Participant Information Sheet and Consent Form

Title:	**A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Severe or Very Severe Alopecia Areata (BRAVE-AA2)**
Protocol Number:	**I4V-MC-JAIR**
Sponsor:	**Eli Lilly Australia Pty Ltd**
Investigator:	**Dr. Shireen Sidhu**
Address:	**230 St. Bernards Road Hectorville, South Australia 5073**
Telephone:	**8 8336 9073 (business hours) or 0417 838 199 (after hours)**

1. Introduction:

You are invited to take part voluntarily in a research study of a study drug known as Baricitinib (LY3009104).

This Participant Information Sheet and Consent Form tells you about the study. It explains the purpose, procedures, benefits, risks, discomforts, precautions, tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

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 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 study, you will be asked to sign the Consent Form. By signing it you are telling us that you;

- Understand what you have read
- Consent to take part in the study
- Consent to have the tests and treatments that are described
- Consent to 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. Purpose of the Study

The primary purpose of your participation in this study is to help answer the following research question(s):

- Whether baricitinib is better than placebo in the treatment of participants with severe alopecia areata (AA).
- How safe baricitinib is and if there are any side effects when you take it.

Baricitinib is an experimental treatment. This means that it is not an approved treatment for AA in Australia.

2.1 Duration of the Study and Number of Participants

Your participation in this study is expected to last up to 113 weeks.

Up to 476 participants will be taking part in this study. Up to 58 participants will be taking part in this study in Australia. At this study centre, 5 participants are expected to take part in this study.

3. Study Procedures

Before any study assessments and procedures are performed you will be asked to sign the consent form. The study staff will discuss what is required for you to be part of this study. You may need to have some exams or tests done to find out if you are suitable.

3.1 Treatment Schedule

You will be participating in a randomised controlled research 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. You will be assigned to either the low dose, high dose or placebo groups. The results are compared to see if one is better. Whether you receive baricitinib or the placebo will be determined by chance (random). 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.

You will be participating in a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving.

The study includes 4 periods: a screening period that may last up to 5 weeks, a 36-week treatment period, a 68-week extension period (this includes a decrease in the baricitinib dose), and a 4-week post-treatment follow-up period.

Screening Period (Period 1): You will be screened to see if you meet the requirements to be in the study. You may need to stop taking certain medications during part or all of the study. Your study doctor will discuss this with you.

Treatment Period (Period 2 from Week 0 to Week 36): You will receive either baricitinib low dose, baricitinib high dose or placebo once a day. Neither you nor the study doctor will know which medicine you are taking. The chance you will receive baricitinib is 5 in 7 if there are 2 doses. However, the study team may decide to include only 1 dose of baricitinib in the study, in that case the chance you will receive baricitinib is 1 in 2.

Long-Term Extension Period (Period 3 from Week 36 to Week 104): All participants who have completed Period 2 will enter the extension period (up to 68 weeks of additional treatment). Neither you nor the study doctor will know which medicine you are taking. From Week 36 to Week 52, you will continue to take the same treatment you were taking during Period 2, unless you were assigned to take placebo. If you were taking placebo, you will be switched to take study drug at Week 36 unless you have experienced natural regrowth of hair. If you were taking baricitinib in Period 2, you will continue receiving the dose of baricitinib you were receiving in that period.

