APPROVED BY SALUS IRB: 20 NOVEMBER 2017

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A CLINICAL INVESTIGATION

Protocol #: W-5107-103
Title: A Phase I, Open-label Study of the Metabolism, and Excretion of [^{14}C] Zidebactam (WCK 5107) Following a Single Intravenous Infusion in Healthy Male Subjects

Principal Investigator: (Study Doctor) Nicholas Siebers, MD

Research Site Address: Covance Clinical Research Unit, Inc.
3402 Kinsman Boulevard
Madison, Wisconsin 53704

Telephone #: (608) 442-8200

24 hour Telephone #: (608) 442-8200

Sponsor: Wockhardt Bio AG

You are invited to participate in a drug research study. However, before you give your consent to be a study participant, please read the following and ask as many questions as necessary to be sure that you understand what your participation will involve. You will be given a copy of this form to take home with you.

INTRODUCTION

Your participation in this research study is voluntary. It is important that you read and understand the following explanation of the proposed procedures. This form describes the purpose, activities, benefits, alternatives, recognized or known risks, discomforts, and precautions of the study, including the duration and nature of your participation. It also describes your right to withdraw from the study at any time. To enter the study, you, as the study participant, must sign and date this consent form.

Please Note: If you are not completely truthful with your study doctor regarding your health history, including allergies and medication usage, you may harm yourself by participating in this study.

Covance Clinical Research Unit Inc. is paid to test new drugs. The study doctors in this study work for Covance, but do not have a financial interest in the outcome of this study.

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

NATURE AND PURPOSE OF THE STUDY

Zidebactam is an investigational antibiotic drug being developed for the treatment of bacterial infections. An investigational drug is a drug that has not approved by the U.S. Food and Drug Administration (FDA).

The purpose of this study is to measure how much of the study drug gets into the bloodstream, how the body processes the study drug, and how long it takes the body to get rid of it. In addition, the safety and tolerability of the study drug will be evaluated.

This type of study is called a radiolabeled study. For this study, zidebactam has been specially prepared to contain radiolabeled carbon [^{14}C]. [^{14}C] is a naturally occurring radioactive form of the element carbon. Adding a low dose of radiation to the study drug does not change how the drug works, but helps us to see how the drug appears in the blood, urine, and stool after it is given to you.

This study is for research purposes only and is not intended to treat any medical condition.

STUDY PARTICIPANT SELECTION

You are invited to participate in this research study because you are a healthy male between the ages of 18 and 55, inclusive, and meet all of the criteria to participate in this study.

It is important that you answer all of the screening questions truthfully and completely. You must disclose all past and present diseases, allergies and all medications that you are taking, including prescription and non-prescription drugs. **It could be dangerous to your health if you do not completely disclose all information about your medical history, any medical condition you have and any medication that you have taken.**

Approximately 8 participants will be enrolled in this single-site research study. This will be the only site participating in this study.

STUDY DURATION

The duration of your participation in this study is up to approximately 14 days, not including a screening visit. This study requires one clinic confinement of up to 8 days/7 nights. During your stay on the research unit, it is possible that you may be discharged earlier than 8 days if your body has gotten rid of the study drug before then. It is possible that you may only need to stay 6 days (5 nights) at the research unit. It is important that your schedule is flexible enough to adjust to a shorter stay. A Follow Up telephone call will be made 2-6 days after discharge from the research unit. A screening visit is also required up to 28 days prior to the start of the research study to determine if you qualify and are willing to participate in this research study.

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

STUDY DESIGN

On Day 1, you will be given a single dose of 1 g [^{14}C]-zidebactam given as an intravenous (IV; needle inserted into a vein) infusion over 1 hour.

The study drug will be given in the morning after an overnight fast (no food or drink other than water) of 8 hours.

SCREENING

You will come to the clinic for a screening visit to determine if you are eligible and willing to participate in this study. Prior to any procedures being performed, you will be asked to sign this informed consent form. You may have your photo taken for study identification.

During this screening visit, the following procedures will be completed:

- Demographic information will be collected (age, sex, race, ethnicity).
- A medical history (including medications you are taking), measurement of vital signs (temperature, pulse, blood pressure and breathing rate), measurements of height, weight, and body mass index (BMI; a measure of your body fat based on your height and weight) will be completed.
- Electrocardiogram (ECG; heart rhythm tracing) will be performed. You may need to have your chest hair shaved before the ECGs so the ECG patches will stick to your skin.
- Review of inclusion and exclusion criteria.
- Blood and urine samples for clinical laboratory testing will be obtained.
- A screening for human immunodeficiency virus (HIV), hepatitis, cotinine (a test for nicotine) and drugs of abuse will be done.

HIV is the virus that can cause acquired immunodeficiency syndrome (AIDS). Before you can qualify to be in this study, you must test negative for signs of HIV infection. A blood test can show if you have been exposed to, or are infected with HIV by checking for the virus (antigens) or antibodies. Antibodies are substances produced by the body's immune system to fight infection.

Agreeing to have the HIV test done is a voluntary decision that only you can make. However, if you choose not to have the HIV test performed, you will not be able to participate in this study.

The HIV antibody test will be done confidentially. Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get medical or study records without your permission. A positive HIV result does not mean that you have HIV or AIDS, and a negative test result does not mean that you are not infected because it can take up to three months for the test to indicate infection. Positive

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

results for hepatitis and HIV must be reported to a local health agency. This is the legal obligation of health professionals in this state. If you have any questions about what information is required to be reported please ask the study staff. If the test is positive, you will be told about counseling.

You will be permitted to participate in the study, at the discretion of the study doctor, if the results of the study screening laboratory tests and other assessments are satisfactory. Screening procedures may need to be repeated in order to qualify for this study. You will be advised of the study restrictions and when to report to the research unit to begin the study. You may be considered an alternate for this study until such time that you have received study drug.

Covance checks in more people than are needed for the study in case someone fails to check-in or becomes ineligible for the study. Not everyone will be chosen to stay in the study long enough to take the research drug.

Some screening procedures may require repeating at check-in to confirm eligibility. These tests may show a change from screening which indicates a change to your health or physical being which may make you ineligible at check-in**.**

If you are not chosen to stay in the study, you will go home from the research unit the same day or the next morning. You will be paid for the time spent in the research unit.

STUDY PROCEDURES

Periodically during the study, vital signs will be measured and ECGs will be performed. You will also be asked about how you are feeling and if you have taken any medications. In addition, the blood and/or urine samples collected in this study may be used for routine clinical laboratory testing or study drug analysis.

The study doctor may require longer observation after Day 5 (but no longer than Day 7) at the research unit. Additional laboratory testing may be taken based on the recovery of the radiolabeled drug as determined by continued urine and stool collection.

Please note that the exact schedule for the procedures described in this consent form is subject to change. Some procedures may not be performed, and some may be added or moved to other study days.

<u>Day -1 (Check-in)</u>

You will come to the research center the day prior to dosing (Day -1) to begin your clinic confinement. You will stay at the research center for up to 8 days and 7 nights. The following will occur on Day -1:

- Review medications you are taking and adverse events (AEs; health issues you may be experiencing or have experienced since screening)

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

- Review inclusion/exclusion criteria
- Review medical history
- Measure vital signs
- Weight measured and BMI calculated
- Physical examination will be performed
- ECG will be performed
- Collect urine sample to screen for drugs of abuse (including cotinine) and an alcohol breath test
- Collect blood and urine samples for clinical laboratory testing
- Collect all of your stool and urine in special containers
- Begin clinic confinement

Day 1

- Prior to dosing:
  - Review medications you are taking and AEs
  - Measure vital signs
  - Blood samples collected
  - Collect all of your stool and urine in special containers
- You will then receive study drug over 1 hour infusion.
- After dosing:
  - Measure vital signs
  - Blood samples will be collected 14 times over the next 20 hours
  - Collect all of your stool and urine in special containers

Day 2

- Review medications you are taking and AEs
- Measure vital signs
- Blood and urine samples collected
- Collect all of your stool and urine in special containers

Days 3 to 4

- Review medications you are taking and AEs
- Measure vital signs
- Blood samples collected
- Collect all of your stool and urine in special containers

Day 5 (Possible Discharge or Early Termination)

You will remain at the research unit until at least the morning of Day 5. If you qualify for discharge, the following procedures will be completed:

- Review medications you are taking and AEs
- Blood and urine samples will be collected

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

- Measure vital signs
- ECG will be performed (only if discharging)
- Physical examination will be performed (only if discharging)
- Collect all of your stool and urine in special containers until discharge
- You will be discharged from the clinic.

Additional Days at the Research Unit (Days 6 through 7)
If you are required to stay at the research unit for longer observation, the following procedures will be performed on each day:

- Review medications you are taking and AEs
- Vital signs measured
- Blood samples collected
- Collect all of your stool and urine in special containers until discharge.

Follow-up Phone Call (2-6 days after discharge)
You will receive a phone call and be asked questions about how you are feeling, about any AEs you may have experienced since discharge, and about any medications you may have been taking.

At the completion of these final study procedures, your participation in this study will be complete.

If necessary, the study doctor may require that you stay longer for observation in the research unit or for additional laboratory testing based on the effects of the study drug or the results of the laboratory tests.

If you should develop a visible side effect, such as a skin rash, you may be asked to allow pictures of the side effect (rash) to be taken for the study records.

WITHDRAWAL PROCEDURES

If you withdraw early from the study, for any reason, you may be asked to complete the lab testing and procedures outlined in the Possible Discharge or Early Termination section.

MEALS

Standardized high fiber meals and snacks will be served at regular times during your clinic confinement except when fasting is required or as otherwise noted.

STUDY PARTICIPANT RESPONSIBILITIES

As a study participant you will be asked to complete the study procedures for this study, come to the study clinic for all of your scheduled visits, follow the instructions listed in this informed consent form, and notify the study doctor if any information regarding your

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

health or availability to participate in this study changes.

RESTRICTIONS

- You must not use any tobacco products or nicotine products (smoking, patches, gums, e-cigarettes, etc.) within 3 months prior to Check-in (Day -1) and throughout the study
- You must not have used any investigational drug within 30 days prior to Check-in (Day -1).
- You must not have previously completed or withdrawn from another study investigating zidebactam or previously received the investigational product.
- You must not consume alcohol from 48 hours prior to Check-in (Day -1) and throughout the study.
- You must not consume any caffeine- or xanthine-containing products (for example, coffee, tea, chocolate, soda, or energy drinks) from 48 hours prior to Check-in (Day -1) and throughout the study.
- You must not consume food or beverages containing grapefruit, poppy seeds, or Seville oranges from 7 days prior to Check-in (Day -1) and throughout the study.
- You must not have received blood products within 2 months prior to Check-in (Day -1).
- You must not have donated blood within 56 days, plasma (for example, plasmapheresis) within 2 weeks, or platelets within 6 weeks prior to Screening until after the Follow-up phone call.
- You must not use or intend to use nonprescription medications/products including vitamins, minerals, and phytotherapeutic/herbal/plant-derived preparations (eg, ephedra, gingko, ginseng, licorice, and kava) within 7 days prior to Check-in (Day -1).
- You must not use or intend to use slow-release medications/products considered to still be active within 14 days prior to Check-in (Day -1).
- You must not use or intend to use medications/products known to alter drug absorption, metabolism, or elimination processes (eg, St. John's wort) within 14 days prior to Check-in (Day -1).
- You must not use or intend to use any prescription medications/products within 14 days prior to Check-in (Day -1).
- You must not take part in any strenuous exercise within 48 hours prior to Check-in (Day -1) and throughout the study.
- You must not have participated in a radiolabeled study within the last 4 months or participated in more than 2 radiolabeled studies within the last 4-12 months prior to Check-in (Day -1).
- You must not have been exposed to significant radiation (eg, serial x-ray, or computed tomography scans, barium meal, current employment in a job requiring radiation exposure monitoring) within 12 months prior to Check-in (Day -1).

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

- If you are sexually active with a female partner of childbearing potential, you must use a male condom with spermicide from Check-in until 90 days after dosing.
- You must not donate sperm from Check-in until 90 days after dosing.

RISKS AND DISCOMFORTS

Risks are possible side effects of the study drug and those of taking blood. While on this study, you are at risk for the side effects listed in this form. However, you may also experience side effects which are unexpected and unforeseen. You should discuss all of them with the Study Doctor.

Risks of Zidebacatam (WCK 5107)

To date, zidebactam has been administered to 107 healthy adult human subjects. Overall, single doses (250 to 3000 mg) and multiple doses (1 or 2 g every 8 hours for 7 days resulting in a total of 3 or 6 g) of zidebactam were well tolerated by healthy subjects.

