**INFORMED CONSENT FORM**
**AND**
**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

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| **Sponsor / Study Title:** | **Immuron Limited / "A randomized, double-blind, placebo-controlled trial assessing the efficacy of once-daily dosing of IMM-124E in a controlled human infection model for ETEC"** |
| | **Clinical Trial registration: NCT 05933525** |
| **Principal Investigator: (Study Doctor)** | **Mohamed Al-Ibrahim, MB, ChB** |
| **Address:** | **Pharmaron CPC**<br>**800 West Baltimore Street**<br>**5th and 6th Floor**<br>**Baltimore, MD 21201** |

**KEY INFORMATION**

You are invited to take part in a research study. This research study is investigating a new drug called IMM-124E (also called Travelan®) in healthy subjects as a possible prevention of travelers' diarrhea. The United States Department of Defense (DOD) is funding this clinical research study and Immuron, Limited is sponsoring this research study. This study is being done to help understand if it can prevent travelers' diarrhea and to learn more about the safety and tolerability (to see if people can comfortably take (IMM-124E) of multiple dose of IMM-124E taken once daily.

This study will take place at one site: the Pharmaron Clinical Pharmacology Center (CPC) in Baltimore, Maryland. You will be asked to come for 1-3 screening visits, a 12-day inpatient stay, 2 follow-up outpatient visits and a follow-up phone call. The study duration is 181 days not including the screening period (up to 60 days).

In this study, approximately 60 healthy adult subjects will take a dose of Study Drug (IMM-124E or placebo are sometimes called Study Drug in this document) for seven days in a row. Placebo treatment looks like IMM-124E, but does not contain any medication. Study drug is taken in the morning on an empty stomach. On the third study day, 30 minutes after you take the study drug, you will drink a liquid containing a challenge dose of bacteria that usually causes diarrhea.

The Pharmaron CPC staff will collect all of the stool that you produce beginning the day before your first dose of Study Drug until your discharge from the Pharmaron CPC. You will receive

antibiotics no later than 5 days after the challenge dose of bacteria to help resolve any diarrhea, if it occurs, and kill the challenge bacteria.

You may want to join this study to help Immuron, Limited develop a new medication useful to prevent travelers' diarrhea. It may not be in your interest to join the study if any of the procedures described in this document are unacceptable to you or if you do not have time to commit to the study. Although all of the procedures of this study are typical for this type of research, if you have never participated in a clinical trial, some of them may be new for you. As a result, you should read this document carefully so that you know exactly what the study will involve. In order to properly document the study, some information about your health will be collected. A code will be used in place of your name on all study records and samples. Your records will only be shared with people who are allowed to see them for study oversight. All of the study activities are described in this document.

Please read this form carefully. Take your time to ask the Study Doctor or study staff as many questions about the study as you would like. The Study Doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the Study Doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

**WHY IS THIS RESEARCH BEING DONE?**

Certain types of bacteria or germs can cause diarrhea. Diarrhea can occur when people eat or drink food and water that has the bacteria in it. The Centers for Disease Control and Prevention provide regular food safety updates about bacteria outbreaks linked to contaminated food which cause food borne illnesses in the United States. Food poisoning symptoms can be mild to very serious depending on the germs you swallow. The most common symptoms of food poisoning are:

- Upset stomach
- Stomach cramps
- Nausea
- Vomiting
- Diarrhea
- Fever

This is also the most frequent health problem affecting people travelling from an area of more highly developed hygiene and sanitation infrastructure to a less developed one when food or water is consumed which is infected with bacteria.

This research study is to see if a cow's milk product (IMM-124E) can prevent diarrhea by taking a daily dose and then being challenged with the bacteria that may or may not cause diarrhea. The Placebo is a milk product that will not prevent diarrhea.

There are currently no diarrheal preventative medicines in the USA and therefore approaches to prevent bacteria from causing diarrhea, especially when traveling overseas are in great need.

**BACKGROUND AND PURPOSE**

You are being asked to participate in this research study because you are a healthy male or female adult, 18-50 years of age.

The purpose of this study is to help understand if a multiple dose of IMM-124E taken once daily can safely prevent diarrhea. Examining the number, amount and consistency of stool samples collected during this study is the main way that Study Doctors can see how well IMM-124E works. In addition, Study Doctors are interested in how safely and comfortably IMM-124E can be used.

In this document, you will see the terms “Study Drug” and “Study Treatment.” These are terms used in clinical studies. They apply to the research of this Study Drug and the parts of the study where you will be receiving this Study Drug. They do not mean you will receive medical treatment for any condition. It is not expected that you will obtain medical benefit from participating in this study.

The use of Study Drug in this study is investigational. An investigational use is one that is not approved by the United States Food and Drug Administration (FDA). The Study Drug has been previously tested in challenge studies similar to this study using different dose levels.

About 60 subjects will participate in this study. It is expected that one-half of these subjects will receive IMM-124E and one-half will receive placebo. You and the Study Doctors will not know which treatment you receive, and the treatment assignment will be made randomly (like a flip of a coin).

**TO BE IN THIS STUDY**

You must be generally healthy. You cannot be in this study if you are taking any drugs of abuse (illegal and/or prescription). A urine test will be performed to check for the use of these drugs:

- Amphetamine
- Opiates
- Methadone
- Cocaine
- Barbiturates
- Benzodiazepines
- Phencyclidine
- Propoxyphene

In addition, there are certain medications that you must not take. Study staff will determine if you use medications that are not permitted.

In addition, you cannot be in this study if:

- You are a woman who is pregnant or breastfeeding.
- You have lactose intolerance or an allergy to milk or milk products.
- You take certain medications that might interfere with the Study Drug.
- You have used antibiotics during the 30 days before challenge dosing or have taken more than 2 courses of antibiotics over the three months prior to challenge dosing.

Subject Responsibilities:

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures.
- Be willing to follow the Pharmaron CPC's COVID-19 policies including being willing to be tested for COVID-19.
- Tell the study staff about any side effects or problems.
- Ask questions as you think of them.
- Tell the Study Doctor or the study staff if you change your mind about staying in the study.
- Use appropriate contraception throughout the study duration.

It is very important you inform the Study Doctor of any medications you take, including prescription, over the counter, herbal remedies or vitamins. Some over the counter medications, such as acetaminophen or ibuprofen and birth control pills may be allowed in some cases.

**COVID-19 TESTING**

During the Screening visit, you will be asked some questions to determine your risk of having a SARS-CoV-2 infection.

You will be required to undergo testing for SARS-CoV-2 (COVID-19) at the time of admission to the Pharmaron CPC and again on Study day 2. This testing will require a nasal swab examination.

This test is done to check if there are small pieces of the virus that causes SARS-CoV-2 present in the cells in your sinuses. These pieces of the virus are called "RNA." The test is done by using a small elongated rod which resembles a "Q-tip" only it is longer and much thinner, called a nasal swab. The swab is inserted into your nose and pushed until it contacts the middle of your nasal cavity. We may also use an oral swab or other acceptable swab. The swab is then removed and processed by the laboratory. You will be asked to wear a surgical mask that will cover only your mouth to help protect others if you should cough while obtaining the swab.

You may be required to have another nasal swab examination for the early detection of SARS-CoV-2 at any time you experience any symptoms associated with SARS-CoV-2.

The study doctor may be required by law to report a positive test result to the local health authority.

**WHAT WILL HAPPEN DURING THE STUDY?**

Screening:

The screening visit may be broken down into 1-3 visits, occurring over a period of up to 2 months.

Before any study-related tests and procedures are performed, you will be asked to read, sign and date this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- You will be provided with an oral and/or audio/video presentation describing the study, its risks, schedule and requirements. After you have completed this presentation, you will be asked to take a written test and pass with at last 70% of the questions correct to enroll in the study. We will ask you to sign this form once you fully understand and are willing to participate in the study.
- We will ask about your past illnesses and what medicines you take. We will ask you questions about yourself and you will complete other forms.
- We will perform a physical examination on you.
- We will take your pulse, breathing rate, oral temperature and blood pressure.
- You will have an electrocardiogram (ECG) to test your heart.
- We will measure your height and weight and ask about your race and ethnicity.
- You will be asked to drink 150 ml of sodium bicarbonate buffer to assess your ability to tolerate.
- We will take about 4 teaspoons of blood. We will test the blood for standard tests like your blood count and tests for your kidney and liver function. We will also:
    - Do tests for hepatitis B, hepatitis C and HIV.
    - We will determine your blood type.
    - If you are a woman, we will test your blood to see if you are pregnant.
    - We will do a standard urine check to check your general health and test your urine for drugs of abuse, both illegal and prescription.
- You will be asked questions to assess your eligibility to participate in the study.

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

Study Treatment:

If you are qualified for the study, you must be willing and available to stay at Pharmaron CPC (the same building as the screening appointment) for 12 days and 11 nights.

In addition, you will also be required to return to the Pharmaron CPC for 2 follow-up visits 2 and 4 weeks after the challenge dose. About 6 months after the challenge dose, you will be required to complete a telephone follow-up call with a member of the Pharmaron CPC staff.

After you have checked into the inpatient unit, you will not be allowed to leave Pharmaron CPC until you are eligible for discharge or you decide to leave the study.

There are strict rules that you must be willing to follow during your stay:

- You cannot have visitors or deliveries.
- We will provide all your meals and snacks.
- You will not be allowed to smoke.
- You will not be allowed to have alcohol or any illicit drugs.
- You will not be allowed to exercise strenuously.

Study Drug will be provided as 6 caplets that you will swallow with water at the same time of day, every day for 7 days in a row. The challenge dose will be given after subjects have received 3 doses of Study Drug and antibiotics will be started no later than the day after the last dose of Study Drug. The Study Doctor may decide that some subjects should begin their antibiotics earlier. All Study Drug and the challenge dose will be given at Pharmaron CPC. Although antibiotics will be started at Pharmaron CPC, some subjects may be discharged from the site and finish their antibiotics at home. You will have the following study visits and undergo the following procedures:

<u>Day -3 = First Day (Admission):</u>

- You will be given a COVID-19 nasal swab test.
- You will be admitted to the Pharmaron CPC (if the COVID-19 nasal swab test is negative).
- We will explain the Rules and Procedures of the research unit.
- You will have a physical examination.
- We will take your pulse, breathing rate, oral temperature and blood pressure.
- You will have your blood drawn and urine will be collected for safety and research testing.
- If you are a woman, we will test your urine to see if you are pregnant.
- You will be asked questions to determine how you are feeling, and confirm that you are still eligible to begin the study.
- Your stool will be collected.

If you still qualify for the study, you may be asked to participate in the study.

<u>Days -2 to 5 (Study Drug Dosing)</u>

- You will be randomly assigned by chance (like the flip of a coin) to receive either IMM-124E or placebo every day before breakfast

- We will take your pulse, breathing rate, oral temperature and blood pressure at least 3 times a day; once in the morning, afternoon, and evening, each day.
- You will have a physical examination each day.
- All of your stool will be collected each day. If you are unable to produce a stool sample, a sample may be obtained from your rectum using a swab.
- Blood will be collected.
- Urine may be collected from some subjects.
- The Study Doctor may decide to begin giving you antibiotics.
- You will not be permitted to eat anything after midnight on Day -1.

Day 1 (Challenge Dose)

- You will take the dose of Study Drug on an empty stomach.
- About 30 minutes after taking Study Drug, you will drink about one-half of a cup of slightly salty liquid. Within 2 minutes, you will be required to finish drinking the liquid.
- You will then swallow the challenge dose in about 2 tablespoons of the same type of liquid.
- About 90 minutes after the challenge dose, you will resume normal meals.

Days 6 to 7 (Antibiotics and Possible Early Discharge from CRU)

- We will take your pulse, breathing rate, oral temperature and blood pressure at least 3 times a day; once in the morning, afternoon, and evening, each day.
- You may have a focused physical examination each day.
- You will have your blood drawn for safety testing.
- All of your stool will be collected each day. If you are unable to produce a stool sample, a sample may be obtained from your rectum using a swab.
- You will begin taking antibiotics on Day 6 (unless the Study Doctor has started you on antibiotics earlier).
- Depending on how you are feeling, the Study Doctor may discharge you from Pharmaron CPC. If this happens, you will be required to finish taking the antibiotics at home (for a total of 3 days).

Days 8 to 9 (Inpatient discharge)

As soon as all diarrhea symptoms are resolved or getting better, and you have had two stools in a row that test negative for the challenge bacteria, and you have taken at least 2 doses of antibiotics, you may be eligible for discharge from the Pharmaron CPC. If you are not eligible to be discharged:

- You will be asked questions to see how you are feeling, each day.
- We will take your pulse, breathing rate, oral temperature and blood pressure at least 3 times a day; once in the morning, afternoon, and evening, each day.