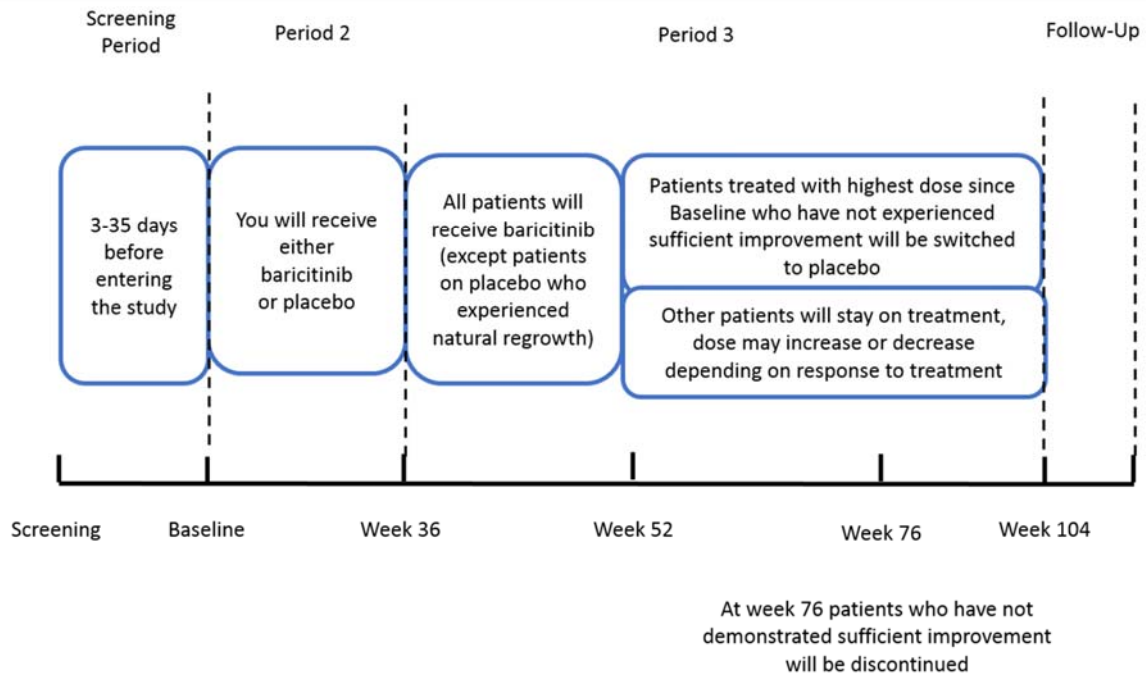
At Week 52, if you were taking high-dose baricitinib and have responded well, you will be eligible for a decrease in the dose of your treatment. If your treatment changed from placebo to baricitinib when you entered Period 3, your dose will not be decreased.

If you were in the high-dose treatment group and did not respond well, you will be switched to placebo.

Neither you nor the study doctor will know what changes will be made to your treatment assignment at Week 52.

If you have never had successful hair regrowth on your scalp, eyebrows, or eyelashes, study drug will be stopped at Week 76 and you will be removed from the study.

Post-Treatment Follow-Up Period (Period 4): You will have a follow-up visit approximately 28 days after the last dose of study drug.



Early Termination: You may choose to leave the study at any time. If you have taken at least 1 dose of study drug, you must return for a follow-up visit approximately 28 days after the last time you take study drug. If you discontinue early, you will be asked to attend study visits until Week 36.

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.

3.2 Length of Treatment Time Including Length of Each Visit

The study includes 4 periods: a screening period that may last up to 5 weeks, a 36-week treatment period, a 68-week extension period (this includes a decrease in the baricitinib dose), and a 4-week post-treatment follow-up period. You may visit the study centre up to 19 times for scheduled visits. The length of each visit is approximately 1.5-3 hours.

3.3 Requirements to Participate

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

You cannot take part in this study if you:

- Have hair loss due to AA for less than 6 months or have had regrowth of hair on your scalp without treatment in the last 6 months.
- Have hair loss due to AA on half or more of your scalp for more than 8 years without any areas of regrowth in the past 8 years.
- Currently have hair loss due to other causes than AA.
- Have recently taken certain medications, which your study doctor will discuss with you.
- Have certain medical conditions, which your study doctor will discuss with you.
- Have certain serious infections, including tuberculosis (TB), hepatitis, or HIV, the virus that causes AIDS.
- Have recently received certain vaccines, your study doctor will discuss this with you.
- Have had major surgery within 8 weeks of the start of the study.
- Have a history of alcohol or substance abuse.
- Have given blood within 4 weeks of the start of the study.
- Have abnormal lab tests results at the screening visit.

You must not participate in the study 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 study.

You will be taking study drug home. You agree to use the study drug only as instructed by your study doctor and staff, and to return any unused study drug (and empty containers) at the end of your participation in the study or as otherwise instructed by the study doctor. You should not give the study drug to other people and should keep it out of the reach of small children.

Whilst you are participating in this study, 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 study. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the study.

You must not donate blood, blood products or sperm during the study and for a period of 4 weeks after the last dose of study drug.

You will be asked to remain consistent with your hair style and colouring. If you prefer to shave your scalp, you will be asked to not do that 2 weeks before study visits.

4. Risks and Discomforts

There may be risks to you if you take part in this study.

Eli Lilly and Company (Lilly) regularly reviews all important safety information for their study drugs. As of 13 August 2018, a total of 6067 people have taken one or more doses of this drug in studies. This number includes healthy people and people with arthritis, lupus, dermatitis, diabetic kidney disease, and psoriasis. It is also being provided to children and young adult people with very rare diseases. The drug is being sold in many countries around the world. It is estimated that 28,300 people have taken the drug worldwide as of 31 July 2018. Lilly looked at the most recent data from all of these people. The risks and discomforts found are described below.

Risks and Discomforts Associated with Baricitinib

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

Infections:

Upper respiratory tract infections include symptoms similar to the common cold (cough, stuffy or runny nose, scratchy or sore throat, sneezing). These have been very common (10% or greater) during studies in people taking the study drug. Infections that were common include shingles and cold sores.

Serious infections requiring hospitalisation have also occurred in people taking the study drug. These were common during studies (1 to less than 10% of study participants).

Unusual infections can occur in people with weakened immune systems. These infections include tuberculosis, invasive fungal infections, and some viruses. These have been uncommonly reported in people taking the study drug (0.1 to less than 1%).

Your doctor will decide what treatment, if any, you may need for an infection.

Cancers:

Drugs that affect the immune system may increase the risk for cancer. Individual events of cancer have been reported in people taking the study drug. Reported cancers included cancers of the skin, blood cells, lung, prostate, breast, uterus, ovary, kidney, and colon. Cancers were uncommonly reported during the studies (0.1 to less than 1%).

Blood Clots in the Blood Vessels:

Some people who received the study drug developed blood clots in the blood vessels of their legs. These clots may then dislodge and travel to the lungs. The study drug should be used with caution in people who are at high risk for blood clots in their blood vessels. Blood clots were uncommonly reported in people taking the study drug (0.1 to less than 1%).

Tell your doctor if you have had blood clots in the veins of your legs or lungs in the past. The study drug will be stopped if signs or symptoms of blood clots develop.

Digestive System:

Small increases in blood tests related to the liver were common in people taking the study drug during trials. These increases were also seen when the study drug was given along with another medicine (methotrexate) used to treat arthritis. This medicine (methotrexate) is known to be associated with effects on the liver.

Upset stomach has been commonly reported with the study drug. This has usually been seen when first starting the study drug. In most people, the upset stomach got better with continued study drug use.

Blood Tests:

Higher amounts of cholesterol in the blood (good and bad cholesterol) were very common in people who took the study drug. Higher amounts of fat in the blood were uncommon. . Taking the study drug has not been shown to increase the chance of having heart related problems such as heart disease, heart attack, heart failure, or stroke. However the consequences of long term treatment remains unknown.

A higher number of parts of the blood that aid in clotting (blood platelets) were commonly reported in people taking the study drug. These increases have not been associated with an increased risk of stroke, heart attack, or blood clots.

Small changes in blood tests related to muscle have been seen uncommonly in people treated with the study drug. In most people with these changes, the changes were temporary. Although there was no clear link with any muscle problems, symptoms such as muscle aches and pain were reported by some people.

The study drug affects your immune system. It may decrease the number of parts of the blood that aid in fighting infections (white blood cells). This decrease may increase your risk for infections. Decreases in white blood cells have been uncommon with the study drug.

Skin:

Acne has been seen uncommonly in people taking the study drug.

Additional Information:

Your doctor will frequently check your general health. Your doctor will also check your white blood cell count, platelet count, kidney function, liver function, blood tests related to muscles, and levels of blood cholesterol and fat during the study.

You should report any changes in your medical condition to your doctor. Make sure you tell your doctor about any medicine that you take, including prescription medicine, over-the-counter medicine, and herbal products.

The study drug is removed from the body by the kidneys. People with reduced kidney function do not remove the study drug as quickly as those with normal kidney function. People with reduced kidney function may require a lower dose of the study drug.

The following table lists the risks and discomforts associated with the study drug.

Very Common (10% or Greater)	Common (1 to less than 10%)	Uncommon (0.1 to less than 1%)
• higher amounts of cholesterol in the blood • upper respiratory tract infections	• small increases in blood tests related to the liver • higher number of blood platelets (parts of the blood that aid in clotting) • cold sores and shingles • upset stomach	• changes in blood tests related to muscle • acne • lower number of white blood cells, including special types of white blood cells (blood cells that fight infections) • higher amounts of fat in the blood

Additional Risks Specific to the Elderly:

Only a small number of people who are 75 years old or older have taken the study drug. Based on the data in people 65 years old or older, unwanted effects appear to be the same as those seen in younger people.

Pregnancy and Breastfeeding:

Taking part in this study can result in risks to an unborn child or breastfeeding child.

Animal studies of the drug have shown harmful effects to both the mother and unborn babies, including a harmful effect on the bones of the babies. There is little information about the use of the study drug in pregnant women. The available information has not shown any harmful effects on the unborn baby. But, the number of pregnancies in people is too small to know the risks to the unborn baby.

If you are a woman who can have children, you must not become pregnant while taking the study drug. You should use appropriate precautions to avoid pregnancy during the study.

Your doctor may provide other guidelines for how long to wait after taking your last dose of the study drug before trying to get pregnant.

In one animal study, the study drug was present in breast milk. Women who are breastfeeding should not take the drug.

- **Female Participants**: you should not become pregnant or breastfeed a child while in this study. Naturally, the best way to not become pregnant is not to have vaginal sex (intercourse). If you are sexually active, you must use 2 forms of birth control during the course of the study and for a period of 4 weeks after the last dose of the study drug. You should talk with your doctor about the types of birth control that are best for you and your partner. If you do become pregnant or think you are pregnant whilst participating in the study, you should advise your study doctor immediately. Your study doctor will withdraw you from the study and advise on further medical attention should this be necessary. You must not continue in the study if you become pregnant.
- **Male Participants:** you should not father a baby while in this study. You should not have vaginal sex (intercourse) without using 2 forms of birth control during the course of the study and for a period of 4 weeks after the last dose of the study drug. It is highly recommended that you inform your partner of your participation in the study and the need to avoid pregnancy. You should talk with your doctor about the types of birth control that are best for you and your partner. You should advise your study doctor immediately if your partner becomes pregnant or thinks she may be pregnant while participating in the study. Your study doctor will advise on medical attention for your partner should this be necessary. Also, you should not donate semen/sperm during the course of the study and for a period of 4 weeks after the last dose of the study drug.

Study Procedure Risks

Risks of 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.

Risks of Electrocardiograms (ECGs):

There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.

Risks of X-Rays:

You will have 1 chest x-ray done during the study. The amount of radiation that you are exposed to during a chest x-ray is very small. The risk of any damage to cells in your body from an x-ray is very low. One x-ray will expose you to about 0.1 mSv. This is about the same as the naturally occurring radiation (ultraviolet rays of the sun, soil, and so forth) you receive in approximately 10 days.

Purified Protein Derivative (PPD) Skin Test for Tuberculosis (TB):

TB testing is required for this study. If your study doctor uses a PPD skin test for the TB testing, the needle stick and injection of the testing liquid just under the skin does not cause any serious problems for most people. You may have a pinching sensation at the time of injection and may develop pain, bruising, redness, itching, or irritation at the injection site.

Risks of Questions on Your Well-Being:

The answers that you give are confidential, but there is always a risk that your answers will be read by people who should not read your personal information. You may also feel uncomfortable answering some of the questions.

Other Risks

At any time during this study, you may experience a return or worsening of your AA, if you receive placebo (a tablet that has a similar appearance to the study drug but has no medicine) as your study drug.

In addition to the risks already described, baricitinib and the study procedures may have other unknown risks.

There may also be unknown risks to an embryo, foetus, or breastfeeding infant.

5. Ionising Radiation

This research study involves exposure to ionising radiation. You will have 1 chest x-ray during the study.

6. Possible Benefits

Although Baricitinib is being tested as a possible treatment for a condition that you may have, you may not receive any medical benefit.

You may receive information about your health from any physical examinations and laboratory tests to be done in this study. People with AA and other people in the future may benefit through information gained from this study.

Study drug and study procedures will be provided at no cost to you.

7. Alternatives to Participation

You do not have to take part in this study to be treated for your illness or condition. Alopecia areata can be reversible, either spontaneously or after various types of treatments, but results are inconsistent. The study doctor can discuss these treatments and therapies with you.

8. Test Samples

Samples of your blood and urine will be collected as part of this study. The use of your samples and type of tests are outlined in this section. The collection of these samples are required for you to participate in this study.

General Information Regarding Sample Collection

Various blood and urine samples will be collected from you during this study. The specific procedures for collecting these samples and the risks associated with collection are explained in the procedure table and risks section in this document. Your samples will be identified by your study participant number, and not by your name.

The analysis of your samples may contribute to the creation of new laboratory tests, new medicines, or other items that may be commercially valuable to the sponsor. The sponsor has no plans to provide you, either now or in the future, any compensation, royalty, or any other financial benefit that might result from any product, procedure, or other item that may be developed from studying your sample(s) or any information or data that is derived from such research.

Samples for Study Qualification and Health Monitoring

Blood and urine samples will be collected to determine if you meet the requirements to participate in this study.

Additional blood and urine samples will be collected throughout the study to monitor your health and your response to study drug.

The blood tests include a screening test for HIV (also called the 'AIDS' virus) and Hepatitis B and C which are serious and contagious diseases and the study doctors need to know. You will receive information and counselling 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.

All samples collected for Study Qualification and Health Monitoring **will be destroyed within 60 days of confirmation of the test results, unless laws, regulations**, or international **laboratory certification standards require a longer retention period**. This confirmation will either occur immediately after initial testing, or may require that samples be held to be retested at a defined later point in time.

Samples for Genetic Research

Blood will be collected to study your DNA/RNA. DNA/RNA is genetic material found in all the cells of your body. DNA/RNA contains instructions that your body reads to understand how it should be built and work. Some of these instructions tell your body how to react to medicines. For this reason, looking at DNA/RNA can sometimes help explain why people with a disease respond differently to the same medicine. For example, some people taking this study medicine may respond well. Others may have little or no response, or have side effects.

Researchers may study your DNA/RNA to learn how the study medicine works for you. Information about your DNA/RNA may be used to create or improve tests to measure these genetic factors. Researchers may also study your DNA/RNA to better understand the AA for which this study drug is developed.

The DNA/RNA sample may be stored for up to **15** years after this study is finished.

Neither you nor we will obtain the results of these tests. This type of testing is done to further our knowledge about how the study drug works and it will not produce the type of results that will have any useful meaning that would affect your health or treatment. Therefore, you will not be informed of the results of the tests.

The type of testing being done in this study is not testing that would result in information about your 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.

Samples for Biomarker Research

Sometimes scientists measure substances in the body to diagnose, evaluate, or monitor a person's medical condition or disease. For example, cholesterol levels in the blood can be used to monitor a person's risk for heart disease. In this example, cholesterol is a biomarker.

Blood will be collected to identify or better understand biomarkers.

Researchers may use biomarkers to learn more about AA or how study participants respond to study drug or other medicines that you are taking during this study. Your sample(s) may also be used to create or improve tests to help identify study participants in the future who may respond to this study drug.

The sample(s) may be stored for up to **15** years after this study is finished.

The samples obtained for the purpose of this study will be transferred to Q2 Solutions East Asia, 79 Science Park Drive #04-08 Cintech IV, Singapore Science Park I, Singapore, 118264 and may be sent to BioStorage Technologies during the study or after it completes. The samples may be moved for further analysis at the request or notification of the Sponsor.

9. Voluntary Participation/Right to Refuse or Withdraw

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time, without a penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your routine treatment, your relationship with those treating you or your relationship with the study doctor.

If you decide to withdraw from the study, please notify a member of the research team before you withdraw. This notice will allow that person or the research 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 study 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 study results. If you do not want them to do this, you must tell them before you join the study.

10. Confidentiality

The study data sent by the study doctor to the sponsor does not include your name, address, or other information that directly identifies you. Instead, the study doctor assigns a participant number or code to the study data. Your personal information will be kept securely and will only be accessible by authorised personnel who have been trained in the handling of such confidential and sensitive information. Participants should note that, some data derived from your participation in this study will be sent overseas; the regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. If you have any questions about this direct them to the Principal Investigator.

The study doctor and staff will handle your personal health information in a confidential manner. Your personal health information will be stored in limited-access databases. Your health information will be used and disclosed in accordance with the Data Privacy Statement included with this document. Access to all information is limited and accessed only as indicated in this document. Steps are taken to reduce the risk of your personal health information being misused or accessed by unauthorized people. However, these risks cannot be eliminated.

If you decide to participate in this study, the study doctor will inform your local doctor.

11. Costs

All medication and study-related tests will be provided at no cost to you. You should ask the study doctor to explain any payments for which you may be responsible.

You will be reimbursed for any reasonable travel, parking and meal expenses associated with the study visit.

- You will be paid $60.00 per study visit to reimburse you for transportation, parking, meal, or other expenses related to your participation in this study. You may receive $60.00 for an unscheduled visit if it is needed based on the study requirements. If you withdraw from the study early, you will be paid for these expenses for the portion of the study that you did complete. You will be reimbursed $25.00 for meals, at visits 2, 5, 7, 8, 11, 14, 16, and 18 along with early termination or follow up visit (801). However, your expenses could be more than the amount you are reimbursed. Additional compensation is available for participants that have excessive travel. The study staff can discuss payment with you further.

12. Illness or Injury

If you have any injury, bad effect, or any other unusual health experience during this study, make sure that you immediately tell the study doctor or study staff right away. In case of an emergency ring 000 or attend the Emergency Department.

You can contact the study doctor and study staff on:

8 8336 9073 (business hours) or 0417 838 199 (after hours).

You can call at any time, day or night, to report such health experiences. She or he will then give you all necessary information and treatment and will inform the trial sponsor.

13. Compensation for Injury

If you are injured as a result of your participation in this trial you may be entitled to compensation.

Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors.

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines.

These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Issues/Information – Clinical Trials – Indemnity & Compensation Guidelines. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

14. Termination of the Study

If you stop being part of this study, the study doctor or one of the staff members will talk to you about any medical issues regarding the stopping of your participation.

Your participation also may be stopped by the study doctor or sponsor without your consent. If this happens, it might be due to a bad reaction you have to Baricitinib or new information about Baricitinib's safety or effectiveness.

15. Investigators Benefits

This study is being sponsored by Eli Lilly Australia Pty Ltd.

The sponsor is paying the study doctor for their work in this study.

16. New Information Arising During the Study

If any important new information is found during this study that may affect you wanting to continue to be part of this study, 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 study you will be asked to sign an updated consent form.

17. End of Study and Results

A description of the study will be available at http://www.clinicaltrials.gov. This website will not include any information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

At the end of the study you may receive the study results including any publication(s) (if applicable) on request from the study doctor.

Your personal health information and study data will be retained for at least 15 years after the end of the study.

18. Consent

Your study doctor is required to provide you with all information regarding the nature and purpose of the study, risks/benefits and the possibility of alternative treatment and you should be given the opportunity to discuss these. It must be stated that you are free to withdraw anytime and that if you do not participate you will not suffer any prejudice.

19. Advice and Information

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact:

Dr. Shireen Sidhu on **8 8336 9073 (business hours) or 0417 838 199 (after hours).**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The Bellberry HREC has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited on 08 8361 3222.

Attachment 1 - Data Privacy Statement

As part of the conduct of this research study, it will be necessary to share medical information about you with persons other than the study doctor. This Data Privacy Statement explains how your personal health information will be used and to whom it will be given ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

Your personal health information is information about you that could be used to identify you. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study ("study data"). Information about your participation in this research project may be recorded in your health records.

