

## Blood sample collection

Samples for purpose of research to send to the laboratory of molecular genetics and cell-lines bank

Each blood sample must be accompanied with the identification form and with a copy of the informed consent.

### Important!!

Before any sending, please contact K Sylla: [khaoussou.sylla@bct.aphp.fr](mailto:khaoussou.sylla@bct.aphp.fr), for travelling procedure. There will be no reimbursement if you have organized and paid the sending by yourself

#### I) Nature of blood samples

- **Preservation and cell-line procedure**

10 ml blood sample is sterilely collected on A-C-D for Acetate-Citrate Dextrose (yellow hood) tube.

- **DNA extraction**

10ml blood sample (5ml for children) is collected on EDTA tube + 1ml on Heparin/Lithium tube

#### II) Preservation

Tubes are preserved and sent at room temperature, they must be neither frozen nor put in the fridge.

#### III) Packaging

Please pack carefully, protect from shocks and join a copy of identification form to the sending.

#### IV) Routing:

Always at room temperature, as fast as possible (24h delay at the maximum).

Samples are received at the laboratory from Monday to Thursday before 4pm and on Friday before noon.

# Development of a tool for early diagnosis of Behçet's disease in children for further international epidemiological studies

## Information form for patients and parents

We are making a research on Behçet's disease (BD), a rare disorder that affects your child. The cause of BD is still unknown. The course is characterized by attacks of both oral and genital ulcers as well as episodes of eye inflammation (uveitis). BD can affect variably other organs such as skin, nervous system, joints, and may sometimes cause thrombosis (clots in the blood vessels). Onset of BD before 16 years has been reported but remains exceptional. At this age, the recognition of the disease is difficult for the physicians, especially because children have only few symptoms and because there is no specific biological test to make a definite diagnosis.

This research aims to define a tool, based on a set of clinical signs that may help to recognize BD earlier. This clinical set could avoid you to go under useless examinations in the future and will facilitate earlier and more appropriate medical care.

An on-line database has been specifically created for this research, in order to collect prospective information provided by your dealing physician Dr., Pr. .... during a period of at least four years. A specific questionnaire will be filled-up at the time of inclusion in the study then will be yearly (or upon event) updated with all informative data.

We would like your permission to enrol your child in this clinical research.

The protocol has received ethical and regulatory approval according to local regulation (*Name of the ethical committee*).

Representatives of the sponsors of this study, as well as local and international health authorities will have access to, and may review medical records and data obtained from, your participation in this study. However, all data produced by your participation and collected will be kept confidential and identified only by code numbers.

The data may be also made available for scientific purposes outside Europe e.g. USA where European data protection acts do not apply.

The study results may be published in medical or scientific journals, but your identity will not be revealed.

According to our national law relative to data computing, you have the right of access and rectification. You also have a right of opposition on data covered by the professional secret and susceptible to be used and treated within the context of this research.

This observational study takes place in the context of your child's usual clinical follow-up, thus he/she will not have to undergo complementary visit and he/she will not receive particular treatment.

If you agree to participate, blood samples will be taken from your child as well as from both parents. This material will be kept for further genetic analyses in the laboratory of molecular genetics, La Timone, Hospital, Marseilles (France) under the responsibility of Pr. Nicolas Levy.

Your participation in this study is totally voluntary and you may refuse to participate or you may withdraw from participation at any time without losing the medical care you are entitled to receive.

In some cases you may have been enrolled with the best intent by permission of a relative or your witnessed verbal consent because your condition at the time was too acute. In such case, you may also withdraw from further participation.

We would use any study data collected up to your formal withdrawal, as this is very necessary for the scientific analysis, unless you also indicate that you do not agree to this.

Your participation in this study is totally voluntary and you will not perceive payment. Having read and understood this information form, you will have the choice to participate or not in this study. You may refuse to participate or you may withdraw from participation at any time without losing the medical care you child is entitled to receive.

Since you have read this notice and since you have obtained all information you need, we will ask you, if you agree, to sign the informed consent form that has been drawn for the PED-BD study. You are acknowledging that the procedures and requirements of this study have been explained to you with your questions answered to your satisfaction

We thank you warmly for your contribution.

Place .....

Place .....

Date:

Subject's representative Name, first name  
(father, mother, holder of the parental authority)

Subject's representative Name, first name  
(father, mother, parental authority)

Signature

Signature

Date:

Investigator's name:

Physician's signature:

**Informed consent of participation in a biomedical research  
(Minor subject)**

**Development of a tool for early diagnosis of Behçet's disease in children for further  
international epidemiological studies**

Us, undersigned

Mrs, Miss, Mr. (Name, First name) .....  
(Father, Mother, Holder of the parental authority) and

Mrs, Miss, Mr. (Name, First name) .....  
(Father, Mother, Holder of the parental authority)

We accept freely and voluntarily that our child "Name, First name" participates in the entitled biomedical research "Development of a tool for early diagnosis of Behçet's disease in children for further international epidemiological studies" that Doctor (name, first name, telephone).....has proposed to us.

Being understood that :

Your participation in this study is totally voluntary and you may refuse to participate or you may withdraw from participation at any time without losing the medical care you are entitled to receive.

In some cases you may have been enrolled with the best intent by permission of a relative or your witnessed verbal consent because your condition at the time was too acute. In such case, you may also withdraw from further participation.

We would use any study data collected up to your formal withdrawal, as this is very necessary for the scientific analysis, unless you also indicate that you do not agree to this.

During or at the end of the research, this physician will keep us informed on our child's health status

If we are interested, our doctor will give us overall results at the end of the study

Our consent does not discharge our Doctor and the study promoter from their responsibility and we keep all our rights being guaranteed by the law.

Representatives of the sponsors of this study, as well as local and international health authorities will have access to, and may review medical records and data obtained from, your participation in this study. However, all data produced by your participation and collected will be kept confidential and identified only by code numbers.

The data may be also made available for scientific purposes outside Europe e.g. USA where European data protection acts do not apply

The study results may be published in medical or scientific journals, but your identity will not be revealed.

A signed/dated copy of this document will be given to you.

By freely signing the consent form, you are giving permission for participation in this clinical research study and the use of medical and scientific data collected. You are also acknowledging that the procedures and requirements of this study and the possible risks and discomforts have been explained to you with your questions answered to your satisfaction.

Place .....

Place .....

Date:

Subject's representative Name, first name  
(father, mother, holder of the parental authority)

Subject's representative Name, first name  
(father, mother, parental authority)

Signature

Signature

I confirm that the study has been explained to the subject (or subjects representative.) above and that consent to participate has been given. By signing this form, I confirm that the information in this consent form has been appropriately explained to, and apparently understood by the subject or the subject's representative, and that informed consent was freely given.

Date:

Investigator's name:

Physician's signature:

**Informed consent of participation in a biomedical research  
(Adolescent subject)**

**Development of a tool for early diagnosis of Behçet's disease in children for further  
international epidemiological studies**

Me, undersigned

Mrs, Miss, Mr. (Name, First name) .....

Mrs, Miss, Mr. (Name, First name) .....  
(Father, Mother, Holder of the parental authority)

I accept freely and voluntarily to participate in the entitled biomedical research "Development of a tool for early diagnosis of Behçet's disease in children for further international epidemiological studies" that Doctor (name, first name, telephone).....has proposed to me.

Being understood that :

My participation in this study is totally voluntary and may refuse to participate or may withdraw from participation at any time without losing the medical care I am entitled to receive.

In some cases I may have been enrolled with the best intent by permission of a relative or my witnessed verbal consent because my condition at the time was too acute. In such case, I may also withdraw from further participation.

We would use any study data collected up to your formal withdrawal, as this is very necessary for the scientific analysis, unless you also indicate that you do not agree to this.

During or at the end of the research, this physician will keep me informed on my health status

If I am interested, my doctor will give me overall results at the end of the study

My consent does not discharge my Doctor and the study promoter from their responsibility and I keep all my rights being guaranteed by the law.

Representatives of the sponsors of this study, as well as local and international health authorities will have access to, and may review medical records and data obtained from, my participation in this study. However, all data produced by my participation and collected will be kept confidential and identified only by code numbers.

The data may be also made available for scientific purposes outside Europe e.g. USA where European data protection acts do not apply.

The study results may be published in medical or scientific journals, but my identity will not be revealed.

A signed/dated copy of this document will be given to me.

By freely signing the consent form, I am giving permission for participation in this clinical research study and the use of medical and scientific data collected. I am also acknowledging that the procedures and requirements of this study and the possible risks and discomforts have been explained to me with my questions answered to my satisfaction.

Place .....

Place .....

Date

Subject Name, first name

Subject representative's signature

Signature

Signature

I confirm that the study has been explained to the subject (or subjects representative.) above and that consent to participate has been given. By signing this form, I confirm that the information in this consent form has been appropriately explained to, and apparently understood by the subject or the subject's representative, and that informed consent was freely given.

Date:

Investigator's name:

Physician's signature: