

APPROVED BY SALUS IRB: 12 OCTOBER 2023

IBD Flares Informed Consent

Informed Consent for Participation in Research Activities

Project Title:

At-Home Blood Study for Measuring Immune Activity in
Inflammatory Bowel Disease (IBD) Flares

Principal Investigator (PI):

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Sponsor of this Research: ImYoo Inc.

Approval Period:

03/01/2023 - 03/01/2025

Purpose of this Research Study:

The goal of this specific study is to collect information about what happens to people with inflammatory bowel disease (IBD) when their symptoms get significantly worse (flares). ImYoo wants to look at how your body's immune system changes during a flare compared to when you're having low or no inflammation. This could help us find out which biological signals are linked to flares, which could lead to better ways of predicting or treating flares with the right type of medicine.

Background:

Inflammatory Bowel Disease (IBD) is an umbrella term for two conditions: Crohn's Disease (CD) and Ulcerative Colitis (UC). People with IBD can have periods of time when their symptoms get worse, called flares. Flares can cause pain in the stomach, blood in the stool, joint swelling, fever, and skin rashes. They can last up to 8 weeks and it is hard to know how bad or long a flare will be. People with IBD can have [up to 20 bathroom trips](#) a day during a flare, making it hard to leave the house. In some cases, flares can be so bad that hospitalization or surgery is needed.

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Recently, scientists have been studying single-cell ribonucleic acid sequencing (scRNA-seq) [to make a diagnosis in IBD](#) and [to predict flares in rheumatoid arthritis](#). ImYoo will use this same kind of research to try to figure out what causes flares and how to predict them in IBD. This could help people with IBD and Systemic Chronic Inflammation (SCI) have more control over their lives.

Who Can Participate:

Individuals with a formal diagnosis of inflammatory bowel disease (IBD), which may include Crohn's disease (CD), Ulcerative colitis (UC), and/or indeterminate colitis (IC) are eligible for this sub-study. The formal diagnosis must be delivered by a gastroenterologist.

What Will Be Done:

_____ I have reviewed the general process of self-collection as outlined in the Umbrella Informed Consent Form.

In this study, you'll need to keep track of your symptoms and collect 6 samples over the course of about 3 months. Three of the samples should be collected when you have no symptoms (baseline), and 3 should be collected when you have flare symptoms. Depending on when you flare, this 3 month period may last longer or shorter. Before you get your collection kits in the mail, an ImYoo staff member may talk to you about your flare symptoms and what steps to take at that time.

You'll 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 process 6 times. 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 1 hour of your time to collect your sample.

If you've already collected sample(s) in a previous ImYoo study, you may not need to

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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.

This sub-study begins enrollment March 1st, 2023 and is scheduled to end March 1st, 2025. This study's completion goal is at least 50 study participants. ImYoo must return your individual data and release study insights 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:

Physical discomfort: Flares can range from mild to serious. It's important to talk to your doctor about the signs of a serious flare, which can be life-threatening. If you notice these signs, don't wait to get medical help. The ImYoo surveys are not meant to diagnose a flare. If you think you may have a flare and haven't talked to your doctor yet, it's important to do that first before you take the ImYoo survey.

Psychological discomfort: Flares can affect your mental health. They can cause physical pain, make you feel lonely, and impact your finances. Taking care of your mental health is important while you're in the study and after it's over. Your physical and mental health are connected, so it's important to take care of both.

Storage of Biological Material:

____ I have reviewed the section on the Storage of Biological Material in the Umbrella Informed Consent.

ImYoo may have the opportunity to use your collected samples again for different research studies, which could mean using your samples for ImYoo studies other than

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this one. You can also ask ImYoo 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.

Return of Research Data:

___ I have reviewed the section on the Return of Research Data in the Umbrella Informed Consent.

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.

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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.

Possible Benefits:

By taking part in this scientific research, you can help the autoimmune community as a whole. If we can find out what causes flares, it could lead to new medicines and more personalized treatments with existing drugs.

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 in control during a flare and give you a sense of being able to do something about it.

Alternatives: 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.

Compensation: This specific study is offering monetary compensation in the form of either an Amazon or Charityvest virtual gift card.

The compensation will be \$125 for 3 samples collected or \$250 for 6 samples collected. (Unfortunately, we cannot count your backup sample collections toward this.)

This compensation will be emailed to you as a virtual gift card. After we've successfully processed your first 3 samples, we will email you a gift card within approximately 7 business days. If you collect 3 more samples, we will email you another gift card after we have processed them.

Samples that ImYoo fails to process (e.g. due to loss of sample viability in transit), may not count toward this sample count. In other words, as stated in "What Will Be Done," ImYoo may require additional sample collections to replace non-viable samples.

There may be delays in sending you your compensation, but we will aim to deliver your compensation within 7 business days of processing your third or sixth sample. If we've already processed 3 or 6 samples from you for this study, we will retro-actively compensate you as soon as we can.

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Participation Cost: 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.

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.

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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 subject@salusirb.com. Please reference study 23015.

Conflict of Interest: Tatyana Dobрева, 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 Dobрева, 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

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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 presented above.

Print Subject's Name: _____

Subject's Signature: _____ Date: _____

Subject's E-mail: _____

Signature for Person Conducting the Consent Process:

Print Investigator's Name: _____

Investigator's Signature: _____ Date: _____

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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