INDEPENDENT IRB 1550 Sawgrass Corporate Parkway, Suite 120 | Sunrise, FL 33323 | phone 954.327.0778 | fax 866.258.6674 | www.iirb.com

**DATE:** September 27, 2012

**TO:** Robert Pyrtle,
Principal Investigator

**FROM:** Authorized Signatory
Independent IRB, Inc.

**SUBJECT:** Approval for Ongoing Research;

**PROTOCOL:** (SDP-001) Specialty Diagnostic Products Program

At the meeting held on September 27, 2012 the Independent IRB, Inc. had an opportunity to review the above referenced Progress Report and current consent form in use for the above noted research study. The information provided in the Study Progress Report is found to be consistent with the information on file. The IRB verified that all new information regarding the study risks and changes to procedures have been reported. Utilizing this information, the IRB has conducted a risk-benefit assessment and is satisfied that there have been no significant changes that would alter the criteria for approval.

The research approval extends from **27-Sep-2012** to **26-Sep-2013**. The Progress Report is accepted. If the study is completed prior to that time period, the Independent IRB is to be advised of the completion of the study and the Investigator is to provide a final Progress Report. If there are any changes to the protocol (amendments), changes in risks to subjects, significant protocol deviations, or other unanticipated problems involving risks to the human subjects, the Investigator is to notify the IIRB as soon as possible. Serious adverse reactions must be reported in accordance with protocol requirements.

Thank you for your cooperation.

SB/vd/ja:mc

# INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A CLINICAL INVESTIGATION

**TITLE:** (Protocol #: SDP-001) Specialty Diagnostic Products Program

**PRINCIPAL INVESTIGATOR:** Robert Pyrtle

**SITE OF INVESTIGATION:** Access Plasma/Saturn Biomedical
3209 Madison Avenue
Indianapolis, IN 46227

**TELEPHONE #:** (760) 931-8444 or (760) 473-4542

**SPONSOR:** Access Biologicals

**PARTICIPANT'S NAME:** _____

## INTRODUCTION

You are invited to participate in a research study. However, before you give your consent to be a research participant, we want you to read this informed consent form which will describe this research study. This consent form may contain words that you do not understand. Please ask as many questions as necessary to be sure that you understand what your participation will involve.

A person who takes part in a research study is called a research participant. In this consent form "you" always refers to the research participant, except in this introductory section. If you are the parent or guardian, please remember that "you" means the research participant.

If your child/legal dependent is 16 years of age to the legal age of consent, the child will be asked to sign an "assent form" and be given the chance to indicate whether he/she wants to participate in this study.

## PURPOSE OF THE STUDY

The purpose of this study is to collect specific bodily fluids (whole blood, plasma, serum or urine) for research purposes. The blood or plasma specimens will be obtained through a standard blood collection procedure or through plasmapheresis (procedure that separates plasma from the blood). These specimens will be used as diagnostic controls for clinical laboratory tests and may aid in the development of new diagnostic kits for use in clinical settings. The type of bodily fluids collected in this study will be based on the current industry needs.

## RESEARCH PARTICIPANT SELECTION

You are being asked to participate in a research study because you are between 16 and 70 years age, and are a healthy individual or have a known medical condition.



Approved By
Independent IRB
Signature
04-Oct-2011
Date

Initials: _____
Date: _____

Females must not be pregnant in order to participate in this study.

Approximately 1,200 research participants will be enrolled each year in this single site research study.

**DURATION**
Your participation in this study will involve one study visit.

You can participate in the study more than once if you choose, but each visit must be separated by at least 56 days for whole blood donation and no more than two times in a 7 day period for plasmapheresis.

**SCREENING**
Before undergoing any procedures for this study, you will be provided with an information packet about the study, which will include sample consent forms that outline the plasmapheresis/specimen collection procedures, a medical history questionnaire and a medical records release form. If you meet the initial criteria to participate in this study, you will be offered an appointment at the collection site.

