

# **PARENT/LEGAL GUARDIAN INFORMATION SHEET**

## **Study title - Childhood Immunity Study**

Study Duration – 5 months

We would like to invite you and your child to take part in our research study. Before you decide whether to participate or not, we would like you to understand why the research is being done and what it will involve.

Please go through this information and don't hesitate to email (info@ingredients4life.co.uk) or call us (Tel: +44 7948 352008) to ask any questions you may have.

You may talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you and your child if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please take time to decide whether or not you want your child to take part.

## **Part 1 – to give you first thoughts about the project**

### **1. What is the purpose of the study?**

The purpose of our study is to see if a liquid nutritional supplement called Imunoglukan P4H® containing beta-glucan from Oyster mushrooms can help strengthen children's immune systems and reduce the number of coughs and colds they get. We want to find out if taking this supplement regularly can lead to fewer respiratory infections in children aged 4 to 11 years, helping them stay healthier and enjoy their daily activities more.

### **2. Why have we been chosen?**

Your child has been chosen because they often get respiratory infections like coughs, colds, earaches, or sore throats. For 4–6-year-olds, this means having 6 or more of these infections in a year. For 7–11-year-olds, it's 3 or more in a year. We're looking for children aged 4 to 11 who get sick more often than most children their age. We hope to have 140 children in this study from across the UK and Ireland.

### **3. Do we have to take part?**

No, taking part is completely voluntary. It's up to you and your child to decide if you want to join the study. We've provided this information to help you make that choice. If you're interested in participating, you will find a consent form on the study app after downloading and signing up on the app. You can click 'Yes' or 'No' to indicate your decision. Your child will also have their own section where they can click 'Yes' or 'No' to

show if they want to take part. You will be able to select if you want your consent choices sent to you via email for your records. Remember, even if you say yes now, you're free to change your mind and stop participating at any time without giving any reason and without penalty.

#### **4. What will happen to my child if we agree to take part and what will we have to do?**

If you agree to participate in the study, you will be required to download a free mobile App called "Ingredients for Life™" which works well on both Apple and Android phones and sign up as the entire study will be conducted via the app. The study involves two phases for a period of 5 months. In the first phase (8 weeks), you will only be required to complete wellness check-ins twice a week on behalf of your child and answer additional questions if your child is unwell. It is required that you log your child's symptoms on the app as soon as you notice them, not only on the day of the check-in. Your child will not be required to take any supplement during this phase.

In the next phase, you will be sent a 12-week supply of Imunoglukan P4H®. During this period, your child will need to take the supplement once a day at a dosage of 1 ml per 5 kg of body weight, and at an increased dosage of 2 ml per kg of body weight during periods of increased need, such as illness. As a parent or guardian, you will continue completing wellness check-ins twice a week and responding to further questions if your child becomes unwell. In addition, you will be responsible for administering the supplement to your child daily for 12 weeks and confirming the daily administration by logging it in the app.

At the end of the study, you will complete a final questionnaire about your child's health and quality of life. The study is conducted entirely through the app, so there are no clinic visits required, and you won't need to provide photos or videos of your child. There are no restrictions on your child's activities or diet; just continue any prescribed medications as usual. Participation is voluntary, and everything can be done from home.

NB: Please continue to administer any prescribed medication (e.g. Asthma medication) that your child might be taking.

#### **5. Will there be any reward for participating?**

As a thank you for participating in the study, all eligible participants who maintain at least 70% app engagement by the end of each study phase will qualify for rewards. At the end of Phase 1, one participant will win a £500 Selfridges voucher, and ten participants will each receive a £50 M&S Food voucher. In addition, all eligible participants will enjoy a 25% discount on elénzia products. During Phase 2, one participant will win a £1000 Virgin Experience Days voucher, while ten participants can choose to receive either a £100 John Lewis voucher or a five-month supply of Imunoglukan P4H®. Furthermore, all participants who achieve 70% or higher app engagement in Phase 2 will receive a £15 Uber Eats voucher. We encourage you to stay actively engaged with the app throughout the study to maximize your chances of earning these exciting rewards. All rewards will be sent to qualified participants at the end of each study phase. If you encounter any problems with the app, our support team is available to assist you.

## 6. **What does App engagement mean?**

App engagement refers to how regularly and actively you use the study app to complete required tasks. Specifically, this means logging wellness check-ins twice a week on behalf of your child and answering additional questions whenever your child is unwell. During the supplement phase, it also includes confirming daily administration of the supplement in the app. App engagement is measured by these consistent user actions—opening the app, completing symptom entries, and confirming supplement intake as instructed. Maintaining a certain level of engagement (typically at least 70%) throughout each study phase is essential to qualify for rewards and to help ensure accurate and meaningful data collection for the study.

## 7. **What are the possible disadvantages and risks of taking part?**

Participating in the study will require about 30 seconds of your time bi-weekly and at least 5 minutes of your time in periods when your child is unwell, primarily through the mobile app. Some parents may find interacting with the app especially when their child is unwell distressing or overwhelming. If at any point you feel overwhelmed or distressed, you can come back to the app the next day to answer the previous day's questions. It is important to note that Imunoglukan P4H® is generally safe but, like all supplements, carries a small risk of unexpected reactions such as mild stomach discomfort, nausea, mild allergic reactions (e.g. skin itching or rash) which are very rare. However, contact us immediately (Email: [info@ingredients4life.co.uk](mailto:info@ingredients4life.co.uk), Tel: +44 7948 352008) with any concerns about your child's well-being. We're committed to promptly addressing any issues that arise.

## 8. **What are the possible benefits of taking part?**

While your child **may or may not** experience direct benefits from taking part, the information we gather could contribute to advancements in healthcare that benefit other children facing similar health challenges. By joining the study, you are helping us learn more about childhood immunity, which can lead to better strategies for preventing and managing respiratory illnesses in children.

## 9. **What are the side effects of the treatment?**

Imunoglukan P4H® is generally well-tolerated, and no significant adverse effects have been reported in previous studies. Over 20 million bottles have been sold already in 36 countries across Europe and Canada, excluding the UK. Most users do not experience any side effects. However, some mild side effects may occur, such as stomach upset or minor allergic reactions, although these are rare. If you are concerned that your child might need treatment, please contact your usual healthcare provider or other appropriate service and then notify us at the earliest opportunity. Overall, Imunoglukan P4H® is considered safe for children and can be used alongside other medications. If any health issues arise while your child is taking the supplement, please contact us immediately via the email provided.

## 10. **What happens when the research study stops?**

When the 5-month study period ends, we will gather all the information collected through the app and analyse it carefully. Our team of researchers will examine the data to determine if Imunoglukan P4H® has been effective in strengthening children's immune systems and reducing the frequency of respiratory infections. After our analysis

is complete, we will share individual and overall findings of the study with all participants. This will give you an insight into how your child may have benefited from supplementation. Remember, all personal information will remain confidential, and only anonymized, group-level results will be reported.

**11. What if there is a problem?**

If you or your child experience any issues or have concerns during the study, we are here to help. Any complaints regarding your experience or any potential harm will be taken seriously and addressed promptly. Detailed information on how to report concerns and the steps we will take to resolve them can be found in Part 2 of this document. Your feedback is important to us, and we are committed to ensuring a positive experience for all participants.

**12. Will my child's taking part in the research project be kept confidential?**

Yes, your child's participation in the study will be kept completely confidential. We are committed to following ethical and legal guidelines to ensure that all information related to your child is handled with the utmost care and privacy. For more detailed information about how we protect your child's data, please refer to Part 2 of this document. Your trust is important to us, and we take confidentiality very seriously.

**13. Contact for further information**

If you would like any further information about this study, please contact:

Name: Godsfavour Oghifo  
Designation: Lead Researcher  
Department: elénzia MEDICAL Nutrition  
Tel: +44 7948 352008  
Email: info@ingredients4life.co.uk

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

**Part 2 - more detail – information you need to know if you still want to take part.**

**14. What if new information becomes available?**

During the study, it's possible that new information may come to light through our ongoing research or from other scientific studies. This new information could potentially affect how we understand the effects of Imunoglukan P4H® on childhood immunity or how we interpret the data we're collecting. If such information becomes available, a member of our research team will inform you promptly. We'll explain what the new information means and discuss any potential impact it might have on your child's participation in the study. This new information won't affect your child's place in the study. However, if you feel uncomfortable continuing based on this new information, you're free to withdraw at any time without any negative consequences. If you choose to continue participating after learning about the new information, we may ask you to sign an updated consent form to confirm your ongoing agreement. Remember, your child's

well-being is our top priority, and we're committed to keeping you fully informed throughout the study.

**15. What will happen if we don't want to carry on with the study?**

You have the right to withdraw from the study at any point in time and all participant information will be destroyed within 28 days of the request.

**16. What if there is a problem?**

**Complaints**

If you have a concern about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

Name: Godsfavour Oghifo  
Designation: Lead Researcher  
Department: elénzia MEDICAL Nutrition  
Tel: +44 7948 352008  
Email: info@ingredients4life.co.uk

**Harm**

While we prioritize participant safety, if your child is harmed due to our negligence during the study, you may have grounds for legal action. Imunoglukan P4H® is generally safe but, like all supplements, carries a small risk of unexpected reactions. Contact us immediately with any concerns about your child's well-being. We're committed to promptly addressing any issues that arise.

**Compensation**

In the event of your child developing an adverse reaction, side effect or complication because of your participation in the study, elénzia MEDICAL has a responsibility to ensure the adverse event is managed properly and resolved satisfactorily. If required agreed costs of medical treatment will be provided and you will be appropriately compensated for any adverse reaction, side effect or complication which is a direct result of your child's participation in this study. In this unlikely event, compensation will be paid on a "no-fault basis".

**17. Will taking part in this study be kept confidential?**

All information which is collected about you or your child during the study will be kept strictly confidential. As participants will be included from outside the UK (Ireland), we may share data about you outside the UK for research related purposes with GPs, pharmacists, and other healthcare providers in both the UK and Ireland. Any information about your child which leaves elénzia MEDICAL will have their name and address removed so that your child cannot be recognised from it. Once the study is complete all personal information will be kept for a maximum of 180 days.

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 2018 and GDPR.

**18. What will happen to the results of the research study?**

When the study has finished, we will present our findings to pharmacists and other healthcare providers. We would also like to put a summary on our elénzia MEDICAL website so that you will be able to read about our results too. This will be available at the end of the study, in June 2026 (<https://medical.elenzia.com>). All results published will be anonymised and will not contain any information regarding your child's identity.

**19. Who is organising and funding the research?**

Researchers at elénzia MEDICAL oversee the research and it is fully funded by elénzia MEDICAL. elénzia MEDICAL is dedicated to improving health through scientifically proven, natural solutions. Partnering with leading experts, we aim to reduce the burden of RRTIs, improve children's well-being, and make a real difference in families' lives.

**20. Who has reviewed the study?**

This research study has been reviewed by Reading Independent Ethics Committee, an independent group concerned with welfare and safety of study participants. The Committee was content to give a favourable approval for the study to be conducted by elénzia MEDICAL.

**21. How can we find out more about the study?**

More information about taking part in the study can be found at:  
<https://medical.elenzia.com>

If you and your child decide to take part in this study, you will both be required to give your consent on the study App and you will be able to download the signed consent and assent forms from the app to keep.

Thank you for taking the time to read this information sheet.

Please feel free to go ahead and download the study app (Ingredients for Life™).

