SUBJECT INFORMATION AND CONSENT FORM
AND
AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

TITLE	A Phase I, Double-blind, Placebo-controlled, Randomized, Single Ascending Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of INDV-2000 (C4X_3256) under Fasting and Fed Conditions in Healthy Volunteers
PROTOCOL NO.	INDV-2000-101 Part 1
PRINCIPAL INVESTIGATOR (STUDY DOCTOR)	[redacted], M.D., PhD, MPH
RESEARCH SITE ADDRESS	Altasciences Clinical Kansas, Inc. 10103 and/or 10203 and/or 10183 Metcalf Avenue Overland Park, KS 66212
TELEPHONE NUMBER	(913) 696-1601 (24-hour number)
SPONSOR	Indivior

KEY INFORMATION ON THE STUDY

- During the study you will receive a single oral dose of either the investigational drug (INDV-2000) that is being developed for the potential treatment of opioid use disorder or a placebo (dummy substance that looks like the investigational drug without any active drug).
- **This is the first study in which INDV-2000 is being tested in humans. It has been tested in animals.**
- Throughout the study, the following procedures will be done to ensure your safety:
  - Physical exam
  - Electrocardiogram (ECG) - a test to monitor the electrical activity of your heart
  - Vital signs
  - Laboratory tests (blood and urine samples will be taken)
  - Monitoring by the study staff
  - Confinement at the research site for 4 nights (Days -1 to Day 4)
  - Follow-up visit on Day 11
- Throughout the study, the following procedures will be done to learn about the effects of the study drug:
  - Sedation Visual Analog Scale (VAS) – An assessment that will measure your level of sleepiness
  - Blood and urine sample collection to measure study drug levels

PURPOSE OF THE SUBJECT INFORMATION AND CONSENT FORM

This Subject Information and Consent Form may contain words or procedures you do not understand. Please ask the study staff to explain any words or procedures that you do not understand.

The purpose of this form is to give you information about this research study. This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of this research study. You should only take part in the study if you want to do so. You may refuse to take part in this study, or you may choose to withdraw from this study, at any time, without a penalty or loss of the benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form, ask as many questions as needed, and do not sign this form if you have any questions that have not been answered to your liking. Once you have read this document, if you agree to take part, you will be asked to sign the consent form. By signing this document, you are stating that you have been fully informed and give your consent to take part in the study.

A copy of this signed and dated consent form will be given to you to keep. Be sure to take the time to read through this information carefully to decide if you would like to take part in this study.

DESCRIPTION AND PURPOSE OF THE STUDY

The name of the investigational drug that you will receive in this study is INDV-2000. INDV-2000 is being developed for the potential treatment of opioid use disorder. Investigational means that the drug has not been approved by the U.S. Food and Drug Administration (FDA). You may be given placebo (dummy substance that looks like INDV-2000 without any active drug) instead of INDV-2000. The dosage will be in capsule or solution (liquid) form depending on the amount being administered and will be taken orally (by mouth).

The intent of this research study is to evaluate the safety, tolerability, and pharmacokinetics (PK) of a single, escalating oral dose of INDV-2000 in healthy adult subjects. Pharmacokinetics (PK) is the study of how a drug is absorbed, distributed, metabolized, and eventually eliminated by the body. Blood samples will be drawn throughout the study for PK analysis. Another intent of this research study is to determine the maximum tolerated dosage and the effects of a high-fat meal on the PK of INDV-2000.

There are two parts to this study. You can only participate in one part. **This is the subject information and consent form for Part 1.**

It is important that you understand how often you will need to come to the research site for the visits, how long the in-house stay is, and that you are able to keep to the study schedule and follow the rules of the research site.

The duration of your participation in this study will be approximately 39 days including the screening visit. Screening will occur within 28 days prior to you taking the study drug.

If you qualify and decide to participate, you will be one of approximately 48 healthy, non-smoking, non-tobacco using, adult male and non-childbearing potential female subjects, between the ages of 18 and 55, inclusive, participating in this part of the research study. The total number of participants for both parts of this research study is 56 people. Additional subjects in each group may also be admitted to the research site the day before dosing for each group and may serve as back-up study subjects. You may be selected to participate in this research study as either a study subject or a back-up study subject.

This is the only research site participating in this study.

DOSING AND PROCEDURES

This is a "double-blind" study. This means that neither you, nor study staff, will know if you are taking INDV-2000 or placebo. During the study, you will be assigned to receive INDV-2000 or placebo randomly (by chance, like flipping a coin). The pharmacy staff at the research site will know which study drug will be administered to you. In an emergency, the study staff can find out if you have been given INDV-2000 if it is necessary for your medical care.

You will participate in 1 of 6 possible dose groups. In each dose group, subjects will be divided into two subgroups, for safety purposes. The first subgroup will include two subjects. One subject will receive INDV-2000 and one subject will receive placebo. A safety review of data collected from the first subgroup will be done to ensure that it is safe to continue with the second subgroup. At least one day after, the second subgroup, made up of the six remaining subjects, will receive the study drug (INDV-2000 or placebo). In total, six subjects will be given INDV-2000 and 2 subjects will be given placebo in each dose group.

If you are selected to be part of the first subgroup, you have a 1 in 2 (50%) chance of receiving INDV-2000. If you are selected to be part of the second subgroup you have a 5 in 6 (83%) chance of receiving INDV-2000.

The safety review for the first subgroup of each dose group will be performed by the study staff and medically qualified personnel representing the sponsor.

You will only be participating in one group. The planned doses for groups 1-6 are provided below.

Group	No. of Subjects	Dose	Capsule or Solution	Number of subjects receiving INDV-2000 / Placebo
1 (1st subgroup)	2	1 mg	Solution	1/1
1 (2nd subgroup)	6	1 mg	Solution	5/1
2 (1st subgroup)	2	5 mg	Solution	1/1
2 (2nd subgroup)	6	5 mg	Solution	5/1
3 (1st subgroup)	2	20 mg	Capsule	1/1
3 (2nd subgroup)	6	20 mg	Capsule	5/1
4 (1st subgroup)	2	50 mg	Capsule	1/1
4 (2nd subgroup)	6	50 mg	Capsule	5/1
5 (1st subgroup)	2	120 mg	Capsule	1/1
5 (2nd subgroup)	6	120 mg	Capsule	5/1
6 (1st subgroup)	2	200 mg	Capsule	1/1
6 (2nd subgroup)	6	200 mg	Capsule	5/1

All doses will be given in the fasted state (no food or drink other than water for a minimum of 10 hours) and will be taken with approximately 240 mL (8 ounces) of water.

You will only receive one dose of INDV-2000 or placebo in the morning on Day 1 of the study.

If you are in dose groups 2 to 6, or any additional dose group, the decision to increase your dose level will be made by the Data Review and Safety Committee after they review all laboratory tests, vital signs, ECG data, reported side effects, and PK data from previous dose group(s). This is to be sure the prior dose level was well-tolerated. Depending on the overall results of this review, the dose for your group could be higher, lower, the same, or the study could be stopped. No dose will be higher than 200 mg.

Additional dose groups may be enrolled at the discretion of the sponsor.

Screening

Before the study starts, you will be asked to sign this consent form. You will be asked to give personal information about yourself such as date of birth, race, etc. You will be asked about your medical and medication history. You must be honest with the study staff about your health and medication history, or it may not be safe for you to be in this study. You will be asked and it is very important that you tell the study staff if you take any over-the-counter or prescription medicines, vitamins, herbal products, or nutritional supplements. You will also be asked about prior caffeine, alcohol, tobacco, illicit drug and controlled substance use. Any positive test result for prohibited and illicit drugs or alcohol at screening or at check in will exclude you from participating further in the study.

The study staff will do some tests to find out if you can be in the study. These tests include the following:

- Complete physical examination
- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature)
- Height and weight
- Calculate Body Mass Index (BMI) - a measure of your weight in relation to your height)
- Single ECG (male subjects may be required to have their chest shaved for the ECG; female subjects may not be allowed to wear a bra for the ECG)
- Blood and urine samples for laboratory tests
- Urine drug screen*
- Blood test for human immunodeficiency virus (HIV) and Hepatitis B and C*
- Blood pregnancy test for females*
- Blood test to confirm menopausal status for female subjects
- Alcohol urine test*

*These tests must be negative in order to continue in the study.

Prior to the above tests, you will need to fast (no food or drink other than water) for at least 8 hours.

HIV Antibody and Hepatitis Testing

As required for participation in this research study, you must have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes AIDS. If you have a positive HIV or hepatitis test, you cannot be in the study. It may take weeks or months after being infected with HIV for the test to be positive.

If either of these tests is positive, a confirmation test will be done by the laboratory.

If the HIV or hepatitis test are positive, you will be notified by the research site and given information on how to follow-up for further medical care. As required by law, positive test results must be reported

by the research site to the State Department of Health. If you have any questions about what information is required to be reported, please ask the study staff.

Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

STUDY PROCEDURES

Research Site Admission - Day -1

You will report to the research site. You will be confined to the research site for 4 nights. Standard meals and drinks during your stay will be provided. You will eat only the food and drinks provided at the scheduled meal times.

Upon admission to the research site, the following procedures will take place:

- Brief Physical examination
- Single ECG
- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature) will be taken
- Blood and urine samples for laboratory tests
- You will be asked about medical and medication history since your screening visit or if you have experienced any changes in health since your screening visit
- Urine drug screen*
- Urine pregnancy test for females*
- Alcohol urine test*
- Sedation Visual Analog Scale (VAS) training – An assessment that will measure your level of sleepiness

*These tests must be negative in order to continue in the study.

After completion of these procedures, it will be determined by the study staff if you may continue in the study.

You will begin fasting (no food or drink other than water) in the evening to ensure a minimum of 10 hours without food before dosing.

Day 1

Before you receive the study drug (INDV-2000 or placebo), the following procedures will take place:

- Continuous ECG recording using a Holter monitor will be performed from at least 2 hours prior to dosing with the study drug until 24 hours after dosing (approximately 26 hours). A Holter monitor uses electrodes and a recording device to track your heart's rhythm. You will not be allowed to take a shower during this 26-hour monitoring time.
- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature) recorded 3 times
- Single ECG recorded 3 times
- Blood sample for PK analysis
- Urine sample for PK analysis
- Sedation VAS
- BITREX solution (used to mask any bitter taste differences between INDV-2000 and placebo), to rinse the mouth for 30 seconds, 5 minutes before dosing (For dose groups 1 and 2 only)
- You will be asked how you are feeling and if you have taken any medications

Study drug will then be administered with approximately 240 mL (8 ounces) of water.

After receiving the study drug, the following procedures will take place:

- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature) will be taken approximately 1, 2, 3, 4, 8, and 12 hours after dosing
- Single ECG will be done approximately 1, 2, 3, 4, 8, and 12 hours after dosing
- Continuous ECG recording via a Holter monitor
- Blood samples for PK analysis approximately 30 minutes after dosing and 1, 2, 3, 4, 6, 8, and 12 hours after dosing
- Urine samples for PK analysis will be collected every time you urinate
- Sedation VAS will be done approximately 1 to 2 hours after dosing

You will continue to fast (no food or drink) for approximately 4 hours after dosing. You will be able to drink water as desired except for at least 1 hour before drug administration and for at least 1 hour after drug administration.

You will be served a standard meal and drink at appropriate times thereafter.

