

## **PARTICIPANT INFORMATION SHEET AND CONSENT FORM FOR CHILDREN AGED 10-17 YEARS**

### **Determining the effectiveness of Sambucol in reducing the duration and symptoms of the common cold in children and teens**

#### **Investigators:**

Emeritus Professor Stephen Myers (Principal Investigator & Director NatMed Research)<sup>1,2,3</sup>, Professor Con Stough (Investigator)<sup>4</sup>, Justine Lomas (Research assistant)<sup>3</sup> & Shelley Robinson (Trial Coordinator)<sup>1,3</sup>

<sup>1</sup>*Southern Cross University*, <sup>2</sup>*Western Sydney University*, <sup>3</sup>*NatMed Research*, <sup>4</sup>*Metavate*

**Study site:** Tele trial with supervising site in Evans Heads, NSW

This letter tells you about the research project. Please read it carefully. If the words are too tricky, ask a grown up to help you.

Knowing all about the study will help you decide if you want to be in it or not. Ask questions about anything that you are not sure of. Before choosing if you want to take part, you should talk about it with your parent or guardian. Taking part in this study is your choice. If you don't want to take part, you don't have to. If you do want to take part in the study, you will be asked to sign the Consent Form.

By signing it you are telling us that you:

- understand what you have read
- give your permission to take part in the research project
- give your permission to have the tests and treatments that are described
- give your permission for your personal and health information to be used as described.

A copy of this letter will be sent in an email to your parent for you to keep.

#### **What this project is about?**

Sambucol® Black Elderberry Cold & Flu is made from elderberry juice. This study is testing if it is useful for children and teens with cold and flu symptoms or not.

If it does help, we also want to know more about how it does, like which symptoms it works on.

#### **Why am I being asked to be in this study?**

We are inviting you because you have signs of cold and/or flu and are taking Sambucol® Black Elderberry Cold & Flu.

#### **What will I have to do?**

If you decide you want to take part, we will ask you to help your parent or guardian to do a daily survey on their phone. The questions in the survey will ask about how you feel each day, your general health, and what medicines you take. Here are some examples of the questions asked:

- *“How many children are there in your family?”*
- *“Do you have a headache today?”*
- *“Since yesterday, have you taken any other medications for your cold symptoms?”*
- *“Compared to yesterday how is your cold?”*

There is no time limit for answering the questions, but we think it will take 10-15 minutes to answer them all.

The number of days you are in the study will depend on how long you are having symptoms of cold and flu. We are asking people in the study to complete a survey at the same time every day until they feel better. We think this will be between 2 and 15 days in total, but it will depend on your own case.

To remind you to complete the survey each day, the study app will send you a prompt so that you don't forget.

We will need a parent to give permission for you to take part in the study, but the choice to take part is up to you. Even if your parent/guardian says it's ok to take part in the study you do not have to do it.

### **Medical care**

If you are feeling unwell, or start to feel worse, you should visit your doctor for a check-up.

### **Risks and discomforts**

Sambucol is safe for people to drink. Sometimes, people can have tummy upsets like nausea, vomiting or diarrhea. This doesn't happen often.

If you become sick or hurt, please tell your parents right away who can also help you to contact your study doctor. The doctor will give you information about what to do and will also tell the trial Sponsor. In the case of an emergency, call emergency services on 000.

### **Possible benefits**

We cannot promise that you will get any personal benefits from this study. We hope the results will help to better inform people who take Sambucol® Black Elderberry Cold & Flu in the future.

### **Alternatives to taking part**

You don't have to take part in this study. You won't be treated differently, whatever you do.

You can still take Sambucol Black Elderberry Cold & Flu for your cold and flu symptoms without taking part in this study.

### **Your right to withdraw consent**

You do not have to take part in the study if you don't want to. You won't be treated differently, whatever you do. If you start the study, you can stop whenever you like. You do not have to say why you want to stop and there won't be any consequences for you or your parent/guardian.

### **Privacy & Confidentiality**

If you do this study, your answers will be kept secret. Only the researchers for this study will see your answers and they won't let anyone else see them. When your answers are finished, the researchers will delete your name and other personal details and put random numbers there instead. This helps to keep your answers secret while we do the study.

### **Who is funding this research?**

Pharmacare is an Australian Registered company who makes Sambucol® Black Elderberry Cold & Flu and has provided the money to run this study. There is no cost to you to take part in the study.

### **Participant Compensation**

To repay participants for their time and effort in participating in this study, parent/guardians will be given a \$50 Westfield voucher and one bottle of Sambucol® Black Elderberry Cold & Flu .

### **Researcher interests**

Researchers have been paid by Pharmacare to run this study. Professor Myers is the Director of NatMed Research and primary supervisor of the study. The researchers are committed to make sure the study is run properly and fairly.

### **What happens if I am injured during the project?**

In the unlikely event that you have an injury because of this project, the public health service will give you hospital care and treatment at no cost to you if you are eligible for Medicare and elect to be treated as a public patient.

If applicable, you will be able to seek payment if you are injured because of this study. This can happen either by going to the study Sponsor or through the courts. You should ask for advice from a lawyer before seeking compensation for injury.

### **Ending the study early**

This project may be stopped for a variety of reasons such as:

- Unacceptable side effects,
- Sambucol® Black Elderberry Cold & Flu being shown not to work,
- Sambucol® Black Elderberry Cold & Flu being shown to work and not need further research.

### **New information during the project**

During the study, new information about the risks and benefits of the project may be found. If this happens, you will be told about this new information. New details could mean that you should stop the study. If this occurs, the person(s) supervising the research will stop your participation.

### **Sharing study results**

The researchers will share what they learned from this study by writing articles, giving talks, and sending reports. The researchers will only share group results so that you will not be named.

### **Further information about the project – who to contact**

If you have any questions or would like any more information about this study you can contact:

Name: Shelley Robinson

Role: Trial coordination

Telephone: 0475 247 721

Email: [sambucol@natmedresearch.com.au](mailto:sambucol@natmedresearch.com.au)

Name: Prof Stephen Myers

Role: Principal Investigator

Email:

[stephen.myers@natmedresearch.com.au](mailto:stephen.myers@natmedresearch.com.au)

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the *National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates*.

This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact:

Operations Manager, Bellberry Limited on **08 8361 3222**.

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I consent to take part in the project named above. I have read the project information letter, Version 1, dated 02.09.22, which fully explains how long the study will take, what I will be asked to do and any possible discomforts that might be expected. Any questions I have asked have been answered to my satisfaction.

***By clicking "YES" at the bottom of this page you will provide informed consent, meaning you agree:***

- (a) to participate in the study according to the project information letter, including to complete daily surveys about the way you feel from day to day, your general health, and what medicines you take each day while you have symptoms of cold and flu.
- (b) that your participation is voluntary and that you are free to withdraw from the project at any time without explanation. If you decide to withdraw from the study, you agree that the information collected about you up to the point when you withdraw may continue to be processed.
- (c) that the study is for the purpose of research and may not benefit you directly;
- (d) that any identifiable information about you which is gathered during and as the result of participating in this project will be
  - (i) collected and held for the purpose of this study; and
  - (ii) accessed and analysed by the researcher(s) for the purpose of conducting this project; and
  - (iii) accessed for quality assurance, auditing and in the event of a serious adverse event and you consent to this access
- (e) your privacy is preserved, and you will not be identified in publications or otherwise without your express written permission.

Do you agree to participate in this project?  YES  NO