

PARENT PERMISSION/CONSENT FORM

[For Camp Participants]

PLASMA: Peer-Led Asthma Self-Management for Adolescents
Principal Investigator: Hyekyun Rhee, PhD, PNP

This permission/consent form describes a research study, what you may expect if you and your teen decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate and let your teen participate or at any time. You may take this permission form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you or your teen can change your mind and stop at any time.
- If you choose not to take part, your teen’s routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you and your teen.

Introduction

This form describes a research study and what to expect if you decide to participate and allow your son or daughter to participate. You and your teen are being asked to participate because your teen is between the ages of 12-17 and has been diagnosed with asthma. This study is being conducted by Dr. Hyekyun Rhee of the University of Rochester's School of Nursing.

Purpose of Study

The purpose of this study is to compare two types of asthma self-management programs that we designed specifically for teens. Healthcare professionals will lead one program, and teen peer leaders will lead the other. Asthma is common chronic disease in teens. Many teens have not had a chance to learn how to self-manage their asthma effectively. So, we designed these programs to help teens manage their asthma better.

Description of Study Procedures

If you decide to participate and have your teen take part in this study, you/your teen will expect the following:

1. You will provide demographic information about yourself and your teen, and any asthma related questions such as medications, devices (e.g., nebulizer, spacer, etc.), and family history of asthma, at enrollment. Then, we will contact you every 3 months to collect information about your teen’s healthcare use/costs related to asthma care,

2. Your teen will fill out a set of seven questionnaires, at enrollment, and after camp at 3-, 6-, 9-, 12- and 15-months later. The questionnaires will ask about your teen's asthma symptoms and medications, asthma-related knowledge/skills, how asthma affects your life, and how she/he deals with asthma on an everyday basis. It will take about 20-25 minutes to complete the set of questionnaires. The questionnaires will be completed online for all the assessment points, except for the assessment at the camp in which paper-pencil questionnaires will be used instead. If your teen does not have access to a computer with Internet capability either at home or at school, a study nurse will meet with your teen in the study office or at home.
3. At the camp, we will draw small amount of blood (about 7mls) from your teen's forearm to see if his/her asthma is related to any allergy.
4. Your teen will be assigned by the luck of draw to attend a one-day camp either run by healthcare professionals or peer leaders. At camp, your teen will participate in a structured asthma self-management training program with other teens with asthma. In addition to the instructional activities, your teen will engage in recreational activities offered at the camp.
5. After camp, your teen will receive bimonthly contacts from either a research assistant or a peer leader depending on the type of camp your teen participated. For the bimonthly contacts, your teen will choose how he/she would like to be contacted (e.g., telephones, emails or text messaging).
6. Your teen will be asked to measure and record peak flow rates twice a day (morning and evening) during study participation using a peak flow meter that the study team will provide.
7. We will also assess your teen's lung function using spirometer, a machine into which your teen will breathe. The spirometry test will be done twice, at camp and 15-month after camp (final assessment point).
8. With permission we will review your teen's medical record or insurance/Medicaid data for asthma-related medications and healthcare services that he/she used between 3 months before enrollment and 3 months after completion of the 15-month follow-up.

Number of Subjects

Approximately 378 teens and their parents from 3 study centers in 3 states across the East Coast will take part in this research.

Duration of the Study

Your teen's participation in this study will last for 18 months (3 months before camp plus 15 months after camp). Each time your teen fills out questionnaires, it should take about 20-25 minutes. The camp will last one full day. Your teen will expect follow-up contacts every other month after camp. Each follow-up contact should take about 10-15 minutes.

Risks of Participation

This study involves minimal risk. This study is not invasive and your teen's current asthma treatment will not change. Your teen might get bored or physically and mentally tired filling out the questionnaires or participating in full-day instructional activities at camp. Your teen will be allowed to take breaks whenever needed. Your teen may experience temporal anxiety and discomfort/pain associated with blood draw. Blood drawing will be done by a skilled phlebotomist to minimize discomfort. If your teen expresses excessive anxiety, she or he can opt out of blood drawing. There may be a possibility that your teen would get a minor physical injury during recreational activities at camp. A number of adults will be present at the camp to

provide assistance and supervision for every activity and to ensure campers' safety. Also, there will be first-aid supplies and a healthcare professional on site to handle most of minor physical injuries occurred in the camp. Although unlikely, there is a risk that someone other than the study team may see your teen's information or breach confidentiality. To prevent this from occurring, we will not use your teen's name, but will identify your teen by a study number. Any information your teen shared with the study will be kept in a secure server and/or in a locked cabinet in an office with limited access.

Benefits of Participation

Your teen might benefit from being in this research study. The potential benefit might be learning about asthma self-management and getting an opportunity to make some friends who also have asthma.

New Study Findings

If we discover anything that might make you change your mind about allowing your teen to continue in this study, we will let you know.

Sponsor Support

The University of Rochester is receiving payment from National Institute of Health for conducting this research study.

Costs

There will be no cost to you to participate in this study.

Payments

Your teen will be paid up to \$250 in total for being in this study (\$30 at the completion of a set of questionnaires at each assessment point, except for the camp and the 15-month assessment points for which your teen will receive \$50 each).

Circumstances for Dismissal

Your teen may be withdrawn from the study if she/he does not show up at the camp or misses 3 or more assessment points in a row.

Early Termination

Any teen that becomes pregnant or incarcerated during the study period will be withdrawn due to the influence it will have on the study procedures and outcomes.

Compensation for Injury

If your teen is directly injured by participating in the study, you may need to pay for treatment of your teen's injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your teen's health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and Authorization to Use and Disclose Information for

Research Purposes The University of Rochester makes every effort to keep the information collected from you and your teen private. In order to do so, we will not use your and your teen's name, but we will give you and him/her a number, we will keep all information in a locked office or on a password protected computer. Sometimes, however, researchers need to share information that may identify you and your teen with people that work for the University, regulators or the study sponsor. Results of the research may be presented at meetings or in publications, but your teen's name will not be used.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study team will get you and your teen's personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you and your teen?

- The research team
- URMC and Affiliates
- University at Buffalo

You and your teen's information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- National Institute of Health
- University at Buffalo

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you and your teen will not be used.

What if I decide not to give permission to use and give out my teen's health information?

Then you and your teen will not be able to be in this research study.

May I review or copy my and my teen's information?

Yes, but only after the research is over.

How long will this permission be valid?

This permission will last indefinitely

May I cancel my permission to use and disclose information about me and my teen?

You may cancel your permission to use and disclose your and your teen's health information at any time. You do this by sending written notice to the study team. Upon receiving the written notice, the study team will no longer use or disclose your and your teen's health information and you and your teen will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw myself my teen from the study?

If you withdraw yourself and your teen's permission to be in the study, no new health information identifying you and your teen will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my and my teen's health information protected after it has been given to others?

There is a risk that your and your teen's information will be given to others without your permission.

Clinical Trials

A description of this clinical trial is available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify your teen. At most, the Web site will include a summary of the results. You/your teen can search this website at any time.

Contact Persons

For more information concerning this research or if you feel that your teen's participation has resulted in any emotional or physical discomfort please contact: Dr. Rhee at 585.276.3570

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 or University at Buffalo Institutional Review Board (UBIRB), Office of Research Compliance | Clinical and Translational Research Center Room 5018, 875 Ellicott St. | Buffalo, NY 14203, Telephone (716)-829-3977 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to allow your teen to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information your teen has already provided will be kept in a confidential manner.

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to your teen;
- Other options you may have instead of being in the study;
- How your teen's personal information will be protected;
- What to do if you have problems or questions about this study.

Please initial the following if you consent:

I consent to the use of audio recording during instructional activities in the camp.

I consent that I may be contacted for future research studies.

Saving your teen's blood samples for future research:

It is likely that new biological indicators will be discovered in the future that explain asthma severity and its relationship to inflammation. Therefore, after tests are done on your teen's blood in this study, we would like your permission to keep any remaining blood to use in possible future research studies. The remaining sample will be stored in a laboratory in the School of Nursing at the University of Rochester Medical Center. The sample will not be sold or used directly for the production of commercial products. Reports about future research done with your teen's sample will not be kept in his/her health records, or with data that identifies your teen. Your teen's blood sample will be coded and will not be linked to his/her name. You will not be informed of the results of the future research testing as there will not be clinical information specific to your teen. You can decide if you want your teen's sample to be used for future research.

Your teen's blood sample may be saved for future research, even though the purpose of the future research is not known at this time.

I consent to have my teen's de-identified blood sample saved for an indefinite period of time for future research as described above.

I do not consent to have my teen's unused sample for other future studies. Destroy my teen's unused blood sample at the end of his/her participation in this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to have my teen participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name (Printed by Subject)

Signature of Subject

Date**Person Obtaining Consent**

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

Name and Title (Print)

Signature of Person Obtaining Consent

Date