Appendix: Patient consent/assent statements

SAMPLE CONSENT FORM

The Johns Hopkins University
School of Hygiene and Public Health
Committee on Human Research

Title of Research Project: Childhood Asthma Management Program (CAMP)

Purpose of Study

To determine which of three drug treatments is best for long term use in children with moderate asthma. If your child has moderate asthma and is 5 to 12 years of age, he or she may qualify for this study.

Study Procedures

1. Initiation

To qualify for the study, your child must pass certain screening tests. The tests will include (1) two standard types of breathing tests: spirometry and methacholine inhalation; (2) allergy testing by skin tests; (3) physical examination including height, weight, and sexual maturation; (4) a blood test (1 tablespoon, 15 cc); (5) bone density measurements to determine bone thickness; and (6) tests of intelligence, attention, memory, and academic achievement and interviews about behaviors and feelings. The interview about behaviors and feelings will include such questions as "do you feel lonely", "do you get teased a lot", "do you think about hurting or killing yourself".

You will also fill out questionnaires about (1) your child's behavior (eg, does your child argue a lot, deliberately harm him/herself, hear voices, set fires, or talk about killing him/herself); (2) family characteristics and relationships (eg, True/False: family members sometimes get so angry that they throw things; there is a feeling of togetherness in our family); and (3) how your child's asthma affects your family life (eg, Agree/Disagree: the illness is causing financial problems for the family; I think about not having more children because of the illness).

These screening tests will be performed over several visits. During this screening period, we will ask your child to stop taking all of his/her regular asthma medications. We will prescribe albuterol for your child to use to control asthma symptoms. Albuterol is a short-acting inhaled bronchodilator and is commonly prescribed for mild to moderate asthma in children. We will monitor your child's asthma symptoms during this period, and additional medication will be prescribed if needed. This screening period will help us decide if your child should enroll in CAMP.

2. Treatment

If qualified for the study, your child will be assigned to be in one of three groups for asthma treatment. The assignment is made using a chance procedure similar to rolling dice.

Children assigned to Group 1 will receive two study medicines: budesonide (also known as Pulmicort®), and albuterol (also known as Ventolin® or Proventil®). The budesonide is given by inhalation twice a day. The albuterol is a back-up medicine to be used only as needed to control your child's asthma symptoms. Budesonide is an inhaled steroid.

Children assigned to Group 2 will receive two study medicines: nedocromil (also known as Tilade®), and albuterol. The nedocromil is given by inhalation twice a day. The albuterol is a back-up medicine to be used only as needed to control your child's asthma symptoms. Nedocromil is a nonsteroidal anti-inflammatory agent (like cromolyn).

Children assigned to Group 3 will receive a dummy inhaler that does not contain any medicine, and albuterol. The dummy inhaler will be used twice a day. The albuterol is a back-up medicine to be used only as needed to control your child's asthma symptoms.

Budesonide is an experimental medicine for moderate asthma not yet licensed in the US. Nedocromil has been approved by the FDA for treating mild to moderate asthma in patients age 12 and older. Many children of all ages have received these medicines in Europe and Canada. Long-term studies are needed, however, to see whether either of these medicines or albuterol is better for treating asthma. The study will also find out about side effects of these medicines.

Neither you nor the study doctors and nurses will know whether your child is receiving an active medication or the dummy inhaler. This is necessary to find out about the effect of the medicines without bias in favor or against any of them.

3. Education

During the first few visits, you and your child will learn how to use the study medicines, how to use a peak flow meter, and how to complete the study diary cards. You and your child will also learn about asthma. You will learn what triggers it, how to tell when it is getting worse, what to do should an attack occur, and how to clean and organize your home environment. You will keep a daily diary of asthma medicines taken, asthma symptoms, and peak flow meter readings.

4. Followup in the First Year

- After your child begins a medication, there will be followup visits to the clinic at 2 months and every 4 months from baseline.

- About 3 to 6 months after joining the study, a technician will visit your home to collect a house dust specimen.

- At 2, 4, and 8 months, we will review your child's progress, provide new medicines as needed, and repeat height and weight measurements and breathing tests. The

methacholine inhalation test will be done at the eight month visit. These visits could take up to 90 minutes.

- At the end of the first year, we will do a complete exam. It will include height and weight measurements, sexual maturation, breathing tests, and bone density measurements. We will repeat the interviews with your child that measure some of your child's behavior and feelings. We will repeat the interviews with you about your child's behavior, family relationships, and how your child's asthma affects your family life. These evaluations could take up to two hours.

- If your child has been doing well for 8 months in a row, we may decrease the daily asthma medication. This will depend upon your child's albuterol usage, asthma symptoms, and spirometry results. The reduction can occur anytime during the study after the first 8 months.

- At any time during the study, if your child's asthma is inadequately controlled, your child's asthma will be treated by your regular doctor according to his/her discretion. We will still ask your child to come in for his/her regularly scheduled visits. Treatment will be changed if asthma symptoms change.

5. Visits in the Following Years

The study will continue for 5 years or possibly longer. Until the end of the study, visits will be similar to the first year except that there will be only 3 visits each year. Your child will repeat the intelligence, attention, memory and academic achievement tests during the third and fifth years. After 3 years and after moving to a new home, we will collect another house dust specimen from your home. After 5 years, we will repeat the allergy skin tests, and collect and analyze a blood sample.

Risks/Discomforts

- We will monitor all children in the study for adverse effects on behavior, changes in growth patterns and bone density (thickness), and other side-effects which occasionally occur in patients receiving one or more of these medicines.

- The study requirements include taking blood samples of about one tablespoon (15 cc) for testing at the beginning of the study and after 5 years. This is upsetting for some children. Other than the pain of the needle stick and occasional bruising, it is not harmful.

- The amount of calcium (density) in your child's spine will be measured once a year using a bone densitometer. The child will lay still on a table for 5 to 10 minutes for the measurement. There is no discomfort. Each year the measurement will expose the child to about ¼ the amount of radiation of a standard chest x-ray.

- Budesonide may cause cough, throat irritation, and hoarseness. It is a steroid and may affect growth. It may also have a bad taste, and may cause headache, nausea, and

dryness of the throat. Nedocromil may have an unpleasant taste. It may also cause headache and nausea. Albuterol may cause tremor, palpitations, and irritability.

- Allergy skin tests involve placing a small drop of solution on the skin and then pricking the skin through the drop. Some children may have an additional set of skin tests where a small drop of solution is placed underneath the skin with a needle. These skin tests may lead to a local hive or itching. Allergy reactions such as wheezing or generalized hives very rarely may result from skin testing.

- The sexual maturation exam (Tanner staging) will include the examination of pubic hair growth, development of genitalia in boys and girls, and breast development in girls. This examination may be embarrassing for your child; we will try to minimize any embarrassment.

- The safety of these drugs during pregnancy is unknown. Girls who have reached puberty will receive counseling about pregnancy and may be asked to take a pregnancy test. Girls who become pregnant will stop the study medication and will be treated according to the best medical judgment of their doctor. The girl will continue to return to the CAMP clinic for examinations and interviews.

- Methacholine may cause your child to experience mild asthma symptoms. The methacholine test consists of breathing in increasing doses of methacholine. Each time the dose is increased, a breathing test is performed. If asthma symptoms develop, the test ends. The asthma is reversed and symptoms are relieved by inhalation of albuterol (a bronchodilator) or, if needed, by other asthma treatments.

- It is possible that lung function tests may cause cough, wheeze, or shortness of breath. Inhalation of albuterol will be used to relieve the symptoms.

Benefits

Benefits for participation in this study include:

- Complete respiratory and allergy evaluations
- Assessment of home environment with instructions for reducing allergic symptoms along with provision of mattress and pillow covers for dust mite allergy
- Complete asthma education self-management program
- Medicines for asthma provided free of charge
- Twice daily administration of asthma medication
- Study doctors and nurses will be available to manage asthma if it flares
- Children and parents will be invited to outings and group activities especially designed for study participants and their families
- Children will be given small personal rewards (such as: sugar-free gum, small toys, tee shirts, baseball tickets, coupons for food) from time to time.

In addition, there will be reimbursement for travel, cost of a meal, and parking.

Alternatives to Participation

If you do not wish to have your child participate in this study, you may continue to receive asthma care from your regular doctor. We will also refer you to other sources for asthma care, allergy evaluation, asthma education programs, and developmental and educational testing. If you do choose to participate, you and your child may withdraw from the study at any time without penalty.

Rights and Responsibilities

- Your child's entry into the study is voluntary.
- Your child may withdraw from the study at any time and still get care at this institution. However, we would like to know the status of all patients at the end of the study. We may telephone you periodically, even after you withdraw from the study, to ask you about your child's asthma. Even if you do not respond to phone calls, you may still receive the same quality of medical care available at this institution.
- Clinic staff are available to answer any questions or discuss concerns you or your child may have now or in the future.
- The success of this trial depends on regular and complete data collection. If you know now that your child will be unable to come to the clinic for regularly scheduled visits for 5 years, please do not enroll.
- You are responsible for informing clinic staff of changes in your child's address and phone number.
- We ask that you discuss with us any plans for your child's participation in another drug study before you enroll in that study.

Confidentiality

The investigators working on this study know that confidentiality is an important concern to many people. Every effort will be made to keep your records confidential. Our procedures are:

- We will ask you to provide your child's home address and phone number. This information is kept in a locking file cabinet in a secure place, and separate from other study data. Only direct-care clinic staff are allowed to see or use that information.
- Study data are identified by study ID codes only. These data are kept in a secure place. Only people working on the study (or your child's doctor if you request it) will have access to study data.
- The identity of all study participants is confidential. When the results of this study are published, no data will be listed by name or ID number.

- Data important to your child's medical care may be placed in your child's medical record at this clinic. Clinical data with name will be released only to you. Clinical data with ID number will be released to the study coordinating center. Clinical data without name or ID number may be released to the US Food and Drug Administration (FDA) and the pharmaceutical sponsors of the study without your child's or your consent. Release of information about your child to any other person(s) or organization(s) will require your written consent.

- As a way to establish and maintain a trusting relationship with your child, it is necessary that we keep confidential any discussions that we have with him/her about certain sensitive subjects (eg, alcohol or drug use, sexual activities) unless your child permits otherwise, or unless there is a strong compelling medical reason for doing differently.

Your child's participation in this research project is completely voluntary. You have the right to withdraw your child from the research study at any time. Even if you do not want your child to join the study, or if you withdraw your child from the study, your child will still receive the same quality of medical care available to your child at _____. Your decision also will not jeopardize your employment at _____. You and your child should ask the principal investigator listed below any questions you may have about this research study. You may ask him/her questions in the future if you do not understand something that is being done. The investigators (or doctors) will share with you any new findings that may develop while your child is participating in this study.

If you want to talk to anyone about this research study because you or your child think you have not been treated fairly or think your child has been hurt by joining the study, or you have any other questions about the study, you should call the principal investigator, _____ at _____ or call the Office for Research Subjects at [telephone #]. Either the principal investigator or the people in the IRB office will answer your questions and/or help you find medical care if you feel your child has suffered an injury. The [name of institution], and the Federal Government do not have any program to provide compensation to you if your child experiences injury or other bad effects which are not the fault of the investigators.

The information obtained from this study will be included in the Privacy Act System of Records 09-25-0126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI, Federal Register, Vol 56 FR pp. 1295-1296. January 11, 1991.

This project has been explained to my child in my presence, in language that is understandable. My child has been encouraged to ask questions, both now and in the future, about the research study. I have had the opportunity to have my questions answered. If I have other questions later, I understand that I can contact a study center staff member [name and telephone #].

If you agree to your child's participation in this study please sign your name below.

_____

CAMP Protocol

Appendix: Patient Consent and Assent Statements

Subject's signature
(including children, when applicable)

_____
Signature of Parent or Guardian (when applicable)

_____
Witness to Consent Procedures*

_____
Signature of Investigator

_____
Date

*Optional unless patient is illiterate, or unable to sign

Note: Signed copies of this consent form must be a) retained on file by the Principal Investigator, b) given to the participant, and c) put in the patient's medical record (when applicable).