A PHARMACOKINETIC STUDY OF VIVITROL IN HEALTHY PARTICIPANTS

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Overview: The aim of this study is to monitor naltrexone level in participants' blood who will be receiving monthly administration of Vivitrol, which is an FDA-approved version of extended-release naltrexone. Naltrexone is an opioid blocker and Vivitrol is used to treat alcohol and opioid addiction. Vivitrol is administered by a single injection in the buttock region and is designed to release a steady dose of naltrexone for up to 28 days following each injection. Vivitrol injection will be administered 6 times, every 28 days, and the aim of the study is to measure the level of naltrexone in the blood through the study duration which is 196 days.

Voluntary: As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

Procedures: This study is only offered to participants who completed study with naltrexone implant (#7698). If you decide to participate in this study, you will initially be assessed for eligibility. You will be provided with a dated schedule of visits once you are enrolled into the study. You will be asked to attend the research clinic for a screening visit, where you will be seen by the trial doctor who will discuss the study with you, ask questions about your medical and psychiatric history, obtain ECG and bloods, and give you a physical exam. Once you have given consent to participate in this trial, you will be admitted to the Clinilabs facility for 48 hours. While there, you will be given a naloxone challenge to ensure you do not have any opiates in your system. Afterwards, you will be given a Vivitrol injection which will release a steady dose of naltrexone for up to 28 days. Following the injection, you will give several blood samples while in the hospital. After you are discharged from the hospital you will be scheduled to attend the research clinic located at Clinilabs for your follow-up appointments. At each study visit, you will have a blood draw, be asked to provide urine samples which will be tested for the presence of drugs, complete safety questionnaires, be asked about side effects or issues since your injection, and new medications you have taken since the previous visit. Additionally, you will be given a Vivitrol injection every 28 days for maximum of six times in the study. You will also be asked to fill in some questionnaires at your post discharge visits.

Risks: Vivitrol is currently approved by the FDA for treatment and research purposes.

1. Participants who require narcotic painkillers for severe pain will have a greatly reduced effect while naltrexone is being released from Vivitrol, and higher doses of high potency opioids may need to be used or alternative, non-opioid treatments.
2. Vivitrol injection may cause pain, irritation or inflammation at or near the site of administration as a result of an allergic response or other inflammatory process.
3. Known side-effects from naltrexone include difficulty sleeping, anxiety, nervousness, abdominal pain/cramps, nausea and/or vomiting, low energy, join and muscle pain, headache, loss of appetite, diarrhea, constipation, increased thirst, increased energy, depressive mood, irritability, dizziness, skin rash, delayed ejaculation, erection dysfunction, reduced sexual desire, and chills.
4. Some studies have shown a reversible liver injury by elevated liver enzymes at naltrexone doses which are much higher than those proposed in this study.
5. Naloxone or naltrexone may cause withdrawal symptoms in people who have been taking opioids such as prescription painkillers or heroin. Withdrawal symptoms include nausea, vomiting, diarrhea, stomach pain, fever, sweating, body aches, weakness, running nose, goosebumps, shivering, increased heart rate, and anxiety.
6. During the declared COVID-19 public health emergency, there is an increased risk related to the necessary travel to the research clinic and the visit at the clinic. This may include a risk of getting exposed to the virus and the risk of getting infected and developing an infection-related disorder (e.g. COVID-19).

Benefits: This research study is not meant to benefit you directly. This study is designed to collect information which will be used to determine whether extended release naltrexone implant could be used as a treatment for people with opioid use disorder, and to help obtain approval from the US Food and Drug Administration (FDA).

Alternatives: Information is being collected for research purposes only. You may choose to not participate in this study. 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 otherwise are entitled to if you don't want to be in this study

Compensation: The total compensation will depend on the total number of visits you will be scheduled for and make. We predict that on average your participation in the study may last 6 months in which case you will be compensated $4,580 if you make all scheduled visits.

Questions: You may contact the study doctor, Adam Bisaga, MD at (646) 774-6155 with any questions.

NEW YORK STATE PSYCHIATRIC INSTITUTE COLUMBIA UNIVERSITY DEPARTMENT OF PSYCHIATRY

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH

A PHARMACOKINETIC STUDY OF VIVITROL IN HEALTHY PARTICIPANTS

I. Purpose and Overview

Because you participated in the prior study (IRB#7698) in which you received the naltrexone implant, you are now invited to participate in a research study to investigate the pharmacokinetic parameters (changes in medication level in the blood) after receiving injections of Vivitrol, which is an FDA-approved version of extended-release naltrexone. Naltrexone is an opioid blocker and Vivitrol is used to treat alcohol and opioid addiction. Vivitrol is administered by a single injection in the buttock region and is designed to release a steady dose of naltrexone for up to 28 days following each injection. Vivitrol injection will be administered 6 times, every 28 days, and the aim of the study is to measure the level of naltrexone in the blood through the study duration which is 196 days (approximately 6 months).

During the study you will receive a total of six injections. One injection will be given every 28 days into the muscle of the buttock region, and alternate buttocks will be used for each injection to minimize discomfort from repeated injections. Possible risks associated with the Vivitrol injection include an inflammatory reaction (itching, pain, swelling) to the injection material and the risk of liver damage. Any inflammatory response will naturally recover over a few days following administration or if severe, it can be treated with medication. The health of your liver will be monitored routinely over the course of the study.

Vivitrol contains naltrexone in the form of small grains containing naltrexone which slowly dissolve over a month releasing the medication. The amount of naltrexone being released from the Vivitrol will be measured by collecting blood samples at regular time points for up to 196 days or just over 6 months. In people with opioid addiction, naltrexone blocks the effects of opioids and reduces cravings, but the naltrexone itself has no opioid-like effects and is not a controlled substance.

This study will be conducted by personnel from the New York State Psychiatric Institute (NYSPI), Columbia University Irving Medical Center (CUIMC), 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 CUIMC. 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

Study procedures are generally similar to procedures used in the prior study with naltrexone implant that you have participated in.

If you decide to participate in this study, you will be initially assessed for your suitability to participate after signing consent for a screening evaluation. In order to determine possible eligibility for the research study, it is necessary for NYSPI and Clinilabs to know if you are currently participating in a clinical research study or have recently participated in one. NYSPI and Clinilabs use 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 need 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.

Additionally, you will be asked to undergo specific health related procedures to minimize the risk and spread of Covid-19. Upon entering the facility, you will be given a Covid-19 screening survey and have your temperature checked. You will also be asked to maintain proper hygienic measure like washing your hands, as well as maintaining the appropriate six feel social distance between you and other staff.

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 weeks after injection. If you are planning to get pregnant in the next year you should also not participate in this study.

You will be asked to attend Clinilabs for a 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, your substance use and undergo a physical exam and have blood and urine samples collected, and if applicable a pregnancy test. 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 in the inpatient unit at Clinilabs for two nights. On the first day, you will be given a naloxone challenge test, where a dose of naloxone will be injected 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 be administered an injection of Vivitrol. Each injection contains small grains containing naltrexone suspended in approximately 4mL of fluid. This fluid is injected into the muscular area of the buttock region. This injection is repeated every 28 days for a total of 6 injections.

Prior to the first and sixth injection only, an IV line will be placed in your forearm to aid blood collection and administration of medications if needed. You will then be asked to give blood samples for testing at the following scheduled time points; 1, 2, 4, 8, 12, 24, 36, 42 and 48 hours after the Vivitrol injection.

After you leave the Clinilabs you will be asked to return for your follow-up appointments and repeat injections according to the schedule outlined in the Table 1 below. All follow-up appointments will occur at the Clinilabs research unit and each visit will last about 30 minutes. At each follow-up visit, you will be asked about any medication that you have taken and if you have had any side effects or issues since your Vivitrol injection, and the doctor will assess the medication injection site. Blood (about 2 teaspoons) will be drawn at each follow-up visit to test the level of naltrexone that the Vivitrol is releasing into your system. At monthly follow-up visits, blood (another 2 teaspoons) will also be drawn for routine blood tests (blood chemistries and cell counts). At most follow-up 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 drugs.

During the monthly follow-up visits, you will undergo additional, second through fifth, Vivitrol injections. For the final and sixth Vivitrol injection, you will be required to stay at Clinilabs for two overnights again and provide multiple blood samples at 1, 2, 4, 8, 12, 24, 36, 42 and 48 hours after the final injection, and afterwards you will return for follow-up visits.

Once you are enrolled into the study, you will be provided with a detailed schedule of all required visits. You may be asked to attend further visits past day 196 if you have any ongoing medical issues relating to the trial or to give further blood samples to measure the level of naltrexone.

Table 1. Schedule of follow-up visits and procedures after the first injection

Days after initial injection	Information / Samples Collected
Day 3	Adverse Events (AE) Monitoring, Questionnaires, Blood (2 teaspoons)
Day 5	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 7	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 10	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 14	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 17	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 21	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 24	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 28	AE Monitoring, Questionnaires, Blood (2 teaspoons), Liver test, Pregnancy test, Urine Drug screen, Vivitrol 2nd injection
Day 56	AE Monitoring, Questionnaires, Blood (2 teaspoons), Liver test, Pregnancy test, Urine Drug screen, Vivitrol 3rd injection
Day 84	AE Monitoring, Questionnaires, Blood (2 teaspoons), Liver test, Pregnancy test, Urine Drug screen, Vivitrol 4th injection
Day 112	AE Monitoring, Questionnaires, Blood (2 teaspoons), Liver test, Pregnancy test, Urine Drug screen, Vivitrol 5th injection
Admission Day 140	Blood (2 teaspoons), AE Monitoring, Questionnaires, Liver test, Pregnancy test, Urine Drug screen, Vivitrol 6th injection, Blood (10 teaspoons)
Admission Day 141	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Admission Day 142	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 143	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 145	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 147	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 150	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 154	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 157	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 161	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 164	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 168	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 182	AE Monitoring, Questionnaires, Blood (2 teaspoons)
Day 196	Physical and mental exam, ECG, Questionnaires, Liver test, Pregnancy test, AE Monitoring, Urine Drug screen, Blood (2 teaspoons)

V. Risks and Inconveniences

Vivitrol is approved by the FDA and the doses being used in accordance with its product labelling, as this is not the population that the study drug was approved for.

