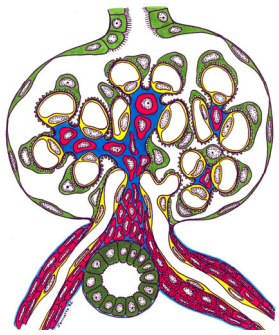
A Newsletter from the Glomerular Disease Collaborative Network

Kidney Care

Fall 2022

Approved by the UNC-CH Institutional Review Board



Health care professionals and patients working together to learn more about diseases that affect the filters (glomeruli) in the kidney.

UNC HEALTH CARE
KIDNEY CENTER
www.unckidneycenter.org
@unckidney

Patient Perspective: The Beginnings Of My CKD Diagnosis

By: Jasmine Andrews

Growing up and well into adulthood, I never paid much attention to my kidneys. I can say I didn't always eat healthily but have always been active. I would run three miles several times a week and lift weights. I am also a K9 handler with NC State University Police Department, so being in shape is a must.

In January of 2022, I found out how important your kidneys are. I called out of work a couple of times because I was feeling very tired and started to have acid reflux issues and was not eating. I told myself I needed to go to the doctor's office. My family doctor gave me meds for my stomach and conducted a renal panel test. I went home and went back to sleep. I was sleeping up to 14 hours a day which is unusual for me. It was a weird feeling because I am not a person who gets sick. I can count on one hand how many times I felt under the weather. I didn't think anything was seriously wrong as I had no fever or flu-like symptoms (Covid was really bad around this time).

I had a video conference with my doctor who informed me to go to the emergency room because my kidneys were shutting down. I called my husband and he took me to the emergency room. I went from being a healthy, outgoing person to now wondering if I was going to die. After talking with doctors and realizing how severe my diagnosis was, depression and anger kicked in. I remember feeling like I was the only one with this diagnosis. My husband is my rock and has been there for me, but I didn't know how to talk with him about this situation. I didn't understand where chronic kidney disease (CKD) came from because no one in my family had this disease. With the doctors giving me so much information at one time it became very overwhelming. I was put on so many medications. This was hard for me because the only medication I took was Advil or Aleve once in a while for a headache.

My job consists of being in control of myself at all times. I felt my body betrayed me and I had no control over anything. I had no control over a war that was going on in my body. I talked with the Chaplin while I was in the hospital which helped, but I was still sad and angry. I started to talk to my husband about the situation we were in and how to move forward. My doctor in the hospital explained my diagnosis in detail which helped me have a better understanding of what was going on in my body. After leaving the hospital, I started seeing my kidney doctor (nephrologist). She was very helpful in getting me to understand the Do's and Don'ts of CKD and what to expect.

Continued on next page…..

UNDERSTANDING THE IMPACT OF FSGS AND IGAN ON PATIENTS AND CAREGIVERS STUDY (HONUS)

HONUS is a global research study focused on understanding the real-world impact of rare kidney diseases on patients and their caregivers.

Why should I participate? Similar to the way researchers study diseases to better treat and, eventually cure them, it is equally important to study and understand the lived experiences of patients and caregivers impacted by rare kidney diseases like FSGS and IgAN.

How long is the survey? We estimate it will take you 30-40 minutes to complete.

Who is eligible to participate?

1. Adult patients with FSGS or IgA with a family caregiver also willing to participate in the online survey
2. Parents/caregivers of children/adolescents with FSGS or IgA

If I choose to participate, will I be paid for my time? All participants who complete the survey will receive an Amazon Gift Card.

I am ready to participate, what next? Email kidneytrials@unc.edu for more information.

Patient Perspective Continued from page 1..

I remember my first doctor's visit; due to the steroids I was on, my blood pressure was very high so I had to go on more medications. I was so scared that I was crying in the doctor's office. My doctors talked with me and calmed me down.

As the days and months passed, my labs started to look better, which gave me the motivation to keep doing better. I learned what I needed to eat and how to cook. I realized the way I cooked was very unhealthy. I learned that spices are my best friend. I learned to read the labels of all foods that were bought. I learned the different words used for the word salt. My water intake has tripled. I also listened to my doctor. When my doctor told me to do something, I did it. I started exercising by walking and over time I started walking miles. I am back at work full time.

The author with one of her K9 co-workers

This is just the start of my journey. The scariest part of this diagnosis for me is that it progresses over time. I decided I will do what needs to be done to slow it down. This diagnosis has changed my lifestyle dramatically, but I have embraced it and am moving forward. I also have a great support system at home and work.

KEEPING UP WITH THE KEOP

During this past year with Covid still around us all, the Kidney Education and Outreach Program (KEOP) remained committed to spreading the word about kidney health and disease prevention, in ways that were safe.

We participated in the annual National Kidney Foundation (NKF) walk in November 2021, raising money as the UNC Kidney Center team and supporting the NKF in their efforts. We enjoyed getting back out into the community at 2 recent events; HEAL '22 Raleigh Health Fair, and the Kinston Community Health Fair, held during National Health Center Week. Community members were able to collect education brochures and talk about ways to keep their kidneys healthy. We look forward to more community events this Fall, and to again incorporate screenings into our program.

Over the past few months, we have significantly strengthened our partnership with the NKF of North Carolina to be able to complement each other's screening and education efforts throughout the state. We have also continued to strengthen our community partnerships with organizations in Nash and Edgecombe counties.

Make sure to stay up to date with the KEOP: https://unckidneycenter.org/outreach/

You can also follow us on twitter at: https://twitter.com/UNCKidney

KidneyTalk®
24/7 Podcast Radio Show
Informative. Inspirational. Entertaining.

RSN's KidneyTalk® is an informative, inspirational, and entertaining, half-hour online radio talk show that launched in 2006. RSN Founder & President Lori Hartwell, who has been a renal disease survivor since 1968, serves as host. KidneyTalk™ provides the audience with practical advice on how to live a full and productive life despite CKD. The show features healthcare professionals and people living successfully with kidney disease who share personal experiences and wisdom. Visit www.rsnhope.org for a full list of podcasts or find them on Apple Podcasts, Google Play and on iHeart Radio. Popular episodes include "Surviving & Thriving: A life-long Kidney Journey", "Tips to Help the Search for a Living Kidney Donor", and "Cooking for your Kidneys".

Teen Raises Funds to Research Rare Disease

By: Kim Morris

There's a mutual commitment between community supported agriculture and life in a community. The farm feeds people fresh food and, in turn, the people support the farm. But it's not always about veggies and flowers. The allegiance can be the heart of a healthy community like in Little Washington, where Petals and Produce, the VanStaalduinen father-son business, has served Beaufort County for 21 years. When Tom's wife Heather faced a rare, hard-to-diagnose illness, their daughter Hannah had an idea. The community responded.

Hannah VanStaalduinen (center) presented a check to the UNC Health Foundation, with her mom Heather (left) and Dr. Vimal Derebail.

During the summer of 2019, Heather began to notice extreme foot pain that progressively traveled up her body and attacked her joints. Then the fatigue came and she was losing weight. She was bedridden for nearly two months with no clear diagnosis from local doctors. It wasn't until January 2020, when Heather was hospitalized for over two weeks, that the family got answers, announced on the Petals and Produce Facebook page.
"Our fierce fighter Heather has been sick since September and her amazing medical team was finally able to make a diagnosis after two weeks in the hospital."

Her medical team at East Carolina University/Vidant Medical Center in Greenville, NC, had determined Heather had granulomatosis with polyangiitis (GPA), formerly known as Wegener's vasculitis.

Heather began to improve with treatment under Vidant's supervision. Following her discharge, she learned that the UNC Kidney Center in Chapel Hill is a center for excellence for glomerular disease and vasculitis, under the leadership of Dr. Ron Falk. She decided to establish joint care at UNC so that she could contribute to the ongoing, longstanding research in vasculitis.

During her first visit, Heather met Dr. Vimal Derebail, associate professor of medicine and one of the faculty in the UNC Glomerular Disease and Vasculitis Clinic. "I was awestruck at Heather's incredible energy," said Dr. Derebail. "She had more motivation as someone just recovering from a life-threatening illness than most people when they're well. Many of her questions focused on what was needed to get better and back to normal but also on what to do to be able to help others with this disease."

GPA causes inflammation in various tissues, including the blood vessels. It can also impact parts of the respiratory tract and kidneys. It is a rare disease, found in an estimated three out of 100,000 people, and at present has no definitive cure.

Heather's daughter Hannah wants to change that. "I've always liked missionary work and have led local missions in my county," said Hannah, who is a junior in high school and thinking about becoming a nurse. Growing up in the Dutch family's business, with four brothers, in a community of faith, shared responsibilities instill values of charity and generosity. *Continued next page...*

VASCULITIS FOUNDATION VIRTUAL CONFERENCE 2022: RECORDINGS AVAILABLE NOW!

All of the presentations from the 2022 Vasculitis Adult and Pediatric Conferences are now available for viewing on the VF website. Visit **https://www.vasculitisfoundation.org/educational-videos/** to view the following presentations:

- Looking Forward – Meet Our Young Clinicians/Investigators
- Vasculitis Patient-Powered Research (VPPRN) Network Update
- Living with Vasculitis: Mental Health and Education
- Vasculitis Foundation Trivial Pursuit Game

VASCULITIS FOUNDATION

Teen Raises Funds continued from page 4..

Hannah helped raise funds to dig two wells in Uganda. She also held a yard sale to benefit Bright Futures, an organization that supports education in Beaufort County Schools. "I want to do everything I can to help out and do my part," she said. "I knew I wanted to hold a fundraiser that would go toward research of the disease."

Hannah planned a yard sale. She asked people in the community to donate items, and she promoted the event in the family's stores in Pinetown and Washington. People in the community responded, dropping off everything from toys, clothing and kitchen items, to sports equipment and furniture. On March 23, when Heather had a follow-up appointment with Dr. Derebail, Hannah came, too. She presented the UNC Kidney Center with a check for $1,200.

Altogether, Hannah raised $1,500 by holding a community yard sale and selling t-shirts.

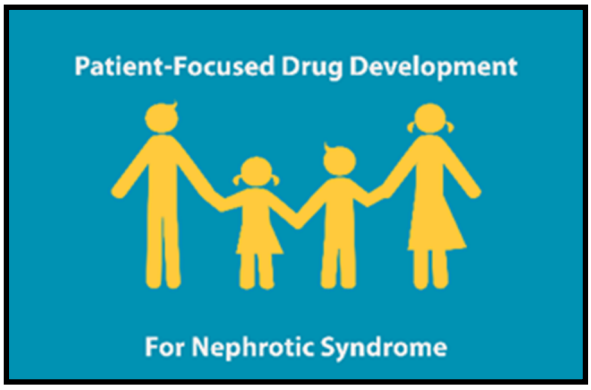
However, Hannah wanted to do more. She sold t-shirts at the family's store, with uplifting messages and inspiring scripture, and she raised an additional $300.

"What feeds Hannah's soul and captures her attention is loving and serving others well," Heather said. "Her own ambitions and goals have been surpassed by the support of our loving community. Great things have come about and burdens have been lightened since my sickness and diagnosis of GPA, because of my amazing family, friends, and community. Hannah's roadmap for life is love, and I can't wait to see where the roads lead her in the future. "Today, Heather's vasculitis is in remission, but Hannah says she won't be stopping, and plans to do more. "There is no cure, so there's no reason to stop yet."

Dr. Falk described her as an extraordinary teenager. "Hannah's commitment and perseverance is incredibly inspiring, and makes us all want to work harder to find the cause and cure for this disease."

Now Enrolling: PREPARing a Clinical Outcomes Assessment Set for Nephrotic Syndrome: Prepare-NS

Participation in a 1-hour interview could help researchers get one step closer to finding new therapies for Nephrotic Syndrome and other rare kidney diseases. Please consider participating in the Prepare-NS research study.



Researchers from the University of Michigan and Northwestern University are studying people's experiences with swelling, or edema, and want to learn from those impacted by Nephrotic Syndrome. The information collected from the interviews will be used to develop a survey to use when testing new medications for Nephrotic Syndrome.

What is involved?

- A sixty minute phone or Zoom interview to discuss your experiences with swelling
- Receive $50 after the interview

Who can participate?

Group 1: Parents or Caregivers of children with Nephrotic Syndrome

- You must be at least 18 years old, speak English, and be caring for a child aged 2-11 years with a diagnosis of Nephrotic Syndrome or specific kidney disease that causes nephrotic syndrome such as Minimal change Disease, FSGS, IgM Nephropathy, or Membranous Nephropathy
- The child must have current swelling or a history of swelling within the past 3 months
- The child must not be receiving dialysis

Group 2: People with Nephrotic Syndrome

- You must be at least 8 years old, speak English, and have a diagnosis of Nephrotic Syndrome or specific kidney disease that causes nephrotic syndrome such as Minimal change Disease, FSGS, IgM Nephropathy, or Membranous Nephropathy
- You must have current swelling or a history of swelling within the past 3 months
- You must not be receiving dialysis

If you are interested or would like more information, please use the QR code below and fill out a contact form and a member of the Prepare-NS team will get back with you soon. Or you can contact the Prepare-NS study team by calling 734-232-4830 or emailing Prepare-NS@med.umich.edu.

Prepare-NS

RECENT PUBLICATIONS USING GDCN REGISTRY DATA

Thanks to your generous participation in our patient registry, we are able to conduct a wide range of studies to help further our understanding of glomerular (kidney) diseases. See below for some of our most recent publications. To read more, you can look up these articles on www.pubmed.com.

Are fertility and menopause different in women with glomerular disease?

Women who have chronic kidney disease are more likely to have menstrual (period) irregularities, difficulty conceiving (subfertility) and early menopause. Autoimmune diseases, like lupus, can also increase the chances of subfertility as can some of the medications that may be needed to treat severe disease, such as cyclophosphamide. Dr. Monica Reynolds, a GDCN researcher, sent a women's health survey to GDCN participants between the ages of 18—65 years old. Female participants were asked to answer questions like "Have you ever tried to become pregnant for more than 6 months without success?" and "Have your periods (menses) stopped permanently?".

The survey responses were returned by 189 women, with the most common underlying glomerular diseases being IgA nephropathy, lupus nephritis, ANCA vasculitis and FSGS. About a third (33%) of participants reported abnormal menstrual cycles (periods) and about 25% reported subfertility (difficulty conceiving a child after an extended period). Neither disease type or cyclophosphamide therapy was significantly associated with subfertility. Among the women who were above the age of 45, 41% reported early menopause, which is much higher than that of the general population (5-10%).

These findings highlight the importance of family planning discussions between nephrologists and women with glomerular disease, as well as the need to assess women with glomerular disease for early menopause.

Subfertility and early menopause in women with glomerular disease. Reynolds ML, Poulton CJ, Blazek LN, Hogan SL, Falk RJ, Derebail VK. Nephrol Dial Transplant. 2021 Apr 26;36(5):948-950.
Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8075376/

How did COVID-19 impact the management of ANCA Vasculitis?

As Coronavirus Disease 2019 (COVID-19) arrived as a global threat, many providers and patients were concerned about the higher risk of infection, difficulty clearing the virus and decrease in antibody production in patients who might be treated with medications that suppress the immune system. As a result, many providers considered changing their approach to treating patients with autoimmune diseases to use medications that might not suppress the immune system as long and that could be stopped easily if needed. GDCN researchers, led by Dr. Manish Saha, collaborated with an international group of centers who care for patients with autoimmune disease to see how COVID-19 influenced the approach to treating patients with ANCA vasculitis and how patient outcomes were affected.