- You will have a focused physical examination, based on how you feel, each day.
- You will continue antibiotics until the 3-day course is complete.
- Blood will be collected.
- All of your stool will be collected each day. If you are unable to produce a stool sample, a sample may be obtained from your rectum using a swab.

Before you are discharged from the Pharmaron CPC:

- You will be asked questions to see how you are feeling.
- We will take your pulse, breathing rate, oral temperature and blood pressure.
- You will have a physical examination.
- You will continue antibiotics until the 3-day course is complete.

Day 15 (First Follow-Up Visit)

- You will return to Pharmaron CPC.
- We will ask you questions to see if you might have COVID-19.
- You will be asked questions to see how you are feeling.
- We will ask you if you have taken any medications.
- We will take your pulse, breathing rate, oral temperature and blood pressure.
- You will have a physical examination.
- You will have your blood drawn for safety and research testing.
- Your stool will be collected.
- Your urine will be collected to check your health.

Day 29 (Second Follow-Up Visit)

- You will return to Pharmaron CPC.
- We will ask you questions to see if you might have COVID-19.
- You will be asked questions to see how you are feeling.
- We will ask you if you have taken any medications.
- We will take your pulse, breathing rate, oral temperature and blood pressure.
- You will have a physical examination.
- If you are female, we will give you a urine pregnancy test.
- You will have your blood drawn for safety and research testing.
- Your stool will be collected.

Day 181 (Telephone Follow-Up)

- You will be asked questions to see how you are feeling.
- We will ask you if you have taken any medications.
- We will ask you questions about your bowel function.

After you have completed the Day 181 telephone follow-up, you will have completed your participation in this study.

**EARLY TERMINATION/EARLY DISCHARGE**

- If you leave the study before it is planned to be over, we will ask you to complete all of the procedures scheduled for the final study day before you leave the research unit.
- You will also be asked for updated contact information.

**EXPECTATIONS**

If you participate in this study, you will be expected to:

- Complete all of your study visits and study procedures as scheduled.
- Provide a complete and truthful medical history.
- Use proper birth control, as described below.
- Remain in at Pharmaron CPC until you meet discharge criteria and are discharged.
- Follow the Pharmaron CPC rules.
- Contact the study staff or doctor right away if you are not feeling well or feel concerned about symptoms.
- Additional expectations have been listed above under “Subject Responsibilities”.

**RISKS, SIDE EFFECTS AND/OR DISCOMFORTS**

Study Drug

IMM-124E and placebo have been safely given to humans in several clinical studies. Side effects have been reported as minor, the most common symptoms are:

- Bloating,
- Abdominal discomfort,
- Constipation,
- Flatulence (gas)
- Nausea
- Diarrhea (which is usually related to lactose intolerance as IMM-124E and placebo are milk products).

Challenge Dose

Usually, the challenge dose results in mild-to-severe, watery diarrhea.

Nausea, vomiting, abdominal cramping, headache, abdominal gurgling or gas, lack of appetite, fever, muscle and/or joint aches, and fatigue, may occur.

For healthy adults these side effects are not life threatening but often lead to mild to moderate dehydration and significant inconvenience associated with loss of sleep and activity. You will be monitored carefully to treat dehydration.

On rare occasions, more severe side effects have occurred, to include:

- Bleeding of the intestinal tract.
- Infection, to include high fever.
- Unexplained abdominal discomfort or pain associated with changes in normal bowel patterns.

Antibiotics

The most commonly reported side effects for **ciprofloxacin** in adult patients (occurring in up to 5% of patients) were

- Diarrhea,
- Nausea
- Vomiting.

Less than 1% of patients reported:

- Rash,
- Dizziness,
- Headache
- Allergic reactions.

Drugs such as ciprofloxacin have been associated with disabling and potentially irreversible serious adverse reactions, including:

- Tendinitis (inflammation of tendons) and tendon rupture.
- Peripheral neuropathy (nerve damage causing possible numbness, pain and/or loss of motor function).
- Central nervous system effects (such as an increased risk of seizures).

~~damage to tendons.~~

The most common adverse effects of **doxycycline** are:

- Headaches
- Nausea
- Vomiting
- Skin being sensitive to sunlight.
- Rare effects can be severe allergic reactions.

The most common adverse effects of **trimethoprim-sulfamethoxazole** are:

- Nausea
- Vomiting
- Lack of appetite
- Allergic skin reactions.
- Rare effects can be severe allergic reactions.

The most common adverse reactions (greater than 1% of patients) of **ampicillin** are:

- Diarrhea
- Vomiting
- Nausea
- Rash.

You may experience certain unwanted effects and symptoms as a result of study treatment. You may have none, some or all of the effects listed above, and if you do experience them, 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 researchers do not expect or do not know about and that may be serious. Tell your Study Doctor immediately about any new or unusual symptoms that you may have. Many side effects go away shortly after study treatment ends. However, sometimes side effects can be serious, long-lasting, permanent or fatal. Your Study Doctor will discuss the best way of managing any side effects with you.

**RISK OF ALLERGIC REACTION**

Allergic reactions to any drug can occur.

Mild allergic reactions may include:

- Skin rash
- Itching
- Swelling around the mouth, throat or eyes
- Sweating
- Fast pulse
- Numbness

Severe allergic reactions may include:

- Low blood pressure (making you feed dizzy or lightheaded)
- Difficulty breathing
- Wheezing when you breathe
- Shock
- Heart arrest
- Death

You must tell the study staff immediately if you have any of these symptoms. If any allergic symptoms occur, we will treat you right away. If you are outside the study facility, you should get medical help and contact the Study Doctor or study staff if you have any of these or any other possible side effects during the study.

**RISK OF HOSPITALIZATION**

If you become seriously ill, we will take you to the hospital to manage your care. We do not expect this to happen.

**RISKS IN PREGNANCY**

There have been no studies of IMM-124E, the challenge dose or the antibiotics in pregnant women or men whose partners become pregnant. That is why subjects invited to participate in the study are either unable to have children, or are using proper birth control.

**RISKS OF STUDY PROCEDURES**

- Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising or bleeding at the site of puncture. There is also a slight possibility of infection. We will draw up to approximately 1.4 cups of blood over the course of the study.
- Nasal swabs: You may experience discomfort, eye watering, sneezing, or bleeding.
- You may experience minor discomfort, annoyance or embarrassment related to stool collection and rectal swabs.
- Isolation from friends, family, work, school and sharing space with strangers can cause discomfort.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or the gel that is used.
- Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

**RISKS TO CONFIDENTIALITY**

We will take care to keep your personal health information confidential. There is a small risk that someone who is not allowed may see your records by mistake. We keep your study records in a secure place, such as a locked office and/or locked cabinet. We password protect computers that may have study information. We use a code in place of you name on all study records and samples. We only share your records with people who are allowed to see them for study oversight. Any record that can identify you will be destroyed two years after the end of the trial. Other records will be kept longer for regulatory obligations but cannot be linked to you personally. We will make every effort to keep the records as confidential as possible, within the limits of the law.

Other ways the Study Doctor will try to lessen the potential risks.

We will monitor your safety throughout the study. These people look out for the safety of all study participants:

- Study staff

- Your main Study Doctor
- An independent medical monitor: This is another doctor who is not involved in the study and who will review all serious safety events (including those based on your lab results and side-effects you report)

There may be other risks in this study which are not yet known. If we learn about any new findings that might change your decision to be in this study, we will tell you. You may be asked to sign a new consent form if this occurs.

**HIV AND HEPATITIS TESTING**

Your blood will be tested at screening for hepatitis viruses and for HIV. HIV is the virus that causes AIDS. Also, if any person is exposed to your blood, you will be asked to have your blood tested for the hepatitis viruses and for HIV. If you have a positive HIV or hepatitis test you cannot be in the study.

There may be physical, psychological and social risks if you test positive for hepatitis B, hepatitis C and/or HIV. If you have a positive test, you will be told in private, counseled and referred for treatment.

It may take weeks after being infected with HIV for the test to be positive. The HIV test is not always right and it should be repeated to confirm.

Positive test results are required to be reported to the Maryland State Department of Health. If you have any questions about what information is required to be reported, please ask the Study Doctor or study staff.

Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

**UNFORESEEN RISKS**

Since the Study Drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo or fetus (unborn baby) if you or your female partner becomes pregnant.

**BIRTH CONTROL REQUIREMENTS FOR FEMALES**

Taking the Study Drug may involve risks to a pregnant woman, an embryo, fetus or nursing infant.

In order to reduce the risk of pregnancy, you and your partner should use an effective hormonal or barrier method of birth control while you are participating in this study (until Day 181). Acceptable methods of birth control for use in this study are:

- Oral contraceptive pills.
- Patches.