Day 2
The following procedures will take place:

- Brief physical exam
- Blood and urine samples for laboratory tests
- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature) will be taken approximately 24 hours after dosing
- Single ECG will be done approximately 24 hours after dosing
- Continuous ECG recording via a Holter monitor will end approximately 24 hours after dosing
- Blood samples for PK analysis approximately 24 hours after dosing
- Urine samples for PK analysis will be collected every time you urinate
- You will be asked how you are feeling and if you have taken any medications

Day 3
The following procedures will take place:

- Blood samples for PK analysis approximately 48 hours after dosing
- Urine samples for PK analysis will be collected every time you urinate
- You will be asked how you are feeling and if you have taken any medications

Day 4
The following procedures will take place:

- Brief physical exam
- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature) will be taken approximately 72 hours after dosing
- Single ECG will be done approximately 72 hours after dosing
- Blood samples for PK analysis approximately 72 hours after dosing
- Urine samples for PK analysis will be collected every time you urinate
- You will be asked how you are feeling and if you have taken any medications

Following the procedures on Day 4, you will be discharged from the research site if the study staff determines it is medically acceptable for you to leave. You will be instructed on when to return to the research site for your Follow-Up Visit.

Follow-Up Visit (Day 11)
The following procedures will take place:

- You will be asked how you are feeling and if you have taken any medications
- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature)
- Single ECG
- Brief physical examination
- Blood samples for laboratory tests
- Urine pregnancy test for females

Your participation in the study will end at this time.

Early Termination
Should you stop your participation in the study early, the study staff will request that you have the following procedures done:

- You will be asked how you are feeling and if you have taken any medications
- Vital signs (blood pressure, heart rate, breathing rate, and oral body temperature)
- Single ECG
- Brief physical examination
- Blood samples for laboratory tests
- Urine pregnancy test for females

How long procedures may take and the length of time for research site restrictions is an approximation and may be longer based on other procedures and study activities scheduled during your stay.

ADDITIONAL DRUG AND ALCOHOL SCREENS
Random urine drug and alcohol screens to ensure compliance may be repeated at any time during the study if the study staff suspects alcohol or drug use. If you test positive for drug or alcohol use, at any time after the first dose of study drug, you will be discontinued from the study.

CONTROLLED SEARCH
Designated study staff reserves the right to do a controlled search by having you put on a gown in order to have your clothes and person checked for disallowed (prohibited) items that may have been brought into the research site. This search involves removing all undergarments as well as putting on a gown so that there is no place the disallowed items could be kept.

RESTRICTIONS
Throughout your entire participation in the research study, the following restrictions will apply:

- Do not participate in any heavy exercise or strenuous activities 24 hours (1 day) prior to dosing with study drug and until after the follow-up visit
- Refrain from drinking alcohol during the study from 24 hours before admission until after the follow-up visit
- Do not consume any poppy seeds, grapefruit, Seville oranges, grapefruit-containing foods or beverages, and Seville oranges- containing foods or beverages for at least 7 days before dosing with study drug and until after the follow-up visit
- Do not consume any caffeine/xanthine-containing foods or beverages (for example coffee, tea, cola, chocolate, caffeine-containing soda (Mountain Dew, Dr. Pepper, etc.), caffeine/xanthine-containing

"energy drinks" (Red Bull, Extreme Energy Shot, etc.) 16 hours prior to check-in and until after the follow-up visit
- Do not smoke or use any nicotine products for at least 90 days before dosing with study drug and until after the follow-up visit
- Do not use of any prescription, non-prescription, topical medications, or herbal remedies for at least 14 days before dosing with study drug (this restriction period may be longer [30 days] depending on the drug)*
- You must not have used any investigational drug within 30 days prior to dosing with study drug. You must not have donated blood of approximately 500 mL of more within 56 days or plasma donation within 7 days of screening.

* *The use of some medications may be allowed by the study staff (for example, hormone replacement therapy, hormonal contraception, acetaminophen)*

BLOOD SAMPLES

Blood samples will be drawn by single needle-sticks or intravenous (IV) catheter, as determined by the study staff. An IV catheter is a small plastic tube inserted into your arm vein by a needle. The needle is removed, but the tube temporarily remains in your vein. This tube allows the removal of blood without having to stick you each time. The total amount of blood drawn will be approximately 147 mL (approximately ¾ cup). For comparison, a standard blood donation at a blood collection center, once in any 56-day period, is about 2 cups (500 mL) of blood.

Additional blood samples may be drawn during the study, if the study staff considers it necessary for monitoring your health.

SUBJECT RESPONSIBILITIES

As a subject in this study, you have certain responsibilities to help ensure your safety. These responsibilities are listed below.

- Complete all required visits
- Follow all instructions from study staff
- Report all possible side effects and medical problems to the study staff
- Inform the study staff if you decide to discontinue your participation in the study
- You may be asked to complete the early termination visit procedures as described in this consent form

POTENTIAL RISKS AND DISCOMFORTS

Since INDV-2000 has not been studied in people, the side effects are unknown. Everyone taking part in the study will be watched carefully.

Research studies conducted in dogs and rats with this study drug were done at doses higher than what you could be receiving. Those studies showed an increase in blood pressure in dogs (dose of 100 mg/kg) and a decrease in locomotor activity (muscular and skeletal systems) in rat studies (dose of 500 mg/kg). There may be changes in your heart rhythm. However, no significant effects were observed in the central nervous system or respiratory system.

It is also possible to experience a serious allergic reaction, which could become life-threatening or fatal. Symptoms of an allergic reaction include rash, hives, itching, swelling of the mouth, face, lips or tongue, dizziness, tightness in the chest or trouble breathing.

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

ECG 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 ECG patches.

Blood Sample risks
Local pain, bruising, bleeding, inflammation or infection might occur at the site of the needle stick or IV catheter where blood is drawn. There is a possibility of dizziness or fainting while your blood is being drawn. Precautions will be taken to minimize the above complications.

Unknown/Unforeseeable Risks
In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this study drug, including allergic reaction or interaction with another medication. You must notify the study staff immediately if you experience an allergic reaction such as rash, hives, or itching. If you experience any of the above symptoms, you must call the study staff at 913-696-1601.

PREGNANCY/BIRTH CONTROL

Females
The effect of INDV-2000 on the embryo, fetus, or nursing infant is unknown at this time. Therefore, it is important that women who are pregnant, may become pregnant or who are breastfeeding NOT participate in this study. Females must be of non-childbearing potential to participate in this study.

Female subjects must:

- not have a uterus
- have been surgically sterilized by complete hysterectomy, bilateral oophorectomy, bilateral tubal ligation (tubes tied)
- have permanent lack of ovarian function due to ovarian failure or surgical removal of the ovaries
- be post-menopausal (at least 12 months without a menses, and confirmed by blood test)

Males
The effect of INDV-2000 on the embryo, fetus, or nursing infant is unknown at this time. The effect of the study drug on the male reproductive system is unknown. Therefore, if you are sexually active with a female partner of child-bearing potential you MUST use a condom plus an approved method of effective contraception from the time of screening and until 90 days after the last dose of the study drug. Approved methods of effective contraception include:

- Combined (oestrogen and progestogen-containing) hormonal contraception including oral, intravaginal, or transdermal methods
- Implantable intrauterine device (IUD)
- Progestogen-only hormonal contraception including oral, injectable, implantable, and intrauterine hormone-releasing system (IUS)
- Surgical sterilization (for example, vasectomy or bilateral tubal ligation)
- Male condom with spermicidal gel/foam or with female cap or diaphragm (double barrier)

You may NOT donate sperm at any time through the entire study and for at least 90 days after your last dose of the study drug.

If your female partner has become pregnant during the course of the study, your partner will be asked for permission to collect information about the pregnancy and its outcome by signing a separate consent form.

NEW INFORMATION

You will be informed verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

POTENTIAL BENEFITS AND ALTERNATIVE TREATMENTS

Since the drug in this study is not being given to treat any symptoms or illness, there will be no medical benefit. An alternative would be to not take part in the study.

COSTS AND COMPENSATION

There is no charge to you for participating in this research study. The study sponsor pays all the study costs associated with conducting this study. Altasciences Clinical Kansas, Inc. and Altasciences Clinical Kansas, P.A. will receive payment from the sponsor for conducting this research study.

