Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Melbourne Sexual Health Centre

Study title	A Phase III, Randomized, Multicenter, Open-Label Study in Adolescent and Adult Participants Comparing the Efficacy and Safety of Gepotidacin to Ceftriaxone Plus Azithromycin in the Treatment of Uncomplicated Urogenital Gonorrhoea Caused by *Neisseria gonorrhoeae*
Short Title	Phase III, Comparator-Controlled, Efficacy and Safety Study of Gepotidacin in the Treatment of Uncomplicated Urogenital Gonorrhea
Protocol Number	BTZ116577
HREC Reference	HREC/56581/Alfred-2019
Global Sponsor	**GlaxoSmithKline (GSK) UK**
Local sponsor	**PPD Australia Pty Ltd**
Coordinating Principal Investigator	**Dr James McMahon**
Principal Investigator	*A/Prof. Marcus Chen*
Associate Investigator(s)	*Dr. Ian Denham*
Location)	*Melbourne Sexual Health Centre*
Local Project Number	*738.19*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have gonorrhoea. The research project is testing a new antibiotic treatment for gonorrhoea. The new treatment is called gepotidacin.

This Participant Information Sheet/Consent Form tells you about the research project. It describes a type of research study called a clinical trial. 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?

This research study is being performed to learn more about gonorrhoea also known as uncomplicated urogenital gonorrhoea and if a new medicine called gepotidacin can make you better.

Gepotidacin is an experimental treatment. This means that it is not an approved treatment for gonorrhoea in Australia.

We also would like to answer the following questions:

- How well does the new medicine gepotidacin work to treat gonorrhoea caused by *Neisseria gonorrhoeae*?
- Is gepotidacin safe?

This study is conducted and funded by GlaxoSmithKline (GSK) UK, the global sponsor of the study. PPD Australia Pty Ltd is the local study sponsor in Australia.

The ECG machine that will be used in this clinical trial is registered with the Therapeutic Goods Administration for use in Australia by a different sponsor; this allows only that sponsor to import the ECG machine. However, PPD Australia Pty Ltd has sought permission from the Therapeutic Goods Administration to import the ECG machine for the purposes of this study.

3 What does participation in this research involve?

You are being asked to take part in this study because you have been diagnosed with gonorrhoea. Your participation in the study will be for approximately 21 days.

This study will compare gepotidacin with ceftriaxone plus oral azithromycin, antibiotics that are currently used as a standard treatment for your condition (also referred to as a "Standard of care" treatment).

Study participants will be divided into 2 groups: one group will take gepotidacin (3000 milligrams by mouth, followed by another 3000 mg within 6-12 hours) and the other group will take ceftriaxone (500-mg, by injection into a muscle) plus azithromycin (1000mg, by mouth). The effects of the medicines, both good and bad, will be compared. All doses of medicine will need to be taken with food.

A computer will be used to assign study participants into treatment groups by chance. This is called randomisation. You will have a 1 in 2 chance of being placed in either group.

You, your study doctor, study staff and the local sponsor PPD Australia Pty Ltd will know which treatment you receive. Only the global sponsor of this study GlaxoSmithKline (GSK) will not know. This is to make sure the results of each group being studied are handled in the same way.

You will need to visit the clinic 3 times over a period of about 21 days. Most visits will require about 2-3 hours of your time.

Visit 1 (this visit will take approximately 2 to 3 hours):

