Umbrella Consent Form

Consent Form for Participation in Research Activities

This consent form may have words that you do not understand. Ask the investigator or study staff to explain anything you do not understand. Reading this form and talking with the investigator or study staff can help you decide if you want to participate in the study.

Project Title:
At-Home Capillary Blood Study for Measuring Immune Activity

Principal Investigator (PI):
Tatyana Dobreva, PhD
CEO/Co-Founder, ImYoo Inc.
534 Grand Ave.
South San Francisco, CA 94080
Phone: 650-869-9335

Sponsor of this Research:
ImYoo Inc.

Background:
Currently, there are no standard biomarkers (substances that indicate the presence of some disease or infection) for measuring some autoimmune conditions. Biomarkers can be measured with molecular techniques but require very thorough studies to be cleared for clinical use. These types of studies are expensive and time consuming, as they typically require study participants to commute to a sample collection site multiple times. Allowing study participants to self-collect their biological samples from home allows for greater diversity in clinical research.

This study will have participants self-collect their blood samples. Participants will use an investigational device called the TAP II. This study is not evaluating the TAP II device, it is only being used to collect the blood samples. This device is investigational (not approved by the Food and Drug Administration for market) and can only be used for research. The researchers decided to use this device because it is easy to use at home instead of going to a sample collection site.

Purpose of this Research Study:
The goal of this study is for people to take their own blood samples at home and send them to ImYoo, where researchers will measure the immune state of the cells. Gene

expression is a way scientists can learn more about how cells work. By building a database and a biobank with the blood samples collected, ImYoo hopes to figure out the relationship between autoimmune diseases and mechanisms of inflammation. By better understanding how inflammation drives different diseases, there is potential to discover new therapeutic targets.

Who Can Participate:

Participants must be 18 years old or older, have access to the internet, and– if they mail their sample– a working freezer. There will be sub-studies under this main study that may have other specific criteria. You will be told about those sub-studies and the required criteria as they become available.

What Will Be Done:

If you agree to be in this study, you will need to:

- Sign this umbrella consent form and
- complete a screening questionnaire. The questions will be about your contact information, your demographics and about your health including your diagnosis and your medical treatments. This may take about 5 - 25 minutes to complete.

Once this information is collected you may be contacted to participate in a sub-study.

If you are contacted to take part in a sub-study, you will:

- Sign the consent form for the given sub-study. The details of the sub-study (condition being studied, number of samples needed to be collected and duration) will be provided then. You can refuse to take part in the sub-study but can keep your consent for the umbrella study active.
- Collect and return your blood sample(s) using the self-collection kits.*
- Surveys may also be requested specific to the sub-study. The average survey takes 20 minutes to complete.

*You may disregard the following language on self-collection kits if ImYoo has already collected the minimum amount of sample required for you to participate in your corresponding study. However, if you'd like to contribute more samples in the future, you may find it useful to review the following information.

Self-collection kits (TAP II device):

- If you collect from home, ImYoo staff will mail you self-collection kits. Otherwise, you may be provided self-collection kits in-person.
- After receiving your self-collection kits, you have the choice to sample wherever you like. Self-collection kits allow you to collect your blood sample from home in

a manner that is relatively fast and comfortable compared to the standard blood draw. It uses microneedles and suction to withdraw capillary blood from your arm. The needles go a tiny bit under the skin of your arm (1mm deep).

- Video tutorials will be provided to you to explain how the device works if you are interested in learning more about the TAP II device.
- You will be able to choose the times to self-collect your sample. You may administer the TAP II device yourself or request help from someone else.
- You may have an onboarding call with ImYoo staff. Instructions for self-collection can be reviewed in your onboarding call and can also be provided in your kits.
- If you are mailed a collection kit, you may be sent cold packs that you will need to freeze at least 24 hours before you collect the sample. These cold packs must be put in the shipping packaging to ensure stability of the samples and minimize loss of the biological signals.

