IRB APPROVED
Jun 28, 2022

RESEARCH SUBJECT CONSENT FORM

TITLE:	Rapid methods (OncoSure ™) for isolation and profiling of Oncosomes for the early detection and monitoring the treatment of all human cancers from the peripheral blood.
PROTOCOL NO.:	INGLB061322 WCG IRB Protocol #20223192
SPONSOR:	Dr. Ramesh Babu
INVESTIGATOR:	Ramesh Babu, MBA 8865 Commodity Circle Suite 2 Orlando, Florida 32819 United States
STUDY-RELATED PHONE NUMBER(S):	321-946-0403 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed above.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

Someone will explain this research to you.

Taking part in this research is voluntary. Whether you take part is up to you.

If you do not take part, it will not be held against you.

You can take part now and later drop out, and it will not be held against you

If you do not understand, ask questions.

Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last less than 1 day and will include 1 study visit, which will take 15 to 30 minutes for completing required forms and specimen collection.

Why is this research being done?

The purpose of this research is to determine if a simple, experimental, liquid biopsy (blood) test can detect and monitor the treatment of all human cancers.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include a collection of a small amount of blood (2-3 cc) which is generally simple and has very minimal discomfort. Complications are uncommon and would be minimal, such as redness at the site of needle insertion. Study participation has minimal risk.

Could being in this research hurt me?

The potential risks of participating in this study include the following:

- Generally, collection of a small amount of blood (2-3 cc) which is generally simple and has very minimal discomfort. Complications are uncommon and would be minimal, such as redness at the site of needle insertion.
- No test is perfect; thus, incorrect test results are possible. **Note:** The test used in this study is not authorized or approved for screening and shall NOT be used either for clinical diagnosis or for patient management. No medical treatment or guidance on treatment decisions will be provided. Further evaluation with your standard physician would be necessary to determine cancer status or any efficacy of a cancer treatment.
    - A positive test result may be incorrect (false positive) – this means the test result was positive when you don't have any clinical symptoms associated with cancer and other standard methods fail to detect cancer. You may be given another opportunity for screening at a later point to see if the initial results persist and other methods provide positive results
    - A negative test result may be incorrect (false negative) – this means the test result was negative when you actually have a cancer.
    - The test may not be able to produce a result. A non-reportable result will not be reported back to you, and you will have to continue your medical care as per the normal standard of care

There may be a risk of loss of confidentiality, and there may be risks, which are currently unknown.

Will being in this research benefit me?

This study is for research purposes only. Thus, there are no anticipated health benefits to the subject for participating in this study. Information gained from evaluation of the study specimens may support the development of a new product, in this case a screening and a monitoring test which could potentially affect care given to cancer patients in the future.

What other choices do I have besides taking part in this research?

Your alternative is not to be in the research study. This study does not involve diagnosis of or treatment of any condition. The study is for research purposes only to evaluate the performance of the research OncoSure™ test.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is use of your specimen(s) for research and commercial purposes may result in new products, tests, or discoveries that have commercial value. You will not receive any compensation or share in any financial benefits from these products, tests, or discoveries, and you agree that you do not retain any property rights to any products, tests, or discoveries that are developed. All retention and uses of your specimen(s) and test results will follow applicable law.

As part of this study, we may conduct genetic tests on your specimen(s). You agree that we have no obligation to contact you to provide information about tests of your specimen(s) or the results of such tests.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

In this consent form "you" generally refers to the research subject. If you are being asked as the parent, or legal guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

What should I know about this research?

Someone will explain this research to you.

This form sums up that explanation.

Taking part in this research is voluntary. Whether you take part is up to you.

You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.

You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.

If you do not understand, ask questions.

Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to determine if a simple liquid biopsy (blood) test can detect and monitor the treatment of all human cancers. Use of blood specimens is for research use only. About 500 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last less than 1 day and will include 1 study visit, which will take 15 to 30 minutes for completing required forms and specimen collection.

What happens to me if I agree to take part in this research?

Your participation in this study will last less than 1 day and will include 1 study visit, which will take 15 to 30 minutes for completing required forms and specimen collection.

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. You may have been asked to complete a questionnaire prior to signing this document; this questionnaire allows us to get some information such as your age, ethnicity, and race and whether you have had any symptoms of cancer.

After consenting to the study, the following procedures will be performed. All procedures are research related and are not considered standard of care.

- An alphanumeric string supplied by the sponsors will be placed on the blood sample tube with no other information, from the participating physician practices
- The sample will be sent to InteGen LLC, the Sponsors location in Orlando
  The alphanumeric string with patient demographics and clinical history will be sent by the investigators to an independent third-party study coordinator who has agreed to strict confidentiality and nondisclosure of results to any party until the entire study is complete
- The testing facility (Sponsor) will send results with attached alphanumeric string to the study coordinator
- Once the study coordinator has been informed that the study is complete, the coordinator will match the clinical data and the laboratory testing data with the alphanumeric string and generate a master study results EXCEL spread sheet
- The master EXCEL spread sheet will then be shared simultaneously to the Sponsor and to the participating investigators.
- Neither the sponsor nor the participating investigators are allowed to alter the master results database

- Any perceived discrepancies will be clarified in coordination with the original database kept by the study coordinator.
- The results will be decoded and analyzed for specificity, sensitivity, and overall accuracy of the test OncoSure™ in detecting and monitoring human malignancies noninvasively from the peripheral blood.
- Results will be shared with you for information purposes ONLY. No clinical decisions will be taken based on the study results.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Prepare for blood specimen collection by going to a designated blood collection place.

Could being in this research hurt me?

The potential risks of participating in this study include the following:

- Generally, collection of a small amount of blood (2-3 cc) which is generally simple and has very minimal discomfort. Complications are uncommon and would be minimal, such as redness at the site of needle insertion, pain, bruising, and fainting.
- There may be a risk of loss of confidentiality, and there may be risks, which are currently unknown.

Your privacy is protected in the study though various measures. Study data and identifying specimens will be labeled using a Subject ID. Only the collection site will have access to a key that links your study ID to you. This key will be stored in a secured location at the collection site. Because your samples contain genetic information that is unique, there is still a chance that someone could trace your samples back to you. The risk of this happening is small but may be greater in the future.

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records, which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

Will it cost me money to take part in this research?

There will be no charge to you for your participation in this study. The study visit will be provided at no charge to you or your insurance company.

Will being in this research benefit me?

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- If you did not provide any specimens
- If you fail to follow directions for participating in the study
- The research is canceled by the FDA or the sponsor

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that

the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Will I be paid for taking part in this research?

You will be paid $50 as reimbursement for your travel expenses, for taking part in this research.

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Consent and Assent Instructions:

Consent: Subjects 18 years and older must sign on the subject line below

Assent: All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted

If assent is obtained, have the person obtaining assent document assent on the consent form

Statement of Consent:

Your signature documents your permission for you, or the individual named below to take part in this research.

Signature of adult subject capable of consent, child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care	Date
Printed name of subject (not required if subject personally provided consent)	Date
Signature of person obtaining consent	Date

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CONSENT/ASSENT SECTION:

Statement of person conducting consent/assent discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. I believe the subject's decision to enroll is voluntary.
4. The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____

Signature of Person Conducting Consent/Assent Discussion Date