16.1.3 List of IECs or IRBs - Representative Written Information for Subject and Sample Consent Forms

Table of Contents

List of IEC/IRB
Participant Information and Consent Form - Part 1 Low Dose Version 2.0 dated 06-JUN-2019
Participant Information and Consent Form - Part 2 SAD Version 2.0 dated 04-JUN-2019
Participant Information and Consent Form - Part 3 MAD Version 2.0 dated 06-JUN-2019

List of IEC/IRB

Site	IEC/IRB	Chair
Nucleus Network Limited (Australia)	Alfred Health, Alfred Hospital Human Research Ethics Committee 55 Commercial Road Melbourne, VIC Australia, 3004	Professor John J. McNeil

Participant Information and Consent Form - Part 1 Low Dose Version 2.0 dated 06-JUN-2019

Participant Information and Consent Form

Low Dose Cohort

Alfred Project Number:	64/19
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT Peptide in healthy participants
Protocol Number:	AB001
Test Drug Code:	LSALT peptide
International Sponsor:	Arch Biopartners Inc
Local Sponsor:	Arch Clinical Pty Ltd
Principal Investigator:	Dr Ben Snyder
Location:	Centre for Clinical Studies

PART 1 - What does my participation involve?

1. Introduction

You are invited to take part in this research study because you are a healthy male/female aged 18-55 years old who potentially meets the study participation requirements.

This project is testing the safety, tolerability, pharmacokinetics (PK, the amount of study drug in your blood) of a single/multiple intravenous (IV) infusion (into the vein) doses of a new drug called LSALT.

This Participant Information and Consent Form (PICF) tells you about the research study. It also explains the tests and treatments that will be completed during study participation. This information is given to you to help you decide if you want to take part in this research study. Please read this information carefully and ask the study doctor questions about anything that you don't understand or want to know more about before deciding whether or not you want to take part. If you wish to do so, please take the time to talk about it with a relative, friend or your local doctor before deciding to participate.

Once you understand what the study is about and if you agree to take part in it, you will be asked to sign a Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research study.

Your information regarding participation in the study will be provided to your usual doctor if you opt to provide their contact details to study staff.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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

- understand the information you have read;
- consent to take part in the research study;
- consent to follow the study requirements
- consent to have the tests and treatments that are described;
- consent to follow the study requirements and to keep follow-up appointments that are described;
- consent to the use of your personal and health information as described.

A description of this clinical trial is available on www.clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results after the trial is completed. You can search this website at any time.

You will be given a signed copy of the Participant Information and Consent Form to keep.

2. What is the purpose of this research?

Arch Biopartners Inc is developing the study drug LSALT peptide as a potential new treatment for acute kidney injury. Acute kidney injury is a common disease in people who are hospitalized or undergoing major surgery. Acute kidney injury is a serious complication that increases the risk of death and other serious health problems. Thus preventing acute kidney injury is desirable and may improve the health of people at risk of this complication. Currently, there are no specific treatments to prevent acute kidney injury. The LSALT peptide is a drug that is being developed to prevent acute kidney injury in people. LSALT works to prevent immune cells entering damaged parts of the body such as the kidneys. Preventing immune cells entering these parts of the body could potentially reduce the amount of damage from insults such as blockage of the blood supply. In animal studies, the LSALT peptide has been shown to be very effective in protecting the kidney. In order to start treating kidney disease with the LSALT peptide in humans, researchers must first understand the safety profile of the drug and what happens to the drug once it is injected.

The purpose of this research is to determine the safety and behaviour of LSALT peptide in people. If the LSALT peptide is found to be safe, this will lead to future clinical trials testing the effectiveness of the drug in preventing acute kidney injury in people. This research will also lead to the design of new and improved versions of the LSALT peptide

Medications, drugs and devices must be approved for use by the Australian Federal Government; the Therapeutic Goods Administration (TGA). LSALT peptide has not been approved for marketing by the TGA in Australia (and is not yet approved anywhere else in the world). Therefore, the use of LSALT peptide in this study is experimental.

LSALT peptide has been tested in animals and found to be safe at doses much higher than planned in this study. LSALT peptide has never been tested in humans. **Although unlikely, there is a risk of death in first in human studies such as this study.**

In other studies, some unexpected serious, life-threatening side effects have occurred following the administration of new experimental treatments. It is unknown, however unlikely, whether some unexpected serious, life threatening side effects could occur with LSALT peptide. You will be monitored closely for them and treated if they occur.

This study is being conducted at the Centre for Clinical Studies at Nucleus Network Pty. Ltd., Melbourne, Australia. The Clinical Research Organisation involved in monitoring the study is Syneos health. Arch Biopartners Inc is the international company sponsoring this study along with Arch Clinical Pty Ltd who is the Australian Company.

3. What does participation in this research involve?

Before you begin the study, you will be given detailed information about LSALT peptide, the study, and any other relevant information by research staff. You are encouraged to ask questions until you are sure that you fully understand the nature of and requirements of the study.

If you decide to be assessed for inclusion in the study, you will be asked to visit the Centre for Clinical Studies for an initial assessment visit (screening visit). Before any procedures are undertaken, you will be asked to sign a consent form. You will then have some tests to check that the study is suitable for you. The screening visit may take between 1 and 2 hours.

This study will enrol approximately 52 participants into 3 parts;

- **Part 1- Low dose Cohort**- 4 participants will be dosed with a low dose of the study drug (0.01mg, 0.1mg, 0.3mg and 0.5mg), 1 dose of increasing strength for each participant. Participants will be dosed on Day 1 with a single dose of the study drug and will stay in the unit for an inpatient stay of 2 days. You are then required to return for a single follow up visit.
- **Part 2- Single Ascending dose Cohort**- 24 participants will be split into 3 cohorts (groups) of 8 and will be dosed with a single dose of the study drug (1mg, 2.5mg and 5mg) during an inpatient stay of 2 days. You are then required to return for 2 separate follow up visits
- **Part 3- Multiple Ascending dose Cohort**- 16 participants will be split in 2 cohorts (groups) of 8. Participants will be dosed with the study drug once or twice per day for 3 days with an inpatient stay of 4 nights. You are then required to return for 3 separate follow up visits.

This PICF will only outline the requirements of Part 1 of the study, the Low Dose cohort.

Part 1 will enrol 4 participants in a low dose cohort. The first participant will be given the lowest strength study drug, monitored for 24 hours and then discharged. Once discharged, the participant will have to return for a follow up visit to ensure there are no safety concerns. The results will be reviewed, then the next low dose participant (participant 2) will be admitted. This pattern will continue for all 4 low doses.

	Admission	Dose	Discharge	Follow up
Participant 1	Day -1	0.01mg	Day 2	Day 4
Participant 2	Day 4	0.1mg	Day 6	Day 8
Participant 3	Day 8	0.3mg	Day 10	Day 12
Participant 4	Day 12	0.5mg	Day 14	Day 16

As this is a dose escalation study, the first participant enrolled will receive the lowest dose and once it is considered to be safe, the next participant will be enrolled to receive the next higher dose. Dose escalation will only proceed following review of all available safety data by the Principal Investigator in consultation with the sponsor and there is confirmation that it is safe to continue with the next higher dose strength in the next group. The study can be stopped at any time, based on evaluation of the side effects of the study medication.

The dose levels planned for this part of the study range from 0.01 to 0.5 milligrams. You will be informed of the exact dose when you check in to the clinical unit .

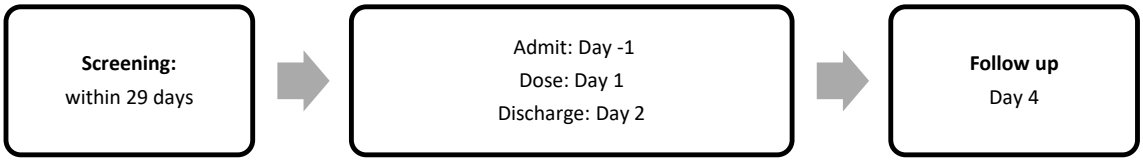
Study sequence: Your total participation in the study will consist of approximately 5 weeks as follows:

- **Screening visit**: will occur within 29 days of your dose. You will undergo assessments to determine if you are eligible for the study

- **Admission and treatment period:** in patient period of 2 nights
- **Follow up period**: a single out patient follow up visit is required

Below is a picture outlining an example schedule for the study (Participant 1):

Please see above table for requirements for each participant



If you decide to be assessed for inclusion into the study, you will be asked to visit the Centre for Clinical Studies for the screening visit. The screening visit may take between 1 and 2 hours.

Screening visit (between Day -29 to Day -2)

After reading this information sheet and if you agree to participate in the study, you will be asked to sign the attached consent form. The study doctor will perform a medical examination to ensure that it is appropriate for you to be part of the study. You will undergo the following assessments:

- You will be asked about your **current health status** and about your **medical history**, including all medications, over-the-counter and herbal medications that you have been, and are currently taking.
- You will be asked some personal details about yourself, including your date of birth.
- You will be asked about your alcohol history and you will undergo an alcohol breath test.
- You will be asked to provide a **urine sample** to assess your general health and to test for medications of addiction as listed below:
  - to test for nicotinine level (to test if you have smoked cigarettes)
    - to test for drugs of addiction (such as Methamphetamine, Cocaine, Cannabinoids, Opiates, Phencyclidine, Barbiturates, Benzodiazepines, Methadone, and Amphetamine). This is a study requirement and the results will remain confidential. The tests may reveal that you have previously used illegal medications. That information will be stored in a re-identified (or coded) format. If the Centre for Clinical Studies is required to disclose that information, it may be used against you in legal proceedings or otherwise. If you test positive for any of these substances, you will be excluded from further participation in this study.
- Your **vital signs** such as blood pressure, pulse rate and oral body temperature will be measured.
- You will have a full **physical examination** (PE), your height and weight will be measured to determine your body mass index (BMI).
- You will have **electrocardiograms** (ECG) (recording of your heart's electrical activity and rhythm).
- **Blood sample** (approximately 25mL / 5 teaspoons) will be collected for general safety assessemnts and to screen for HIV (AIDS virus), and hepatitis B and C. This is because the study doctors need to know about your general health and the health of your immune system. You will have to be fasting 8 hours for screening blood collection.
    - You will receive information and counselling before the HIV and hepatitis tests. If a test shows you have HIV or hepatitis you will not be included in this study, but you

will have follow-up counselling and medical advice. If your test results are positive, the researchers are required by law to notify the Victorian government. Signing the consent form means you agree to have this testing. It will not be done without your consent.

- **Pregnancy Test:** from your blood sample, a pregnancy test will be performed.
- **Chest x-ray:** you will have a chest x-ray at a local clinc since the LSALT peptide could affect your lungs. You will be provided with details about where to go for this assessment when appropriate.

If for any reason, the trial is found to not be suitable for you, staff from the Centre for Clinical Studies will contact you and provide follow-up treatment advice where applicable.

Treatment and Follow-up Period

If you are eligible to enter the study, you will be admitted to the clinical unit the day before the planned dosing day. You will undergo a number of procedures to confirm your suitability for participation in the trial (see table below).

To ensure sufficient number of participants are available for dosing, additional volunteers called 'alternates' will be recruited and admitted to the clinical unit. If you are an alternate, you may be asked to participate in the study if someone is not included in the dosing group. You will be informed if you are an alternate before treatment is given.

The following day, the study drug will be administered as an IV infusion over a period of approximately 2 hours, or as determined by the PI and the safety monitoring committee.

On the morning of your first day in the clinical unit, a cannula will be inserted into a vein in your arm. This is a small, flexible tube which will allow blood to be collected easily throughout your unit stay and prevents the need for repeated needles to be inserted in your vein to collect each sample. The location of the cannula may need to be repositioned if required.

During the occasions that you are required to stay overnight, you will be provided meals. You will need to have fasted from all food and drink except water for at least 8 hours before providing blood samples.

You will undergo the following procedures at various time points during the study, the table of assessments below outlines when these events will take place:

- **Vital signs**: Oral temperature, pulse rate and blood pressure will be measured.
- **12-Lead Electrocardiogram (ECG):** will be performed to assess your heart rhythm.
- **Physical Examination:** will be performed to assess your general health. This will include measuring your body weight.
- **Safety blood and urine samples:** approximately 25 ml (approx. 4 teaspoons) of blood and a urine sample will be collected to assess your general health. When you check in, the urine sample will also be collected to test for drugs of addiction and to test if you have smoked. A positive test will exclude you from further participation in the trial. A pregnancy test will also be performed from your urine sample a number of times during the study.
- **Alcohol breath test:** You will undergo an alcohol breath test when you check into the clinical unit to see if you have been drinking any alcohol in the past 24 hours. A positive test will exclude you from further participation in the trial.
- **Study drug administration:** The study drug will be administered as an IV infusion over approximately 2 hours.
- **Pharmacokinetic (PK) samples**: will be collected to measure the amount of LSALT peptide in your blood, the break down products and to assess the effect it has on your body. Approximately 5 mL of blood (approx. 1 teaspoon) will be collected at various time points during a study visit.