The most commonly observed adverse events were the following:

- Headache
- Infusion site swelling
- Site erythema (redness at the infusion site)

Other adverse events that have been observed with zidebactam alone or together with cefepime, another antibiotic, include:

- Abdominal pain
- Diarrhea
- Urticaria (hives)
- Numbness around the mouth
- Rash

All events were mild or moderate in severity. No findings of clinical relevance were noted for any subject in clinical laboratory evaluations, 12-lead electrocardiograms (ECGs), or vital signs.

SIDE EFFECTS POTENTIALLY ASSOCIATED WITH RADIATION

Radiation exposure is measured in millirems. The highest amount of radiation allowed by law in a single dose for research participants is 3,000 millirems per research study and cannot exceed 5,000 millirems a year. In this study, you will receive up to 5 millirems of radiation, depending on the calculation used. This is in addition to the amount of radiation that you receive from the natural and artificial (such as medical) sources in the environment each year. In the Madison area, the annual amount of natural radiation is 360 millirems. Individuals are routinely exposed to natural

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

environmental radiation.

Natural environment radiation can come from cosmic radiation, radiation from the earth, radiation inside your body, and radiation from radon gas, among other natural sources.

Although there are no proven harmful effects from the radiation you will receive in this study, long term effects of this radiation on your health cannot be known for certain.

UNKNOWN/UNFORESEEABLE RISKS
There are certain risks and discomforts that may be associated with this research. As with all investigational products, there may be risks with the study drug that are unknown and cannot be predicted at this time. If you have questions about possible side effects, please ask your study doctor. **Because of the potential risks and side effects that can occur with the study product, it is important that you inform the Investigator of any changes in your condition while participating in the study.**

ALLERGIC REACTION
In addition to the risks listed above, there may be unknown, infrequent, and unforeseeable risks associated with the use of this medication, including severe or life threatening allergic reactions or unexpected interactions with another medication. Symptoms of an allergic reaction may include rash, flushing, itching, sneezing or runny nose, abdominal pain, diarrhea, swelling of face, tongue or throat, dizziness, lightheaded or fainting, trouble breathing, irregular or racing heart rate, and seizures.

NEW INFORMATION
You will be informed in a timely manner, both verbally and in writing, of any new information, findings or changes to the way the research will be done that might influence your willingness to continue your participation in this study.

If you experience an injury, bad effect, or any other unusual health experience during this study, you must immediately contact the study doctor or the study staff.

RISKS TO THE UNBORN
***Pregnancy/Fetal Risks*:** The effects of the study drug on the unborn child are unknown and may be hazardous. It is important that you use the appropriate forms of birth control for the duration of the study and that your female partner does not become pregnant, or breastfeed a baby. If you think that your partner may have become pregnant during the study it is important that you inform the study doctor immediately. If your partner becomes pregnant or thinks that she may be pregnant, the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility. The study doctor may request to track the pregnancy and will report the pregnancy and outcome to the Sponsor and the IRB.

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

If you are sexually active with female partners of childbearing potential (able to get pregnant) you will be required to use a male condom with spermicide from Check-in (Day -1) until 90 days after the last dose of study drug.

In addition you must refrain from donating sperm from Check-in (Day -1) until 90 days after the last dose of study drug.
Subjects who practice true abstinence, because of the subject's lifestyle choice (ie, the subject should not become abstinent just for the purpose of study participation), are exempt from contraceptive requirements. Periodic abstinence (eg, calendar, ovulation, symptothermal, postovulation methods for your female partner) and withdrawal are not acceptable methods of contraception. If you are abstinent at the time of signing the ICF but become sexually active with a female partner, you must agree to use contraception as described previously.

For subjects who are exclusively in same-sex relationships, contraceptive requirements do not apply. If a subject who is in a same-sex relationship at the time of signing the ICF becomes engaged in a heterosexual relationship, they must agree to use contraception as described previously.

BLOOD SAMPLING
Blood samples will be taken approximately 24 times if you remain confined to the research unit through Day 7. Approximately 323 mL of blood, (a little less than 1.5 cups), will be drawn throughout the study. Additional blood samples may be required if any of your lab values are abnormal. It is possible that more than one attempt to obtain a blood sample may be necessary. For comparison, a standard blood donation at a blood collection center, once in any 56-day period, is about 500 mL (about 2 cups) of blood. Additional blood samples may be drawn during the study if the study doctor considers it necessary for monitoring your health.

During the collection of blood samples, you may experience pain and/or bruising at the insertion site of the needle/catheter or location of the blood pressure cuff. Localized clot formation, nerve damage and infections may occur. Lightheadedness and/or fainting may also occur during or shortly after the blood draw.

Any biological (blood or urine) samples collected during your Screening Visit that are left over after screening lab tests are complete, may be used in the laboratory for quality control purposes. If any of your leftover biological samples are used this way, your direct identification will first be removed from the sample. Results of this testing will not be reported from the lab nor linked to you or the study.

STUDY PROCEDURE RISKS
ECG patches may cause a skin reaction such as redness or itching. You may also experience localized skin discomforts and/or hair loss associated with the placement of

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

ECG leads.

BENEFITS

Participation in this study is purely for research purposes. You may benefit by having physical examinations. The results of laboratory tests done at the screening visit will be made available to you upon request. However, if you are disqualified for study participation by other screening procedures, some laboratory tests may not be conducted.

ALTERNATIVES TO PARTICIPATION

Since this study is for research only, your alternative is to not participate in this study.

COST

There is no cost for participating in this research study (the study sponsor pays all the study costs). However, you are responsible for any transportation and/or living costs incurred while traveling to and from the research unit. This includes having adequate travel arrangements should you not be selected for the study for any reason.

COMPENSATION FOR BEING IN THIS STUDY

You will be compensated for taking part in this research study as outlined below. This is to compensate you for your time and inconvenience. Each portion of the research study has a dollar value assigned to it, which accumulates as you participate in this study.

Compensation Schedule

Screening Visit	-0-
Research unit Confinement Nights Minimum: : (5 nights x $250.00) Maximum: (7 nights x $250.00)	 $1,250.00 $1,750.00
Follow-up Phone Call (1 x $25.00)	$25.00
Time Commitment	$800.00
TOTAL (Up to)	$2,575.00

Total compensation for study completion will be up to $2,575.00. If you choose to withdraw from the research study, you will receive compensation only for the portion of the study that you have completed as outlined above. If it is necessary for you to return to the research unit for additional safety follow up visits, you will be compensated $150.00 for each completed visit.

If it is determined by the study doctor or sponsor that you should stop the study early, you will be compensated for the portion of the study you completed.

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

If you are selected as an alternate and not selected to participate in the study, you will be compensated $250.00 for each overnight stay. As an alternate, if you test positive for any unauthorized drugs, cotinine or alcohol, you will not be compensated.

All study participants will receive their compensation within 21 days of the completion of their participation in the study. Compensation will be issued in the form of a check or direct deposit. The form of compensation will be determined by the study staff.

In agreeing to participate in this study, you will be acting in your individual capacity, not as an employee of Covance Clinical Research Unit, Inc. No taxes are deducted from your check. You are responsible for paying any state, federal, or Social Security taxes. You will be required to provide your Social Security number or tax identification number to Covance, if you have one. If you receive $600 or more in one calendar year from Covance, you will receive a 1099 tax form the following January. Covance reports the money you receive to the Internal Revenue Service.

If you do not have a social security number or tax identification number, the Internal Revenue Service (IRS) requires Covance to deduct 30% from your compensation. You will need to follow IRS guidelines to determine if you are eligible for a refund or contact a tax professional to assist you.

RIGHT TO WITHDRAW OR REMOVAL FROM STUDY

Your participation in this study is completely voluntary. You are free to withdraw from this study at any time; however, you must inform the study doctor immediately if you intend to withdraw. Your decision to participate in this study or to withdraw from this study will not influence the availability of your future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled. If you withdraw from the study or are removed from the study, no new data about you will be collected for study purposes. All data that have already been collected for study purposes will be shared with the study sponsor.

The study sponsor or study doctor in charge of the study can remove you from this study without your consent for any reason, including, but not limited to:

- His/her judgment that any condition or circumstance may jeopardize your welfare or the integrity of the study
- Your failure to follow the instructions of the Study Team
- If the study is stopped by the sponsor, FDA, IRB and/or doctors participating in the study prior to completion, or the sponsor asks that you be removed from the study.

It is possible that because of the effects of the study drug/s, the study doctor may

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

determine that it is unsafe for you to drive a motor vehicle. If you wish to leave the study, the study staff will assist you in making the necessary transportation arrangements for you to leave safely.

CONFIDENTIALITY

If you agree to take part in the research study, information about your identity, health and your participation will be collected, recorded, and stored electronically by the study staff.

The Sponsor and its representatives, US Food and Drug Administration (FDA), health authorities and Salus IRB may inspect your paper and electronically stored research medical records which may include your name, address and other personal information that identifies you. If necessary, some or all of your medical records may be copied during these inspections.

The results of this research study may be presented at meetings or in publications. However, you will not be personally identified in any presentations or publications.

Because of the need to use information as noted above, absolute confidentiality cannot be guaranteed. Covance may need to share the personal health information we collect with other research facilities in order to protect your safety and/or to safeguard the integrity of the study data.

BUSINESS CONFIDENTIALITY

The information and any materials or items that you are given during the study, such as information identifying the research unit, the sponsor, any study drug(s), and/or the type of study being performed, should be considered confidential business information of Covance and the study sponsor. You are, of course, free to discuss such information in confidence with your personal doctor or with your friends and family while considering whether to participate in this study or at any time when discussing your present or future healthcare. However, distributing confidential business information as described above to the media or posting it on the Internet is prohibited.

IN CASE OF INJURY

Your safety is the major concern of every member of the staff. Please contact the study staff as soon as possible if you have side effects or injuries. The phone number for Covance is (608) 442 -8200.

Covance will provide immediate medical treatment and follow-up care, without cost to you, for side effects or injuries caused by being in this study. The costs for any other medical problems, not caused by being in this study, are your responsibility. There are no plans to provide you with financial compensation for such things as lost wages, disability or discomfort due to injury.

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

PERSONS TO CONTACT FOR QUESTIONS, CONCERNS, OR COMPLAINTS

If you have any questions, concerns or complaints about this study, call The study doctor at the number listed on the first page of this document.

You have the right to ask any questions concerning the potential and/or unknown hazards of this study, at any time. If you have any questions concerning your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction to the study drug, contact the study doctor listed on the first page of this document.

If you have questions about your rights, general questions, complaints or concerns about this research, or questions about your rights as a person taking part in this study, contact Salus IRB:

Salus IRB
2111 West Braker Lane, Suite 400
Austin, TX 78758
Phone: 855-300-0815 between 8:00 am and 5:00 pm Central Time
Email: salus@salusirb.com

Salus IRB has approved this study and this informed consent document. Salus IRB is a committee of scientific and non-scientific individuals who review, require modifications to, and approve or disapprove research studies by following the federal laws. This group is also required by the federal regulations to provide periodic review of ongoing research studies.

If, at any time during or after your participation in this research, you would like information or to offer input about your research experience, you can call Salus IRB at the number above or you can go to the Salus IRB website at www.salusirb.com and share your comments. Either way, you do not have to provide your name, if you do not want to.

LEGAL RIGHTS

You will not lose any of your legal rights to which you are otherwise entitled by signing this consent form.

CLOSING STATEMENT

You have read the information which has been stated above and have received satisfactory answers to all of the questions which you have asked and you willingly sign this consent form. You will receive a copy of the signed and dated informed consent document to keep. You hereby consent to be a participant in this study.

You may withdraw this consent at any time.

APPROVED BY SALUS IRB: 20 NOVEMBER 2017

Please read the following paragraph out loud to the person obtaining the consent.

- I have read the above information in a language that I understand well.
- The content and meaning of this information have been explained to me.
- I have been given an opportunity to ask my questions in private as well as to meet with a study doctor to discuss this study.
- Covance will invite more people to check-in than are needed in case someone cannot participate. It is possible that I may not be selected to participate in the study once my check-in procedures have been completed. If this occurs, I will be compensated for my time and participation as outlined in this consent form.
- **I have asked the staff any questions I may have and have had enough time to decide if I want to take part in this study.**
- I hereby voluntarily consent and offer to take part in this study and authorize the use and disclosure of my medical information.
- **I also agree to the HIV testing as described in this document.**

_____	_____
Print Participant Name	Participant Signature
_____	_____
Date	Time
_____	_____
Initials of Person conducting the Informed Consent discussion and verification of literacy	Date

I have received a signed and dated copy of this study consent form to keep.

_____

Your Signature **Date**

FOR SALUS IRB USE ONLY
Initial draft mys: 20Nov17

To be Completed by Covance Staff Only:

QC'd by _____Date _____