**Executive Summary of the**

**Participant Information Sheet/Consent Form – Person Responsible**

**Standardised Treatment and Monitoring of Phage Therapy (STAMP)**

**[Local Chief Investigator]**

The participant is invited to participate in the above research study because they have a bacterial infection that their doctor has determined would benefit from Phage Therapyand their doctor believes this could be a suitable treatment option. A detailed Information Statement about the study is attached and this is a summary of the essential information about the trial and where to find the relevant detailed information later in the Information Statement. You should read the Information Statement in full and discuss it with your family and medical practitioners before deciding to agree to participation of the person you are responsible for in this study. You may contact the study staff *[or provide a name]* to discuss or asks questions about the study on [phone number] or by email [email address].

This study aims to look at how Phage Therapy can be given to patients in a standardised way that will help better understand how the treatment affects them and other patients. If you agree, the person you are responsible for will receive a specific Phage Therapy product that is suitable for them as decided by their doctor. For a full description of the purpose and rationale for this research see pages 2-4.

Participation in this study is voluntary and refusal to participate or withdrawal from the study at a later stage will not affect the treatment they receive at *[department/hospital]*

If you decide the person you are responsible for should participate in this study they will be required to receive Phage Therapy as directed by their doctor. How long they will need to take the Phage Therapy for will be decided by their doctor, taking into consideration medical history and the type of infection they have. During treatment information about the participant’s background medical condition, infection, the reason for Phage Therapy and response to treatment will be collected. They will have blood and other samples (swabs, sputum samples etc.) collected. The schedule for study visits and a full list of all tests and procedures is on page 4. After the study treatment has finished they will be followed by their primary doctor for at least 6 months and asked to complete a questionnaire after treatment.

The most common risks to participants from Phage Therapy is a brief inflammatory reaction (fever, headache, muscle aches). A full list of the side-effects from Phage Therapy and other risks associated with the study procedures are on page 6.

There is additional information about what information will be collected about the participant during the study, how that information will be used, and their privacy protected on pages 8-9. Their rights and additional regulatory information that we are obligated to provide on pages 9-10.

**Please make sure you have completely understood what the study involves before you decide to consent to participation on behalf of the person you are responsible for.**

**Participant Information Sheet/Consent Form – Person Responsible**

**Standardised Treatment and Monitoring of Phage therapy (STAMP)**

*Person responsible consenting on behalf of participant*

|  |  |
| --- | --- |
| **Title** | Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy |
| **Short Title** | Standardised Treatment and Monitoring of Phage therapy (STAMP) |
| **Project Sponsor** | Western Sydney Local Health District |
| **Coordinating Principal Investigator** | Prof Jonathan Iredell |
| **Site Principal Investigator** | *[Site PI name]* |
| **Location** | *[Location]* |

**Part 1 What does participation involve?**

**1 Introduction**

The participant is invited to take part in this research project because they have a bacterial infection that their doctor has determined would benefit from Phage Therapy. The research project is investigating the best way to provide Phage Therapy to patients, including how doctors should monitor the treatment.

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 the participant 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 the participant should take part, you might want to talk about it with a relative, friend or your doctors.

Participation in this research is voluntary. If you don’t wish for the participant to take part, they don’t have to. They will receive the best possible care whether or not they take part.

If you decide you want the participant 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 for the participant to take part in the research project

• Consent for the participant to have the tests and treatments that are described

• Consent to the use of the participant’s personal and health information as described.

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

**2 What is the purpose of this research?**

Phage Therapy is an experimental treatment. This means that it is not an approved treatment for bacterial infections in Australia. The participant will be receiving this treatment under the Special Access Scheme (SAS) of the Australian Therapeutic Goods Administration (TGA) which is sometimes referred to as “compassionate access”. The decision to provide Phage Therapy to the participant and the specific phage product they will receive, has been decided by their doctors and is not part of this research project. This research will investigate how the treatment can be given to the participant in a standardised way so that we can better understand how the treatment affects the participant and other patients.

This research has been initiated by the study doctors, Professor Iredell, Associate Professor Steven Tong and Dr’s Ameneh Khatami and Morgyn Warner. It has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage Australia Network of researchers (<https://criticalinfection.com/phage-australia/>).

**3 What does participation in this research involve?**

Once your doctor has determined that the participant may benefit from Phage Therapy, and a suitable phage product has been found, they will refer the participant to one of the study doctors. The study doctors will confirm that they are eligible to be enrolled in this research. This will include checking that all of the approvals that are required from Government agencies and other local hospital approvals that may be required have been obtained by their doctor. You will then be asked to sign a consent form before the participant can take part in the study.

The dose and duration of treatment with Phage Therapy, and the way in which it will be given to the participant (e.g. intravenously, by mouth, nebulised or topically) will be decided by one of the study doctors, after discussion with the participant’s primary (referring) doctor, taking into consideration the participant’s background medical conditions and the specific infection they have. Most patients will receive Phage Therapy for 2 weeks, given intravenously (through a drip, in a vein), and this will be provided to the participant in hospital. For some patients, if the Phage Therapy is required for a longer duration, this may be given to the participant in their home or an outpatient clinic. For other patients who only need Phage Therapy topically (e.g. onto a wound) or by a nebuliser (to be breathed into your lungs), this may also be given to the participant in their home or an outpatient clinic. In any circumstance, Phage Therapy will be given by qualified doctors and nurses, and prescribed to the participant in the same way as other medications.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), this will be given once daily, in the morning for the first 2 days, and then twice a day (morning and evening) for the next 12 days. It is possible that the participant may have once daily treatment for longer than 2 days during the 2 weeks, based on blood levels of the phage that will be measured throughout the treatment. The participant’s doctors and nurses will also monitor their heart rate, breathing rate, blood pressure and temperature before and after each dose of phage.

Information regarding the participant’s background medical condition, their infection, the reason for Phage Therapy and their response to treatment will be collected in a standardised database. We will also collect blood and other samples that might be relevant for the participant’s specific infection (e.g. swabs or sputum samples). These samples will be collected at specified time-points before, during and after completion of the treatment to investigate how effective the treatment has been at clearing the participant’s infection, how it has affected their body in other ways, such as their kidneys and liver, and how their immune system has responded to the treatment.

For most people receiving 2 weeks of Phage Therapy intravenously (through a drip), blood samples will be collected the day before starting Phage Therapy (day 0), and again, 1, 3, 7, 10 and 14 days **after** their first dose (day 1). 4 weeks after the participant’s first dose of phage, which is about 2 weeks after their last dose of phage, the participant will have a follow-up visit with more blood tests and collection of relevant samples. On some days the participant will be asked to provide a blood sample 3 times: once before the morning dose of phage, and then 30-60 minutes, and 2-3 hours after the dose. This will help the study doctors understand how quickly phage is cleared from the body, and will also help determine whether they should receive once or twice daily treatment. The table below shows what days the participant will have blood tests compared to the first and last dose of phage they receive, and how many blood samples are needed each time.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Day** | **0** | **1** | **2** | **4** | **8** | **11** | **14** | **15** | **29** |
| **Number of blood samples** | x1 | First dose of phage | x3 | x3 | x3 | x3 | Last dose of phage | x1 | x1 |

Patients who do not receive any Phage Therapy through a drip in the vein, or by mouth, will have fewer blood tests. They will not have any blood tests on day 11, and on each day will only have a single set of blood samples taken.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Day** | **0** | **1** | **2** | **4** | **8** | **14** | **15** | **29** |
| **Number of blood samples** | x1 | First dose of phage | x1 | x1 | x1 | Last dose of phage | x1 | x1 |

Patients who have longer courses of Phage Therapy will continue to have blood tests to monitor their treatment every month. All blood samples will be collected by qualified health professionals (e.g. doctors, nurses or blood collectors).

