

[INSERT LETTERHEAD]

Participant Information Sheet/Consent Form

[Insert site name]

Title	An open-label, multicentre, single-arm trial of monthly injections of extended release buprenorphine in people with opioid dependence
Short Title	CoLAB
Protocol Number	SVH No: 18/194
Project Sponsor	University of New South Wales (UNSW) Sydney
Co-ordinating Principal Investigator	Prof Michael Farrell
Location	[INSERT HOSPITAL NAME & LOCATION]

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are in opioid substitution therapy (buprenorphine) for opioid dependence; which is the term used by the World Health Organization to describe the symptoms where a person has difficulty controlling their use of opioids, and continues to use opioids despite experiencing negative consequences.

The research project is testing whether a new treatment of monthly buprenorphine injection is acceptable and effective for people with opioid dependence. The new treatment is called 'Sublocade®'.

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

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

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

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

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

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

2 What is the purpose of this research?

Sublocade® is a new form of buprenorphine administered by injection under the skin in the abdominal area. The buprenorphine is combined with a gel-like substance called ATRIGEL® so

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that it forms a small mass under the skin, which slowly releases buprenorphine into the bloodstream over at least 28 days. Studies where people have been treated with Sublocade® show that it maintains blood levels of buprenorphine that are enough to control cravings and withdrawal symptoms, and that it is well tolerated by clients, with possible side effects similar to buprenorphine taken sublingually, underneath the tongue

The purpose of this study is to evaluate how feasible and acceptable Sublocade® is for treatment of people with opioid dependence, in particular whether people continue with this treatment. Participants will be people already receiving sublingual buprenorphine, and will be asked by their doctor if they would like to have the new treatment. All participants in the study will receive treatment with Sublocade® for 12 months.

The study will assess how acceptable the new treatment is by looking at the proportion of people who continue on Sublocade® for 12 months. It will also assess the percentage of people completing 6 monthly injections. It will examine people's experience of the treatment, how people use the medication (e.g. doses used), and its impact upon substance use, health and social conditions.

Sublocade® has been recently approved by the Food and Drugs Administration (FDA) in the United States, and is currently being considered for approval by the Therapeutic Goods Administration (TGA) in Australia.

This study is sponsored by the National Drug and Alcohol Research Centre (NDARC) at the University of New South Wales (UNSW) in Sydney. The study is an investigator initiated or so called collaborative study and funding for the study (together with supply of Sublocade®) is from the pharmaceutical company Indivior Pty Ltd.

3 What does participation in this research involve?

If you agree to participate in this project, you will be asked to sign the Participant Consent Form prior to any study assessments being performed. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

If you agree to take part, your participation would be for up to 13 months. Below is an outline of the clinic visits you would be required to attend, and what would happen at the visits. There are three phases of the study: screening (seeing whether you are eligible and want to take part in the study, lasting up to a 1 month period); treatment (12 months); and follow up after the last study treatment visit (1 month). Only participants who meet all eligibility criteria assessed during screening will be able to enter the treatment phase of the study. Participants who aren't eligible for treatment can continue treatment with sublingual buprenorphine. Participants who stop study treatment for any reason before the end of the study will be asked to remain in the study and continue research assessments.

SCREENING PHASE

Your study doctor will do some assessments (history, physical and mental health examination, blood and urine tests) to see if you are eligible to enter the treatment phase of the study. You will have the following tests and procedures over one or more clinic visits within a four-week period:

- the study doctor will take a medical history from you and complete a mental health assessment over the past 12 months
- the study doctor will perform an examination (this may require you to partially undress)
- you may be asked to provide a urine sample for an urine test. This is a research sample to tests for the presence of certain drugs including opiates, amphetamines, cannabis, cocaine, oxycodone, ecstasy, fentanyl and benzodiazepines. You and the study doctor

and nurse will not receive the results from this test. The results of the urine drug test will not affect whether or not you can participate in the study.

- a pregnancy test (urine) will be done for females who can fall pregnant
- the study doctor will ask you about any medications you are using

TREATMENT PHASE

The Baseline Visit

If you meet all the requirements and want to continue in the study, you will commence treatment at the Baseline visit. This will take place within four weeks of screening assessments (when your doctor has all of your results from screening). This visit will approximately take approximately half an hour to complete.

The following assessments will be performed at the baseline visit:

- you may be asked to provide a urine sample for an urine test. This is a research sample to tests for the presence of certain drugs including amphetamines, cocaine and opiates. A positive drug test will not affect whether or not you can participate in the study.
- a pregnancy test (urine) will be done for females who can fall pregnant
- the study doctor will ask you about any illness or injury, and any medications you are taking since the last visit
- Additionally, your study doctor will assess your symptoms of opiate withdrawal
- The study doctor or nurse will administer your first dose of Sublocade® by injecting it into the skin on your stomach

Within 7 days prior to your clinic visit, a researcher will conduct an interview with you. The interview usually takes about 60 minutes to complete. The researcher will ask you questions about:

- Your recent drug and alcohol use, and whether you have been craving drugs
- How happy you are with your recent buprenorphine treatment
- How you are feeling in your health and quality of life
- Whether you have needed to use other health services or miss work recently, due to your health

On-treatment Visits

You will be required to attend the clinic every 4 weeks to receive your next Sublocade® injection. The study doctor or nurse will perform the tests and procedures below:

- the study doctor or nurse will perform a clinical assessment asking you about your treatment, adequacy of the dose, any side effects and use of other medications
 - you may be asked to provide a urine sample for an urine test. This is a research sample to tests for the presence of certain drugs including amphetamines, cocaine and opiates. A positive drug test will not affect whether or not you can continue in the study and the results will not be made available to your treatment team
 - a pregnancy test (urine) will be done for females who can fall pregnant
- your study doctor will assess your symptoms of opiate withdrawal.
- The study doctor or nurse will administer your dose of Sublocade® by injecting it into the skin on your stomach

Within 4 days of each clinic visit, a researcher will conduct an interview with you. The interview should take about 60 minutes to complete at baseline and week 12, 24, 36 and 48. The interview should take about 20 minutes to complete at week 4, 8, 16, 20, 28, 32, 40 and 44 . The researcher will ask you questions about:

- Your recent drug and alcohol use, and whether you have been craving drugs
- How happy you are with your recent buprenorphine treatment

- How you are feeling, physically and mentally and if you have been experiencing any pain
- Whether you have needed to go to the doctor or miss work recently, due to your health

If you decide that you want to stop treatment before week 44, or your study doctor decides it is unsafe for you to continue in the study, you will be asked to complete the tests and procedures that are part of the 'Clinical Safety' follow up visit, then carry on with research interview at defined time points during the study.

End of Study Visit

You will be required to attend the clinic 4 weeks after the last Sublocade® injection you receive as part of the study (this visit could be 48 weeks after the first dose). The study doctor or nurse will perform the tests and procedures below:

The following assessments will be performed:

- you may be asked to provide a urine sample for an urine test. This is a research sample to tests for the presence of certain drugs including amphetamines, cocaine and opiates. A positive drug test will not affect whether or not you can continue in the study and the results will not be made available to your treatment team
 - the study doctor or nurse will perform an examination (this may require you to partially undress), to check if you have any irritation at the injection sites
 - a urine pregnancy test will be done (for females of child bearing potential)
 - the study doctor or nurse will ask you about any illness or injury, and any medications you are using

Within 4 days of each clinic visit, a researcher will conduct an interview with you which should take about 60 minutes to complete.

The researcher will ask you questions about:

- Your recent drug and alcohol use, and whether you have been craving drugs
- How happy you are with your recent buprenorphine treatment
- How you are feeling, physically and mentally and if you have been experiencing any pain
- Whether you have needed to go to the doctor or miss work recently, due to your health

What is the study treatment?

All participants will receive injections of the same treatment, called Sublocade® every 4 weeks. This is a new form of buprenorphine combined with a gel-like substance that means when it is injected into the skin of the stomach it is released slowly into the bloodstream over one month or more. All participants will receive a dose of 300mg at the baseline visit and week 4 visit. From the third dose onwards, patients and their doctor will be able to choose between a dose of 100mg or 300mg. Previous experience suggests some patients may prefer the higher dose, and others the lower dose.

Whilst the doses are scheduled to occur every 4 weeks, there will be some flexibility about dosing, allowing for doses to be given 2 days earlier or two week after the usual 4 week dose. In exceptional circumstances, the study doctor may authorise a short period of treatment with sublingual buprenorphine if required.

Will I receive payment for being part of this project?

Participation in this study (including clinic visits and medications) will be provided free of charge. You will be reimbursed for your time participating in research assessments and reasonable travel expenses up to the amount of \$50 per visit, and \$60 for the week 48 visit. Reimbursement will be organised by the researchers following completion of each research interview.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

4 What do I have to do?

If you decide to be in this study, there are certain rules you must follow before, during, and after the study period. Some are listed below, but there could be others that the study doctor will discuss with you:

- You must be able to provide written consent to be in this study.
- It is possible that taking the study drug with your regular medications or supplements may change how the study drug, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study including those you take as needed or which you take only occasionally.
- You must check with your study doctor before you take any new medications during the study.
- If you decide to take part in this study, it is very important that you attend all visits as scheduled.
- You must follow all instructions given to you while you are participating in this study. If you do not, you may be removed from the study. If you are unsure about what you are supposed to do, ask the study doctor.
- You must not be pregnant, become pregnant or father a child during this study. Please see the Pregnancy section below for more information.
- It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

If you cannot follow these restrictions, you should not be in this study.

It is important that you attend study visits every month. If you miss a visit and are more than 4 weeks overdue for a Sublocade® injection, the study doctor cannot continue your Sublocade® treatment. If this happens, you will be offered alternative treatments for your opioid dependence.

5 Other relevant information about the research project

The study is sponsored by the University of New South Wales Sydney, and supported by a grant from Indivior, the company that manufactures Sublocade®.

The study will involve a total of 100 participants in different states in Australia.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with UNSW Sydney, the clinic you attend, or medical or other staff caring for you.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive buprenorphine treatment at this clinic. Sublocade® is currently only available in Australia by participating in this study, however other treatment options for opioid dependence are available. These include continuing on sublingual buprenorphine. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

There is no guarantee that you will receive personal benefit from taking part in this study. It is hoped that Sublocade® may effectively and safely manage your opioid dependence, and allow you to attend the clinic and take buprenorphine less frequently (for monthly Sublocade® injection instead of daily sublingual buprenorphine). However, it is possible that you may still need sublingual buprenorphine. Your participation may provide valuable information to improve the management of people with opioid dependence in the future.

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

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

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get. Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. At each study visit, the study doctor or nurse will check on how you are feeling and to see if you have had any side effects. They will discuss with you the best way to manage mild side effects. If a severe side effect or reaction occurs, you may need to attend the clinic for review by the study nurse or study doctor. The study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

In studies with this treatment most of the side effects experienced by patients taking Sublocade® were similar to patients taking sublingual buprenorphine, and the side effects were considered mild. Safety of Sublocade® has been characterised in 8 clinical studies to date in which 484 participants have taken Sublocade®. The most common side effects were constipation (11%), headache (9%), nausea (10%), vomiting (6%) and abnormal liver enzymes (10%).

However, having a drug injected may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. In research with Sublocade® so far, injection site pruritus (itchiness) was experienced by 7% of people, and 8% of people had pain at the site of injection.

It is not expected that you will have any or all of these side effects. Other side effects may occur that are not listed here or were not seen before. Please speak to your study doctor for more information. Side effects are usually temporary and can often be treated. However, it is very important that you report all side effects to your study nurse at any time during the study as it is possible that side effects may suggest a serious or fatal health problem.

Pregnancy:

Care must be taken to avoid pregnancy in female participants during this study and for up to 6 months following completion of study treatment. The effects of Sublocade® on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breastfeeding. If you are male, you should not father a child or donate sperm for at least 6 months after the last dose of study medication.

Female Participants only: Throughout the study women who are able to have children will have regular pregnancy tests to check that they have not fallen pregnant since their last visit. These will be performed at screening, baseline, and every four weeks during treatment. You must notify your study doctor or nurse immediately if you suspect you might be pregnant. Your study doctor may withdraw you from the study and advise on further medical attention should this be necessary.

[APPLICABLE FOR NON-CATHOLIC INSTITUTIONS delete or include as applicable]

This study has very specific instructions regarding birth control and pregnancy which should be adhered to during participation to this study.

Please ask your doctor if you have any questions about the birth control methods below.

From screening until 6 months after the last dose of Sublocade®, you and your partner must agree to use 1 effective method of contraception when having sexual intercourse.

The method can be a non-hormonal barrier method that prevents transmission of fluids or hormonal methods such as the oral contraception pill, the hormonal implant, the hormonal injection, the hormonal or copper IUD, the vaginal ring and the transdermal contraceptive patch. Other acceptable methods are tubal sterilisation or vasectomy in males.

[APPLICABLE FOR CATHOLIC INSTITUTIONS delete or include as applicable]

Female participants need to avoid pregnancy during the course of the study and for a period of 6 months after the last dose of study medication. Male participants with female partners need to avoid fathering a child during the course of the study and for a period of 6 months after last dose of study medication. You should speak to the study doctor about the need to avoid pregnancy during this study.

Other risks or discomforts of the study

Occasionally, people have allergic reactions (including life-threatening reactions) when taking any medication. Symptoms of any allergic reaction can include: rash, hives, itching and/or trouble breathing, closing of the throat, swelling of the lips, tongue or face, and rarely death. Immediately get emergency medical care if you have any of these symptoms. Stop taking your study drugs and let your study doctor know.

In general, allergic reactions to medicines are more likely to occur in people who already have allergies. If you are allergic to other drugs, foods or things in the environment, such as dust or grass, you should let your study doctor know. Also, if you have asthma, let your study doctor know.

Blood draws

Drawing blood may cause local pain, bruising, occasional light-headedness, fainting, and very rarely, infection at the site of the blood draw.

Drug use

This research project involves the collection of information about your use of drugs. Participation in the research project includes urine analysis to determine the presence of various drugs (marijuana (THC), methamphetamines, amphetamines, opiates, cocaine benzodiazepines, oxycodone, fentanyl, ecstasy, methadone and alcohol). The tests are used for research purposes only and the results will not be available to your treatment team. The results will in no way affect your treatment. If your treating doctor wants a urine drug test for clinical purposes, they will let you know that a separate urine specimen will be collected. Drug use information collected for this study will be stored in a re-identifiable (or coded) format. In the event that UNSW is required to disclose that information, it may be used against you in legal proceedings or otherwise.

10 What will happen to my test samples?

Urine samples

If you are female and able to fall pregnant you will have urine samples collected at screening, baseline and each study visit. Your study doctor or nurse will use the urine sample to test for pregnancy before administering the next Sublocade® injection.

You may be asked to provide a urine sample at some visits to check for recent drug use. The urine sample is for research purposes only. It allows the researchers to check whether overall drug use reported by participants in the research interviews matches drugs detected in urine. The urine will be sent to the laboratory working with the clinic, and identified by will only be identified with a unique study identification number, your initials and date of birth. The test will check for the presence of different drugs, marijuana, methamphetamines, amphetamines, opiates, cocaine, benzodiazepines, oxycodone, ecstasy, methadone and fentanyl. Your study doctor or nurse will not receive the results. If drugs are detected in your urine this will not affect your ability to stay in the study and continue treatment with Sublocade®. Any leftover urine not needed for this testing will be destroyed by the laboratory.

11 What if new information arises during this research project?

Sometimes during the course of a research project, 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 project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

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

12 Can I have other treatments during this research project?

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

13 What if I withdraw from this research project?

You can withdraw from treatment at any time, but the researchers will want to continue to follow you up for research interviews for the 12 month period.

If you decide to withdraw from the research project, please notify a member of the research team before you withdraw. This notice will allow that person to discuss any health issues or complications. Special requirements linked to withdrawals are safety reasons, pregnancy, removal of depot and you not adhering to study procedures.

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

14 Could this research project be stopped unexpectedly?

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

- Unacceptable side effects
- Sublocade® being shown not to be effective
- Sublocade® being shown to work and not need further testing
- Decisions made by local regulatory/health authorities

15 What happens when the research project ends?

Once the research project ends you may be able to continue treatment with Sublocade®. Near the end of the study, your doctor will talk with you about continuing the treatment after the study ends.

If by then Sublocade® is approved by Therapeutic Goods Administration (TGA) and is accessible via the Pharmaceutical Benefits Scheme (PBS), your doctor will be able to arrange for continuation as part of your routine care; otherwise your study doctor may be able to access it from the company. If you prefer, you can be treated with sublingual buprenorphine instead of Sublocade®. Please ask your study doctor or nurse for more information about what the treatment options are after the research project ends

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. When you enrol in the study you will be given a unique study identification number. This number will be used throughout the study and all samples and data collected from you will be identified by this ID number, your initials and your date of birth not your name. Your personal information may be collected to contact you for research interviews (name, phone number). This will be stored separately from study data and only authorised researchers will have access to the code linking this to your study ID number. All of your samples and data will be stored securely and

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only authorised study personnel including monitors, auditors, ethics committees and inspectors will have access to them. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, UNSW Sydney, the institution relevant to this Participant Information Sheet, St Vincent's Hospital Sydney Human Research Ethics Committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Your unique study identification number will ensure your confidentiality.

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

In accordance with relevant Australian and/or [NAME OF STATE/TERRITORY] 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.

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

17 Complaints and compensation

Complaints

This study has been approved by the St Vincent's Hospital Sydney Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 8382 4960 and quote reference number (HREC/18/SVH/221)

The conduct of this study at the [NAME OF SITE] has been authorised by the [NAME OF ORGANISATION]. Any person with concerns or complaints about the conduct of this study should refer to Section 20 for details of who to contact.

Compensation

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible and you will be assisted in 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.

In the event of loss or injury, the parties involved in this research project have agreed that you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study. If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

The study is a collaborative study conducted by the UNSW Sydney and supported by funding and provision of drug from the pharmaceutical company Indivior Pty Ltd. No member of the research team will receive a personal financial benefit from their involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital Sydney. The HREC Reference Number is (HREC/18/SVH/221)

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

20 Further information and who to contact

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

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

Clinical contact person

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

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

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Position	[Research Office Manager]
Telephone	[(02) 8382 4960] SVHS.research@SVHA.org.au

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

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St Vincent's Hospital Sydney HREC
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

[INSERT LETTERHEAD]

Consent Form

Title	An open-label, multicentre, single-arm trial of monthly injections of extended release buprenorphine in people with opioid dependence
Short Title	CoLAB
Protocol Number	SVH No. 18/194
Project Sponsor	University of New South Wales (UNSW) Sydney
Co-ordinating Principal Investigator	Prof Michael Farrell
Location	[INSERT HOSPITAL NAME & LOCATION]

Declaration by Participant

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

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to [INSERT SITE NAME] concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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

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

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

Name of Participant (please _____)

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please
print) _____

Signature _____ Date _____

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

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

Signature _____ Date _____

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

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

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

[INSERT LETTERHEAD]

Form for Withdrawal of Participation

Title	An open-label, multicentre, single-arm trial of monthly injections of extended release buprenorphine in people with opioid dependence
Short Title	CoLAB
Protocol Number	SVH No; 18/194
Project Sponsor	University of New South Wales (UNSW) Sydney
Co-ordinating Principal Investigator	Prof Michael Farrell
Location	[INSERT HOSPITAL NAME & LOCATION]

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with [INSERT SITE NAME].

I wish to withdraw my research samples from the above research project.

Name of Participant (please print) _____
Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher[†]

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

Name of Study Doctor/ Senior Researcher [†] (please print) _____
Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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