Informed Consent for Participation in Research Activities

Sponsor / Study Title:	**Imyoo Inc. / "Single-cell immune profiling from self-collected capillary blood"**
Principal Investigator:	**Tatyana Dobreva, PhD**
Telephone:	**626-773-2258 (24-Hour)**
Address:	**Illumina** **200 Lincoln Centre Dr** **Foster City, CA 94404**

Purpose of this Research Study:

The purpose of this study is research. This is not a clinical study and we do not provide medical advice or treatment. Data from this study will help us understand how human genetics can be looked at in blood collected from the capillaries (very small blood vessels). Capillary collection is usually done by pricking the finger (adults) or heel (infants and small children). The study will also look at sample stability and how that affects genetic tests. The samples will be part of a database to study the immune system and how it varies across age and other demographic and lifestyle factors.

A recently released blood collection device, the TAP, from Seventh Sense Biosystems, allows for the collection of small volumes (100 uL [microliters]) of blood with less pain and equal to or less risk than a finger prick device, and is designed for use by non-clinicians. The device is FDA approved for collection of blood samples for monitoring of HbA1c (an indicator of blood glucose control), but its use in this study is investigational.

While we will be happy to talk to you more about the scientific findings of our work, we will not be able to give you any clinical feedback.

The study will take approximately 10 minutes.

If you have any questions about any part of this informed consent, please ask the Principal Investigator or study staff. Questions are encouraged.

Background:

The human immune system can play a role in numerous diseases and is an important indicator of health that is used to guide treatment for diseases. While current blood tests look at things such as cell counts and protein abundance, researchers have learned how to investigate cell health from small tissue samples.

Single-cell RNA sequencing (scRNA-seq) is a new technique which allows researchers to observe the health of thousands of cells by looking at the messenger RNA molecules that are present within individual cells in a sample. This can provide important insights into an individual's immune systems.

This study will help us understand if collection and transport of samples using the TAP device will provide valid samples for our Single-cell RNA sequencing (scRNA-seq) research.

Who Can Participate:

We anticipate that this study will include up to 500 subjects in the age ranges of 18-65 Years. Only subjects who are between 18-65 will qualify for this study.

What Will Be Done:

For your first visit, we will ask you to fill out a 1-2 minute questionnaire about yourself. You may answer only the questions you feel comfortable answering. Then, we can show you a demo version of the TAP device and the information pamphlet before you decide whether or not you would like to participate in this research study. We can show you an example of the amount of blood that will be taken.

If you agree to participate, then for each blood draw, we will start you off with an additional 1-2 minute questionnaire about your recent activity. We will invite you in and you will sit in a chair. We will ask you to pull up your sleeve to expose the shoulder of your choice. We will wipe down an area of your upper arm with an alcohol swab, and will then place the TAP device on your skin. The TAP device has an adhesive and will stick to your skin like tape. Then, when you are ready, we will push the button on the TAP device, and it will extend 30 tiny needles just below the surface of your skin, and immediately retract them. Finally, the TAP device will suction blood from the needle poke for 1-7 minutes. Once the device is complete, we will remove it and place a small adhesive bandage on the site.

We may contact you in the future to ask additional questions about you, in order to gain additional insight from the data. You may respond to only the questions you feel comfortable answering. You may ask to be removed from future follow-up at any point.

Possible Risks and Discomforts:

The following side effects are expected from the usage of TAP II Device as per the manufacturer:

- Sensation of pressure or suction during use.
- Dizziness, lightheadedness, or fainting at time of collection.

- Minor dermal (skin) response such as erythema (redness), edema (swelling), or bruising around the sampling site that can last several days.
- Temporary sensitivity and/or pain at the sampling site following use.

If you experience adverse effects (side effects) not listed above please notify the Principal Investigator or study staff immediately, at the phone number listed on the first page of this form.

You may experience slight discomfort from the microneedle extension and suction, like poking yourself with your fingernail. A previous study has shown that most people experience no pain at all. You will see a small red ring where the microneedles pierced the skin which will dissipate in a few days to a week.

The device has an adhesive to keep it in place during the procedure; you should proceed with the study only if you do not have allergic reactions to adhesives. Additionally, there may be some discomfort when removing the adhesive, as it may attach to hair, similar to an adhesive bandage.

If you are immunocompromised, be aware that this procedure does result in a small open wound, much like a fingerstick would, and you should proceed with this study only if such open wounds are considered safe. If you are immunocompromised, we recommend that you consult with your regular physician before enrolling in this study.

Your genetic data will be accessible to a small number of researchers performing the initial data processing steps; however, your name and contact information will be disconnected from this genetic data. We use the genetic data to identify which genes are being expressed in each of your cells, and after this identification step, all analysis and published research only looks at the levels of gene expression in your cells as opposed to your unique genomic sequence. If you are uncomfortable with your genetic data being seen by a small number of researchers, we recommend you do not participate in this study. If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. This risk is minimized by protections described in the Confidentiality section below.

Unforeseen Risks
There may be other risks that are unknown.

