

Appendix B: Participant information sheet and consent form for members of the optimization study
[parents, plain language November 2018]

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Contact person in your country: ... (name and telephone number of respective country PI)

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PARENTING FOR LIFELONG HEALTH 2-9 Information Sheet for Parents

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can quit the study at any time.**
- **Please take as much time as you need to make your choice.**

Why am I asked to be part in this research study?

We want to learn more about how well different versions of a parenting program work. We want to identify the optimal combination of different program components.

The name of the program is *Parenting for Lifelong Health for Young Children, PLH Children*. We are asking people like you who have a child aged 2 to 9 years to help us. A total of 864 parents will be part of the study, 288 in Macedonia. Many other parents have participated in this program in the past.

What if I don't understand something?

- This form may have words you don't understand. Research staff will read it with you, if you like.
- You may ask as many questions as you like before you decide whether you want to be in this study.
- You are free to ask questions at any time before, during, or after you are in the study.

What if I say yes, I want to be in this study?

We first will see if you fit into the study. Therefore, we will ask some questions about your child.

To be part of the study, you need to be a parent or caregiver of a child between the ages of 2 and 9 years whose behavior you are having challenges with. You also have to agree to participate in the parenting program and provide consent in the full study.

If you qualify, we will do these things

- ask about your life, your feelings and your relationship with your child
- read the questions out loud and enter your answers in this electronic tablet
- let you listen to questions by an audio record
- give you a brief form with questions about adverse events in the last week/the last two weeks



- let you skip any question you do not want to answer
- The last section of the interview will be audio recorded but only for parents with a child aged 6 years or older. This is to document how the interviewer is performing and to determine the quality of data collection. If you do not want to be audio recorded, please tell us and we will not record this section.
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This will take about 60 minutes.

- We will ask you to participate in the parenting program. The program wants to improve relationships between parents and children. Parents also learn strategies how to deal with their children in challenging situations.
- The program will take place in groups with other families. Two people will deliver the program in community centers / university clinics. Your child will not attend the groups but childcare will be provided if you need it in order to attend the group.
- Before, you will have an individual meeting with your group leader. This person will explain the program in detail to you. During the parent groups, you will do activities and also practice at home. You will only have to do the activities if you wish to.
- During the program, we will use a video to document how well the program is delivered by the facilitators. Further, we will use these videos for our training in order to improve the skills of the facilitators. If you do not want to be in the video, please tell us. We will make sure that you are not in the view of the video camera.
- There are different program activities which might be helpful. In order to have a closer look what works best with families like yours, there will be a randomization process. Randomization means that we will put you into one of the activities by chance. Importantly, you will be in the parenting program, no matter to which group you are assigned.
- We will contact you again after completion of the program. We will ask you the same questions that we will ask you at the beginning. This will take about 60 minutes.
- We will then contact you about 3 months later to ask you the same questions for the last time (approximately 60 minutes). All the interviews will take place at a community center / university clinic, you can decide.
- If you are currently in a relationship, we will also invite your partner/spouse to participate in the study, but they are not required to participate for you to be part of this study.

What if I say no, I do not want to be in this study?

- Nothing bad will happen.

What happens if I say yes, but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen.
- You do not have to give any reasons.
- If you wish to be taken out of the study, please contact ... (*enter address of respective country PI*).

Who will see the information about me that is collected?

- We will store all of your research records in locked cabinets and secure computer files. Only the research team has access. We will take your name off of any information where this is possible.
- Personal identifying information needed for research purposes (e.g., videos) will be kept for 10 years, after which it will be destroyed. Identifying information such as your name and contact details be destroyed at the end of the study unless you agreed to be contacted in the future in which case we will only keep your name and contact details.
- We will keep all your anonymized as well as personal information confidential as provided by law. The only exception is any risk of possible harm to you or others. If a child is harmed or is

at risk for harm, the research team will consult with one another and decide on the best course of action in line with international UNICEF Child protection standards and the Child Protection standards and Policies in your country.

- We will share our study results via the Internet and an open database. Your name or address or other personal identifying information will not appear.
- We will share the results of the study in academic journals, research reports and at conferences. We will take off your name or any other identifying information.
- After the study is finished, you can see the results of the study on our website www.rise-plh.eu.

Will it cost me anything to be in the study?

The study will not cost you anything.

Will I be paid?

You will be receiving a food/gift voucher (approximately 5€) after the end of each interview. If you do not miss more than one group session, we will give you an award of worth approximately 3 Euros.

Will being in this study help me in any way?

- You can participate in the parenting program for free.
- Being in the study may or may not help you, but may help other parents to have a better relationship with their child in the future.
- We do not know whether being in the study and the program activities specifically will help you individually but we do know that the program activities have helped many other parents like you throughout the world.

What are the risks of being in this study?

- The risks of this study are no more than what happens in everyday life.
- The questions we will ask may make you feel sad, upset or uncomfortable. We will be happy to help you. In that case, we can refer you to support services.

What if I have questions?

- Please call the local head researcher of the study ... (*enter name and telephone number of respective country PI*) if you
 - ✓ have any questions about this study
 - ✓ have questions about your rights
 - ✓ feel you have been injured in any way by being in this study

You can also call the office that supervises research (*add name and contact details chair of the local Human Research Ethics Commission*) if you

- ✓ have questions about this study
- ✓ have questions about your rights
- ✓ can't reach the study team
- ✓ need to speak to someone not directly involved with this study

What should I do if I want to be in the study?

- ✓ Sign this form.
- ✓ You can wait up to 7 days to decide whether you want to be in the study or not.
- ✓ We will give you a copy of this form to keep.



Consent Form for Parents in the Optimization Study

By agreeing to the project, I am saying

- I understand that joining this study is voluntary.
- I agree to be in the study.
- Someone talked with me about the information in this document and answered all my questions.
- I understand that the information I provide (without any identifying information) may be combined with other families' experiences of similar programs from other countries so that we can understand how they work across the world.

I know that:

- I can stop any and all parts of the study at any time and nothing bad will happen to me.
- I can call the office that supervises research (*name and contact details chair of the local Human Research Ethics Commission*) if I have any questions about the study or about my rights.
- I do not give up any of my rights by signing this form.

Date: _____

Yes, I agree

No, I do not agree

We would like to ask for your permission to contact you in the future to participate in other studies. Would you be willing to be contacted in the future (if you cross "yes" we will keep your name and address in separate files to allow contacting you in the future)?

Yes

No