- Sign the informed consent form before any study-related procedures are performed.
- Answer questions about the symptoms that you are experiencing.
- Answer some questions regarding your age and ethnic origin. (Ethnic and racial background are collected for clinical research purposes only).
- Answer some social and sexual history questions.
- Receive a complete physical examination including height and weight, body temperature, blood pressure and pulse rate.
- Answer questions about your health, any illnesses or surgeries that you may have or had in the past, and any medicines that you are taking (including over-the-counter medicine, vitamins, or herbal treatments).
- Electrocardiogram (ECG) will be performed to record the electrical activity of your heart.
- Blood samples will be taken (about 1 tablespoon or 14 millilitres) for laboratory tests.
    - Some of this blood will be used to test for HIV (also called the 'AIDS' virus). If you are HIV positive this will not be necessary. Hepatitis B & C testing will also be done. This is because the study doctors need to know the baseline characteristics of the population.
    - You will receive information and counselling before the test. If a test shows you have HIV or Hepatitis, you will have follow-up counselling and medical advice. If your test results are positive, the study doctors are required by law to notify government health authorities. Signing the consent form means that you agree to have this testing; it will not be done without your consent.
- A urine sample will be taken for:
    - A routine urinalysis check

- Testing of drug and alcohol levels. This test is done to help the Sponsor more accurately interpret the safety profile of the study drug and is a compulsory part of the trial. Drugs tested for include amphetamine, barbiturates, benzodiazepines, cannabinoids, cocaine metabolites, methadone, opiates, phencyclidine, propoxyphene, and alcohol. The results of this test will be held centrally by the sponsor and not shared with either you or your study doctor, except in the case of a serious adverse event or medical emergency, in which case your study doctor can access the information. In the event that Melbourne Sexual Health Centre and GSK are both ordered by a court of law to disclose information regarding your use of drugs of addiction, it may be used against you in legal proceedings or otherwise as the court directs. As this information will not otherwise be shared with you or the site, this is considered to be highly unlikely, but is theoretically possible. If you do not want to undergo a urine drug test you do not have to, but you will be unable to participate in the study. Your health care will continue and treatment will be given as per standard of care policy of Melbourne Sexual Health Centre.
- If you menstruate (have periods) some urine will be tested to make sure you are not pregnant before joining the study.
- If you are male a swab will be taken from your urethra, if you are female a swab will be taken from your vagina. These swabs are known as urogenital swabs.
- Swab specimens may be obtained from the rectum and back of your throat if you separately consent.
    - These are optional samples and you will be asked to indicate if you consent to these or not on the Consent Form towards the end of this document.
- If you meet all the study requirements, you will receive one of the study medicines and start Day 1 study procedures.
- If you are in the group that takes a dose of gepotidacin at home, record the date and time on the dosing card when you take this dose (please refer to the dosing card that your study doctor will provide to you).
    - You will also be contacted via telephone, email, or text message for confirmation that you took your second gepotidacin dose.
    - If you agree to be contacted via text message, you will be asked to sign a separate text message consent form.

Visit 2 (4 to 8 days after starting study medication) (this visit will take approximately 1-2 hours):

- At this visit the study doctor or study nurse will check for signs and symptoms of your gonorrhoea infection and take your body temperature, blood pressure, and pulse rate.
- Blood (less than 2 teaspoons, 8 mL) and urine samples will be collected.
- If you menstruate (have periods) some urine will be tested to make sure you are not pregnant.
- Urogenital swab specimens will be obtained.
- Swab specimens may need to be obtained from the rectum and back of your throat (if you consented to this previously and these samples were obtained at Visit 1).

- You will be asked how you feel and if any health events have occurred since your last visit, including taking any other medicines.
- You will be asked about your sexual history since your last visit.
- Participants who tested positive for other infections such as *Chlamydia trachomatis* and/or *Mycoplasma genitalium* at Visit 1 will be treated per local standard of care at or after Visit 2 or at Visit 3.

Visit 3 (14 to 21 days after you began the study) (this visit will take approximately 1-2 hours):

- At this visit the study doctor will check for signs and symptoms of your gonorrhoea infection.
- Urogenital swab specimens will be obtained.
- Swab specimens may need to be obtained from the back of your throat (if you consented to this previously and these samples were obtained at Visit 1).
- A urine sample may be taken to check infection status.
- You will be asked how you feel and if any health events have occurred since your last visit, including taking any other medicines.
- You will be asked about your sexual history since your last visit.
- Participants who tested positive for other infections such as *Chlamydia trachomatis* and/or *Mycoplasma genitalium* at Visit 1 will be treated per local standard of care at this visit (if treatment has not already been started).

Do I have to pay anything to be in the study?

There will be no costs or charges to you for taking part in this study. As part of the study, you will receive the study medicine, gepotidacin or azithromycin and ceftriaxone, and all the study tests and procedures at no cost to you.

You, Medicare and/or your insurance company will continue to pay for your regular health care.

Will I be paid for being in the study?

You will not be paid for participating in this research project. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

4 What do I have to do?

- Please keep in mind how the study tests and visits described above will affect your work, school, and family schedules. Consider if you need transportation to and from the clinic. You may find that these tests and visits require planning. Some tests may be uncomfortable. Ask the study doctor if you have any questions about the tests and procedures for the study.

- The study doctor or study nurse will call you to remind you of upcoming visits. The study doctor or study nurse may also send you text reminders of upcoming visits and reminders to take your study medication.
    - If you agree to receive these text messages, you will be asked to sign a separate text message consent form.
- If you are sexually active, you will be requested to abstain from all sexual contact or use condoms for all forms of sex from Visit 1 through Visit 2 to prevent possible re-infection.
- If you agree, the study doctor may tell your regular doctor that you are taking part in a study, which may include sharing this Participant Information and Consent Form.
- Tell the study doctor if you are currently in another research study. You should know that you may not be able to take part in in this study while taking part in another research study. You may still be considered for this study if another research study you are taking part in is observational, and there are no interventions either with procedures or drugs (please discuss with your study doctor)

5 Other relevant information about the research project

This study will include approximately 500 to 600 study participants in 6 countries and the study will run for about 18 months.

A description and summary results of this clinical study will be available on the GSK Study Register (http://www.gsk-clinicalstudyregister.com/). They may also appear in similar registries in other countries. These postings will not include information that can identify you.

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

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 *Melbourne Sexual Health Centre.*

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital.

You can choose to be treated with another antibiotic. Talk with your doctor about your options before you decide if you will take part in this research project. The study doctor can advise you if you need more information. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include:

- This study may be useful in curing your infection.
- You will have regular health check-ups.
- This study will help to learn more about gonorrhoea infection and the effects of the study medicine. Your participation will help to understand gonorrhoea better and develop new medicines for other people infected with gonorrhoea.

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

It is very important that you tell the study staff immediately about how you feel and any side effects. It is also very important that you do not share your opinion with other study participants.

Because this medicine is not approved, all the side effects may not be known. There may be some rare and unknown side effects.

Known side effects of gepotidacin are listed below:

- Very common (may affect more than 1 in 10 people)
  - Nausea (upset stomach)
  - Diarrhoea
- Common (may affect up to 1 in 10 people)
  - Flatulence (gas)
  - Soft stools
- Uncommon (may affect up to 1 in 100 people)
  - Abdominal discomfort
  - Vomiting

In a smaller number of people, mild increases in liver enzymes (indicates liver damage) have been seen; they were reversible and did not show any symptoms. Also, some people have experienced dizziness, mouth discomfort, sweating and headaches.

In some participants gepotidacin has been shown to slightly increase the heart rate and to modify the electrical activity of the heart (ECG) for a short period of time. These changes were not significant.

Known side effects of treatment with ceftriaxone plus azithromycin are listed below:

- Very Common (may affect more than 1 in 10 people)
  - Warmth or tightness at injection site
- Common (may affect up to 1 in 10 people)
  - Diarrhoea/loose stools
  - Nausea (upset stomach)
  - Abdominal discomfort
  - Rash
  - Vomiting
- Uncommon (may affect up to 1 in 100 people)
  - Injection site pain or tenderness
  - Itchy or wanting to scratch
  - Fever or chills
  - Pain, itching, discharge of the vagina

All antibiotics, including both the new one being tested in this study (gepotidacin) and the standard treatment being used in this study (azithromycin and ceftriaxone), can be associated with diarrhea due to a bacterial infection caused by *Clostridium difficile*. This infection can occur up to several weeks after study medication has been completed and requires treatment. It is important to tell the study doctor if you develop diarrhea or loose stools after the study.

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

The side effects listed below require immediate medical attention or advice. **Call the study doctor or emergency services immediately if you have any of these side effects:**

- Swelling
- Tingling around the mouth or throat
- Difficulty breathing
- Bad skin rash which could be itchy

- You feel very tired or faint
- You feel a rapid heard rate when not exercising
- You become confused

Risks associated with study procedures/tests are listed below:

- When giving blood, you may feel faint or experience mild pain, bruising, irritation, or redness from the needle.
- Bruising can occur at the sites of repetitive blood draws.
- If you are in the group who receives ceftriaxone and azithromycin, you will receive an injection (needle) into a muscle. You may feel faint or experience mild pain, bruising, irritation, or redness from the needle.
- The ECG test is a recording of the electrical activity of the heart. The sticky pads used may be cold when applied and sometimes cause discomfort such as redness and itching.
- The collection of urogenital swab specimens may be uncomfortable.
- The collection of optional back of the throat and rectal swab specimens may be uncomfortable.

Risks associated with pregnancy and breastfeeding

The effects of gepotidacin, ceftriaxone, or azithromycin 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 breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not donate sperm while you are participating in the study.

Both male and female participants are strongly advised to use effective contraception during the course of the research. You should discuss methods of effective contraception with your study doctor.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant, but you may remain in the study for follow-up. Your study doctor will follow-up with you until the delivery of the baby.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

10 What will happen to my test samples?

You will be asked to give blood and urine samples for testing.

Your blood, urine, and swab (urogenital, and rectal and/or throat if you have consented to these optional swabs) specimens will be given a code (so that none of your personal information, such as name or date of birth, is not displayed on the samples) and stored securely at the central labs performing the testing: PPD Global Central Labs (Highland Heights, KY, USA), PPD Global Central Labs (Zaventem, Belgium), and PPD Global Central Labs (Singapore). Once the samples are tested, any remaining material is destroyed, unless you have consented to the use of these samples in optional further research (see section 11) Anyone who works with your samples will hold the coded information and results securely and in confidence.

GSK may store your blood and urine samples until the data is fully analysed, approximately 6 months after the last participant has their last visit. The samples will be stored at the following location:

PPD Laboratories
61 Science Park Road
#02-11/15, The Galen, Singapore Science Park ii
Singapore 117525

You may request destruction of samples at any time by telling the study doctor.

If you choose to stop participating in the study after giving a sample, we will not conduct any new tests on the sample. GSK will keep and use any results generated before you withdrew from the study.

Some testing is not mandatory. Why is it being done?

The back of throat and rectal swabs are part of this study. These are not mandatory samples.

- We want to learn more about how gepotidacin may work to treat infections at other body sites.
- You can choose to participate in all the sample collections or any combination of optional samples from the different body sites: rectal and back of the throat swab specimens for bacterial testing. If you chose to participate in optional samples,

the optional swabs will be collected at Visit 1 (before dosing), Visit 2, and Visit 3. Providing these swab samples may be uncomfortable.

- Your swab samples will be given a code and stored securely. Anyone who works with your samples will hold the coded information and results securely and in confidence.

11 Optional further research participation

The sponsor of this study is also requesting your consent to allow optional further research on the samples you provide. Your decision whether to take part or not to take part in this optional research, or to take part and then withdraw, will not affect your participation in the main study, your routine treatment, your relationship with those treating you or your relationship with *Melbourne Sexual Health Centre.*

If you give permission (by checking 'Yes' on the Consent Form), GSK or others, such as universities or other companies, may do additional testing on your samples to better understand the results of this study.

GSK (alone or working with others) may use your coded study data and samples and other information for other research uses that may not be directly related to this study, such as:

- To learn more about gepotidacin and other products and gonorrhoea infections and other diseases and conditions.
- To publish the results of these other research efforts. Your name will not appear in any publication.
- To share coded study data with other companies, organisations or universities to carry out research separate from GSK.
- To plan how to do future studies.

If you choose to stop participating in the optional further research after giving a sample, we will not conduct any new tests on the sample. GSK will keep and use any results generated before you withdrew from the study.

12 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.

13 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 your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the 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.

14 What if I withdraw from this research project?

If you decide to withdraw 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. No new information will be collected or processed.

If you choose to stop receiving the study medicine, you can still be involved in the study. The study doctor may ask you to return to the clinic to complete the remaining visits.

The study staff may ask to contact you by phone to learn more about your health. Knowing about your health is very important. It will help to learn more about the potential long-term effects of the study medicine.

At any time, you can withdraw consent for the use of your personal information. This applies either for the study or for further research or for both. If you withdraw consent for the use of your personal information for this study, then you will leave the study. This will not affect your medical care.

If you withdraw consent for the use of your personal information for the study or for further research, GSK may still use your personal information if it needs to do so for legal reasons or if necessary for certain scientific research purposes and where permitted by law.

15 Could this research project be stopped unexpectedly?

You may need to leave the study if:

- Test results show that this study is not right for you.
- You do not follow study instructions.
- The study doctor thinks it is best for you to stop, for example, if you have specific health problems.

- You decide that you want to become pregnant.

It is possible that the entire study may need to be stopped for everyone. It may include reasons such as:

- Unacceptable side effects
- The drug/treatment/device being shown not to be effective
- The drug/treatment/device being shown to work and not need further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

If this happens, the study doctor will explain the reason to you as soon as possible.

16 What happens when the research project ends?

When the study is completed at all the study sites, the data will be analysed. You will have an opportunity to learn of the study results. You may ask the study doctor for the results and to have them explained to you.

Part 2 How is the research project being conducted?

17 What will happen to information about me?

What personal information is collected about me for the study?

Your personal information will be collected as part of the research study described in this informed consent form. This section of the Participant Information and Consent Form describes how your personal information will be used. It also describes your rights relating to that personal information. GSK is the global sponsor of the study and PPD Australia Pty Ltd is the local sponsor.

The study doctor and other study staff will collect your personal information. This may include the following:

- Your name, address, telephone number, and health insurance number, where applicable.
- Your age and gender.
- Your ethnic and racial background is to be collected for clinical research purposes only.
- Lifestyle information and health and medical history.
- Your study treatments and response to study treatments.
- Data resulting from testing your biological samples.

Who has access to my personal information?

All personal information collected for this study will be stored in the study medical records at the study site. **Your personal information that directly identifies you will not leave the study site.**

GSK and PPD Australia Pty Ltd staff, Independent Review Boards (IRBs), and Ethics Committees (ECs) (that approve and monitor studies) and others may check the study records. This is done to make sure that the study is being run properly.

Regulatory agencies, such as the US Food and Drug Administration, European Medicine Agency, Australian Therapeutic Goods Administration (TGA) or others, including the Biomedical Advanced Research and Development Authority (BARDA), review and approve new medicines. These agencies will be granted direct access to your information, so they can verify the clinical trial procedures and/or data.

How is my personal information coded?

. To maintain your confidentiality, your study data will only be identified by a unique numerical code (such as '123456') that will be assigned to you at the beginning of the study and will be kept securely and confidentially by the study site. Only coded study data that does not contain any personal information that directly identifies you (such as your name, date of birth, address, etc) will be sent to GSK or PPD Australia Pty Ltd with the study results.

How is my personal information anonymised?

When the code list is destroyed, your information is "anonymised". Once your information is anonymised, it can *no longer be linked to you.* All personal identifiers have been completely removed.

GSK and other scientists and organisations use anonymised information to learn about diseases and medicines. It may be used for this study or other purposes, including further research (if you specifically consent to this use), once the study is complete.

How long will my personal information be used?

Your personal information will be used for only as long is needed for the study and further research, with your consent. It may be retained for longer, where required by law. GSK must retain data from clinical trials for up to 30 years.

How is my personal information protected? What if it is transferred?

Appropriate measures will be taken to protect your personal information. These measures will comply with the data protection and privacy laws that apply.

Personal information may be transferred to trusted persons in other countries. The data protection and privacy laws may not be as strong in these countries as the laws in Australia. When personal information is transferred, GSK and PPD Australia Pty Ltd will make sure that appropriate and suitable safeguards are used.

More information about the safeguards used is found at:

- https://ec.europa.eu (use the site search function to search for "model contracts

for the transfer of personal data"); and

- http://se.gsk.com/media/248019/binding-corporate-rules-policy.pdf (GSK Rules and Policies)

What right do I have to access my personal information?

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.

You may also:

- Request to transfer your personal information to a third party (such as your personal doctor), in a format suitable for re-use.
- Object to what is done to your personal information.
- Complain to your local data protection authority, if your privacy rights are violated.
- Claim compensation for damages or distress incurred or suffered from the unlawful use of your personal information, 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). Please refer to http://www.oaic.gov.au/privacy/privacy-complaints for more information.

Who owns the study results?

GSK will be the owner of the study results. GSK plans to use the results and may get patents, sell the product in the future, or make profits in other ways. You will not be paid any part of such profits.

What is a data controller?

A data controller collects and processes personal information. It determines why and how it is processed. GSK is the data controller for this study. GSK's Data Privacy Officer can be contacted at EU.DPO@gsk.com. In order to retain your anonymity, please contact persons listed in section 20 "Further information and who to contact" as a first option.

18 Complaints and compensation

If you suffer 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 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 project:

- The pharmaceutical industry has set up a compensation process, with which the Sponsor PPD Australia Pty Ltd of this research project has agreed to comply. Details of the 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. A copy of the Guidelines is available to you from the research staff on request. If you have any questions about the Guidelines, please contact The Human Research Ethics Committee at Alfred Hospital on telephone (03) 9076 3619.
- You may be able to seek compensation through the courts.

Signing this document will not affect your right to take legal action if you believe that you were injured because you were in this study.

19 Who is organising and funding the research?

This research is being conducted by GlaxoSmithKline (also called “GSK”) and sponsored in Australia by PPD Australia Pty Ltd. GSK is a healthcare company that discovers and makes vaccines, medicines and other health products.

GSK is also the global study sponsor, which means they pay *Melbourne Sexual Health Centre* to run this study. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

GSK has received money from the Biomedical Advanced Research and Development Authority (BARDA) – part of the US Department of Health and Human Services – to do this study. The doctors at *Melbourne Sexual Health Centre* have no financial interest in GSK or BARDA.

20 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 Alfred Health, the Alfred Hospital Ethics Committee.

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.

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 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 *03 9341 6262* or any of the following people:

Clinical contact person

Name	A/Prof. Marcus Chen
Position	Principal Investigator
Telephone	03 9341 6260
Email	mchen@mshc.org.au

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

Name	The Complaints Officer
Position	The Complaints Officer
Telephone	03 9076 3619
Email	research@alfred.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	Alfred Hospital Ethics Committee
Position	HREC Executive Officer
Telephone	03 9076 3619
Email	research@alfred.org.au

