Version No.2 – 02/05/2016

INFORMATION FORM FOR PARENTS OR LEGAL GUARDIANS OF CHILDREN

Interventional study to evaluate the contribution of blood protein S100B levels in caring for infant mild traumatic brain injury
PROS100B

- **Promoter:** **University Hospital of Clermont-Ferrand**
  58 Rue de Montalembert, 63003 Clermont-Ferrand Cedex 1, France
- **Coordinating investigator:** **Damien Bouvier**
  Medical biochemistry department
  University Hospital of Clermont-Ferrand

Mrs, Mr,

We would like to know whether you will allow your child to participate in the research project with the title mentioned above, which will take place in the Emergency Paediatric Departments of several hospitals in France.

The aim of this study is to improve the strategy used to care for children with brain injuries.

By evaluating the blood protein (protein S100B) level, we can shorten hospitalisation time in the case of a normal result, and reduce the number of additional examinations of the child.

Protein S100B is synthesised mostly in the brain cells and is released into the blood in the case of brain injury.

The study will be carried out in 2 steps:

- Your child will benefit randomly (by drawing lots):
  - from routine treatment according to the French Society of Emergency Medicine and the French-language Paediatric Reanimation and Emergency Group

  or
  - from treatment with blood protein S100B. In this case, a sample of your child's blood will be taken by a nurse in the department. The level of protein S100B requires taking a sample of a single tube of blood, or by routine sampling (about 1 ml of blood), or by the micro-method for infants under 6 months (sample taken from the fingertip or possibly the heel).
    - If the result is normal, your child may shorten their stay in the emergency department with the usual instructions for observation at home.
    - If the result is abnormal, the usual course of care will be administered. The samples will be destroyed at the end of the study.
- Following this, a member of the medical staff will call you at home 48 hours and three weeks after your child's injury to ask you several questions concerning their state of health.

Your child's participation in this study will contribute towards progress in the therapeutic resources made available to the medical staff.

The blood sample will be taken under stringent aseptic conditions. The risks to which your child will be exposed are those that may occur when a blood sample is taken (discomfort, bruising at the point of penetration, localised pain, etc.).

Your participation in this biomedical research will not incur any additional expense for you in comparison to what you would normally pay in the case of your child being cared for in the usual way. However, you must be affiliated with or be covered by a social security scheme.

The University Hospital of Clermont Ferrand, which is organising this biomedical research in its capacity as promoter, has taken out an insurance policy in conformity with the legislation, guaranteeing its civil liability and that of all its staff with the Société Hospitalière d'Assurances Mutuelles (SHAM, contract no.147161). In the case where your child's state of health is affected by their participation in the study, you shall be entitled to receive compensation in the framework of this specific insurance in conformity with the Law on Public Health no.2004-806 of 9 August 2004.

This research received the approbation of the Ethics Committee Sud Est VI on 08/06/2016 and the preliminary authorisation of the competent health authority.

This research may be interrupted, if the circumstances so require, by the sponsor or at the request of the health authority. The information relating to the study collected by the investigator shall be treated confidentially (anonymised computer processing).

Protection of your personal data:

In the framework of this research, the University Hospital of Clermont-Ferrand is responsible for processing data of a personal nature. The aim of this computer processing is to analyse the results of the research in relation with the goal presented to you.

The legal basis, with respect to article 6 of the RGPD (General Regulations on Data Protection) is the legitimate interest of the sponsor in processing medical data for the purpose of scientific research (article 9.2 of the RGPD). To this end, the medical data concerning your child and the data relating to your living habits necessary for the research shall be sent to the Sponsor, or to persons or companies acting on its behalf, in France and abroad.

These data shall be identified by a code number and the initials of your child. These data may also, under conditions ensuring their confidentiality, be sent to the French health authorities and to other entities of the University Hospital of Clermont Ferrand. The data shall be kept for at least 15 years after the termination of the research, according to the legal provisions in force.

In conformity with the provisions of the law on Computer Technology and Freedom of 6 January 1978, since amended, you are entitled to access, correct and limit the processing of your child's data. You are also entitled to oppose the transmission of data covered by professional secrecy liable to be used in the framework of this research and be processed.

In conformity with article 17.3 of the RGPD, data collected prior to the withdrawal of consent, if such be the case, cannot be deleted and may continue to be processed under the conditions specified for the research.