- **Concomitant Medication review:** you will be asked if you have recently taken any medications.
- **Adverse Events:** You will be asked about how you are feeling (whether you feel alright, different from normal or unwell) at regular intervals, please tell a study team member if you have any changes in your health or concerns.

You will be discharged from the clinical unit once all study procedures are complete and the clinical staff sees no changes in your health which would prevent your discharge from the clinical unit.

Follow up visits

You will be reqired to return to the study center for a single follow up visit 2 days after your discharge.

The study doctor will ask you to return to the research unit on the follow up day and may ask you to return after this period, if he/she feels it is necessary. In the event it is necessary to further evaluate the safety or effects of the medication, it may be necessary to have access to additional information about your health status. Your study doctor may attempt to obtain study-related information about your health from you or from other sources, including your primary care physician. This may include contacting you again by phone or letter.

The table below outlines the assessments that will be performed during the low dose cohort:

Participant		1				2				3				4			
Study Day	**Screening -29 to -2**	**-1**	**1**	**2**	**4**	**4**	**5**	**6**	**8**	**8**	**9**	**10**	**12**	**12**	**13**	**14**	**16**
In patient period		X	X			X	X			X	X			X	X		
Informed consent	X																
Vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical Exam	X	X		X	X	X		X	X	X		X	X	X		X	X
Alcohol Breath test	X	X				X				X				X			
Drugs of abuse testing (urine sample)	X	X				X				X				X			
Urinalysis	X	X		X	X	X		X	X	X		X	X	X		X	X
Complete blood count (CBC)	X	X		X	X	X		X	X	X		X	X	X		X	X
Chemistry	X	X		X	X	X		X	X	X		X	X	X		X	X
Creatinine/eGFR	X	X		X	X	X		X	X	X		X	X	X		X	X
LFTs blood sample for (blood clotting ability)	X	X		X	X	X		X	X	X		X	X	X		X	X
INR/PTT	X			X	X			X	X	X		X	X	X		X	X
Chest X-ray	X																
Electrocardiogram ECG	X	X	X		X	X	X		X	X			X	X	X		X
B-hCG blood sample for pregnancy test	X	X			X	X			X	X			X	X			X
Adverse Event	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
LSALT Administration			X				X				X				X		
Discharge from unit				X				X				X				X	
Follow up					X				X				X				X

Key; LFT= liver function tests, INR/PTT=blood clotting ability, B-hCG= pregnancy test

4. What do I have to do?

It is important for your own safety that you inform the study doctor or staff of your complete medical history and all medications, supplements, and/or herbal preparations that you have taken within the past 6 months or are currently taking. If you have any health problems, please notify your study doctor immediately. As mentioned earlier in this document, if you notice any changes in your health or have concerns during your participation in the study, also inform your study doctor or study staff as soon as possible. So long as you continue to participate, you should take the study drug as directed. You must always follow the instructions of the study doctor and staff.

Please note that in the days leading up to your admission to the clinical unit, there are a few things you must avoid to be included in the study:

- You should not have participated in other clinical trials within 1 month before signing this consent form.
- You should not have donated blood within 60 days before admission into the unit.
- You will be asked to come to the Centre for Clinical Studies in fasting condition (no consumption of any food or drinks, with the exception of water, during the 8 hours prior to arrival), at admission to the clinical unit and at the follow-up visit. During your stay in the clinical unit, you should follow the instructions of the study staff concerning your intake of food and beverages
- Please do not take any prescription medication for 2 weeks prior to your admission to the clinical unit.
- Please do not take any over the counter medication for 7 days prior to admission. Occasional use of paracetamol or ibuprofen (up to 1000 mg and 400 mg/day respectively) are acceptable. Routine vitamins and supplements are permissible at the discretion of the investigator. Please ask if you have any questions.
- Social and light smokers (up to 10 cigarettes per day) are allowed to enter the study, however they must agree and be able to abstain from smoking for the full inpatient period.
- Please do not consume any caffeine, quinine (tonic water) and xanthine containing beverages (tea, coffee, cola, chocolate) for 48 hours prior to your screening appointment and 48 hours prior to your admission to the clinical unit. Consumption of quinine, caffeine and xanthine containing beverages is not allowed throughout the clinical stay. Please ask your study doctor if you have any questions regarding the above restrictions.
- Please do not consume alcohol for 48 hours prior to your admission to the clinical unit until after your final visit.
- Please do not perform any strenuous exercise for 2 days prior to your admission to the clinical unit and until after your final visit.
- You should not have donated blood in the 2 months prior to starting the study and should refrain from donating blood during the study and within 2 months after your final visit. If you donate blood after this period, you must inform donor centre staff that you have recently been involved in a clinical study.

Please note that you will not be allowed to smoke while at the study centre.

In case of emergency, you must be easily contactable by phone and/or email. You will be given a Participant Wallet Card which contains emergency contact information and information about your study commitments. You must carry the Participant Wallet Card with you at all times until the end of the study.

5. Other relevant information about the research study

This study is being conducted at the Centre for Clinical Studies in Australia. There are no researchers from other organisations working in collaboration.

A representative of Arch Biopartners Inc (study sponsor) may be present for inspections in the unit during the study.

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

Participation in any research study is voluntary. If you do not wish to take part, you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time without providing any reason. Your study doctor may ask you the reason for your withdrawal, you can answer or not.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the Centre for Clinical Studies and will not involve any penalty or loss of benefits to which you would be otherwise entitled. Should you withdraw from the study before the final visit you may receive a partial payment according to the number of visits you have attended.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research study. You can ask for any information you want. Sign the Consent Form only if you agree to participate and only after you have had a chance to ask your questions and have received satisfactory answers.

7. What are the alternatives to participation?

Since this study is intended only to evaluate the safety, tolerability and pharmacokinetics of LSALT peptide, your alternative to be a volunteer in this study is to choose not to participate in the study.

8. What are the possible benefits of taking part?

If you agree to take part in this study, there will be no direct benefit to you. However, your participation in this study may help develop important scientific knowledge that could contribute to the development of this medication for kidney diseases. We hope the information learned from this study will benefit others in the future.

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

LSALT peptide is an experimental medication, therefore the risks to human participants have not been fully evaluated.

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with a study doctor. Your doctor and study staff will also be watching you closely for side effects.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your doctor may need to stop your treatment. Tell your study doctor or site staff if you notice any changes in your health or have concerns. Your study doctor will discuss the best way of managing any side effects with you.

There may also be side effects that are not expected or are not known that may be serious. Tell your doctor immediately about any new or unusual symptoms or changes in your health that you become aware of. The treatment of the side effects will depend on the type and severity of the symptom(s).

If during screening or participation in this research study a previously unknown medical condition is discovered the study doctor will discuss:

- whether you are eligible for study participation
- if you require referral to your usual physician or to a specialist

Risks of Study Drug:

Currently, the risks of LSALT peptide in humans are unknown. There may be side effects related to the infusion of the drug such as lightheadedness, nausea or an allergic reaction. In animals, these infusion related side effects were easily treated with anti-histamines. However, the drug will be given at much lower doses than the amount administered to animals, and will be infused very slowly to minimize these side effects.There is also a small risk that you may develop antibodies against the the LSALT peptide which may cause some medical problems, especially if you were to receive the drug again in the future.

Blood Draw/ Cannula Insertion Risks:

You may have pain or bruising at the site where blood is drawn or a cannula (a temporary small plastic tube) is inserted. An infection at the site of blood draws or cannula insertion is also possible. The insertion of the cannula (small plastic tube) or the drawing of blood may be associated with some pain. Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising or bleeding at the site of puncture. These will normally disappear a few days after the procedure.

Blood Pressure Measurement Risks:

There is no risk to your health when having your blood pressure tested. You may experience some feeling on discomfort as the cuff inflates and squeezes your arm, but it should only last a few seconds. Sometimes, there are tiny red spots that appear after the test just below the location of the cuff, they should be painless.

Electrocardiogram (ECG) risks:

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If there is hair in the area where patches need to be applied, this area will be shaved in order to complete the ECG. Shaving may result in irritation.

Risks of Chest X-ray (Radiation Risk)This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.02 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

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

Allergic Reaction Risks:

There is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death.

Symptoms may include difficulty in breathing, dizziness, itching, swelling of the lips, tongue or throat, coughing, rash.

In general, most symptoms are manageable. They are mild to moderate in severity. But life-threatening reactions may occur at any drug dose. If you believe you are having a serious allergic reaction, you should seek emergency medical assistance immediately.

Please notify the study doctor immediately if you experience any of these symptoms. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

You will be monitored very carefully for any signs or symptoms that you may be having an allergic reaction and appropriate care will be taken by the study doctor and nursing staff.

If you do not understand what some of these side effects or risks mean, ask the study doctor or the study staff to explain them to you.

Pregnancy Risk:

The risks of the study drug to an unborn child or nursing infant are unknown and may be hazardous. It is important that you use the appropriate forms of birth control as described below:
If you are male, you must be either vasectomised, sexually abstinent (when this is in line with your preferred and usual lifestyle) or agree to use a condom. If you use a condom and your partner is of childbearing potential, she must use another method of contraception resulting in a highly effective method of birth control for the full duration of the study and for 3 months after the last dose of study drug.

If you are female and of childbearing potential, you must also use a double barrier method of contraception for at least 90 days after the last dose of study drug.

Double barrier contraception is defined as a condom AND one of the following;

- Birth control pills (The Pill)
- Birth Control Patch (e.g. Ortho Evra)
- NuvaRing®
- Depot or injectable birth control
- IUD (Intra Uterine Device)
- Documented evidence of surgical sterilization at least 6 months prior to screening visit, i.e., tubal ligation or hysterectomy for women or vasectomy for men.

Please ask you study doctor if you have any questions regarding the forms of birth control that must be used while participating in this study.

If you are male, you must not donate sperm for at least 90 days after last dose of study drug.

If you/your partner becomes pregnant during the study or up to 90 days after the last dose of study drug, please tell your study doctor or staff immediately as we would like to request permission to follow this pregnancy and its outcome. The study doctor will also report the pregnancy to the Human Research Ethics Committee and to the study Sponsor.

Allowing the pregnancy and outcome to be followed is optional. If your partner agrees to have this pregnancy followed, then she will be asked to sign a separate Pregnancy Follow-Up Participant Information and Consent Form. The information collected is similar to that which would be routinely collected during a typical pregnancy consultation. The consultation will be done in person at the Centre for Clinical Studies, and/or by telephone.

In addition, she will be asked to notify the study doctor about the outcome of the pregnancy. If she forgets, she will be contacted to obtain this information. This outcome data collected includes: pregnancy complications and outcome, birth weight, birth defects (if any), and additional factors that may have had an impact on the outcome of the pregnancy (drugs, infections, family history etc.).

The study doctor may also need to contact the gynecologist of your partner.

10. What will happen to my test samples?

By consenting to take part in this study, you also consent to the collection and testing of your urine and blood samples for this research. The total volume of blood taken for the entire study is approximately 80ml (approx. 5 tablespoons). For comparison, a standard blood donation is approximately 470mL (approx. 2 cups). Additional blood samples may also be collected for safety reasons.

The blood and urine samples collected for the assessment of your health status (e.g. liver and kidney function tests) will be processed by a local pathology laboratory. These samples will be labelled with your unique study participant number, your initials and date of birth, and will not contain any information that can identify you personally. These samples will be destroyed following analysis.

This research project involves the collection of information about your use of drugs and alcohol. Participation in the research project includes blood and urine analysis to determine the presence of drugs such as amphetamines, methamphetamines, benzodiazepines, barbiturates, marijuana, cocaine, PCP, methadone, opioids (narcotics). The test may reveal that you have previously used illegal drugs. That information will be stored in a re-identifiable (or coded) format. This is a study requirement and the results will remain confidential. In the event that the Centre for Clinical Studies is required to disclose that information, it may be used against you in legal proceedings or otherwise. If you test positive for any drugs of addiction, you will not be able to participate in this study.

You will receive information and counselling before the HIV and hepatitis tests. If a test shows you have HIV or hepatitis you will not be included in this study, but you will have follow-up counselling and medical advice. If your test results are positive, the researchers are required by law to notify the Victorian government. Signing the consent form means you agree to have this testing. It will not be done without your consent.

Blood samples taken for pharmacokinetics will be sent to various Sponsor-approved laboratories in Canada. These samples will be labelled with your unique study participant number and will not contain any information that can identify you personally. These samples will be stored during the study at a secure premise and the samples will be destroyed following analysis at the end of the study.

11. What if new information arises during this research study?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research study. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research study you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research study. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

12. Can I have other treatments during this research study?

Whilst you are participating in this research study, you are not able to take any medications or treatments other than those agreed upon at the start of your participation in the study. It is important to tell your study doctor and the study staff, at each clinic visit, about any treatments or medications you may have taken, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

13. What if I withdraw from this research study?

If you decide to withdraw from the study, please notify your study doctor or staff before you withdraw. This notice will allow the study doctor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research study, any information collected on you up to the point of withdrawal will be used. Data collected after your withdrawal, if any, may be used:

• If you decide to withdraw from the study, any adverse event not resolved at this time will be followed until its resolution by your research doctor to ensure your medical follow-up. You may also contact your research doctor if you experience a new adverse event.

• If you withdraw from the study for a reason other than your own decision, your research doctor may contact you to request any relevant information and / or documentation regarding your medical care.

• If you withdraw your consent, all your biological sample(s) will be destroyed without disclosing your identity. If analysis is required for the study, it will be analysed before destroying your samples.

14. Could this research be stopped unexpectedly?

This research study may be stopped unexpectedly for the reasons listed below.

- Unacceptable side effects
- The drug being shown not to be safe
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities
- If you don't follow the instructions of the clinical unit staff; or
- If the study doctor decides it is in the best interest of your health and welfare to stop.

15. What will happen when the research study ends?

The study drug will not be available to you following completion of participation.

The study data will be analysed, and a final report provided to the study doctor, who will share the results with you when requested. The disclosure and/or any published results will be available to you when requested. It is usual for a number of years to elapse before definitive

results of this type of study are available. These may be published in medical journals that are available to the public. You should feel free to ask the study staff about this.

Part 2 - How is this study being conducted?

16. What will happen to information about me?

Any information and data obtained/retained in connection with this research study that can identify you will remain confidential and will only be used for the purpose of this research study and future research related to the pathway being studied and related disease conditions.

Information about you may be obtained from your health records held at other health services for the purpose of this research. By signing the consent form you agree to the study team, including Sponsor delegates, accessing health records if they are relevant to your participation in this research study to ensure data accuracy. Whilst every effort will be made to keep your personal information confidential, the data gathered for this study will also be reviewed by a Sponsor delegate. This delegate will have access to your medical records, without violating your confidentiality to the extent permitted by local laws and regulations, to verify the data are correct and complete.

The data collected as part of this research study may be reviewed by representatives of the international sponsor, Arch Biopartners Inc, its affiliated companies and/or subcontractors, the local sponsor, Arch Clinical Pty Ltd, the Research Ethics Committee of Alfred HREC, by authorised representatives of the Australian Therapeutic Goods Administration or other regulatory agencies. Information may be transferred to parties in countries (and regions) other than Australia including the US, and Europe for these purposes. Syneos Health, Arch Biopartners Inc representatives, collaborators and contracted agencies comply with internal procedures to protect personal information even in countries whose data privacy laws are less strict than those of this country. In all cases when dealing with your personal (coded) information. Arch Biopartners Inc, and any of their agents will comply with the Privacy Act 1988. If you have any concerns on how your information is handled, please feel free to ask a member of the study team for more information.

By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Study Medical Records

Data from your study medical record will be identifiable and stored in secured offices at the Centre for Clinical Studies. Only research team members and authorised representatives from the Sponsor, the Ethics Committee or regulatory agencies will have access to your medical records.

You have a right to access and request correction to your information.

Case Report Form (CRF)

Information you provide us will be recorded in electronic case report forms (CRF). Your information will be coded by your unique study number, your gender and birth date only and thus will be considered re-identifiable. The recorded data will be kept in an electronic database which will be managed throughout the study by Syneos Health who are monitoring the study. Information from these CRFs will form part of the study results, which may be published. A copy of the CRF entries and your deidentified study medical record will be kept indefinitely with all other study related documents.

By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Publications

A report of the study results may be submitted for publication. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you want to know more about the Centre for Clinical Studies' approach to privacy or access any of your information held by the Centre for Clinical Studies, you can contact Dr Ben Snyder at the Centre for Clinical Studies.

It is desirable that your local doctor be advised of your decision to participate in this research study. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research study.

Information about your participation in this research study may be recorded in your health records.

17. Complaints and compensation

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

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

- The pharmaceutical industry has set up a compensation process, with which the local sponsor of this research study, Arch Biopartners Inc, has agreed to comply. Details of this process and conditions are set out in the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and if so, how much. The research staff will give you a copy of the Guidelines together with this Participant Information and Consent Form. If you have any questions about the Guidelines, please contact Dr Ben Snyder on 03 8593 9800.
- You may be able to seek compensation through the courts.

If you are not satisfied with how your personal information has been handled (as laid out in the Privacy Act, 1988), then you can make a complaint to the Office of the Australian Information Commissioner (OAIC). It is free to lodge a complaint and you do not need a lawyer, however if you do decide to hire a lawyer, you must pay for the lawyer yourself. You can choose to withdraw your complaint at any time. Please refer to http://www.oaic.gov.au/privacy/privacy-complaints for more information.

18 Who is organising and funding the research?

This research is being conducted by Arch Biopartners Inc based in Canada and in Australia by Arch Clinical Pty Ltd. The Clinical research organisation monitoring the study is Syneos Health. Arch Biopartners Inc may benefit financially from this research study if, for example, the study assists to obtain approval for a new drug.

By taking part in this research study you agree that samples of your blood (or data generated from analysis of these materials) may be provided to Arch Biopartners Inc.

Arch Biopartners Inc may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

If knowledge acquired through this research leads to discoveries that are of commercial value to Arch Biopartners Inc, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Arch Biopartners Inc, other researchers, or research companies may patent or sell discoveries that result from this research. Neither Arch Biopartners Inc nor the study doctor will compensate you if this happens.

Contractors engaged by Arch Biopartners Inc will receive a payment from Arch Biopartners Inc for undertaking this research study.

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

19. Will I be reimbursed to take part in this research study?

If you are eligible to enter the study, you will be reimbursed $75.00 for the screening and follow-up visits, and at an hourly rate of $12.50 per hour for the in-clinic stay part of this study. The total payment for participants who complete the entire study will be $830.00.

Regardless of whether you withdraw early or complete the study, you will be reimbursed within 10 business days of the end of study visit via electronic funds transfer directly into your bank account. Should you withdraw from the study before the final visit you will receive a partial payment according to the number of visits you have attended.

Reimbursement compensates for your time, travel expenses, parking and inconvenience. This reimbursement is not made for undergoing risk nor is it to compensate you for any loss of earnings as a result of your participation.

It is not anticipated that participation in this research study will result in any additional cost to you.

20. Who has reviewed the research study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC) who make sure that the rights, safety and well-being of participants in a study are protected. The ethical aspects of this research study have been approved by The Alfred Ethics Committee.

This study will be carried out according to the National Statement on Ethical Conduct in Human Research (March 2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

21. Further information and who to contact

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

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the principal study doctor (Dr Ben Snyder) on 03 8593 9800 or any of the following:

General Enquiries: **1800 243 733**

After hours contact (Centre for Clinical Studies) 24 hours 7 days a week

On-call mobile: 0429 353 069

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

Complaints contact person

Position	Complaints
Email	complaintsofficer@nucleusnetwork.com.au

Privacy contact person

Position	Privacy Officer
Email	privacyofficer@nucleusnetwork.com.au

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

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Alfred Hospital Ethics Committee
Position	Governance Officer, Ethics and Research Governance, Alfred Health
Telephone	(03) 9076 3619
Email	research@alfred.org.au

Please reference the following Alfred Project number: 64/19

CONSENT

Alfred Project Number:	64/19
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT Peptide in healthy participants
Protocol Number:	AB001
Test Drug Code:	LSALT peptide
International Sponsor:	Arch Biopartners Inc
Local Sponsor:	Arch Clinical Pty Ltd
Principal Investigator:	Dr Ben Snyder
Location:	Centre for Clinical Studies

- I am 18 years of age or over
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received. I have been given the name of a person to contact if I have any questions during the study.
- 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 to reveal my identity.
- I understand the purposes, procedures and risks of the research described for this study.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Centre for Clinical Studies for the purposes of this study. I understand that such information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any stage during the study without prejudice to future treatment. If I 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 understand that I will be given a signed copy of this document to keep.

Participant's Name (printed) ……..…Middle Initial..……Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

Witness (only if required)

Name of Witness to Participants signature (printed) ……..…Middle Initial…..…Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

* 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.

Declaration by Study Doctor/Senior Researcher

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

Study Doctor/Researcher's Name (printed) ……..……Middle Initial……..Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

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

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

FORM FOR WITHDRAWAL OF PARTICIPATION

Alfred Project Number:	64/19	Protocol Number:	AB001
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT Peptide in healthy participants		
Test Drug Code:	LSALT Peptide		
International Sponsor:	Arch Biopartners Inc		
Local Sponsor:	Arch Clinical Pty Ltd		
Principal Investigator:	Dr Ben Snyder	Location:	Centre for Clinical Studies

Declaration by Participant

I wish to withdraw from participation in the above research study and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the Centre for Clinical Studies.

Participant's Name (printed) …….Middle Initial…..…Surname…….....

Signature

Date _____/_____/_____ Time _____:_____

Study Doctor to include a description of the circumstances for withdrawal, if provided by the participant.

Declaration by Study Doctor

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

Study Doctor/Researcher's Name (printed) ……..……Middle Initial……..Surname…….....

Signature

Date _____/_____/_____ Time _____:_____

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

Participant Information and Consent Form - Part 2 SAD Version 2.0 dated 04-JUN-2019

Participant Information and Consent Form

Part 2- Single Ascending Dose (SAD) Cohort

Alfred Project Number:	64/19
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT peptide in healthy participants
Protocol Number:	AB001
Test Drug Code:	LSALT peptide
International Sponsor:	Arch Biopartners Inc
Local Sponsor:	Arch Clinical Pty Ltd
Principal Investigator:	Dr Ben Snyder
Location:	Centre for Clinical Studies

PART 1 - What does my participation involve?

1. Introduction

You are invited to take part in this research study because you are a healthy male/female aged 18-55 years old who potentially meets the study participation requirements.

This project is testing the safety, tolerability, pharmacokinetics (PK, the amount of study drug in your blood) of a single/multiple intravenous (IV) infusion (into the vein) doses of a new drug called LSALT.

This Participant Information and Consent Form (PICF) tells you about the research study. It also explains the tests and treatments that will be completed during study participation. This information is given to you to help you decide if you want to take part in this research study. Please read this information carefully and ask the study doctor questions about anything that you don't understand or want to know more about before deciding whether or not you want to take part. If you wish to do so, please take the time to talk about it with a relative, friend or your local doctor before deciding to participate.

Once you understand what the study is about and if you agree to take part in it, you will be asked to sign a Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research study.

Your information regarding participation in the study will be provided to your usual doctor if you opt to provide their contact details to study staff.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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

- understand the information you have read;
- consent to take part in the research study;
- consent to follow the study requirements
- consent to have the tests and treatments that are described;
- consent to follow the study requirements and to keep follow-up appointments that are described;
- consent to the use of your personal and health information as described.

A description of this clinical trial is available on www.clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results after the trial is completed. You can search this website at any time.

You will be given a signed copy of the Participant Information and Consent Form to keep.

2. What is the purpose of this research?

Arch Biopartners Inc is developing the study drug LSALT peptide as a potential new treatment for acute kidney injury. Acute kidney injury is a common disease in people who are hospitalized or undergoing major surgery. Acute kidney injury is a serious complication that increases the risk of death and other serious health problems. Thus preventing acute kidney injury is desirable and may improve the health of people at risk of this complication. Currently, there are no specific treatments to prevent acute kidney injury. The LSALT peptide is a drug that is being developed to prevent acute kidney injury in people. LSALT works to prevent immune cells entering damaged parts of the body such as the kidneys. Preventing immune cells entering these parts of the body could potentially reduce the amount of damage from insults such as blockage of the blood supply. In animal studies, the LSALT peptide has been shown to be very effective in protecting the kidney. In order to start treating kidney disease with the LSALT peptide in humans, researchers must first understand the safety profile of the drug and what happens to the drug once it is injected.

The purpose of this research is to determine the safety and behaviour of LSALT peptide in people. If the LSALT peptide is found to be safe, this will lead to future clinical trials testing the effectiveness of the drug in preventing acute kidney injury in people. This research will also lead to the design of new and improved versions of the LSALT peptide

Medications, drugs and devices must be approved for use by the Australian Federal Government; the Therapeutic Goods Administration (TGA). LSALT peptide has not been approved for marketing by the TGA in Australia (and is not yet approved anywhere else in the world). Therefore, the use of LSALT peptide in this study is experimental.

LSALT peptide has been tested in animals and found to be safe at doses much higher than planned in this study. LSALT peptide has never been tested in humans. **Although unlikely, there is a risk of death in first in human studies such as this study.**

In other studies, some unexpected serious, life-threatening side effects have occurred following the administration of new experimental treatments. It is unknown, however unlikely, whether some unexpected serious, life threatening side effects could occur with LSALT peptide. You will be monitored closely for them and treated if they occur.

This study is being conducted at the Centre for Clinical Studies at Nucleus Network Pty. Ltd., Melbourne, Australia. The Clinical Research Organisation involved in monitoring the study is Syneos Health.Arch Biopartners Inc is the international company sponsoring this study, along with Arch Clinical Pty Ltd, the Australain company

3. What does participation in this research involve?

Before you begin the study, you will be given detailed information about LSALT peptide, the study, and any other relevant information by research staff. You are encouraged to ask questions until you are sure that you fully understand the nature of and requirements of the study.

