Informed Consent for Clinical Study Participation

"WHOLE BLOOD TRANSCRIPTOMIC SIGNAL ACCORDING TO CORONARY ATHEROSCLEROTIC PLAQUE BURDEN ASSESSED BY CT ANGIOGRAPHY: CORPLAQ-TRAIT PILOT STUDY"

Dear Participant:

We invite you to participate in a clinical study to be conducted at Sanatorio Julio Méndez, at Centro Diagnóstico MEDITER, owned by Diagnóstico MEDITER S.A., CUIT 30-70996765-3, located at Av Avellaneda 538 Piso 4to A. CABA . CP 1405 (the "Center"), under the sponsorship and organization of MULTIPLAI TANGO SAS (the "Sponsor"), and conducted by the Study Principal Investigator Dr. Rosana Poggio rosana.poggio@multiplaihealth.com and the Center Principal Investigator, **Dr Guillermo Ganum** guillermoganum@gmail.com, **+54 011 5108 8900.**

It is the Sponsor's concern to seek better ways to diagnose and treat heart disease and your contribution to this end will be appreciated. You are invited to participate in this study because you have a medical indication to undergo coronary angiography by computed tomography (Angio-tomography).

Your participation is strictly voluntary, and you may refuse to participate in the study without prejudice, as well as withdraw from the study at any time you wish. Furthermore, your participation does not entail any change to the treatments that have been previously agreed upon with your primary care physician.

Clinical trials and studies are fundamental to the advancement of medicine and the understanding of diseases. In order to achieve these objectives, it is necessary to conduct clinical studies with the voluntary participation of patients. To do so, patients must be informed of the scope and risks of their participation, and sign an informed consent form that supports their decision to be part of the study. Please read the following paragraphs carefully to understand the study, and then you will have the opportunity to discuss it with one of the investigators to answer any questions you may have. Finally, if you agree, sign this consent form if you:

- have understood the scope of the study and the procedures to be performed.
- are ready and willing to participate in the study.
- know and have been explained your rights to participate in this study.
- have understood the form and purposes for which your personal data will be treated..

1 What does the study consist of?

The objective of the Study Sponsor is to develop a diagnostic method for the detection of cardiovascular disease by means of a blood test. To do this, a blood sample is taken to analyze its RNA (a subtype of DNA) and another sample is taken to perform a clinical analysis (blood glucose, cholesterol, hematocrit, etc.). A buccal swab is then performed in order to obtain a DNA sample.

The results of the analyses will be used by the Sponsor to train an artificial intelligence algorithm to differentiate which of the samples carry the genetic information of the disease and which do not.

At the end of the follow-up study, it will also be explored whether the genetic information contained in the blood sample differs between participants who eventually developed a cardiovascular event (e.g., heart attack, stroke) and those who did not.

2 What are the procedures to be performed during the development of the study?

The blood collection procedure for RNA analysis is very simple, as you must donate only 2.5 milliliters of blood (¼ of the usual amount collected during a routine clinical analysis). The collection is performed from a peripheral vein using a standard technique. The RNA from your blood will be sent to a Sponsor laboratory located in the United Kingdom for analysis, as no such studies are performed in the United Kingdom. The second blood draw (clinical analysis) will be 10 ml and is performed following the same procedure. This sample will be sent to Stamboulian Laboratory, a local clinical testing laboratory owned by Diagnóstico MEDITER S.A., or to another local clinical testing laboratory to be designated in the future that meets industry standards. The third procedure consists of a cheek and gum swab for the collection of a cell sample to obtain DNA. In all cases, care will be taken to ensure that the samples submitted do not contain data that would allow third parties to identify you and/or link that RNA sample to you. The fourth procedure consists of the identification of the images of the Angio-tomography donated by you and its associated data in order to download and analyze them for the study. Once the blood, saliva and the images of the Angio-tomography have been donated, an interviewer from the Center will call you by telephone once a year and will ask you a series of questions about your state of health. If, during the duration of the study (5 years), you have any problems related to your health, an investigator authorized by the Center for such purposes will collect that information from your medical records or other available source document (epicrisis).

3 What are the risks of my participation in the study?

The risks to your health are minimal, since the blood collection is the one that is routinely performed. Complications of this procedure are rare, and may consist of transient pain at the site of collection or the formation of a local hematoma. Rarely, more serious complications such as thrombophlebitis or local infection may occur. To reduce this complication, the blood sample will be drawn by a technician trained in this procedure.

Regarding the cheek swabbing, it consists of obtaining the sample by rubbing a buccal swab against the inside of the cheeks and gums, and does not pose any risk to your health.

By signing this Informed Consent you do not waive your rights under the Civil and Commercial Code, and Argentine laws regarding civil liability for damages. In case of damage, injury or adverse event related to the study and you are covered by PRUDENCIA CIA ARG. DE SEGUROS GENERALES S.A. under policy number 00182398 - Contact: (011)5235-8816/(011) 15-6473-PRUD(7783)/0800-345-0085, E-MAIL prudencia@prudenciaseguros.com.ar. If you have any questions about your participation in this study or in case of any discomfort related to the study, you may contact Dr. Guillermo Ganum at guillermoganum@gmail.com.

4. **Does my participation in the study bring me any benefits?**

Every study participant will receive a written return (Report) from the Center's investigators with information provided by the Sponsor, with a laboratory evaluation. You will be able to give this report to your primary care physician. The information obtained from this study will allow us to improve the early detection of future diseases in the future.

5. What categories of my Personal Data will be processed and for what purposes?

5.1 For the purposes of your participation in the study, the following categories of data will be collected:

5.1.1 Identifying Data:

- Full name
- DNI
- Sex
- Address
- Contact information (e-mail and telephone)

5.1.2. Medical Data: Data collected or inferred from the procedures detailed in point 2 of this document, and from any interview conducted within the framework of the study by the Center's physicians.

5.1.3. Pseudonymization of Data: For the purposes of conducting the study, it is intended that your Identifying Information and Medical Data will be handled pseudonymously, using a coding mechanism so that third parties other than the Center and/or the Center's investigators will not be able to identify you or associate you and your Identifying Information with the Medical Data obtained in connection with the study. Whenever the Center or the Sponsor sends your Medical Data to any other entity involved in the conduct of any activity related to this study, it will do so in a pseudonymized form. In this sense, the treatment of your Identifying Information that we call "pseudonymization" implies that access to it will be protected at all times by passwords, only accessible to the Center and/or the Center's Investigators, but not to the Sponsor or any other entity or third party.

In this sense, your Identifying Data will only be included at the time of recruitment in a form kept separately from the rest of the study by the Center, and coded, and only for the purpose of follow-up by the Center.

5.2. The purposes for which your Personal Data will be collected and processed are as follows:

5.2.1. Processing of Identifying Data: This data will be collected and processed by the Center for the following purposes:

- Storage, treatment and conservation for the registration of the participants of the study by the Center, and to be able to receive and evacuate queries from the participants as well as requests for access, updating, rectification or suppression of personal data by the participants and holders of personal data.

- To provide participants with the Report containing information provided by the Sponsor on the presence and extent of coronary artery calcifications, which is useful as a tool for cardiovascular prevention.

- Follow-up of the participants and be able to contact them to interview them and ask questions about the participant's health status, within the framework of the study and always with the purposes of the study as indicated herein.

- Collect and process the information from the interviews with the participants, and enter it into the participant's clinical history and other available source documents (epicrisis).

- Collect and process interview information and share the results of the interviews with the Sponsor or such entities as the Sponsor may direct the Center to share, in a pseudonymized manner and for the purposes stated herein.

- To comply with the obligations of storage, treatment and conservation of the data of the participants of medical studies, for the terms and by virtue of the legal obligations of the Center in relation to the applicable regulations.

5.2.2. Treatment of Pseudonymized Medical Data: This data will be collected and treated by the Center, the Sponsor and/or other entities involved in the study for the following purposes:

- Storage, processing and preservation for the Sponsor's health-related medical-scientific research and analysis purposes.

-- Storage, treatment and conservation for legal purposes of the Center and to be able to receive and evacuate consultations of the participants as well as requests of access, update, rectification or suppression of personal data on the part of the participants and holders of personal data.

- Investigación médico-científica del Patrocinador para desarrollar mejores formas de detección, diagnóstico y tratamiento de las enfermedades cardiovasculares, por medio de los análisis de sangre y otras muestras.

- Sponsor's medical-scientific research to develop better ways to detect, diagnose, and treat cardiovascular disease by analyzing blood and other samples.

- Sponsor's medical-scientific research to train artificial intelligence algorithms or other technologies developed or to be developed in the future, with the objective of differentiating which of the samples carry the genetic information of cardiovascular disease and which do not, and also to train artificial intelligence algorithms or other technologies developed or to be developed in the future, for other purposes of detection, diagnosis and treatment of diseases in general.

- Collaboration of the Sponsor with the Center's Researchers with the Reports to be delivered to the participants on the presence and extent of coronary artery calcifications, which is useful as a tool for cardiovascular prevention.

- Collaborate with the Center's Investigators in the elaboration of follow-up interviews of the participants and any other reports to be delivered to the participants.

- Validate results obtained through experts and/or technologies developed or to be developed in the future.

- Elaborate and present scientific-medical reports and/or publications on the topics addressed by the study, or its results, as well as on other related topics.

- Elaboration of new medical-scientific research questions or processes.

- Sponsor's medical-scientific research to train artificial intelligence algorithms or other technologies developed or to be developed in the future, related to health that may or may not be used and/or patented and/or commercialized by Sponsor or third parties.

6. How is your Pseudonymized Health Data shared?

In order to fulfill the purposes detailed herein, your pseudonymized Medical Data may be shared by the Sponsor with different entities both locally and located in other jurisdictions. In addition, your Medical Data may also be transferred to entities located in other jurisdictions for storage and processing purposes.

By signing the present, You expressly consent to the manner in which we will share your pseudonymized Medical Data as well as the international transfer of your pseudonymized Medical Data, all of this to the following jurisdictions and entities:

6.1.- To Amazon Web Services (AWS) with jurisdiction in the United States of America, an international data storage and processing company recognized and used worldwide, where the Sponsor will host the databases in which its pseudonymized Medical Data is stored and processed.

6.2. To a laboratory of the Sponsor located in the United Kingdom for the medical-scientific research purposes detailed herein.

6.3. To an independent medical professional, located abroad (United Kingdom) for the medical-scientific research purposes detailed herein and entrusted by the Sponsor, also

for the purpose of validating the results obtained at the request of the Sponsor, always within the framework of the purposes indicated herein.

6.4. To the Stamboulian Laboratory, a local clinical analysis laboratory owned by Diagnóstico MEDITER S.A., for the medical-scientific research purposes entrusted by the Sponsor.

6.5. To a biobank to be defined by the Sponsor for the purposes foreseen herein and entrusted by the Sponsor. In relation to this point, we inform you that Certain biological samples obtained by virtue of the processes detailed in point 2 herein (also included in the definition of Medical Data), will be stored in a biobank operating within FLENI, or in a biobank belonging to the Sponsor or to a third party designated by the Sponsor, either in Argentina or abroad, for scientific and statistical purposes. In the event that the Sponsor determines that the biobank will be a biobank located abroad, the Sponsor will comply with the legal safeguards required by the applicable regulations regarding the international transfer of its pseudonymized Medical Data.

6.6. To other entities to be defined by the Sponsor and always within the framework of the purposes set forth herein and entrusted by the Sponsor to such entities. In the event that the Sponsor determines to share the data with any other entity, the Sponsor will comply with the legal safeguards required by the applicable regulations in relation to the assignment and/or international transfer of its pseudonymized Medical Data. After the end of the 5-year period covered by the study, the Sponsor of the study may require that the pseudonymized Medical Data be completely anonymized or dissociated from your Identifying Data, and be shared with you, so that such Medical Data will not allow you to be identified. The anonymized Medical Data may then be used by the Sponsor of the study, MULTIPLAI TANGO SAS, for scientific and statistical purposes, without this implying any processing of your Personal Data.

Likewise, once the study is completed, the Center shall keep your Identification Data and your Medical Data for the term established by the applicable regulations, and may only use them for the purposes set forth in such regulations.

