



SUBJECTS WITH PRIMARY IMMUNE DEFICIENCY NEEDED FOR RESEARCH STUDY USING AN IMMUNOGLOBULIN PRODUCT

**David Geffen School of Medicine at UCLA, Department of Pediatrics
Division of Immunology/Allergy/Rheumatology**

We would like to ask you to consider participating in (or allowing your child to participate) in a clinical study. The purpose of this study is to collect information about how well and how safely an intravenous gammaglobulin (IGIV) drug called Omr-IgG-am™ works in patients between 3 to 75 years old who have a condition called Primary Immune Deficiency. You must already be receiving another IGIV product to participate.

You may be eligible if you do NOT have any of the following conditions:

- Allergic reactions to immunoglobulins or other blood products
- Known to be intolerant to any component of Omr-IgG-am™ such as maltose
- Abnormal liver function
- Long-term daily use of steroids
- Immunosuppressive or immunomodulatory drugs
- Uncontrolled high blood pressure
- Anemia
- HIV or Hepatitis B or C positive
- Known to abuse alcohol, illegal or prescription drugs, or have done so within the past 12 months
- Kidney disease
- Malignancies or cancer
- Heart disease
- History of blood clots or thrombotic complications of IGIV therapy
- Participation in another clinical study assessing another investigational product
- Pregnant or nursing

Subjects in this study will receive a compensation of \$50 for each infusion visit and \$50 for each other visit (approximately \$850 to \$1050 for the whole study). The product will be free. The nursing costs for giving the product as well as laboratory studies will also be free. Approximately 12 to 15 visits to UCLA would be required by the study for infusions. There will be additional blood draws that may be done at UCLA or by home-health nurses.

Should you have any questions or need additional information, feel free to contact Dr. Robert L. Roberts at (310) 825-6481 or (310) 825-6777. You may also email him at roberts@mednet.ucla.edu or contact his study coordinator, Sherry Jeffery, at (310) 794-2587. We will then set up for a telephone interview where the study will be explained in more detail.

Date of Preparation: October 20, 2006

UCLA IRB #: 06-11-023-01

Expiration Date: