



## VASCULITIS CLINICAL RESEARCH CONSORTIUM

**A Multi-Center,  
Open-Label Pilot Study  
of Abatacept in the Treatment  
of Wegener's of Mild Relapsing**

## Wegener's Granulomatosis

### Why participate?

By participating in this clinical trial you will help researchers better understand Wegener's Granulomatosis and work toward developing more effective and safer therapies.

### Where will the study take place?

### How do I participate?

If you are interested in participating in this study or would like additional information, please contact a study coordinator at the clinical center most convenient for you:

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## What is this study?

The current standard treatment for Wegener's granulomatosis involves a number of different medications and is based on disease severity. Unfortunately, more than 50% of people experience a relapse after remission, placing them at risk for additional organ damage and toxicity from medication. To prevent this, safer and more effective treatments for mild to moderate relapses are needed. We especially need to find treatments to help reduce the amount of prednisone patients need to take. The purpose of this pilot study is to determine the safety of the medication abatacept in Wegener's granulomatosis and to gain information about whether abatacept may be effective in the treatment of mild relapsing Wegener's granulomatosis.

### What does this study involve?

This is a treatment study, with a total of 20 people with mild relapsing Wegener's granulomatosis taking part in this study at several hospitals. For safety reasons, there are specific criteria to be able to participate in this trial. In this study abatacept is given intravenously at study visits on Days 1, 15, 29 and once a month thereafter. Participation in this study may last between 7 and 24 months. Study visits include the following:

- abatacept infusions
- blood tests; for clinical and for research purposes
- questionnaires to measure quality of life
- chest x-rays and CT scans of the chest and/or sinuses

### Who qualifies?

To participate, you must:

1. Have an established diagnosis of Wegener's granulomatosis
2. Be experiencing a relapse of mild Wegener's granulomatosis that would not necessitate treatment with cyclophosphamide or prednisone at a dose greater than 30mg daily.
3. Be 15 years of age or older
4. Be willing and able to provide informed consent and comply with treatment and follow-up procedures
5. Be willing to use effective means of birth control while receiving treatment through this study