Before starting Phage Therapy, at the end of the course and again 3 and 6 months after the participant’s treatment they will also be asked to complete an online questionnaire. This will ask questions about their experience of the Phage Therapy and how it may have affected their quality of life. It will take 10 minutes to complete. We would ask that you help the participant complete these questionnaires. Although we would like the participant to complete the entire questionnaire, they and you can skip any questions that you do not wish to answer.



For most patients, their main involvement in the study will be for 1 month. This includes the 2 weeks of Phage Therapy and the follow-up visit 2 weeks after completing Phage Therapy. During this time, in addition to the tests described above, you and the participant will be asked about any symptoms and health events that may have occurred so that study doctors can determine the safety of Phage Therapy. For some patients who are receiving longer courses of Phage Therapy, their involvement in the study will be determined by the duration of Phage Therapy that has been recommended for them. Once the Phage Therapy has finished, the participant will be followed up by the participant’s primary doctor for at least 6 months. The frequency of follow-up visits will be determined by the participant’s doctor, based on any underlying medical conditions. During this follow-up period, they will also continue to receive invitations to complete the quality-of-life questionnaire at 3 and 6 months after their initial course of treatment.

There are no additional costs associated with participating in this research project, nor will you or the participant be paid. All medication, tests and medical care required as part of the research project will be provided to the participant free of charge.

It is desirable that your local (family) 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 the participant’s participation in this research project.

**4 What does the participant have to do?**

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. It is important that administration of phage (including any dose changes) and all of the monitoring tests are done in a standardised way as written in the study protocol. It is also important that all of the information is collected in a standardised way so that the data from all participants in the study can be collated and analysed together. This includes answers you and the participant provide in the quality-of-life questionnaires. However, there will be no other restrictions on the participant with respect to diet, exercise or other activities, or other medications they may need. All of the participant’s other routine health care will continue as normal, and as determined by their doctor(s).

**5 Other relevant information about the research project**

This research is being conducted at multiple hospitals around Australia and will continue for 5 years. We are aiming to recruit 50-100 participants in the study during this time. At *[Location where the research will be conducted]* we expect around 2-3 participants to be recruited each year. The research is a collaboration between multiple hospitals, universities and research institutes working together.

**6 Does the participant have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish for the participant to take part, they do not have to. If you decide to take part and later change your mind, you are free to withdraw the participant from the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet 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 the participant’s routine treatment, you or the participant’s relationship with those treating the participant or you or the participant’s relationship with *[Institution]*.

**7 What are the alternatives to participation?**

The participant does not have to take part in this research project to receive treatment at this hospital. If you choose not to participate in this research, the participant’s doctor(s) may still decide to offer them Phage Therapy but it may not be monitored in the way outlined in this research. This includes having access to some of the special tests that are not available in routine hospital or community labs. The study doctor will discuss these options with you before you decide whether or not you want the participant to take part in this research project. You can also discuss the options with the participant’s primary or local doctor.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that the participant will receive any benefits from this research; however, possible benefits may include clearance of their infection, or stabilisation or improvement in their symptoms. In addition, the participant’s treatment will be overseen and monitored by a group of study doctors which include specialists in infectious diseases and Phage Therapy from around Australia and internationally. Importantly, the information that we collect in this research will help us and other researchers determine the best way to provide Phage Therapy to patients in the future. It may also help us be able to make Phage Therapy more widely available in Australia.

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

Any medical treatment can cause side effects. The participant may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If the participant has any of these side effects, or you are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

The specific phage product the participant will receive will be determined by their own doctor. This will be discussed with one of the study doctors, but this decision is not included in the research. The participant’s doctor can provide you with specific information about the phage product the participant will receive, including where it has been sourced from and how it has been manufactured. Below is some general information about possible risks that might occur for patients receiving Phage Therapy.

**Phage Therapy general information and risks**

Phages are viruses that infect and kill bacterial cells, but they do not attack human cells. For this reason, phage therapy is considered very safe. It has been used for over 100 years to treat patients with bacterial infections. When phages are well purified to remove contaminants, they cause very few side effects. Only phage products that meet regulatory requirements regarding purification standards will be used in this research.

Sometimes a brief inflammatory reaction is seen after the initial doses of phage. This is mostly due to the phage attacking and killing the bacteria causing the participant’s infection. It is usually a good sign that the phages are doing their job but it may be uncomfortable for the participant. They may have a fever or feel unwell in other ways (chills, headache, muscle aches). Depending on the site of the participant’s bacterial infection, they may also experience pain at the site. Usually this inflammatory response is brief, lasting a few hours and can be managed with simple medication like paracetamol or ibuprofen. Rarely, there may be a severe reaction which may mean that further doses of phage are delayed or not given.

Other side effects that may occur during the participant’s treatment include abnormalities in results of tests of their liver or kidney function, blood cells and immune responses. If such abnormalities are seen, they will be monitored until they return to their baseline value. In our experience of treating patients in Australia, as well as reports from patients treated in other countries, these abnormalities in lab tests are usually not severe and resolve after a few weeks of stopping the Phage Therapy.

**Unknown risks of Phage Therapy**

There may also be side effects that we do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms that the participant experiences. Sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop your treatment. The study doctor will discuss the best way of managing any side effects with you. Any side effects that may occur during your treatment will be managed or treated by the study doctors and the participant’s own doctors according to usual health care practice.

**Risks of taking part in this research project**

There are very few risks or disadvantages to taking part in this research because the study is mainly investigating how Phage Therapy should be given and monitored. As part of the research, the participant will be asked to provide blood and other samples at specific timepoints, and the phage will be given to the participant at specific times of the day, for most patients injected through an intravenous drip. Having a treatment injected or blood samples taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If the participant becomes upset or distressed as a result of their participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

**10 What will happen to the participant’s test samples?**

Most of the tests that will be performed to monitor the participant’s treatment are the same routine lab tests used by doctors to monitor infections. These tests will be performed at the usual labs where patient samples from *[Location where the research will be conducted]* are always processed. Once the testing is completed in these labs, the samples will be discarded and destroyed in the same way as other patient samples are handled by labs.

Some of the tests are specific to the Phage Therapy, including tests to determine the levels of phage in the participant’s blood, tests to look at how the participant’s immune system is responding to the Phage Therapy and tests that will investigate the participant’s microbiome (the collection of bacteria and other microorganisms, including viruses, which live in your body). The participant’s blood and other samples (e.g. urine, sputum, faeces) for these tests may need to be sent to another lab in Australia that specialises in Phage Therapy. If this is the case, the samples will be sent in an anonymised way, using only a study code that will be assigned to the participant for the research project. No personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. Only study doctors from *[Location where the research will be conducted]* and the participant’s clinical team will be able to re-identify these samples as belonging to the participant, using their specific study code.

These tests are all required for the participant to take part in the research. Once testing on these samples is completed, any remaining samples will be stored in the external lab in case further testing is required in the future (for this research project). We will also ask your permission to use these stored samples in other related research projects in the future, however this is optional. The participant can still take part in this research if you do not wish to have their samples used in other projects. Any leftover samples will be destroyed 15 years after the end of the study in the usual safe way that human samples are discarded and destroyed and according to law.

Genetic tests that will be performed in this research will be:

1) to investigate the participant’s microbiome which includes all of the bacteria, fungi and viruses that normally live in our bodies, and how these might change during Phage Therapy. This test will not look at any human genetic material, only at the genetic material of microorganisms.

2) to investigate the genes responsible for the participant’s immune system and how it responds to the Phage Therapy. This test will not look at any of the participant’s other genes so it is unlikely that it will identify any genetic disorders. There is a small chance that we may find that the participant’s immune system is not responding as well to infections as in other people. If that is the case, study doctors would let the participant’s doctor know the results so that they can discuss these with you and arrange any other investigations that might be needed.

**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, the study doctor will tell you about it and discuss with you whether you want the participant to continue in the research project. If you decide to withdraw, the study doctor will make arrangements for the participant’s 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, the study doctor might consider it to be in the participant’s best interests to withdraw them from the research project. If this happens, he/ she will explain the reasons and arrange for the participant’s regular health care to continue.

**12 Can the participant have other treatments during this research project?**

Participating in this research project will not affect the participant’s ability to take other medications or treatments for their condition or for other reasons. However, it is important to tell the study doctor and the study staff about any treatments or medications they may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these while the participant is taking part in the research project.

**13 What if I withdraw the participant from this research project?**

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

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional information from or about the participant, although information already collected will be kept as part of the research to ensure that the results of the research can be measured properly and to comply with law. This information will only ever be used in an anonymised way and no personal or identifiable information about the participant will be used for research purposes. You should be aware that data collected by the sponsor up to the time you withdraw the participant will form part of the research project results. If you do not want them to do this, you must tell the study team before the participant joins the research project.

**14 Could this research project be stopped unexpectedly?**

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons, including unacceptable side effects or safety concerns.

**15 What happens when the research project ends?**

Once the participant has completed their course of Phage Therapy for their infection, no further ongoing access to Phage Therapy will be required. If further episodes of infection occur, including relapses or recurrence of the same infection, that require further courses of Phage Therapy, these future episodes will be treated as separate events and will be assessed for eligibility for the participant to be re-enrolled in the research project, in the same way as for the initial course of treatment.

All other health care that may be required by the participant after the end of Phage Therapy will be according to routine practice and will be managed by the participant’s primary or local doctor.

After the project is completed in 5 years’ time, the results of the research will be published in a scientific journal or may be presented at scientific meetings. A summary of publications and presentations will be made available for participants and the public on the Phage Australia website (<https://criticalinfection.com/phage-australia/>).

**Part 2 How is the research project being conducted?**

**16 What will happen to information about the participant?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal and health information about the participant for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential and securely stored. The participant’s 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 the participant may be obtained from their health records held at this and other health services for the purpose of this research (e.g. results of lab tests or scans). By signing the consent form you agree to the study team accessing health records if they are relevant to the participant taking part in this research project.

All study information will be entered into a web-based database called REDCap. This is hosted by the University of Sydney and is protected so that only the study team can access the information. Within this database the participant would be assigned a study code. The participant’s email address will be saved in RedCap for the purpose of emailing the Quality of Life surveys during the follow-up period, and will not be stored beyond the duration of follow-up for the study. The participant’s personal and identifiable information would only be available to the clinical team looking after the participant and the study team at *[Location where the research will be conducted]* so that they can discuss the best possible way to provide Phage Therapy to the participant, including any changes that might be needed in the dose of phage they are receiving. The rest of the research team would only have access to non-personal information through the participant’s anonymised study code.

Any of the participant’s blood or other samples that need to be sent to external labs will also only be identified with their study code and none of the participant’s personal or identifiable information will be sent outside of *[Location where the research will be conducted]*. 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 the participant cannot be identified, except with your permission. All personal and identifiable information will be removed from the data when it is analysed and reported.

Paper documents, including copies of signed consent forms that include any personal or identifiable information will be stored in locked cupboards in offices at *[Location where the research will be conducted]*. All research data will be stored for 15 years after completion of the project, at which point all electronic documents with any identifiable information will be destroyed by permanent deletion and all paper files will be destroyed by shredding.

We will ask your permission to use the participant’s anonymised information in other related research projects in the future, however this is optional. The participant can still take part in this research if you do not wish to have their information used in other projects. Only anonymised information would be used for other future research projects and the participant’s personal or identifiable information will not be shared with anyone outside of the clinical team looking after the participant and the study team at *[Location where the research will be conducted]* without your permission.

The participant’s 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, Western Sydney Local Health District, the institution relevant to this Participant Information Sheet, Sydney Children’s Hospitals Network 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.

In accordance with relevant Australian and *[Name of state/territory]* privacy and other relevant laws, you have the right to request access to the participant’s 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 the participant’s information.

**17 Complaints and Compensation**

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

**18 Who is organising and funding the research?**

This research has been funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) of Australia. It is being conducted by the Phage Australia Network of researchers (<https://criticalinfection.com/phage-australia/>), including *[Name of local PI and relevant study staff]*.

No member of the research team will receive a personal financial benefit from the participant’s 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 Sydney Children’s Hospitals Network.

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 the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor *[Name of local PI]* on *[phone number]* or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | During normal working hours: *[Site PI name]*After hours or if unable to contact *[Site PI name]*: Infectious diseases registrar or consultant on call |
| Position | *[Title/position/department of Site PI]* |
| Telephone | During normal working hours: *[Site PI contact number]*After hours: Infectious diseases registrar or consultant on call via *[Hospital switch/on call Phone number]* |
| Email | *[ Site PI Email address]* |

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 | Sydney Children’s Hospital Network |
| HREC Executive Officer | Caitlin Braude |
| Telephone | (02) 7825 1253 |
| Email | SCHN-Ethics@health.nsw.gov.au  |

**Consent Form – Person Responsible**

|  |  |
| --- | --- |
| **Title** | Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy |
| **Short Title** | Standardised Treatment and Monitoring of Phage therapy (STAMP) |
| **Project Sponsor** | Western Sydney Local Health District |
| **Coordinating Principal Investigator** | Prof Jonathan Iredell |
| **Site Principal Investigator** | *[Site PI name]* |
| **Location** | *[Location]* |

**Declaration by Person Responsible**

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 the participant’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning the participant’s 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 the participant taking part in this research project as described and understand that I am free to withdraw the participant at any time during the study without affecting their future health care.

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

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

• This specific research project only

• This research project and other research that is closely related to this research project

*Strike out one option above and initial next to your choice.*

I consent to the storage and use of the participant’s de-identified (anonymous) information, as described in the relevant section of the Participant Information Sheet, for:

• This specific research project only

• This research project and other research that is closely related to this research project

*Strike out one option above and initial next to your choice.*

I agree to the use of the participant’s samples for genetic testing, as outlined in the relevant Section of the Participant Information Sheet.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Participant (please print) |   |  |
|  |  |  |  |
|  |  |  |  |  |  |
|  | Name of Person Responsible (please print) |  |  |
|  |  |  |  |
|  | Signature of Person Responsible |  | Date |  |  |
|  |

*If the person providing consent is unable to read, an impartial witness should be present during the entire informed consent discussion*

|  |
| --- |
|  |
|  | Name of Witness\* to Person Responsible’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 Person Responsible 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.

**Form for Withdrawal of Participation – Person Responsible**

|  |  |
| --- | --- |
| **Title** | Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy |
| **Short Title** | Standardised Treatment and Monitoring of Phage therapy (STAMP) |
| **Project Sponsor** | Western Sydney Local Health District |
| **Coordinating Principal Investigator** | Prof Jonathan Iredell |
| **Site Principal Investigator** | *[Site PI name]* |
| **Location** | *[Location]* |

**Declaration by Person Responsible**

I wish to withdraw the participant from participation in the above research project and understand that such withdrawal will not affect the participant’s routine treatment, our relationship with those treating the participant or our relationship with *[Institution]*.

• I wish to withdraw the participant from any further collection of samples and clinical data for this research

• I wish to withdraw the participant from any further collection of samples but I am allowing continued collection of the participant’s clinical data for this research

*Strike out one option above and initial next to your choice.*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Participant (please print) |  |  |
|  |  |  |  |
|  | Name of Person Responsible (please print) |  |  |
|  |  |  |  |
|  | Signature of Person Responsible  |  | Date |  |  |
|  |

*In the event that the person responsible’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the Person Responsible 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.