CURRICULUM VITAE

Matthew Cooper, M.D. Professor of Surgery Georgetown University School of Medicine Director, Kidney and Pancreas Transplantation Medstar Georgetown Transplant Institute

Date: August 2014

Work Address: Medstar Georgetown Transplant Institute

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Matthew.Cooper@gunet.georgetown.edu

Current Appointments:

Director, Kidney and Pancreas Transplantation

-Medstar Georgetown Transplant Institute

-Medstar Georgetown Transplant Institute at Washington Hospital Center

-Children's National Medical Center

Medical Director Peri-operative Services, Georgetown University Hospital

Washington, DC

Education

Undergraduate: University of Scranton

Scranton, Pennsylvania

Dates Attended: 8/1986- 5/1990

Degree: Bachelor of Science in Biochemistry

Minors: Spanish and Philosophy

Undergraduate Thesis: Carbon-Hydrogen Bond Activation

Graduate/Professional: Georgetown University School of Medicine

Washington, D.C.

Dates Attended: 8/1990- 6/1994 Degree: Doctor of Medicine

Post Graduate Education and Training

Residency: Medical College of Wisconsin Affiliated Hospitals

Milwaukee, Wisconsin

Residency in General Surgery Dates Attended: 7/1994- 6/2000

Postdoctoral Training: Johns Hopkins Hospital

Baltimore, Maryland

Fellow in Transplant Surgery

Dates: 7/2000- 6/2002

Research: Medical College of Wisconsin

Milwaukee, Wisconsin

Division of Transplant Surgery

Dates: 7/1996- 6/1997

Certification

1996 USMLE, Step I, II, III #4-000-981-3

2001 Qualifying Examination

American Board of Surgery

2003 Certifying Examination

American Board of Surgery #48586

Medical Licensure

1994-2000 Wisconsin Medical License #37971

2000- Maryland Medical License #D0056067

2004-2013 Delaware Medical License #C1-0007439

2012- Washington, DC Medical License #MD040706

2013 - Virginia Medical License #0101254579

Professional Experience

2000-2002 Instructor of Surgery, The Johns Hopkins University School of Medicine,

Baltimore, MD

2002-2005 Assistant Professor of Surgery, The Johns Hopkins University School of

Medicine, Baltimore, MD

2005-2012 Associate Professor of Surgery, University of Maryland School of

Medicine, Baltimore, MD

2012- Professor of Surgery, Georgetown University School of Medicine,

Washington, DC

Hospital Appointments

2002 - 2005	Johns Hopkins Hospital, Baltimore, MD
2005 - 2012	University of Maryland Medical System, Baltimore, MD
2012 -	Medstar Georgetown University Hospital, Washington, DC
2012 -	Medstar Washington Hospital Center, Washington, DC
2012-	Children's National Medical Center, Washington, DC

Study Sections/Steering Committees

2008, 2009 HRSA-08-075

Clinical Interventions to Increase Organ Procurement

Washington, DC Role: Grant Reviewer

Professional Society Memberships

Member, American Medical Association

Member, American Society of Transplant Surgeons Member, American Society of Transplant Physicians

Member, The Transplantation Society

Member, International Liver Transplant Society

Member, DC Chapter of the American College of Surgeons

Member, Association of Academic Surgeons Member, Association for Surgical Education Member, American College of Surgeons

Honors and Awards

1990	Magna cum laude – University of Scranton
1990	Excellence in Biochemistry – University of Scranton
1990	National Jesuit Alumni Society Award for Loyalty and Service
1994	National Jesuit Leadership and Service Award – Georgetown University

Honors and Awards (Continued)

1994-1995	Junior Surgical Resident of the Year – Medical College of Wisconsin
1997	First Place – Milwaukee Academy of Surgeons Resident Research Presentation Night
1997	American Trauma Society's Young Investigator Award
1997	First Place, Basic Science Research – Wisconsin Surgical Society
1998	First Place – Medical College of Wisconsin Robert E. Condon Research Awards
1999-2000	Chief Administrative Resident – Medical College of Wisconsin
2007-2008	Surgical Educator of the Year – University of Maryland Department of Surgery
2011-2014	Washington Post Magazine's Super Doctors
2011-2013	Baltimore Magazines' Top Docs

Administrative Service

Institutional Appointments:

2003-2005	Johns Hopkins Hospital Performance Improvement Committee
2003-2005	Johns Hopkins Hospital OR Advisory Committee – Transplant/Vascular/Trauma
2004-2005	Johns Hopkins School of Medicine Education Committee
2004-2005	Johns Hopkins School of Medicine Clinical Research Steering Committee
2004-2005	Johns Hopkins School of Medicine Medical School Council – Dept. of Surgery Representative
2004-2005	Johns Hopkins Hospital DVT Collaborative – Divisional Chair
2006-2012	University of Maryland Division of Transplantation Resident and Medical Student Educational Coordinator

Institutional Appointments (Continued):

2007- 2009	University of Maryland School of Medicine Council – Department of Surgery Representative
2008-2012	University of Maryland Division of Transplantation – Chair, Living Donor Ethics Committee
2008-2012	University of Maryland Division of Transplantation – "Ask the Expert" web-based patient site
2009-2012	University of Maryland Department of Surgery Peer Review Committee
2010-2012	University of Maryland Department of Surgery Medical Student Grading Committee
2011-2012	University of Maryland Medical Center Co-worker Civility Committee
2012-	Georgetown University Hospital/Disney Institute – Patient Experience, Physician Engagement Group
2012-	GUH Organ Donation Committee
2013-	Medical Director, MGUH Operating Rooms
2014-	MGUH Peri-operative Governance Council
2014-	Clinical Resource Allocation Group – MGUH
2014-	MGUH OR Safety Committee

Local and National Service:

2003-2008	Scientific Advisory Board, Genzyme Pharmaceuticals
2003-	Scientific Advisory Board, Novartis Pharmaceuticals
2004-	Ad Hoc Reviewer, Archives of Surgery
2004	Reviewer, Baltimore Academy of Surgery Resident Research Presentations
2004-2006	Member, OPTN/UNOS Living Donor Region 2 Representative

Local and National Service (Continued):

2006-2009	Member, Scientific Studies Committee, American Society of Transplant Surgeons
2006-	Member, OPTN/UNOS Subcommittee, Kidney Paired Donation Program
2006-2009	Reviewer, National Kidney Foundation of Maryland Research Grants
2006-2009	Member, OPTN/UNOS Subcommittee, Living Donor Data
2008-	Reviewer, American Transplant Congress Abstract Submissions
2007-2009	Data Safety Monitoring Board, Y's Therapeutics
2008	Reviewer, ASTS Student Mentor Awards
2008-2010	Chair, UNOS Living Donor Committee
2008-2011	Member, ASTS Fellow's Curriculum Committee
2008- 2010	Clinical Advisory Board/ Data Safety Monitoring Board Quark Pharmaceuticals
2008-	Ad Hoc Reviewer, American Journal of Transplantation
2008-	Ad Hoc Reviewer, Clinical Transplantation
2008-	Ad Hoc Reviewer, Transplantation
2009-2012	Vice-Chairman, Living Legacy OPO's Advisory Board of Trustees
2009-2013	Board Member, National Kidney Foundation of Maryland
2009-2012	Member, National Kidney Foundation End the Wait! Taskforce
2010-	Member, National Kidney Foundation Public Policy Committee
2010-2012	Chairman, National Kidney Foundation of Maryland's Rappel for Kidney Health, Baltimore, MD
2010-	Member, National Kidney Foundation's Living Donor Executive Council

Local and National Service (Continued):

2010	Steering Committee, Living Kidney Donor Follow-up: State of the Art and Future Directions, Crystal City, MD
2010-	Ad Hoc Reviewer, Immunotherapy
2011-2012	Member, UNOS Living Donor Joint Society Working Group
2011	Member, ACOT Realignment Working Group
2011	Co-Chair, 2012 ATC Abstract Review Committee
2011	Program Committee, 2012 24 th International Congress of the Transplantation Society
2012-	American Transplant Congress Program Committee
2012-2014	Board Member, United Network of Organ Sharing
2012-	Board Member, Washington Regional Transplant Community OPO
2012-	Medical Steering Committee, National Capitol Area National Kidney Foundation
2012-	Member, UNOS Kidney Paired Donation Joint Society Working Group
2013-	Board Member, National Capitol Area National Kidney Foundation
2013-	Board Member, American Foundation for Donation and Transplantation
2013 -	Clinical Trial Steering Committee, Opsona Pharmaceuticals
2014-	Steering Committee, AST Sponsored Best Practices in Living Donation
2014-	Board Member, National Kidney Foundation

Educational Activities

Teaching:

Classroom Instruction:

2003- 3rd Year Surgical Clerkship Lecture
Abdominal Organ Transplantation
Vascular Access
Transplant Complications
45, 3rd Year Medical Students – 8 contact hours/yr

Clinical Instruction:

- 2003- Attending Physician In-patient Service 1 fellow, 2 residents, 1 intern, 2 jr. medical students 3 hours/day, 5 months/year
- 2003- Medical Student Instructor/Small group preceptor 4-5 medical students on weekly basis/quarter Case presentations and patient-oriented instruction 1.5 hours/wk, 8 months/year
- 2003- Medical Student Mentor/Advisor
 One-on-one advisor role to second-fourth year medical students with particular interest in a surgical career
 2 hours/month, 12 months/year

CME Instruction:

- 2003 ABC's of Renal Transplantation Towson, MD Course Director
- 2004 Incompatible Renal Transplantation: Solving the Puzzle Baltimore, MD Small-group leader
- Palliative Care: What Every Surgeon Needs to Know
 Baltimore, MD
 Invited lecturer 'Educating the Resident in End-of-Life Issues'
- Symposium on Transplant and Dialysis Center Relationships: Promoting the Partnership
 Baltimore, MD
 Invited lecturer 'Expanded Criteria Donors'

CME Instruction (Continued):

2007 MPA as a Cornerstone Therapy in Immunosuppression

American Transplant Congress

San Francisco, CA

Invited lecturer – 'The Importance of MPA Optimal Dose in Solid Organ

Transplantation'

2007 Optimal MPA Dosing: The Key to Improved Long Term Graft Outcome

European Society of Transplantation

Prague, Check Slovakia Moderator and Lecturer

2008 Maintaining Optimal MPA Dosing Following Kidney Transplantation

Milwaukee, WI

2008 Hot Topics in Kidney Transplantation

WEB-based/Teleconference

Invited Faculty

2010 Extending Allograft Function and Recipient Survival

Baltimore, MD Pittsburgh, PA

Invited Lecturer - Management of Immunosuppression

Mentoring:

Advisees (House staff):

Andrew Singer (2003-2005)

Matthew Weiss (2004-2005)

Joseph Scalea (2007-2012)

Josephine Kweku (2008-2012)

Julia Terhune (2010-2012)

Sarah Carter (2012 – 2012)

Jayme Locke (2003-2005)

Joseph Scalea (2007-2012)

Philip Brazio (2009-2012)

Gabriel Ivey (2012 –

Duncan Yoder (2012 -2014)

Students

Geoffrey Roelant (2005-2008) Khayree Butler (2006-2008) Gerald Gant (2006-2010) Preetha Umamheswaran (2007-2008) Josephine Kweku (2007-2008) Joseph Jones (2007-2008) Caroline Butler (2007-2009) Keri Quinn (2008-2009) Poornima Vanguri (2008-2009) Andres Correa (2008-2010) Burm Lee (2009-2010) Veronica Bustillo (2009-2010) Daniel Smith (2010-2012) Catherine Njathi (2009-2011) John Berquist (2010-2012) Colin Powers (2011-2012)

Grant Support

6/9/04 - 6/9/06

National Kidney Foundation of Maryland, Inc.

A cross-sectional study of African American living kidney donors to assess the risk for adverse renal outcomes

This is single-center, cross-sectional study designed to assess the risk of adverse renal and related risks in African American living kidney donors who donated at the University of Maryland between March 1996 and March 2002 as compared to non-African American living kidney donors.

Principle Investigator: Joseph Nogueira, MD

Role: Co-investigator

Total Direct Costs: \$10,000

6/9/04 - 6/9/06

National Kidney Foundation of Maryland, Inc.

A cross-sectional study of obese living kidney donors to assess the risk for adverse renal outcomes

This is single-center, cross sectional study designed to assess the risk of adverse renal and related risks in obese living kidney donors who donated at the University of Maryland between March 1996 and March 2002 as compared to non-obese living kidney donors from the same period.

Principle Investigator: Joseph Nogueira, MD

Role: Co-investigator Total Direct Costs: \$8,500

7/25/07 - 7/27/09

University of Maryland Other Tobacco-Related Diseases Research Grant
A long-term follow-up pilot study of living kidney donors to assess patterns of smoking and to assess if obesity, African American race and smoking are associated with adverse health outcomes

This is single-center, cross-sectional study designed to (1) compile baseline medical and social information as well as pre-donation evaluation "process of care" data on a large cohort of our center's live donor population, (2) provide data on the link between short-term perioperative smoking cessation and long-term abstinence, (3) provide important data on the adequacy of medical follow-up in live kidney donors, and (4) provide critical data on the health status of prior kidney donors that will help us better estimate the risks associated with obesity, race and smoking in live kidney donors.

Principle Investigator: Joseph Nogueira, MD

Role: Co-Investigator Total Direct Costs: \$50,000

Grant Support (Continued):

1-08-CR-60 01/01/08 - 12/31/10

American Diabetes Association

Steroid Challenge and the Prediction of Post Transplant Diabetes Mellitus

The goal of this project is to determine if a prednisone modified oral glucose tolerance test performed prior to renal transplant in non-diabetic patients predicts who will develop post transplant diabetes mellitus.

Principle Investigator: Kristi Silver, MD

Role: Co-investigator

Total Direct Costs: \$516,462 Total Indirect Costs: \$77,469

Clinical Trial Support:

-Britol-Myers Squibb

12/21/2001-6/24/2003

Open-label, randomized, controlled, multiple-dose study of efficacy and safety of BMS-224818 as Part of a Quadruple Drug Regimen in Renal Transplant Recipients

This protocol looks to assess the efficacy at 6 months of BMS-224818 versus CsA when used in combination with Cellcept, corticosteroids, and basiliximab using a non-inferiority design.

Role: PI

Total Direct Costs: \$245,000

-Fugisawa Healthcare

8/25/2003-4/03/2005

Phase III, Randomized, Open-Label, Comparative, Multi-Center Study to assess the safety and efficacy of Prograf (tacrolimus) and Cellcept, Modified Release (MR) Tacrolimus and Cellcept, and Neoral and Cellcept in de novo Kidney Transplant Recipients

This study investigates the new once-a-day formulation of Tacrolimus versus standard twice dosing Tacrolimus and Neoral in first time kidney transplant recipients.

Role: PI

Direct Costs: \$174,160

-Genzyme Medical Corporation

1/12/2004- 11/18/2005

Randomized, Prospective, Phase II Study Comparing Thymoglobulin in a Rapid Discontinuation of Corticosteroids Protocol with standard corticosteroid therapy in Living Donor Renal Transplantation.

This protocol investigates the avoidance of steroid administration in living donor kidney transplant recipients utilizing polyclonal antibody induction therapy.

Role: PI

Total Direct Costs: \$130,000

-Wyeth Pharmaceuticals

2/01/2004- 4/04/2005

Randomized open-Label Study to Compare the Safety and Efficacy of Two Different Sirolimus Regimens with a Tacrolimus and Mycophenolate Mofetil Regimen in de novo Renal Allograft Recipients.

This protocol investigates two varying immunosuppressive medication levels in order to determine efficacy with the avoidance of medication side effects versus a standard immunosuppressive regimen.

Role: PI

Total Direct Costs: \$106,299

-Novartis Pharmaceuticals

2/01/2004-6/30/2005

A prospective multcenter, open label, randomized study of the safety tolerability, and efficacy of Certican with Simulect, corticosteroids and lower levels versus higher levels of tacrolimus in de novo renal transplantation.

This protocol evaluates the use of an investigational antimetabolite and its cumulative effects with tacrolimus in order to determine and effective and safe medication administration dosage.

Role: PI

Total Direct Costs: \$72,660

-Roche Laboratories Inc

7/18/2004-6/30/2005

An open-label, prospective, randomized, controlled multi-center study assessing fixed dose vs. concentration controlled Cellcept regimens for patients following a single organ renal transplant in combination with full dose and reduced dose calcineurin inhibitors.

The purpose of this protocol is to compare the efficacy and the effects on renal function of a regimen of reduced concentration of calcineurin inhibitor and monitored Cellcept to a regimen of standard concentrations of calcineurin inhibitor and fixed-dose Cellcept.

