Boston Children's Hospital

RESEARCH CONSENT FORM

DO NOT PLACE IN MEDICAL RECORD

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title: Clinical and Biological Phenotyping of PFAPA Syndrome: Wearable thermometer Study

Principal Investigator: Fatma Dedeoglu, MD

Why is this research study being conducted; What is its purpose?

PFAPA (periodic fevers, aphthous stomatitis, pharyngitis, and adenitis) is one of the periodic fever syndromes that presents with features as described in the disease name including periodic fevers, mouth ulcers, sore throat, and swollen glands in the neck. PFAPA is one of many periodic fever syndromes (also called autoinflammatory diseases) that affects children. Since there is no confirmatory test to diagnose PFAPA, the diagnosis is given based on the clinical (and sometimes laboratory) presentation. Recurrent fevers may be caused by a number of other conditions, so making the diagnosis of PFAPA is challenging. A particular feature common to PFAPA is the recurrence of fevers at near-clockwork intervals, completely symptom-free episodes in between disease flares, and otherwise normal growth and development of affected children. These characteristics aid in making the diagnosis. One or two doses of oral corticosteroids given at the onset of symptoms abort the episodes in the majority of patients. In recent years, adenotonsillectomy (surgical removal of adenoids and tonsils) was also shown to be very effective in preventing further fever flares. There is no known genetic basis in patients with PFAPA.

Despite the fact that PFAPA is becoming increasingly recognized by doctors throughout the world, we still know little about this condition, and it remains quite challenging to diagnose. The purpose of this research is to study collect clinical information and temperature data from children with a diagnosis of PFAPA. We hope that this will allow doctors to more rapidly and accurately diagnose patients with PFAPA in the future.

Who is conducting this research study, and where is it being conducted?

The Principal Investigators are Fatma Dedeoglu, MD, and Jonathan Hausmann, MD. Boston Children's Hospital is collaborating with your local pediatric rheumatologist in order to identify patients at multiple hospitals across the country. Boston Children's Hospital is organizing the study and will collect and analyze the information.

This study is funded by a grant from the Childhood Arthritis and Rheumatology Research Alliance (CARRA), a collaboration of pediatric rheumatologists from across the United States and Canada.

The wearable thermometers (iThermonitors) are being purchased from Raiing Medical Company. Raiing is not involved in the study design and will not be involved in writing the results of this study. They will not have access to any identifiable information. They are not supplying any funding to this study or to the investigators listed above. Boston Children's Hospital has equity in Raiing Medical Company.

How are individuals selected for this research study? How many will participate?

Children who are given a diagnosis of PFAPA by their rheumatologists will be included in the study. Accordingly, you/your child may be eligible to participate in the study.

Participants should be 18 or younger. We will attempt to include all the patients with the diagnosis of PFAPA. The study is anticipated to be finished in one year.

We are asking any patients seen by a pediatric rheumatologist and diagnosed with PFAPA to participate in the study. You /your child was identified by your primary Rheumatologist as possibly eligible to participate in this study.

What do I have to do if I am in this research study?

Participation involves wearing a wireless thermometer under the arm to continuously monitor body temperature prior, during, and after a PFAPA fever flare. We hope that this will give the study doctors a better understanding of fevers in PFAPA.

The device, "iThermonitor", and companion app are FDA-approved and made by Raiing Medical Company.

Permission for further contact.
As this study evolves, we would like to be able to contact you by letter or telephone to request further help with aspects of this research. For example, we may have additional questions about you/your child's illness history, or we may ask you to consider participating in further studies that emerge from this initial work. You will, of course, have the opportunity to agree or refuse, on a case by case basis. We will send you periodic updates as to the progress of this study, to ensure that you stay "in the loop" as to the findings resulting from this research, and so that you have updated contact information should you have any questions or concerns. Participation in future contact is optional. Please indicate your preference below whether you would like us to contact you in the future for any of the above-mentioned reasons:

___Yes ___No

Please note that all patients, whether enrolled in this study or not, will receive the same medical care by the same clinicians as usual – there is no "intervention" aspect to this research. Data collected on children may help us in diagnosing PFAPA syndrome more accurately in other children who have developed this condition.

Description and explanation of procedures

Continuous Temperature Monitoring
We are collecting information about the nature of PFAPA fevers. To best record the pattern of these fevers, we are asking patients to wear a wireless thermometer which adheres to the skin under the arm and sends the temperature automatically to an app on your iPhone. The study doctor and research assistants will provide you with a detailed explanation of how to use the device, how to install the app on your phone, and answer any questions you may have before you decide to participate. Because of the predictable nature of PFAPA flares, we ask participants to wear the device for a couple of days preceding a flare, during a flare, and for a couple of days thereafter. You will be given supplies and instructions to change the adhesive pad daily during this time. Additionally, a paper log will be provided to record temperatures captured by an oral digital thermometer that will also be provided. You may treat the fever episode as indicated by your primary rheumatologist.

If you chose to participate, you will be provided with instructions on how to place the device and use the app. A paper log will also be provided for you to record temperatures manually. For your reference, instructions are also posted on the manufacturer's website at: PFAPAstudy.com.

You should always follow the direction of your rheumatologist and continue to maintain whatever course of treatment has been discussed with your doctor.

What are the risks of this research study? What could go wrong?

Use of the iThermonitor device - The iThermonitor device is attached to the skin using hydrogel dressing. This is a standard dressing used for many medical uses and is considered safe. However, there is always a risk of skin reaction. Please monitor the site of the iThermonitor device on your child's skin regularly to check for any skin reaction. If you are worried about skin reaction, you may use a different kind of adhesive material to keep the iThermonitor in place.

Loss of Confidentiality - The iThermonitor device wirelessly transmits your body temperature data to a companion app installed on your mobile device. This information will be de-identified and stored with a research ID number on an online database without any personal identifiable information. Drs. Dedeoglu and Hausmann will be the only ones who have knowledge of your name and research ID number. Therefore, no one, except for these doctors, will be able to link temperature records to specific patients. Raiing Medical Company will not have access to your medical record or health information.

Your / your child's participation in this study is entirely voluntary, and will not effect the medical care you/your child receives at Children's Hospital, Boston.

What are the benefits of this research study?

This is an observational study and will not influence the diagnostic evaluation or treatment of your child. Accordingly, you and your family will not directly benefit by participating in this research. However, we hope that information obtained from this research study will help doctors to provide children with more timely and accurate diagnosis of PFAPA in the future.

Are there costs associated with this research study? Will I receive any payments?

There is no cost to you/your child for participating in this study. There is no reimbursement for participation in this study. You will keep the iThermonitor and oral digital thermometers after the end of the study.

What will happen with the information obtained as part of this research study? What about confidentiality?

The information will be coded so that only researchers from Children's Hospital will know that the data came from you, or your child. This list will be kept in a locked room to ensure patient confidentially. This data may be stored indefinitely by Children's Hospital prior to sending for analysis. Only the principal investigators will have access to you/your child's identifying information. If your data is shared with another collaborator, it will be identified only by its unique number and possibly by non-identifying information such as age, gender. If results of tests performed on your/your child's data form all or part of the basis of a publication in the medical literature, no identifying information will be included. The results of this study are performed for research purposes and will not be placed in your/your child's medical record. In this manner, it will be unlikely that your primary rheumatologist, others within the hospital, an insurance company, or employer would ever learn of these results

During this research, information about your or your child's health will be collected. In general, under federal law, information about patients is private, but there are exceptions and you should know who will have access to this information and might see it. The following people will be able to see this information:

- Medical and research staff at Children's Hospital, including people listed on your informed consent.
- Medical staff who are directly involved in your care that is related to the research or arise from it.
- People who oversee, advise or conduct research at Children's Hospital, and people who oversee or evaluate research and care, including the Committee on Clinical Investigation, staff working on quality improvement, and other clinicians and administrative staff of Children's Hospital.
- People from agencies and organizations that provide independent accreditation and oversight of research
- Sponsors or others involved in funding the research
- Federal agencies that oversee or review research information.
- Government agencies and sponsors.
- If some law or court requires us to share the information, we would have to follow that law or final ruling

You/your child should be aware that the federal privacy rule does not cover all of these possible uses. This means that once some of the above-mentioned users receive your/your child's health information they do not have to follow the same rules. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Children's Hospital Privacy Officer at 617-355-5502

If I do not want to take part in this research study, what are the other choices?

You/your child can choose not to participate in this study. A choice not to participate will in no way affect the care you/your child receive by your primary rheumatologist.

What are my rights as a research participant?

You/your child may at any time withdraw your/your child's consent to participate.

There are no known circumstances under which participation would be discontinued by the investigator prior to the end of the study.

As described above, we will be unable to disclose to you research results obtained in the course of this study since these has no clinically verified value.

Are there other things I should know about?

What information do I need to know about the Health Insurance Portability and Accountability Act (HIPAA)?

You/your child's health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research including those funding and regulating the study may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it.
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital.

- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program
- People from agencies and organizations that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories, and others
- Your health insurer for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you/your child decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Boston Children's Hospital Privacy Office at 857-218-4680 which is set up to help you understand privacy and confidentiality.

Because research is ongoing we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However your name or identifying information will not be used without your specific permission.

Your privacy rights

If you or your child do not want to participate in this study, you do not have to. If you do want to participate, however, you must sign this form.

If you do not sign this form, it will not affect your care or your child's pediatric rheumatology care, now or in the future and there will be no penalty or loss of benefits. You/your child can withdraw from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information will need to do so in writing.

You/your child may have the right to get some the information that was shared with others for research, treatment or payment. This information is available after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 857-218-4680.

Contact Information:

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call…	At	If I have questions or concerns about
Investigators: **Fatma Dedeoglu, MD**	Phone: **617-355-6117** Pager: 617-355-7243 **Pager #2402**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Jonathan Hausmann, MD	Phone 617-355-6117	
	Pager 617-355-7243 Pager #6747	
Office of Clinical Investigations	Phone: **617-355-7052**	▪ Rights of a research subject ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints. ▪ If investigator/study contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Study Contact or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this study.
- This research study has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research study is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for my/my child's participation in this research study and for the use of associated protected health information as described above (HIPAA).

Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research study is a foster child *or a* ward of the state *please notify the researcher or their staff who is obtaining your consent.*

■ _____ _____ _____
Date (MM/DD/YEAR) Signature of **Parent** or **Legal Guardian** Relationship to child

Child Assent (if applicable) ■ _____

_____
Date (MM/DD/YEAR) Signature of **Child/Adolescent Subject**

■ If child/adolescent's assent is **not** obtained above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form
☐ Child is too young
☐ Other reason (e.g. sedated), please specify: _____

Adult Subject (if applicable)

■ _____ _____
Date (MM/DD/YEAR) Signature of **Adult Subject** *(18+ years)*

Investigator or Associate's Statement & Signature

- I have fully explained the research study described above, including the possible risks and benefits, to all involved parties (subject/parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the study.
- I have provided a copy of the consent form sign by the subject/ parent / guardian and a copy of the hospital's privacy notification (if requested)

■ _____ _____
Date (MM/DD/YEAR) Signature of **Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the subject or legal representative, **or**

☐ The individual has certain communication impairments that limit the subject's ability to clearly express consent **or**

☐: Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the subject, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

☐ _____ _____

Date (MM/DD/YEAR) Signature of **Witness**

Or

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the subject or legal representative and this consent document serves as the summary for such consent. I confirm that the information in this consent form was presented orally to the subject, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.☐ _____ _____

Date (MM/DD/YEAR) Signature of **Witness** and **Interpreter**