If you decide to be assessed for inclusion in the study, you will be asked to visit the Centre for Clinical Studies for an initial assessment visit (screening visit). Before any procedures are undertaken, you will be asked to sign a consent form. You will then have some tests to check that the study is suitable for you. The screening visit may take between 1 and 2 hours.

This study will enrol approximately 52 participants into 3 parts;

- **Part 1- Low dose Cohort**- 4 participants will be dosed with a low dose of the study drug (0.01mg, 0.1mg, 0.3mg and 0.5mg), 1 dose of increasing strength for each participant. Participants will be dosed on Day 1 with a single dose of the study drug and will stay in the unit for an inpatient stay of 2 days. You are then required to return for a single follow up visit.
- **Part 2- Single Ascending dose Cohort-** 24 participants will be split into 3 cohorts (groups) of 8 and will be dosed with a single dose of the study drug (1mg, 2.5mg and 5mg) during an inpatient stay of 2 days. You are then required to return for 2 separate follow up visits
- **Part 3- Multiple Ascending dose Cohort**- 16 participants will be split in 2 cohorts (groups) of 8. Participants will be dosed with the study drug once or twice per day for 3 days with an inpatient stay of 4 nights. You are then required to return for 3 separate follow up visits.

This PICF will only outline the requirements of Part 2 (Single Ascending Dose) cohort of the study.

This study will enrol approximately 24 participants into 3 groups (or cohorts) with 8 participants in each cohort.

There will be 2 participants from each cohort that will be given the study drug or placebo at least 24 hours before the rest of the participants; one will get the active drug and the other one will get the placebo. These 2 participants are called “sentinels”. You will be told if you are assigned to the sentinel group.

The study is placebo controlled, meaning that some participants will receive a dose containing active study drug and some will receive a dose containing placebo drug. The dose containing the placebo will look the same as the dose containing active study drug but will not contain any active ingredients in it. You will not have a choice as to whether you receive the active study drug or the placebo (you will be assigned randomly, like flipping a coin). Neither you nor the study staff will know if you are assigned to receive the active study drug or the placebo, although in an emergency, the study staff can find out.

As this is a dose escalation study, the first group enrolled will receive the lowest dose and once it is considered to be safe, the next group will be enrolled who will receive the next higher dose. Dose escalation will only proceed following review of all available safety data by the Principal Investigator in consultation with the sponsor and there is confirmation that it is safe to continue with the next higher dose strength in the next group. The study can be stopped at any time, based on evaluation of the side effects of the study medication.

The dose levels planned for this study range from 1.0 to 5 milligrams. You will be informed of the exact dose for your cohort when you check in to the clinical unit.

The table on the next page explains the planned doses for this study:

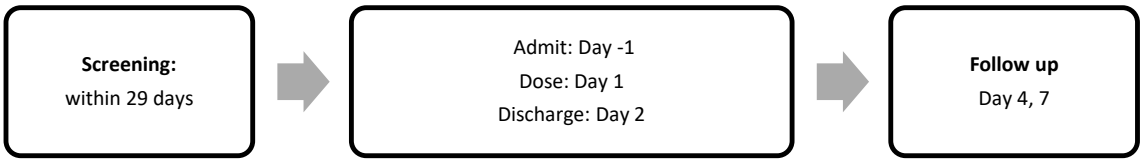
Cohort	Dose
1	Single dose 1.0 mg
2	Single dose 2.5 mg
3	Single dose 5 mg

Study sequence:

Your total participation in the study will consist of approximately 6 weeks as follows;

- **Screening visit**: will occur within 29 days of your dose. You will undergo assessments to determine if you are eligible for the study
- **Admission and treatment period**: you will be required to attend the study centre for a 2 night in patient stay
- **Follow up period:** you will be required to return to the study centre for 2 follow up visits

Below is a picture outlining the study schedule for the study:



If you decide to be assessed for inclusion into the study, you will be asked to visit the Centre for Clinical Studies for the screening visit. The screening visit may take between 1 and 2 hours.

Screening visit (between Day -29 to Day -2)

After reading this information sheet and if you agree to participate in the study, you will be asked to sign the attached consent form. The study doctor will perform a medical examination to ensure that it is appropriate for you to be part of the study. You will undergo the following assessments:

- You will be asked about your **current health status** and about your **medical history**, including all medications, over-the-counter and herbal medications that you have been, and are currently taking.
- You will be asked some personal details about yourself, including your date of birth.
- You will be asked about your alcohol history and you will undergo an alcohol breath test.
- You will be asked to provide a **urine sample** to assess your general healthy and to test for medications of addiction as listed below:
    - to test for nicotinine level (to test if you have smoked cigarettes)
        - to test for drugs of addiction (such as Methamphetamine, Cocaine, Cannabinoids, Opiates, Phencyclidine, Barbiturates, Benzodiazepines, Methadone, and Amphetamine). This is a study requirement and the results will remain confidential. The tests may reveal that you have previously used illegal medications. That information will be stored in a re-identified (or coded) format. If the Centre for Clinical Studies is required to disclose that information, it may be used against you in legal proceedings or otherwise. If you test positive for any of these substances, you will be excluded from further participation in this study.

- Your **vital signs** such as blood pressure, pulse rate and oral body temperature will be measured.
- You will have a full **physical examination** (PE), your height and weight will be measured to determine your body mass index (BMI).
- You will have **electrocardiograms** (ECG) (recording of your heart's electrical activity and rhythm).
- **Blood sample** (approximately 25mL / 5 teaspoons) will be collected for general safety assessemnts and to screen for HIV (AIDS virus), and hepatitis B and C. This is because the study doctors need to know about your general health and the health of your immune system. You will have to be fasting 8 hours for screening blood collection.
    - You will receive information and counselling before the HIV and hepatitis tests. If a test shows you have HIV or hepatitis you will not be included in this study, but you will have follow-up counselling and medical advice. If your test results are positive, the researchers are required by law to notify the Victorian government. Signing the consent form means you agree to have this testing. It will not be done without your consent.
- **Pregnancy Test:** from your blood sample, a pregnancy test will be performed.
- **Chest x-ray:** you will have a chest x-ray at a local clinic since the LSALT peptide could affect your lungs. You will be provided with details about where to go for this assessment when appropriate.

If for any reason, the trial is found to not be suitable for you, staff from the Centre for Clinical Studies will contact you and provide follow-up treatment advice where applicable.

Treatment and Follow-up Period

If you are eligible to enter the study, you will be admitted to the clinical unit the day before the planned dosing day. You will undergo a number of procedures to confirm your suitability for participation in the trial (see table below).

You will be required to stay in the clinical unit for 2 consecutive nights and discharged home on Day 2.

To ensure sufficient number of participants are available for dosing, additional volunteers called 'alternates' will be recruited and admitted to the clinical unit. If you are an alternate, you may be asked to participate in the study if someone is not included in the dosing group. You will be informed if you are an alternate before treatment is given.

The study drug will be administered as an IV infusion over a period of approximately 2 hours, or as determined by the PI and the safety monitoring committee.

On the morning following your first day in the clinical unit, a cannula will be inserted into a vein in your arm. This is a small, flexible tube which will allow blood to be collected easily throughout your unit stay and prevents the need for repeated needles to be inserted in your vein to collect each sample. The location of the cannula may need to be repositioned if required.

During the occasions that you are required to stay overnight, you will be provided meals. You will need to have fasted from all food and drink except water for at least 8 hours before providing blood samples.

You will undergo the following procedures at various time points during the study, the table of assessments below outlines when these events will take place:

- **Vital signs**: Oral temperature, pulse rate and blood pressure will be measured.
- **12-Lead Electrocardiogram (ECG):** will be performed to assess your heart rhythm.
- **Physical Examination:** will be performed to assess your general health. This will include measuring your body weight.

- **Safety blood and urine samples:** approximately 25 ml (approx. 4 teaspoons) of blood and a urine sample will be collected to assess your general health. When you check in, the urine sample will also be collected to test for drugs of addiction and to test if you have smoked. A positive test will exclude you from further participation in the trial. A pregnancy test will also be performed from your urine sample a number of times during the study.
- **Alcohol breath test:** You will undergo an alcohol breath test when you check into the clinical unit to see if you have been drinking any alcohol in the past 24 hours. A positive test will exclude you from further participation in the trial.
- **Study drug administration:** The study drug will be administered as an IV infusion over approximately 2 hours.
- **Pharmacokinetic (PK) samples**: will be collected to measure the amount of LSALT peptide in your blood, the break down products and to assess the effect it has on your body. Approximately 5 mL of blood (approx. 1 teaspoon) will be collected at various time points during a study visit.
- **Concomitant Medication review:** you will be asked if you have recently taken any medications.
- **Adverse Events:** You will be asked about how you are feeling (whether you feel alright, different from normal or unwell) at regular intervals, please tell a study team member if you have any changes in your health or concerns.

You will be discharged from the clinical unit once all study procedures are complete and the clinical staff sees no changes in your health which would prevent your discharge from the clinical unit.

Follow up visits

Following discharge on Day 2, you will be required to attend the Centre for Clinical Studies on two separate occasions, Day 4, and 7.

The study doctor will ask you to return to the research unit on these days and may ask you to return after this period, if he feels it is necessary. In the event it is necessary to further evaluate the safety or effects of the medication, it may be necessary to have access to additional information about your health status. Your study doctor may attempt to obtain study-related information about your health from you or from other sources, including your primary care physician. This may include contacting you again by phone or letter.

The table below outlines the assessments that will be performed during Part 2 (Single Ascending Dose) cohort of the study:

Study Day	Screen -29 to -2	-1	1	2	4	7
In patient period		X	X			
Informed consent	X					
Vital signs	X	X	X	X	X	X
Physical Exam	X	X		X	X	X
Alcohol Breath Test/drug screen	X	X				
Urinalysis	X	X				X
Complete blood count (CBC)	X	X		X		X
Chemistry	X	X		X		X
Creatine/eGFR	X	X		X		X
LFTs- Liver function test (blood sample)	X	X		X		X
PK			X	X	X	X
INR/PTT blood sample for (blood clotting ability)	X			X		
Chest X-ray	X					X
Electrocardiogram ECG	X	X	X	X	X	X
B-hCG blood sample for pregnancy test	X	X				X
Adverse Event	X	X	X	X	X	X
LSALT Administration			X			
Discharge from unit				X		
Follow up					X	X

Key; LFT= liver function tests. PK= pharmacokinetic, INR/PTT=blood clotting ability, B-hCG= pregnancy test

4. What do I have to do?

It is important for your own safety that you inform the study doctor or staff of your complete medical history and all medications, supplements, and/or herbal preparations that you have taken within the past 6 months or are currently taking. If you have any health problems, please notify your study doctor immediately. As mentioned earlier in this document, if you notice any changes in your health or have concerns during your participation in the study, also inform your study doctor or study staff as soon as possible. So long as you continue to participate, you should take the study drug as directed. You must always follow the instructions of the study doctor and staff.

Please note that in the days leading up to your admission to the clinical unit, there are a few things you must avoid to be included in the study:

- You should not have participated in other clinical trials within 1 month before signing this consent form.
- You should not have donated blood within 60 days before admission into the unit.
- You will be asked to come to the Centre for Clinical Studies in fasting condition (no consumption of any food or drinks, with the exception of water, during the 8 hours prior to arrival), at admission to the clinical unit and at the follow-up visit. During your stay in the clinical unit, you should follow the instructions of the study staff concerning your intake of food and beverages
- Please do not take any prescription medication for 2 weeks prior to your admission to the clinical unit.
- Please do not take any over the counter medication for 7 days prior to admission. Occasional use of paracetamol or ibuprofen (up to 1000 mg and 400 mg/day respectively) are acceptable. Routine vitamins and supplements are permissible at the discretion of the investigator. Please ask if you have any questions.
- Social and light smokers (up to 10 cigarettes per day) are allowed to enter the study, however they must agree and be able to abstain from smoking for the full inpatient period.
- Please do not consume any caffeine, quinine (tonic water) and xanthine containing beverages (tea, coffee, cola, chocolate) for 48 hours prior to your screening appointment and 48 hours prior to your admission to the clinical unit. Consumption of quinine, caffeine and xanthine containing beverages is not allowed throughout the clinical stay. Please ask your study doctor if you have any questions regarding the above restrictions.
- Please do not consume alcohol for 48 hours prior to your admission to the clinical unit until after your final visit.
- Please do not perform any strenuous exercise for 2 days prior to your admission to the clinical unit and until after your final visit.
- You should not have donated blood in the 2 months prior to starting the study and should refrain from donating blood during the study and within 2 months after your final visit. If you donate blood after this period, you must inform donor centre staff that you have recently been involved in a clinical study.

Please note that you will not be allowed to smoke while at the study centre.

In case of emergency, you must be easily contactable by phone and/or email. You will be given a Participant Wallet Card which contains emergency contact information and information about your study commitments. You must carry the Participant Wallet Card with you at all times until the end of the study.

5. Other relevant information about the research study

This study is being conducted at the Centre for Clinical Studies in Australia. There are no researchers from other organisations working in collaboration.

A representative of Arch Biopartners Inc (study sponsor) may be present for inspections in the unit during the study.

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

Participation in any research study is voluntary. If you do not wish to take part, you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time without providing any reason. Your study doctor may ask you the reason for your withdrawal, you can answer or not.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the Centre for Clinical Studies and will not involve any penalty or loss of benefits to which you would be otherwise entitled. Should you withdraw from the study before the final visit you may receive a partial payment according to the number of visits you have attended.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research study. You can ask for any information you want. Sign the Consent Form only if you agree to participate and only after you have had a chance to ask your questions and have received satisfactory answers.

7. What are the alternatives to participation?

Since this study is intended only to evaluate the safety, tolerability and pharmacokinetics of LSALT peptide, your alternative to be a volunteer in this study is to choose not to participate in the study.

8. What are the possible benefits of taking part?

If you agree to take part in this study, there will be no direct benefit to you. However, your participation in this study may help develop important scientific knowledge that could contribute to the development of this medication for kidney diseases. We hope the information learned from this study will benefit others in the future.

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

LSALT peptide is an experimental medication, therefore the risks to human participants have not been fully evaluated.

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with a study doctor. Your doctor and study staff will also be watching you closely for side effects.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your doctor may need to stop your treatment. Tell your study doctor or site staff if you notice any changes in your health or have concerns. Your study doctor will discuss the best way of managing any side effects with you.

There may also be side effects that are not expected or are not known that may be serious. Tell your doctor immediately about any new or unusual symptoms or changes in your health that you become aware of. The treatment of the side effects will depend on the type and severity of the symptom(s).

If during screening or participation in this research study a previously unknown medical condition is discovered the study doctor will discuss:

- whether you are eligible for study participation
- if you require referral to your usual physician or to a specialist

Risks of Study Drug:

Currently, the risks of LSALT peptide in humans are unknown. There may be side effects related to the infusion of the drug such as lightheadedness, nausea or an allergic reaction. In animals, these infusion related side effects were easily treated with anti-histamines. However, the drug will be given at much lower doses than the amount administered to animals, and will be infused very slowly to minimize these side effects.There is also a small risk that you may develop antibodies against the the LSALT peptide which may cause some medical problems, especially if you were to receive the drug again in the future.

Blood Draw/ Cannula Insertion Risks:

You may have pain or bruising at the site where blood is drawn or a cannula (a temporary small plastic tube) is inserted. An infection at the site of blood draws or cannula insertion is also possible. The insertion of the cannula (small plastic tube) or the drawing of blood may be associated with some pain. Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising or bleeding at the site of puncture. These will normally disappear a few days after the procedure.

Blood Pressure Measurement Risks:

There is no risk to your health when having your blood pressure tested. You may experience some feeling on discomfort as the cuff inflates and squeezes your arm, but it should only last a few seconds. Sometimes, there are tiny red spots that appear after the test just below the location of the cuff, they should be painless.

Electrocardiogram (ECG) risks:

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If there is hair in the area where patches need to be applied, this area will be shaved in order to complete the ECG. Shaving may result in irritation.

Risks of Chest X-ray (Radiation Risk)

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.04 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

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

You will be required to provide this information to researchers of any future research projects involving exposure to radiation.

Allergic Reaction Risks:

There is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death.

Symptoms may include difficulty in breathing, dizziness, itching, swelling of the lips, tongue or throat, coughing, rash.

In general, most symptoms are manageable. They are mild to moderate in severity. But life-threatening reactions may occur at any drug dose. If you believe you are having a serious allergic reaction, you should seek emergency medical assistance immediately.

Please notify the study doctor immediately if you experience any of these symptoms. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

You will be monitored very carefully for any signs or symptoms that you may be having an allergic reaction and appropriate care will be taken by the study doctor and nursing staff.

If you do not understand what some of these side effects or risks mean, ask the study doctor or the study staff to explain them to you.

Pregnancy Risk:

The risks of the study drug to an unborn child or nursing infant are unknown and may be hazardous. It is important that you use the appropriate forms of birth control as described below:
If you are male, you must be either vasectomised, sexually abstinent (when this is in line with your preferred and usual lifestyle) or agree to use a condom. If you use a condom and your partner is of childbearing potential, she must use another method of contraception resulting in a highly effective method of birth control for the full duration of the study and for 3 months after the last dose of study drug.

If you are female and of childbearing potential, you must also use a double barrier method of contraception for at least 90 days after the last dose of study drug.

Double barrier contraception is defined as a condom AND one of the following;

- Birth control pills (The Pill)
- Birth Control Patch (e.g. Ortho Evra)
- NuvaRing®
- Depot or injectable birth control
- IUD (Intra Uterine Device)
- Documented evidence of surgical sterilization at least 6 months prior to screening visit, i.e., tubal ligation or hysterectomy for women or vasectomy for men.

Please ask you study doctor if you have any questions regarding the forms of birth control that must be used while participating in this study.

If you are male, you must not donate sperm for at least 90 days after last dose of study drug.

If you/your partner becomes pregnant during the study or up to 90 days after the last dose of study drug, please tell your study doctor or staff immediately as we would like to request permission to follow this pregnancy and its outcome. The study doctor will also report the pregnancy to the Human Research Ethics Committee and to the study Sponsor.

Allowing the pregnancy and outcome to be followed is optional. If your partner agrees to have this pregnancy followed, then she will be asked to sign a separate Pregnancy Follow-Up Participant Information and Consent Form. The information collected is similar to that which would be routinely collected during a typical pregnancy consultation. The consultation will be done in person at the Centre for Clinical Studies, and/or by telephone.

In addition, she will be asked to notify the study doctor about the outcome of the pregnancy. If she forgets, she will be contacted to obtain this information. This outcome data collected includes: pregnancy complications and outcome, birth weight, birth defects (if any), and additional factors that may have had an impact on the outcome of the pregnancy (drugs, infections, family history etc.).

The study doctor may also need to contact the gynecologist of your partner.

10. What will happen to my test samples?

By consenting to take part in this study, you also consent to the collection and testing of your urine and blood samples for this research. The total volume of blood taken for the entire study is approximately 170ml (approx. 1/2 cup). For comparison, a standard blood donation is approximately 470mL (approx. 2 cups). Additional blood samples may also be collected for safety reasons.

The blood and urine samples collected for the assessment of your health status (e.g. liver and kidney function tests) will be processed by a local pathology laboratory. These samples will be labelled with your unique study participant number, your initials and date of birth, and will not contain any information that can identify you personally. These samples will be destroyed following analysis.

This research project involves the collection of information about your use of drugs and alcohol. Participation in the research project includes blood and urine analysis to determine the presence of drugs such as amphetamines, methamphetamines, benzodiazepines, barbiturates, marijuana, cocaine, PCP, methadone, opioids (narcotics). The test may reveal that you have previously used illegal drugs. That information will be stored in a re-identifiable (or coded) format. This is a study requirement and the results will remain confidential. In the event that the Centre for Clinical Studies is required to disclose that information, it may be used against you in legal proceedings or otherwise. If you test positive for any drugs of addiction, you will not be able to participate in this study.

You will receive information and counselling before the HIV and hepatitis tests. If a test shows you have HIV or hepatitis you will not be included in this study, but you will have follow-up counselling and medical advice. If your test results are positive, the researchers are required by law to notify the Victorian government. Signing the consent form means you agree to have this testing. It will not be done without your consent.

Blood samples taken for pharmacokinetics will be sent to various Sponsor-approved laboratories in Canada. These samples will be labelled with your unique study participant number and will not contain any information that can identify you personally. These samples will be stored during the study at a secure premise and the samples will be destroyed following analysis at the end of the study.

11. What if new information arises during this research study?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research study. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research study you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research study. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

12. Can I have other treatments during this research study?

Whilst you are participating in this research study, you are not able to take any medications or treatments other than those agreed upon at the start of your participation in the study. It is important to tell your study doctor and the study staff, at each clinic visit, about any treatments or medications you may have taken, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

13. What if I withdraw from this research study?

If you decide to withdraw from the study, please notify your study doctor or staff before you withdraw. This notice will allow the study doctor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research study, any information collected on you up to the point of withdrawal will be used. Data collected after your withdrawal, if any, may be used:

• If you decide to withdraw from the study, any adverse event not resolved at this time will be followed until its resolution by your research doctor to ensure your medical follow-up. You may also contact your research doctor if you experience a new adverse event.

• If you withdraw from the study for a reason other than your own decision, your research doctor may contact you to request any relevant information and / or documentation regarding your medical care.

• If you withdraw your consent, all your biological sample(s) will be destroyed without disclosing your identity. If analysis is required for the study, it will be analysed before destroying your samples.

14. Could this research be stopped unexpectedly?

This research study may be stopped unexpectedly for the reasons listed below.

- Unacceptable side effects
- The drug being shown not to be safe
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities
- If you don’t follow the instructions of the clinical unit staff; or
- If the study doctor decides it is in the best interest of your health and welfare to stop.

15. What will happen when the research study ends?

The study drug will not be available to you following completion of participation.

The study data will be analysed, and a final report provided to the study doctor, who will share the results with you when requested. The disclosure and/or any published results will be available to you when requested. It is usual for a number of years to elapse before definitive results of this type of study are available. These may be published in medical journals that are available to the public. You should feel free to ask the study staff about this.

Part 2 - How is this study being conducted?

16. What will happen to information about me?

Any information and data obtained/retained in connection with this research study that can identify you will remain confidential and will only be used for the purpose of this research study and future research related to the pathway being studied and related disease conditions.

Information about you may be obtained from your health records held at other health services for the purpose of this research. By signing the consent form you agree to the study team, including Sponsor delegates, accessing health records if they are relevant to your participation in this research study to ensure data accuracy. Whilst every effort will be made to keep your personal information confidential, the data gathered for this study will also be reviewed by a Sponsor delegate. This delegate will have access to your medical records, without violating your confidentiality to the extent permitted by local laws and regulations, to verify the data are correct and complete.

The data collected as part of this research study may be reviewed by representatives of the international sponsor, Arch Biopartners Inc, its affiliated companies and/or subcontractors, the local sponsor, Arch Clinical Pty Ltd, the Research Ethics Committee of Alfred HREC, by authorised representatives of the Australian Therapeutic Goods Administration or other regulatory agencies. Information may be transferred to parties in countries (and regions) other than Australia including the US, and Europe for these purposes. Syneos Health, Arch Biopartners Inc representatives, collaborators and contracted agencies comply with internal procedures to protect personal information even in countries whose data privacy laws are less strict than those of this country. In all cases when dealing with your personal (coded) information. Arch Biopartners Inc, and any of their agents will comply with the Privacy Act 1988. If you have any concerns on how your information is handled, please feel free to ask a member of the study team for more information.

By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Study Medical Records

Data from your study medical record will be identifiable and stored in secured offices at the Centre for Clinical Studies. Only research team members and authorised representatives from the Sponsor, the Ethics Committee or regulatory agencies will have access to your medical records.

You have a right to access and request correction to your information.

Case Report Form (CRF)

Information you provide us will be recorded in electronic case report forms (CRF). Your information will be coded by your unique study number, your gender and birth date only and

thus will be considered re-identifiable. The recorded data will be kept in an electronic database which will be managed throughout the study by Syneos Health who are monitoring the study. Information from these CRFs will form part of the study results, which may be published. A copy of the CRF entries and your deidentified study medical record will be kept indefinitely with all other study related documents.

By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Publications

A report of the study results may be submitted for publication. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you want to know more about the Centre for Clinical Studies' approach to privacy or access any of your information held by the Centre for Clinical Studies, you can contact Dr Ben Snyder at the Centre for Clinical Studies.

It is desirable that your local doctor be advised of your decision to participate in this research study. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research study.

Information about your participation in this research study may be recorded in your health records.

17. Complaints and compensation

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

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

- The pharmaceutical industry has set up a compensation process, with which the local sponsor of this research study, Arch Biopartners Inc, has agreed to comply. Details of this process and conditions are set out in the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and if so, how much. The research staff will give you a copy of the Guidelines together with this Participant Information and Consent Form. If you have any questions about the Guidelines, please contact Dr Ben Snyder on 03 8593 9800.
- You may be able to seek compensation through the courts.

If you are not satisfied with how your personal information has been handled (as laid out in the Privacy Act, 1988), then you can make a complaint to the Office of the Australian Information Commissioner (OAIC). It is free to lodge a complaint and you do not need a lawyer,

however if you do decide to hire a lawyer, you must pay for the lawyer yourself. You can choose to withdraw your complaint at any time. Please refer to http://www.oaic.gov.au/privacy/privacy-complaints for more information.

18 Who is organising and funding the research?

This research is being conducted by Arch Biopartners Inc based in Canada and in Australia by Arch Clinical Pty Ltd. The Clinical Research Organisation monitoring the study is Syneos Health. Arch Biopartners Inc may benefit financially from this research study if, for example, the study assists to obtain approval for a new drug.

By taking part in this research study you agree that samples of your blood (or data generated from analysis of these materials) may be provided to Arch Biopartners Inc.

Arch Biopartners Inc may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

If knowledge acquired through this research leads to discoveries that are of commercial value to Arch Biopartners Inc, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Arch Biopartners Inc, other researchers, or research companies may patent or sell discoveries that result from this research. Neither Arch Biopartners Inc nor the study doctor will compensate you if this happens.

Contractors engaged by Arch Biopartners Inc will receive a payment from Arch Biopartners Inc for undertaking this research study.

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

19. Will I be reimbursed to take part in this research study?

If you are eligible to enter the study, you will be reimbursed $75.00 for the screening and follow-up visits, and at an hourly rate of $12.50 per hour for the in-clinic stay part of this study. The total payment for participants who complete the entire study will be $975.00.

Regardless of whether you withdraw early or complete the study, you will be reimbursed within 10 business days of the end of study visit via electronic funds transfer directly into your bank account. Should you withdraw from the study before the final visit you will receive a partial payment according to the number of visits you have attended.

Reimbursement compensates for your time, travel expenses, parking and inconvenience. This reimbursement is not made for undergoing risk nor is it to compensate you for any loss of earnings as a result of your participation.

It is not anticipated that participation in this research study will result in any additional cost to you.

20. Who has reviewed the research study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC) who make sure that the rights, safety and well-being of participants in a study are protected. The ethical aspects of this research study have been approved by The Alfred Ethics Committee.

This study will be carried out according to the National Statement on Ethical Conduct in Human Research (March 2007) produced by the National Health and Medical Research Council of

Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

21. Further information and who to contact

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

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the principal study doctor (Dr Ben Snyder) on 03 8593 9800 or any of the following:

General Enquiries: 1800 243 733

After hours contact (Centre for Clinical Studies) 24 hours 7 days a week

On-call mobile: 0429 353 069

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

Complaints contact person

Position	Complaints
Email	complaintsofficer@nucleusnetwork.com.au

Privacy contact person

Position	Privacy Officer
Email	privacyofficer@nucleusnetwork.com.au

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

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Alfred Hospital Ethics Committee
Position	Governance Officer, Ethics and Research Governance, Alfred Health
Telephone	(03) 9076 3619
Email	research@alfred.org.au

Please reference the following Alfred Project number: 64/19

CONSENT

Alfred Project Number:	64/19
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT peptide in healthy participants
Protocol Number:	AB001
Test Drug Code:	LSALT peptide
International Sponsor:	Arch Biopartners Inc
Local Sponsor:	Arch Clinical Pty Ltd
Principal Investigator:	Dr Ben Snyder
Location:	Centre for Clinical Studies

- I am 18 years of age or over
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received. I have been given the name of a person to contact if I have any questions during the study.
- 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 to reveal my identity.
- I understand the purposes, procedures and risks of the research described for this study.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Centre for Clinical Studies for the purposes of this study. I understand that such information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any stage during the study without prejudice to future treatment. If I 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 understand that I will be given a signed copy of this document to keep.

Participant's Name (printed) ……Middle Initial..……Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

Witness (only if required)

Name of Witness to Participants signature (printed) ……Middle Initial…..…Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

* 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.

Declaration by Study Doctor/Senior Researcher

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

Study Doctor/Researcher's Name (printed) ……Middle Initial……..Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

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

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

FORM FOR WITHDRAWAL OF PARTICIPATION

Alfred Project Number:	64/19	Protocol Number:	AB001
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT peptide in healthy participants		
Test Drug Code:	LSALT peptide		
International Sponsor:	Arch Biopartners Inc		
Local Sponsor:	Arch Clinical Pty Ltd		
Principal Investigator:	Dr Ben Snyder	Location:	Centre for Clinical Studies

Declaration by Participant

I wish to withdraw from participation in the above research study and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the Centre for Clinical Studies.

Participant's Name (printed) …….Middle Initial…..…Surname…….....

Signature

Date _____/_____/_____ Time _____:_____

Study Doctor to include a description of the circumstances for withdrawal, if provided by the participant.

Declaration by Study Doctor

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

Study Doctor/Researcher's Name (printed) ……..……Middle Initial……..Surname…….....

Signature

Date _____/_____/_____ Time _____:_____

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

Participant Information and Consent Form - Part 3 MAD Version 2.0 dated 06-JUN-2019

Participant Information and Consent Form

Part 3- Multiple Ascending Dose (MAD) Cohort

Alfred Project Number:	64/19
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT peptide in healthy participants
Protocol Number:	AB001
Test Drug Code:	LSALT peptide
International Sponsor:	Arch Biopartners Inc
Local Sponsor:	Arch Clinical Pty Ltd
Principal Investigator:	Dr Ben Snyder
Location:	Centre for Clinical Studies

PART 1 - What does my participation involve?

1. Introduction

You are invited to take part in this research study because you are a healthy male/female aged 18-55 years old who potentially meets the study participation requirements.

This project is testing the safety, tolerability, pharmacokinetics (PK, the amount of study drug in your blood) of a single/multiple intravenous (IV) infusion (into the vein) doses of a new drug called LSALT.

This Participant Information and Consent Form (PICF) tells you about the research study. It also explains the tests and treatments that will be completed during study participation. This information is given to you to help you decide if you want to take part in this research study. Please read this information carefully and ask the study doctor questions about anything that you don't understand or want to know more about before deciding whether or not you want to take part. If you wish to do so, please take the time to talk about it with a relative, friend or your local doctor before deciding to participate.

Once you understand what the study is about and if you agree to take part in it, you will be asked to sign a Consent Form . By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research study.

Your information regarding participation in the study will be provided to your usual doctor if you opt to provide their contact details to study staff.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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

- understand the information you have read;
- consent to take part in the research study;
- consent to follow the study requirements
- consent to have the tests and treatments that are described;
- consent to follow the study requirements and to keep follow-up appointments that are described;
- consent to the use of your personal and health information as described.

A description of this clinical trial is available on www.clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results after the trial is completed. You can search this website at any time.

You will be given a signed copy of the Participant Information and Consent Form to keep.

2. What is the purpose of this research?

Arch Biopartners Inc is developing the study drug LSALT peptide as a potential new treatment for acute kidney injury. Acute kidney injury is a common disease in people who are hospitalized or undergoing major surgery. Acute kidney injury is a serious complication that increases the risk of death and other serious health problems. Thus preventing acute kidney injury is desirable and may improve the health of people at risk of this complication. Currently, there are no specific treatments to prevent acute kidney injury. The LSALT peptide is a drug that is being developed to prevent acute kidney injury in people. LSALT works to prevent immune cells entering damaged parts of the body such as the kidneys. Preventing immune cells entering these parts of the body could potentially reduce the amount of damage from insults such as blockage of the blood supply. In animal studies, the LSALT peptide has been shown to be very effective in protecting the kidney. In order to start treating kidney disease with the LSALT peptide in humans, researchers must first understand the safety profile of the drug and what happens to the drug once it is injected.

The purpose of this research is to determine the safety and behaviour of LSALT peptide in people. If the LSALT peptide is found to be safe, this will lead to future clinical trials testing the effectiveness of the drug in preventing acute kidney injury in people. This research will also lead to the design of new and improved versions of the LSALT peptide

Medications, drugs and devices must be approved for use by the Australian Federal Government; the Therapeutic Goods Administration (TGA). LSALT peptide has not been approved for marketing by the TGA in Australia (and is not yet approved anywhere else in the world). Therefore, the use of LSALT peptide in this study is experimental.

LSALT peptide has been tested in animals and found to be safe at doses much higher than planned in this study. LSALT peptide has never been tested in humans. **Although unlikely, there is a risk of death in first in human studies such as this study.**

In other studies, some unexpected serious, life-threatening side effects have occurred following the administration of new experimental treatments. It is unknown, however unlikely, whether some unexpected serious, life threatening side effects could occur with LSALT peptide. You will be monitored closely for them and treated if they occur.

This study is being conducted at the Centre for Clinical Studies at Nucleus Network Pty. Ltd., Melbourne, Australia. The Clinical Research Organisation involved in monitoring the study is Syneos Health. Arch Biopartners Inc is the international company sponsoring the study, along with Arch Clinical Pty Ltd, the Australian company .

3. What does participation in this research involve?

Before you begin the study, you will be given detailed information about LSALT peptide, the study, and any other relevant information by research staff. You are encouraged to ask questions until you are sure that you fully understand the nature of and requirements of the study.

If you decide to be assessed for inclusion in the study, you will be asked to visit the Centre for Clinical Studies for an initial assessment visit (screening visit). Before any procedures are undertaken, you will be asked to sign a consent form. You will then have some tests to check that the study is suitable for you. The screening visit may take between 1 and 2 hours.

This study will enrol approximately 52 participants into 3 parts;

- **Part 1- Low dose Cohort**- 4 participants will be dosed with a low dose of the study drug (0.01mg, 0.1mg, 0.3mg and 0.5mg), 1 dose of increasing strength for each participant. Participants will be dosed on Day 1 with a single dose of the study drug and will stay in the unit for an inpatient stay of 2 days. You are then required to return for a single follow up visit.
- **Part 2- Single Ascending dose Cohort**- 24 participants will be split into 3 cohorts (groups) of 8 and will be dosed with a single dose of the study drug (1mg, 2.5mg and 5mg) during an inpatient stay of 2 days. You are then required to return for 2 separate follow up visits
- **Part 3- Multiple Ascending dose Cohort**- 16 participants will be split in 2 cohorts (groups) of 8. Participants will be dosed with the study drug once or twice per day for 3 days with an inpatient stay of 4 nights. You are then required to return for 3 separate follow up visits.

This PICF will only outline the requirements of Part 3 of the study, the Multiple Ascending Dose cohort

This study will enrol approximately 16 participants into 2 groups (or cohorts) with 8 participants in each cohort.

There will be 2 participants from each cohort that will be given the study drug or placebo at least 24 hours before the rest of the participants; one will get the active drug and the other one will get the placebo. These 2 participants are called “sentinels”. You will be told if you are assigned to the sentinel group.

The study is placebo controlled, meaning that some participants will receive a dose containing active study drug and some will receive a dose containing placebo drug. The dose containing the placebo will look the same as the dose containing active study drug but will not contain any active ingredients in it. You will not have a choice as to whether you receive the active study drug or the placebo (you will be assigned randomly, like flipping a coin). Neither you nor the study staff will know if you are assigned to receive the active study drug or the placebo, although in an emergency, the study staff can find out.

As this is a dose escalation study, the first group enrolled will receive the lowest dose and once it is considered to be safe, the next group will be enrolled who will receive the next higher dose. Dose escalation will only proceed following review of all available safety data by the Principal Investigator in consultation with the sponsor and there is confirmation that it is safe to continue with the next higher dose strength in the next group. The study can be stopped at any time, based on evaluation of the side effects of the study medication.

The dose levels planned for the MAD cohort of the study will range from 1.0 to 10 milligrams, depending on the safety results reviewed from the previous part of the study where a safe dose will be decided. You will be informed of the exact dose for your cohort when you check in to the clinical unit (Day 1).

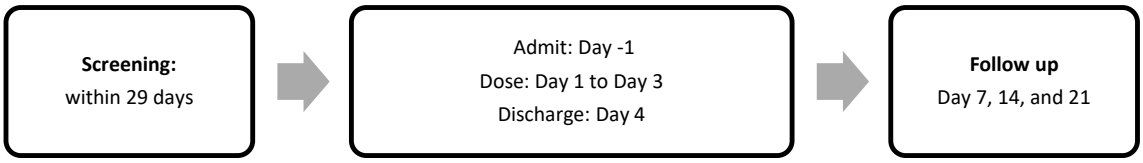
Study sequence:

Study Drug- LSALT peptide

Your total participation in the study will consist of approximately 8 weeks as follows;

- **Screening visit**: will occur within 29 days of your first dose. You will undergo assessments to determine if you are eligible for the study
- **Admission and treatment period**: you will be required to attend the study centre for a 4 night in patient stay
- **Follow up period:** you will be required to return to the study centre for 3 follow up visits

Below is a picture outlining the study schedule for the study:



If you decide to be assessed for inclusion into the study, you will be asked to visit the Centre for Clinical Studies for the screening visits. The screening visit may take between 1 and 2 hours.

Screening visit (between Day -29 to Day -2)

After reading this information sheet and if you agree to participate in the study, you will be asked to sign the attached consent form. The study doctor will perform a medical examination to ensure that it is appropriate for you to be part of the study. You will undergo the following assessments:

- You will be asked about your **current health status** and about your **medical history**, including all medications, over-the-counter and herbal medications that you have been, and are currently taking.
- You will be asked some personal details about yourself, including your date of birth.
- You will be asked about your alcohol history and you will undergo an alcohol breath test.
- You will be asked to provide a **urine sample** to assess your general healthy and to test for medications of addiction as listed below:
    - to test for nicotinine level (to test if you have smoked cigarettes)
    - to test for drugs of addiction (such as Methamphetamine, Cocaine, Cannabinoids, Opiates, Phencyclidine, Barbiturates, Benzodiazepines, Methadone, and Amphetamine). This is a study requirement and the results will remain confidential. The tests may reveal that you have previously used illegal medications. That information will be stored in a re-identified (or coded) format. If the Centre for Clinical Studies is required to disclose that information, it may be used against you in legal proceedings or otherwise. If you test positive for any of these substances, you will be excluded from further participation in this study.
- Your **vital signs** such as blood pressure, pulse rate and oral body temperature will be measured.
- You will have a full **physical examination** (PE), your height and weight will be measured to determine your body mass index (BMI).
- You will have **electrocardiograms** (ECG) (recording of your heart's electrical activity and rhythm).
- **Blood sample** (approximately 25mL / 5 teaspoons) will be collected for general safety assessemnts and to screen for HIV (AIDS virus), and hepatitis B and C. This is because the study doctors need to know about your general health and the health of your immune system. You will have to be fasting 8 hours for screening blood collection.

    - You will receive information and counselling before the HIV and hepatitis tests. If a test shows you have HIV or hepatitis you will not be included in this study, but you will have follow-up counselling and medical advice. If your test results are positive, the researchers are required by law to notify the Victorian government. Signing the consent form means you agree to have this testing. It will not be done without your consent.

- **Pregnancy Test:** from your blood sample, a pregnancy test will be performed.
- **Chest x-ray:** you will have a chest x-ray at a local clinic since the LSALT peptide could affect your lungs. You will be provided with details about where to go for this assessment when appropriate.

If for any reason, the trial is found to not be suitable for you, staff from the Centre for Clinical Studies will contact you and provide follow-up treatment advice where applicable.

Treatment and Follow-up Period

If you are eligible to enter the study, you will be admitted to the clinical unit the day before the planned dosing day. You will undergo a number of procedures to confirm your suitability for participation in the trial (see table below).

You will be required to stay in the clinical unit for 4 consecutive nights and discharged home on Day 4. You will receive the experimental drug on Days 1, 2 and 3.

To ensure sufficient number of participants are available for dosing, additional volunteers called 'alternates' will be recruited and admitted to the clinical unit. If you are an alternate, you may be asked to participate in the study if someone is not included in the dosing group. You will be informed if you are an alternate on Day 1 before treatment is given.

The study drug will be administered as an IV infusion over a period of approximately 2 hours, or as determined by the PI and the safety monitoring committee.

On the morning following your first day in the clinical unit, a cannula will be inserted into a vein in your arm. This is a small, flexible tube which will allow blood to be collected easily throughout your unit stay and prevents the need for repeated needles to be inserted in your vein to collect each sample. The location of the cannula may need to be repositioned if required.

During the occasions that you are required to stay overnight, you will be provided meals. You will need to have fasted from all food and drink except water for at least 8 hours before providing blood samples.

You will undergo the following procedures at various time points during the study, the table of assessments below outlines when these events will take place:

- **Vital signs**: Oral temperature, pulse rate and blood pressure will be measured.
- **12-Lead Electrocardiogram (ECG):** will be performed to assess your heart rhythm.
- **Physical Examination:** will be performed to assess your general health. This will include measuring your body weight.
- **Safety blood and urine samples:** approximately 25 ml (approx. 3 teaspoons) of blood and a urine sample will be collected to assess your general health. When you check in, the urine sample will also be collected to test for drugs of addiction and to test if you have smoked. A positive test will exclude you from further participation in the trial. A pregnancy test will also be performed from your urine sample a number of times during the study.
- **Alcohol breath test:** You will undergo an alcohol breath test when you check into the clinical unit to see if you have been drinking any alcohol in the past 24 hours. A positive test will exclude you from further participation in the trial.
- **Study drug administration:** The study drug will be administered as an IV infusion over approximately 2 hours on Days 1, 2 and 3.

- **Pharmacokinetic (PK) samples**: will be collected to measure the amount of LSALT peptide in your blood, the break down products and to assess the effect it has on your body. Approximately 5 mL of blood (approx. 1 teaspoon) will be collected at various time points during a study visit.
- **Concomitant Medication review:** you will be asked if you have recently taken any medications.
- **Adverse Events:** You will be asked about how you are feeling (whether you feel alright, different from normal or unwell) at regular intervals, please tell a study team member if you have any changes in your health or concerns.

You will be discharged from the clinical unit once all study procedures are complete and the clinical staff sees no changes in your health which would prevent your discharge from the clinical unit.

Follow up visits

Following discharge on Day 4, you will be required to attend the Centre for Clinical Studies on three separate occasions, Day 7, 14, and 21.

The study doctor will ask you to return to the research unit on these days and may ask you to return after this period, if he feels it is necessary. In the event it is necessary to further evaluate the safety or effects of the medication, it may be necessary to have access to additional information about your health status. Your study doctor may attempt to obtain study-related information about your health from you or from other sources, including your primary care physician. This may include contacting you again by phone or letter.

The table below outlines the assessments that will be performed during part 3 (Multiple Ascending Dose) cohort of the study:

Study Day	Screening -29 to -2	-1	1	2	3	4	7	14	21
In patient period		X	X	X	X				
Informed consent	X								
Vital signs	X	X	X	X	X	X	X	X	X
Physical Examination	X	X		X	X	X	X	X	X
Alcohol Breath Test	X	X							
Drugs of Abuse urine sample	X	X							
Urinalysis	X	X		X		X	X	X	X
Complete blood count (CBC)	X	X		X		X	X	X	X
Chemistry	X	X		X		X	X	X	X
Creatinine/eGFR	X	X		X		X	X	X	X
LFTs- Liver function test (blood sample)	X	X		X		X	X	X	X
PK			X	X	X	X	X		
INR/PTT blood sample for (blood clotting ability)	X			X		X	X		
Chest X-ray	X					X			
Electrocardiogram ECG	X	X	X	X	X	X			X
B-hCG (blood sample for pregnancy test)	X	X							X
Adverse Event	X		X	X	X	X	X	X	X
Anti-Drug Antibodies								X	
LSALT Administration			X	X	X				
Discharge from unit						X			
Follow up							X	X	X

Key; LFT= liver function tests. PK= pharmacokinetic, INR/PTT=blood clotting ability, B-hCG= pregnancy test

4. What do I have to do?

It is important for your own safety that you inform the study doctor or staff of your complete medical history and all medications, supplements, and/or herbal preparations that you have taken within the past 6 months or are currently taking. If you have any health problems, please notify your study doctor immediately. As mentioned earlier in this document, if you notice any changes in your health or have concerns during your participation in the study, also inform your study doctor or study staff as soon as possible. So long as you continue to participate, you should take the study drug as directed. You must always follow the instructions of the study doctor and staff.

Please note that in the days leading up to your admission to the clinical unit, there are a few things you must avoid to be included in the study:

- You should not have participated in other clinical trials within 1 month before signing this consent form.
- You should not have donated blood within 60 days before admission into the unit.
- You will be asked to come to the Centre for Clinical Studies in fasting condition (no consumption of any food or drinks, with the exception of water, during the 8 hours prior to arrival), at admission to the clinical unit and at the follow-up visit. During your stay in the clinical unit, you should follow the instructions of the study staff concerning your intake of food and beverages.
- Please do not take any prescription medication for 2 weeks prior to your admission to the clinical unit.
- Please do not take any over the counter medication for 7 days prior to admission. Occasional use of paracetamol or ibuprofen (up to 1000 mg and 400 mg/day respectively) are acceptable. Routine vitamins and supplements are permissible at the discretion of the investigator. Please ask if you have any questions.
- Social and light smokers (up to 10 cigarettes per day) are allowed to enter the study, however they must agree and be able to abstain from smoking for the full inpatient period.
- Please do not consume any caffeine, quinine (tonic water) and xanthine containing beverages (tea, coffee, cola, chocolate) for 48 hours prior to your screening appointment and 48 hours prior to your admission to the clinical unit. Consumption of quinine, caffeine and xanthine containing beverages is not allowed throughout the clinical stay. Please ask your study doctor if you have any questions regarding the above restrictions.
- Please do not consume alcohol for 48 hours prior to your admission to the clinical unit until after your final visit.
- Please do not perform any strenuous exercise for 2 days prior to your admission to the clinical unit and until after your final visit.
- You should not have donated blood in the 2 months prior to starting the study and should refrain from donating blood during the study and within 2 months after your final visit. If you donate blood after this period, you must inform donor centre staff that you have recently been involved in a clinical study.

Please note that you will not be allowed to smoke while at the study centre.

In case of emergency, you must be easily contactable by phone and/or email. You will be given a Participant Wallet Card which contains emergency contact information and information about your study commitments. You must carry the Participant Wallet Card with you at all times until the end of the study.

5. Other relevant information about the research study

This study is being conducted at the Centre for Clinical Studies in Australia. There are no researchers from other organisations working in collaboration.

A representative of Arch Biopartners Inc (study sponsor) may be present for inspections in the unit during the study.

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

Participation in any research study is voluntary. If you do not wish to take part, you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time without providing any reason. Your study doctor may ask you the reason for your withdrawal, you can answer or not.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the Centre for Clinical Studies and will not involve any penalty or loss of benefits to which you would be otherwise entitled. Should you withdraw from the study before the final visit you may receive a partial payment according to the number of visits you have attended.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research study. You can ask for any information you want. Sign the Consent Form only if you agree to participate and only after you have had a chance to ask your questions and have received satisfactory answers.

7. What are the alternatives to participation?

Since this study is intended only to evaluate the safety, tolerability and pharmacokinetics of LSALT peptide, your alternative to be a volunteer in this study is to choose not to participate in the study.

8. What are the possible benefits of taking part?

If you agree to take part in this study, there will be no direct benefit to you. However, your participation in this study may help develop important scientific knowledge that could contribute to the development of this medication for kidney diseases. We hope the information learned from this study will benefit others in the future.

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

LSALT peptide is an experimental medication, therefore the risks to human participants have not been fully evaluated.

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with a study doctor. Your doctor and study staff will also be watching you closely for side effects.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your doctor may need to stop your treatment. Tell your study doctor or site staff if you notice any changes in your health or have concerns. Your study doctor will discuss the best way of managing any side effects with you.

There may also be side effects that are not expected or are not known that may be serious. Tell your doctor immediately about any new or unusual symptoms or changes in your health that you become aware of. The treatment of the side effects will depend on the type and severity of the symptom(s).

If during screening or participation in this research study a previously unknown medical condition is discovered the study doctor will discuss:

- whether you are eligible for study participation
- if you require referral to your usual physician or to a specialist

Risks of Study Drug:

Currently, the risks of LSALT peptide in humans are unknown. There may be side effects related to the infusion of the drug such as lightheadedness, nausea or an allergic reaction. In animals, these infusion related side effects were easily treated with anti-histamines. However, the drug will be given at much lower doses than the amount administered to animals, and will be infused very slowly to minimize these side effects.There is also a small risk that you may develop antibodies against the the LSALT peptide which may cause some medical problems, especially if you were to receive the drug again in the future.

Blood Draw/ Cannula Insertion Risks:

You may have pain or bruising at the site where blood is drawn or a cannula (a temporary small plastic tube) is inserted. An infection at the site of blood draws or cannula insertion is also possible. The insertion of the cannula (small plastic tube) or the drawing of blood may be associated with some pain. Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising or bleeding at the site of puncture. These will normally disappear a few days after the procedure.

Blood Pressure Measurement Risks:

There is no risk to your health when having your blood pressure tested. You may experience some feeling on discomfort as the cuff inflates and squeezes your arm, but it should only last a few seconds. Sometimes, there are tiny red spots that appear after the test just below the location of the cuff, they should be painless.

Electrocardiogram (ECG) risks:

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If there is hair in the area where patches need to be applied, this area will be shaved in order to complete the ECG. Shaving may result in irritation.

Risks of Chest X-ray (Radiation Risk)

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.04 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

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

Allergic Reaction Risks:

There is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death.

Symptoms may include difficulty in breathing, dizziness, itching, swelling of the lips, tongue or throat, coughing, rash.

In general, most symptoms are manageable. They are mild to moderate in severity. But life-threatening reactions may occur at any drug dose. If you believe you are having a serious allergic reaction, you should seek emergency medical assistance immediately.

Please notify the study doctor immediately if you experience any of these symptoms. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

You will be monitored very carefully for any signs or symptoms that you may be having an allergic reaction and appropriate care will be taken by the study doctor and nursing staff.

If you do not understand what some of these side effects or risks mean, ask the study doctor or the study staff to explain them to you.

Pregnancy Risk:

The risks of the study drug to an unborn child or nursing infant are unknown and may be hazardous. It is important that you use the appropriate forms of birth control as described below:
If you are male, you must be either vasectomised, sexually abstinent (when this is in line with your preferred and usual lifestyle) or agree to use a condom. If you use a condom and your partner is of childbearing potential, she must use another method of contraception resulting in a highly effective method of birth control for the full duration of the study and for 3 months after the last dose of study drug.

If you are female and of childbearing potential, you must also use a double barrier method of contraception for at least 90 days after the last dose of study drug.

Double barrier contraception is defined as a condom AND one of the following;

- Birth control pills (The Pill)
- Birth Control Patch (e.g. Ortho Evra)
- NuvaRing®
- Depot or injectable birth control
- IUD (Intra Uterine Device)
- Documented evidence of surgical sterilization at least 6 months prior to screening visit, i.e., tubal ligation or hysterectomy for women or vasectomy for men.

Please ask you study doctor if you have any questions regarding the forms of birth control that must be used while participating in this study.

If you are male, you must not donate sperm for at least 90 days after last dose of study drug.

If you/your partner becomes pregnant during the study or up to 90 days after the last dose of study drug please tell your study doctor or staff immediately as we would like to request

permission to follow this pregnancy and its outcome. The study doctor will also report the pregnancy to the Human Research Ethics Committee and to the study Sponsor.

Allowing the pregnancy and outcome to be followed is optional. If your partner agrees to have this pregnancy followed, then she will be asked to sign a separate Pregnancy Follow-Up Participant Information and Consent Form. The information collected is similar to that which would be routinely collected during a typical pregnancy consultation. The consultation will be done in person at the Centre for Clinical Studies, and/or by telephone.

In addition, she will be asked to notify the study doctor about the outcome of the pregnancy. If she forgets, she will be contacted to obtain this information. This outcome data collected includes: pregnancy complications and outcome, birth weight, birth defects (if any), and additional factors that may have had an impact on the outcome of the pregnancy (drugs, infections, family history etc.).

The study doctor may also need to contact the gynecologist of your partner.

10. What will happen to my test samples?

By consenting to take part in this study, you also consent to the collection and testing of your urine and blood samples for this research. The total volume of blood taken for the entire study is approximately 290ml (approx. 1 cup). For comparison, a standard blood donation is approximately 470mL (approx. 2 cups). Additional blood samples may also be collected for safety reasons.

The blood and urine samples collected for the assessment of your health status (e.g. liver and kidney function tests) will be processed by a local pathology laboratory. These samples will be labelled with your unique study participant number, your initials and date of birth, and will not contain any information that can identify you personally. These samples will be destroyed following analysis.

This research project involves the collection of information about your use of drugs and alcohol. Participation in the research project includes blood and urine analysis to determine the presence of drugs such as amphetamines, methamphetamines, benzodiazepines, barbiturates, marijuana, cocaine, PCP, methadone, opioids (narcotics). The test may reveal that you have previously used illegal drugs. That information will be stored in a re-identifiable (or coded) format. This is a study requirement and the results will remain confidential. In the event that the Centre for Clinical Studies is required to disclose that information, it may be used against you in legal proceedings or otherwise. If you test positive for any drugs of addiction, you will not be able to participate in this study.

You will receive information and counselling before the HIV and hepatitis tests. If a test shows you have HIV or hepatitis you will not be included in this study, but you will have follow-up counselling and medical advice. If your test results are positive, the researchers are required by law to notify the Victorian government. Signing the consent form means you agree to have this testing. It will not be done without your consent.

Blood samples taken for pharmacokinetics will be sent to various Sponsor-approved laboratories in Canada. These samples will be labelled with your unique study participant number and will not contain any information that can identify you personally. These samples will be stored during the study at a secure premise and the samples will be destroyed following analysis at the end of the study.

11. What if new information arises during this research study?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research study. If you decide to withdraw,

your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research study you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research study. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

12. Can I have other treatments during this research study?

Whilst you are participating in this research study, you are not able to take any medications or treatments other than those agreed upon at the start of your participation in the study. It is important to tell your study doctor and the study staff, at each clinic visit, about any treatments or medications you may have taken, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

13. What if I withdraw from this research study?

If you decide to withdraw from the study, please notify your study doctor or staff before you withdraw. This notice will allow the study doctor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research study, any information collected on you up to the point of withdrawal will be used. Data collected after your withdrawal, if any, may be used:

• If you decide to withdraw from the study, any adverse event not resolved at this time will be followed until its resolution by your research doctor to ensure your medical follow-up. You may also contact your research doctor if you experience a new adverse event.

• If you withdraw from the study for a reason other than your own decision, your research doctor may contact you to request any relevant information and / or documentation regarding your medical care.

• If you withdraw your consent, all your biological sample(s) will be destroyed without disclosing your identity. If analysis is required for the study, it will be analysed before destroying your samples.

14. Could this research be stopped unexpectedly?

This research study may be stopped unexpectedly for the reasons listed below.

- Unacceptable side effects
- The drug being shown not to be safe
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities
- If you don't follow the instructions of the clinical unit staff; or
- If the study doctor decides it is in the best interest of your health and welfare to stop.

15. What will happen when the research study ends?

The study drug will not be available to you following completion of participation.

The study data will be analysed, and a final report provided to the study doctor, who will share the results with you when requested. The disclosure and/or any published results will be

available to you when requested. It is usual for a number of years to elapse before definitive results of this type of study are available. These may be published in medical journals that are available to the public. You should feel free to ask the study staff about this.

Part 2 - How is this study being conducted?

16. What will happen to information about me?

Any information and data obtained/retained in connection with this research study that can identify you will remain confidential and will only be used for the purpose of this research study and future research related to the pathway being studied and related disease conditions.

Information about you may be obtained from your health records held at other health services for the purpose of this research. By signing the consent form you agree to the study team, including Sponsor delegates, accessing health records if they are relevant to your participation in this research study to ensure data accuracy. Whilst every effort will be made to keep your personal information confidential, the data gathered for this study will also be reviewed by a Sponsor delegate. This delegate will have access to your medical records, without violating your confidentiality to the extent permitted by local laws and regulations, to verify the data are correct and complete.

The data collected as part of this research study may be reviewed by representatives of the international sponsor, Arch Biopartners Inc, its affiliated companies and/or subcontractors, the local sponsor, Arch Clinical Pty Ltd, the Research Ethics Committee of Alfred HREC, by authorised representatives of the Australian Therapeutic Goods Administration or other regulatory agencies. Information may be transferred to parties in countries (and regions) other than Australia including the US, and Europe for these purposes. Syneos Health, Arch Biopartners Inc representatives, collaborators and contracted agencies comply with internal procedures to protect personal information even in countries whose data privacy laws are less strict than those of this country. In all cases when dealing with your personal (coded) information. Arch Biopartners Inc, and any of their agents will comply with the Privacy Act 1988. If you have any concerns on how your information is handled, please feel free to ask a member of the study team for more information.

By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Study Medical Records

Data from your study medical record will be identifiable and stored in secured offices at the Centre for Clinical Studies. Only research team members and authorised representatives from the Sponsor, the Ethics Committee or regulatory agencies will have access to your medical records.

You have a right to access and request correction to your information.

Case Report Form (CRF)

Information you provide us will be recorded in electronic case report forms (CRF). Your information will be coded by your unique study number, your gender and birth date only and thus will be considered re-identifiable. The recorded data will be kept in an electronic database which will be managed throughout the study by Syneos Health who are monitoring the study. Information from these CRFs will form part of the study results, which may be published. A copy of the CRF entries and your deidentified study medical record will be kept indefinitely with all other study related documents.

By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Publications

A report of the study results may be submitted for publication. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

If you want to know more about the Centre for Clinical Studies' approach to privacy or access any of your information held by the Centre for Clinical Studies, you can contact Dr Ben Snyder or the Centre for Clinical Studies.

It is desirable that your local doctor be advised of your decision to participate in this research study. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research study.

Information about your participation in this research study may be recorded in your health records.

17. Complaints and compensation

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

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

- The pharmaceutical industry has set up a compensation process, with which the local sponsor of this research study, Arch Biopartners Inc, has agreed to comply. Details of this process and conditions are set out in the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and if so, how much. The research staff will give you a copy of the Guidelines together with this Participant Information and Consent Form. If you have any questions about the Guidelines, please contact Dr Ben Snyder on 03 8593 9800.
- You may be able to seek compensation through the courts.

If you are not satisfied with how your personal information has been handled (as laid out in the Privacy Act, 1988), then you can make a complaint to the Office of the Australian Information Commissioner (OAIC). It is free to lodge a complaint and you do not need a lawyer, however if you do decide to hire a lawyer, you must pay for the lawyer yourself. You can choose to withdraw your complaint at any time. Please refer to http://www.oaic.gov.au/privacy/privacy-complaints for more information.

18 Who is organising and funding the research?

This research is being conducted by Arch Biopartners Inc based in Canada and in Australia by Arch Clinical Pty Ltd. The Clinical research organisation monitoring the study is Syneos Health. Arch Biopartners Inc may benefit financially from this research study if, for example, the study assists to obtain approval for a new drug.

By taking part in this research study you agree that samples of your blood (or data generated from analysis of these materials) may be provided to Arch Biopartners Inc.

Arch Biopartners Inc may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

If knowledge acquired through this research leads to discoveries that are of commercial value to Arch Biopartners Inc, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Arch Biopartners Inc, other researchers, or research companies may patent or sell discoveries that result from this research. Neither Arch Biopartners Inc nor the study doctor will compensate you if this happens.

Contractors engaged by Arch Biopartners Inc will receive a payment from Arch Biopartners Inc for undertaking this research study.

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

19. Will I be reimbursed to take part in this research study?

If you are eligible to enter the study, you will be reimbursed $75.00 for the screening and follow-up visits, and at an hourly rate of $12.50 per hour for the in-clinic stay part of this study. The total payment for participants who complete the entire study will be $1,650.

Regardless of whether you withdraw early or complete the study, you will be reimbursed within 10 business days of the end of study visit via electronic funds transfer directly into your bank account. Should you withdraw from the study before the final visit you will receive a partial payment according to the number of visits you have attended.

Reimbursement compensates for your time, travel expenses, parking and inconvenience. This reimbursement is not made for undergoing risk nor is it to compensate you for any loss of earnings as a result of your participation.

It is not anticipated that participation in this research study will result in any additional cost to you.

20. Who has reviewed the research study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC) who make sure that the rights, safety and well-being of participants in a study are protected. The ethical aspects of this research study have been approved by The Alfred Ethics Committee.

This study will be carried out according to the National Statement on Ethical Conduct in Human Research (March 2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

21. Further information and who to contact

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

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the principal study doctor (Dr Ben Snyder) on 03 8593 9800 or any of the following:

General Enquiries: **1800 243 733**

After hours contact (Centre for Clinical Studies) 24 hours 7 days a week

On-call mobile: 0429 353 069

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

Complaints contact person

Position	Complaints
Email	complaintsofficer@nucleusnetwork.com.au

Privacy contact person

Position	Privacy Officer
Email	privacyofficer@nucleusnetwork.com.au

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

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Alfred Hospital Ethics Committee
Position	Governance Officer, Ethics and Research Governance, Alfred Health
Telephone	(03) 9076 3619
Email	research@alfred.org.au

Please reference the following Alfred Project number: 64/19

CONSENT

Alfred Project Number:	64/19
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, intra-participant single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT Peptide in healthy participants
Protocol Number:	AB001
Test Drug Code:	LSALT peptide
International Sponsor:	Arch Biopartners Inc
Local Sponsor:	Arch Clinical Pty Ltd
Principal Investigator:	Dr Ben Snyder
Location:	Centre for Clinical Studies

- I am 18 years of age or over
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received. I have been given the name of a person to contact if I have any questions during the study.
- 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 to reveal my identity.
- I understand the purposes, procedures and risks of the research described for this study.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Centre for Clinical Studies for the purposes of this study. I understand that such information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any stage during the study without prejudice to future treatment. If I 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 understand that I will be given a signed copy of this document to keep.

Participant's Name (printed) ……Middle Initial..……Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

Witness (only if required)

Name of Witness to Participants signature (printed) ……Middle Initial…..…Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

* 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.

Declaration by Study Doctor/Senior Researcher

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

Study Doctor/Researcher's Name (printed) ……Middle Initial……..Surname…….…….....

Signature

Date _____/_____/_____ Time _____:_____

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

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

FORM FOR WITHDRAWAL OF PARTICIPATION

Alfred Project Number:	64/19	Protocol Number:	AB001
Full Study Title:	A phase I double-blind, placebo-controlled, randomized, intra-participant single and multiple ascending dose finding study to evaluate the safety and pharmacokinetic profile of LSALT Peptide in healthy participants		
Test Drug Code:	LSALT peptide		
International Sponsor:	Arch Biopartners Inc		
Local Sponsor:	Arch Clinical Pty Ltd		
Principal Investigator:	Dr Ben Snyder	Location:	Centre for Clinical Studies

Declaration by Participant

I wish to withdraw from participation in the above research study and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the Centre for Clinical Studies.

Participant's Name (printed) …….Middle Initial…..…Surname…….....

Signature

Date _____/_____/_____ Time _____:_____

Study Doctor to include a description of the circumstances for withdrawal, if provided by the participant.

Declaration by Study Doctor

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

Study Doctor/Researcher's Name (printed) ……..……Middle Initial……..Surname…….....

Signature

Date _____/_____/_____ Time _____:_____

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