I.LEGAL TITLE OF THE PROTOCOL:

      Laboratory Evaluation of Multiple Sclerosis and Autoimmune Neurological Disease and Multiple Sclerosis Registry

II.INVESTIGATORS:

      Johanna Rosenthal MD. Principal Investigator
      Additional Investigators from Arrowhead Regional Medical Center Neurology Department
      Additional Investigators from Riverside Community Hospital
      Additional Investigators Board Certified Neurologists from the California Neurology Society
      Medical Students from California University of Science and Medicine

III.INTRODUCTION: Currently there are multiple new drugs for Multiple Sclerosis and Autoimmune Neurological Disease. The drugs are averaging $50,000 to $80,000 per year. Currently there is not a standardized protocol for quantified measurement of the immune system. Ideally there would be a standardized sequence of measurements during the time of diagnosing Multiple Sclerosis, testing after initial treatment with Methylprednisolone or other steroids, and testing after DMT Disease Modifying Therapy.

IV:STUDY TYPE: The study is a prospective study and a Registry. The purpose is to establish a California Registry to follow Multiple Sclerosis and Autoimmune Neurology patients. As part of the Registry **DE-IDENTIFIED** lab and other results are to be obtained at regular intervals including immunoglobulin subclasses and lymphocyte populations by Flow Cytometry. The Hypothesis is that the new Disease Modifying Therapies are affecting Immunoglobulins Subclasses and the different lymphocytes populations that can be measured by Flow Cytometry. Ultimately an Excel type of format of lab results will be frozen quarterly, and the **DE-IDENTIFIED DATA** will be available to clinicians to assess and compare patient responses to the newer expensive medications

V: METHODS AND LOCATION: An investigator that is a Board-Certified Neurologist and a member of the California Neurology Society may submit data from a patient that is under the investigator's care. Data Collection will be attempted from female or male patients, male or female, that are over 18 years old and not incarcerated. They may be physically handicapped. If they are cognitively impaired or comatose, the guardian may sign the consent if the guardian approves submission of data to the study. The inclusion criteria are that the Board Certified Neurologist must be assessing and or treating the patient for Multiple Sclerosis and other similar Autoimmune Neurological Disease. Pregnant and other patients may be included if they sign the consent and agree to the three blood tests. The investigator will obtain testing including Venous Blood Tests at the recommended intervals before and after treatment per the protocol. The blood tests and all other data about the patient will be attached to a numerical 4-digit code. The doctor treating the patient will keep all PHI Information private. The only information submitted to the Study and the Registry will be **DE-IDENTIFIED data** and test results. The plan is to collect data from 100 patients. The data will be entered into in an Excel type of format for computer analysis and statistical studies by assistants, medical students, and research coordinators. The Initial cohort will be evaluated for one year. If the analysis shows beneficial information the study may be continued for more years. Only the doctor submitting the study will have access to any Personal Health Information. The Master List of Code numbers of the patients is to be kept in a locked secure location in a paper format by the Principal Investigator, and each doctor submitting data will also keep the code

separate from the patient chart to ensure privacy. The data will be permanently placed on a secure protected server in an encrypted format at Arrowhead Regional Medical Center and maintained for at least 10 years with access by Dr. Rosenthal, and Dr. Hajjafar and other Investigators if approved by Dr. Rosenthal and Dr. Hajjafar.

VI.Study Design and Analysis: Subjects will be selected by the investigators outlined above. The data includes categories of disease such as Multiple Sclerosis, NMO-Neuromyelitis Optica, MOGAD Myelin Oligodendrocyte Disorder or other Autoimmune Neurological Disorders as well as controls if they have had the 3 specific lab tests.

Lab (venous blood tests) are obtained including Lymphocyte Subset Panel, IgG subclasses, and Flow Cytometry known as a Leukemia Lymphoma Evaluation, other data is included as available including MRI tests, Evoked Potentials and Lumbar puncture results. Every 3 months, data is frozen for updated statistical analysis. Deidentified statistical analysis can be done by any investigator that has submitted data. Summated data will be published if accepted, and the registry will be available for research.

The study will be conducted at Arrowhead Regional Medical Center and Riverside Community Hospital. There will be information on the California Neurology Society Web portal. There will be Email announcements to California Neurologists to ask Neurologists to submit data for the Registry and join the prospective study. The announcements will have our "Mission Statement" and will request that doctors enroll their patients in the study. The announcements will document briefly an outline of the protocol.

VII.Risks/Benefits

The patients are under the care of their own Neurologist. The lab tests are ordered before any treatment, after 5 days of Solumedrol and every 3 months while on a Disease Modifying Therapy. The blood test has a risk of minor discomfort and can be obtained at the time that their own doctor is obtaining routine blood tests. Minors and prisoners are not included. Pregnant women can be included if their Neurologist agrees. The benefit to the patient would be to expand the knowledge of how these new expensive DMT Disease Modifying Therapy medications affect the immune system, and to confirm that there is laboratory evidence to justify the expense.

VIII:FUNDING A funding source will be accepted if offered, currently there is no funding source. Medical Students will perform data collection and computer input.