The study doctor and staff will handle your personal health information in a confidential manner. All precautions will be taken to ensure that all information collected during this study will be handled in accordance with Australian privacy and other relevant laws.

By signing the consent form for this study, you give permission ("authorisation") for the use and disclosure of your personal health information in the following ways:

- Your personal health information may be shared with or viewed by:
    - the study doctor and staff,
    - the sponsor and its representatives (referred to as the "sponsor"),
    - the regulatory authorities in this country and in other countries,
    - the ethical review board overseeing this study, and
    - doctors at other institutions participating in the study, whether in Australia or elsewhere.
- The sponsor may send your study data outside of this country and may also share your study data with their related companies and business partners.
- The sponsor will use the study data for research purposes:
    - to support the scientific objectives of the study described in the consent document,
    - to assess the safety or efficacy of any drug or treatment included in the study,
    - to better understand the disease(s) included in the study, or
    - to improve the design of future studies.
- Study data that does not identify you may be published.

You have the right to see and ask for a copy of your personal health information and ask for it to be corrected if you think it is wrong. If you would like to ask for a copy of your information, or to correct it or to make a complaint you can contact us at **8 8336 9073 (business hours) or 0417 838 199 (after hours).** However, you may not be able to review some of the study data until after the study has been completed.

Your study data will be kept for as long as it is needed for legitimate business purposes according to the sponsor's records retention policies and applicable laws and regulations.

You may cancel your authorisation for the use and disclosure of your personal health information at any time by providing written notice to the study doctor.
If you cancel your authorisation:

- The study doctor and staff will no longer use or disclose your personal health information in connection with this study.
    - However, the study doctor and staff may need to use or disclose some of your personal health information to confirm the accuracy of the study data.
- The sponsor will still use study data that was collected before you cancelled your authorisation.
- You will no longer be able to participate in the study.

Attachment 2 – Consent Form

(Participant Information Sheet MUST be attached)

Title:	**A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Severe or Very Severe Alopecia Areata (BRAVE-AA2)**
Protocol Number:	**I4V-MC-JAIR**
Sponsor:	**Eli Lilly Australia Pty Ltd**
Investigator:	**Dr. Shireen Sidhu**
Address:	**230 St. Bernards Road** **Hectorville, South Australia 5073**
Telephone:	**8 8336 9073 (business hours) or 0417 838 199 (after hours)**

To become a part of this study, and to authorise use and disclosure of your personal health information, you [or your legal representative] must sign and date this page.

I _____the undersigned hereby voluntarily consent to my involvement in the study titled _____.

I acknowledge that the nature, purpose and risks of the study and alternatives to participation have been fully explained to my satisfaction by Dr _____.

Specifically, the details of the procedure(s) proposed and the anticipated length of time it will take, the frequency with which the procedure(s) will be performed and an indication of any discomfort that may be expected have been explained to me.

- I freely agree to participate in this study according to the conditions in the Participant Information Sheet which I confirm has been provided to me.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have been given the opportunity to have a member of my family or another person present while the study is explained to me.
- I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.
- I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event and I consent to this access.
- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I am 18 years of age or over.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.
- I declare that all my questions have been answered to my satisfaction.
- I have read, or have had read to me in a language in which I am fluent, and I understand the Participant Information Sheet, and have had time to think about participating.

A signed and dated copy of this Participant Information Sheet and Consent Form MUST be provided to the participant or Legal Representative.

NAME OF STUDY PARTICIPANT:

SIGNATURE OF STUDY PARTICIPANT: **DATE**:

Declaration by Principal Investigator (PI) or Co-Investigator (CI)[†]: a verbal explanation of the study, its procedures and risks has been given to the participant and I believe that the participant has understood that explanation.

NAME OF INVESTIGATOR:

SIGNATURE OF INVESTIGATOR: **DATE**:

[†] A senior member of the research team that is qualified by education, qualifications and training must provide the explanation and provision of information concerning the study.

Legal Representative (if applicable; use this section only if required):

NAME OF LEGAL REPRESENTATIVE:

RELATIONSHIP TO PARTICIPANT:

SIGNATURE OF LEGAL REPRESENTATIVE: **DATE**:

Declaration by Impartial Witness* (if applicable; use this section only if required): I declare that I have been present when the research was explained to the above-named participant and to the best of my observation and belief was understood and the consent freely given.

FULL NAME OF WITNESS:

SIGNATURE OF WITNESS: **DATE**:

ADDRESS:

*Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Attachment 3 – Revocation of Consent

Title:	**A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Severe or Very Severe Alopecia Areata (BRAVE-AA2)**
Protocol Number:	**I4V-MC-JAIR**
Sponsor:	**Eli Lilly Australia Pty Ltd**
Investigator:	**Dr. Shireen Sidhu**
Address:	**230 St. Bernards Road Hectorville, South Australia 5073**
Telephone:	**8 8336 9073 (business hours) or 0417 838 199 (after hours)**

I hereby WITHDRAW my consent to participate in the study named above and understand that withdrawal will not prejudice any of my current or future treatment.

❑ I do not want any further involvement or follow up in regard to this study.

OR

❑ I agree to be involved for follow up only until the end of the study.

PARTICIPANT'S NAME (Printed): _____

SIGNATURE: _____ **DATE**: _____

Acknowledged by:

PRINCIPAL INVESTIGATOR NAME: _____

SIGNATURE: _____ **DATE**: _____

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

Please detach this section "Revocation of Consent".

Keep a copy and send the original to Dr. Shireen Sidhu at

230 St. Bernards Road
Hectorville, South Australia 5073

If you would like to speak to one of the study staff please call: **8 8336 9073 (business hours) or 0417 838 199 (after hours).**

Attachment 4 - I4V-MC-JAIR Study Procedures

	Screening	Double-Blind Treatment Period							Long-Term Extension											PT F/U
	Period 1	Period 2 (36 weeks)							Period 3 (68 weeks)											Period 4
Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18 or ET**	**UV[1]**	**801**
Weeks from Randomization		**0**	**4**	**8**	**12**	**16**	**24**	**36**	**40**	**44**	**52**	**56**	**60**	**64**	**68**	**76**	**88**	**104**		
Estimated Visit Length (in hours)	1-1.5	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1.5-3	1-3	1.5
Informed Consent	X																			
Procedures																				
The study doctor will ask how you are feeling and what medications you have taken, and what you are taking now	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Alcohol and tobacco use	X																			
Height and weight[2]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Vital signs (BP and pulse)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Physical examination	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ECG	X																			
Chest x-ray	X																			
TB test	X																			
Study drug given		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	
Study drug returned			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

	Screening	Double-Blind Treatment Period							Long-Term Extension											PT F/U
	Period 1	Period 2 (36 weeks)							Period 3 (68 weeks)											Period 4
Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18 or ET**	**UV[1]**	**801**
Weeks from Randomization		**0**	**4**	**8**	**12**	**16**	**24**	**36**	**40**	**44**	**52**	**56**	**60**	**64**	**68**	**76**	**88**	**104**		
Questionnaires	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood tests (approximate volume in mL/tsp)[3]	37/8	36/7#	7/1	7/1	26/5#	7/1	26/5	26/5#	7/1	7/1	26/5#	7/1		26/5#		26/5#	7/1	26/5		26/5#
Pregnancy Test[4]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Urinalysis	X	X	X	X	X	X	X	X			X	X	X	X	X		X	X		X

[1] Only applicable to participants enrolled during Stage 1, who will need an unscheduled visit(s) after the Decision Point to potentially transition to the baricitinib high dose and to participants who experience a loss of benefit after Week 52 if no scheduled visit available. Not applicable to unscheduled visits conducted for other reasons.

[2] Height will be measured at Visit 1; weight will be measured at all the visits.

[3] An additional 3-10 mL may be drawn depending on other needed tests.

[4] Blood test at Visit 1; urine tests for the remainder of the visits.

#These are fasting blood draws.

Abbreviations: BP = blood pressure; ECG = electrocardiogram; ET = early termination; PT F/U = post-treatment follow-up; TB = tuberculosis; UV = unscheduled visit.