Informed consent adult form
Information for the participant

**Title of the study:** “The Voice of Diabetes: A mixed-methods study on the needs of people living with type 1 diabetes and their caregivers to co-design a voice-based digital health solution to support diabetes distress management”

**Acronym:** PsyVoice

**Sponsor of the study:** Luxembourg Institute of Health

**Chief Scientific Investigator of the study:** Dr. Guy Fagherazzi, Director of Department of Precision Health (DoPH)

**Study assistant:** +352 26970-747 or contact.psyvoice@lih.lu

1 INTRODUCTION: ABOUT OUR STUDY

You are invited to take part in «PsyVoice».

«PsyVoice» is a study about what people living with type 1 diabetes think about new technologies, particularly those integrating vocal biomarker analysis.

Vocal biomarkers are components of the human voice, such as rhythm and pitch. Their analysis with artificial intelligence can be helpful to detect diseases and health risks.

The purpose of this document is to provide you with the information you might need to decide whether would like to participate in it. Your participation is entirely voluntary. If you choose to take part, you may withdraw at any time without having to give any reason.

This study is subject to the Luxembourgish law of 8th March 2018 on Hospitals (Art. 27).

This study was authorized by the Ministry of Health and approved by the National Research Ethics Committee on XX/XX/XX. However, you should not take this latter information as an incentive to participate in this study.

2 WHAT IS THE AIM OF PSYVOICE?

This study has the objective to explore the interests and worries of people living with type 1 diabetes concerning the development of voice-based technologies aiming to support diabetes management.

**Why voice-based technology?** New developments incorporating vocal analysis could become an inexpensive and easy-to-use option for detecting and monitoring small but important changes related to people’s health. In the case of people living with type 1 diabetes, it could detect a psychological factor called “diabetes distress”, a common symptom with a negative influence on the results of their diabetes treatments.
Why ask people about their opinions on this topic? Knowing the wishes, interests, and concerns of potential users, will help us to shape technology according to their real needs but also create resources that they are willing to use, a procedure known as co-design process.

For co-designing a voice-based technological solution for supporting diabetes management, we planned to invite 20 people to participate in our study. To be able to collaborate in our study, participants must be 13 years old or older and rather have a diabetes type 1 diagnosis or be in charge of caring for a minor with this diagnosis.

3 HOW YOUR PARTICIPATION DOES WORKS?

If you received this document, is because you have expressed your interest in participating in Psyvoice by contacting the research team. You might have been previously informed about this possibility through the diabetes association, by your doctor, or by seeing a flyer in a health center.

At the beginning of the study, you have been asked to provide information about yourself that may be relevant for planning the following steps of our journey together. For example, we requested your date of birth to make an approximation of your age. With this data, we can prepare the documents we would like you to read and answer, according to your age, as in the case of this information notice and its corresponding consent form. By reading and posteriorly signing this document, you are taking the first step to join our study.

Once we received the signed consent form, your participation is considered as confirmed. You will be then able to access some questionnaires to be filled out. We will also contact you again to arrange an appointment for a video call interview (we use a tool called WebEx), according to your availability.

The questionnaires we ask you to fill out are related to some of your personal characteristics (e.g. year or grade you are in at school), diabetes distress, and how familiar you are with some health concepts. You might need between 20 and 30 minutes to answer them. We recommend doing this before the interview.

During the interview, we will ask about your opinion and experiences related to the use of technology for managing diabetes and about your wishes and worries in relation to future inventions. This activity may require 50 and 70 minutes to be completed.

4 WHAT ARE WE GOING TO DO WITH THE INFORMATION YOU ARE GOING TO GIVE US?

You are invited to:

- Contribute with your participation in the two parts (questionnaires and interview) of this study and
- Allow the use of data you give us (with the exception of your direct identifying data) for future research.

If you give your consent for future research, by ticking the box provided for this purpose in the consent form that follows, this means that the LIH will be able to make your data available for use in other research projects conducted by the LIH.

The principles described in this document will also apply to any future studies. As these future studies may be conducted by a different team than the one involved in PsyVoice, keep in mind that:

- Information may not be available on these future studies and the people in charge of the study may be different and
• If you withdraw your consent in later stages, you will no longer be able to ask us to destroy the information already sent to other research teams.

Your data will only be used for studies that do not contradict the options you selected on the following informed consent form. In all cases, the teams receiving your data will not have access to any information that could make it possible to identify you.