Consent Form - *Adult providing own consent*

Study title	A Phase III, Randomized, Multicenter, Open-Label Study in Adolescent and Adult Participants Comparing the Efficacy and Safety of Gepotidacin to Ceftriaxone Plus Azithromycin in the Treatment of Uncomplicated Urogenital Gonorrhea Caused by *Neisseria gonorrhoeae*
Short Title	Phase III, Comparator-Controlled, Efficacy and Safety Study of Gepotidacin in the Treatment of Uncomplicated Urogenital Gonorrhea
Protocol Number	BTZ116577
HREC Reference	HREC/56581/Alfred-2019
Global Sponsor	**GlaxoSmithKline (GSK) UK**
Local sponsor	**PPD Australia Pty Ltd**
Coordinating Principal Investigator	**Dr James McMahon**
Principal Investigator	*A/Prof. Marcus Chen*
Associate Investigator(s)	*Dr. Ian Denham*
Location	*Melbourne Sexual Health Centre*
Local Project Number	*738.19*

Consent for the Study and Further Research Explained

1) **Consenting to use of your personal information for the study:**
If you check "Yes" on the signature page where it says:

"*I consent to GSK, study staff, and others accessing and using my medical and personal information for the study as described in this form*",

GSK (alone or working with others) may use your coded study data and samples and other information for these study purposes:

- To carry out this study and to understand the results of this study.
- To learn more about gepotidacin or about gonorrhoea infections.

- To publish the results of these research efforts. Your name will not appear in any publication.
- To work with government agencies or insurers to have gepotidacin approved for medical use or approved for payment coverage.

2) Consenting to use of your personal information for FURTHER RESEARCH:

If you also check "Yes" on the signature page where it says:

"*I consent to GSK, study staff, and others accessing and using my medical and personal information FOR FURTHER RESEARCH, once the study is complete*,"

GSK (alone or working with others) may use your coded study data and samples and other information for other research uses that may not be directly related to this study, such as:

- To learn more about gepotidacin and other products and gonorrhoea infections and other diseases and conditions.
- To publish the results of these other research efforts. Your name will not appear in any publication.
- To share coded study data with other companies, organisations or universities to carry out research separate from GSK.
- To plan how to do future studies.

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 *Melbourne Sexual Health Centre* 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.

STUDY PARTICIPANT CONSENT TO PROCESSING PERSONAL INFORMATION

I consent to GSK, study staff and others accessing and using my medical and personal information for the study.

☐ YES

☐ NO

I know that I can withdraw this consent for use of my medical and personal information at any time.

OPTIONAL SAMPLES/RESEARCH

I consent to GSK, study staff and others accessing and using my medical and personal information FOR OPTIONAL FURTHER RESEARCH, once the study is complete.

☐ YES

☐ NO

The back of throat and rectal swabs are part of this study. These are NOT mandatory samples, they are optional. Do you agree to allow the study doctor and staff to collect these samples?

Back of Throat swab	Rectal swab
☐ YES	☐ YES
☐ NO	☐ NO

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required.*

Name of Witness* to Participant's Signature (please print) _____ ☐ not applicable

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.

Form for Withdrawal of Participation - *Adult providing own consent*

Study title	A Phase III, Randomized, Multicenter, Open-Label Study in Adolescent and Adult Participants Comparing the Efficacy and Safety of Gepotidacin to Ceftriaxone Plus Azithromycin in the Treatment of Uncomplicated Urogenital Gonorrhea Caused by *Neisseria gonorrhoeae*
Short Title	Phase III, Comparator-Controlled, Efficacy and Safety Study of Gepotidacin in the Treatment of Uncomplicated Urogenital Gonorrhea
Protocol Number	BTZ116577
HREC Reference	HREC/56581/Alfred-2019
Global Sponsor	**GlaxoSmithKline (GSK) UK**
Local sponsor	**PPD Australia Pty Ltd**
Coordinating Principal Investigator	**Dr James McMahon**
Principal Investigator	*A/Prof. Marcus Chen*
Associate Investigator(s)	*Dr. Ian Denham*
Location	*Melbourne Sexual Health Centre*
Local Project Number	*738.19*

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 *Melbourne Sexual Health Centre.*

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant'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 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.