Cincinnati Children's Research Foundation Clinical Trials Office Draft of CEPHALON Asthma Study Web Page Version 1 CCHMC IRB Approval

# Are You An Adult with Asthma? Do You Use an Inhaler?

Investigational Asthma Medication Research Study

#### What is the purpose of this study?

The purpose of this research study is to evaluate the safety and effectiveness of an investigational medication. The study will examine whether this medication is beneficial in improving lung function in patients with moderate to severe asthma and compare its effectiveness among certain types of patients.

#### Who can participate?

Adults 18 to 75 years old who:

- Have been diagnosed with moderate or severe asthma
- Are on an inhaled corticosteroid (like Flovent, Advair, etc.)

#### What is involved?

If you choose to participate, you will be in the research study for a minimum of 30 weeks (not to exceed 32-weeks) and be asked to complete 8 study visits.

During the study visits at the clinic, you will receive the study medication or a placebo, a substance that looks like study medication but has no active ingredient in it, through an intravenous (iv) infusion. You will also complete health-assessments, including:

- Review of your medical and medication history
- Physical exams (including your height, vital signs, blood pressure, heart rate, respiration rate, oral temperature and body weight)
- Lung function tests
- ECGs (tests that record the heart's electrical activity)
- Blood and urine tests

A detailed list of procedures will be provided to anyone interested in knowing more about this study.

## What are the benefits?

You may or may not receive a direct medical benefit from being in this study. However, the information gained from this study may help us understand more about the investigational drug and develop other treatment options for asthma.

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## Will I get all the facts about the study?

You will be given a consent form that thoroughly explains all of the details of the study. The form covers all of the procedures, the risks, the benefits, the pay, who to contact with questions or concerns and more. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered.

#### What are the risks and discomforts of this study?

Generally, all medications cause side effects in some people. Everyone taking part in the study will be observed by the study doctor and staff for any side effects. Other possible discomforts or risks will be discussed with you if you are interested in learning more about the study.

# Do participants receive pay, compensation or reimbursement?

Participants may receive compensation fro their travel and time.

#### Who should I contact for more information?

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