NEW YORK STATE PSYCHIATRIC INSTITUTE COLUMBIA UNIVERSITY DEPARTMENT OF PSYCHIATRY

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH

A Pilot Pharmacokinetic Trial of the O'Neil Long Acting Naltrexone Implant (OLANI)

I. Purpose and Overview

You are being invited to participate in a research study with the aim of this study to investigate the O'Neil Long Acting Naltrexone Implant (OLANI) in healthy volunteers. The OLANI is inserted through a small incision into the tissue bellow the skin of the abdomen, just below the belly button. The OLANI has been designed to slowly release a constant dose of naltrexone for up to 540 days (18 months) before it is broken down (biodegraded) by the body until it is fully absorbed. Naltrexone is an opioid blocker and is used to treat alcohol and opioid addiction.

You will receive two implants, each consisting of 10 pea-size pellets (a total of 20 pellets), inserted through an incision in the skin of the abdomen, just below the belly button, with one implant placed to the left and one to the right of the incision. The OLANI has been designed to slowly release a constant dose of naltrexone for six months or longer before it is broken down (biodegraded) by the body and slowly dissolved. It is important to note that the OLANI implant cannot be easily removed after approximately 10 days from its placement. Removing the implant after that time will require surgery under general anesthesia and will likely leave a scar. The most common risks associated with the OLANI implant are inflammation on the abdomen around where the OLANI is implanted, and the risk of liver damage.

The OLANI is made from similar material as biodegradable stiches and does not need to be removed, since it slowly dissolves by itself over time but the implant can be felt under the skin for many months after all naltrexone was released, for up to a year or longer. The amount of naltrexone being released from the OLANI will be measured by collecting blood samples at regular time points for up to 540 days or 18 months. It is anticipated that your blood naltrexone level may fall below a detectable level earlier than 540 days. If this is the case for 2 consecutive appointments, then you will be assessed as having completed the trial and will not be asked to attend any further appointments unless there are any outstanding side effects or adverse events that you are experiencing.

This study will be conducted by personnel from the New York State Psychiatric Institute (NYSPI) and Columbia University Medical Center (CUMC) at the Substance Use Research Centre (SURC), and Clinilabs, with funding provided by the National Institute of Drug Abuse.

II. Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A

decision not to participate or withdraw your participation will not affect your current or future treatment at the NYSPI or CUMC. If applicable, you will be notified of significant new findings that may relate to your willingness to continue to participate.

III. Alternative Treatments/Alternative to Participation

Information is being collected for research purposes only. The alternative to participating is not to participate. If you decide not to take part in this research study, it will have no effect on your medical care. You will not lose any benefits or access to treatment that you are otherwise entitled to if you don't want to be in this study.

IV. Procedures

If you decide to participate in this study, you will initially be assessed for your suitability to participate after signing consent for a screening evaluation. In order to determine if you may be eligible to participate in a clinical research study, it is necessary for NYSPI and Clinilabs to know if you are participating in another clinical research study or have recently participated in a clinical research study. NYSPI and Clinilabs uses the Verified Clinical Trials (VCT) database to help determine whether potential clinical research subjects are participating or have recently participated in other clinical research studies. NYSPI and Clinilabs needs information about your participation in other clinical research studies because it is important that you not participate in more than one clinical research study at a time involving investigational drugs or other investigational products.

If you are taking opioid painkiller medications or other opioids, you should not participate in this study, because the naltrexone could make you very sick and will block the effect of opioid painkillers for many months after the implantation. If you are planning to get pregnant in the next two years you should also not participate in this study.

You will be asked to attend the SURC for an initial screening visit, where you will be seen by a study doctor who will check that you are suitable for the study, ask some questions about your medical and psychiatric history, general health, treatment history, and undergo a physical exam. You will then be asked to return for a second screening visit where you will be asked about your substance use, and have blood and urine samples collected, and if applicable a pregnancy test will be carried out. If you have been assessed as suitable to participate in the study, you will then be asked to attend a recruitment visit where you will be asked to give your consent to participate in this trial.

Once you have given your consent to participate in this trial, you will stay on the inpatient unit at SURC for 2 **or** 3 nights. On the first day, you will have a naloxone challenge test, where you will be injected with a dose of naloxone into your arm. If you have used any opiates, or opiate medications within the last few days, naloxone will cause you to have an opioid withdrawal reaction with symptoms such as nausea, vomiting, diarrhea, stomach pain, fever, sweating, body aches, weakness, running nose, goosebumps, shivering, increased heart rate, and anxiety. Most of these effects will wear off after 20-30 minutes and treatment is usually not needed. If you do experience severe symptoms, you will be offered treatment with medications such as clonidine and/or clonazepam to help alleviate your symptoms. You will be monitored for up to 6 hours

until all symptoms resolve, and then you can be released from the unit. This circumstance will be considered a naloxone challenge test failure and you will not be included in the study.

If you have no withdrawal reaction to naloxone, you will then undergo a surgical procedure the next day at the surgical suite at the CUMC to be implanted with the OLANI. Each OLANI implant consists of 10 pea-size round tablets. A small incision (cut) is made in the skin below the belly button. Two implants (10 tablets per each implant, 20 tablets total) will be placed under the skin through the incision, one to the left and one to the right from the incision.

Prior to the surgical procedure, an IV will be placed in your forearm to administer an antibiotic and to aid blood collection and administration of medications if needed. Local anaesthetic will be administered into the skin below the belt line. The local anaesthetic is a medication that will make the skin go numb so that the implant procedure can take place with minimal discomfort. A cut is made into the skin and a tunnel made in the fat underneath the skin with a blunt sterile surgical instrument to the point at which the implant will be positioned. The implants (10 tablets each) are then pushed through the incision into the tunnel prepared for them, one implant to each side of the incision.

After the OLANI's are inserted, a stitch is used to close the wound and surgical glue is used to glue the skin together. Dressings are placed over the wound to keep it clean and these will be changed frequently.

You will then be asked to give blood samples for testing at the following scheduled time points; 3, 6, 12, 24 and 48 hours after the implant procedure. You will have the option to remain on the inpatient unit until the 48 hour assessments have been collected, or you can be discharged from the inpatient unit following the 24 hour blood sample collection returning to the SURC clinic for the 48 hour observation and assessments. You will then be asked to return for your follow-up appointments according to the schedule outlined in the table below. In general, all follow-up appointments will occur at the Clinilabs research unit except for the final visit at 18 months or sooner should you complete the study which will occur at the SURC clinic. However, some follow-up visits may occur at the SURC clinic (e.g. if medically appropriate or if traveling to the Clinilabs research unit presents a hardship to you). Each visit will last about 30 minutes. At each visit, you will be asked about any medication that you have taken and if you have had any side effects or issues since your implant procedure. An assessment of the wound site/implant site will also be carried out. Blood (about 2 teaspoons) will be drawn at each visit to test the level of naltrexone that the implant is releasing into your system. At most visits, blood (another 2 teaspoons) will also be drawn for routine blood tests (blood chemistries and cell counts). At most visits you will also be asked to fill out some questionnaires about your general health and mental health, and to give urine samples that will be tested for the presence of illicit drugs. You will be provided with a dated schedule of visits once you are enrolled onto the study. You may be asked to attend further visits if required past day 540 if you have any ongoing medical issues relating to the trial or we required you to give further blood samples to measure the level of naltrexone. Additionally, you may be asked to attend additional visits, to monitor any ongoing medical issues related to the study.

Days after implant procedure	Information / Samples Collected
Day 4	Blood (2 teaspoons)
Day 8 (1 Week)	Blood (2 teaspoons)
Day 14 (2 Weeks)	Blood (2 teaspoons)
Day 21 (3 Weeks)	Blood (2 teaspoons)
Day 28 (4 Weeks)	Blood (4 teaspoons), Urine Drug screen (UDS), Questionnaires
Day 35 (5 Weeks)	Blood (2 teaspoons)
Day 42 (6 Weeks)	Blood (2 teaspoons)
Day 49 (7 Weeks)	Blood (2 teaspoons)
Day 56 (8 Weeks)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 90 (3 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 120 (4 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 150 (5 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 180 (6 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 210 (7 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 240 (8 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 270 (9 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 300 (10 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 330 (11 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 360 (12 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 390 (13 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 420 (14 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 450 (15 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 480 (16 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 510 (17 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires
Day 540 (18 Months)	Blood (4 teaspoons), Urine Drug Screen, Questionnaires

V. Risks and Inconveniences

The OLANI implant is not currently approved by the FDA and it is being used for research purposes.

1. The site of implantation will be sore when the local anaesthetic wears off.
2. In the event that you need narcotic painkillers for severe pain, most will not work while the OLANI is active, because the naltrexone medication contained in OLANI blocks the effects of opioid medications. This may mean that other non-opioid methods of controlling pain are required. In instances where pain cannot be controlled by other means, the OLANI will have to be removed surgically. This may result in a scar.

3. Some participants might experience some allergic reaction or inflammation around the implant site, that is, itching, pain and swelling. Allergic responses will be treated with corticosteroids. The side effects of the corticosteroids may include weight gain, high blood pressure, restlessness, and trouble sleeping. You should call and visit the clinic doctor if you experience discomfort at the implant site.
4. Known side-effects from naltrexone include difficulty sleeping, anxiety, nervousness, abdominal pain/cramps, nausea, and/or vomiting, low energy, joint and muscle pain, headache, loss of appetite, diarrhea, constipation, increased thirst, increased energy, depressive mood, irritability, dizziness, skin rash, delayed ejaculation, erectile dysfunction, reduced sexual desire, and chills.
5. An infection may be introduced at the time the OLANI's are inserted. Any surgical procedure carries some risk of infection. The risk is minimized by the use of an antibiotic before the surgery and the appropriate sterile technique during the insertion of the OLANI. The OLANI is manufactured under strict pharmaceutical standards for sterility and provided in a sterilized double layer package. If you experience any signs of infection (redness, swelling, pain, fever chills) you should contact the study team as soon as possible to be assessed.
6. Some studies have shown a reversible liver injury indicated by elevated liver enzymes at naltrexone doses which are much higher than those proposed in this study. At low doses, similar to those proposed in this study, clinical studies indicate that the risk of liver injury is low. Therefore, you will be screened for any liver impairment (via routine Liver Function blood tests) and if you should be found to have readings significantly greater than the normal range you will not be enrolled into this study. You may be referred to another doctor who can propose a treatment plan for your elevated liver enzymes.
7. You should not participate in this study if you take opioid (narcotic) painkillers (such as codeine, oxycodone, fentanyl), or opioid street drugs such as heroin. This is because naltrexone, the medication contained in the OLANI implant, would block the effects of the opioid drugs and cause severe opioid withdrawal (like a severe flu, with nausea, vomiting, diarrhea, stomach pain, fever, sweating, body aches, weakness, running nose, goosebumps, shivering, increased heart rate, anxiety, and even confusion). To ensure that your system is free of opioids before you start the study, you will be administered an injection of a short-acting opioid blocking medication called naloxone. If you have opioids in your system, this will cause you to experience withdrawal symptoms.
8. (for Females) The OLANI implant is not considered safe during pregnancy or breast-feeding, because there is concern about causing permanent damage to a developing fetus or young infant (for example, birth defects, or problems that emerge during infancy or childhood). Therefore, you should not participate in this research if you are pregnant, or breast feeding a baby, or if you plan to become pregnant during the time you are in the study.

   To determine your eligibility for this study, a blood pregnancy test will be conducted before you enter the study. If the test is positive, you will not be able to participate in the study. Pregnancy tests will be repeated monthly] during the study. It is important to understand that even if a pregnancy test is negative, you could still be pregnant, because these tests cannot detect very early pregnancies (that is, within the first few days). If you are sexually active, it is very important that you use an effective form of birth control before and throughout your

study participation. Methods of birth control considered to be effective include: double barrier methods (condom plus spermicide, or diaphragm plus spermicide), any form of hormonal contraception such as Depo-Provera, daily oral contraceptive, transdermal patch or NuvaRing, or intra-uterine devices. It is important to understand that even if you use an effective birth control method, there is still a chance you could become pregnant. Also, if you do not use the birth control method consistently (for example if you don't use condom/spermicide some of the time) you may become pregnant. If you think you might be pregnant, it is important to let the study team know right away. The study team will conduct a pregnancy test and help you decide what to do next.

(for Males) The risk of the study medication is unknown to the sperm/fetus, therefore we strongly encourage you use contraceptives.

9. You will be compensated with a Clincard for your participation in the research study. If you receive over $600, this amount is considered to be income, and therefore may result in potential tax implications.
10. Personal expenses may be made when traveling to your study visits. You will be reimbursed $20 for travel expenses at each visit. If your travel expenses are more than $20, you may submit receipts for reimbursement up to $50 total for travel.

VI. Withdrawal from the Study

You can withdraw from the study at any time without giving a reason. If you decide to withdraw you have two options: 1) Leave the implant in place or 2) Ask for the implant to be removed by surgery. You should be aware that each option carries with it some risk.

Option 1: No further participation in the trial without removal of the OLANI
The OLANI provides a slow release of naltrexone for approximately 6-12 months, but the release for up to 18 months is also possible until all of the naltrexone in the implant is used up. The bonding material used in the manufacture of the OLANI takes roughly 18 months to be fully broken down and absorbed by the body. Blood levels of naltrexone are expected to be in the "opioid blocking" range for at least 6 months and during that time the effectiveness of narcotic painkillers will be reduced.

