APPROVED BY
INTEGREVIEW IRB
SEPTEMBER 14, 2018

Olympian Clinical Research
Pre-Screening Informed Consent

Study Sites 4700 N. Habana Avenue, Suite 303, Tampa, FL 33614 | 1201 S. Myrtle Ave, Clearwater, FL 33756

Telephone (813) 849-5566 (24-Hours)

INTRODUCTION

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

This pre-screening consent form is for use in determining potential participation in research studies.

Before agreeing to participate in this/these pre-screening test(s), it is important that you read and understand the following explanation of the proposed pre-screening and of the purpose, procedures, benefits, risks, discomforts and precautions of these tests. It also describes the alternative procedures that are available to you and your right to withdraw from the pre-screening at any time. No guarantees or assurances can be made as to the results of the pre-screening.

IntegReview IRB has approved the information in this consent document and has given approval for the pre-screening doctor to do the pre-screening visit. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the pre-screening visit. You can think about the information in this consent document for yourself. You can then decide if you want to do the pre-screening visit.

PURPOSE

The purpose of this form is to obtain your consent to allow us to collect and review your general health and medical information to determine if you may eligible to participate in a research study being conducted at Olympian Clinical Research (OCR). Your information will then be filed and maintained. By signing this consent form, you are not agreeing to participate in a research study, but are only agreeing to have certain routine pre-screening procedures performed as described below, and have your information stored in our electronic database.

The purpose of this/these pre-screening test(s) is to determine if you pre-qualify to participate in a research study being conducted at OCR. You are being asked to allow us to obtain information and perform certain routine procedures to determine if you would be eligible to participate in future research studies at OCR. Studies may involve numerous clinic visits over a period of time (weeks, months, or years), further screening and testing, and the use of investigational drugs, biologics, or devices. If it is determined from this general pre-screening you may be eligible for a research study and you voluntarily agree to participate, you will be asked to sign a study-specific consent form for the research that you have chosen to participate in, which will contain complete information about the research requirements and procedures.

If you are not completely truthful with the OCR staff regarding your health history, you may harm yourself by participating in this pre-screening.

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SCREENING PROCEDURES

Before any pre-screening tests or procedures are performed, you will be asked to read and sign this informed consent document. Procedures which may be performed as part of this pre-screening visit include:

- Review and record your past and present medical history
- Review and record your medication history
- A general psychological and intellectual assessment, as it relates to your ability to participate in a research study
- Vital signs—including height, weight, BMI and blood pressure
- Urine Pregnancy Screen, if you are female
- "Finger-stick" glucose or cholesterol testing
- Tests for drug and alcohol use
- Blood and urine samples collected to test for things such as blood sugar levels, cholesterol levels, kidney and liver function, pregnancy, and other general laboratory tests for your safety
- Electrocardiogram (ECG) to measure the electrical activity of your heart
- A general physical examination
- Dermatological assessment

When blood is collected in the pre-screening, the total amount of blood drawn will be about 3 mL per kg and collection may not occur more frequently than 2 times per week. For comparison, the standard blood donation is about 480 mL (two cups).

If an unsuspected abnormality is uncovered as a result of any of the pre-screening procedures, the research doctor and/or research staff will notify you and may advise you to consult your primary care physician or a specialist for further evaluation.

HOW LONG THE PRE-SCREENING TESTS WILL LAST

The pre-screening tests will last no more than 4 hours.

RISKS

The pre-screening procedures are expected to be minimal risk to you, but there is no absolute guarantee that an unexpected risk or adverse event will not occur.

1) You may feel discomfort during cuff inflation while having your blood pressure taken.
2) If you are giving a blood specimen you may experience pain, bruising and/or infection at the site where blood is taken.
3) You may become dizzy or feel faint during the blood draw.
4) Skin irritation is very rare but could occur during an Electrocardiogram (ECG) from the electrodes or gel that is used.

BENEFITS

There is no direct medical benefit to you for participating in the pre-screening test(s). This pre-screening does not take the place of seeing your primary care physician or specialist.

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COMPENSATION FOR INJURY

If you are injured as a result of procedures performed for the purpose of this pre-screening, you will be responsible for those medical expenses necessary to treat your injuries not covered by your medical insurance or any other third party coverage. There are no plans to provide other compensation beyond that which is listed in this informed consent document. You will not lose any of your legal rights or release the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

COST OF PRE-SCREENING VISIT AND PROCEDURES

The pre-screening test(s) will be done at no cost to you or your insurance company. You are responsible for the costs associated with your medical care.

COMPENSATION FOR PARTICIPATION

No compensation is available for your participation in the pre-screening test process.

ALTERNATIVES

Your alternative is not to participate in the pre-screening procedures and to seek diagnosis and treatment from your doctor.

VOLUNTARY PARTICIPATION/WITHDRAWALS

Your participation in this pre-screening is voluntary. You may decide not to participate, and you are free to stop the test at any time without prejudice to your future participation in medical treatment, health screenings or in other research studies.

CONFIDENTIALITY

This section provides information about how your medical records and health information (together, called your “records”) will be used and disclosed from this pre-screening. Your records may include information about your blood samples, physical examinations, medical history and any other data collected or reviewed during the course of the pre-screening. During your participation in the pre-screening test(s), OCR study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures undergone), and record it in your records. These will contain medical and other information that could be used to identify you (referred to as "Protected Health Information" or "PHI").

This consent form allows the research doctor and the research staff to use your records to determine eligibility for potential participation in a clinical research study and to store the collected information in both paper form and/or electronically. By signing this form, you are agreeing to allow OCR to use your PHI to determine if you may qualify for a research study. You may not participate in this pre-screening if you do not sign this form. If you do not sign this consent form, we cannot collect the necessary information.

With your permission, OCR will retain your PHI on file and/or in a database for the purpose of contacting you regarding possible participation in future studies. Your identity will remain confidential.

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INTEGREVIEW IRB
SEPTEMBER 14, 2018

If you qualify for a research study and agree to participate, your PHI will be placed in your study-related records and used for the purpose of conducting the study. Your PHI may be disclosed to the sponsor or persons working on behalf of the sponsor. In addition, the United States Food and Drug Administration ("FDA") or other regulatory agencies, and the institutional review board ("IRB"), an independent committee that helps protect the rights and welfare of research subjects, will have access to your PHI. Except for these disclosures, your PHI will not be shared with others unless such disclosure is required by law. If your PHI is given to the parties listed above or others, your PHI may no longer be protected by the federal Privacy Rule and could possibly be used or disclosed in ways other than those listed here.

This Authorization does not expire unless you revoke (cancel or withdraw) it. You have a right to revoke it at any time. If you revoke the Authorization, OCR will no longer use your PHI, except to the extent study staff have already taken action based upon your Authorization. To revoke your Authorization, you must write to OCR and tell a staff member that you are revoking your authorization to use or disclose your protected health information. If you revoke this Authorization, you will not be allowed to continue with the pre-screening process.

If you agree to this pre-screening, you will receive a fully executed, signed and dated copy of this consent form for your records.

CONTACT INFORMATION

If you have questions, concerns, or complaints about the screening tests or to report a screening related injury, contact:

Olympian Clinical Research
(813) 849-5566 (24-Hours)

If you are unable to reach anyone at the number(s) listed above and you need medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, or if you have concerns or complaints about the pre-screening, you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

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SEPTEMBER 14, 2018

CONSENT

I have read (or it has been read to me) and understand the information in this consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to undergo this pre-screening visit, to participate in the pre-screening test(s) described in this consent document and related procedures until I decide otherwise. Information obtained during this visit will be retained, and I agree to possible future contact in regards to my potential participation in a specific research study. I consent to the use and disclosure of my health information to the parties listed in this form for the purposes described above. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed document after I have signed and dated it.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

I attest that the subject named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in the pre-screening visit as described above.

_____
Printed Name of Person Obtaining Subject Consent

_____ _____
Signature of Person Obtaining Subject Consent Date

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
clw/4-28-16 bam/9-14-18

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SEPTEMBER 14, 2018

The signature lines below are required when adult screening participants are not able to legally give consent.

I certify that under applicable law I am the legally authorized representative of the subject named above. I am permitted by law to sign this form on behalf of the subject.

_____
Legally Authorized Representative's (LAR) Printed Name

_____ _____
Legally Authorized Representative's (LAR) Signature Date

_____
Legally Authorized Representative's (LAR) Relationship to Subject

I attest that the subject and legally authorized representative named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in the pre-screening visit as described above.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

~~APPROVED BY~~
~~INTEGREVIEW IRB~~
~~APRIL 28, 2016~~

Olympian Clinical Research
Pre-Screening Informed Consent

Study Sites **4700 N. Habana Avenue, Suite 303**~~2919 Swann Ave, Suite 205~~ 1201 S. Myrtle Ave
Tampa, FL **33614**~~33609~~ Clearwater, FL 33756

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Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

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toll free at 1-877-562-1589

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between 8 a.m. and 5 p.m. Central Time

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CONSENT

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_____
Printed Name of Subject

_____ _____
Signature of Subject Date

I attest that the subject named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in the pre-screening visit as described above.

_____
Printed Name of Person Obtaining Subject Consent

_____ _____
Signature of Person Obtaining Subject Consent Date

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I certify that under applicable law I am the legally authorized representative of the subject named above. I am permitted by law to sign this form on behalf of the subject.

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Legally Authorized Representative's (LAR) Printed Name

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Legally Authorized Representative's (LAR) Signature Date

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Legally Authorized Representative's (LAR) Relationship to Subject

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