5 WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN PSYVOICE?

There are risks associated with the fact that the study involves the recording of data online (e.g. hacking, which endangers the confidentiality of participants’ personal data). This risk is low but exists. The LIH has implemented extensive data protection measures to minimize this risk. These measures are explained in the section "Confidentiality and Protection of Personal Data”.

6 WHAT ARE THE BENEFITS OF TAKING PART IN PSYVOICE?

You will not benefit directly by taking part in this study. You will receive no form of compensation for your involvement. However, your participation is essential for the progress of diabetes research and the development of user-friendly technology dedicated to people living with diabetes.

7 CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

Please read the information document describing how we will process your personal data as part of this study (this document has been submitted by the person responsible for introducing you to the study).

8 COSTS ASSOCIATED WITH YOUR PARTICIPATION

If you decide to participate in this study, then there will be no additional cost to you or your insurer.

9 INSURANCE

The cyber insurance policy taken out by the Sponsor will cover its liability for a data breach involving sensitive information, such as personal data.

10 YOUR DECISION TO TAKE PART

Your decision to accept or decline to take part in this study will in no way influence the quality of the care you receive.

If you first choose to take part and later change your mind, you may withdraw at any time without giving a reason.

Before you take part in the study, you will need to provide your written consent by completing the form below. The LIH will keep an electronic copy of this document in a safe place. You will receive your own copy of the document. Should you have any questions about this study, you can contact a member of the study’s team at any time.

If you decide to take part in this observational study, we ask that you:
- Give your full cooperation throughout the study;
- Do not share details about the questionnaires and interviews with other potential participants.

If you would like to know more about Psyvoice, please contact the study assistant at +352 26970-747 or contact.psyvoice@lih.lu
Informed consent for parents of a minor participant (caregiver) form

Title of the study: "The Voice of Diabetes: A mixed-methods study on the needs of people living with type 1 diabetes and their caregivers to co-design a voice-based digital health solution to support diabetes distress management"

Acronym: PsyVoice

Sponsor of the study: Luxembourg Institute of Health

Chief Scientific Investigator of the study: Dr. Guy Fagherazzi, Director of Department of Precision Health (DoPH)

Study assistant: +352 26970-747 or contact.psyvoice@lih.lu

1 INTRODUCTION: ABOUT OUR STUDY

Your child is invited to take part in «PsyVoice».

«PsyVoice» is a study about what people living with type 1 diabetes think about new technologies, particularly those integrating vocal biomarker analysis.

Vocal biomarkers are components of the human voice, such as rhythm and pitch. Their analysis with artificial intelligence can be helpful to detect diseases and health risks.

The purpose of this document is to provide you with the information you might need to decide whether would allow the participation of your child. Participation is entirely voluntary. If your child takes part, he or she may withdraw at any time without having to give any reason.

This study is subject to the Luxembourgish law of 8th March 2018 on Hospitals (Art. 27).

This study was authorized by the Ministry of Health and approved by the National Research Ethics Committee on XX/XX/XX. However, you should not take this latter information as an incentive to participate in this study.

2 WHAT IS THE AIM OF PSYVOICE?

This study has the objective to explore the interests and worries of people living with type 1 diabetes concerning the development of voice-based technologies aiming to support diabetes management.

Why voice-based technology? New developments incorporating vocal analysis could become an inexpensive and easy-to-use option for detecting and monitoring small but important changes related to people’s health. In
the case of people living with type 1 diabetes, it could detect a psychological factor called “diabetes distress”, a common symptom with a negative influence on the results of their diabetes treatments.

Why ask people about their opinions on this topic? Knowing the wishes, interests, and concerns of potential users, will help us to shape technology according to their real needs but also create resources that they are willing to use, a procedure known as co-design process.

For co-designing a voice-based technological solution for supporting diabetes management, we planned to invite 20 people to participate in our study. To be able to collaborate in our study, participants must be 13 years old or older and rather have a diabetes type 1 diagnosis or be in charge of caring for a minor with this diagnosis.

3 HOW DOES THE PARTICIPATION OF YOUR CHILD WORKS?

If you received this document, is because you and your child have expressed interest in participating in Psyvoice by contacting the research team. You might have been previously informed about this possibility through the diabetes association, your child’s doctor, or by seeing a flyer in a health centre.

At the beginning of the study, your child has been asked to provide information about him or herself that may be relevant for planning the following steps of our journey together. For example, we requested your child’s date of birth to make an approximation of his or her age. With this data, we can prepare the documents we would like your child to read and answer, according to his or her age. By reading and posteriorly signing this document, you are taking the first step to join our study.

Once we receive the present consent form signed by the two legal representatives of your child and the assent form signed by your child, the participation of your child is considered as confirmed. Your child will be then able to access some questionnaires to be filled out. We will also contact your child again to arrange an appointment for a video call interview (we use a tool called WebEx), according to his or her availability.

The questionnaires we ask your child to fill out are related to some personal characteristics (e.g. year or grade your child is in at school), diabetes distress, and how familiar he or she is with some health concepts. Your child might need between 20 and 30 minutes to answer them. We recommend doing this before the interview.

During the interview, we will ask about your child’s opinion and experiences related to the use of technology for managing diabetes and about his or her wishes and worries in relation to future inventions. This activity may require 50 and 70 minutes to be completed.

4 WHAT ARE WE GOING TO DO WITH THE INFORMATION YOUR CHILD WILL GIVE US?

Your child is invited to:

- Contribute with his or her participation in the two parts (questionnaires and interview) of this study,
- Allow the use of data he or she gave us (with the exception of direct identifying data) for future research.

If you give your consent for future research, by ticking the box provided for this purpose in the consent form that follows, this means that the LIH will be able to make the data available for use in other research projects conducted by the LIH.
The principles described in this document will also apply to any future studies. As these future studies may be conducted by a different team than the one involved in PsyVoice, keep in mind that:

- Information may not be available on these future studies and the people in charge of the study may be different and
- If you withdraw your consent in later stages, you will no longer be able to ask us to destroy the information already sent to other research teams.

Data will only be used for studies that do not contradict the options you selected on the following informed consent form. In all cases, the teams receiving your data will not have access to any information that could make it possible to identify you.

5 WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN PSYVOICE?

There are risks associated with the fact that the study involves the recording of data online (e.g. hacking, which endangers the confidentiality of participants’ personal data). This risk is low but exists. The LIH has implemented extensive data protection measures to minimize this risk. These measures are explained in the section “Confidentiality and Protection of Personal Data”.

6 WHAT ARE THE BENEFITS OF TAKING PART IN PSYVOICE?

You and your child will not benefit directly by taking part in this study. You will receive no form of compensation for your involvement. However, your participation is essential for the progress of diabetes research and the development of user-friendly technology dedicated to people living with diabetes.

7 CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

Please read the information document describing how we will process your personal data as part of this study (this document has been submitted by the person responsible for introducing you to the study).

8 COSTS ASSOCIATED WITH YOUR PARTICIPATION

If you decide to allow your child to participate in this study, then there will be no additional cost to you or your insurer.

9 INSURANCE

The cyber insurance policy taken out by the Sponsor will cover its liability for a data breach involving sensitive information, such as the personal data of your child.

10 THE DECISION TO TAKE PART

Your decision to accept or decline your child’s participation in this study will in no way influence the quality of the care you or your child receive.

If you and your child first choose to take part and later change your minds, you may withdraw at any time without giving a reason.
Before your child takes part in the study, you will need to provide your written consent by completing the form below. The LIH will keep an electronic copy of this document in a safe place. You will receive your own copy of the document. Should you or your child have any questions about this study, you can contact a member of the study’s team at any time.

If you decide to take part in this observational study, we ask that you and your child:

- Give your full cooperation throughout the study;
- Do not share details about the questionnaires and interviews with other potential participants.

If you would like to know more about Psyvoice, please contact the study assistant at +352 26970-747 or contact.psyvoice@lih.lu
Informed consent form

- I declare that I am authorized to legally represent my child as a parent or legal guardian.
- I declare that I have read and understood the information provided above.
- I have had enough time to consider my child’s participation in the study and to discuss it with a person of my choice, such as the doctor or a member of my family.
- I have had the opportunity to ask all of the questions that have occurred to me in relation to the study and I have received satisfactory responses to each of them.
- I am aware of what is expected of my child as a participant in this study.
- I am aware that my participation in this study is entirely voluntary and that I and my child are free to withdraw at any time without giving a reason for my decision and without being held liable for any material or non-material damages. I will only need to inform the study assistant of the decision.
- I accept that the results from this study may be disclosed and reported in scientific publications. The way in which these results are presented will in no way enable my child to be identified, either directly or indirectly.
- As described in the information document on the processing of my child’s personal data as part of this study, I understand that any personal information gathered in relation to this study will be treated as strictly confidential, in accordance with the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 (known as the GDPR) and all subsequent texts replacing or supplementing this Regulation (in particular, Luxembourg’s law of 1 August 2018 on the organization of its National Commission for Data Protection and the implementation of the GDPR).
- I have received a copy of the present document, together with the information document explaining how my child’s personal data will be processed as part of this study.

In the table below, if you answer NO to any of the statements followed by an asterisk (*), your child will not be able to take part in PsyVoice, as these are essential to the study objectives.
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<th>agrees</th>
<th>NO</th>
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<tr>
<td>YES</td>
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</table>

| I willingly agree to my child’s participation in this study under the terms set out on the attached information sheet. (*) |
| First name and surname of parent (1) or legal representative: |
| ☐ | ☐ |

| I willingly agree to my child’s participation in this study under the terms set out on the attached information sheet. (*) |
| First name and surname of parent (2) or legal representative: |
| ☐ | ☐ |

| I agree with the secondary use of the pseudonymized data of my child for other biomedical research **in the same field**. |
| ☐ | ☐ |

| I agree to the secondary use of the pseudonymized data of my child **for any other biomedical research**. |
| ☐ | ☐ |

| I agree to be contacted again by the person leading the study with a view to taking part in another study. |
| ☐ | ☐ |

All documents informing possible and confirmed participants about the conditions of the PsyVoice study have been previously reviewed and approved by the **Chief Scientific Investigator**.
Consent withdrawal form

I, the undersigned, ..................................................... (insert your name) hereby confirm that .......................................................... (insert the patient’s / participant’s name) has withdrawn his/her consent to take part in this study.

Date signed (day/month/year): Signature:
Informed consent form

- I declare that I have read and understood the information provided above.
- I have had enough time to consider my participation in the study and to discuss it with a person of my choice, such as my doctor or a member of my family.
- I have had the opportunity to ask all of the questions that have occurred to me in relation to the study and I have received satisfactory responses to each of them.
- I am aware of what is expected of me as a participant in this study.
- I am aware that my participation in this study is entirely voluntary and that I am free to withdraw at any time without giving a reason for my decision and without being held liable for any material or non-material damages. I will only need to inform the study assistant of my decision.
- I accept that the results from this study may be disclosed and reported in scientific publications. The way in which these results are presented will in no way enable me to be identified, either directly or indirectly.
- As described in the information document on the processing of my personal data as part of this study, I understand that any personal information gathered in relation to this study will be treated as strictly confidential, in accordance with the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 (known as the GDPR) and all subsequent texts replacing or supplementing this Regulation (in particular, Luxembourg’s law of 1 August 2018 on the organization of its National Commission for Data Protection and the implementation of the GDPR).
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<table>
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<tr>
<td>I agree to the secondary use of my pseudonymized data for other biomedical research in the same field.</td>
<td>☐</td>
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<tr>
<td>I agree to the secondary use of my pseudonymized data for any other biomedical research.</td>
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Consent withdrawal form

I, the undersigned, ....................................................... (insert your name) hereby confirm that ................................................................. (insert the patient’s / participant’s name) has withdrawn his/her consent to take part in this study.

Date signed (day/month/year):      Signature:
1. INTRODUCTION AND AIMS OF THE STUDY

You are invited to take part in «PsyVoice».

«PsyVoice» is a study about what people living with type 1 diabetes think about new technologies, particularly those integrating vocal biomarker analysis.

Vocal biomarkers are components of the human voice, such as rhythm and pitch. Their analysis with artificial intelligence can be helpful to detect diseases and health risks.

This study has the objective to explore the interests and worries of people living with type 1 diabetes concerning the development of voice-based technologies aiming to support diabetes management.

Why voice-based technology? New technology using vocal biomarkers analysis could become a convenient and easy-to-use solution for monitoring people’s health. In the case of people living with type 1 diabetes, it could detect a psychological factor called “diabetes distress”.

Diabetes distress is when a person feels frustrated or overwhelmed by diabetes. It is a common symptom, but when it becomes persistent, it can have a negative influence on that person’s treatment for diabetes.

Why do we want to know your opinion on this topic? Knowing your wishes, interests, and concerns as a future user, will help us to shape technology according to the needs of people like you, and to create resources that they are willing to use (something called “co-designing”).