To exercise these rights or for any question on the processing of your child's data, you can contact our data protection representative: CHU de Clermont-Ferrand – Direction de la Qualité – Gestion des Risques et Droits des Usagers – 58 rue Montalembert – 63003 Clermont-Ferrand cedex 1 (or dpd@chu-clermontferrand.fr).

You can also access all your child's medical data directly, or by way of a doctor of your choice, by invoking the provisions of article L. 1111-7 of the public health code. These rights can be exercised by way of the doctor who follows up your child in the framework of the research and who knows their identity.

If you esteem, after having contacted us, that your rights according to the law on Computer Technology and Freedom have not been conformed with or that the access control system does not conform to the rules on data protection, you can send a complaint to the CNIL by letter.

You are free to accept or refuse the participation of your child in this research without having to justify your decision. In addition, you can exercise your right to withdraw from this research at any time without having to give a reason. The fact of no longer participating in this research will not change the quality of the care administered to your child. You can ask for additional information from the medical team caring for your child at any time. Furthermore, you can be kept informed of the overall results of this research at the end of the study.

After you have read this information form and obtained the answers to the questions you asked to the investigating doctor, you will be asked whether you agree to give your written consent by signing the document prepared for this purpose after a moment's reflection away from the presence of a member of the University Hospital.

Date: …../…./…..

Signature of the parents or legal guardians: **Initials of the investigator**

(Preceded by the mention "read and approved")

CONSENT FORM FOR PARTICIPATION IN BIOMEDICAL RESEARCH FOR PARENTS OR LEGAL GUARDIANS OF CHILDREN

Interventional study to evaluate the level of blood protein S100B in the care of infant mild traumatic brain injury PROS100B

Coordinating investigator: **Damien Bouvier**
Medical Biochemistry Department – University Hospital of Clermont-Ferrand

I, the undersigned,
Mrs, Mr (*name, first name*)……
Born on ……
Living at ……
Landline number …….. Cell phone number ……
Declare:
- that Doctor (*name, first name*)…….. proposed that my child could participate in the study mentioned above,
- that he explained the protocol to me in detail,
- that, in particular, he informed of:
  - the objective, method and duration of the study;
  - the potential constraints and risks incurred;
  - the telephone follow-up after 48h and 3 weeks;
  - my right to refuse to participate in case of disagreement and to withdraw my consent at any time;
  - my obligation to subscribe to a social security system;
  - that, if I wish, I shall be informed of the overall results of the research by the investigating doctor;
  - that the Ethics Committee Sud Est VI approved this research on 08/06/2016;
  - that in the framework of this study, the sponsor, the University Hospital of Clermont-Ferrand, has taken out an insurance policy covering this research.

The information concerning the study collected by the investigator is treated confidentially.

I accept that the data recorded for this research may be subjected to anonymized data processing. I have clearly understood that the rights of access, correction, opposition and limitation of data processing provided for by the law on Computer Technology and Freedom of 6 January 1978, since amended, can be exercised at any time through the doctor following up my child in the framework of the research and who knows the identity of my child, or the data protection representative of the sponsor whose contact information features on the information form given to me.

I can at any time ask for additional information from Dr ..... by calling .....
After having discussed freely and obtained the answers to all my questions, I accept freely and voluntarily to participate in this biomedical research under the conditions set out in the information and consent form.

Patient's name and first name:	**Investigator's name:**
……	**……**
Date:……/……/…….	**Date:……/……/…….**
Signature of parents or legal guardians:	**Signature:**
Preceded by the mention "read and approved":	

Two copies of this form must be filled-in. The first must be kept by the investigator for 15 years; the other must be provided to the person having given their consent.

INFORMATION FORM FOR ADOLESCENTS

Interventional study to evaluate the blood protein S100B levels in treating infant mild traumatic brain injury
PROS100B

- **Promoter**
  University Hospital of Clermont-Ferrand
  58 Rue de Montalembert, 63003 Clermont-Ferrand Cedex 1

- **Coordinating investigator: Damien Bouvier**
  Medical Biochemistry Department
  University Hospital of Clermont-Ferrand

Miss, Sir,

We invite you to participate in a research programme with the title mentioned above, organised by the Paediatric Emergency Department of the University Hospital of Clermont-Ferrand.

The objective of the study is to improve the strategy for caring for children with mild traumatic brain injuries.

By evaluating the level of a protein (protein S100B) in the blood, we could shorten hospitalisation time in the case of a normal result, and reduce the number of additional examinations.

Protein S100B is mostly synthesised in the brain cells and is released into the blood in the case of a traumatic brain injury.

The study is carried out as follows:

- You will benefit randomly (drawing lots):
  - from routine treatment according to the French Society of Emergency Medicine and the French-language Paediatric Reanimation and Emergency Group

  or

  - from treatment with blood protein S100B. In this case, a nurse from the department will take a sample of your blood. Evaluating the level of protein S100B requires taking only one tube of blood by routine sampling (about 1 ml of blood).
    - If your result is normal, you can shorten your stay in the emergency department, with the usual instructions for observation at home.
    - If the result is abnormal, routine treatment will be administered. The blood samples will be destroyed at the end of the study.

- Following this, a member of the medical staff will call you (you or your parents) at home 48 hours and three weeks after your injury to ask you a few questions about your state of health.

Your participation in this study can help doctors to better treat patients.

The blood sample will be taken under stringent aseptic conditions. The risks to which you will be exposed are those that may occur when a blood sample is taken (discomfort, bruising at the point of penetration, localised pain, etc.).

Your participation in this biomedical research will not lead to any additional expense for your parents in comparison to that they would have had for routine treatment.

However, your parents must be affiliated with or be covered by a social security scheme.

The University Hospital of Clermont Ferrand, which is organising this biomedical research in its capacity as promoter, has taken out an insurance policy in conformity with the legislation, guaranteeing its civil liability and that of all its staff with the Société Hospitalière d'Assurances Mutuelles (SHAM, contract no.147161). If your state of health is affected due to your participation in

this study, you shall be entitled to receive compensation in the framework of this specific insurance in conformity with Law on Public Health no.2004-806 of 9 August 2004.

This research received the approbation of the Ethics Committee Sud Est VI on 08/06/2016 and the preliminary authorisation of the competent health authority.

The information relating to the study collected by the investigator shall be treated confidentially (anonymised computer processing).

Protection of your personal data

In the framework of this research, the University Hospital of Clermont-Ferrand is responsible for processing data of a personal nature. The aim of this computer processing is to analyse the results of the research.

According to article 6 of the RGPD (General Regulations on Data Protection), the medical data concerning you and the data relating to your living habits required for the research will be sent to the Promoter, or to other persons or companies acting on its behalf in France and abroad.

These data shall be identified by a code number and your initials. These data may also, under conditions ensuring their confidentiality, be sent to the French health authorities and to other entities of the University Hospital of Clermont Ferrand.

The data shall be kept for at least 15 years after the termination of the research, according to the legal provisions in force.

In conformity with the provisions of the law on Computer Technology and Freedom of 6 January 1978, since amended, you are entitled to access, correct and limit the processing of your data. You are also entitled to oppose the transmission of data covered by professional secrecy liable to be used in the framework of this research and be processed.

You can also access all your medical data directly, or by way of a doctor of your choice, according to the provisions of article L. 1111-7 of the public health code. These rights can be exercised by way of the doctor who follows you up in the framework of the research and who knows your identity.

You are free to accept or refuse to participate in this research without having to justify your decision. In addition, you can exercise your right to withdraw from this research at any time without having to give a reason. The fact of no longer participating in this research will not change the quality of the care administered to you. You can ask for additional information from the medical care team.

Furthermore, you can be kept informed of the overall results of this research at the end of the study.

After you have read this information form and obtained the answers to the questions you asked to the investigating doctor, you will be asked whether you agree to give your written consent by signing the document prepared for this purpose after a moment's reflection away from the presence of a member of the University Hospital.

Date: ...../..../.....

Patient's signature:
(Preceded by the mention
"read and approved")

Initials of the investigator

ADOLESCENT'S CONSENT FORM FOR PARTICPATION IN BIOMEDICAL RESEARCH

Interventional study to evaluate the level of blood protein S100B in the care of infant mild traumatic brain injury PROS100B

Coordinating investigator: **Damien Bouvier**
Medical Biochemistry Department – University Hospital of Clermont-Ferrand

I, the undersigned,
Mrs, Mr (*name, first name*)……
Born on ……
Living at ……
Landline number …….. Cell phone number ……
Declare:
- that Doctor (*name, first name*)…….. proposed that my child could participate in the study mentioned above,
- that he explained the protocol to me in detail,
- that, in particular, he informed of:
  - the objective, method and duration of the study;
  - the potential constraints and risks incurred;
  - the telephone follow-up after 48h and 3 weeks;
  - my right to refuse to participate in case of disagreement and to withdraw my consent at any time;
  - my obligation to subscribe to a social security system;
  - that, if I wish, I shall be informed of the overall results of the research by the investigating doctor;
  - that the Ethics Committee Sud Est VI approved this research on 08/06/2016;
  - that in the framework of this study, the sponsor, the University Hospital of Clermont-Ferrand, has taken out an insurance policy covering this research.