1. In the event that you require narcotic painkillers for severe pain (e.g., following the accident or in case of a new medical condition) most will have a greatly reduced effect whilst naltrexone is still being released from Vivitrol and higher doses of high potency opioids may need to be used or alternative, non-opioid treatments.
2. Vivitrol injection may cause pain, irritation or inflammation at or near the site of administration as a result of an allergic response or other inflammatory process.
3. Known side-effects from naltrexone include difficulty sleeping, anxiety, nervousness,

abdominal pain/cramps, nausea and/or vomiting, low energy, join and muscle pain, headache, loss of appetite, diarrhea, constipation, increased thirst, increased energy, depressive mood, irritability, dizziness, skin rash, delayed ejaculation, erection dysfunction, reduced sexual desire, and chills.

4. 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 blood Liver Function Tests) and if you are found to have levels 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.

5. Naloxone injection may cause withdrawal symptoms in individuals who are opioid dependent including nausea, vomiting, diarrhea, stomach pain, fever, sweating, body aches, weakness, running nose, goosebumps, shivering, increased heart rate, and anxiety. You should not participate in this study if you take opioid (narcotic) painkillers such as (such as codeine, oxycodone, fentanyl).

6. (for Females) The procedures of this study are not considered safe during pregnancy or breast-feeding, because there is concern about Vivitrol/naltrexone 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.

7. 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.

8. **You will be compensated with a Clincard for your participation in the research study.** If you received over $600, this amount is considered to be income, and therefore may result in potential tax implications.

9. 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.

10. During the declared public health emergency, such as the community spread of the novel coronavirus, there is an increased risk related to the necessary travel to the research clinic and the visit at the clinic. This may include a risk of getting exposed to the virus and the risk of getting infected and developing an infection-related disorder (e.g. COVID-19). This risk can be reduced by taking recommended precautions which include: always wearing a mask in public and while traveling, practicing hand hygiene especially after being in the public spaces, and staying at least 6 feet away from others. It is also important that you remain informed about public health recommendations, such as CDC guidelines and local government guidelines and directives, and we will also provide you with such updates as they become available.
11. If you do not feel comfortable traveling to the research clinic for an appointment, for example if the subway you would normally take is crowded, you can reschedule, or we may be able to arrange alternative transportation.
12. If you are unable to attend scheduled visits because of the restriction on travel we may not be able to detect abnormal blood test results in time and your health may be compromised. Similarly, if you do not have regular pregnancy tests as directed by the team you may miss signs of early pregnancy.

VI. Withdrawal from the Study

You can withdraw from the study at any time without giving a reason. If you decide to withdraw from the study then data collection will cease and there will be no further contact with study site. Please be mindful that for a period of 30 days after your last Vivitrol injection there may a risk that opioid based medication may have a reduced affect. There is no option to remove Vivitrol.

In addition, participants **may** be withdrawn from the study by the investigator for reasons such as: adverse event, or any other medical condition (e.g., pregnancy), meeting an exclusion criterion, loss to follow-up, or a clinical deterioration.

VII. Benefits

There are no direct benefits to you for participating in this study as this was not designed for your benefit. This study has been designed to collect information which will be used to help determine whether future slow release naltrexone preparations 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 biological specimens 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. However, your biological specimens may be used for commercial profit and you will not share in this commercial profit. In the event that this occurs, there will be no personal information linking you to the data you provided. This study will not include whole genome sequencing.

Any clinically significant abnormalities detected on the safety laboratory reports or the ECG will be communicated to you.

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 the 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.

IX. Study Compensation

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

- $50 for the screening and the consent visit
- $200 for each inpatient day (4 days)
- $50 for each scheduled outpatient visit (23 visits). You will also receive an additional incremental bonus of $10 for each subsequent 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. This schedule is designed to reinforce adherence to all study safety assessments.
- 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 further follow-up visits, or an unscheduled visit due to public health emergency then you will receive $50.

The total amount of reimbursement should you attend every scheduled visit is $4,580.

We are required by law to report earning 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 the 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.

X. 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 study sponsor and the manufacturer of the implant, Go Medical will pay these providers for any reasonable medical expenses to treat your injury. The study sponsor, 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.

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

XII. 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: _____

XIII. 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: _____

XIV. 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: _____