For your participation in this study, you may be compensated as follows:

Visit 1	Screening	[redacted]
Visit 2 - 5	Day -1 to -3 Inpatient	[redacted]
Visit 6	Day 4 Discharge	[redacted]
Visit 7	Day 11 End-of-Study Office Visit	[redacted]
	Completion Amount	[redacted]
	Total up to	[redacted]

Visit 1 will be compensated in the amount of [redacted] at the completion of the visit.

Visits 2 through 5 will be compensated in the amount of [redacted] upon discharge at Visit 6.

Visit 7 will be compensated in the amount of [redacted] at the completion of the visit.

Compensation will be issued in the form of a check, pre-loaded MasterCard, or cash. The form of compensation will be determined by the study staff.

Unscheduled visits may be compensated up to [redacted] as determined by the study staff.

All visits must be completed within the scheduled timeframe in order to receive the end of study completion amount of [redacted] on Visit 7. Failure to complete all visits within the allowable timeframe will make you ineligible to receive the completion amount.

Money may be deducted from your study compensation if you do not follow the in-house rules or other reasonable instructions given by the study staff. For example, if illegal substances are brought into the research site or you are found to be using an illegal substance while in house, up to half of your previously earned amount may be deducted and you may be withdrawn from the study as determined by the study staff.

If you withdraw or are withdrawn from the study early, you will only be compensated for the visits that you complete.

If you discontinue from the in-house portion of the study early for any reason, you will only be compensated one night's earned stipend. The remainder of your earned in-house stipend will be compensated to you on the originally scheduled study day/date of discharge from the in-house portion of the study.

You may be required to report the compensation received for this study to the Internal Revenue Service as taxable income. According to the IRS (Internal Revenue Service) guidelines, you will be responsible for paying taxes on any compensation that you receive from your study participation. Altasciences Clinical Kansas, Inc. will send you a 1099-form for this purpose. Altasciences Clinical Kansas, Inc. will also report to the IRS any compensation that you receive that totals $600.00 or more for the calendar year. You must tell Altasciences Clinical Kansas, Inc. of your new mailing address if you move after your participation in a study. This is to make sure you receive your 1099 for your year-end tax reporting.

RESEARCH-RELATED INJURIES

If you have any side effects to the study drug or changes in your physical or mental condition during the course of the study, you must immediately notify the study staff at 913-696-1601.

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to an underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Further information regarding medical treatment for research-related injuries can be obtained from the study staff. You must notify the study staff immediately of any possible research-related injury.

RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- Study staff
- Study sponsor and their representatives (monitors, auditors, Contract Research Organization (CRO))
- The Food and Drug Administration (FDA)
- Other governmental agencies
- Midlands Independent Review Board (MLIRB)

The Independent Review Board (IRB) is a group of individuals responsible for the review and approval of research proposed to be conducted.

The IRB and governmental agencies may inspect and copy your records, which may have your name on them. Therefore, your total privacy cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

Your blood and urine samples collected during the study may be used to perform additional tests related to INDV-2000 or its mechanism of action after the study is completed without additional consent from you.

RIGHT TO WITHDRAW OR REMOVAL FROM STUDY

You are free to withdraw from this study at any time. You should inform the study staff immediately if you intend to withdraw. Your decision to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled.

The study staff 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
- Failure on your part to follow the instructions of the study staff
- Discontinuation of the study by the sponsor and/or study staff participating in the study prior to completion.

If you withdraw or are withdrawn from the study after having taken the study drug, you will be asked to come back to the research site for an early termination visit. At this visit, you will have discharge procedures performed and blood tests to ensure that there are no changes to your current health status. You will be asked about any changes in your health and about any medications you are taking.

CONFIDENTIALITY AND AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you.

If you sign this consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. However, if you do not, you will not be able to participate in the study.

Who Will Use and Disclose your Health Information?

The sponsor and the study staff at Altasciences Clinical Kansas, Inc. and Altasciences Clinical Kansas, P.A. may use your health information to conduct, review, and determine the results of the study. The study staff may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication. The study staff may disclose your information to others, as discussed in the next section.

What Health Information Will Be Used and Disclosed?

The study staff will record your medical and medication history, and the results of examinations and tests done during the study on study forms. Your name will not appear on the study forms. You will be assigned a subject identification number. Study forms may include your subject identification number and your initials. The study staff will send the completed study forms to the study sponsor. This type of information may also be shared with others, as described in the next section.

Your medical records may include other health information about you and may include documents that directly identify you. Representatives from the groups identified in the next section may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Reviews like that will take place at the research site or where the medical records are stored and can take place after the study is over.

In addition, biological samples collected as part of this study will contain your subject identification number, but will not contain your name. Only Altasciences will be able to link your subject identification number to your name.

Who Will Receive your Health Information?

Your study information may be shared with the following people or groups:

- The study sponsor, Indivior, or its representatives, including companies it hires to provide study-related services;
- Midlands Independent Review Board (MLIRB) that approved this study and any other committees responsible for overseeing the research;
- Government health agencies (such as the Food and Drug Administration) in the U.S. or other countries;
- Health care providers who provide services to you in connection with this study, and laboratories and other individuals and organizations that analyze your health information in connection with this study.

Representatives from these groups may receive information from your study forms and/or your medical records.

Will your Information Be Protected by the Privacy Rule After It Is Disclosed to Others?

Altasciences Clinical Kansas, Inc. and Altasciences Clinical Kansas, P.A. is required by the Privacy Rule to protect your health information. After your information is shared with others, like the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. When using the information in these ways, the sponsor may share it with other researchers, its business partners, or companies it hires to provide research-related services. However, your name will never appear in any sponsor forms, reports, databases, or publications, or in any future disclosures by the sponsor.

What Happens if You Leave the Study Early?

If you stop participating in the study early, for any reason, the study staff will tell the sponsor why. If the study staff asks you to come to any more study visits and you agree, the study staff will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will your Authorization Ever Expire?

This authorization does not have an expiration date. The study staff may need to correct or provide missing information about you even after your study participation is over. The review of your medical records may also take place after the study is over.

May You Take Back Your Authorization?

You have the right to revoke (take back) your authorization, at any time, by sending a written notice to the Study Doctor at the following address:

[redacted], M.D., PhD, MPH
Altasciences Clinical Kansas, Inc.
10103 Metcalf Avenue

Overland Park, KS 66212
Phone: (913) 696-1601

If you revoke your authorization, the study staff will not collect any new health information about you, however, they can continue to use and disclose any already collected information necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your authorization, you can no longer continue to participate in this study.

May You Look at Your Study Information?

You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

This research site contains open areas and semi-private sleeping rooms. In this environment, it is possible that someone might recognize you or could overhear your response to medical questions during study procedures. We are concerned about protecting your privacy and take precautions to protect it.

PERSONS TO CONTACT FOR QUESTIONS, CONCERNS, OR COMPLAINTS

If you have any questions, concerns or complaints about this study, call [redacted], M.D., PhD, MPH. at 913-696-1601.

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, call the Midlands Independent Review Board (MLIRB) at (913) 385-1414 or (800) 636-4445. 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 MLIRB or you can go to the MLIRB website at www.MLIRB.com and give your comments. Either way you do not have to give your name, if you do not want to.

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 [redacted], M.D., PhD, MPH at 913-696-1601.

LEGAL RIGHTS

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

CONSENT

- You have read (or someone has read to you) this Informed Consent Document.
- This document describes the purpose and nature of this study.
- You have had time to review this information.
- You have been offered a chance to ask questions.
- You received satisfactory answers to your questions.
- If you do not take part in the study, you will not lose any benefits.
- If you leave the study, you will not lose any benefits.
- If you leave the study, you will not lose any legal rights.
- Your participation in this study is completely voluntary.

You will receive a copy of this signed and dated Informed Consent Document for your records.

You agree to participate in this study.

__ __/__ __ __/__ __ __ __	_____	_____	__ __:__ __
D D M M M Y Y Y Y	Subject Name (Print)	Subject Signature	Time

__ __/__ __ __/__ __ __ __	_____	_____	__ __:__ __
D D M M M Y Y Y Y	Person Conducting Consent (Print)	Person Conducting Consent Signature	Time