- You will receive instructions on what will be needed to return the collection kit. This should take about 30 to 60 minutes to complete. The following steps will need to be taken:
    - performing the blood collection using the TAP II device (takes 5 minutes),
    - submit a picture of your collected sample (takes 5 minutes),
    - answer surveys about your symptoms and an optional Feedback Survey (can take up to 45 minutes), and
    - if required, package your sample with the provided materials (takes 5 minutes).
- If you're collecting your sample from home, you may drop off your sample at a nearby mail carrier or notify ImYoo to request pickup from your residence. Shipping will be pre-paid.

Additionally, you may be asked for the following:

- information on certain lab results done by your medical provider,
- conduct other tests, for example, fecal (stool) home collection. You have the right to decline both these types of requests and still take part in the sub-study,
- collect another sample, due to a logistical error (e.g., lost in the mail). Your decision to not provide another sample may impact your eligibility for the current or future sub-studies. ImYoo will contact you if you have been withdrawn from a sub-study.

Possible Risks and Discomforts:

Physical discomfort:

The TAP II collection device may only be mildly uncomfortable. Most individuals report not even feeling the device, other than its removal, which is a gentle adhesive. Think of removing a band aid, but less sticky.

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 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.

You will be provided an optional Follow Up Survey (about 5 - 15 minutes to complete). You are encouraged to share your feedback and experiences, including any of the adverse effects listed above, which are normal, expected, and temporary, if they occur at all.If you experience adverse effects not listed above, please seek the appropriate medical care, and notify:

Email: studies@imyoo.health
Phone: 650-869-9335

Explanation of Treatment and Compensation for Injury:
In the unlikely event of illness or physical injury resulting from participation in this study, you should call 911 to get the medical attention needed. This study does not provide financial assistance for medical or other related costs. You can bill your insurance carrier for the cost of such treatment. You, however, do not waive any of your legal rights by signing this form.

Psychological discomfort:
Some people are afraid to look at their blood, but this amount of blood is very small (less than a teaspoon).

Loss of Confidentiality:
There is also a risk that the information you provide might be compromised due to a breach in security. The study information will be kept password protected and only authorized persons can access it. While we have taken these steps to ensure that all

information is kept confidential, there is no guarantee that a breach will not occur. You can find more information about how information is maintained in the “Confidentiality of Records” section below.

Confidentiality of Records:

Any information from this study in which you might be identified will be kept as private as possible. By signing this form, however, you allow the study investigators to make your records available to funding or regulatory agencies like the Food and Drug Administration (FDA) and the Institutional Review Board (IRB). If information generated by this study is published, you will never be identified by name.

Data collected from this study will be kept on a secure server hosted by ImYoo Inc. ImYoo 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. The samples and information from the study will be kept indefinitely.

Storage and Transfer of the Blood Sample and Analysis:

Your sample(s) will be stored at ImYoo labs, in the refrigerator or freezer. For long-term storage, cryopreservant will be used and your sample will be frozen at -80C or with liquid nitrogen.

Each sample will be given a unique code consisting of letters and numbers, and all tubes related to that sample will be labeled with it instead of your name. Only ImYoo authorized staff will have access to the names and corresponding codes. It will not contain any of your identifiable information. The results of the study of your specimen will be used by ImYoo scientists for their own study analyses and technology optimization. Additionally, under a material transfer agreement, partners may access de-identified data and/or biological materials for joint or transactional studies. ImYoo’s partners will not be able to identify you from your sample. You can have your sample removed and destroyed at any time by contacting ImYoo staff at 650-869-9335 or studies@imyoo.health.

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 and are not intended to guide clinical decisions.

It is possible to perform genome sequencing from your biological material collected in our study. We will store this residual biological material and only perform genome sequencing in the event that either ImYoo or one of its partners requires it. While ImYoo's current focus is single-cell RNA sequencing, genome sequencing is still a possibility for future analyses.

Sometimes study subjects have been required to give information from genetic testing for health insurance, life insurance, and/or a job. A federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

It is possible for stem cells to be created from your biological sample. However, ImYoo will not create stem cells from your sample before first contacting you and requesting your consent, as stem cells are currently outside the scope of this study, "At-Home Capillary Blood Study for Measuring Immune Activity." Upon requesting your consent, ImYoo will fully inform you of the associated risks to consider with stem cell research and you will have the option to either accept or decline.

Return of Research Data:

Upon analysis and processing of your sample, you may be contacted with information on accessing the data generated from your sample, and from the study as a whole. This is provided to you as a research participant so that you can get a look at how your sample is being used and what research ImYoo is doing. You do not have to see the results if you do not want to.

By choosing to receive your results, you acknowledge that you are receiving research results which are not meant to diagnose or provide a suggested course of treatment. Biological research may yield results that are confusing and disappointing, and all medical decisions and advice should only come from a healthcare professional. Prior to viewing your results you will be provided with a detailed disclaimer.

With the thrill of scientific discovery comes uncertainty about which results may arise in the data. You cannot unlearn what data you've seen, nor the thoughts or ideas you may have after the fact.

Study Findings:

You may receive email updates from ImYoo staff about the progress of the sub-study in which you are enrolled. Once the study is complete, ImYoo may share the combined anonymous findings of the study to the public.

Each sub-study will set a goal for the minimum number of participants to reach completion. Until that minimum number is met, ImYoo may not be able to return any data. If you do not complete the sub-study in which you are enrolled, you may not receive your individual data. ImYoo does not wish to return data that is incomplete.

You may access the status of your samples by contacting ImYoo. The status may include the location of the sample, whether it has been processed, and/or analyzed.

Once a sufficient number of your sub-study samples have reached the status, “analyzed,” ImYoo will contact you and provide you with information about receiving your individualized results. ImYoo will return your individualized results by email no later than 90 days of sub-study completion (i.e., receipt of the last sample from the last participant that meets the minimum requirements for completion). ImYoo may return additional results as new findings arise. You may notify ImYoo if you wish to not receive your individual results by emailing studies@imyoo.health.

If you have questions regarding your results, you may contact studies@imyoo.health. ImYoo staff are not trained medical professionals and will direct you to your physician to learn about the clinical significance of any findings.

Usage of Research Data:

Secondary research:

We may also share your de-identified information and biological samples with research collaborators outside of the research done at ImYoo. To learn about conditions that result from abnormal activity of immune cells, ImYoo combines the data from its sub-studies into a company database. ImYoo may sell access to its database or market specific findings to help others develop therapies and diagnostics. Your de-identified data may ultimately be sold or used for these secondary research purposes.

While we will not share information that identifies you directly (your name, date of birth, or address), biological samples can be used to find out information specific to you and in some cases, be used in public databases that may identify you.

If you consent, we will notify you via email or participant portal after we have shared your samples or data with external organizations (e.g. after selling access to your data). Our objective is to keep you informed about how your data is being used, so we’ll share a project description and/or the name of the organization receiving your sample or data in the transaction. As a research company we are responsible to both you (the study participant) and our scientific collaborators. Therefore, we may be telling you who is accessing your data or what it's being used for after-the-fact (i.e. after the collaboration is already in progress). This means that we are telling you this information to keep you informed, not to ask for your permission. (Recall that earlier in this section, we explained that we may share your de-identified information with research collaborators.)

After we inform you about how or with whom your data is being used, it's possible you will disagree with our decision. In that specific instance, we may not be able to remove your data, as the collaboration is likely in progress. However, you always reserve the right to revoke your consent for *future* sample collections or analyses. While revoking your consent ensures that your information is removed from future sample and data sharing, we cannot necessarily erase your data from previous analyses.

Please initial **one option** below to indicate whether you want to be informed after we have shared your samples or data with external organizations:

Option 1	I want to be informed:	Option 2	I do not want to be informed:
______	I consent to ImYoo notifying me after they've shared my samples or data with external organizations.	______	I do not consent to ImYoo notifying me after they've shared my samples or data with external organizations

If you change your mind about wanting to be informed after we have shared your samples or data with external organizations, let us know as soon as possible at studies@imyoo.health. At any point in time, you can ask ImYoo to retroactively retrieve this information for you, and we will inform you as soon as we can.

<u>Possible Benefits</u>:

You should not expect to benefit from participating in this study. The data generated from this study is clinical research and is not intended to guide medical decisions. Always discuss any concerns and subsequent actions with your medical provider.

For the chronic inflammation and autoimmune communities, this research may help extend our understanding of immune cell population genetic expression data. This could give us new insights into immune system states at different time points and solutions that were not able to be achieved before.

Compensation and Cost:
You may be compensated for participating in this study, however, compensation for this study is not guaranteed.

You will not pay for your participation in this study or for any materials used in this study.

The knowledge gained from this study may produce commercial and/or financial benefits, you may not be compensated or attributed directly.

Voluntary Participation and Withdrawal from Study:
Your participation is voluntary. Your alternative is to choose not to participate in this study. To get your genetic or biomarker information, that is not experimental, please reach out to your medical provider for resources.

You can choose not to take part or withdraw your consent and discontinue your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

To withdraw from the study, contact ImYoo staff at 650-869-9335 or studies@imyoo.health. You may be asked to explain your reasons, but you will not be required to do so.

ImYoo may also withdraw you from the study without your consent. Reasons for stopping your participation may include that the study ended, that it is in your best interest to stop, or that-- for scientific or technical reasons-- it is in the best interest of the study for you to stop.

You have been informed that your participation in this research study is voluntary. You are free to refuse or withdraw your consent for participation in any part of this study. There will be no penalties or loss of benefits to you for refusing or withdrawing from the study.

Offer to Answer Questions and Research Injury Notification:
The Principal Investigator or their research associates will answer all questions regarding your participation in this research study. If you have any further questions, concerns, complaints, want to offer input or in the event of a research-related injury, you can contact ImYoo staff at 650-869-9335 or studies@imyoo.health.

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 subject@salusirb.com. Please reference study 23015.

Conflict of Interest:

ImYoo Inc. is the sponsor of this study. The Principal Investigator, Tatyana Dobreva, is the CEO and co-founder of ImYoo Inc. The study investigators, Tatyana Dobreva, David Brown, Jong Hwee (Jeff) Park, and Emily Harari are all employees of ImYoo Inc. They all are paid employees and own shares of ImYoo Inc.

Emily Harari is a board member of the Patient Centric Sampling Interest Group. If you have any questions about this, please contact ImYoo staff at 650-869-9335 or studies@imyoo.health.

Signature for Consent:

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

Initial the below statements:

___ I acknowledge that the individual data ImYoo may return to me is only intended for research.

___ I acknowledge that the individual data ImYoo may return to me is not intended to guide clinical decisions in any manner.

___ I will consult my medical provider prior to acting on any of the results that ImYoo may return to me.

___ I will not take medical action, or otherwise encourage other individuals to take similar action, on my ImYoo report data without consulting with my medical provider first. If I do so, ImYoo is not responsible for any related outcomes, and I may be ineligible for future ImYoo studies.

___ I agree to communicate the previous point to anyone with whom I may share my individual results, especially biological relatives.

____I consent to the use of my individual deidentified data and sample for external research and future products, publications using non-aggregated data, and ImYoo data.

Print Participant's Name: ___________________________

Participant's Signature: ____________________________ Date: ___________

Participant’s E-mail: _______________________________

Future Contact:

ImYoo or their research associates may want to contact you in the future, by email or phone, about participating in other research studies.

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

___ I agree to future contact.

___ I DO NOT agree to future contact.

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

____
Print Name of participant