Option 2: Removal of the OLANI
Removing the OLANI implants is reasonably easy within the first 10 days, for example if you have a bad reaction to them. Once the implants start to breakdown (biodegrade), removal is a complicated surgical procedure which requires a general anaesthetic and may result in a large scar. The risks associated with general anaesthetic vary between people – you should discuss your individual risk with the study's doctor or your own doctor. Following general anaesthetic, about 20% of people have minor side effects, and 0.2% have major side effects, including death.

VII. Benefits

There are no direct benefits to you for participating in this study as this study was not designed for your benefit. This study has been designed to collect information which will be used to help

determine whether the OLANI implant should be used as a treatment for people with an opioid use disorder, and to help obtain approval from the U.S. Food and Drug Administration (FDA).

VIII. Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely. We will do everything we can to keep others from learning about your participation in the research. To further help us protect your privacy, the investigators will obtain a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer, employer or other outside party, learns of your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, the Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child or threatened violence to self or others. Such information will be reported to the appropriate authorities.

All information will remain confidential so that you will never be identified in any report. All research study data related to your information will be de-identified by assigning an alpha-numeric code. Your identity will be known only to the investigators, who are bound by strict ethical guidelines never to release your name. Your data will definitely not be disclosed to any other person outside the study team unless required to do so by law. All records will be stored in locked files and will be kept confidential to the extent permitted by law. Any private information or biospecimens that are collected as part of this research will not be used for future research studies or distributed to another investigator for future research studies, with or without identifiers.

Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). The following individuals and/or agencies will be able to look at and copy your research records:

- The investigator, study staff, Columbia University staff, and Clinilabs staff who may be evaluating the study or providing services for the study.
- Authorities from Columbia University and New York State Psychiatric Institute, including the Institutional Review Board.
- The United States Food and Drug Administration (FDA)
- The manufacturer of the O'Neil Long Acting Naltrexone Implant, Go Medical Industries Pty Ltd including persons or organizations working with or owned by the manufacturer.
- The financial sponsor of this study, the National Institute on Drug Abuse (NIDA)
- Other government regulatory agencies (including agencies in other countries) if the manufacturer is seeking approval for new products resulting from this research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site may include a summary of the results. You can search this Web site at any time.

I. Study Compensation

If you choose to participate in this trial, you will be compensated based on the following schedule:

- $50 for each screening visit (2 visits)
- $50 for the consent visit (1 visit)
- $100 for each inpatient day (4 days total)
- $50 for each scheduled outpatient visit (25 visits). You will also receive an additional incremental bonus of $10 for each subsequent outpatient visit attended (Visit 1: $50, visit 2: $50+$10, Visit 3: $50+$20, Visit 4: $50 +$30 …). In case the scheduled visit is missed the value of the bonus is reset to the starting value of $10.
- If you are asked to return for further visits, you will receive $50 plus the incremental bonus
- In addition, you will also receive $20 at each visit for transportation and parking reimbursement. If your transportation costs exceed $20, you can be reimbursed up to $50 with receipts for travel.
- If you are asked to return for additional visits, you will receive $50 plus transportation reimbursement.
- You will receive a card like a debit card (called a ClinCard), and money will be added each day after you have completed your study visit.

The total amount of compensation, should you attend every scheduled visit, is approximately $4,800 if you are followed for the full 18 months of the study. However, your follow-up visits may end earlier than 18-month end of study time point based on the assessment of your blood naltrexone levels. We predict that on average your participation in the study will last at least 12 months in which case you will earn approximately $3,210 if you make all scheduled visits. You will not be asked to attend or be compensated for the remaining follow-up visits after your participation is terminated.

We are required by law to report earnings over $600 to the IRS. If you earn more than $600, your Social Security Number and amount earned will be reported, and you will receive the appropriate IRS form at the end of the year in which you were paid. Please note that payment for this study may affect your eligibility for Medicaid and other city and state support services. No information about which study you participated in will be provided to the IRS.

IX. In Case of Injury

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and

inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the New York-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance. If this medical care is provided by NYPH or by a Columbia doctor, the manufacturer of the implant, Go Medical, may pay these providers for any reasonable medical expenses to treat your injury. Go Medical, however, is not offering to pay for medical expenses that are covered by your insurance provider or if your injury was not caused by the study drug/device or a study procedure.

Columbia University and New York-Presbyterian Hospital (NYPH) are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator at (646) 774-6155 or (212) 923-1397 so that you can review the matter and identify the medical resources that may be available to you.

Please be aware that:

1. The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital
2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
3. No monetary compensation for wages lost as a result of injury will be paid to you by the New York State Psychiatric Institute, Columbia University, Research Foundation for Mental Hygiene or by New York Presbyterian Hospital.
4. By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

X. Questions

If you have any questions relating to your participation in this study now or in the future, the investigator will try to answer them to the best of their ability. If applicable, you will be notified of significant new findings that may relate to their willingness to continue to participate.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Office at (646) 774-7155 during regular office hours.

If you have any questions about your rights as a subject, you may contact:
Institutional Review Board
Columbia University Medical Center

154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883

If you have any medical problems relating to the study, you can contact the medical staff 24 hours day on (646) 774 6155.

XI. Documentation of Consent for Screening

I voluntarily agree to participate in the screening for the research study described above.

Print name: _____
(Participant)

Signed: _____Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Print name: _____
(Person Designated to Obtain Consent)

Signed: _____ Date: _____

XII. Documentation of Consent

I voluntarily consent to participate in the study. I have read this consent form which includes information about the nature and the purpose of the study, as well as a description of study procedures.

I have discussed the study with the investigator or study staff, have had the opportunity to ask questions and have received satisfactory answers. The explanation I have been given has mentioned both the possible risks and benefits to participating in the study and the alternatives to participation.

I understand that I am free to not participate in the study or to withdraw at any time. My decision to not participate, or to withdraw from the study will not affect my future care or status with this investigator.

Print name: _____

Signed: _____

Date: _____

XIII. Investigator

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Print Investigator name: _____

Investigator Signed: _____

Date: _____

Addendum 1

Verified Clinical Trials (VCT) Research Subject Database Personal Information Consent

Verified Clinical Trials is a secure internet-based registry of clinical research subjects. The registry stores specific information regarding a research subject's screening and participation in various clinical trial sites. VCT is a privately owned company and has an agreement with NYSPI and Clinilabs to run this registry. VCT does not take part in the performance of the study or in the operation of NYSPI and Clinilabs. The purpose of this registry is to capture the screening dates, dosing dates, last blood draw dates, investigational drug use and enrollment status of subjects. This will help prevent subjects from enrolling in more than one study. This registry is intended to help ensure data integrity (reliability) and protect the research subject.

Information such as portions of your first and last name as well as middle initial or full name may be entered into the VCT system with or without your fingerprint. The VCT system de-identifies your full or partial name identifiers and creates a unique identification code. This means that by looking at the code you would not be able to tell what the person's name is or their private information. The code (Unique Identification Code) is created by information entered into the database: partial name, date of birth, gender, and last 5 digits of valid ID numbers such as Driver's license number, passport number, cedula number or military ID number and state or country of issue. If fingerprints or biometric information is utilized, the actual fingerprint is not collected nor stored. Only a portion of the fingerprint is utilized and again is de-identified. NYSPI and Clinilabs will only enter your information into the Database after you sign this personal information authorization form. By signing this form, you grant permission to give your information to Verified Clinical Trials, the company that operates the Database.

Your Confidentiality will be respected and no information that discloses your identity will be released or published without your authorization, except as described in this form and unless required by law. The data contained in this registry will be stored securely by VCT, and accessed by NYSPI and Clinilabs Staff and authorized VCT personnel.
Your information may be used and shared with these people for the following purposes:

- The study doctor and study staff to help determine whether you are eligible for this particular research study
- VCT for maintaining its database and working with clients

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information.

At the end of your participation in the current study, the study doctor and study staff or VCT staff members will update your status in the registry. The information will remain secure within the database. It will be used for future reference when screening and enrolling in clinical trials only. You have the option to review your personal information in the database. You may inquire about your personal information in the database at any point in time by contacting Verified Clinical Trials at 516-998-7499.

You may withdraw your personal identifiable information (partial name, date of birth, partial ID information) from the VCT registry at any time without penalty or loss of benefits. However, your ability to enroll or continue in the clinical trial that you are screening for may require your participation in this registry. Although you withdraw your personal information from the registry and delete your personal information, your de-identified unique identification code (UIC) and de-identified fingerprint code (connected to your study history will remain in the VCT system.

Your information will remain in the Verified Clinical Trials Database for a period of up to 50 years, at which point it will be destroyed. To remove your personal identifiable information from the VCT Database, please contact VCT at 516-998-7499 or in writing that you no longer wish to have your personal information stored with VCT. VCT's mailing address is Verified Clinical Trials, 1305 Franklin Avenue, #150, Garden City, NY 11530. VCT's email address is info@verifiedclinicaltrials.com. This authorization expires in 50 years.

CONSENT

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

Print name: _____
(Participant)

Signed: _____Date: _____

Print name: _____
(Person Designated to Obtain Consent)

Signed:_____