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

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We are looking for subjects with Primary Immune Deficiency who are currently receiving immunoglobulin therapy, either intravenously (IV), subcutaneously (SQ), or intramuscularly (IM). The subjects must be 13 years old or older to participate. The purpose of this study is to see how well the product GAMUNEX®, which is already FDA approved for IV administration, works when given SQ. The GAMUNEX® will be given IV initially for 3 months and then for about 6 months SQ. Approximately 25 tablespoons of blood will be drawn over the course of the whole study. There are approximately 10 visits during the course of the study, therefore at each visit you will have 2 ½ tablespoons of blood drawn.

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 GAMUNEX®
- Abnormal liver function
- Long-term daily use of steroids
- Immunosuppressive or immunomodulatory drugs
- Anemia
- History of alcohol abuse, opiates, psychotropic agents, or use of other drugs
- Kidney disease
- Malignancies or cancer
- History of HIV infection
- 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 $1450 for the whole study). The GAMUNEX® will be free if it is given intravenously (IV) or subcutaneously (SQ). The nursing costs for giving the GAMUNEX® 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 rroberts@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.

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