Role: PI

Total Direct Costs: \$100,000

-Novartis Pharmaceuticals

10/01/2004-6/30/2005

A three-month, open-label, two cohort study to investigate the safety and tolerability of Myfortic in combination with Neoral or Tacrolimus in renal transplant recipients with GI intolerance. The objective of this study is to assess the tolerability of Myfortic in combination with CNIs as determined by gastrointestinal symptom rating scale (GSRS) after conversion from Cellcept within 3 months.

Role: PI

Total Direct Costs: \$130,000

-Fugisawa Healthcare

11/21/2004-6/30/2005

A Phase 2, proof of concept, randomized, open-label, two-arm, parallel group, multi-center study to assess the efficacy and safety of FK778 compared with standard care in renal transplant recipients with untreated biopsy-diagnosed BK Nephropathy.

This protocol looks to assess the efficacy and safety of FK778 vs. standard care of CNI, anti-proliferative agent, and steroids in patients diagnosed with BK nephropathy confirmed by renal biopsy.

Role: PI

Total Direct Costs: \$154,000

-Novartis Pharmaceuticals

01/01/06-12/01/09

A 24-month, multi-center, randomized, open-label non-inferiority study of the efficacy and safety comparing two concentration-controlled Certican regimens with reduced Neoral versus Myfortic with standard dose Neoral in de novo renal transplant recipients

This protocol examines the benefit of a newly-developed mTOR inhibitor (Certican) in combination with reduced CNI compared to standard CNI.

Role: PI

Total Direct Costs: \$187,200

-Isotechnika, Inc.

07/01/06-12/31/07

A Phase IIB, randomized, multi-center, open-label, concentration-controlled, safety study of ISA247 and Tacrolimus (Prograf®) in de novo renal transplant patients

This protocol examines the benefit of a new CNI (ISA247) with limited renal toxicity compared to standard CNI in newly transplanted renal recipients.

Role: PI

Total Direct Costs: \$150,125

-Novartis Pharmaceuticals

08/01/06-02/02/09

A six-month, prospective, multi-center, open label, parallel, randomized study of the safety, tolerability and efficacy of Myfortic (ERL080) with Simulect, Corticosteroids, and two different levels of Tacrolimus in de novo renal transplant recipients.

This protocol evaluates the safety and efficacy of a newly developed mycophenolic acid product (Myfortic) in combination with CNI compared to standard Cellcept.

Role: PI

Total Direct Costs: \$92,611

-Novartis Pharmaceuticals

01/31/07-08/01/08

A 4-week, multicenter, double-blind, randomized, parallel group study to compare the gastrointestinal and tolerability of Myfortic and MMF (CellCept) when administered in combination with calcineurin inhibitors in renal transplant recipients experiencing gastrointestinal intolerance.

This protocol seeks to demonstrated improved tolerability of Myfortic compared to Cellcept in combination with CNI for those renal transplant recipients experiencing GI toxicity secondary to MPA therapy.

Role: PI

Total Direct Costs: \$36,913

-Pfizer, Inc.

11/01/08-07/31/10

A Phase 2 randomized , multicenter, active comparator-controlled trial to evaluate the safety and efficacy of coadministration of CP-690,550 and Mycophenolate Mofetil/Mycophenolate Sodium in de novo kidney allograft recipients (A3921030)

This protocol evaluates the safety and efficacy of a newly developed JAK-3 inhibitor (CP-690,550) compared to CNI with MPA in renal transplant recipients.

Role: PI

Total Direct Costs: \$255,124

-Astellas Pharmaceuticals

04/01/09-3/30/2011

A Phase 2, Randomized, Open-Label, Parallel Group, Multi-Center Study to Assess the Safety and Efficacy of Alefacept in de novo Kidney Transplant Recipients

This protocol evaluates the safety and efficacy of anti-CD2 (Alefacept) vs. CNI in newly transplanted renal recipients.

Role: PI

Total Direct Costs: \$226,210

-Alavita Inc.

03/01/09-03/01/10

A Phase 2, Two-Part Study of the Safety and Tolerability of Diannexin in Kidney Transplant Recipients

This protocol evaluates the impact of a novel phosphodiesterase inhibitor (Diannexin) on the development and the duration of delayed graft function in newly transplanted renal recipients. Role:PI

Total Direct Costs: \$249,134

-LifeCell 08/01/09-05/01/10

Incisional hernia repair in multiple morbid patients: A multicenter, prospective, randomized, controlled, single blinded study of Strattice TM reconstructive tissue matrix vs Proceed

This protocol seeks to compare the safety and efficacy of two products (Strattice – bioprosthetic v. Proceed – artificially produced) utilized in complex hernia repair in multiply morbid patients such as transplant recipients.

Role: PI

Total Direct Costs: \$125,990

-Quark Pharmaceuticals, Inc.

11/01/10-5/31/2013

Controlled, Randomized, Prospective, Double-Blind, Multicenter, Phase I/II, Dose-Escalation Study of the Safety, PK, and Clinical Activity of I5NP for Prophylaxis of Delayed Graft Function in Patients Undergoing Deceased Donor Kidney Transplantation

This protocol evaluates the effect of a small interfering ribonucleic acid (siRNA or I5NP) on the development and duration of delayed graft function (DGF) in newly transplanted kidney recipients.

Role: PI

Total Direct Costs: \$141,765

-Novartis Pharmaceuticals

05/01/10 - 3/13/2012

A 12 month, multi-center, randomized, open-label noninferiority study comparing the safety and efficacy of concentration-controlled Everolimus with low dose tacrolimus to CellCept® (mycophenolate mofetil) with standard dose tacrolimus in de novo renal transplant recipients.

This protocol examines the efficacy and safety of mTOR inhibition (Everolimus) compared to CNI in evaluating the 12 month kidney function of newly transplanted renal allograft recipients.

Role: PI

Total Direct Costs: \$296,320

-Angion Pharmaceuticals

6/28/2011 - present

Multicenter Pilot Study of BB3 to Improve Renal Function in Patients with Signs and Symptoms of Significant Renal Injury after Kidney Transplantation and at Risk for Dialysis

This protocol evaluates the use of a small molecule mimetic of hepatocyte growth factor/scatter factor (HGF/SF or BB3) whose activity is expected to preserve tissue viability and attenuate dysfunction in the setting of organ injury on the development of delayed graft function in kidney transplant recipients.

Role: PI

Total Direct Costs: \$248,013

-Immune Tolerance Network (ITN)

2/19/2011 - 6/60/2012

Immunosuppression with Antithymocyte Globulin, Rituximab, Tacrolimus, and Sirolimus, Followed by Withdrawal of Tacrolimus and Sirolimus, in Living-donor Renal Transplant Recipients.

This protocol sponsored by the ITN seeks to demonstrate immune tolerance of living donor kidney transplant recipients by progressively weaning patients off immunosuppressive medications over a 3 year period.

Role:PI

Total Direct Costs:

-Alberta Transplant Applied Genomics Centre

6/22/2011 - 6/30/2012

The International Collaborative Microarray (INTERCOM) Study

This project aims to develop a new diagnostic system that combines the molecular and histopathological features of kidney transplant biopsies, plus clinical and laboratory parameters, to create the first Integrated Diagnostic System to better direct the care of kidney transplant recipients.

PI: Jonathan Bromberg, MD

Role: Co-investigator

Total Direct Costs: \$56,144

-American Society of Transplant Surgeons

6/29/2011 - 6/30/2012

Changes in the human microbiota induced by post-transplant medication

This protocol is a highly innovative human microbiome research project with the goal to determine the functional setup of the healthy human microbiota, in order to develop prebiotic, probiotic or antibiotic options that could be used as a concomitant treatment in addition to the standard immunosuppressive and antimicrobial therapy.

PI: Jonathan Bromberg, MD

Role: Co-investigator

Total Direct Costs: \$100,000

-Alexion Pharmaceuticals

10/11/2012 - present

A randomized, open-label, multi-center trial to determine safety and efficacy of Eculizumab in the prevention of antibody mediated rejection (AMR) in living donor kidney transplant recipients requiring desensitization.

This protocol was designed to determine the efficacy of employing a complement-inhibitor in the prevention of AMR in living donor pairs who have been found to have a positive crossmatch and in need of pre-transplant desensitization.

Role: PI

Total Direct Costs: \$129,366

-Genentech, Inc

3/3/2013 - present

A phase II randomized, double-blind, placebo-controlled trial of MCMV5322A/MCMV3068A for the prevention of cytomegalovirus disease in high-risk kidney allograft recipients

The purpose of this trial is to evaluate the safety of multiple doses of MCMV5322A/MCMV3068A given intravenously (IV) to CMV seronegative recipients of a renal transplant from a CMV seropositive donor in the absence of standard prophylaxis.

Role: PI

Total Direct Costs: \$355,268.80

-KCI USA, Inc.

7/15/2013- present

The use of Provena incision management system on closed recipient site incisions in renal transplant subjects

The goal of this investigator-initiated trial is to demonstrate decreased wound complications (ie. infections, seromas, dehiscense) with the use of a negative-pressure wound closure devise compared to standard of care.

Role: PI

Total Direct Costs: \$653,751.50

-Opsona Therapeutics

7/15/2013 –present

A three-part, multi-center, randomized, double-blind, placebo-controlled, parallel-group, sequential adaptive phase 2 study to evaluate the safety, tolerability, and efficacy of OPN305, a humanized, monoclonal antibody that blocks toll-like receptor 2, in renal transplant recipients at high risk of delayed graft function.

The purpose of this trial is to assess the efficacy of an antibody formulated against the TLL-2 receptor which has been demonstrated to be significantly upregulated during ischemia reperfusion injury in kidney transplant recipients of an organ from an expanded criteria donor.

Role: PI

Total Direct Costs: \$218,220.80

Publications (Peer – Reviewed)

- 1. <u>Cooper M</u>, Dembny KD, Lindholm P, Lai C, Moore G, Johnson CP, Adams MB, Pieper GM, Roza AM: Effect of Nitric Oxide Scavenging and Inhibition of NF-κB Activity on Cardiac Allograft Survival. *Surg Forum XLVII*: 500-503, 1997.
- 2. <u>Cooper M</u>, Lindholm P, Pieper GM, Seibel R, Moore G, Nakanishi A, Dembny KD, Komorowski RJ, Johnson CP, Adams MB, Roza AM: Myocardial Nuclear Factor KappaB (NF-κB) Activity and Nitric Oxide Production in Rejecting Cardiac Allografts. *Transplantation* 66(7): 838-44, 1998.
- 3. Pieper GM, Cooper M, Nakashini A, Dembny KD, Lindholm P, Lai C, Moore G, Johnson CP, Adams MB, Roza AM: Nuclear Factor KappaB (NF-κB), Nitosomyoglobin Signals and Increased Nitric Oxide in Cardiac Transplantation. *Nit Oxide: Bio and Chem* 2: 296, 1998.
- 4. Pieper GM, <u>Cooper M</u>, Johnson CP, Adams MB, Felix C, Roza AM: Reduction of Myocardial Nitrosyl Complex Formation by a Nitric Oxide Scavenger Prolong Cardiac Allograft Survival. *J Cardiovasc Pharmacol* 35: 114-121, 2000.
- 5. Roza AM, <u>Cooper M</u>, Pieper GM, Hilton G, Dembny KD, Lai C, Lindholm P, Komorowski RJ, Felix C, Johnson CP, Adams MB: Nox 100, A Nitric Oxide Scavenger, Enhances Cardiac Allograft Survival and Promotes Long-Term Graft Acceptance. *Transplantation* 69(2): 227-231, 2000.
- 6. Arepally A, Dagli M, Hofmann LV, Kim HS, <u>Cooper M</u>, Klein A: Treatment of Splenic Artery Aneurysm with the Use of a Stent-Graft. *J Interven Radiol* 13(6): 227-31, 2002.
- 7. Molmenti EP, Pinto PA, Montgomery RA, Su LM, Kraus E, <u>Cooper M</u>, Sonnenday CJ, Klein AS, Kavoussi LR, Ratner LE: Concomitant Surgery with Laparoscopic Donor Nephrectomy. *Am J Transplant* 3(2): 219-23, 2003.
- 8. Sonnenday CJ, <u>Cooper M</u>, Kraus E, Gage F, Handley C, Montgomery RA: The Hazards of Acceptance of Cadaveric Renal Allografts on Pulsatile Perfusion Parameters Alone. *Transplantation* 75(12): 2029-33, 2003.
- 9. Montgomery RA, <u>Cooper M</u>, Kraus E, Rabb H, Samaniego M, Simpkins CE, Sonnenday CJ, Ugarte RM, Warren DS, Zachary AA: Renal Transplantation at the Johns Hopkins Comprehensive Transplant Center. *Clin Transpl* 199-213, 2003.
- 10. Sonnenday CJ, Warren DS, <u>Cooper M</u>, Samaniego M, Haas M, King KE, Shirey RS, Simpkins CE, Montgomery RA: Plasmapheresis, CMV hyperimmune globulin, and anti-CD20 allow ABO-incompatible renal transplantation without splenectomy. *Am J Transplant* 4(4): 1315-1322, 2004.

- 11. Warren DS, Zachary AA, Sonnenday CJ, King KE, <u>Cooper M</u>, Ratner LE, Shirey RS, Haas M, Leffell MS, Montgomery RA: Successful Renal Transplantation Across ABO Incompatible and Positive Crossmatch Barriers. *Am J Transplant* 4(4): 561-568, 2004.
- 12. Warren DS, Simpkins CE, <u>Cooper M</u>, Montgomery RA: Modulating Alloimmune Responses with Plasmapheresis and IVIG. *Curr Drug Targets Cardiovasc Haematol Disord* 5(3): 215-222, 2005.
- 13. Segev DL, Simpkins CE, Warren DS, <u>Cooper M</u>, Maley WR, Melancon JK, Kozlowski T, Montgomery RA: ABO Incompatible High Titer Renal Transplantation without Splenectomy or Anti-CD20 Treatment. *Am J Transplant* 5(10): 2570-2575, 2005.
- 14. Montgomery RA, Zachary AA, Ratner LE, Segev DL, Hiller JM, Houp J, <u>Cooper M</u>, Kavoussi L, Jarrett T, Burdick J, Maley WR, Melancon JK, Kozlowski T, Simpkins CE, Phillips M, Desai A, Collins V, Reeb B, Kraus E, Rabb H, Warren DS: Clinical Results from Transplanting Incompatible Live Kidney Donor/Recipient Pairs Using Kidney Paired Donation. *JAMA* 294(4): 1655-63, 2005.
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- 145. Mismatched Eplets in HLA Antigens May Predict Development of De Novo Donor Specific Antibody in Kidney Transplant Recipients. Verbesey J, Timofeeva O, Li D, Javaid B, Grafals M, Gilbert A, Rosen-Bronson S, Cooper M. 2014 World Transplant Congress, San Francisco, CA July 28, 2014.
- 146. Recurrence Without Reduced Survival: The Risk of Kidney Allograft Failure Due to Recurrent IgA Nephropathy. Gilbert A, Cooper M, Verbesey J, Weems P, Ghasemian S, Moore J, Grafals M, Nilubol C, Moore J, Javaid B. 2014 World Transplant Congress, San Francisco, CA July 28, 2014.
- 147. Cause and Effect: Membanoproliferative Glomerulonephritis Type 1 and Type II Recur Frequently and Result in Significant Graft Loss. Gilbert A, Cooper M, Verbesey J, Weems P, Ghasemian S, Grafals M, Nilubol C, Javaid B. 2014 World Transplant Congress, San Francisco, CA July 28, 2014.
- 148. The Benefits of a Well Functioning Allograft: Poorer Graft Function After Renal Transplantation Predisposes to Higher Rates of CMV Viremia. Gilbert A, Ko E, Abi-Nader M, Weems P, Ghasemian S, Moore J, Verbesey J, Grafals M, Cooper M, Javaid B. 2014 World Transplant Congress, San Francisco, CA July 30, 2014.

Invited Publications:

- 1. <u>Cooper M</u>. National Kidney Foundation's End the Wait Campaign A Physician's Perspective 2009.
- 2. Manitpiskitul W, <u>Cooper M</u>. Mycophenolic acid agents: is enteric coating the answer? *Trans Research Risk Mgmt* 2010.
- 3. <u>Cooper M</u>, Forland C. The Elderly As Recipients of Living Donor Kidneys: How Old is Too Old? *Curr Opin Trans* 16(2): 250-5, 2010.
- 4. Dew MA, <u>Cooper M</u>. Successful Follow-up of Living Donors: Strategies to Make it Happen. *Prog Trans* 21(2): 94-96, 2011.
- 5. Invited Critique Just Because You Can, Doesn't Mean You Should...Because Many of Us Really Can't! *Arch Surg* 146(7): 850, 2011.
- 6. Scalea J, Cooper M. Surgical Strategies for Type 2 Diabetes. Transplant Rev 2011.
- 7. Scalea J, <u>Cooper M</u>. Current Status of Kidney/Pancreas Combined Transplantation. *J Intens Care Med* 2011.

