Appendix B
PICSS-PF English Consent forms

INFORMATION SHEET AND CONSENT FORM FOR FAMILY CAREGIVER

Application for participation in a medical research project:

Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]

Dear Sir/Madam
We invite you to participate in our research project.
Your participation is entirely voluntary. All data collected in this project are subject to strict data protection rules.
The research project is conducted by by IUFRS, l'Institut universitaire de formation et de recherche en soins of the CHUV. We will send you the results if you wish.
During a meeting, we will present you the essential elements and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed information after.

Why are we conducting this research project?

- A hospitalization in pediatric intensive care unit (PICU) can have consequences for the health of patients and their families.
- This study is performed, with the aim of understanding outcomes of PICU hospitalization in children and their family.
- The purpose of our research project is to determine how the physical, emotional, cognitive and social health of children and families change after PICU hospitalization, find children and families at risk, and factors that can help them for better outcomes.

What do I do if I accept to participate? – What happens to me if I participate?

- Form of participation: If you agree to participate in our project, you will be asked to respond to questionnaires regarding your physical and phsychological health and your experience during hospitalization of your child at PICU, and if your child is less than 8 years old to respond questionnaires regarding their health.
- Procedure for participants: If you participate in the project, you will be required to fill out 45 to 60 minutes questionnaires that we will be sent to you at the time of PICU discharge, 1, 3, and 6 months after PICU discharge of your child.

What are the benefits and risks of the participation in the project?

Benefits

- There will be no direct benefit to you from your participation in this research project.
- By participating, you are helping future patients who have the same condition.

Risks and constrains

- It is possible that the questionnaires, which concern your well-being or PICU environment cause discomfort for a short time, if you experience psychological difficulties we will offer you helps that are already in place in the hospitals.

- This study does not pose any particular risk to you or your child. It will not change the way your child is cared for by the medical staff and will not include any additional procedures on your child.

By signing at the end of this document, you certify that you have understood the content and freely consent to participate in the project.

Detailed information

1. Purpose of the project and selection of participants

In this information sheet, our research project is also simply referred to as the project. If you agree to take part, you are a participant in the project.

The purpose of this project is to determine how the physical, emotional, cognitive and social health of children and their families change after hospitalization, find children and families at risk, and find factors that help them to have a better outcomes.

We are asking you to participate because participation is open to all parents of individuals who were hospitalized in PICU more than 48 hours.

2. General information about the project

- We still know little about health outcomes in children and their families after PICU hospitalization in four domains of physical, emotional, cognitive and social. So we are doing this project to find out more about this topic to be able to better help children and their families after PICU discharge.
- If you accept to participate, you will be in this study up to 6 months after PICU discharge. We will send you questionnaires related to the four domains of health in PICU, at the time of PICU discharge, as well as 1, 3, and 6 months after PICU discharge. The questionnaires will take between 45 to 60 minutes to complete.
- This project is a multicenter, national study and the approximate number of participants is around 500 children hospitalized in PICU, 500 parents and 300 siblings. This means almost 100 patients, 100 parents, and 60 siblings from this hospital. The total project duration will be 2 years.
- This project is carried out in compliance with the requirements of Swiss legislation. In addition, we follow all internationally recognized guidelines. The competent ethics commission has examined and approved this project.

3. Project process

- If you accept to participate in the study, we will ask you to respond to the questionnaires at different moments: at the time of PICU discharge of your child, as well as 1, 3 and 6 months after PICU discharge. However, after discharge from the hospital, people may be contacted when they should not be, which we regret. We apologize if you find yourself in this situation, or if you have experienced particularly painful events or a bereavement situation. We will therefore ask you at the beginning of each time point (1, 3, and 6 months after PICU discharge) to confirm that you are still eligible and willing to continue participating in this study.
- The questionnaires will be distributed through a secure online system sent to you by the way of preference, to your email address or your phone number. If you prefer paper based questionnaires you can request that as well.
- The questionnaires are related to your physical, emotional, cognitive and social health.
- The filling of questionnaire will take between 45 to 60 minutes each time.

4. Benefits

There will be no direct benefit for your participation in the project, but the results of this research may help people with the same condition and their families in future.

5. Voluntary nature of participation and obligations

Your participation is entirely voluntary. If you choose not to participate, or if you choose to participate and change your mind during the course of the project, you will not be required to explain your decision. This decision will not adversely affect you or your child future medical care.

If you choose to participate in this research project, you will be required to:

Follow the instructions and fulfill the requirements set forth in the research protocol to answer the questionnaires that will be sent to you.

6. Risks and limits

- There is no determined risk in this study.
- It is possible that the questionnaires, which concern your well-being or PICU environment cause discomfort for a short time, if you experience psychological difficulties we will offer you helps that are already in place in the hospitals.
- This study does not represent any particular risk to you or your loved ones. It will not change your child care by medical staff and will not include any additional procedures on you or your child.

7. Alternatives

If you do not wish to participate in this research project, but remain open to the possibility of participation in other projects, please indicate this to the investigator.

8. Results

The project provides different results:

1. Individual outcomes that directly affect you,

2. The final objective results of the project as a whole.

The investigator will inform you during the project of any important new findings about you. You will be notified orally and in written form, and you will be able to decide again if you wish to continue your participation in the project.

The investigator can send you a summary of the overall results at the end of the project.

9. Confidentiality of data

9.1. Data processing and coding

- In the context of this research project, data about you, your health, and your child health are collected and processed, partly in an automated way. This information is coded at the time of collection. Coding means that all identifying data (name, date of birth, etc.) are replaced by a code. It is not possible to link the data to you without the code, which remains permanently within the institution IUFRS/CHUV secure server.
- Only a limited number of people can view your data in uncoded form, and only in order to carry out tasks necessary for the project. These persons are bound by professional secrecy. As a participant, you have the right to view your data at any time.

9.2. Data and sample protection

All data protection guidelines are carefully enforced. It may be necessary for your data to be transferred in coded form, e.g. for publication, and for the data to be available to other researchers. When health-related data are stored on-site, they may be made available to other researchers for use in publications: When health-related data are stored on-site, they form a data bank for research purposes.

9.3. Data protection in case of re-use

Your data may later prove to be important for answering other questions and/or be sent to another database in Switzerland or abroad to be used in other research projects (re-use). This database must however comply with the same standards and requirements as the database of this project.

For this reuse, we ask you to sign a separate consent form at the end of this information sheet. This second consent is independent of participation in the project.

9.4. Right of consultation in the event of inspections

The project may be subject to inspections. These may be carried out by the relevant ethics committee or by the sponsor who initiated the project. In such cases, the investigator must provide your data for the purpose of such inspections. All people involved are bound by strict confidentiality.

10. Withdrawal of the project

You can withdraw from the project at any time if you wish. However, the medical data collected up to that point may still be analyzed in coded form.

In the event of withdrawal, your data will continue to appear in coded form in the project documents. You must therefore agree to this before giving your consent.

11. Compensation

Your family will receive CHF 30 as a gift card/electronic voucher after completion of the questionnaires by all members of the family at each time point as a compensation for participation in this research project.

Your participation will have no financial consequences for you or your health insurance.

12. Liability

The University Hospital of Lausanne/CHUV initiated the research project and is responsible for its implementation and liable for any damage you may suffer in connection with the project. The conditions and procedure are set by law.

13. Financement

This project is completely funded by Swiss Nursing Science Foundation (Stiftung Pflegewissenschaft) and ESICM (European Society of Intensive Care Medicine)

14. Interlocuteur(s)

You can ask questions about the project at any time. If you have any uncertainties during or after the project, you can contact:

The principal investigator for this study is Dr. Zahra Rahmaty who is conducting this study under the supervision of Prof Anne-Sylvie Ramelet at CHUV in Lausanne.
The local principal investigator helping with the study conduct at CHUV is Dr. Marie-Hélène Perez who will answer your questions. You can also ask your questions from the main principal investigator.