This document aims to explain what you need to do to participate in this study. Therefore, you should read this letter carefully before making your choice. At the end of this document, you will find a phone number and an
email address that you can call or write with your parents to ask any questions you might want to ask before making a decision.

Remember that your participation is entirely voluntary. If you first choose to take part and later you change your mind, you may withdraw at any time.

2. **HOW YOUR PARTICIPATION DOES WORKS?**

Your participation in this study is voluntary, which means that you can freely decide whether you want to participate in the study or not.

This study is divided into two parts:

First, we will ask you to fill out some questionnaires. The questionnaires we ask you to fill out are related to some of your personal characteristics (e.g. year or grade you are in at school), diabetes distress, and how familiar you are with some health concepts. It will probably take you between 20 and 30 minutes to answer them.

Second, once you already answered the questionnaires, we will have a video call interview (we use a tool called WebEx). During the interview, we will ask about your opinion and experiences related to the use of technology in general, but also for controlling diabetes. We will also ask about your wishes and worries in relation to future inventions. For completing this activity, we will expend between 50 and 70 minutes in the interview.

3. **WHAT ARE WE GOING TO DO WITH THE INFORMATION YOU ARE GOING TO GIVE US?**

You are invited to:

- contribute with your participation in the two parts (questionnaires and interview) of this study and
- to allow the use of data you give us (with the exception of your direct identifying data) for future studies.

If you give your consent for future studies, this means that we will be able to make your data available for use in other projects that we or our colleagues at the LiH will be carrying out. As these future studies may be conducted by a different team than the one involved in PsyVoice, keep in mind that:

- we don’t know yet what these future studies will be about or who will be in charge or involved in them.
- if you change your mind in later stages and ask us then to destroy the information you gave us, we might not be able anymore to destroy the information we already sent to other research teams.

Your data will only be used for studies that do not contradict the options you selected on the following informed consent form. In all cases, the teams receiving your data will not have access to any information that could make it possible to identify you.
4. **WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN PSYVOICE?**

There are risks associated with the fact that the study involves entering your data into an online platform (e.g. hacking, which endangers the confidentiality of participants’ personal data). This risk is minimal but exists.

It is always possible that someone is trying to steal this information. We do everything we can to ensure that this does not happen and if it might happen, your name will not be associated with the information you will give us. We will replace your name with a code.

5. **WHAT ARE THE BENEFITS OF TAKING PART IN PSYVOICE?**

You will not benefit directly by taking part in this study. You will receive no form of compensation for your involvement. However, your participation is essential for the progress of diabetes research and the development of user-friendly technology dedicated to people living with diabetes.

6. **CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA**

Please read the information document describing how we will process your personal data as part of this study (this document has been submitted by the person responsible for introducing you to the study).

7. **COSTS ASSOCIATED WITH YOUR PARTICIPATION**

If you decide to participate in this study, then there will be no additional cost to your parents or their insurer.

8. **INSURANCE**

The cyber insurance policy taken out by the LIH will cover its liability for a data breach involving sensitive information, such as personal data and health records.

9. **YOUR DECISION TO TAKE PART**

Your participation is voluntary. If you first choose to take part and later change your mind, you may withdraw at any time without giving a reason.

Before you take part in the study, you and your parents will need to provide written consent by completing the respective Informed consent forms. The LIH will keep an electronic copy of this document in a safe place. You will receive your own copy of the document. Should you have any questions about this study, you can contact a member of the study’s team at any time.

If you decide to take part in this observational study, we ask that you:

- Give your full cooperation throughout the study;
- Do not share details about the questionnaires and interviews with other potential participants.

If you have any questions, you can contact us at +352 26970-747 or contact.psyvoice@lih.lu
Informed consent form for participants from 13 years of age

- I declare that I read and understood the information about the PsyVoice study.
- I spoke to my parents and those responsible for this study, and they have answered all my questions.
- I know what my participation in this study implies.
- I understand that I can stop participating in this study at any time by notifying my parents and the research team.
- I agree:

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To participate in this study by filling out the study questionnaires and joining a WebEx video conference call

Date:

First name and surname of the participant:

All documents informing possible and confirmed participants about the conditions of the PsyVoice study have been previously reviewed and approved by the Chief Scientific Investigator.
Consent withdrawal form

I, the undersigned, ...................................................... (insert your name) hereby confirm that ............................................................... (insert patient’s / participant’s name) has withdrawn his/her consent to take part in this study.

Date signed (day/month/year): 

Signature: