SCHULMAN APPROVED
IRB# 201209845
DATE: 06/11/13

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A CLINICAL INVESTIGATION

Title: Prospective Collection of Samples for Research

Principal Investigator:

Site of Investigation:

24 hour Telephone #:

Sponsor: SeraTrials, LLC

Participant's Name: _____

This consent form may contain words you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

Introduction

You are being asked to participate in a research study because you have been diagnosed with a specific disease and meet the study criteria for participation. If you cannot read because of vision problems, this form will be read to you. Before you decide to be part of this research study, you need to understand the risks and benefits so that you can make an informed decision. This is known as informed consent. This consent form provides information about the research study. You will be asked to read this consent form and talk with your doctor or study staff about anything you do not understand. If you decide to participate in the study, you will be asked to sign and date this consent form. You will be given a copy of this signed and dated consent form.

Purpose of the Study

This study may aid in the development of new diagnostic test kits and devices for particular diseases and illnesses. Your samples may be stored and used for future research purposes and may be sold to a third party for commercial research. These samples may be used for genetic research.

Number of Subjects

Up to 50,000 patients may be enrolled in this multiple site research study.

Duration of Participation and Responsibilities
The duration of your participation in this study may be up to one year. Your participation in this study may be completed in one visit to the collection site. However additional visits may be requested at the time of collection, up to a maximum of 10 visits, in one year.

Study Procedures
Approximately 50 mL of your blood (a little more than 3 tablespoons) will be collected according to routine blood collection procedures at each visit. A sample of blood will be collected which requires withdrawing blood from a vein using a needle. Urine will be collected by urinating into a sterile urine container. In addition, swab specimens of the nasal or nasopharyngeal area or throat; a wash specimen of the nasal or nasopharyngeal areas; and specimens of mucous, sputum, saliva and feces may also be collected. The study staff will instruct you and assist you with obtaining these specimens. Information about your medical/medication history will also be collected.

Research Results
The researchers do not plan to provide you with the results of any of the studies done on your samples, because other research may be necessary before these results are meaningful. Results of the research will not be applicable to any individual subjects in the study. **It is important that you do not participate in this study for the purpose of evaluating your health status.**

Potential Risks
You will have blood samples drawn during this research study. The blood sample drawing procedure may cause pain, bruising, infection, accidental arterial puncture, clotting of the vein at the site where the needle is inserted, and/or a fainting spell. There are no known risks to providing urine samples, mucous, sputum, saliva or feces. There may be risks to participation in this study that are unknown and unforeseeable. You may experience irritation of the nose and/or throat from nasal swabs, nasal washes, nasopharyngeal swabs, nasopharyngeal wash and throat swabs. It is possible that you may experience a nosebleed, choke or gag during these procedures.

Although procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you, there is a remote possibility that information from your participation in this study would adversely affect you or your family in some way, such as obtaining a job or health insurance.

Benefits
There are no direct benefits to you for participating in this study.

Payments
There will be a monetary reimbursement of per visit. You will be paid at the completion of the visit. The Principal Investigator may receive reimbursement for their time in connection with this study. The study sponsor and their affiliated or partnered research collaborators and institutions will have ownership of the results of research utilizing the biological materials and data collected for this study. There will be no payment to the donor in respect to the eventual commercialization of the research resulting from the use of the biological materials and data collected for this study.

Cost of Participation
There will be no cost to you for participating in the study. You are responsible for the costs associated with your routine medical care.

Alternative Treatments
This study is for academic or commercial research. Your participation in this study is not to replace routine screenings, testing or treatments. Your alternative is to not participate in the study.

Voluntary Participation/Withdrawal from the Study
Your participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you may change your mind about being in the study and quit any time prior to your sample being received at SeraTrials, LLC. without penalty or loss of benefits regarding your future care. Once the sample is received at SeraTrials, LLC. it cannot be withdrawn from the study. The Principal Investigator or Study Monitor has the right to withdraw you from the study at any time without regard to your consent for any reason. If the amount of blood drawn is found to be too small to test, you may be removed from the study without your consent. If there is any new information about the study that may cause you to change your mind about the study, you or your legally authorized representative will be notified verbally and in writing. The study doctor may withdraw you from the study at any time for any reason.

Compensation for Study Related Injuries
If you experience injury or illness associated with this study, you should contact the study doctor at the phone number under Principal Investigator on this Informed Consent Form. Emergency treatment will be made available, at no cost to you, at an appropriate medical facility. If you desire, you may arrange to have treatment performed by another licensed doctor whom you select. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available; however, **you do not waive your legal rights by signing this form.**

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

As part of this clinical sample collection, the Principal Investigator and the office staff will keep records of your participation in this collection. These study records will include personal health information that you provide including your age, sex, race, blood test results performed during and before the collection, and other medical information relating to your participation in this study. Under federal law, your study records cannot be used or disclosed by the study doctor for research purposes unless you sign this authorization.