Local Principal Investigator:

Main Principal Investigator:

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PICSS-PF

Consent Statement

Written consent statement for participation in a research project
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required to participate in the project.

BASEC number	2022-02128
Title :	
Institution responsable	
Location :	
Responsible for the project on the site :	
Site of the Study:	
Participant : Last name and first name : Date of birth:	

- I declare that I have been informed orally and in writing by a member of the undersigned research team of the objectives and progress of the research project, as well as the possible advantages and disadvantages and the possible risks.
- I am participating in this project on a voluntary basis and accept the contents of the information sheet provided to me on the above-mentioned project. I have had sufficient time to make my decision.
- I have received answers to the questions I asked in relation to participation in this project. I have kept the information sheet and have received a copy of my written consent.
- I agree that the competent specialists of the project management and the competent ethics commission may consult my uncoded data for the purpose of checks and inspections, provided that the confidentiality of these data is strictly assured.
- I will be informed of the results that have a direct impact on my health or/and my child's health. If I do not wish to receive this information, I will contact the investigator.
- I am aware that my personal data, health data may be transmitted for research purposes within the scope of this project and only in coded form except to except for the CHUV secure REDCap, where my first and family name, my preference of communication, and other data related to the conduct of the study will appear. I may revoke my consent to participate in the project at any time and without having to justify it, without this decision having any adverse impact on my further care. However, the data collected up to the time of withdrawal will be analysed as part of the project.
- I am aware that CHUV is responsible for any damage caused by the project.
- I agree to be contacted again by members of the research team for future studies. It remains understood that I may revoke this permission at any time. If I do not agree, I may still participate in the study.

Place, date	Signature of the participant

Declaration of the research nurse:

I hereby declare that I have explained to the participant the nature, importance and scope of the project. I hereby declare that I meet all obligations in connection with this project in accordance with the applicable Swiss law. Should I become aware, at any time during the implementation of the project, of elements that could affect the participant's consent to take part in the project, I undertake to inform him/her immediately.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Written consent for reuse of data in coded form for future studies

BASEC number	
Title	
Participant : Printed full name: Date of Birth:	

I agree that my data obtained in this study may be used for medical research purposes. This consent is valid for an unlimited period of time.

I give my consent voluntarily and I can withdraw my consent at any time. If I withdraw my consent, my data will be made anonymous. I simply have to inform the study director and I do not have to justify my decision. I know that my data is stored in coded form and that the identification list is kept in a safe place. All legal provisions regarding data protection are respected.

As a rule, the data is evaluated in a comprehensive manner and the results are published in summary form. If the analysis of the data reveals a finding relevant to my health or/ and my child's health, the study director will contact me. If I do not wish to be informed, I am responsible for informing the study director. I waive all rights to commercial use of my data.

Place, date	Signature of the participant

Declaration of the research nurse: I hereby certify that I have explained to the participant the nature, importance and scope of the re-use of the data.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Centre hospitalier universitaire vaudois

PICSS-PF

INFORMATION SHEET AND CONSENT FORM FOR SURVIVORS WHO ARE LESS THAN 14 YEARS TO BE SIGNED BY PARENTS

Application for participation in a medical research project:

Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]

Dear Sir/Madam
We invite your child to participate in our research project.
Her/his participation is entirely voluntary. All data collected in this project are subject to strict data protection rules.
The research project is conducted by Institute of Higher Education and Research in Healthcare-IUFRS of the CHUV. We will send you the results if you wish.
During a meeting, we will present you the essential elements and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed information after.

Why are we conducting this research project?

- A hospitalization in pediatric intensive care unit (PICU) can have consequences for the health of patients and their families.
- This study is performed, with the aim of understanding outcomes of PICU hospitalization in children and their family .
- The purpose of our research project is to determine how the physical, emotional, cognitive and social health of children and families change after PICU hospitalization, find children and families at risk, and factors that help them for better outcomes.

What does my child do if I accept her/his participation?

- Form of participation: If you agree your child's participation in our project, we will send her/him questionnaires [child <8 years old, will send the questionnaires to you] to be filled out and we will access the child medical records.
- Procedure for participants: If your child participate in the project, she/her will be required to fill out 30 minutes questionnaires that we will sent her/him at the time of PICU discharge, 1, 3, and 6 months after PICU discharge.

What are the benefits and risks of the participation in the project?

Benefits

- There will be no direct benefit to your child from their participation in this research project.
- By participating, your child is helping future patients with the same condition.

Risks and constrains

- It is possible that the questionnaires, which concern your child well-being or PICU environment cause discomfort for a short time, if she/he experience psychological difficulties we will offer helps that are already in place in the hospitals.
- This study does not pose any particular risk to you or your child. It will not change the way your child is cared for by the medical staff and will not include any additional procedures on your child.

By signing at the end of this document, you certify that you have understood the content and freely consent for your child to participate in the project.

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PICSS-PF

Detailed information

1. Purpose of the project and selection of participants

In this information sheet, our research project is also simply referred to as the project. If you agree that your child participate, your child is the participant in the project.

The purpose of this project is to determine how the physical, emotional, cognitive and social health of children and their families change after PICU hospitalization, find children and families at risk, and find factors that help them to have a better outcomes.

We are asking your child participation because participation is open to all individuals who were hospitalized in PICU more than 48 hours.

2. General information about the project

- The hospitalization in intensive care unit can have consequences for the health of patients and their families. We still know little about health outcomes in children and their families after PICU hospitalization in four domains of physical, emotional, cognitive and social.
- We are conducting this project to find out more to be able to better help children and their families after PICU discharge.
- If you accept that your child attend to participate, your child will be in this study up to 6 months after PICU discharge. We will send your child questionnaires related to the four domains of health, at the time of PICU discharge, as well as 1, 3, and 6 months after PICU discharge. The questionnaires will take 30 minutes to be completed.
- The total project duration will be 2 years. This project is a multicenter, national study and the approximate number of participants is around 500 individuals hospitalized in PICU, 500 parents and 300 siblings, and around 100 patient, 100 parents and 60 siblings at this hospital.
- This project is carried out in compliance with the requirements of Swiss legislation. In addition, we follow all internationally recognized guidelines. The competent ethics commission has examined and approved this project.

3. Project process

- Your child's participation will not change his/her treatment by the medical staff and will not include any additional actions on your child.
- We only collect data from the usual assessment that is in place in hospital and is recorded electronically.
- We also will send questionnaires to your child [>8 years] to ask about their health or will ask you to answer for them [<8 years]
- The questionnaire will be sent to the email address or phone number provided based on families' preferences. These questionnaires will be available on an online secure platform and he/she will have access to them through a personal access available via a secure platform. If they wish, they can also fill out these questionnaires in paper format.
- Questions are related to physical, emotional, cognitive and social health of each person.
- The filling of questionnaire will take 30 minutes each time.
- The questionnaires need to be filled out in PICU, at the time of PICU discharge, as well as 1, 3 and 6 months after PICU discharge.

4. Benefits

There will be no direct benefit for your child participation in the project, but the results of this research may be important for people with the same condition and their families in future.

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PICSS-PF

5. Voluntary nature of participation and obligations

Your child participation is entirely voluntary. If you or your child choose not to participate, or if you choose to participate and change your mind during the course of the project, you will not be required to explain your decision. This decision will not adversely affect your child future medical care.

If your child choose to participate in this research project, she/he will be required to: Follow the instructions and fulfill the requirements set forth in the research protocol to answer the questionnaires that will be sent to them.

6. Risks and limits

- It is possible that the questionnaires, which concern your child well-being or PICU environment cause discomfort for a short time, if she/he experience psychological difficulties we will offer helps that are already in place in the hospitals.
- This study does not pose any particular risk to you or your child. It will not change the way your child is cared for by the medical staff and will not include any additional procedures on your child.

7. Alternatives

If you do not wish your child to participate in this research project, but remain open to the possibility of participation in other projects, please indicate this to the investigator.

8. Results

The project provides different results:

1. Individual outcomes that directly affect your child,

2. The final objective results of the project as a whole.

1. The investigator will inform you during the project of any important new findings about your child. You will be notified orally and in written form, and you will be able to decide again if you wish your child to continue participation in the project.

2. The investigator can send you a summary of the overall results at the end of the project.

9. Confidentiality of data

9.1. Data processing and coding

In the context of this research project, data about your child and her/his health are collected and processed, partly in an automated way. This information is coded at the time of collection. Coding means that all identifying data (name, date of birth, etc.) are replaced by a code. It is not possible to link the data to your child without the code, which remains permanently within the IUFRS, CHUV.

Only a limited number of people from IUFRS, CHUV can view your child data in uncoded form, and only in order to carry out tasks necessary for the project. These persons are bound by professional secrecy. As a legal guardian of the participant, you have the right to view your child data at any time.

9.2. Data protection

All data protection guidelines are carefully enforced. It may be necessary for your child data to be transferred in coded form, e.g. for publication, and for the data to be available to other researchers. When health-related data are stored on-site, they may be made available to other researchers for use in publications: When health-related data are stored on-site, they form a data bank for research purposes.

9.3. Data protection in case of re-use

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PICSS-PF

Your child data may later prove to be important for answering other questions and/or be sent to another database in Switzerland or abroad to be used in other research projects (re-use). This database must however comply with the same standards and requirements as the database of this project. For this reuse, we ask you to sign a separate consent form at the end of this information sheet. This second consent is independent of participation in the project.

9.4. Right of consultation in the event of inspections

The project may be subject to inspections. These may be carried out by the relevant ethics committee or by the sponsor who initiated the project. In such cases, the investigator must provide your child data for the purpose of such inspections. All people involved are bound by strict confidentiality.

10. Withdrawal of the project

You can withdraw your consent for your child participation from the project at any time if you wish. However, the medical data collected up to that point may still be analyzed in coded form.

In the event of withdrawal, your child's data will continue to appear in coded form in the project documents. You must therefore agree to this before giving your consent.

11. Compensation

Your family will receive CHF 30 as a gift card/electronic voucher after completion of the questionnaires by all members of the family at each time point as a compensation for participation in this research project.

Your child's participation will have no financial consequences for you or your health insurance.

12. Liability

The University Hospital of Lausanne/CHUV initiated the research project and is responsible for its implementation and liable for any damage your child may suffer in connection with the project. The conditions and procedure are set by law.

13. Financement

This project is completely funded by Swiss Nursing Science Foundation (Stiftung Pflegewissenschaft) and ESICM (European Society of Intensive Care Medicine).

14. Interlocuteur(s)

You can ask questions about the project at any time. If you have any uncertainties during or after the project, you can contact:

The principal investigator for this study is Dr. Zahra Rahmaty who is conducting this study under the supervision of Prof Anne-Sylvie Ramelet at CHUV in Lausanne.
The local principal investigator helping with the study conduct at the CHUV is Dr. Marie-Hélène Perez who will answer your questions. You can also ask your questions from the main principal investigator.
Local Principal Investigator:

Main Principal Investigator:

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PICSS-PE

Consent Statement

Written consent statement for participation in a research project
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required for your child to participate in the project.

BASEC number	
Title :	
Institution responsable	
Location :	
Responsible for the project on the site :	
Site of the Study:	
Participant : Last name and first name : Date of birth:	

For the legal guardian/parent to sign

- I declare that I have been informed orally and in writing by a member of the undersigned research team of the objectives and progress of the research project, as well as the possible advantages and disadvantages and the possible risks.
- My child participating in this project on a voluntary basis and accept the contents of the information sheet provided to me on the above-mentioned project. I have had sufficient time to make my decision.
- I have received answers to the questions I asked in relation to participation of my child in this project. I have kept the information sheet and have received a copy of my written consent.
- I agree that the competent specialists of the project management and the competent ethics commission may consult my child uncoded data for the purpose of checks and inspections, provided that the confidentiality of these data is strictly assured.
- Me and my child will be informed of the results that have a direct impact on her/his health. If we do not wish to receive this information, we will contact the investigator.
- I am aware that my child personal data, health data may be transmitted for research purposes within the scope of this project and only in coded form, except for the CHUV secure REDCap, where the first and family name, the preference of communication, and other data related to the conduct of the study will appear.
- I may revoke my consent for my child participation in the project at any time and without having to justify it, without this decision having any adverse impact on my child further care. However, the data and samples collected up to the time of withdrawal will be analysed as part of the project.
- I am aware that CHUV is responsible for any damage caused by the project.

Place, date	Signature of the legal guardian

Declaration of the research nurse:

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PICSS-PF

I hereby declare that I have explained to the participant and her/his legal guardian the nature, importance and scope of the project. I hereby declare that I meet all obligations in connection with this project in accordance with the applicable Swiss law. Should I become aware, at any time during the implementation of the project, of elements that could affect the participant's or her/his legal guardian's consent to take part in the project, I undertake to inform them immediately.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Written consent for reuse of data in coded form for future studies

BASEC number	
Title	Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]
Participant Printed full name: Date of Birth:	
Legal guardian/parent Printed full name: Date of Birth:	

For the legal guardian/parent
I agree that my child data obtained in this study may be used for medical research purposes. This consent is valid for an unlimited period of time.

I give my consent voluntarily and I can withdraw my consent at any time. If I withdraw my consent, my child data will be made anonymous. I simply have to inform the study director and I do not have to justify my decision. I know that my child data is stored in coded form and that the identification list is kept in a safe place. All legal provisions regarding data protection are respected.

As a rule, the data is evaluated in a comprehensive manner and the results are published in summary form. If the analysis of the data reveals a finding relevant to my child health, the study director will contact me. If I do not wish to be informed, I am responsible for informing the study director. I waive all rights to commercial use of my data.

Place, date	Signature of the legal guardian

Declaration of the research nurse: I hereby certify that I have explained to the participant and his/her legal guardian the nature, importance and scope of the re-use of the data.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

INFORMATION SHEET AND CONSENT FORM FOR SURVIVORS WHO 11-14 YEARS TO BE SIGNED BY THE SURVIVOR

Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]

The research project is done by: IUFRS, l'Institut universitaire de formation et de recherche en soins of the CHUV.

Hello,

We invite you to participate in our research project.

1. What is this study and why it is done?

We want to know how the physical, and emotional health of children and their family are impacted and changes after hospitalization in the Pediatric Intensive Care Unit (PICU).

2. Why we contacted you?

We want to understand if your health has changed after your hospitalization in the PICU.

Participation is open to all PICU patients who were in PICU more than 48 hours.

3. What is next/what should you do?

- If you agree to participate in the study, we will ask you to answer questionnaires at different times: at the time of your discharge from the PICU, and then at 1 month, 3 months and 6 months following the discharge from the PICU.
- These questionnaires will be available on an online platform and you will have access to them through a link that we send you. If you wish, it is also possible to fill out these questionnaires in paper format.
- The questions concern your physical, emotional and social health.
- It takes an estimated 30 minutes to complete the questionnaire.

