born as a boy or a girl.

There are about 23,000 genes that make up a human being and genes are arranged along a chemical substance called DNA. If you provide consent for genetic analysis we will extract DNA from your blood sample. We will look to see if there are genetic features in your DNA that might be associated with COVID-19 responses, how your immune system functions, how the vaccinations changed your immune responses, and whether they alter the ability for BCG to protect against COVID-19.

The genetic analysis that we are doing is for research purposes only and the significance of the results are unknown, therefore we will not provide individual results to you.

This part of our study is voluntary, if you agree to this, please tick the box on the final page of this form.

#### <Australian sites: optional inclusion

#### OPTIONAL CONSENT – stool sample collection for microbiome analysis

The gut microbiome refers to the types and relative amounts of different bacteria and organisms that are found in the gut. Many previous studies have shown that the gut microbiome can have strong influences on immune responses in the body including, potentially, immune responses to vaccination.

If you provide consent for stool sample collection, we will provide you with a collection kit for you to take home and you will be able to return the sample in the mail. There will be no financial cost to you to do this as we will provide you with everything you need to collect the sample and a postage-paid envelope to return the sample. We will then extract DNA from your stool sample and we will determine the abundance of microbes (and the genes they encode) in your sample and investigate whether the gut microbiome is associated with immune responses to the BCG vaccine or any of the other outcomes being measured in the trial.

The microbiome analysis that we are doing is for research purposes only and the significance of the results are unknown, therefore we will not provide individual results to you.

This part of our study is voluntary, if you agree to this, please tick the box on the final page of this form.>

#### <site specific: OPTIONAL CONSENT – additional biological sample during episode of illness

We can learn more about COVID-19 infections and how BCG might help to protect against or reduce the severity of COVID-19 by collecting biological samples such as blood and saliva/respiratory swabs from people with the infection. This will help us to answer important questions including: What does the immune response to COVID-19 look like? Why do some people have more severe COVID-19 illnesses than others? How does BCG change the way your body responds to COVID-19 and other infections?

If you provide consent for additional biological sample collection during an episode of illness, a trained member of the study team may take a blood sample (up to 30mL) and saliva/respiratory swab/s from you during or up to one month after resolution of an episode of illness with fever or respiratory symptoms.

The sample collection will be done by trained staff at a study site or at your home. We will aim to take these samples at the same time as any other clinical or research samples where possible to minimise the number of tests for you.

This part of our study is voluntary, if you agree to this, please tick the box on the final page of this form.>

#### **4 What do I have to do?**

You will need to:

- Complete a diary questionnaire about your vaccination site and any local reaction you have. The questionnaire will include the option to send us a photograph of your vaccine site (taken with your smartphone)
- Fill out a questionnaire each time you are unwell with a fever or respiratory symptoms during the study <country specific: using a smartphone application designed for the trial or via phone calls>
- Complete 4 longer questionnaires (approximately 10 minutes) 3, 6, 9 and 12 months after your enrolment
- Reply to a weekly prompt from <country specific: the study app or via phone >with yes/no as to whether if you have not been unwell with a fever or respiratory symptoms. If we don't hear from you we will send an email reminder and may also phone you.
- Undergo respiratory swab testing for COVID-19 on each occasion you have any symptoms consistent with this infection
- Attend a study visit for randomisation, vaccination and blood collection, and four follow-up study visits for blood collection. <country/site specific: The blood collections at 6 months and 9 months may be done by self-administered finger prick blood spots that you return/post to the study site instead of study visits>

#### **5 Other relevant information about the trial**

We will not tell the hospital that you work for which of their staff members have consented, refused or were ineligible to participate in this trial.

There are no costs associated with participating in this trial, nor will you be paid. All medication, tests and medical care required as part of the trial will be provided to you free of charge.

Some research studies do not allow participants to be in two studies. We allow this but other studies may not. If you participate in this trial you will not be able to participate in trials of other preventative measures for COVID-19.

#### **6 Do I have to take part in this trial?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the trial at any stage.

If you do decide to take part, you will need to sign this Participant Information and Consent Form. We will give you a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with [Institution].

#### **7 What are the alternatives to participation?**

If you decide not to be in this trial you can possibly take part in other trials testing other preventive interventions.

## **8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this trial. However, we hope that the BCG vaccine may boost your immune system. It may provide you with non-specific protection to other illnesses.

Information we collect in this trial will help to inform how we respond to outbreaks of new diseases in the future.

## **9 What are the possible risks and disadvantages of taking part?**

BCG is one of the most widely used vaccines in the world with an established safety record. It has been given to children since the 1920s. Most vaccines are injected into muscle, BCG is a little different as it is given just under the skin (into the 'intra-dermal' layer) of the left upper arm. BCG immunisation hurts a little, but this is minimised when given by experienced immunisation staff such as those who will be performing the procedure in this study.

The usual expected reaction to BCG vaccination is redness and/or a small 'papule' (a pimple or lump) at the injection site that appears weeks to months after vaccination. A few weeks later, the papule usually softens and breaks down to a small ulcer (an open sore - usually less than 15 mm in diameter). The ulcer is painless and may last from weeks to months. Once the ulcer has healed, this usually (but not always) leaves a small flat scar. Most people in Australia over the age of 50 and any that lived or travelled to a country with high levels of TB as a child, will have this scar.

Having an ulcer will not impact your ability to go to work. You can cover it with a bandage during the day while it is an open wound.

BCG vaccination can occasionally cause adverse effects, these usually get better by themselves, without requiring any specific treatment. The risk of these reactions is minimised by use of correct immunisation technique by trained staff. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, contact us.

Participants who have had active TB in the past will be excluded. If someone has had active TB in the past, they are immune to TB so there is no indication to give BCG clinically. Because of this, there is no data available on the safety of giving BCG to people who have had active TB in the past.

### Common adverse reactions:

These reactions are seen in less than 1 in 100 people immunised with BCG and usually resolve without any specific treatment:

- Abscess at the injection site or a larger ulcer
- Keloid scar at injection site (it means 'a scar thicker than usual')
- Swelling of local gland (lymph node) near the injection site (usually under the arm or near the neck)

### Rare adverse reaction (less than 1 in 1000):

- Infection of the armpit lymph node, with swelling, abscess or ulcer.

### Very rare adverse reaction (less than 1 in 1 million)

These conditions are usually associated with underlying inherited issues with the patient's immune system.



- Disseminated BCG infection, where the vaccine bacteria spread throughout the body or to the bone occurs in 1-4 in 1 million doses.
- Anaphylaxis (a severe allergic reaction) to the BCG vaccine has been reported only 2-3 times in the 100 years the BCG vaccine has been used.

An excessive response to the BCG vaccine may result in an ulcer with some discharge. If this happens, you should encourage the ulcer to dry and avoid abrasion (by tight clothes, for example).

Information for participants who have previously had a BCG vaccine or previous positive tuberculosis screening test (suggesting previous BCG vaccine or exposure/natural infection):

You can be in the study whether or not you have had the BCG vaccine in the past. There is no data available on the safety of giving BCG to people who have had active TB in the past. If you have had TB you should not have BCG vaccine.

If you have had a BCG vaccination previously, there is an increased risk that you may have an earlier, “accelerated” reaction which may begin within 24-48 hours of vaccination with toughening of the tissue followed by pustule formation in 5-7 days and healing within 10-15 days. Local skin lesions (ulceration and discharge) are more frequent in adults who have had a previous BCG vaccine than those who have never had BCG vaccine before. However, the risk of severe armpit lymph gland infection and disseminated BCG or reactivated tuberculosis disease has not been found to be more common in adults who have had previous BCG vaccine or positive tuberculosis screening tests.

Revaccination with the BCG as a part of this trial does not align with current vaccination guidelines, however it has been carefully considered upon systematic review of the literature to date. Adverse events will be actively monitored during the trial and medical review available for any participants who have concerns about their BCG vaccination site or scar.