In no case will your Identifying Information be published or shared; only the principal investigator of the Center will have access to your Identifying Information and for the term of the law. Furthermore, your Identifying Information will be kept confidential, even in case of publication of the research results, according to Law Nº 25.326. All study personnel agree to comply with National Law 25.326 on Personal Data Protection. In the future, the information obtained from this study could be used for the development of new research questions.

7. How can I access, modify or delete my personal and genetic data?

In accordance with the provisions of Law No. 25.326, you may at any time access, modify or delete your Identifying Data and/or Medical Data, including blood samples stored in biobanks.

In order to exercise your right to access, update, or rectify, you should contact the Center by sending an e-mail to juliomendezcdi@gmail.com . The Center may require

you to identify yourself by asking to see documentation verifying your identity or the information you wish to modify, which will be discarded, if applicable, after verification of the personal data you wish to access.

You may at any time request the Center to delete your Identifying Data and/or Medical Data by sending an e-mail to juliomendezcdi@gmail.com . The Center may require you to identify yourself by requesting to see documentation verifying your identity, which will be discarded, if applicable, after verification of the personal data you wish to delete. Please note that certain personal data may not be deleted by the Center under applicable law.

Likewise, you may only exercise your rights of access, updating, rectification and deletion conferred by Law 25.326 against the Center and not against the Sponsor, considering that due to the pseudonymization procedure mentioned in point 6, and the eventual anonymization process also mentioned in point 6, the Sponsor of the study, MULTIPLAI TANGO SAS, will not have at any time, neither during nor after the study, the factual possibility to access, modify or delete your Identifying Data and/or Medical Data.

You agree that the data collected about you that are anonymized will not be subject to the exercise of the right of access, modification or deletion, since they are not personal data, since it is not possible to identify you from them.

The Agency for Access to Public Information, the controlling body of Law No. 25,326, is responsible for dealing with complaints and claims filed in relation to non-compliance with the rules on personal data protection.

8. Does my participation in the study have any cost, and will I receive any compensation for my participation?

No, your participation is voluntary, there is no cost to you and you will not receive any compensation for doing so.

9. Who are the researchers in charge of this study?

Dr. Rosana Poggio as principal investigator of the study and Dr. Guillermo Ganum, as principal investigator of the Center. Both will be in charge of the development of the study..

10. Who has evaluated and approved this study?

The present research work has been evaluated and approved by the Clinical Research Ethics Committee (CEIC).If you have any questions about your rights as a participant in a study, please contact us at (5411) 4372-8316, Monday through Friday from 10:00 am to 4:00 pm or by e-mail at info@comitedeeticaceic.com.ar. In the case that an ethical monitoring is carried out at the Center, patients may be summoned with the agreement and authorization of the Principal Investigator (PI), in order to have a conversation about their participation in the study.

11. Who pays for this study?

The budget for the study will be provided exclusively by its Sponsor, MULTIPLAI TANGO SAS. Notwithstanding the foregoing, you are hereby informed that any reference herein to MULTIPLAI TANGO SAS shall also be understood as a reference to MULTIPLAI HEALTH LTD and any other affiliated, controlling or controlled legal entity of the aforementioned legal entities.

12. If I have any questions at a later date, or wish to withdraw from the study, how do I do?

If you have any questions about the study, please contact the investigators through the following communication channels: Dr. Rosana Poggio

e-mail: rosana.poggio@multiplaihealth.com

Dr. Guillermo Ganum

e-mail: guillermoganum@gmail.com

Teléfono: **+54 011 5108 8900.**

Having understood the scope of your participation in the study, and having agreed to comply with the procedures that were explained to you, we then asked for your **consent to participate** in the study.

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Participant's Name Date Participant's signature

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Investigator's Name Date Investigator´s signature

I have been informed about the process and purpose of storage of my biological samples.

□ I voluntarily **consent** to my biological samples being stored for further unspecified future studies.

□ I **do not consent** to my blood sample being stored.

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Nombre del Participante Fecha Firma del Participante

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Nombre del Investigador Fecha Firma del Investigador

If it is determined that the participant, in the investigator's opinion, presents some degree of vulnerability that justifies it, a witness to the consent process and to the understanding of the scope and procedures of the study, and of the willingness to participate in it, will be requested to sign the consent form:

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Witness's name Date Witness's signature