You may not participate in this study unless you sign this authorization. If you sign this informed consent, you will be agreeing to the disclosures described below:

A. Some or all of the test results and other information will be reported to SeraTrials, LLC., the Sponsor of this study, and its associates, who are helping the Sponsor conduct the study, and other consultants who work with the Sponsor to analyze the study results. As part of this study, samples may be transferred from the study sponsor to their affiliated or partnered research collaborators and institutions, which may be in other countries. The Sponsor and its consultants will analyze and evaluate these results and information and may report them to the U.S. Food and Drug Administration (F.D.A.) or similar agencies in foreign countries. **Your study records will be assigned a code number by the study team and you will not be identified by name in the study records that are sent to the Sponsor.** The Sponsor may use your data for further research purposes by adding it to research databases in order to conduct safety and effectiveness studies on this and other products or therapies, develop a better understanding of disease, or improve the efficiency of future clinical trials.
B. Personnel from the Sponsor may be visiting the office of the study doctor to monitor the conduct of the study, and these individuals may be reviewing your study records and your medical records for verification of data reported in the study documents.
C. Your study records and medical records may also be reviewed by Schulman Associates IRB, Inc. (an ethics committee that reviews the conduct of human research studies). The review board may review and use your study records only for the purposes of this study. They will keep your identity confidential and will not disclose your study records unless disclosure is required by law.
D. Once the study doctor releases the coded information in your study or medical records, the information will no longer be protected by federal law. Absolute confidentiality cannot be guaranteed. The Sponsor will only use your information for purposes of the study and further research as described in Section A, above, and will not disclose your study records to parties other than the F.D.A. or similar government agencies, unless disclosure is required by law.
E. If reports or articles are written about the study, you will not be identified by name in them.

This authorization has no expiration date. You have the right to revoke this authorization at any time. You can do this by giving written notice to the study doctor, informing them that you are revoking authorization to use and disclose medical information. You can reach the study doctor at the address listed on page 1 of this document.

If you revoke this authorization to use and disclose your medical information, you will not be permitted to continue your participation in the study after the revocation. If you drop out of the study, you do not have to revoke your authorization to use and disclose your medical information. If you decide to revoke your authorization to use and disclose your medical information, the information that has already been collected in your study record may continue to be used and disclosed as described above, however, no new information will be obtained or added.

Whom to contact with Questions

The Principal Investigator, , agrees to answer any inquires that you have concerning the study procedures, risks or injuries in the event of a study related emergency. You may contact the Principal Investigator at

If you have any questions regarding your rights as a research participant, please contact the Schulman Associates IRB, Inc., at toll free 1-(877) 888-4472 during regular working hours. You can also contact Schulman Associates IRB, Inc. if you would like to report problems in a research study, express concerns, ask questions, request information, or provide input. Schulman Associates IRB, Inc. is a committee established for the purpose of protecting the rights of participants in a research study. For more information about your rights and role as a research participant you can visit the Subject section of Schulman Associates IRB, Inc. website at www.sairb.com.

Closing Statement

I have read in a language that I understand information in this consent form. The study has been clearly explained to me. All oral and written information and discussions about this study are in a language that I understand well. I hereby freely and voluntarily consent to participate in the study described above and authorize the use and disclosure of my personal health information. I understand that my blood and urine may be used in the development of a new diagnostic assay (test), and that my samples may be stored and used for future research purposes. I will receive a signed and dated copy of this informed consent.

Subject's name (print)

Subject's signature

Date/Time _____/_____/_____ ____

Name of Investigator or designee administering informed consent (print)

Signature of Investigator or designee administering informed consent

Date/Time _____/_____/_____ _____

Copy of consent form given to subject on (date) _____ by (initials) _____

Schulman Associates IRB

Approved: 05/31/12; Revised: 06/11/13

SCHULMAN ASSOCIATES IRB

Offices: Cincinnati, Ohio | Ft. Lauderdale, Florida
www.sairb.com

June 13, 2013

FROM: Schulman Associates IRB, Inc. ("Schulman" or the "Board") - Board #3
TO:
SUBJECT: Updated Approval Documents
SPONSOR: SeraTrials, LLC
PROTOCOL NO: 05035
PROTOCOL TITLE: Prospective Collection of Samples for Research

The following item(s) were reviewed and approved by Full Board or Expedited Review on the dates listed below:

- **Informed Consent, version 06/11/13** **Expedited: 06/11/13**

Based on review of the item(s) listed above, the Board revised the Informed Consent(s).

Enclosed is the "Schulman Approved" revised Informed Consent(s), approved on 06/11/13. If enrollment remains open, use the revised Informed Consent(s) in the initial consent process for prospective subjects.

Please refer to the Informed Consent comparison document(s) available for download on SiteAccess at www.sairb.com.

Respectfully,

Suzanne Balandis Jr

Suzanne Balandis, PharmD
Chairperson

Schulman Associates IRB, Inc.

SB/ja:ep

PLEASE REFERENCE IRB #201209845 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless