TITLE OF THE STUDY
Body Temperature in Patients with Primary Immunodeficiency

SPONSOR OF THE STUDY
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INTRODUCTION
You are invited to join an Immune Deficiency Foundation (IDF) research study to look at body temperature in patients with primary immunodeficiency disease (PI). This study is 100% independently funded directly by the Immune Deficiency Foundation.

Please read this information carefully and take your time making your decision. You should only take part in the study if you want to volunteer. You are free to choose to not participate in this research or withdraw at any time without any penalty or loss of benefits you are your family receive from IDF.

In this research study, we are investigating to see if adults with a primary immunodeficiency disease have a different body temperature than those adults who do not have a PI.

We aim to do this by randomly selecting households that have an adult patient with PI and another adult in the household who does not have a PI. The adult without PI must also be willing to participate in the study. We need the person without PI to participate so we can compare the body temperatures of those who have a PI, with those who do not. These non-PI adults will have their own consent forms, similar to this one.
BACKGROUND

Infection is normally the issue most people face when they have a PI. Fever is often the first sign of infection. Because of this, doctor's offices, hospitals or emergency care centers will take a person’s body temperature, with a body temperature over 101°F indicating the possibility of infection.

However, many people with PI in online discussion groups such as in IDF Friends and in the IDF PI CONNECT Research Forum, report having a lower than normal average body temperature so that when they do have signs of an infection, frequently their temperature does not rise to that 101°F. This means patients with PI may not receive proper treatment for their infection.

Currently, there are no known studies that look at the average body temperature of patients with PI. IDF would like to conduct a study to find evidence of a lower than average body temperature in patients with PI compared to the general population. Understanding this could help lead to improvements in the diagnosis and treatment for persons with PI seeking treatment for possible infection.

WHAT IS INVOLVED IN THIS STUDY?

If you decide to participate and are selected, you will be asked to take your temperature with an oral digital thermometer, supplied by the Immune Deficiency Foundation (IDF), three times per day. Once in the morning when you first wake up, once in the early evening, and once again just prior to going to bed. You will be instructed to not smoke, eat hot or cold food, drink hot or cold beverages, or chew gum in the 30 minutes before you take your temperature. Participants should also wait an hour after exercising or a hot bath to take their temperature.

After each temperature reading you will be directed to properly disinfect the thermometer (instructions will be included) and have the non-PI adult in the study take their temperature. After which the thermometer should be properly cleaned and stored for the next use.

This study will run for 5 consecutive days during the work week. You would record your temperature and the time of day you took your temperature in a paper booklet provided to you by IDF. You will also be asked to write down any current medications you take and tell us if you thought you were currently ill or had a cold. We think this should take you no more than 10 minutes per day.

During the course of the study, IDF will send you daily reminders to participate through an e-mail address you provide us.

At the end of the one-week study period, IDF will ask you to mail the paper booklet with the recorded information back to IDF. IDF will provide you a self-addressed, postage paid envelope so will not have to pay anything.
POSSIBLE RISKS TO TAKING PART IN THE STUDY

Although we believe the risks associated with this study and the use of a digital, oral thermometer are minimal and carry very little risk of complications, as with any study, there is always the possibility of risk. For this study the risks may include:

- Taking your temperature may be mildly uncomfortable, since you must keep your mouth closed and breathe through your nose while the thermometer is in place.
- Risk of injury to participant’s mouth if the thermometer is not inserted properly, carefully and in a gentle manner.
- If one of the household participants has an active infection or cold- if the thermometer is not properly disinfected, there is a possibility of the transmission of illness from one participant to the other or to other members of the household who may use the thermometer.

BENEFITS TO TAKING PART IN THE STUDY

The primary benefit of participating in this study is that your participation will contribute to our knowledge about primary immunodeficiency diseases, which is something you can feel good about. Although we cannot promise you direct benefits because of this new knowledge, others may benefit from this information in the future.

INCENTIVES

If you complete the study logbook and mail it back to IDF, we will send you, through an e-mail, a $20 Amazon e-gift card as a thank you for your participation. Additionally, you also get to keep the digital, oral, thermometer.

CONFIDENTIALITY

IDF believes it is essential for us to maintain your confidentiality in this study.

All participants selected to participate in the study will be assigned a random, unique study ID number. Data from the logbooks you fill out will use this ID number and not your name or any personally identifying information of yours. There will be a separate document onsite at IDF that links this ID number to other identifying information. This document will reside on a restricted password protected network. Access to this data will be limited to the primary investigators and study staff. The purposes of this linkage is only for administering the study. Upon completion of the study, this linked document will be deleted permanently. Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or the persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name.

All of your data will be de-identified, none of your personal identifying information will be used. Your data will be combined with all the other study participants so that data you provide for the study cannot be linked back to you.
YOU RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled from IDF and it will not harm your relationship with IDF.

CONTACTS FOR QUESTIONS OR PROBLEMS

If you have any questions about your involvement in this study, please contact Christopher Scalchunes of the Immune Deficiency Foundation at 800-296-4433.

Should you have any questions about your rights as a research participant or if you have any concerns regarding this research study for which you would rather speak to someone other than our staff, you can contact Shulman Associates Institutional Review Board Inc. toll free at 1-888-557-2472 during business hours Monday – Friday 8:00 a.m. to 6:00 P.M. EST.

PARTICIPANT CONSENT

I have carefully read and understand the provided information. I understand that if I have any questions I may contact Christopher Scalchunes at the Immune Deficiency Foundation and may do so prior to signing this consent form.

I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form.

O I voluntarily agree to and consent to participate in this study.
O I DO NOT agree to participate in this study

Participant’s name: _________________________________________
Date (mm/dd/yyyy): _______________________________

You may download a copy of this consent form at www.primaryimmune.org/feverstudyconsent02