#### Baseline Informed Consent

## Informed Consent for Participation in Research Activities

### **Project Title:**

At-Home Blood Study for Measuring Immune Variability at Baseline

## Principal Investigator (PI):

Tatyana Dobreva, PhD CEO/Co-Founder, ImYoo Inc. 534 Grand Ave. South San Francisco, CA 94080

**Sponsor of this Research**: ImYoo Inc.

### **Approval Period**:

03/01/2023 - 03/01/2025

### Purpose of this Research Study:

The goal of this study is to understand what different immune systems look like and to establish a metric for "normal". We can use this information to help us learn more about how the immune system works and how it changes over time. ImYoo researchers are analyzing data from capillary blood samples that study participants collect themselves. This data will be incorporated into ImYoo's database in order to learn more about how the immune system varies between different people and across different ages. ImYoo may also look at how stable the samples are and if that affects results related to immune state. The goal is to figure out what normal immune activity is like, so researchers can compare it to disease immune activity.

## Background:

Single-cell ribonucleic acid sequencing (scRNA-seq) is a new technique that can show scientists what kind of cells they are looking at and how they are working. With this technique, scientists can figure out what kind of cells are in your blood and what the cells are doing

This study will use scRNA-seq to look at the human immune system. The immune system plays a critical role in human health and is involved in almost all diseases. The ability to collect high-frequency and diverse samples is necessary to understand what

makes every person's immune system unique; it is critical to empower individuals to collect their own blood samples and maintain the integrity of the samples for useful data.

## Who Can Participate:

Healthy individuals with no medical diagnosis of any active disease, except for moderate obesity.

### What Will Be Done:

\_\_\_\_ I have reviewed the general process of self-collection as outlined in the Umbrella Informed Consent Form, or an alternative consent form I have signed for a prior ImYoo study.

In this study, you'll have the choice to collect your sample once, 6 times, or 12 times, all spaced out approximately 1 week apart. For that reason, this study may last you 1 week or it may last you up to 12 weeks. If you've already collected sample(s) in a previous ImYoo study, you may not need to contribute any more samples to participate in this study (i.e. if your previously collected samples were sufficient for ImYoo's analysis.) However, if the samples were not sufficient to generate reliable data, ImYoo may request additional samples from you to meet the minimum requirement that will generate sufficient data. ImYoo will only require additional samples from you when it is necessary to generate your data reliably and accurately. Once you've satisfied your minimum requirements for this study, you can always re-enroll and repeat this study, too.

Before you get your collection kits in the mail, an ImYoo staff member may talk to you about the best time to take your sample and what steps to take at that time.

If you choose to collect more than one sample, you may receive multiple kits at the start of the study, so you'll have them ready to use. You'll get to decide when exactly you collect your sample, but you'll need to decide at least one full day before you use the kit and notify ImYoo, so that they can coordinate the shipping. After you collect your sample, ImYoo will provide the postage for you to mail it back to the lab or coordinate pickup. You'll need to mail back each sample by 3PM local time the same day that you collect it. Each sample is mailed back separately, so you will repeat this mailing process for as many times as you sample yourself. While the sample collection itself only takes a few minutes, the survey questions will add time, especially on your first attempt. To

ensure you are not rushed, you should set aside 30 minutes of your time to collect your sample.

This sub-study begins enrollment March 1st, 2023 and is scheduled to end March 1st, 2025. This study's completion goal is at least 500 study participants. ImYoo must return your individual data and release its aggregate findings once this goal has been reached, allowing for 90 days after sample processing. Until that minimum number is met, ImYoo may not be able to return any data. If you do not complete this study in which you are enrolled, you may not receive your individual data. ImYoo does not wish to return data that is incomplete or inaccurate.

### Possible Risks and Discomforts:

\_\_\_ I have reviewed the section on the Possible Risks and Discomforts in the Umbrella Informed Consent, or an alternative consent form I have signed for a prior ImYoo study.

## Storage of Biological Material:

\_\_\_ I have reviewed the section on the Storage of Biological Material in the Umbrella Informed Consent, or an alternative consent form I have signed for a prior ImYoo study.

ImYoo might use your collected samples again for different research studies, which could mean using your samples for ImYoo studies other than this one. You can ask them to throw away your sample and/or stop contacting you about other research at any time by emailing studies@imyoo.health..

# Tissue Sampling for Genetic Research:

\_\_\_ I have reviewed the section on the Tissue Sampling for Genetic Research in the Umbrella Informed Consent, or an alternative consent form I have signed for a prior ImYoo study.

#### **Return of Research Data:**

\_\_\_ I have reviewed the section on the Return of Research Data in the Umbrella Informed Consent, or an alternative consent form I have signed for a prior ImYoo study.

Please initial **one option** below to indicate whether you want to get your results back as they are prepared for this specific study:

Option 1	I want my results back:	Option 2	I do not want my results back:
	I consent to having researchers at ImYoo send me my results from this specific study.		I do not wish for researchers at ImYoo to send me my results from this specific study.

If you change your mind about wanting to get your results back, you can also inform ImYoo by emailing them at studies@imyoo.health.

We may not be able to anticipate potentially concerning results that arise. Please initial **one option** below to indicate whether you want to get your results back, considering that they may unexpectedly raise concerns about your health:

Option 1	I want my results back:	Option 2	I do not want my results back:
	I consent to having researchers at ImYoo send me unexpected results that may be cause for concern.		I do not wish for researchers at ImYoo to send me unexpected results that may be cause for concern.

If you change your mind about wanting to get back unexpected and potentially concerning results, let us know as soon as possible at studies@imyoo.health.

# **Usage of Research Data:**

\_\_\_ I have reviewed the section on the Usage of Research Data in the Umbrella Informed Consent, or an alternative consent form I have signed for a prior ImYoo study.

#### **Possible Benefits:**

This research could be beneficial for a lot of people who struggle with getting blood drawn from their veins. It could help us learn more about how genes affect our immune system and give us information that we didn't have access to before.

By taking part in this scientific research, you could help us understand how the immune system relates to different diseases, aging, and even examples of exceptional health.

Regardless of the outcome, taking part in this specific study can still be a great experience. Collecting your own sample and playing an active role in the research could make you feel more engaged, rather than a passive participant.

<u>Alternatives</u>: Your alternative is to choose not to participate in this study. Choosing to not participate in this specific study does not necessarily disqualify you from participating in other ImYoo studies.

<u>Compensation</u>: You may be compensated for this specific study, if ImYoo introduces a relevant activity, contest, or raffle. However, compensation for this study is not guaranteed.

<u>Participation Cost:</u> You will not be expected to pay for participation in this specific study nor will you need to pay for postage to mail back your sample.

### Withdrawal from Sub-Study:

You don't have to take part in this study if you don't want to. You can stop participating at any time without any problems or losing benefits. It won't change your relationship with ImYoo Inc.

To withdraw from the study, contact ImYoo by phone or email. You may be asked to explain your reasons, but you will not be required to do so.

ImYoo may also take you out of the study without your permission for scientific or technical reasons. They may give you an explanation for why, as long as it doesn't give away any sensitive information about the company, the specific study, or other study participants.

## **Confidentiality of Records**:

\_\_\_ I have reviewed the section on the Confidentiality of Records in the Umbrella Informed Consent, or an alternative consent form I have signed for a prior ImYoo study.

#### **Future Contact:**

We may wish to contact you in the future, by email or phone, about participating in other specific studies (i.e. if collecting additional data or samples from you can contribute to another study).

Please initial **one option** below to indicate whether you consent to us contacting you in the future:

Option 1	Contact Allowed:	Option 2	Do Not Contact Me:
	I consent to having researchers at ImYoo contact me about participating in other specific studies with ImYoo.		I do not wish to be contacted about participating in other specific studies with ImYoo.

## Offer to Answer Questions and Research Injury Notification:

The principal investigators or their research associates 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 ImYoo staff at 650-869-9335 or studies@imyoo.health.

## **Explanation of Treatment and Compensation for Injury**:

If you get sick or hurt while participating in this research, ImYoo will tell you to call your doctor or 911, if it could be an emergency. This study won't pay for your treatment, but, if you have insurance, it may cover the costs. You still have all your legal rights after signing 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.

# IRB Review and Impartial Third Party:

This study has been reviewed and approved by Salus IRB. A representative of Salus is available to discuss the review process or your rights as a research subject. You can contact Salus at 1-800-472-3241 or by email <a href="mailto:subject@salusirb.com">subject@salusirb.com</a>. Please reference study 23015.

<u>Conflict of Interest:</u> Tatyana Dobreva, David Brown, Jong Hwee (Jeff) Park, and Emily Harari own shares of ImYoo Inc.

ImYoo Inc. is the sponsor of this study. The principal investigator, Tatyana Dobreva, is the CEO and co-founder of ImYoo Inc. Moreover, David Brown, Jong Hwee (Jeff) Park, and Emily Harari are all employees of ImYoo Inc.

Emily Harari is a board member of the Patient Centric Sampling Interest Group, which

is a non-profit organization that promotes patient-centric sampling.

## **Signature for Consent**:

A member of ImYoo staff has answered any questions you've asked them and you agree to be a research subject in this study. You have carefully read the information contained in this consent form and below in the "Experimental Research Subject's Bill of Rights". You will be given a copy of this consent form.

In signing below, you agree to all the statements presente	ed above.
Print Subject's Name:	
Subject's Signature:	Date:
Subject's E-mail:	
Print Investigator's Name: <u>Tatyana Dobreva</u>	
Investigator's Signature:	Date <sup>.</sup>

## **Experimental Research 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 have read my rights described above:	
Signature of participant	 Date