4. What is the benefit of participating?

There is no direct benefit for you but your participation may help future patients.

5. Do I have to participate?

Participation is free and voluntary: you and your parents can decide whether or not to participate. If you decide not to participate, the doctors and medical teams who take care of you will continue to do so. If you have agreed to participate in this study, but later change your mind, you can also do so at any time without any negative consequences for you.

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PICSS-PF

6. Who can answer my questions?

If you have any questions during or after the study, you can contact the following person at any time.

The principal investigator for this study is Dr. Zahra Rahmaty who is conducting this study under the supervision of Prof Anne-Sylvie Ramelet at CHUV in Lausanne.
The local principal investigator helping with the study conduct at CHUV is Dr. Marie-Hélène Perez who will answer your questions. You can also ask your questions from the main principal investigator.

Local Principal Investigator:

Main Principal Investigator:

Take the time to read this information and ask any questions you may have before you make your decision. If you and your parents agree to participate in this study, you and your parents can sign the consent form.

Centre hospitalier universitaire vaudois

PICSS-PF

Consent Statement

Written consent statement for participation in a research project
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required to participate in the project.

BASEC number	
Title :	
Institution responsable	
Location :	
Responsible for the project on the site :	
Site of the Study:	
Participant : Last name and first name : Date of birth:	
Legal guardian/ parent: Last name and first name : Date of birth:	

- I declare that I have been informed orally and in writing by the investigator about the study "Post-Intensive Care Syndrome in Swiss Pediatrics and their Families [PICSS-PF]".
- I have received satisfactory answers to the questions I asked in connection with participation in this study. I accept the content of the written patient information provided to me regarding the above-mentioned study.
- I am participating in this study on a voluntary basis. I may withdraw from this study at any time without having to provide any reason, or any consequences.
- I have had sufficient time to make our decision.
- I accept that the specialists of the CHUV, the authorities and the cantonal ethics commission may see the research data in order to carry out examinations and controls, if confidentiality is strictly assured.

For patients capable of judgement under 14 years of age:

I certify that the informational interview has taken place and that my daughter/son capable of discretion has given consent to participate in the study and/or has shown no sign of opposition to such participation.

Place, Date	*Name, Family name, signature of the parent/ legal Guardian*
Place, Date	*Name, Family name, signature of the patient*

Certification by the research nurse:
I hereby certify that I have explained to the participant and her/his legal guardian the nature, importance and scope of the re-use of the data.

Signature of the research nurse

Place, date	*Name, family name and Signature of the research nurse*

Centre hospitalier universitaire vaudois

PICSS-PF

INFORMATION SHEET AND CONSENT FORM FOR SURVIVORS WHO ARE MORE THAN 14 YEARS OLD TO BE SIGNED BY THE SURVIVOR

Application for participation in a medical research project:

Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]

Hello,
We invite you to participate in our research project.
Your participation is entirely voluntary. All data collected in this project are subject to strict data protection rules.
The research project is conducted by IUFRS, l'Institut universitaire de formation et de recherche en soins of the CHUV. We will send you the results if you wish.
During a meeting, we will present you the essential elements and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed information after.

Why are we conducting this research project?

- A hospitalization in pediatric intensive care units (PICU) can have consequences for the health of patients and their families.
- This study is performed, with the aim of understanding outcomes of PICU hospitalization in children/ adolescence and their family.
- The purpose of our research project is to determine how the physical, emotional, cognitive and social health of children/ adolescence and families change after PICU hospitalization, find children/ adolescence and families at risk, and factors that can help them for better outcomes.

What do I do if I accept to participate? – What happens to me if I participate?

- Form of participation: If you agree to participate in our project, you will be asked to answer questionnaires and we will also get access to your medical record.
- Procedure for participants: If you participate in the project, you will be required to fill out 30 minutes questionnaires that we will sent you at the time of discharge, 1, 3, and 6 months after the PICU discharge.

What are the benefits and risks of the participation in the project?

Benefits

- There will be no direct benefit to you from your participation in this research project.
- By participating, you are helping future patients that have the same condition as you.

Risks and constrains

- There is no determined risk in this study.
- It is possible that the questionnaires, which concern your well-being or PICU environment cause discomfort for a short time, if you experience psychological difficulties we will offer you helps that are already in place in the hospitals.
- This study does not represent any particular risk to you or your loved ones. It will not change your care by medical staff and will not include any additional procedures on you.

Rahmaty Z, *et al. BMJ Open* 2023; 13:e076023. doi: 10.1136/bmjopen-2023-076023

Centre hospitalier universitaire vaudois

PICSS-PF

By signing at the end of this document, you certify that you have understood the content and freely consent to participate in the project.

Centre hospitalier universitaire vaudois

PICSS-PF

Detailed information

1. Purpose of the project and selection of participants

In this information sheet, our research project is also simply referred to as the project. If you agree to take part, you are a participant in the project.

The purpose of this project is to determine how the physical, emotional, cognitive and social health of children/ adolescence and their families change after PICU hospitalization, find children/ adolescence and families at risk, and find factors that help them to have a better outcomes.

We are asking you to participate because participation is open to all individuals who were hospitalized in PICU more than 48 hours.

2. General information about the project

- We still know little about health outcomes in children/ adolescence and their families after PICU hospitalization in four domains of physical, emotional, cognitive and social. So we are doing this project to find out more about this topic to be able to better help children/ adolescence and their families after PICU discharge.
- If you accept to participate, we will access your health records and you will be in this study up to 6 months after PICU discharge. We will send you questionnaires related to the four domains of health in PICU, at the time of PICU discharge, as well as 1, 3, and 6 months after PICU discharge. The questionnaires will take 30 minutes to be completed.
- The whole results of this project will be ready in 2 years. This project is a multicenter, national study and the approximate number of participants is around 500 individuals hospitalized in PICU, 500 parents and 300 siblings, and almost 100 patient, 100 parents, and 60 sibling in this hospital.
- This project is carried out in compliance with the requirements of Swiss legislation. In addition, we follow all internationally recognized guidelines. The competent ethics commission has examined and approved this project.

3. Project process

- Your participation in the project will not change your care by the medical staff and will not include any additional treatment, or procedure on you.
- If you agree to participate in the project, we will ask you to answer questionnaires at different times: once at the time of your discharge from the PICU, and then at 1 month, 3 months and 6 months following your discharge from the PICU.
- These questionnaires will be available on an online platform and you will have access to them through a personal access available via a secure platform and the link that will be sent to you. If you wish, it is also possible to fill out these questionnaires in paper format
- The questions concern your physical, emotional, cognitive and social health.
- It takes an estimated 30 minutes to complete each questionnaire.

4. Benefits

There will be no direct benefit for your participation in the project, but the results of this research may be important for people with the same condition and their families in future.

5. Voluntary nature of participation and obligations

Your participation is entirely voluntary. If you choose not to participate, or if you choose to participate and change your mind during the course of the project, you will not be required to explain your decision. This decision will not adversely affect your future medical care.

If you choose to participate in this research project, you will be required to:

follow the instructions and fulfill the requirements set forth in the research protocol to answer the questionnaires that will be sent to you.

Rahmaty Z, *et al. BMJ Open* 2023; 13:e076023. doi: 10.1136/bmjopen-2023-076023

Centre hospitalier universitaire vaudois

PICSS-PF

6. Risks and limits

- There is no determined risk in this study.
- It is possible that the questionnaires, which concern your well-being or PICU environment cause discomfort for a short time, if you experience psychological difficulties we will offer you helps that are already in place in the hospitals.
- This study does not represent any particular risk to you or your loved ones. It will not change your care by medical staff and will not include any additional procedures on you.