Potential interaction between BCG and COVID-19 illness

Although there is a hypothetical risk that BCG vaccination could worsen the COVID-19 illness (via an exaggerated immune response) we consider this highly unlikely. We think BCG vaccine is more likely to protect against COVID-19, by reducing the severity of the illness caused by the virus. You may or may not receive any benefit from having the BCG vaccine.

Risks related to Placebo injection

Having an injection can sometimes cause very minor pain from the needle or be uncomfortable. The placebo injection will be administered by a trained immunization nurse.

Adverse effects related to blood collection and throat swabs

Having a blood sample collected may cause some discomfort or bruising. Trained members of the research team will collect these samples. Having a throat or nasal swab can sometimes be uncomfortable.

**10 What will happen to my test samples?**

<<Insert information relating to local storage of samples here>>

Your blood samples and throat and nasal swabs obtained for the purpose of this trial may be transferred to the Murdoch Children’s Research Institute (MCRI). They may be stored in freezers at the Infectious Diseases and Microbiology research laboratory at the MCRI until analysis. Your samples will not be sold by MCRI.

For tests that require equipment or technical expertise not available in Melbourne, select specimens may be sent to collaborating laboratories outside of Melbourne (interstate and/or overseas) for further testing. Samples that leave Australia are not protected by Australian law.

Your samples will be stored labelled with a participant code, not your name or other identifying information. Only the research team will have access to the code.

Only the members of the research team will be able to access your samples and will update reports on their location and processing. The freezers are locked and can only be opened by members of the research team who have access to the key.

## **11 What if new information arises during this trial?**

Sometimes during the course of a trial, new information becomes available about the intervention that is being studied. In this particular case, if we happen to find that BCG is highly effective to prevent COVID-19 disease and/or severity, we will offer BCG vaccine to the participants randomised to the control group (intervention group 1). On the contrary, if BCG appears to be harmful, ie higher rates of disease and/or severity, we will alert participants in the BCG group of the greater risk which may allow them to seek alternative ways to protect themselves from getting the COVID-19 disease.

## **12 Can I have other treatments during this trial?**

You can continue to take your regular medication during the trial.

As the BCG vaccine is live-attenuated, you should not receive any other live-attenuated vaccine (such as measles-mumps-rubella, varicella or yellow fever vaccines) in the month following your inclusion in the trial. Also you cannot receive any vaccinations in the same arm for 3 months after the vaccine is given. However, you can receive all inactivated vaccines at any time in the other arm.

While you are in this study it is important that you do not go and get the BCG vaccine elsewhere.

While you participate in this trial you may not be able to participate in new drug trials or other trials that are aimed at healthcare workers. You should not participate in trials of any other preventative measures for COVID-19 while you are participating in this trial.

## **13 What if I withdraw from this trial?**

Withdrawing from this trial will not guarantee that you can participate in other COVID-19 related interventional trials. Once you have been enrolled in this trial you may not be eligible for other trials.

If you decide to withdraw from the trial, please notify us. This notice will allow us to discuss any health risks or special requirements linked to withdrawing. You do not have to tell us why you are withdrawing.

If you do withdraw your consent during the trial, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the trial can be measured properly. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the trial results. If you do not want them to do this, you must tell them before you join the trial.

## **14 Could this trial be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects

- The BCG vaccine being shown to work and not need further testing
- Decisions made by the study team or local regulatory/health authorities.

## 15 What happens when the trial ends?

After 12 months, the trial will be over and we will contact you to let you know which treatment group you were in. After 12 months we will not contact you for further follow-up related to this trial.

If you have agreed, we may contact you about future research.

## Part 2 How is the research project being conducted?

### 16 What will happen to information about me?

Data will be stored in coded/re-identifiable form which will be password protected.

The principal investigators, co investigators, study team, The Royal Children's Hospital ethics committee and biostatistician will have access to your information as identified by your allocated study number.

The collected information will be stored secure at MCRI in locked filing cabinets or in restricted access folders on the Institute's network drive and will only be accessible to the research team.

We are required to keep information collected as part of a trial for at least 15 years. The research information may be destroyed or kept indefinitely in secure storage after this time. Your information will be stored for future ethically approved research.

Any information we collect that can identify you will be treated as confidential and used only in this project unless otherwise specified. The information will be re-identifiable. This means that we will remove your name and give the information a special code number. Only the BRACE trial research team can match your name to the code number, if it is necessary to do so.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Information about you may be obtained from hospital records for the purposes of this research.

Your hospital information will not be reported in a way that isolates you as an individual. Results will be grouped together, summarised and not identify you in any way.

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the MCRI, the organisation relevant to this PICF, [organisation name] or as required by law. By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

We will present these results at scientific conferences and publish them in scientific journals. The results will not identify any individuals, only group information will be presented. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

To advance science, medicine and public health, we will also need to share your de-identified data with other ethically approved research projects, data repositories, biobanks, or medical journals. When we need to do this, we will remove identifying details such as your name, date of

birth and address and give the data a special code number. Only the BRACE trial research team on this project will be able to match your name to their code number. Information that leaves Australia is not protected by Australian law.

We will put security measures in place to protect your data if and when we give it to other people.

Despite our best efforts, there is a small chance that you could be re-identified by someone outside of this research project. In the unlikely event that this happens, someone from the research team will contact you. If, at any point, you think that you may have been re-identified, please let us know.

## 17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

## 18 Who is organising and funding the research?

This trial is being funded by the Bill and Melinda Gates Foundation, [insert details of site funding] and other philanthropic organisations. No member of the research team will obtain any financial benefit from their involvement in this project (other than their ordinary wages).

This research is being conducted by a collaboration involving researchers based at hospitals globally and the Murdoch Children's Research Institute.

## 19 Who has reviewed the research project?

All research in Australia involving humans 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 HREC of The Royal Children's Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

[insert details of ethics and governance mechanisms outside Australia as required]

## 20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on [phone number] or any of the following people:

### Clinical contact person

Position	BRACE trial program manager
Telephone	+61 409 846 988
Email	brace@mcri.edu.au

**Local Site Clinical Contact Person**

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

Position	The Director, Research Ethics and Governance, The Royal Children's Hospital
Telephone	+61 3 9345 5044
Email	Rch.ethics@rch.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

Reviewing HREC name	The Royal Children's Hospital Human Research Ethics Committee
Telephone	+61 3 9345 5044
Email	Rch.ethics@rch.org.au

**Local HREC Office contact (Single Site - Research Governance Officer)**

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

## Consent Form - *Adult providing own consent*

**Title** BCG vaccination to Reduce the impact of COVID-19 in healthcare workers (BRACE) Trial

**Short Title** BRACE

**Protocol Number** HREC number 62586

**Project Sponsor** Murdoch Children’s Research Institute (MCRI)

**Chief Principal Investigator/  
Principal Investigator** Prof Nigel Curtis / *Principal Investigator*

**Location** *(where CPI/PI will recruit)* *[Location where the research will be conducted]*

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Murdoch Children’s Research Institute concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I understand that taking part in this trial may therefore stop me from participating in other trials that do not allow this.

**OPTIONAL CONSENT:**

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to be contacted about future ethically approved research related to this project.
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to my samples being placed in the biobank and used for future ethically approved research related to immunology, vaccines or infectious diseases.
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to genetic analysis of my samples.
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	<site specific: consent to provide additional biological sample during episode of illness>
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	<Australia sites optional inclusion consent to stool sample collection and microbiome analysis.>

**Declaration by Participant – for participants who have read the information**

Name of Participant (please print) _____  Signature _____ Date _____
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Declaration - for participants unable to read the information and consent form  
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness\*.  
Witness to the informed consent process

Name (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

\* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/  
Senior Researcher† (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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