Main Participant Information Sheet & Consent Form

Interventional Study

The Royal Melbourne Hospital

Title	A Phase 3, Double-Blind, Randomized, Placebo-Controlled Study of Baricitinib to Preserve Beta Cell Function in Participants Newly Diagnosed with Type 1 Diabetes Aged ≥1 to <36 Years
Short Title	BARICADE-PRESERVE
Protocol Number	I4V-MC-JAJK
Project Sponsor	Eli Lilly and Company
Principal Investigator	Professor John Wentworth
Location	The Royal Melbourne Hospital

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research study. This is because you have newly diagnosed type 1 diabetes. The research project is testing a potential new treatment for newly diagnosed type 1 diabetes. The new treatment is called baricitinib.

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

Please read this information carefully. Ask as many questions as possible 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 study 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 research project, 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 research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2. What is the purpose of this research?

Medications, drugs, and devices have to be approved for use by the Australian Federal Government Therapeutics Goods Administration (TGA). Baricitinib is approved in Australia to treat moderate to severe active rheumatoid arthritis, atopic dermatitis and alopecia areata. However, it is not approved to treat newly diagnosed type 1 diabetes. Therefore, it is an experimental treatment for newly diagnosed type 1 diabetes. This means that it must be tested to see if it is an effective treatment for newly diagnosed type 1 diabetes.

Baricitinib may help maintain your body's ability to make and use some of its own insulin in newly diagnosed type 1 diabetes.

The purpose of this study is to learn more about baricitinib, a possible new medicine for the treatment of newly diagnosed type 1 diabetes. The study aims to learn:

- Whether baricitinib can help in managing newly diagnosed type 1 diabetes.
- Whether baricitinib works better than a placebo (a placebo is an inactive or "pretend" study drug).
- The possible side effects people might have when taking baricitinib.

The study is being conducted by Eli Lilly and Company and sponsored in Australia by Eli Lilly Australia Pty Ltd.

3. What does participation in this research involve?

If you agree to take part in this study and the study is suitable for you, you will get treatment as part of this study until the study doctor determines that you should not continue (for example, the study drug is no longer helping) or until the sponsor has collected all the information needed and the study ends. This study will take about 60 weeks to complete.

This study has 3 periods:

- **Screening Period:** Up to 4 weeks, 2 visits
- **Treatment Period:** Up to 52 weeks, 8 visits
- **Follow-Up Period:** 1 visit approximately 4 weeks from your last visit or early discontinuation visit

Throughout the Study

Study activities might occur at the study doctor's office, your home, or other locations as specified for the study and as allowed by local law.

The study doctor will talk to you about the specifics for this study covering topics such as:

- what current treatments you can continue,
- how the study will be done including what will be needed from you, and
- answer any of your questions.

If you have unexpected or troubling symptoms while you are in the study, contact your study doctor and, if you feel necessary, seek emergency medical care.

During the study, the study doctor will need to take a small amount of blood from you for testing and monitoring purposes. It is usually a few tubes of blood. This is similar to what is taken during a regular visit to your doctor. The total amount of blood that will be taken from you will be approximately 236 mL (12 tablespoons) if you are 18 years old or older or 123 mL (6 tablespoons) if you are less than 18 years old.

Screening Period

Before any study-related procedures are done, the study doctor will explain the study to you and you will have time to read this Participant Information Sheet and Consent Form and ask any questions you may have. The study staff will review this document with you and will help answer any questions you may have now and during the study. If you agree to participate in the study you will need to sign and date this consent form. You will be given a copy of the signed Participant Information Sheet and Consent Form to keep, and the original copy will be put in your medical record.

The first part of this study is the Screening Period. It lasts about 4 weeks depending on your personal health care situation.

During this time, you will have some tests and activities, including:

- Review of medical and surgical history and any ongoing medical issues
- Review of current and prior medications
- Measurement of blood pressure and pulse rate
- Measurements of height and weight
- Physical examination
- Blood draws including fasting 2-hour mixed meal tolerance test (MMTT) and urine collection for laboratory tests
- Electrocardiogram (ECG): Only collected if you are 10 years or older
- Females (8 years or older): checking if you have started a menstrual period or not
- Checking if you are using contraception correctly and consistently (where applicable)
- Basic diabetes education and training on proper use of glucose monitors (as required)
  Note: The study staff will provide you with a diary that you will need to complete when you experience a low blood sugar event and a diary to record your insulin doses. You will need to return the diaries to the study staff at your next visit.
- Glucose monitoring
  Note: You will be asked to wear a study provided small continuous glucose monitor (CGM) that will collect your blood sugar levels. If you already use an Automated Insulin Delivery system that includes a CGM you will continue to wear this and share its data with your doctors, but you will also need to wear the study-provided CGM during the study. The study staff will provide you with a CGM that needs to be returned at your next visit.
- Testing for infectious diseases

During this time, you can expect about 2 blood draws and 1 ECG, but you might need to have more. This period will help the study doctor figure out whether you can continue to the next part of the study.

You may be asked if you want to go through another round of screening procedures if you don't meet the screening criteria the first time.

If you are eligible for the study at the end of the Screening Period, you will enter the Treatment Period. If the study doctor decides that you are not eligible to take part in this study, they will discuss other treatment options for your condition with you.

Treatment Period

The treatment period of the study, when participants are given either baricitinib or placebo to compare how well they work, will be different for each patient. If you are eligible to stay in the study after you complete the Screening Period, and you decide to continue, you will enter the Treatment Period of the study.

You will be participating in a randomised controlled study. 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).

This period of the study lasts for about 52 weeks. This is when you get either baricitinib or placebo to compare how well they work. A placebo is a medication with no active ingredients or a procedure without any medical benefit. It looks like the real thing but is not. We refer to these all together as "study drug." Neither you nor your study doctor will know which study drug you are getting. However, in certain circumstances your study doctor can find out which treatment you are receiving.

The likelihood that you will receive the drug being studied will depend on how the study is set up and is determined by chance. You will have a 66.7% (2 in 3) chance of receiving baricitinib and 33.3% (1 in 3) chance of receiving a placebo as a treatment.

During this time:

- You will take study drug for about 52 weeks by mouth. The amount of medicine you get depends on your body weight and whether you can swallow tablets. If you have trouble swallowing tablets, you will get a liquid version of the medicine (called an oral suspension).
- You may be asked to not eat before coming to some of your study visits so that certain testing can be done
- You will have some tests/activities including:
    - Review of current and prior medications
    - Measurement of blood pressure and pulse rate
    - Measurement of height and weight

      Note: Height may not be measured if you are more than 18 years of age.
    - Physical examination
    - Blood draws including fasting 2-hour mixed meal tolerance test (MMTT) and urine collection for laboratory tests
    - Females (8 years or older): checking if you have started a menstrual period or not
    - Checking if you are using contraception correctly and consistently (where applicable)
    - Review of glucose levels and insulin doses

      Note: The study staff will provide you with a diary that you will need to complete when you experience a low blood sugar event and a diary to record your insulin doses. You will need to return the diaries to the study staff at your next visit.
    - Glucose monitoring

      Note: You will be asked to wear a study provided small continuous glucose monitor (CGM) that will collect your blood sugar levels. If you already use an

Automated Insulin Delivery system that includes a CGM you will continue to wear this and share its data with your doctors, but you will also need to wear the study-provided CGM during the study. The study staff will provide you with a CGM that needs to be returned at your next visit.

- Bone X-ray of the hand or wrist, if you are below 18 years of age
- Examination to measure your stage of puberty. If you are aged 7 years or less, or you have reached sexual maturity, this examination will not be performed. We will examine your body for signs that you are sexually maturing. This may include checking for things like the: presence of pubic hair, development of breasts, development of testes. In many cases we will be able to do a visual check. If you do not want a puberty status assessment, please tell us. If you can give us information about your sexual development, we may not need to do this assessment.
- Questionnaires related to your general health and well-being
- Random grouping to baricitinib or placebo and dosing related activities

During this time, you can expect about 8 blood draws and 2 X-rays (if you are below 18 years old) but you might need to have more. Ask the study doctor if you want more information.

Each Treatment Period visit may be different in length depending on what tests will be done, but each visit is expected to take around 4 hours. Your study doctor will explain what you have to do and which tests you will have during the study.

Follow-Up Period

After you have finished with the treatment period and are no longer receiving study drug, the study doctor will continue to check on your health and you may be asked to have more tests. This is called the Follow-up Period, and it lasts for about 4 weeks.

During this time:

- You will no longer receive study drug.
- You will have some tests/activities including:
  - Review of current and prior medications
  - Measurement of blood pressure and pulse rate
  - Measurement of height (or length) and weight
  - Physical examination
  - Blood draws for laboratory tests and urine collection
  - Females (8 years or older): Checking if you have started a menstrual period or not
  - Checking if you are using contraception correctly and consistently (where applicable)
  - Returning the blood glucose monitoring supplies

You can expect 1 blood draw but you might need to have more. Ask the study doctor if you want to more information.

This study has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. If you stop taking the study drug for any reason, the study doctor will still ask you to continue in follow-up.

What are the costs associated with joining the study?

You will receive the study drug, treatments, and procedures that are directly related to the study at no cost. Depending on how your healthcare expenses are paid for, you may have

some personal expenses. The study staff can explain further.

If you spend money to be a part of this study, you may be able to get some or all of it back. You will only be given money back for expenses associated with study activities completed. The study staff will provide you and review more details around how reimbursement will be received.

If you decide to participate in this research project, the study doctor will inform your local doctor that you are participating and also of relevant clinical information disclosed in the conduct of the study.

4. What do I have to do?

If you decide to take part in this study, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your study doctor will review with you. The study doctor will talk to you about any recommended or required lifestyle restrictions.

- You must follow the study procedures and go to all the study visits. Please inform the study doctor if you will not be able to attend a visit.
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.
- You must report any changes to your well-being, including any side effects, to the study doctor.
- You must tell the study staff about any other medication you are taking or if you have any changes to your medications during the study. Tell the study doctor before you start a new medication.
- You are not allowed to take part in any other research study with an investigational product while you are in this research study.
- You must use and/or return the study drug during the study as instructed by the study doctor and study staff.

It is important that you do not become pregnant or father a child while you are in this study. The study doctor will discuss with you if you need to use contraception, which method of contraception is required, and any other restrictions needed while you are in the study.

Vaccinations: Please talk to your study doctor before you have any vaccinations, as live attenuated vaccines are not allowed from 4 weeks before your first dose of the study drug, during the study, and for 1 weeks after your last dose of the study drug. A live attenuated vaccine is a form of the disease-causing agent (e.g. virus) which has been weakened so that it can create an immune response without causing disease. If you are to receive a COVID-19 vaccination, please speak with your study doctor before you have this, as only certain types of COVID-19 vaccines are allowed for participants in this study.

The study doctor or a member of the study staff has discussed with you the requirements for participation in this research project. It is important that you are open and honest with the doctor and staff about your health history. You cannot take part in this research project if you do not meet all qualifications.

5. Other relevant information about the study

Up to 300 participants will be taking part worldwide in this study. Up to 7 participants will be taking part in this study in Australia.

6. Do I have to take part in this study?

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 project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given 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 routine treatment, your relationship with those treating you or your relationship with The Royal Melbourne Hospital.

7. What are the alternatives to participation?

You do not have to take part in this study get treatment to help with your newly diagnosed type 1 diabetes. But currently there are no medicines approved to help your body's ability to make and use some of its own insulin in newly diagnosed type 1 diabetes. The current treatment for type 1 diabetes is to take insulin which is used to lower your blood sugar.

Other choices for your newly diagnosed type 1 diabetes may include:

- Getting no treatment to help your body's ability to make and use some of its own insulin.

The study doctor can discuss your options in more detail with you, including potential benefits and risks that this new medicine can provide, but it is not expected to replace your need for insulin for type 1 diabetes. You can also discuss the options with your local doctor.

8. What are the possible benefits of taking part?

No matter what treatment you receive as part of the study, you may not receive any medical benefits. This means that your newly diagnosed type 1 diabetes may not improve or may get worse.

You will be given close attention from the study staff during the time you are involved in the study. You may get information about your health from physical examinations and medical tests done in this study.

If the results of this study are favourable and lead to approval of baricitinib in humans, there may be benefits for people with newly diagnosed type 1 diabetes in the future.

There will be no clear benefit to you from your participation in this study.

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

Medical treatments often cause side effects. 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, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. **If you have unexpected or troubling symptoms while you are in the study, contact your study doctor and, if you feel it is necessary, seek emergency medical care.** Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you. Provided below are potential risks of your participation in this study.

Allergic reactions and anaphylaxis

Allergic reaction is always possible with a drug especially if you have not taken it before. Serious allergic reactions (anaphylaxis) that can be life-threatening may occur. Some things that happen during an allergic reaction to any type of medication are:

- Rash
- Joint pain
- Having a hard time breathing
- Wheezing when you breathe
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

If you experience these symptoms, you should seek urgent medical help at an Emergency Department or call an ambulance.

Driving and Using Machines

It is possible that study drug may affect your ability to drive or use machines. If you have signs of allergic reaction such as chills, fever or dizziness during treatment, don't drive or use machines until your symptoms go away.

Risks for drug(s) being studied

A total of 14,986 people have taken baricitinib in clinical trials. This number includes healthy people and people with arthritis, lupus, atopic dermatitis, diabetic kidney disease, psoriasis, alopecia areata, primary biliary cholangitis, coronavirus disease 2019 (COVID-19), and children and young adults with rare diseases.

Baricitinib is being sold in many countries around the world, and it is estimated that 1,666,000 people have taken baricitinib worldwide.

Risks for All Studies

Very common, common, and uncommon side effects of baricitinib

Very Common (10 or more out of 100 people)	Common (1 or more, but less than 10, out of 100 people)	Uncommon (1 or more, but less than 10, out of 1000 people)

higher amounts of cholesterol in the blood	increases in blood markers related to the liver[a]	lower number of white blood cells, including special types of white blood cells (blood cells that fight infections)[a,b,c,d]
an infection of the nose and throat	higher number of blood platelets (parts of the blood that aid in clotting)	higher amounts of fat in the blood
	increases in blood markers related to muscle	blood clots in the lungs[a,b]
	cold sores	blood clots in the veins[a]
	a painful skin rash (shingles)	hives
	urinary infection	swelling of the face
	upset stomach	weight gain
	Stomach ache	
	rash	
	headache[b]	
	acne[d]	

[a] In people treated with baricitinib in coronavirus disease 2019 studies, increases in blood markers related to the liver were very common. Blood clots in the lungs, blood clots in the veins, and a lower number of white blood cells were common.

[b] In children and adolescents who were treated with baricitinib during a study for Juvenile idiopathic arthritis (JIA), headache was very common, and lower number of white blood cells was common. Blood clots in the lungs were common, and this was noted in 1 adolescent.

[c] Lower number of white blood cells was common in children and adolescents treated with baricitinib in the paediatric atopic dermatitis (AD) clinical trial.

[d] Lower number of white blood cells was common, and acne was very common in adolescents treated with baricitinib in the paediatric alopecia areata (AA) clinical trial.

Some people had the listed side effects. Some of these events were serious.

- Infections – tuberculosis, and shingles (common)
- Blood clots in the lungs or veins (uncommon), and
- Allergic reactions - swelling of the lips, tongue, or throat, itching or skin rash (uncommon).

Other safety information

Some people who have taken other medicines that work like the study drug have reported the side effects below. Some of these side effects have also been reported with baricitinib.

Baricitinib blocks the effects of proteins in the body called Janus kinases (JAK). Blocking these proteins can affect the immune system. Drugs that affect the immune system can increase the risk of infection and cancer. Baricitinib may also increase these risks and other risks as described below.

Infections

Unusual infections can occur in people with weakened immune systems. These infections include tuberculosis, invasive fungal infections, and some viruses. These were uncommon in people taking baricitinib for longer durations. There was 1 person with lupus who took baricitinib in a clinical trial and developed shingles and inflammation of the spinal cord. Baricitinib should not be taken if you have active tuberculosis.

Cancers

- Drugs that affect the immune system may increase the risk of cancer.
- Cancer has been reported in people taking baricitinib. The types of cancer that were most frequently reported were skin cancer (melanoma) and nonmelanoma cancer types, lung cancer, breast cancer, and cancer of white blood cells.

Heart-related (cardiovascular) events

- In a study, in people with arthritis, heart-related (cardiovascular) events such as heart attack, stroke, or death were more frequent with baricitinib use than with another drug class (tumour necrosis blocker).
- Baricitinib should be used with caution in people who are at risk for heart-related (cardiovascular) events.

Animal Safety Data

Baricitinib has been given to animals. The information from animal studies may be useful to you in considering whether to participate in the study because similar effects could be observed in people. Important effects seen in animals are as follows:

Pregnancy

- Animal studies of baricitinib have shown harmful effects to both the mother and unborn babies, including a harmful effect on the bones of the babies. In 1 animal study, baricitinib was present in breast milk.
- The number of pregnancies in people is too small to know the risks to the unborn baby.

Growth and Bone development

In a study of rats with an age similar to young children, lower body weights were seen in rats. These rats were on higher doses of baricitinib than would be taken by people in a study. These rats also had changes in their bones, such as increased bone thickness and changes in bone development, at doses of baricitinib similar to what would be taken by people in a study.

Important Signs and Symptoms for All Studies

It is important to notify the study doctor right away if you have any of the problems below because they could indicate a serious problem.

Call the Study Doctor Right Away if you Have…	**Because it may indicate…**
For All Participants	
fever, wounds that are slow to heal or become red, swollen, or discharge fluid, and feeling more tired than usual.	that you may have an infection
a cough that won't go away, night sweats, and weight loss	an infectious disease of the lungs
a painful skin rash with blisters	shingles
swelling or pain in one leg, warmth or redness in one leg, shortness of breath which is unexpected, rapid breathing, and chest pain	that you have a blood clot in the lungs or veins

swelling of the lips, tongue, or throat, and itching or skin rash	allergic reactions

Current Medication
During the study, you will continue to take your current medication. Ask your study doctor about any risks that may be associated with your current medication(s). Your study doctor may suggest continuing the medication at the same dose or change the dose.
During the study, you may be asked to take medication to treat symptoms that may arise during the study. The study doctor will discuss any risks with you.

Risks for study procedures
This study will involve medical procedures that may have some risk for you. For example, pain or bruising after a blood draw. Other procedures are listed below with an explanation of the possible risks.

- **Blood Tests**
  For most people, needle punctures for blood draws do not cause any bad problems. However, sometimes they may cause bleeding, bruising, discomfort, infections and/or pain where you had the blood drawn. You may also feel dizzy.
- **Urinalysis**
  You may be asked to urinate or "pee" into a small cup. The test involves only normal urination. There is usually no discomfort.
- **Questionnaires**
  Some people may find certain questions on the questionnaire to be upsetting or embarrassing. You may stop the questionnaires or skip questions if you feel upset or embarrassed.
- **Electrocardiograms (ECGs)**
  There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.
- **Bone Age X-rays (if you are below 18 years old)**
  You will have one or more X-rays during the study. X-rays are used to take pictures of the inside of your body. The X-rays are painless. X-rays radiation at high levels has been shown to increase the risk of developing cancer later in life. The amount of radiation from the X-rays in this study is well below the level where increased risk has been shown; however, this risk may increase over your lifetime with additional radiation procedures.
- **Continuous Glucose Monitoring (CGM) System**
  Participants aged 2 years and older will wear a CGM device during the study. The insertion of the CGM sensor into your skin may cause mild pain and discomfort.
  Wearing the sensor and the adhesive used to keep the sensor in place may cause skin irritation.
- **Glucose Monitoring**
  Blood sugar testing requires pricking your finger and testing a drop of blood. This does not usually cause serious problems, but it can cause some discomfort.
- **Mixed-Meal Tolerance Test (MMTT)**
  You may feel slightly sick to your stomach.

Risks associated with ionising radiation
During your enrolment in this research, you may undergo imaging exams of your body involving the use of radiation that you would not normally receive. These procedures involve exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv)

each year. The effective dose from these extra examinations is approximately 0.04 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

Have you been involved in any other research studies that involve radiation? If so, please tell us. Please keep information contained within the Patient Information and Consent Form about your exposure to radiation in this study, including the radiation dose, for at least five years. You will be required to provide this information to researchers of any future research projects involving exposure to radiation.

Reproductive Risks

The effects of baricitinib on the unborn child and on the newborn baby are not known. There may be some unknown risks that we do not know about, for you or for a baby you might be carrying or breastfeeding. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

All participants (males and females) are strongly advised to use effective contraception during the course of the research project and for 30 days after receiving the last dose of study drug. There may be risks of interactions between the study drug and certain kinds of contraception. Your study doctor can discuss your specific risks in more detail. The study doctor will review with you whether you may need to use contraception, which methods of contraception are required, or any other restrictions needed while you are in the study. Some effective methods of contraception are listed below.

Highly effective methods of contraception include:

- Combined (oestrogen and progesterone containing) hormonal contraception by oral or intravaginal route or dermal patches
- Progestogen-only hormonal contraception associated with inhibition of ovulation given by oral route or by injections or implants
- Intrauterine device (IUD)
- Intrauterine hormone-releasing system (IUS)
- Bilateral tubal occlusion
- Vasectomised partner
- Complete sexual abstinence, where this is your usual and preferred lifestyle

If you or your sexual partner(s) can get pregnant, the following guidance applies:

For female participants: If you can get pregnant, you must use 1 highly effective form together with a barrier method for contraception during the study and for at least 30 days after receiving the last dose of study drug. You should not donate ova/egg for 30 days after receiving the last dose of the study drug. If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

For male participants: Condoms and at least 1 additional effective method of contraception should be used during the study and for 30 days after receiving the last dose of study drug. You should not father a child or donate sperm during the study and for 30 days after receiving the last dose of study drug. You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

Tell your doctor right away if you or your sexual partner(s) become pregnant or plan to breastfeed, as the study doctor may ask for more information about the pregnancy and health of the child.

10. What will happen to my test samples?

Samples of your blood and urine will be collected from you during this study. Please see the information below to learn more about how your samples will be used and who will have access to them. The collection of these samples is required for you to participate in this study.

Type	Purpose	Length of time stored	Who may use it or see your data	Notes
Blood and Urine	To confirm that you can be in the study and monitor your health.	Until tests are done and confirmed	Only researchers in this study	You may be tested for hepatitis, HIV, or other diseases. You will receive information and counselling by the study doctor before the test. If a test shows you have HIV or Hepatitis, you will have follow-up counselling and medical advice. **If your test results are positive, the study doctors are required by law to notify government health authorities.** Signing the consent form means that you agree to have this testing; it will not be done without your consent.
Blood	To see how fast your body breaks down the study drug.	Up to 1 year after all participants have finished the study	Only researchers in this study	

Type	Purpose	Length of time stored	Who may use it or see your data	Notes
Blood	To learn more about newly diagnosed type 1 diabetes or how people respond to the study drug.	Up to 15 years after all participants have finished the study	Study researchers and others*	Biomarkers are substances in the body that can tell researchers about a condition. For example, cholesterol in the blood can be a biomarker for heart disease.
Blood	To learn how the study drug works for you or to help find out why people react to drugs differently. To better understand newly diagnosed type 1 diabetes. To make new genetic tests.	Up to 15 years after all participants have finished the study	Study researchers and others*	DNA tells your body how cells should be built and work. Some of these instructions tell your body how to react to drugs. The type of testing being done in this research project is not testing that would result in information about a participant's future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not part of the trial. For this reason, you will not receive the results of this testing. Sample collection for this purpose is optional. Signing the additional consent for optional sample collection means that you agree to have this testing; it will not be done without your consent.

"Others" refers to a business partner or collaborator of the Sponsor who will be required to sign a written agreement to protect your samples and uses the samples as agreed to in this

Participant Information Sheet/Consent Form.

Test samples obtained for the purpose of this research project will be transferred to the study central laboratory at LabCorp Central Laboratory Services in Singapore. At the end of the study, samples for long term storage (up to 15 years) will be stored at LabCorp Central Laboratory in the USA.

Your samples will be assigned a unique identifying code, but not your name or other individually identifiable information. The study site will share your samples with the Sponsor only after they have been coded, therefore the data is not able to identify you.

All samples will be destroyed based on laboratory procedures, laws, regulations, or international laboratory standards.

11. What if new information arises during this study?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If any important new information is found during this research project that may affect you wanting to continue to be part of this research project, you will be told about it right away.

If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form. Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, your study doctor will explain the reasons and arrange for your regular health care to continue.

12. Can I have other treatments during this study?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

13. What if I withdraw from this study?

If you decide to withdraw from the study, please notify a member of the study team before you withdraw. This notice will allow that person or the study supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the study, 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 research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up

to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14. Could this study be stopped unexpectedly?

This study may be stopped unexpectedly for a variety of reasons. This could happen if the Sponsor or the study doctor learns new information about the safety of the study drug or the trial, if the study drug is shown not to be effective, if the study drug is shown to work and not need further testing, or for decisions made in the interests of the Sponsor or local regulatory/health authorities. If new information is learned that may affect your decision to stay in the study, the study doctor will tell you promptly.

The study doctor or the Sponsor may also remove you from the study or stop your study drug. This may be because of a bad reaction you experience, or because you did not follow the study plan or the instructions of the study staff. If you are taken off the study, you will no longer receive the study drug. If your study drug is stopped, your study doctor will closely monitor your overall health. If you are removed from the study or choose to not continue, the study doctor will discuss any issues with you and answer any questions.

15. What happens when the research project ends?

Currently, baricitinib will not be provided after the end of the study. If your condition requires further treatment, your study doctor will help you decide what treatment is best for you after the end of the study. Your doctor will speak to you about your health care options. At the time that your participation in this study ends, an extension study testing baricitinib may be available for you to join. Your study doctor will tell you about this if the option becomes available for you.

When the study is over, a summary of the results will be made available. The study doctor can provide more details about when and where you can access the results. You may ask your study doctor to explain the results to you.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. Requirements to join the trial and countries participating can be found on this website.

Information regarding this study can also be found at www.euclinicaltrials.eu/search-for-clinical-trials/ with the study number 2025-522170-36-00.

Study data collected as part of this research study may be published in study reports or medical journals, used for scientific presentations, and may also be shared with, or inspected by, health authorities worldwide. Information that identifies you or that reasonably could be used to identify you will not be included in such publications.

Part 2 How is the research project being conducted?

16. What will happen to information about me?

If you choose to participate in this study sponsored by Eli Lilly and Company (“Lilly”), the study doctor and study staff will collect certain personal information (“PI”) about you. This data privacy section describes how your PI will be used and with whom it may be shared. It also describes your rights with respect to this information.

Your information

Your personal information (PI) is information that identifies you or could reasonably be used to identify you. There are different types of PI that can be collected as part of your participation in the study. Categories of PI that are collected include, your basic personal details (e.g., name, alias, birth year, email, etc.), health information (e.g. medical history, prescriptions, test results, etc.), and certain characteristics such as race and ethnicity.

Your PI will be used and shared for the purposes of conducting and overseeing this study as described in this document. Some of the uses include determining if you are eligible for this study, understanding your medical history, assessing your health and providing medical treatment during the study. The study doctor and study staff will collect the PI about you from your existing health records or directly from you, and store it in a study specific database only accessed by authorised individuals.

How is your personal information protected?

The study doctor and study staff will share information that does not directly identify you (e.g name, address and date of birth) with Lilly and representatives working on behalf of Lilly. The study doctor and study staff will assign a code number to your PI to protect your identity.

How is your coded information used and shared?

Lilly may use this coded data in the following ways:

- As part of this study;
- To meet global regulatory requirements and approvals;
- To publish its findings in study reports or scientific presentations;
- For further medical research projects, the specific details of which may not be fully known at present;
- For further examination by Lilly, its affiliates, and with business partners of the safety or efficacy and/or identification of new medical uses of any medical product or treatment included in the study;
- For further examination of the disease(s) or condition(s) that are the subject of the study to identify new learnings; and,
- To analyze how Lilly can improve its clinical research processes.

Lilly may share this coded data for the purposes in this document with its affiliates, business partners, regulatory authorities in countries around the world, and ethics committee(s). Once shared, this data may fall under data protection laws in other countries that may be less protective than data protection laws in the country or region in which you are participating in this study, however, Lilly will continue to protect your coded data and use the data only for the purposes described in this document.

How long will your information be stored?

Records containing your PI will be retained at the study site for a period of up to 15 years after the end of the study. In addition, Lilly will retain the coded data for up to 5 years after marketing of the study drug has completed.

How do I agree to the use of my information for this study?

By signing this document, you agree to the collection, use, and disclosure of your PI as described in this document. If you do not provide your consent, it will not affect your current or future medical treatment, payment for your treatment, enrolment in or eligibility for benefits to which you are otherwise entitled. And, if you do not consent, you will not be able to participate in this study.

What are my rights related to my information that is collected, used, or shared during the study?

You have the right to withdraw your consent for the collection, use, and disclosure of your PI for this study at any time. If you decide to withdraw your consent, you cannot continue to participate in the study. PI collected prior to your withdrawal of consent must be maintained in the study records due to regulatory requirements. To meet regulations, Lilly, its affiliates, or its business partners may need to collect information about your health status after you withdraw from the study.

You may also have other legal rights related to your PI based on where you participate in the study. You may contact the study site staff listed in "Further information and who to contact" to understand your rights.

If you are not satisfied with the response or believe the Study Site or Lilly are not processing your PI in accordance with the law, you can file a complaint with the relevant regulatory authority (e.g., a Data Protection Authority such as the Office of the Australian Information Commissioner, or your applicable state-based equivalent.)

17. Complaints and compensation

If you are physically injured as a direct result of a study procedure or drug, you should contact your study doctor as soon as possible for assistance 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.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this study:

- The pharmaceutical industry has set up a compensation process, with which the Sponsor, Eli Lilly Australia Pty Ltd, of this research project has agreed to comply. Details of the process and conditions are set out in the *Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial.* In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request.
- You may be able to seek compensation through the courts.

18. Who is organising and funding the study?

This study is being conducted by Eli Lilly and Company, and sponsored in Australia by Eli Lilly Australia Pty Ltd.

Eli Lilly and Company may benefit financially from this study if, for example, the project assists Eli Lilly and Company to obtain approval for a new drug/device.

By taking part in this study you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to Eli Lilly and Company. Eli Lilly and Company may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this study even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Eli Lilly and Company.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Eli Lilly and Company, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

The Royal Melbourne Hospital will receive a payment from Eli Lilly and Company for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this study (other than their ordinary wages).

19. Who has reviewed this study?

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 Melbourne Hospital HREC.

This research project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2025)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

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 study or if you have any medical problems which may be related to your involvement in this study (for example, any side effects), you can contact the principal study doctor on +61 422 992 891 or any of the following people:

Clinical contact person

Name	Type 1 Diabetes Research Team
Position	Study Coordinator
Telephone	+61 448 164 306
Email	Type1DResearch@mh.org.au

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

Complaints contact person

Name	Director, Research Governance and Ethics
Position	Complaints Manager
Telephone	(03) 9342 8530
Email	research@mh.org.au

If you have any questions, concerns or complaints about your rights as a participant in a research project, please contact:

Reviewing HREC approving this research project and HREC Executive Officer details

Reviewing HREC Name	The Royal Melbourne Hospital HREC
HREC Executive Officer	Office for Research: Ethics Office
Telephone	03 9342 8530
Email	ethics@mh.org.au

Main Participant Consent Form

Title	A Phase 3, Double-Blind, Randomized, Placebo-Controlled Study of Baricitinib to Preserve Beta Cell Function in Participants Newly Diagnosed with Type 1 Diabetes Aged ≥1 to <36 Years
Short Title	BARICADE-PRESERVE
Protocol Number	I4V-MC-JAJK
Project Sponsor	Eli Lilly and Company
Principal Investigator	Professor John Wentworth
Location	The Royal Melbourne Hospital

Consent Agreement

Joining the study is your decision. To agree to take part in this study, please sign and date below. Signing this consent page means that:

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

I understand all of the information I have been given about this study.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The Royal Melbourne Hospital 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, all of my questions have been answered, and I have had time to think about the study.

I agree to be part of the study as described, and I understand that I can decide to withdraw from the study at any time without affecting my future health care.

I have given my free and informed consent to be part of this research study. I understand that I will be given a signed copy of this document to keep.

Declaration by Participant Who Have Read the Information

Name of Participant (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

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*

Name of Witness to the Informed Consent Process (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

* 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 study, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor or Senior Researcher‡ (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

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

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

Additional Consent for Optional Sample Collection

Title	A Phase 3, Double-Blind, Randomized, Placebo-Controlled Study of Baricitinib to Preserve Beta Cell Function in Participants Newly Diagnosed with Type 1 Diabetes Aged ≥1 to <36 Years
Short Title	BARICADE-PRESERVE
Protocol Number	I4V-MC-JAJK
Project Sponsor	Eli Lilly and Company
Principal Investigator	Professor John Wentworth
Location	The Royal Melbourne Hospital

Consent Agreement

I consent to the collection, storage, and use of blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research

By signing this consent section, I agree to the use of my samples for genetic testing, as outlined in the relevant section of the Participant Information Sheet.

Declaration by Participant Who Have Read the Information

Name of Participant (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

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*

Name of Witness to the Informed Consent Process (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

* 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 study, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor or Senior Researcher‡ (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

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

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

Main Form of Withdrawal of Participation

Title	A Phase 3, Double-Blind, Randomized, Placebo-Controlled Study of Baricitinib to Preserve Beta Cell Function in Participants Newly Diagnosed with Type 1 Diabetes Aged ≥1 to <36 Years
Short Title	BARICADE-PRESERVE
Protocol Number	I4V-MC-JAJK
Project Sponsor	Eli Lilly and Company
Principal Investigator	Professor John Wentworth
Location	The Royal Melbourne Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with The Royal Melbourne Hospital.

Declaration by Participant Who Have Read the Information

Name of Participant (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below:

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the study and I believe that the participant has understood that explanation.

Name of Study Doctor or Senior Researcher‡ (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

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

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