Book Chapters:

- 1. <u>Cooper M</u>, Hawxby A. Vascular Access. In: <u>Current Surgical Therapy</u>, 8th <u>Edition</u>. St. Louis, MO: Mosby-Year Book, Inc, 2004: 828-830.
- 2. Bartlett S, <u>Cooper M</u>. Expanded Criteria Donors. In: <u>Principles of Transplantation</u>. Wiley and Sons, 2012
- 3. Barth R, <u>Cooper M</u>. Single-Site Minimally Invasive Surgery: What is Currently Possible? In: <u>Current Surgical Therapy</u>, 11th <u>Edition</u>. Elsevier, Inc. 2013
- 4. Verbesey J, Cooper M. Paired Kidney Exchange

Oral Presentations:

- 1. Myocardial Nuclear Factor KappaB (NF-κB) Activity and Nitric Oxide Production in Rejecting Cardiac Allografts
 - The American Society of Transplant Surgeons' 23rd Annual Scientific Meeting. Chicago, IL. May, 1997.
 Milwaukee Academy of Surgeons Resident Research Presentation Night. Milwaukee, WI. March, 1997.
 - MCW Department of Surgery Clinic Day. Milwaukee, WI. April, 1997.
- 2. Effects of Nitric Oxide Scavenging and Inhibition of NF-κB Activity on Cardiac Allograft Survival. Surgical Forum, American College of Surgeons' 83rd Annual Clinical Congress. Chicago, IL. October, 1997.
- 3. Long Term Allograft Survival with Nitric Oxide Scavenging. Wisconsin Surgical Society Annual Fall Meeting. Madison, WI. October, 1997.
- 4. Antioxidant Therapy with Low Dose Cyclosporine Enhances Allograft Survival and Promotes Tolerance. Medical College of Wisconsin Robert E. Condon Research Awards. Milwaukee, WI. June, 1998.
- 5. Expanded Criteria Donors. ABC's of Renal Transplantation CME course. Towson, MD. Feb. 2004.
- 6. Positive Crossmatch and ABO-incompatible Kidney Transplantation. Canadian Society of Xenotransplantation. Ontario, Canada. May 2004.
- 7. Teaching Residents about Palliative Care. Palliative Care: What Every Surgeon Needs to Know. Baltimore, MD. May, 2005.
- 8. Laparoscopic Donor Nephrectomy for Transplantation: 10 Years and 1000 Consecutive Cases. World Transplant Congress. Boston, MA. July, 2006.
- 9. Outcomes Following Vascular Reconstruction for 1000 Consecutive Laparoscopic Donor Nephrectomies. World Transplant Congress. Boston, MA. July, 2006.
- 10.Living Kidney Donor Relationship in Caucasian and African-American Populations and Implications For Targeted Donor Education Programs. Academic Surgical Congress. Phoenix, AZ, Feb, 2007.
- 11. Transplant 101: Background for Transplant Nursing Professionals. Baltimore, MD. May 2007.

Oral Presentations (Continued):

- 12. Impact of Induction Agents on Renal Recipient Outcomes of the First 1000 Laparoscopic Donor Nephrectomies at a Single Institution. American Transplant Congress. San Diego, CA, May 2007.
- 13. Renal Transplantation in ESRD with Cirrhosis. ASTS/AST Combined Kidney/Liver Transplant Consensus Conference. Chicago, IL. Sept. 2007.
- 14. New Life. New Challenges. Life Following Transplantation. Transplant Patient Support Group. Baltimore, MD. Nov. 2007.
- 15. As Kidney Transplantation Moves Toward 2009: A View of Potential Advances and the Ongoing Challenges. Novartis Advisory Board Meeting. Dallas, TX. Nov. 2007.
- 16. Successful Simultaneous Bilateral Native Nephrectomy and Living Donor Renal Transplantation for Autosomal Dominant Polycystic Kidney Disease. Academic Surgical Congress. Huntington Beach, CA, Feb. 2008.
- 17. Risk Factors for Delayed Graft Function in Living Donor Transplantation. American Transplant Congress. Toronto, June 2008.
- 18. Shifting Focus Toward Long-Term Outcomes in Kidney Transplantation. Novartis Advisory Board Meeting. Chicago, IL, June 2008.
- 19. Approaches to Optimizing Immunosuppression Regimens to Improve Long-Term Outcomes. Novartis Advisory Board Meeting. Chicago, IL, June 2008.
- 20. Outcomes of African-American Living Kidney Donors. International Transplant Congress. Sydney, AUS, Aug. 2008.
- 21. Volume-Outcome Relationships in the Procurement of Transplantable Deceased Donor Organs. Academic Surgical Congress. Fort Myers, Florida, Feb. 2009.
- 22. Outcomes Associated with Dose Manipulations of Enteric-Coated Mycophenolate Sodium (EC-MPS) vs. Mycophenolate Mofetil (MMF) in Renal Transplantation. American Transplant Congress. Boston, June 2009.
- 23. When Zero-Mismatch Means Zero: The Hazards of Our Deceased Donor Allocation System. American Transplant Congress. Boston, June 2009.
- 24. Valuable Lessons Learned in Pancreas Re-Transplantation over a 20-year Period. IPITA. Venice, Italy, Oct 2009.

Oral Presentations (Continued):

- 25. Diannexin, a Novel Ischemia/Reperfusion Therapeutic Agent, Reduces Delayed Graft Function (DGF) in Renal Transplant Recipients from Marginal Donors. San Diego, CA, American Transplant Congress. May 2, 2010.
- 26. When Asking Too Much Leaves Too Little: An Analysis of Obese Living Kidney Donors To Assess the Risk of Hypertension and Adverse Renal Outcomes at a Single Institution. San Diego, CA, American Transplant Congress. May 3, 2010.
- 27. Living Kidney Donor Relationships in Caucasian and African American Populations and Implications for Targeted Donor Education Programs. Vancouver, CA, XXIII International Congress of the Transplantation Society. Aug 16, 2010.
- 28. Treatment with Diannexin Post-Reperfusion Decreases DGF and Improves GFR in Renal Transplant Recipients of Marginal Kidney Donors. Vancouver, CA, XXIII International Congress of the Transplantation Society. Aug 16, 2010.
- 29. A 12-month Single Center Evaluation of GI-complications In Renal Transplant Recipients Initiated on Mycophenolic Acid Therapy. Vancouver, CA, XXIII International Congress of the Transplantation Society. Aug 19, 2010.
- 30. Portal v. Systemic Drainage of Solitary Pancreas Transplantation: New Views on Old Concepts. Prague, Czech Republic. International Pancreas and Islet Transplantation Association. June 3, 2011.
- 31. Incidence of Wound Events and Lymphocele Formation with *De Novo* Everolimus Use: The Result of 3 RCTs. Boston, MA, American Transplant Congress. June 1, 2012.

Published Multimedia:

- 1. Maryland Health Today Living Kidney Donors. May 2008.
- 2. PeerView Press Comparing MPAs for Renal Transplant Recipients In a Real World Setting: An Expert's Perspective. www.peerviewpress.com/n13 March 2010.
- 3. 'Ask A Doc' Georgetown University Hospital Patient Information Program. Feb. 2013.

Invited Presentations:

- 1. Status of Living Donor Follow-up. Advisory Committee on Transplantation. Rockville, MD Nov. 2008.
- 2. Mycophenolic Acid in Solid Organ Transplantation. Chinese Society of Transplantation. Beijing, China, April 2009.
- 3. Living Donor Nephrectomy and Outcomes. UMMS Transplant Preceptorship, Baltimore, MD, May 2009.
- 4. In the Beginning, There Were Living Donors... American Foundation for Donation and Transplantation Living Kidney Donation Conference. Nashville, TN, Oct 8-9, 2009.
- 5. Understanding the Risks and Benefits of Living Donation. American Foundation for Donation and Transplantation Living Kidney Donation Conference. Nashville, TN, Oct 8-9, 2009.
- 6. Metabolic Surgery for Non-Obese Patients with Type 2 Diabetes Mellitus. IPITA. Venice, Italy, Oct 13, 2009.
- 7. Current Status of the OPTN's Progress in Revising Living Donor Policies. *Transplant News* Webinar. October 22, 2009.
- 8. Living Donor Transplantation. University of Maryland Endocrinology Grand Rounds. Oct 29, 2009.
- 9. Introduction to Transplantation. Centers for Medicare and Medicaid Services, Transplant Center Surveyor Training. Baltimore, MD. December 8, 2009.
- 10. Working Together: The OPO and the Transplant Center. Centers for Medicare and Medicaid Organ Procurement Organization Surveyor Training. Baltimore, MD. Jan. 26, 2010.
- 11. Transplant Surgery: The Surgeon's Perspective. Bristol-Myers-Squibb Medical Team Training Session. Trenton, NJ. April 21, 2010.
- 12. Strategies to Improve Living Donor Follow-up. UNOS Transplant Management Forum. Orland, FL. April 22, 2010.
- 13. Current Status of UNOS Paired Kidney Exchange Program. UNOS Organ Procurement Organization National Meeting. Baltimore, MD. June 18, 2010.
- 14. Living Donor Transplantation. Living Legacy Foundation OPO. Baltimore, MD. June 30, 2010.

Invited Presentations (Continued):

- 15. Transplant Updates. Maryland's NP Educational Program. Baltimore, MD. November 9, 2010.
- 16. Life as a Transplant Surgeon. University of Maryland's Medical Student Surgical Interest Group. Baltimore, MD. March 9, 2011.
- 17. Kidney Allocation and Transplantation. St. Joseph's Hospital Medical Grand Rounds. Towson, MD. March 16, 2011.
- 18. Cardiac Workup for Kidney and Pancreas Transplant Candidates. University of Maryland Anesthesia Grand Rounds. Baltimore, MD. April 7,2011.
- 19. Living Donor Nephrectomy. American Foundation for Donation and Transplantation Living Kidney Donation Conference. Bal Harbour, Fl. May 20, 2011.
- 20. What Should be Considered in Selecting an MPA Agent. Today and Tomorrow in Transplantation (T3 Symposium). Seoul, Korea May 28, 2011.
- 21. The 'Value' of Living Kidney Donation. Loyola College. Towson, MD. Jan 19, 2012.
- 22. A Day in the Life of a Transplant Surgeon. MD Mindset. San Diego, CA. Feb 1, 2012.
- 23. The Past, the Present, and the Future of Kidney Transplantation. The DC Chapter of the International Transplant Nurses' Society. Washington, DC. Dec. 13, 2012.
- 24. Growing Competitive Programs in the Current Environment. 2013 American Transplant Congress, Seattle, WA, May 21, 2013.
- 25. Clinical Trials for Attenuating Ischemia Reperfusion Injury. 2013 American Transplant Congress, Seattle, WA, May 22, 2013.
- 26. Steroid Avoidance Protocols in Kidney Transplantation. Sanofi Transplant Leadership Summit, Prague Oct. 4, 2013.
- 27. Pancreas Transplantation for Type 1 and Type 2 Diabetes. Transplant Fellow's Symposium, Washington, DC, Oct. 9, 2013.
- 28. Kidney Transplantation for the OR Professional. Georgetown University Hospital OR Inservice, Washington, DC, Oct 24, 2013.