

RESEARCH CONSENT FORM

Protocol Title: Feverprints: Body Temperature in Health and Disease

Principal Investigator: Fatma Dedeoglu, M.D.

Welcome

Fever is common to many illnesses, and a frequent reason why children and adults visit their doctors. It can cause significant anxiety for patients, their families, and medical care providers. Unfortunately, we still know very little about what “normal” and “febrile” temperatures are for people of different ages, sexes, weights, and ethnicities.

While most fevers represent an immune response that enhances your body’s ability to fight infections, they sometimes indicate other diseases, including autoimmune conditions. Some patients get recurrent fevers without a known cause. Trying to predict the underlying cause of fevers has been challenging doctors for hundreds of years.

During a fever, many people take medications to lower their temperature in attempts to feel better. Whether these medications are effective, or have any harmful effects is still not known.

With your help, and the power of mobile devices, we aim to create the largest study ever conducted of body temperatures in health and disease. We aim to answer the following questions:

- What are “normal” temperatures for people of different sexes, ages, weights, and ethnicities?
- What temperatures should classify as fever?
- Can we predict the cause of a fever by studying its specific pattern?
- What is the effect of medications to lower fevers on symptoms and duration of illness?

This research study will use the Feverprints app to answer these questions. We will ask you to regularly measure your temperature, and answer question about your health, your medications, and family history. This information will be reported anonymously, which means that the researchers doing the study won’t know who you are. You may stop participating in this study at any time.

If you have any questions, concerns, or suggestions about the research, please contact Dr. Jonathan Hausmann at feverprints@childrens.harvard.edu. For questions about your rights as a research participant, please contact Boston Children’s Hospital at cci@childrens.harvard.edu or call 617-355-6000 and ask to be connected to the IRB office.

Activities

Once you have given your consent to participate in this study, you can start using Feverprints app to:

- Log your temperatures and any associated symptoms.
- Answer survey questions about your medical history, medication, family history, and lifestyle.



The Feverprints app will set occasional reminders to use the app to complete study tasks. These will remind you every week to log your temperature data, and about every three months to take a quick survey about your health. You can choose not to have the app provide reminders.

Sensor and Health Data

If you have a smart thermometer linked to your iPhone, and you give the Feverprints app permission, this temperature information will be automatically uploaded to the Feverprints app. You can also choose to allow your height and weight be automatically uploaded to Feverprints from your Health app. This is “passive” tracking because it happens automatically and you do not need to manually enter temperature information. If you do not have a smart thermometer, you can enter your temperature manually.

Privacy

We will ask you about your health, your medications and drug use, your temperatures, and your family medical history. This information will be reported anonymously, which means that the researchers doing the study won't know who you are.

Utilizing data

The results of this research may be published, including in research journals, and presented at research conferences so that others can learn about the results of this study. The results of the study will not be recorded in a way that identifies individual users.

If required by law, your anonymous study information may be disclosed to United States Department of Health and Human Services agencies, the Office for Human Research Protection, and other agencies as required by law. Also, the Institutional Review Board at Boston Children's Hospital, which monitors the safety and conduct of human research, can look at the anonymous study information you provide.

Time Commitment

We will ask that you complete the main health survey when you join the study. This will take 5-10 minutes.

Every week, we will remind you to log your temperatures and symptoms. You can do this more frequently if you wish. This should only take a couple of minutes to complete.

Every three months, we may send you additional surveys asking about your lifestyle, and allowing you to update your medical information, if needed.

Overall, we ask that you commit to participate in the study for at least 6 months. However, you are free to leave the study at any time.

Study Surveys

The Feverprints app will collect information on your health through short surveys that will include questions about your medical history, diagnoses, medication usage, lifestyle, drug use, ancestry, family history. We will also ask you to log your temperatures and record any associated symptoms. From your responses, we will calculate the Auto-Inflammatory Disease Activity Index (AIDAI), a measure that your doctor can use to track the severity of your symptoms.

Potential Benefits

Your temperature log may give you insights into your health, which you may share with your doctor. However, this information may not help you right now. When we finish this research study, we hope that we will know more about how different illnesses modify temperatures in various ways. This information may help doctors make faster and more accurate diagnoses in the future.

Withdrawing

If you start the research study but later do not wish to participate, you can use the “Leave Study” link in the Profile section of the app. You may choose to leave the study at any time, but this action cannot be undone.

The study investigators may also withdraw you from the study without your consent at any time for any reason, including if the study is cancelled.

Issues to Consider

You may feel inconvenienced by having to enter information into the app, or seeing the reminders or messages that are sent by the app. The app may make you more aware of your body temperatures and associated symptoms.

Any information you provide is completely up to you. You can decline to answer survey questions or participate in the app's tasks. If a survey question makes you feel uncomfortable, you are free to leave questions blank.

As with any smartphone app, use your common sense and follow laws about when and where you use your iPhone. Just as you would not text while driving, do not use the app while driving or doing any other activities that could result in injury. You should always wait until you are in a safe place to use the app. Participating in this study will use some of your phone's data plan, if you enable data transfers through cellular.

Study participation may involve other risks that are not known at this time.

Risk to Privacy

There are some risks that could happen by taking part in this study. One risk is a loss of privacy, which means that someone else would be able to see the information you report using the app because you have the app on your iPhone.

For security, Feverprints requires that your iPhone be protected either by a passcode or the Apple Touch ID fingerprint sensor. This helps to prevent others from entering and using the app.

Whenever app data is transferred from your iPhone to the Feverprints researchers, it will be encrypted so that it would be very difficult for anyone else to see your data.

Consent

By agreeing you confirm that you read the consent and that you wish to take part in this research study.

Participant's name

Participant's signature

Date