7. Alternatives

If you do not wish to participate in this research project but remain open to the possibility of participation in other projects, please indicate this to the investigator.

8. Results

The project provides different results:
1. Individual outcomes that directly affect you,
2. The final objective results of the project as a whole.

1. The investigator will inform you during the project of any important new findings about you. You will be notified orally and in written form, and you will be able to decide again if you wish to continue your participation in the project.
2. The investigator can send you a summary of the overall results at the end of the project.

9. Confidentiality of data

9.1. Data processing and coding

In the context of this research project, data about you and your health are collected and processed, partly in an automated way. This information is coded at the time of collection. Coding means that all identifying data (name, date of birth, etc.) are replaced by a code. It is not possible to link the data to you without the code, which remains permanently within the institution IUFRS/CHUV secure server.
Only a limited number of people can view your data in uncoded form, and only in order to carry out tasks necessary for the project. These persons are bound by professional secrecy. As a participant, you have the right to view your data at any time.

9.2. Data and sample protection

All data protection guidelines are carefully enforced. It may be necessary for your data to be transferred in coded form, e.g. for publication, and for the data to be available to other researchers. When health-related data are stored on-site, they may be made available to other researchers for use in publications: When health-related data are stored on-site, they form a data bank for research purposes.

9.3. Data protection in case of re-use

Your data may later prove to be important for answering other questions and/or be sent to another database in Switzerland or abroad to be used in other research projects (re-use). This database must however comply with the same standards and requirements as the database of this project. For this reuse, we ask you to sign a separate consent form at the end of this information sheet. This second consent is independent of participation in the project.

9.4. Right of consultation in the event of inspections

The project may be subject to inspections. These may be carried out by the relevant ethics committee or by the sponsor who initiated the project. In such cases, the investigator must provide your data for the purpose of such inspections. All people involved are bound by strict confidentiality.

10. Withdrawal of the project

You can withdraw from the project at any time if you wish. However, the medical data collected up to that point may still be analyzed in coded form.
In the event of withdrawal, your data will continue to appear in coded form in the project documents. You must therefore agree to this before giving your consent.

11. Compensation

Your family will receive CHF 30 as a gift card/electronic voucher after completion of the questionnaires by all members of the family at each time point as a compensation for participation in this research project.
Your participation will have no financial consequences for you or your health insurance.

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PICSS-PF

12. Liability
The University Hospital of Lausanne/CHUV initiated the research project and is responsible for its implementation and liable for any damage you may suffer in connection with the project. The conditions and procedure are set by law.

13. Financement
This project is completely funded by Swiss Nursing Science Foundation (Stiftung Pflegewissenschaft) and ESICM (European Society of Intensive Care Medicine).

14. Interlocuteur(s)
You can ask questions about the project at any time. If you have any uncertainties during or after the project, you can contact:

The principal investigator for this study is Dr. Zahra Rahmaty who is conducting this study under the supervision of Prof Anne-Sylvie Ramelet at CHUV in Lausanne.
The local principal investigator helping with the study conduct at the CHUV is Dr. Marie-Hélène Perez who will answer your questions. You can also ask your questions from the main principal investigator.

Local Principal Investigator:

Main Principal Investigator:

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PICSS-PF

Consent Statement

Written consent statement for participation in a research project
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required to participate in the project.

BASEC number	
Title :	
Institution responsable	
Location :	
Responsible for the project on the site :	
Site of the Study:	
Participant : Last name and first name : Date of birth:	

- I declare that I have been informed orally and in writing by a member of the undersigned research team of the objectives and progress of the research project, as well as the possible advantages and disadvantages and the possible risks.
- I am participating in this project on a voluntary basis and accept the contents of the information sheet provided to me on the above-mentioned project. I have had sufficient time to make my decision.
- I have received answers to the questions I asked in relation to participation in this project. I have kept the information sheet and have received a copy of my written consent.
- I agree that the competent specialists of the project management and the competent ethics commission may access my uncoded data for the purpose of checks and inspections, provided that the confidentiality of these data is strictly assured.
- I will be informed of the results that have a direct impact on my health. If I do not wish to receive this information, I will contact the investigator.
- I am aware that my personal data, health data may be transmitted for research purposes within the scope of this project and only in coded form, except for the CHUV secure REDCap, where my first and family name, my preference of communication, and other data related to the conduct of the study will appear.
- I may revoke my consent to participate in the project at any time and without having to justify it, without this decision having any adverse impact on my further care. However, the data and samples collected up to the time of withdrawal will be analysed as part of the project.
- I am aware that CHUV is responsible for any damage caused by the project.
- I agree to be contacted again by members of the research team for future studies. It remains understood that I may revoke this permission at any time. If I do not agree, I may still participate in the study.

Place, date	Signature of the participant

Declaration of the research nurse:

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I hereby declare that I have explained to the participant the nature, importance and scope of the project. I hereby declare that I meet all obligations in connection with this project in accordance with the applicable Swiss law. Should I become aware, at any time during the implementation of the project, of elements that could affect the participant's consent to take part in the project, I undertake to inform him/her immediately.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Written consent for reuse of data in coded form for future studies

BASEC number	
Title	
Participant : Printed full name: Date of Birth:	

I agree that my data obtained in this study may be used for medical research purposes. This consent is valid for an unlimited period of time.

I give my consent voluntarily and I can withdraw my consent at any time. If I withdraw my consent, my data will be made anonymous. I simply have to inform the study director and I do not have to justify my decision. I know that my data is stored in coded form and that the identification list is kept in a safe place. All legal provisions regarding data protection are respected.

As a rule, the data is evaluated in a comprehensive manner and the results are published in summary form. If the analysis of the data reveals a finding relevant to my health, the study director will contact me. If I do not wish to be informed, I am responsible for informing the study director. I waive all rights to commercial use of my data.

Place, date	Signature of the participant

Declaration of the research nurse: I hereby certify that I have explained to the participant the nature, importance and scope of the re-use of the data.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Centre hospitalier universitaire vaudois

PICSS-PF

INFORMATION SHEET AND CONSENT FORM FOR SIBLINGS WHO ARE LESS THAN 14 YEARS TO BE SIGNED BY PARENTS

Application for participation in a medical research project:

Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]

Dear Sir/Madam
We invite your child to participate in our research project.
Her/his participation is entirely voluntary. All data collected in this project are subject to strict data protection rules.
The research project is conducted by Institute of Higher Education and Research in Healthcare-IUFRS of the CHUV. We will send you the results if you wish.
During a meeting, we will present you the essential elements and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed information after.

Why are we conducting this research project?

- This study is performed, with the aim of understanding outcomes of Pediatric Intensive Care Unit (PICU) hospitalization in children and their family.
- The purpose of our research project is to determine how the physical, emotional, cognitive and social health of children and families change after PICU hospitalization, find children and families at risk, and factors that help them for better outcomes.

What my child should do if I accept she/he to participate?

- Form of participation: If you agree your child's participation in our project, we will send her/him questionnaires to be filled out.
- Procedure for participants: If your child participate in the project, she/her will be required to fill out 30 minutes questionnaires that we will sent her/him at the time of her sibiling PICU discharge, 1, 3, and 6 months after PICU discharge.

What are the benefits and risks of the participation in the project?

Benefits

- There will be no direct benefit to your child from your participation in this research project.
- By participating, you are helping future patients.

Risks and constrains

- There is no determined risk in this study.
- It is possible that the questionnaires, which concern your child well-being or PICU environment cause discomfort for a short time, if she/he experience psychological difficulties we will offer help that is already in place in the hospitals.
- This study does not pose any particular risk to you or your child.

By signing at the end of this document, you certify that you have understood the content and freely consent for your child to participate in the project.

Rahmaty Z, *et al. BMJ Open* 2023; 13:e076023. doi: 10.1136/bmjopen-2023-076023

Centre hospitalier universitaire vaudois

PICSS-PF

Detailed information

1. Purpose of the project and selection of participants

In this information sheet, our research project is also simply referred to as the project. If you agree that your child participate, your child is the participant in the project.
The purpose of this project is to determine how the physical, emotional, cognitive and social health of children and their families change after PICU hospitalization, find children and families at risk, and find factors that help them to have a better outcomes.
We are asking your child participation because participation is open to all siblings above 8 years old of the individuals who were hospitalized in PICU more than 48.

2. General information about the project

- The hospitalization in intensive care unit can have consequences for the health of patients and their families. We still know little about health outcomes in children and their families after PICU hospitalization in four domains of physical, emotional, cognitive and social.
- We are conducting this project to be able to better help children and their families after PICU discharge.
- If you accept that your child attend to participate, your child will be in this study up to 6 months after his/her sibling PICU discharge. We will send your child questionnaires related to their health and their caring behaviors.
- The total project duration will be 2 years. This project is a multicenter, national study and the approximate number of participants is around 500 individuals hospitalized in PICU, 500 parents and 300 siblings, and around 100 patient, 100 parents and 60 siblings from this hospital.
- This project is carried out in compliance with the requirements of Swiss legislation. In addition, we follow all internationally recognized guidelines. The competent ethics commission has examined and approved this project.

3. Project process

- We send questionnaires to your child [>8 years] to ask about their health and caring behaviors.
- The questionnaire will be sent to the email address or phone number provided based on families' preferences. These questionnaires will be available on an online platform and he/she will have access to them through a personal access available via a secure platform. If they wish, they can also fill out these questionnaires in paper format.
- The filling of questionnaire will take 30 minutes each time.
- The questionnaires need to be filled out in PICU, at the time of PICU discharge, as well as 1, 3 and 6 months after PICU discharge of their sibling.

4. Benefits

There will be no direct benefit for your child participation in the project, but the results of this research may be important for people with the same condition and their families in future.

5. Voluntary nature of participation and obligations

Your child participation is entirely voluntary. If you or your child choose not to participate, or if you choose to participate and change your mind during the course of the project, you will not be required to explain your decision. If your child chooses to participate in this research project, your child will be required to: follow the instructions and fulfill the requirements set forth in the research protocol to answer the questionnaires that will be sent to her/his.

6. Risks and limits

- There is no determined risk in this study.
- It is possible that the questionnaires, which concern your child well-being or PICU environment cause discomfort for a short time, if she/he experience psychological difficulties we will offer helps that are already in place in the hospitals.

- This study does not pose any particular risk to you or your child.

7. Alternatives

If you do not wish your child to participate in this research project, but remain open to the possibility of participation in other projects, please indicate this to the investigator.

8. Results

The project provides different results:
1. Individual outcomes that directly affect your child,
2. The final objective results of the project as a whole.

1. The investigator will inform you during the project of any important new findings about your child. You will be notified orally and in written form, and you will be able to decide again if you wish your child to continue participation in the project.
2. The investigator can send you a summary of the overall results at the end of the project.

9. Confidentiality of data

9.1. Data processing and coding

In the context of this research project, data about your child and her/his health are collected and processed, partly in an automated way. This information is coded at the time of collection. Coding means that all identifying data (name, date of birth, etc.) are replaced by a code. It is not possible to link the data to your child without the code, which remains permanently within the IUFRS, CHUV.

Only a limited number of people from IUFRS, CHUV can view your child data in uncoded form, and only in order to carry out tasks necessary for the project. These persons are bound by professional secrecy. As a legal guardian of the participant, you have the right to view your child data at any time.

9.2. Data and sample protection

All data protection guidelines are carefully enforced. It may be necessary for your child data to be transferred in coded form, e.g. for publication, and for the data to be available to other researchers. When health-related data are stored on-site, they may be made available to other researchers for use in publications: When health-related data are stored on-site, they form a data bank for research purposes.

9.3. Data protection in case of re-use

Your child data may later prove to be important for answering other questions and/or be sent to another database in Switzerland or abroad to be used in other research projects (re-use). This database must however comply with the same standards and requirements as the database of this project. For this reuse, we ask you to sign a separate consent form at the end of this information sheet. This second consent is independent of participation in the project.

9.4. Right of consultation in the event of inspections

The project may be subject to inspections. These may be carried out by the relevant ethics committee or by the sponsor who initiated the project. In such cases, the investigator must provide your child data for the purpose of such inspections. All people involved are bound by strict confidentiality.

10. Withdrawal of the project

You can withdraw your consent for your child participation from the project at any time if you wish. However, the medical data collected up to that point may still be analyzed in coded form.
In the event of withdrawal, your child's data will continue to appear in coded form in the project documents. You must therefore agree to this before giving your consent.

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11. Compensation

Your family will receive CHF 30 as a gift card/electronic voucher after completion of the questionnaires by all members of the family at each time point as a compensation for participation in this research project.
Your child's participation will have no financial consequences for you or your health insurance.

12. Liability

The University Hospital of Lausanne/CHUV initiated the research project and is responsible for its implementation and liable for any damage your child may suffer in connection with the project. The conditions and procedure are set by law.

13. Financement

This project is completely funded by Swiss Nursing Science Foundation (Stiftung Pflegewissenschaft) and ESICM (European Society of Intensive Care Medicine)

14. Interlocuteur(s)

You can ask questions about the project at any time. If you have any uncertainties during or after the project, you can contact:

The principal investigator for this study is Dr. Zahra Rahmaty who is conducting this study under the supervision of Prof Anne-Sylvie Ramelet at CHUV in Lausanne.
The local principal investigator helping with the study conduct at the CHUV is Dr. Marie-Hélène Perez who will answer your questions. You can also ask your questions from the main principal investigator.

Local Principal Investigator:

Main Principal Investigator:

Consent Statement

Written consent statement for participation in a research project
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required for your child to participate in the project.

BASEC number	
Title :	
Institution responsable	
Location :	
Responsible for the project on the site :	
Site of the Study:	
Participant : Last name and first name : Date of birth:	

For the legal guardian/parent to sign

- I declare that I have been informed orally and in writing by a member of the undersigned research team of the objectives and progress of the research project, as well as the possible advantages and disadvantages and the possible risks.
- My child participating in this project on a voluntary basis and accept the contents of the information sheet provided to me on the above-mentioned project. I have had sufficient time to make my decision.
- I have received answers to the questions I asked in relation to participation of my child in this project. I have kept the information sheet and have received a copy of my written consent.
- I agree that the competent specialists of the project management and the competent ethics commission may consult my child uncoded data for the purpose of checks and inspections, provided that the confidentiality of these data is strictly assured.
- Me and my child will be informed of the results that have a direct impact on her/his health. If we do not wish to receive this information, we will contact the investigator.
- I am aware that my child personal data, health data may be transmitted for research purposes within the scope of this project and only in coded form, except for the CHUV secure REDCap, where the first and family name, the preference of communication, and other data related to the conduct of the study will appear.
- I may revoke my consent for my child participation in the project at any time and without having to justify it, without this decision having any adverse impact on my child further care. However, the data and samples collected up to the time of withdrawal will be analysed as part of the project.
  I am aware that CHUV

Place, date	Signature of the legal guardian

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PICSS-PF

Declaration of the research nurse:
I hereby declare that I have explained to the participant and her/his legal guardian the nature, importance and scope of the project. I hereby declare that I meet all obligations in connection with this project in accordance with the applicable Swiss law. Should I become aware, at any time during the implementation of the project, of elements that could affect the participant's or her/his legal guardian's consent to take part in the project, I undertake to inform them immediately.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Written consent for reuse of data in coded form for future studies

BASEC number	
Title	Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]
Participant Printed full name: Date of Birth:	
Legal guardian/parent Printed full name: Date of Birth:	

For the legal guardian/parent
I agree that my child data obtained in this study may be used for medical research purposes. This consent is valid for an unlimited period of time.