Storage of Biological Material:
You will be asked to provide a sample of blood (specimen). The specimen will be blood extracted using the TAP device, and transferred to a container to be stored in the refrigerator or freezer. Each sample will be given a unique identifier, and all tubes related to that sample will be labeled with it. It will not contain any of your information. The results of the study of your specimen will be used for research purposes only.

You may withdraw your sample at any time.

Tissue Sampling for Genetic Research:
As part of the analysis on your specimen, the investigators will do genetic testing which can be used for genetic research. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include analyzing results of genetic tests, and looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. The results from your specimen will be used for research purposes only.

Sometimes subjects have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job.

Possible Benefits:
You personally will not benefit directly from participation in this research study in any way. This research may help extend our understanding of immune cell population genetic expression data derived from small volumes of blood and how best to obtain samples needed for this research.

Return of Research Data:
This information is for research purposes only and will not be returned to you.

Alternatives:
Your alternative is to choose not to participate in this study.

Compensation:
You will be compensated with a voucher for one free ImYoo Immune Expression kit when it becomes available.

Participation Cost:
You will not be expected to pay for participation in this study.

Withdrawal from Study:
Your participation is voluntary. If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation in this study at any time. Your decision will not affect your relationship, if any, with ImYoo Inc., and you will not be penalized or lose any benefits to which you would otherwise be entitled.

To withdraw from the study, you only need to let the Principal Investigator know. You can do this by calling them on the phone listed on the first page of this form. You will not be asked to explain your reasons.

We may also withdraw you from the study without your consent for scientific or technical reasons. We will not be able to give you detailed explanations of the reasons.

Confidentiality of Records:
Any information from this study in which you might be identified will be confidential. By signing and dating this form, however, you allow the study investigators to make your records available to regulatory or funding agencies as required by law. If information generated by this study is published, you will never be identified by name.

Data collected from this study will be kept in a secure server hosted by ImYoo Inc. We will take reasonable steps to ensure that no unauthorized person will have access to the data generated by this study. Paperwork about this research will be kept in a locked file and digital data will be password protected.

A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

Future Contact:

We may wish to contact you in the future, by email or phone, about participating in other research studies.

Please initial one option below to indicate whether or not you consent to us contacting you in the future:

Contact Allowed Regardless of Funding

_____ I consent to having researchers at ImYoo contact me about any other studies at ImYoo.

Do Not Contact Me

_____ I do not wish to be contacted about participating in future research studies.

Offer to Answer Questions and Research Injury Notification:

The Principal Investigator or their study staff have offered to answer any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact the Principal Investigator at the phone number on the first page of this form.

Explanation of Treatment and Compensation for Injury:

In the unlikely event of illness or physical injury resulting during participation in this research, the Principal Investigator and the study staff will assist you in obtaining appropriate medical treatment by summoning the paramedics by calling 911. Should the medical professionals determine a need, you will be transported to the nearest hospital emergency room. In most cases this would be the San Mateo Medical Center located in San Mateo, CA. This study does not provide financial assistance for medical or other related costs. Your insurance carrier will be billed for the cost of such treatment. You, however, do not waive any legal rights by signing and dating this form.

Voluntary Participation with Right of Refusal:
You have been informed that your participation in this research study is voluntary. You are free to withdraw your consent for participation in any part of this study without any penalty.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and your decision to participate in the study will not have any effect on your/your family member's performance appraisal or employment at this clinical research center. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

WHOM TO CONTACT ABOUT THIS STUDY:
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 the Principal Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00057361.

Conflict of Interest: Tatyana Dobreva, David Brown, and Jong Hwee Park own shares of ImYoo Inc. David Brown has stock in Illumina, Inc. and 10X Technologies, Inc., which are manufacturers of reagents used in this study. Please speak with your Principal Investigator if you have questions about this.

Signature and Date for Consent: The above-named Principal Investigator has answered your questions and you agree to be a research subject in this study. You have carefully read the information contained above and fully understand your rights as a potential subject in a research experiment involving people as subjects.

Print Subject's Name: _____ Date: _____

Subject's Signature: _____ Date: _____

Subject's E-mail: _____

Print Principal Investigator's Name: _____ Date: _____

Principal Investigator's Signature: _____ Date: _____

Experimental Subject's Bill of Rights:

You have been asked to participate as a subject in a research study. Before you decide whether you want to participate in the study, you have a right to:

a. Be informed of the nature and purpose of the experiment;
b. Be given an explanation of the procedures to be followed in the research experiment, and any drug or device to be utilized;
c. Be given a description of any attendant discomforts and risks reasonably to be expected from your participation in the experiment;
d. Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;
e. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you and their relative risks and benefits;
f. Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications should arise;
g. Be given an opportunity to ask any questions concerning the research experiment or the procedures involved;
h. Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the research experiment without prejudice; i. Be given a copy of this form and the signed and dated consent form; and
j. Be given the opportunity to decide to consent or not to consent to the research experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on your decision.

I understand my rights as described above:

_____
Signature of subject