You will be permitted to participate in the study at the discretion of the Principal Investigator. It is possible that you may not qualify for the plasmapheresis procedure, or may require documentation from your regular doctor indicating that you are healthy enough to participate.

**PROCEDURES**
You will come to the collection site for your study visit. Before any procedures are performed, you will be asked to sign this informed consent form.

Standard Blood Collection Procedure
If you are donating a blood specimen, approximately 2 cups of your blood will be collected according to routine blood collection procedures. A phlebotomy procedure, which requires withdrawing blood from a vein with a needle, will be performed.

For comparison, a standard blood donation at a blood collection center, once in any 56-day period, is about 2 cups of blood.

Plasmapheresis Procedure
If you are undergoing plasmapheresis, approximately 690mL to 880mL (Approximately 3 to 4 cups) of your plasma will be collected according to routine blood center collection procedures. The amount of plasma depends on your body weight. The procedure is similar to donating blood. Your plasma will be collected by inserting a sterile needle in one arm. The needle is connected to sterile tubing that draws blood from your vein and separates the plasma from your blood. You will be monitored by medical staff at the blood center throughout the plasmapheresis procedure.



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Urine Collection Procedure
If you are donating a urine specimen, you will collect your urine in a cup provided by the study staff.

All specimens collected in this study will be tested for infectious disease such as HIV, hepatitis C, hepatitis B and syphilis. Positive results for hepatitis, HIV and syphilis must be reported to a local health agency. This is the legal obligation of health professionals in this state. Based on state law or blood center policy, you may be asked to sign a separate HIV consent form.

## RESEARCH RESULTS / STORAGE OF SAMPLES

Results from the research testing done with your samples will not be given to you or your doctor, and these results will not be placed in any of your health records.

Your samples will be stored under a unique identifier and used for future research purposes only. These samples will not be used for genetic research. Information about you such as your gender and medical history will be connected to your samples. While your name will be kept confidential, the other information connected to your samples will be available to investigator who will be performing research on your samples.

## RESEARCH PARTICIPANT RESPONSIBILITIES

As a research participant you will be asked to complete the study procedures for this study, come to the collection site for your scheduled visit, follow the instructions listed in this informed consent form, and notify the study investigator if any information regarding your health or availability to participate in this study changes.

## RISKS AND DISCOMFORTS

The risks from any future sale or use of samples collected in this study are unknown. The use of the samples may result in findings about the risk of diseases in people. These findings could pose social or economic risks to donors, their families or their ethnic group, if someone knew they had these genes. Access Biologicals will not control the use of the samples sold to third parties.

Plasmapheresis Risk
There are potential risks in the plasmapheresis process. These risks are monitored by health workers at the blood center. The most common problem is a drop in blood pressure. Symptoms can be faintness, coldness, dizziness, blurred vision, sweatiness, nausea, numbness or abdominal cramps.

You may experience fainting, inflammation of the vein, infection of the skin, nerve injury, blood loss from the inability to return red blood cells, allergic reaction to materials, or hemolysis (breakage of blood cells).

Standard Blood Collection Risk
During the collection of blood samples, you may experience pain and/or bruising at the insertion site of the needle. Although rare, localized clot formation and infections may occur.



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Lightheadedness and/or fainting may also occur during or shortly after the blood draw procedure.

**UNKNOWN/UNFORESEEABLE RISKS**
In addition to the risks listed above, there may be some unknown and unforeseeable risks related to the study procedures. You will be advised right away both verbally and in writing of any new risks that come up during the study that may affect whether you want to continue in the study.

**BENEFITS**
You will not benefit from taking part in this research study. The information gathered may benefit others by helping researchers to develop new drugs, new diagnostic testing or learn more about disease.

**ALTERNATIVES**
This study is for research purposes only. Your participation in this study, regardless of the type of specimen taken, does not replace routine screenings or testing as recommended by your physician. Your alternative is to not participate.

**COST**
There will be no cost to you for your participation in this study. The study related procedures and study visit will be provided at no cost to you or your insurance company.

**COMPENSATION**
If you choose to take part in this research study, you will be paid $ at the completion of your visit.

**COMPENSATION FOR INJURY**
If during the course of this study any injury occurs to you as a direct result of the study, the sponsor (Access Biologicals) agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the investigators.

Financial compensation for such things as lost wages, disability or discomfort due to injury is not routinely available.

You **DO NOT** waive any of your legal rights by signing this form.

**CONFIDENTIALITY AND DISCLOSURE OF MEDICAL INFORMATION**
As part of this study, the Principal Investigator Robert Pyrtle will keep records of your participation in the study. These records include personal health information (PHI), such as your name and the results of the procedures that occur during this study. This information is necessary for the evaluation of the study data. Records of your participation in this study will be held confidential so far as permitted by law. However, the Sponsor (Access Biologicals), the Food and Drug Administration (FDA), the IRB that reviewed and approved this study (Independent Investigational Review Board, Inc.), and any other appropriate



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regulatory agency will be able to inspect and copy confidential data which identifies you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of the study should be published, you will not be identified by name. Your study records may be retained at the research facility indefinitely following the completion of the study. You will not have the right to review your records while the research is in progress. However, you will be able to review your records after the research has been completed.

This authorization does not expire. However, you have the right to revoke this authorization at any time. You can do this by giving written notice to the Principal Investigator, informing him that you are revoking your authorization to use and disclose medical information. The Principal Investigator's contact information is listed on page 1.

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. However, if you drop out of the study and do 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.

**EMERGENCY CONTACT / IRB CONTACT**

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact Robert Pyrtle at (760) 931-8444 or (760) 473-4542. If you have a medical emergency, please go directly to your physician, an emergency room, or to an immediate care center.

If you have any questions regarding your rights as a research participant, please contact the Independent Investigational Review Board, Inc. at toll free 1-(877) 888-IIRB (4472) during regular working hours. You can also contact the Independent Investigational Review Board, Inc. if you would like to report problems in a research study, express concerns, ask questions, request information, or provide input. The Independent Investigational Review Board 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 Research Participant section of the IIRB, Inc. website at www.iirb.com.

**RIGHT TO WITHDRAW OR REMOVAL FROM STUDY**

Your participation in this study is voluntary. You may decide not to participate or you may withdraw from the study at any time without penalty or loss of benefits to which you would otherwise be entitled and without any effect on the availability of your future medical care.

The investigator or sponsor can stop your participation at any time without your consent for the following reasons; if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if it is discovered that you do not meet the study requirements, at the discretion of the study investigator, if the study is canceled, or for administrative reasons.



Approved By
Independent IRB

Signature

04-Oct-2011
Date

Initials: _____
Date: _____

**CLOSING STATEMENT**

You have read and understood the information which has been stated above and have received satisfactory answers to all of the questions which you have asked and you willingly sign and initial each page of this consent form. You will receive a copy of the signed informed consent. You hereby consent to be a participant (or allow your child to participate) in this study.

**SIGNATURES**

I have read in a language that I understand well, the above information. The content and meaning of this information has been explained to me. I hereby voluntarily consent and offer to take part in this study and authorize the use and disclosure of my (or my child's) medical information.

***Consent and Assent Instructions:***

*Consent* — *Subjects 18 years and older must sign on the research participant line below to participate. For research participants under 18, consent is provided by the parent or guardian.*

*Assent* — *Assent is required for subjects ages 16 and older using the Assent Form.*

_____
Research Participant Name (printed)

_____ _____
Signature of Research Participant (18 years and older) Date/Time

_____ _____
Signature of Parent or Guardian (when applicable) Date/Time

_____ _____
Signature of Person Conducting Informed Consent Discussion Date/Time

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

Independent Investigational Review Board, Inc.

Approved: 04-Oct-2011



Approved By
Independent IRB
Signature
04-Oct-2011
Date

Initials: _____
Date: _____