The research group identified 191 subjects with ANCA vasculitis who had a new diagnosis or a new flare of disease after the pandemic began. Among these patients, rituximab, cyclophosphamide or a combination of both were used for initial treatment along with steroids.

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RECENT PUBLICATIONS USING GDCN REGISTRY DATA

ANCA and COVID Continued from page 7...

During the study period (which was before vaccines or new treatments for COVID-19), sixteen subjects with ANCA were diagnosed with COVID-19. Seven were hospitalized and four died. All of the sites that participated in the study continued to treat subjects with ANCA just as they had prior to the pandemic. The researchers did not find anything to suggest that subjects with ANCA were more susceptible to disease, and since this study was conducted before there were approved treatments for COVID, hospitalizations and deaths were probably higher than if the study had been done later on in the pandemic.

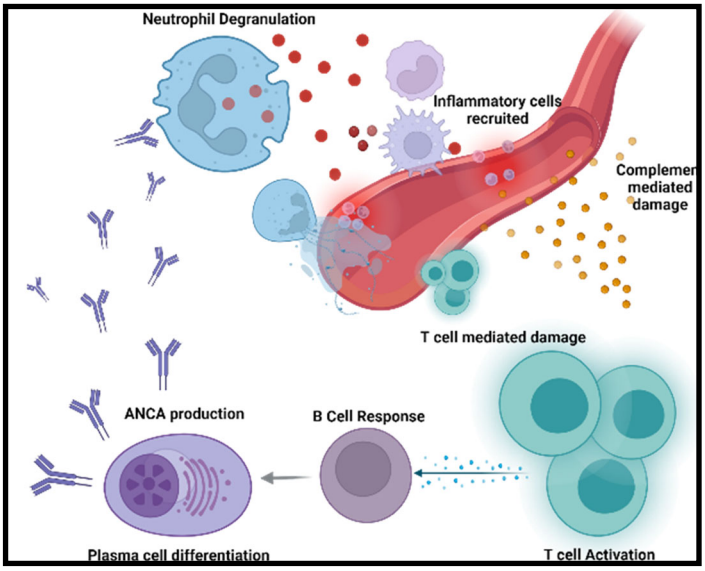
From these data and from other studies that were published that showed immunosuppression may not lead to the highest COVID-19 risks, the researchers felt that optimal treatment was still important and recommended that standard immune treatments should be used to decrease complications and death for patients with severe ANCA vasculitis.

ANCA vasculitis induction management during the COVID-19 pandemic. Salas A, Kant S, Floyd L, Kratky V, Brix SR, Prendecki M, Schönermarck U, Scott J, Saha M, Gauckler P, Li T, Sharma PD, Ayoub I, Morris AD, Dhaygude AP, Hruskova Z, Tesar V, McAdoo SP, Little MA, Derebail VK, Poulton CJ, Seo P, Kronbichler A, Geetha D. Kidney Int Rep. 2021 Nov;6(11):2903-2907. Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8373584/

Do genetic markers have an effect on ANCA Vasculitis?

ANCA vasculitis is an autoimmune disease that has an effect on multiple organs. The disease is characterized by antibodies against either proteinase-3 (PR3) or myeloperoxidase (MPO). The antibodies lead to neutrophil (white blood cells) activation and cause injury to small blood vessels throughout the body. The key immune system components involved include the antigen (PR3 or MPO), antibodies (ANCAs) and different white blood cells (neutrophils, macrophages, monocyte, T cells, plasma cells and B cells). Some of the white blood cells have a molecule called human leukocyte antigen (HLA). This protein helps with activation of the immune system. There are many different types of HLA which are inherited genetically.

We studied clinical outcomes of GDCN participants with ANCA vasculitis and found that participants with a certain type of HLA (HLA-DPB1*04:01) and PR3-ANCA have a higher risk of disease relapse. We found that part of the PR3 protein strongly interacts with HLA-DPB1*04:01 and this leads to activation of T cells which could trigger autoimmune injury. This may explain why patients with HLA-DPB1*04:01 are at increased risk of relapse. We found that when patients are in long term remission off therapy, there is very little interaction between the HLA and PR3.



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CURE GLOMERULONEPHROPATHY (CUREGN) UPDATES

The Cure Glomerulonephropathy Network (CureGN) is a study of 2,400 children and adults with glomerular disease. **282** subjects have now been enrolled from UNC and there are 2639 subjects enrolled overall. Now that we have a few years of data under our belts, studies are taking shape and data is being analyzed. If you would like to see if you are eligible for this study, please contact Maggie D'Angelo at Maggie_dangelo@med.unc.edu or by phone at 919-619-1773.

Are you between the ages of 13-25? Please join the CureGN Adolescent and Young Adult (AYA) Council! Meet with other young people who "get it". Share your experiences and see that you are not alone. We want to hear and learn from you and others do too! Please reach out to CureGN-PACLeads@umich.edu for more information on participating.

Save the Date! The next Fireside Chat is scheduled for Tuesday, November 15th, from 5:30-7:30 EST.

How to Stay Connected with CureGN

Visit the website and view publications: https://curegn-org.webflow.io/publications

CureGN Participant Dashboard: At the time of consent, the patient is notified that by providing their email address they will be sent a link to log in to the dashboard. On the dashboard they can view graphs of their Blood Pressure, Kidney Function (eGFR), Urine Protein (UPC), Urinalysis Protein (dipstick), and Patient Reported Quality of Life. Patients can view the study news feed that contains study information and updates. Lastly, patients can use the dashboard to contact the study team directly through the dashboard. CureGNDashboard.org

If you would like to receive general study communications and updates via email by joining our listserv, contact CureGN-PACLeads@umich.edu

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ANCA genetics Continued from page 8...

Our observations show that there is a clinically important interaction between PR3 and HLA-DPB1 in ANCA vasculitis. We found that when patients are in long term remission, the interaction is similar to healthy individuals. This suggests that we may be able to detect when the immune system is dormant in terms of ANCA vasculitis (immunological remission). Identification of immunologic remission would enable patients and physicians to confidently stop immunosuppressive therapy.

Chen DP, McInnis EA, Wu EY, Stember KG, Hogan SL, Hu Y, Henderson CD, Blazek LN, Mallal S, Karosiene E, Peters B, Sidney J, James EA, Kwok WW, Jennette JC, Ciavatta DJ, Falk RJ, Free ME. Immunological Interaction of HLA-DPB1 and Proteinase 3 in ANCA Vasculitis is Associated with Clinical Disease Activity. J Am Soc Nephrol. 2022 Aug;33 (8):1517-1527. Link: https://pubmed.ncbi.nlm.nih.gov/35672132/

STUDIES CURRENTLY RECRUITING GDCN PATIENTS

The GDCN and the UNC Kidney Center are actively recruiting patients into the studies listed below and on the next page. Please contact the study coordinators listed at the bottom of page 11 or email kidneytrials@unc.edu if you are interested in learning more.

ANCA VASCULITIS

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
CD5 WATCH (NIH)	Vimal Derebail	Anne Froment	Adult Patients with ANCA will be assigned to maintenance therapy or no maintenance therapy based on the level of a type of B cell in their blood.

FOCAL SEGMENTAL GLOMERULOSCLEROSIS

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
PODO (Pfizer)	Amy Mottl	Anne Froment	Patients with FSGS will receive a new investigational drug called PF-06730512 to test for safety, efficacy, and tolerability.
LIPOSORBER (Kaneka)	Koyal Jain	Anne Froment	Patients with primary FSGS that did not respond to standard treatment will use a blood processing device called LIPOSORBER®LA-15.

LUPUS NEPHRITIS

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
MSCs in SLE Trial (NIH)	Sarah Sheikh Keisha Gibson	Julie Walker	Adult patients with moderate to severely active treatment refractory lupus (renal and non-renal) will receive an infusion of mesenchymal stromal cells (stem cells known to possess significant immunosuppressive properties) or placebo.
SANCTUARY (Alexion)	Amy Mottl	Anne Froment	Adult Patients with Lupus Nephritis with 1 gram of proteinuria or more will receive Ravulizumab (a longacting anti-C5 monoclonal antibody) or placebo.
VOCAL (Aurinia)	Keisha Gibson	Fernanda Ochoa Toro	Patients between 12 y.o. and 18 y.o. with Lupus Nephritis will be treated with Voclosporin to assess its efficacy when added to two drugs commonly used to treat this disease; Mycophenolate mofetil (MMF) and corticosteroids.

IGA NEPHROPATHY

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
SANCTUARY (Alexion)	Amy Mottl	Anne Froment	Adult Patients with IgAN with 1 gram of proteinuria or more will receive Ravulizumab (a long-acting anti- C5 monoclonal antibody) or placebo in the first 6 months of the study then will get Ravulizumab.

STUDIES CURRENTLY RECRUITING GDCN PATIENTS

MEMBRANOUS NEPHRITIS

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
REBOOT (NIH)	Vimal Derebail	Anne Froment	Adult Patients with Membranous Nephritis who need treatment with Rituximab will be treated with Rituximab. In addition they will have intramuscular injection of belimumab or placebo.

NEPHROTIC SYNDROME (FSGS, MEMBRANOUS, MINIMAL CHANGE DISEASE, IGAN)

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
CureGN (NIH/NIDDK)	Ronald Falk/ Amy Mottl	Maggie D'Angelo Tashas Cameron-Wheeler	Observational study of children and adults with MN, FSGS, IgA, or Minimal Change Disease biopsied in the last 5 years.
EPPIK (Travere Therapeutics)	Keisha Gibson	Fernanda Ochoa Toro	Children with FSGS, Minimal change disease (MCD), IgAN, Immunoglobulin IgAV, or Alport syndrome (AS) will be treated with Sparsentan to test for safety, efficacy, and tolerability.
AMPLITUDE (Vertex)	Vimal Derebail	Sara Kelley	Adults patients with APOL1-mediated protein-uric kidney disease will be treated with a APOL1 inhibitor or placebo.

DIABETIC KIDNEY DISEASE

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
CureGN Diabetes (NIH)	Any Mottl	Sara Kelley	Observational study of adults with a diagnosis of diabetes MN, FSGS, IgA, or Minimal Change Disease biopsied since 1/1/2009.
Confidence (Bayer)	Amy Mottl	Sara Kelley	Adult patients with chronic kidney disease and type 2 diabetes will be treated with finerenone or empagliflozin or both drugs to compare effi-cacy and safety.

CHRONIC KIDNEY DISEASE

Study name and sponsor	*Study Doctor*	*Study coordinator*	*More about the study*
FIND-CKD (Bayer)	Amy Mottl	Sara Kelley	Adult patients with chronic kidney disease but no diabetes will be treated with finerenone or placebo.

STUDY COORDINATOR CONTACT INFORMATION:

Anne Froment	Maggie D'Angelo	Julie Walker	Fernanda Ochoa-Toro	Sara Kelley
919-445-2622	919-445-2682	919-843-6619	919-445-2671	919-445-2658

Or email us at: kidneytrials@unc.edu

Campus Box #7155
Chapel Hill, NC 27599

Phone: 1-866-462-9371
Fax: 919-962-9635
Email: gdcn@unc.edu

UNC HEALTH CARE
KIDNEY CENTER

www.unckidneycenter.org

@unckidney