Emory University School of Medicine, Department of Medicine
Pediatric Nephrology Open Protocols-2015

1. Adrenocorticotropic Hormone (ACTH) for Frequently Relapsing and Steroid Dependent Nephrotic Syndrome: ATLANTIS Study

**Purpose:** In childhood nephrotic syndrome, the kidneys leak protein, causing body swelling and a variety of possible complications such as infection, blood clots, and kidney failure. The first-line treatment for nephrotic syndrome is corticosteroids. Many children respond to prednisone treatment, but the disease comes back (relapses) when the prednisone is stopped or the dose is reduced. Children with frequently relapsing or steroid dependent nephrotic syndrome are at risk for toxicity from frequent exposure to corticosteroids.

Currently, the standard treatment for frequently relapsing and steroid dependent nephrotic syndrome involves a variety of medications that suppress the immune system, which can produce serious side effects. We propose a study to examine the effects of a different medication, ACTH, on nephrotic syndrome. ACTH is a hormone naturally found in the body. Recently, in adult studies, ACTH has been shown to be effective for the treatment of nephrotic syndrome. It has also been shown to have mild and reversible side effects. ACTH is potentially an attractive therapeutic alternative for the treatment of frequently relapsing and steroid dependent nephrotic syndrome in children. Our study will randomly assign patients with frequently relapsing or steroid dependent nephrotic syndrome to either ACTH treatment or no treatment. This will allow us to study the effects of ACTH on this disease and its side effects, by comparing how patients do on ACTH treatment versus no treatment. We hypothesize that ACTH gel is superior to no treatment in maintaining remission in children with frequently relapsing or steroid dependent nephrotic syndrome.

[https://clinicaltrials.gov/ct2/show/NCT02132195](https://clinicaltrials.gov/ct2/show/NCT02132195)

**Recruitment status:** Enrolling

**Sponsor:** Mallinckrodt Pharmaceuticals

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA and Dr. Chia-shi Wang, 3rd year fellow, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Study coordinator:** Margo Kamel, MSPH

2. An Observational, Multi-Center, Multi-National Long Term Follow-Up Study of Atypical Hemolytic Uremic Syndrome (aHUS) Patients Treated with Eculizumab in a Prior Clinical Study (Study Number: C111-003)
Purpose: The purpose of this study is to collect and analyze medical information about aHUS that will provide a better understanding of the disease and insight into the long-term outcomes of patients who have taken part in a clinical treatment study for aHUS sponsored by Alexion.


Recruitment status: closed to enrollment

Sponsor: Alexion Pharmaceuticals

Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Margo Kamel, MSPH

3. An Observational, Non-Interventional, Multi-Center, Multi-National Study of Patients with Atypical Hemolytic-Uremic Syndrome (aHUS Registry) (Study Number: M11-001)

Purpose: The registry is an observational, non-interventional, multi-center, multi-national, study that has been designed to capture safety and effectiveness data specific to the use of eculizumab in aHUS patients, as well as to compile data on the long term manifestations of TMA complications of aHUS. The registry will enroll aHUS patients treated not with eculizumab. It is anticipated that patients will be followed at least for 5 years. Data collected in the registry will be reported to the FDA and the EMA.


Recruitment status: open to enrollment

Sponsor: Alexion Pharmaceuticals

Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Margo Kamel, MSPH

4. Chronic Kidney Disease in Children Prospective Cohort Study (CKiD III)

Purpose: This is an observational study of children with chronic kidney disease. The primary goals of this study are to determine the risk factors for decline in kidney function and to define how a progressive decline in kidney function impacts neurocognitive function and behavior; the risk factors for cardiovascular disease; and growth failure and its associated morbidity.


Recruitment status: open to enrollment

Version date 06/10/2015
5. Childhood Nephrotic Syndrome Observational Study (CNOS)

**Purpose:** Childhood onset nephrotic syndrome is a condition that affects the kidneys. It causes them to leak protein from the blood into the urine. The purpose of this study is to improve our understanding of the causes, effects, and treatment response of childhood nephrotic syndrome. We are also hoping to find out more information about how nephrotic syndrome progresses in different people and how or why that happens.

**Recruitment status:** open to enrollment

**Sponsor:** Investigator Initiated

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Margo Kamel, MSPH

6. Executive Function in Children with Hypertension

**Purpose:** Studies in young adults indicate that primary hypertension is associated with decreased performance on neurocognitive testing compared with normotensive controls, particularly in the domains of attention, working memory, and executive function. These cognitive deficits can improve in adults when hypertension is subsequently well-controlled, indicating that the neurocognitive deficits seen in hypertensives may represent an early manifestation of hypertensive target organ damage of the brain. The goal of the current proposal is to investigate the relationship between primary hypertension and executive function as an emerging target of hypertensive damage in children. The overall hypothesis is that children with primary hypertension have evidence for central nervous system target organ damage, as manifested by decreased executive function.

**Recruitment status:** open to enrollment

**Sponsor:** NIH

**Site PI:** Dr. Donald Batisky, Director of Hypertension Program, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Priscilla Quach, BS
7. Immune Monitoring and Assay Development in Kidney Transplant Recipients (IMP)

Purpose: Currently, a kidney biopsy is the only way to determine whether a patient with a kidney transplant has rejection of their kidney. The goals of this study are to develop and study urine and blood tests that can determine if a patient is rejecting a transplanted kidney. This will hopefully decrease the need to perform kidney biopsies and allow for earlier diagnosis of rejection.

PIs: Dr. Roshan George and Dr. Pamela Winterberg, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Lu Arechiga, BS

8. International Pediatric Peritoneal Dialysis Network Study (IPPN)

Purpose: The International Pediatric Peritoneal Dialysis Network (IPPN) was created to register and collect data regarding pediatric patients receiving peritoneal dialysis. The purpose of this study is to continuously monitor outcomes in children around the world that are on PD. This registry should provide much needed information to doctors, nurses, dieticians, psychologists, social workers, and health care administrators, and help improve the wellbeing of children currently on PD.

Recruitment status: open to enrollment

Sponsor: International Pediatric Peritoneal Dialysis Network (IPPN)

Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Priscilla Quach, BS

9. A Molecular Pathogenesis-Driven Approach for Diagnosis and Treatment of Complement-Based Renal Diseases (KidCOM)

Purpose: The purpose of this research is to build a registry of patients with aHUS and MPGN. MPGN is a rare disease that can cause problems with how the kidney filters blood and waste. Currently, little is known about how to treat MPGN. There are three different types of MPGN; MPGN I, MPGN II/Dense Deposit Disease (MPGN II/DDD), and MPGN III. Although we will look at all types of MPGN, we are focused on MPGN II/DDD because it is most closely linked to the immune system.

Hemolytic Uremic Syndrome (HUS) is another rare immune disease that affects blood supply to the kidneys, and impairs their function. There are two types of HUS; typical HUS, and atypical HUS. Typical HUS, which is usually diagnosed in childhood, is due to a bacterial infection in the stomach and intestines. Atypical HUS (aHUS) is a hereditary disease that is associated with recurrent episodes.
Recruitment status: open to enrollment

Collaborators: Dr. Christoph Licht at The Hospital for Sick Children, Toronto, Ontario, Canada; Dr. William Smoyer at The Research Institute at Nationwide Children's Hospital, Columbus, Ohio; Dr. Patrick Brophy at University of Iowa Hospitals and Clinics, Iowa City, Iowa.

Sponsors: Foundation for Children with Atypical HUS, and Optherion, Inc.

Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Margo Kamel, MSPH

10. Pediatric Lupus Nephritis Registry (Lupus Registry)

Purpose: This study will examine the incidence, causes, clinical course, and outcomes in children with lupus kidney disease. After informed consent and assent, medical records will be reviewed and history, physical exam findings, laboratory, radiology, hospital events, and medication information will be recorded into a multi-center registry. Longitudinal data will be collected for at least 5 years after entry into the registry.

Recruitment status: open to enrollment

Participating site with Children’s Hospital of Chicago

Site PI: Dr. Donald Batisky, Director of Hypertension Program, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Lu Arechiga, BS

11. Nephrotic Syndrome Study Network (NEPTUNE)

Purpose: The purpose of this study is to find markers of Nephrotic Syndrome (kidney disease with too much protein in the urine). We are particularly interested in diseases called Focal and Segmental Glomerulosclerosis (FSGS), Minimal Change Disease (MCD), and Membranous Nephropathy (MN). By collecting health information and laboratory samples, our goal is to learn more about these kidney diseases and find better ways to prevent and treat people with these kidney diseases.

http://clinicaltrials.gov/ct2/show/NCT01240564

Recruitment status: open to enrollment

Sponsor: National Institutes of Health (NIH)-National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)
Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinators: Priscilla Quach, BS and Lu Arechiga, BS

12. A Phase 2 Multi-Center, Randomized Conversion Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Belatacept Administered to Pediatric Subjects with a Stable Renal Transplant

**Purpose:** This is an open-label, multi-center, active controlled, parallel group conversion study in stable EBV+ pediatric renal transplant recipients between 6 to 17 years of age who are receiving a calcineurin inhibitor (CNI)-based maintenance immunosuppressant therapy. The purpose of this study is to assess the pharmocokinetics (PK) and safety and tolerability of belatacept in these patients.

**Recruitment status:** open to enrollment

**Sponsor:** Bristol-Myers Squibb

Site PI: Dr. Barry Warshaw Associate Professor, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Margo Kamel, MSPH and Lu Arechiga, BS

13. Measurement of Glomerular Filtration Rate in Children with Mild Chronic Kidney Disease

**Purpose:** The purpose of this study is to determine the glomerular filtration rate in children with very mild abnormalities of kidney function (for example, microscopic blood in the urine, protein in the urine, hydronephrotic or dysplastic kidney on ultrasound).

**Recruitment status:** open to enrollment

**Sponsor:** University of Rochester/National Institute of Health (NIH)

Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

Site coordinator: Priscilla Quach, BS

14. A multicenter, open label, uncontrolled study to evaluate the efficacy, acceptance and tolerance of RenaStart (Vitaflo International Ltd), a high energy powdered formula (medical food) with low levels of potassium, protein, calcium, chloride, phosphorous and vitamin A for children aged 1 – 10 years with chronic kidney disease (CKD) (Renastart study)
**Purpose:** The purpose of this study is to study Renastart. Renastart is a medical formula/food. It is low in potassium. It is also low in phosphorus, protein, calcium and vitamin A. It is rich in calories. Renastart was made to lower potassium levels in children with kidney disease. This study will see if Renastart works to lower potassium levels. This study will see if Renastart is effective and tolerated.

**Recruitment status:** not open to enrollment yet

**Sponsor:** Vitaflo International Ltd

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Margo Kamel, MSPH

### 15. Randomized Trial of Two Maintenance Doses of Vitamin D and Trace Element Status in Children with Chronic Kidney Disease

**Purpose:** Vitamin D deficiency is common. It is more common in children with chronic kidney disease. Vitamin D is very important for bone health. We do not know the best way to treat vitamin D deficiency. We are comparing two different doses of vitamin D supplements. We want to see if the higher dose will work better than the lower dose. We are also measuring trace elements in the blood. Trace elements are minerals found in the blood at very low levels. We want to see if children with kidney disease have high or low levels of trace elements.


**Recruitment status:** enrollment closed

**Sponsor:** Children’s Healthcare of Atlanta

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Priscilla Quach, BS and Lu Arechiga, BS

### 16. Bovine Serum Albumin-Related Membranous Nephropathy

**Purpose:** Bovine serum albumin (BSA) is one of the cow’s milk and beef proteins that can escape from the intestinal barrier and induce formation of anti-BSA antibodies. Modern day foods are subjected to a variety of processing conditions that may modify food proteins, and thus could change their digestion and allow their passage into the blood stream. This study will examine individuals with a diagnosis of idiopathic membranous nephropathy and
investigate the involvement of cationic BSA and its relationship to the subject’s clinical presentation, past medical history including dietary history, family history, and clinical course.

**Recruitment status:** Enrolling

**Sponsor:** Investigator Initiated

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Priscilla Quach, BS

**17. The Genetic Contribution to Drug Induced Renal Injury: The Drug Induced Renal Injury Consortium (DIRECT)**

**Purpose:** Patients may have injury to their kidneys after they receive a medication. Kidney injury is more likely with certain medications or if the dose of the medication is too high. Some patients are more likely to have kidney injury after taking a medication because their illness is so severe. In many cases, we do not know why one patient suffers an injury and another patient does not. This study is trying to find out if this difference between patients is due to genetic differences. Patients who have kidney injury due to a medication will be asked to participate in the study. If the patient agrees, we will obtain a DNA sample to study the patient’s genes. The goal is to find out if having certain genes makes a patient more likely to develop kidney injury from a medication. The goal is to use information about a patient’s genes to use medications in a way that decreases the risk of kidney injury.

**Recruitment Status:** Enrolling

**Sponsor:** SAE Consortium

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Priscilla Quach, BS

**18. CureGN: Cure Glomerulonephropathy Network (CureGN)**

**Purpose:** There are several different types of glomerular diseases, such as minimal change disease (MCD), focal segmental glomerulosclerosis (FSGS), membranous nephropathy (MN), and immunoglobulin A nephropathy (IgAN). Over time, these diseases may cause kidney damage. These kidney diseases are rare and because of that, it is difficult for individual researchers to gather a large enough number of people to effectively study underlying causes, identify markers of disease, and identify and evaluate new therapies. The purpose of CureGN is to gather a group of patients with glomerular disease to create a source
of information and blood and urine samples, so that researchers can easily and effectively study glomerular disease.

**Recruitment Status: Enrolling**

**Sponsor:** National Institute of Health (NIH)

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Margo Kamel, MSPH and Matt Bennett, BS

**19. Randomized Trial Comparing Rituximab Against Mycophenolate Mofetil in Children with Refractory Nephrotic Syndrome**

**Purpose:** Children with steroid dependent and frequent relapsing nephrotic syndrome (SDNS and FRNS) are at risk for short-term and long-term steroid toxicity, severe infections, thromboembolic events and acute kidney injury (AKI) during relapses. The reduction of these risks is dependent on the identification of effective therapy. None of the current treatment options are ideal. Calcineurin inhibitors (e.g. cyclosporine, tacrolimus) are effective in more than 50% of patients, but have short-term toxicity and relapses occur once the calcineurin inhibitor is stopped. This is especially problematic given then significant risk of long-term renal damage when taken for more than one year. Cyclophosphamide has a low response rate and has short-term and long-term toxicity. Mycophenolate mofetil (MMF) has a lower response rate than calcineurin inhibitors, but has become the first-line treatment (i.e. the near-standard of care) at many centers because of the favorable toxicity profile. However, the options for patients who fail MMF are not ideal, as detailed above. There is accumulating evidence that rituximab is effective in producing a sustained remission in children with SDNS and FRNS, although some increased risk for infection may be associated with this therapy. Based on the clear need for more effective and less toxic therapies for SDNS and FRNS, we hypothesize that the anti-CD20 monoclonal antibody Rituximab will be more effective than MMF in maintaining remission in children who have had one relapse while receiving MMF. To test this hypothesis, we propose a randomized, multi-center clinical trial to directly compare the ability of MMF and Rituximab to maintain remission for 6 months in children SDNS and FRNS. The rationale for this study is that determining the most effective and least toxic therapy for SDNS and FRNS will add critical new information to help develop an evidence-based approach to the treatment of children with refractory nephrotic syndrome. In addition, enrolling patients who have already had one relapse while taking MMF will improve the likelihood that both the participating physicians and the families will be willing to be randomized to a possible intravenous therapy.

**Recruitment Status:** Not open to enrollment yet
20. Non-Steroidal Anti-Inflammatory Drug Associated Acute Kidney Injury: A Prospective, Observational Study (NSAID)

**Purpose:** Acute kidney injury is an abrupt decrease in kidney function. This type of kidney injury is relatively common in hospitalized children and can be very harmful. This type of kidney injury can be caused by many things. There is evidence that certain types of drugs can cause acute kidney injury. We suspect that a type of drug called NSAIDs (non-steroidal anti-inflammatory drugs like ibuprofen, naproxen, and aspirin), which are commonly used to treat fever and pain, are drugs which can cause kidney injury. We do not fully understand how or why NSAIDs cause acute kidney injury in some patients. The purpose of this study is to collect more data about acute kidney injury and NSAID use so that we can better understand the link between the two. Patients who have had kidney injury will be asked to participate in this study. If patients agree to participate, they will be asked to fill out an anonymous survey. The survey asks about patients' NSAID use and other symptoms leading up to their kidney injury. The purpose of this research is to improve future patient care and help prevent future kidney injury.

**Recruitment Status:** Not open to enrollment yet

**Sponsor:** Investigator Initiated

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Margo Kamel, MSPH

21. "A Phase 3b, Multicenter, Open-label, Randomized Withdrawal Trial of the Effects of Titrated Oral SAMSCA® (Tolvaptan) on Serum Sodium, Pharmacokinetics, and Safety in Children and Adolescent Subjects Hospitalized With Euvolemic or Hypervolemic Hyponatremia" (OTSUKA)

**Purpose:** Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC), is studying an investigational drug called tolvaptan ("Study Drug"). Tolvaptan (Samsca®) is a drug approved for use in the United States (2009) in patients with certain types of hyponatremia (low amount of sodium or salt in the blood) due to syndrome of inappropriate antidiuretic hormone. Tolvaptan (Samsca®) is approved in the European Union (2009) for
treatment of a specific type of hyponatremia due to SIADH. Tolvaptan (Samsca®) has been approved by the Japanese Ministry of Health, Labour, and Welfare (2010) for the treatment of volume overload in heart failure when used in combination with other approved drugs.

Tolvaptan is still being studied to see if it can be used to treat problems associated with various causes of hyponatremia. A low amount of sodium in the blood may be due to abnormal hormone levels, medication that your child has to take, or another disease that your child may have. Low blood sodium levels may result in nausea, vomiting, and muscle discomfort. It may cause weakness and slow, abnormal, or poor thinking. Low blood sodium may cause abnormal behavior, seizures or fits, and coma or unconsciousness. It may cause lack of emotion or slowed breathing. Tests taken during the study will determine how useful tolvaptan will be in treating low blood sodium. The study doctor has determined that your child has low blood sodium levels. Your child is invited to take part in this research study.

The reason for this study is to find out the potential benefits and safety of tolvaptan in the pediatric and adolescent population. About 100 participants will be joining in this study globally or regionally in approximately 50 centers. It is expected that participation will last approximately 21 days for each participant.

**Recruitment Status: Not open to enrollment yet**

**Sponsor:** Otsuka Pharmaceuticals

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Margo Kamel, MSPH

**22. Amgen Study 20130356: A Randomized, Open-Label, Controlled Study to Assess the Efficacy and Safety of Cinacalcet HCl in Pediatric Subjects With Secondary Hyperparathyroidism and Chronic Kidney Disease Receiving Dialysis (AMGEN)**

**Purpose:** The purpose of this study is to find out more about cinacalcet hydrochloride (HCl) in children with secondary hyperparathyroidism and chronic kidney disease receiving dialysis. This study will see if cinacalcet can reduce the parathyroid hormone levels in children by 30% or more from their pre-study levels and whether it causes any side effects.

To do this, cinacalcet HCl will be compared to routine care for children on dialysis with chronic kidney disease and secondary hyperparathyroidism. Cinacalcet HCl is called study drug in this form.

Cinacalcet HCl is approved to treat secondary hyperparathyroidism in adults with chronic
kidney disease who are receiving dialysis, however is not approved by any regulatory health agency (like the Food and Drug Administration [FDA] or European Medicines Agency [EMA]) for use in children with this condition. A total of about 50 children are expected to participate in this study for about 6 months. This includes a 2-week screening period, 20-week treatment period, and a 4-week safety follow-up period.

**Recruitment Status:** Enrolling

**Sponsor:** Amgen, Inc.

**Site PI:** Dr. Stephanie Jernigan, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Luis Arechiga, BS

23. **Assessment of Risky Behavior in Teens with Chronic Kidney Disease: ASK KIDD Study**

**Purpose:** The teenage years are associated with a higher prevalence of risky behavior. These behaviors can have significant effect on the normal physical and emotional development of teenagers. In teens with chronic illness such as CKD the impact of risky behavior is of added importance due to preexisting depression and adjustment disorder that can be associated with chronic illness. Understanding the prevalence of these behaviors will provide useful information into the quality of life issues and challenges teens with CKD face.

**Recruitment status:** Enrolling

**Sponsor:** Investigator Initiated (Abiodun Omoloja, MD; Department of Pediatrics, Wright State University)

**Site PI:** Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

**Site coordinator:** Priscilla Quach, BS

24. **Outcomes of Permanent Vascular Access in Pediatric Hemodialysis Patients**

**Purpose:** The purpose of this study is to define the long-term outcomes of permanent vascular access in pediatric patients using data from many centers across the United States. If the suggested better long-term outcomes can be confirmed by this retrospective study, the pediatric nephrology groups will need to find alternative ways of providing this option to their patients and confronting all the difficulties in the way can be justified.

**Recruitment Status:** Enrolling
Participating site with West Virginia University

Site PI: Dr. Rouba Garro, Division of Pediatric Nephrology, Emory University, Atlanta, GA


**Purpose:** Kidney transplantation is the optimal treatment for children with kidney failure. However, pediatric kidney transplant recipients have increased mortality as children and young adults, principally due to cardiovascular events. Regular exercise may reduce the risk of cardiac disease in these patients, but a variety of factors may limit their exercise, including a fear of allograft injury. This cross-sectional study will enroll kidney transplant recipients at the Children’s Healthcare of Atlanta kidney transplant program. The objectives of this study are to evaluate exercise participation and perceived barriers to participation in pediatric kidney transplant recipients. The study will also describe the rate and etiologies of allograft injury in these patients. Finally, the study will determine if grip strength is decreased in pediatric kidney transplant recipients. These outcomes will be compared to patient characteristics, including documented risk factors for cardiovascular disease (i.e., overweight BMI, diabetes, hyperlipidemia, and hypertension).

**Recruitment Status: Enrolling**

Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA

26. LN Antibodies

**Purpose:** This study will examine the ability of novel antibodies or other biomarkers to predict 1) findings on kidney biopsy, 2) disease progression, or 3) response to therapy in children with lupus nephritis (LN). The intent is to enroll subjects who have or will also enroll in the MWPNC’s Pediatric LN Registry (however, involvement in the registry is not required). After obtaining informed consent and assent, medical records including history, exam findings, laboratory radiology and biopsy findings, treatment information, and outcomes will be prospectively reviewed and recorded. There are 2 levels of involvement for this study. The short term goal of this study will be to measure antibody titers against basement membrane (BM) antigens in the plasma and urine at onset of LN and again 6-mo into therapy. Results would be compared with the currently available clinical indicators of outcome and treatment response. The long-term goal of this study will be to establish a biorepository of blood and urine samples (level 1) and kidney tissue (level 2) to assess the utility
of additional autoantibodies or other biomarkers in MWPNC pediatric LN cohort, and to facilitate collaboration with larger efforts for biomarker identification in SLE that would otherwise not have access to pediatric samples.

**Recruitment Status: Not yet open to enrollment**

**Participating site with Midwest Pediatric Nephrology Consortium (MWPNC)**

**Site PI: Dr. Larry Greenbaum, Director, Division of Pediatric Nephrology, Emory University, Atlanta, GA**