The information concerning the study collected by the investigator is treated confidentially.

I accept that the data recorded for this research may be subjected to anonymized data processing. I have clearly understood that the rights of access, correction, opposition and limitation of data processing provided for by the law on Computer Technology and Freedom of 6 January 1978, since amended, can be exercised at any time through the doctor following up my child in the framework of the research and who knows the identity of my child, or the data protection representative of the promoter whose contact information features on the information form given to me.

I ACCEPT TO PARTICPATE IN THIS RESEARCH UNDER THE CONDITIONS SET OUT IN THE INFORMATION DOCUMENT GIVEN TO ME WITH THIS FORM AND THAT I HAVE READ THEM CAREFULLY.

I can at any time ask for additional information from Dr ……. by calling ……..

Patient's name and first name:	**Investigator's name:**
……	**……**
Date:……/……/…….	**Date:……/……/…….**
Signature:	**Signature:**
Preceded by the mention "read and approved	

Two copies of this form must be filled-in. The first must be kept by the investigator for 15 years; the other must be provided to the person having given their consent.

INFORMATION FORM
FOR CHILDREN AGED FROM 8 TO 13 YEARS OLD

Interventional study to evaluate the contribution of a blood protein S100B levels in caring for infant mild traumatic brain injury
PROS100B

You've just hurt your head and you had to come to hospital for treatment. We invite you to join in a study.

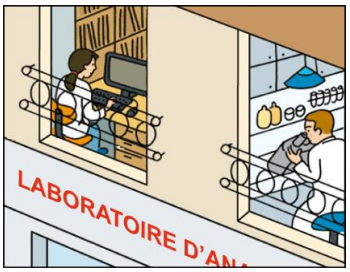
For this study, we might take a sample of your blood. It will let us use a little of your blood to carry out an analysis in the laboratory. The results may help the doctors to evaluate your head injury and thus care for you better.

- The goal is to take a blood sample in order to better monitor children with head injuries.

- The results of your blood test will be used for medical research without your name being written anywhere.

- You can ask the doctor any questions you want.

YOU CAN SAY NO IF YOU DON'T WANT TO PARTICIPATE IN THIS RESEARCH.



BIOMEDICAL RESEARCH PARTICIPATION CONSENT FORM FOR A CHILD AGED FROM 8 TO 13

Interventional study to evaluate the contribution of blood protein S100B levels in treating infant mild brain injury PROS100B

Coordinating investigator: **Damien Bouvier**
Medical Biochemistry Department – University Hospital of Clermont-Ferrand, France

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

Born on .....

Doctor ..... has invited me to participate in a study organised by the University Hospital of Clermont-Ferrand. She/he told me that I am free to accept or refuse this participation; this will not affect our relations. The aim, risks and duration of this study and the way it will take place have been clearly explained to me. I have fully understood all the information that has been given to me.

I can ask for additional information from the doctor at any time, by calling the doctor on ……..

If I wish, I can stop my participation in this study when I want. I will inform Doctor …… of this wish immediately.

I have been told that the results of the blood test will be used without my identity being revealed.

I know that this study received the acceptance of the Independent Ethics Committee (CPP) Sud Est VI on 08/06/2016.

I ACCEPT TO PARTICIPATE IN THIS RESEARCH UNDER THE CONDITIONS DESCRIBED IN THE INFORMATION DOCUMENT GIVEN TO ME WITH THIS FORM WHICH I HAVE READ CAREFULLY.

Patient's name and first name:	**Investigator's name:**
……	**……**
Date:……./……./…….	**Date:……./……./…….**
Signature:	**Signature:**
Preceded by the mention "Read and approved":	

Two copies of this form must be filled-in. The first must be kept by the investigator for 15 years; the other must be provided to the person having given their consent.