- Vaginal rings.
- Long-acting reversible contraception.
- Documented surgical sterilization (e.g., tubal ligation or hysterectomy).
- Condoms with spermicide.
- Abstinence from intercourse with a male partner.

If you are breastfeeding, you cannot participate in the study.

Notify the Study Doctor or study staff if you become pregnant after Day 1 through 3 months after receiving the Study Drug. Your Study Doctor will continue to monitor to you during the course of your pregnancy. The outcome of your pregnancy will be followed-up and documented.

**ALTERNATIVES TO PARTICIPATION**

Please talk to the Study Doctor about your options before you decide whether or not you will take part in this study.

This research study is for research purposes only. The only alternative is to not participate in this study.

**NEW FINDINGS**

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

**WHAT ARE THE BENEFITS OF TAKING PART?**

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future to improve prevention and reduction of diarrheal symptoms for overseas travelers to foreign countries.

**COMPENSATION FOR PARTICIPATION**

You will be paid up to a total of x  if you complete this study. You will be paid for the visits you complete. If you do not complete the study, for any reason, you will be paid for each study visit that you do complete.

You will not be paid for your screening or Day -3 visit if you test positive for drugs or alcohol (except for marijuana). You will be withdrawn from the study if you test positive for drugs or alcohol at any time during the study, and paid only for your completed portion of the study.

If you are withdrawn from the study early due to a significant medical event or cancellation by the Sponsor, you will be compensated for the visits that you completed based on the participant stipend table above.

You will be paid the study completion bonus for completing all study visits that are required for you in this study.

If you are not eligible for discharge on day 8 you will receive $500.00 per additional inpatient day. You will not be paid for missed outpatient visits and may forfeit some or all of your bonus as a result of missed visits or not following directions.

You will receive $50.00 for each unscheduled visit requested by the Study Doctor (such as when lab tests need to be repeated). All subjects will be paid within 7 business days of the completion of their participation in the study. If you are selected as an alternate (not selected to participate in the study) you will be paid for your completed activities according to the table above.

Because payments made to you for participating in this study will be reported to the IRS as income as required by law, you are required to provide your social security number in order to receive payment. No deductions for any state or federal withholding or any other similar taxes will be made. It is your responsibility to report this compensation on state and federal tax returns and to pay any taxes that are due on this compensation.

If you have any questions regarding your compensation for participation, please contact the study staff.

**CONFIDENTIALITY**

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Study Doctor, the sponsor or persons working on behalf of the sponsor and under certain circumstances only with IRB approval, the FDA and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of individuals from the Immuron Limited or its representative, Rho, Inc. (namely its monitors and auditors),
- The institutional review board (IRB) – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants),

- Government regulatory authorities including the United States Department of Defense (DOD), FDA and other foreign regulatory agencies.

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

**COMPENSATION FOR INJURY**

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

If you are injured as a result of taking the Study Drug(s) or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

**COSTS**

There will be no charge to you for your participation in this study. The Study Drug, study-related procedures and study visits will be provided at no charge to you or your insurance company.

**WHAT WILL HAPPEN TO INFORMATION ABOUT ME?**

By signing the consent form you consent to the study doctor collecting and using personal information about you for the research project. Any information collected from you in connection with this research study that can identify you will be protected in accordance with Federal regulations. Personal identifiers (your name, date of birth) will not be released and all information collected about you during the study will be stripped of all identifiers to protect your identity and will be securely stored.

**WHAT WILL HAPPEN TO MY TEST SAMPLES?**

Results from future medical research using your samples or data may be published in scientific journals and presented at meetings but you will not be identified as a study volunteer. Your samples will be coded with numbers not your name.

The biospecimens you give us during this study are important to medical science and may help to assist in the understanding of bacterial diseases. Biospecimens will not be sold for commercial gain. Any unused blood or stool will be stored for future research use. This will include studies related to the microbes in your gut and studies of related diseases such as inflammatory bowel disease. **There will be no genetic testing for known genes that contribute to heritable diseases.**

Your samples will be stored at the Naval Medical Research Institute (NMRC) for future research. The Division and Department head of the Deployment Associated Infections Division (DAID), Operationally relevant infections (ORI Department) are the custodians of the samples.

Agreeing to sample storage is required to join this study. You should not join the study if you do not want your samples to be stored.

You will not own your samples after you give them to the study. There will be no direct benefit to you from any future research use of your samples. You will not be paid for any product or idea created by using the data or samples collected from you.

Sharing information and/or samples is part of medical research and may increase what we can learn from this study. Information, data or sample sharing can change over time and may continue after the study ends. Because medical science constantly advances, we do not yet know what future testing may include. Your data and/or samples not your identity may be shared directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners or through government or other databases/repositories for the purposes of medical research.

**Your samples will be coded to protect your privacy and will not be able to be traced back to you.**

**WHAT WILL HAPPEN AT THE END OF THE RESEARCH STUDY?**

You will not receive the results of research done with your samples. There is no direct link between you and the research study results. When the study is complete in a few years, the study results will be posted on https://clinicaltrials.gov.

The use of your data and biospecimens may lead to new tests, drugs, devices, or other products or services with commercial value. Your samples will not be sold commercially, they will be used only for advancing medical research. You will not be able to claim any financial benefit arising from the use of your samples for medical research.

**COMMERCIAL PROFIT**

Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and **you will not share in this profit**.

**GENOME SEQUENCING**

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research **might include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**WHOM TO CONTACT ABOUT THIS STUDY**

During the study, if you experience any medical problems, suffer a research-related injury or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Study Doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures.

**Please contact the Study Doctor at the telephone number listed on the first page of this consent document.**

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An IRB is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00068865

**VOLUNTARY PARTICIPATION / WITHDRAWAL**

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. You may decide to withdraw your permission to use and share bio-specimens and disclose your health information at any time during the study. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study. However, please note that when you withdraw your permission, no new health information identifying you will be gathered but your samples already collected will be analyzed as planned and the results used for the study. Information that has already been gathered may still be used and given to others.

The Study Doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Study Doctor may ask you to have some end-of-study tests for your safety.

**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

If you decide to be in this study, the Study Doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name;
- Address;
- Phone number;
- Date of birth;
- Medical history;
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers. The United States Department of Defense (DOD) is funding this clinical research study. DOD may have access to identifiable research records for research regulatory oversight activities.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Individuals from Immuron Limited or its representative, Rho, Inc.;
- Representatives of the Clinical Research Unit;
- Representatives of the Advarra IRB (the Institutional Review Board that reviews this study);
- The FDA and other US federal and state agencies;
- Government agencies to whom certain diseases (like HIV, hepatitis and sexually transmitted diseases) must be reported;
- Governmental agencies of other countries;
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study;
- Other research doctors and medical centers participating in this study, if applicable;
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if IMM-124E works and is safe;
- To compare IMM-124E to other drugs;
- For other research activities related to IMM-124E.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke your permission to use and share health data about you at any time by writing to the Study Doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

**PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION**

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

☐**YES** (If yes, please complete the information below)

☐**NO**

| | |
|---|---|
| Name and address of family doctor or primary health care provider: | Name:<br>Address: |
| Telephone and Fax Number: | Tel:<br>Fax: |

**STATEMENT OF CONSENT TO PARTICIPATE IN STUDY**

By signing and dating this Statement of Consent to Participate in Study:

- I understand that this Study involves research with an investigational drug.
- I have read and understand all the information in this informed consent form (or it has been read to me).
- I agree that I have had enough time to ask questions and my questions have been answered to my satisfaction.
- The Study and its risks and benefits, alternative treatments, procedures and purpose have been explained to me.
- I have not given up any legal rights by signing and dating this informed consent form.
- I allow disclosure of my health information to government agencies, the Sponsor, and other persons and entities described in this informed consent form for the purposes described in this informed consent form and as required by law.
- I voluntarily agree to participate in this Study, and I have been told that I will be given a signed and dated copy of this informed consent form.
- I voluntarily agree to allow my health information after the Study is complete.
- I understand that my identity will be kept confidential if the data collected from this Study is used for publication or educational purposes.
- I understand and give permission for my biospecimens to be kept indefinitely for the sole purpose of medical research. I understand that any sample information cannot be traced back to me.
- I understand that I must give my permission for the collection of a nasal swab for the detection of SARS-CoV-2 prior to admission or at any time that I experience any symptoms associated with SARS-CoV-2 if found eligible to participate in this study
- I understand that I will be told about new findings learned by the Study Doctor during the Study that may affect my willingness to stay in the Study.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date