I give my consent voluntarily and I can withdraw my consent at any time. If I withdraw my consent, my child data will be made anonymous. I simply have to inform the study director and I do not have to justify my decision. I know that my child data is stored in coded form and that the identification list is kept in a safe place. All legal provisions regarding data protection are respected.

As a rule, the data is evaluated in a comprehensive manner and the results are published in summary form. If the analysis of the data reveals a finding relevant to my child health, the study director will contact me. If I do not wish to be informed, I am responsible for informing the study director. I waive all rights to commercial use of my data.

Place, date	Signature of the legal guardian

Declaration of the research nurse: I hereby certify that I have explained to the participant and his/her legal guardian the nature, importance and scope of the re-use of the data.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

INFORMATION SHEET AND CONSENT FORM FOR SIBLINGS WHO ARE 11-14 YEARS TO BE SIGNED BY THE SIBLING

Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]

The research project is done by: IUFRS, l'Institut universitaire de formation et de recherche en soins of the CHUV.

Hello,

We invite you to participate in our research project.

1. What is this study and why it is done?

We want to know how the physical, and emotional health of children and their family are impacted and changes after hospitalization in the Pediatric Intensive Care Unit (PICU).

2. Why we contacted you?

We want to understand if your health has changed after your sibling's hospitalization in the PICU

Participation is open to any sibling of a PICU patient who is older than 8 and can complete our questionnaires.

3. What is next/what should you do?

- If you agree to participate in the study, we will ask you to answer questionnaires at different times: at the time of your sibling's discharge from the PICU, and then at 1 month, 3 months and 6 months following discharge from the PICU.
- These questionnaires will be available on an online platform and you will have access to them through a link that we send you. If you wish, it is also possible to fill out these questionnaires in paper format.
- The questions concern your physical and emotional health and your caring activity toward your sibling.
- It takes an estimated 30 minutes to complete the questionnaires.

4. What is the benefit of participating?

There is no direct benefit for you.

5. Do I have to participate?

Participation is free and voluntary: you and your parents can decide whether or not to participate. If you decide not to participate, the doctors and medical teams who care for your brother and sister will continue to do so. If you have agreed to participate in this study, but later change your mind, you can also do so at any time without any negative consequences for you or your brother and sister.

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PICSS-PF

6. Who can answer my questions?

If you have any questions during or after the study, you can contact the following person at any time.

The principal investigator for this study is Dr. Zahra Rahmaty who is conducting this study under the supervision of Prof Anne-Sylvie Ramelet at CHUV in Lausanne.
The local principal investigator helping with the study conduct at the CHUV is Dr. Marie-Hélène Perez who will answer your questions. You can also ask your questions from the main principal investigator.

Local Principal Investigator:

Main Principal Investigator:

Take the time to read this information and ask any questions you may have before you make your decision. If you and your parents agree to participate in this study, you and your parents can sign the consent form.

Centre hospitalier universitaire vaudois

PICSS-PF

Consent Statement

Written consent statement for participation in a research project
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required to participate in the project.

BASEC number	
Title :	
Institution responsable	
Location :	
Responsible for the project on the site :	
Site of the Study:	
Participant : Last name and first name : Date of birth:	
Legal guardian/ parent: Last name and first name : Date of birth:	

- I declare that I have been informed orally and in writing by the investigator about the study "Post-Intensive Care Syndrome in Swiss Pediatrics and their Families [PICSS-PF]".
- I have received satisfactory answers to the questions I asked related to participation in this study. I accept the content of the written patient information provided to me regarding the above-mentioned study.
- I am participating in this study on a voluntary basis. I may withdraw from this study at any time without having to provide any reason, or any consequences.
- I have had sufficient time to make our decision.
- I accept that the specialists of the CHUV, the authorities and the cantonal ethics commission may see the research data in order to carry out examinations and controls, if confidentiality is strictly assured.

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PICSS-PF

For patients capable of judgement under 14 years of age:

I certify that the informational interview has taken place and that my daughter/son capable of discretion has given consent to participate in the study and/or has shown no sign of opposition to such participation.

Place, Date	*Name, Family name, signature of the parent/ legal Guardian*
Place, Date	Name, Family name, signature of the patient

Certification by the research nurse:
I hereby certify that I have explained to the participant the nature, importance and scope of the re-use of the data.

Signature of the research nurse

Place, date	Name, family name and Signature of the research nurse

Centre hospitalier universitaire vaudois

PICSS-PF

INFORMATION SHEET AND CONSENT FORM FOR SIBLING WHO ARE ABOVE 14 YEARS TO BE SIGNED BY SIBLING

Post Intensive Care Syndrome in Swiss Pediatric and their Families [PICSS-PF]

Hello,
We invite you to participate in our research project.
Your participation is entirely voluntary. All data collected in this project are subject to strict data protection rules.
The research project is conducted by IUFRS, l'Institut universitaire de formation et de recherche en soins of the CHUV. We will send you the results if you wish.
During a meeting, we will present you the essential elements and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed information after.

Why are we conducting this research project?

- A hospitalization in pediatric intensive care unit (PICU) can have consequences for the health of patients and their families.
- This study is performed, with the aim of understanding outcomes of PICU hospitalization in children/ adolescence and their family .
- The purpose of our research project is to determine how the physical, emotional, cognitive and social health of children/ adolescence and families change after PICU hospitalization, find children/ adolescence and families at risk, and factors that help them for better outcomes.

What do I do if I accept to participate? – What happens to me if I participate?

- Form of participation: If you agree to participate in our project, you will be asked to answer some questionnaires at the PICU discharge time of your sibiling, and 1, 3, and 6 months post-PICU discharge.
- If you participate in the project, you will be required to fill out questionnaires regarding your health and caring behaviors which takes 30 minutes, at the time of discharge, 1, 3, and 6 months after PICU discharge.

What are the benefits and risks of the participation in the project?

Benefits

- There will be no direct benefit to you from your participation in this research project.
- By participating, you are helping future patients and their families.

Risks and constrains

- It is possible that the questionnaires, which concern your well-being or PICU environment cause discomfort for a short time, if you experience psychological difficulties we will offer you helps that are already in place in the hospitals.

By signing at the end of this document, you certify that you have understood the content and freely consent to participate in the project.

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Detailed information

1. Purpose of the project and selection of participants

In this information sheet, our research project is also simply referred to as the project. If you agree to take part, you are a participant in the project.

The purpose of this project is to determine how the physical, emotional, cognitive and social health of children/ adolescence and their families change after PICU hospitalization, find children/ adolescence and families at risk, and find factors that help them to have a better outcomes.

We are asking you to participate because participation is open to all siblings above 8 years old of the individuals who were hospitalized in PICU more than 48.

2. General information about the project

- We still know little about health outcomes in children/ adolescence and their families after PICU hospitalization in four domains of physical, emotional, cognitive and social. So we are doing this project to find out more about this topic to be able to better help children/ adolescence and their families after PICU discharge.
- If you accept to participate, you will be in this study up to 6 months after PICU discharge. We will send you questionnaires related to the four domains of health in PICU, at the time of PICU discharge, as well as 1, 3, and 6 months after PICU discharge of your sibling. The questionnaires will take 30 minutes to be completed.
- The whole results of this project will be ready in 2 years. This project is a multicenter, national study and the approximate number of participants is around 500 individuals hospitalized in PICU, 500 parents and 300 siblings, and almost 100 patient, 100 parents, and 60 sibling from this hospital.
- This project is carried out in compliance with the requirements of Swiss legislation. In addition, we follow all internationally recognized guidelines. The competent ethics commission has examined and approved this project.

3. Project process

We send questionnaires to you to ask about your health and caring behaviors.
The filling of questionnaire will take 30 minutes each time.
The questionnaires need to be filled, at the time of your sibling discharge from PICU, as well as 1, 3 and 6 months after PICU discharge.

4. Benefits

There will be no direct benefit for you and your participation in the project, but the results of this research may be important for people with the same condition and their families in future.

5. Voluntary nature of participation and obligations

Your participation is entirely voluntary. If you choose not to participate, or if you choose to participate and change your mind during the course of the project, you will not be required to explain your decision. This decision will not adversely affect anything related to you or your sibling.

If you choose to participate in this research project, you will be required to:

- Follow the instructions and fulfill the requirements of the research protocol set forth in the research protocol to answer the questionnaires that will be sent to you.

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6. Risks and limits

- There is no anticipated risk in this project.
- It is possible that the questionnaires, which concern your well-being cause discomfort for a short time, if you experience psychological difficulties we will offer you helps that are already in place in the hospitals.

7. Alternatives

If you do not wish to participate in this research project, but remain open to the possibility of participation in other projects, please indicate this to the investigator.

8. Results

The project provides different results:

1. Individual outcomes that directly is related to you.

2. The final objective results of the project as a whole.

1. The investigator will inform you during the project of any important new findings about you. You will be notified orally and in written form, and you will be able to decide again if you wish to continue your participation in the project.

2. The investigator can send you a summary of the overall results at the end of the project.

9. Confidentiality of data

9.1. Data processing and coding

In the context of this research project, data about you and your health are collected and processed, partly in an automated way. This information is coded at the time of data collection. Coding means that all identifying data (name, date of birth, etc.) are replaced by a code. It is not possible to link the data to you without the code, which remains permanently within the IUFRS/CHUV.

Only a limited number of people can view your data in uncoded form, and only in order to carry out tasks necessary for the project. These persons are bound by professional secrecy. As a participant, you have the right to view your data at any time.

9.2. Data and sample protection

All data protection guidelines are carefully enforced. It may be necessary for your data to be transferred in coded form, e.g. for publication, and for the data to be available to other researchers. When health-related data are stored on-site, they may be made available to other researchers for use in publications: When health-related data are stored on-site, they form a data bank for research purposes.

9.3. Data protection in case of re-use

In case of re-use of health data for other research projects: Your data may later prove to be important for answering other questions and/or be sent to another database in Switzerland or

abroad to be used in other research projects (re-use). This database must however comply with the same standards and requirements as the database of this project.

For this reuse, we ask you to sign a separate consent form at the end of this information sheet. This second consent is independent of participation in the project.

9.4. Right of consultation in the event of inspections

The project may be subject to inspections. These may be carried out by the relevant ethics committee or by the sponsor who initiated the project. In such cases, the investigator must provide your data for the purpose of such inspections. All people involved are bound by strict confidentiality.

10. Withdrawal of the project

You can withdraw from the project at any time if you wish. However, the medical data collected up to that point may still be analyzed in coded form.

In the event of withdrawal, your data will continue to appear in coded form in the project documents. You must therefore agree to this before giving your consent.

11. Compensation

Your family will receive CHF 30 as a gift card/Electronic Voucher after completion of the questionnaires by all members of the family at each time point as a compensation for participation in this research project.

Your participation will have no financial consequences for you or your health insurance.

12. Liability

The University Hospital of Lausanne/CHUV initiated the research project and is responsible for its implementation and liable for any damage you may suffer in connection with the project. The conditions and procedure are set by law.

13. Financement

This project is completely funded by Swiss Nursing Science Foundation (Stiftung Pflegewissenschaft) and ESICM (European Society of Intensive Care Medicine)

14. Interlocuteur(s)

You can ask questions about the project at any time. If you have any uncertainties during or after the project, you can contact:

The principal investigator for this study is Dr. Zahra Rahmaty who is conducting this study under the supervision of Prof Anne-Sylvie Ramelet at CHUV in Lausanne.
The local principal investigator helping with the study conduct at the CHUV is Dr. Marie-Hélène Perez who will answer your questions. You can also ask your questions from the main principal investigator.

Local Principal Investigator:

Main Principal Investigator:

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Consent Statement

Written consent statement for participation in a research project
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required to participate in the project.

BASEC number	
Title :	
Institution responsable	
Location :	
Responsible for the project on the site :	
Site of the Study:	
Participant : Last name and first name : Date of birth:	

- I declare that I have been informed orally and in writing by the research team of the objectives and progress of the research project, as well as the possible advantages and disadvantages and the possible risks.
- I am participating in this project on a voluntary basis and accept the contents of the information sheet provided to me on the above-mentioned project. I have had sufficient time to make my decision.
- I have received answers to the questions I asked in relation to participation in this project. I have kept the information sheet and have received a copy of my written consent.
- I agree that the competent specialists of the project management and the competent ethics commission may access my uncoded data for the purpose of checks and inspections, provided that the confidentiality of these data is strictly assured.
- I will be informed of the results that have a direct impact on my health. If I do not wish to receive this information, I will contact the investigator.
- I am aware that my child personal data, health data may be transmitted for research purposes within the scope of this project and only in coded form, except for the CHUV secure REDCap, where my first and family name, my preference of communication, and other data related to the conduct of the study will appear.
- I may revoke my consent to participate in the project at any time and without having to justify it, without this decision having any adverse impact on my further care. However, the data and samples collected up to the time of withdrawal will be analysed as part of the project.
- I am aware that CHUV is responsible for any damage caused by the project.
- I agree to be contacted again by members of the research team for future studies. It remains understood that I may revoke this permission at any time. If I do not agree, I may still participate in the study.

Place, date	Signature of the participant

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Declaration of the research nurse:
I hereby declare that I have explained to the participant the nature, importance and scope of the project. I hereby declare that I meet all obligations in connection with this project in accordance with the applicable Swiss law. Should I become aware, at any time during the implementation of the project, of elements that could affect the participant's consent to take part in the project, I undertake to inform him/her immediately.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Written consent for reuse of data in coded form for future studies

BASEC number	
Title	
Participant : Printed full name: Date of Birth:	

I agree that my data obtained in this study may be used for medical research purposes. This consent is valid for an unlimited period of time.
I give my consent voluntarily and I can withdraw my consent at any time. If I withdraw my consent, my data will be made anonymous. I simply have to inform the study director and I do not have to justify my decision. I know that my data is stored in coded form and that the identification list is kept in a safe place. All legal provisions regarding data protection are respected.
As a rule, the data is evaluated in a comprehensive manner and the results are published in summary form. If the analysis of the data reveals a finding relevant to my health, the study director will contact me. If I do not wish to be informed, I am responsible for informing the study director. I waive all rights to commercial use of my data.

Place, date	Signature of the participant

Declaration of the research nurse: I hereby certify that I have explained to the participant the nature, importance and scope of the re-use of the data.

Place, date	Last and first name of the research nurse at the local site Signature of the research nurse

Rahmaty Z, *et al. BMJ Open* 2023; 13:e076023. doi: 10.1136/bmjopen-2023-076023