

## BIOGRAPHICAL

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Marital Status: Married; Two children  
  
Date of Birth: December 24, 1963  
Birthplace: Brantford, Ontario  
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## **EDUCATION**

## **UNDERGRADUATE:**

## GRADUATE:

1988-1990	Queen's University Kingston, Ontario, Canada	M.Sc., 1990	Statistics
1993-1999	University of Pittsburgh Pittsburgh, PA	Ph.D., 1999	Epidemiology

## APPOINTMENTS AND POSITIONS

Position	Department	Professor
2020 (July) – Present	Department of Public Health Brody School of Medicine East Carolina University Greenville, NC	

2009 (Feb) – 2018 (June)	CTI Clinical Trial and Consulting Raleigh, NC	Vice President, Biostatistics & Health Outcomes Research
2008 (April) – 2009 (January)	RTI-Health Solutions Research Triangle Park, RTP, NC	Vice President, Biometrics
2004 (May) – 2008 (March)	RTI-Health Solutions Research Triangle Park, RTP, NC	Global Head, Biometrics
2001(April) – 2004 (April)	RTI-Health Solutions Research Triangle Park, RTP, NC	Head, Statistics and Data Management
1998 – 2001 (March)	SangStat Medical Corporation Fremont, CA	Director, Biometrics
1991 - 1997	Thomas E. Starzl Transplantation Institute, Pittsburgh, PA	Research Instructor of Surgery
1990 - 1991 (June)	University of Western Ontario London, Ontario, Canada	Assistant Director, Biostatistics Support Unit

#### **ADJUNCT ACADEMIC APPOINTMENTS**

2021(July) – Present	Department of Mathematics East Carolina University Greenville, NC	Professor
2013 - Present	Department of Surgery Duke University, Durham, NC	Assistant Consulting Professor
2005 – 2009	Department of Internal Medicine Saint Louis University, Saint Louis, MO	Associate Professor
2004 – 2009	Department of Biostatistics UNC-Chapel Hill, NC	Assistant Professor
1999-2000	Department of Statistics Stanford University, Stanford, CA	Industrial Affiliate
1991 - 1997	Department of Mathematics & Natural Sciences Carlow College, Pittsburgh, PA	Lecturer

## **MEMBERSHIPS IN PROFESSIONAL AND SCIENTIFIC SOCIETIES**

The American Society of Transplantation	2003 - Present
International Society for Pharmacoeconomics And Outcomes Research	2004 - Present
Drug Information Association	1997 - Present
The American Statistical Association	1992 - Present
The Statistical Society of Canada	1990 - 1993
The American Mathematical Society	1988 – 2004

## **PUBLICATIONS**

1. Jones DL, Irish WD, Klein GJ: Defibrillation Efficacy: Comparison of defibrillation threshold versus dose-response curve. **Circulation Research** 69:45-51, 1991.
2. McMichael J, Irish WD, McCauley J, Shapiro R, Gordon R, Van Thiel DH, Lieberman R, Fung J, Starzl TE: Evaluation of a novel intelligent dosing system (IDS) for optimizing FK-506 therapy. **Transplantation Proceedings** 23:2780-2782,1991.
3. Jain A, Fung J, Tzakis T, Irish WD, Abu-Elmagd K, Alessiani M, Todo S, Reyes J, Warty V, Venkataraman R, Starzl TE: Comparative study of cyclosporine and FK-506 dosage requirement in adult and pediatric orthotopic liver transplantation. **Transplantation Proceedings** 23:2763-2770,1991.
4. Nikolaidis NL, Abu-Elmagd K, Thomson AW, Rilo HR, Irish WD, Van Thiel DH, Fung JJ, Starzl TE: Metabolic Effects of FK 506 in patients with severe psoriasis: Short-term follow-up of seven cases. **Transplantation Proceedings** 23:3325-3327,1991.
5. Kusne S, Fung J, Irish WD, Alessiani M, Jain A, Abu-Elmagd K, Takaya S, Torre-Cisneros J, Martin M, Todo S, Starzl TE: The incidence of infection during a randomized trial comparing cyclosporine to FK-506 immunosuppression in liver transplantation. **Transplantation Proceedings** 24(1):429-430, 1992.
6. Florel RC, MacDonald DR, Irish WD, Bernstein MA, Leibel SA, Gutin PH, Cairncross JG: Selection Bias, Survival and brachytherapy for glioma. **Journal of Neurosurgery** 76(2):179-183, 1992.

7. Kusne S, Torr-Cisneras J, Manez R, Irish W, Martin M, Fung J, Simmons R, Starzl TE: Factors associated with invasive lung aspergillus and the significance of positive aspergillus culture after liver transplantation. **Journal of Infectious Disease** 166:1379-83, 1992.
8. Shapiro R, Jordan VP, Scantlebury V, Fung JJ, Jensen C, Vivas C, McCauley J, Irish WD, Mitchell S, Demetris AJ, Randhawa P, Jain A, Tzakis A, Kakala TR, Simmons RL, Starzl TE: Randomized trial of FK506/Prednisone vs FK506/Azathioprine/Prednisone after renal transplantation: A preliminary report. **Transplantation** 25(1):669-672, 1993.
9. Shapiro R, McCauley J, Scantlebury V, Woods H, Irish W, McMichael J, Jordan M, Vivas C, Fung JJ, Starzl TE: Effect of recipient race on waiting time for renal transplantation at the University of Pittsburgh. **Transplantation Proceedings** 25:2458-2459, 1993.
10. Scantlebury V, McCauley J, Woods H, Shapiro R, Irish W, McMichael J, Jordan M, Vivas C, Fung J, Starzl TE: Posttransplantation hypertension in blacks versus nonblacks. **Transplantation Proceedings** 25:2456-2457, 1993.
11. Carroll PB, Ricordi C, Shapiro R, Rilo H, Fontes P, Scantlebury V, Irish W, Tzakis AG, Starzl TE: Frequency of kidney rejection in diabetic patients undergoing simultaneous kidney and pancreatic islet cell transplantation. **Transplantation** 55:761-764, 1993.
12. Alessiani M, Cillo U, Fung J, Irish W, Abu-Elmagd K, Jain A, Takaya S, Van Thiel D, Starzl TE: Adverse effects of FK506 overdosing after liver transplantation. **Transplantation Proceedings** 25(1):628-634, 1993.
13. Manez R, Kusne S, Martin M, Linden P, Irish W, Torre-Cineros, Kramer D, Ho H, Starzl TE: The impact of blood transfusion on the occurrence of pneumonitis in primary cytomegalovirus infection after liver transplantation. **Transfusion** 33:594-597, 1993.
14. Abu-Elmagd K, Selby R, Iwatsuki S, Fung J, Tzakis A, Todo S, Demtris A, Baddour N, Irish W, Van Thiel D, Starzl T: Cholangiocarcinoma and sclerosing cholangitis: clinical characteristics and effect on survival after liver transplantation. **Transplantation Proceedings** 25(1 Pt 2):1124-1125, 1993.
15. Carroll P, Ricordi C, Shapiro R, Rilo H, Fontes P, Scantlebury V, Irish W, Tzakis A, Starzl T: Frequency of kidney rejection in diabetic patients undergoing simultaneous kidney and pancreatic islet cell transplantation. **Transplantation** 55(4):761-764, 1993.
16. Rilo HR, Carroll PB, Shapiro R, Fontes P, Scantlebury V, Irish W, Tzakis AG, Starzl T, Ricordi C: Effect of Intraportal human islet transplantation on kidney graft survival in simultaneous kidney-allografts. **Transplantation Proceedings** 25(1 Pt 2):955-956, 1993.

17. Shah G, Demetris A, Irish W, Scheffel J, Mimms L, Van Thiel D: Frequency and severity of HCV infection following orthotopic liver transplantation: Effect of donor and recipient serology for HCV using a second generation ELISA test. **Journal of Hepatology** 18:279-283, 1993.
18. Scantlebury V, McCauley J, Woods H, Shapiro R, Irish W, McMichael J, Jordan M, Vivas C, Fung J, Starzl TE: Post transplant hypertension in blacks versus non-blacks. **Transplantation Proceedings** 25(4):2456-2457, 1993.
19. McCauley J, Shapiro R, Woods H, Scantlebury V, Irish W, McMichael J, Jordan M, Vivas C, Starzl TE: Renal transplantation under FK506 in African-Americans: early experience. **Transplantation Proceedings** 25(4):2468-2469, 1993.
20. Thomson AW, Woo J, Lemster B, Irish W, Huang LL, Carroll PB, Rilo HR, Abu-Elmagd K, Eidelman B: Incidence of CD4+ IL-2R+ and CD4+ 2H4+ T-cells in progressive multiple sclerosis and the influence of short-term (3 months) FK506 therapy. **Annals of the New York Academy of Sciences** 696:245-249, 1993.
21. Scantlebury V, Shapiro R, Tzakis A, Jordan ML, Vivas C, Ellis D, Gilboa N, Hopp L, Irish W, Mitchell S, Hakala TR, Simmons RL, Starzl TE: Pediatric kidney transplantation at the University of Pittsburgh. **Transplantation Proceedings** 26(1):46-47, 1994.
22. Tanabe M, Todo S, Murase N, Irish W, Miyazawa H, Fijisaki S, Starzl TE: Combined immunosuppression therapy with low-dose FK506 and antimetabolites in rat allogeneic heart transplantation, **Transplantation** 58:23-27, 1994.
23. Eghtesad B, Bronshter O, Irish W, Casavilla A, Abu-Elmagd K, Van Thiel D, Tzakis A, Fung J, Starzl TE: Disease gravity and urgency of need as guidelines for liver allocation, **Hepatology** 20(1):56-62, 1994.
24. Frezza EE, Swaminathan A, Asrian A, Doria C, Bonet H, Irish W, Warty SV, Todo S, Starzl TE, Venkataraman R: Water, sodium, potassium and D-xylose absorption in canine small bowel transplantation. **Transplantation Proceedings** 26(3):1661, 1994.
25. Hamamoto I, Takaya S, Todo S, Bronshter O, Fujita S, Van Gulik TM, Nakamura K, Irish W, Starzl TE: Can adenine nucleotides predict primary nonfunction of the human liver homograft? **Transplant International** 7(2):89-95, 1994.
26. Van Thiel DH, Friedlander L, Fagioli S, Wright HI, Irish W, W, Gavaler JS: Response to interferon alpha therapy is influenced by the iron content of the liver. **Journal of Hepatology** 20(3):410-5, 1994.
27. Gayowski TJ, Shunzaboro I, Madariaga J, Selby R, Todo S, Irish W, Starzl TE: Experience in hepatic resection for metastatic colorectal cancer: Analysis of clinical and pathologic risk factors. **Surgery** 16:703-11, 1994.

28. Martin M, Manez R, Linden P, Estores D, Torre-Cisneros J, Kusne S, Ondick L, Ptachcinski R, Irish W, Kisor D: A prospective randomized trial comparing sequential ganciclovir-high dose acyclovir to high dose acyclovir for prevention of cytomegalovirus disease in adult liver transplant recipients. **Transplantation** 58(7):779-85, 1994.
29. Shapiro R, Tzakis A, Scantlebury V, Jordan M, Vivas C, Ellis D, Gilboa N, Irish W, Hopp L, Reyes J, et al.: Improving results of pediatric renal transplantation. **Journal of the American College of Surgeons** 179(4): 424-32, 1994.
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31. Manez R, Kusne S, Abu-Elmagd K, Reyes J, Irish W, Green M, Furukawa H, Kadry Z, Tzakis A, Todo S, et al.: Factors associated with recurrent cytomegalovirus disease after small bowel transplantation. **Transplantation Proceedings** 26(3): 1422-3, 1994.
32. Lemster B, Huang LL, Irish W, Woo J, Carroll PB, Abu-Elmagd K, Rilo H, Johnson N, Russell-Hall R, Fung J, Starzl TE, Thomson A: Influence of FK506 (tacrolimus) on circulating CD4+ T cells expressing CD25 and CD45RA antigens in 19 patients with chronic progressive multiple sclerosis participating in an open label drug safety trial. **Autoimmunity** 19:89-98, 1994.
33. Shapiro R, Jordan M, Scantlebury V, Vivas C, Fung J, McCauley J, Tzakis A, Randhawa P, Demetris AJ, Irish W, Simmons RL, Starzl TE: A prospective, randomized trial of FK-506 in renal transplantation - a comparison between double- and triple-drug therapy. **Clinical Transplantation** 8:508-515, 1994.
34. Shapiro R, Scantlebury V, Jordan M, Vivas C, Tzakis A, Ellis D, Gilboa N, Hopp L, McCauley J, Irish W, et al. FK506 in pediatric kidney transplantation- primary and rescue experience. **Pediatric Nephrology** S43-48, 1995.
35. VanThiel DH, Wright H, Carroll P, Abu-Elmagd K, Rodriguez-Rilo H, McMichael J, Irish W, Starzl TE: Tacrolimus: a potential new treatment for autoimmune chronic active hepatitis - results of a open-label preliminary trial. **American Journal of Gastroenterology** 90:771-776, 1995.
36. Scantlebury V, Shapiro R, McCauley J, Jordan M, Vivas C, Irish W, Tzakis A, Ellis D, Gilboa N, Starzl TE: Renal transplantation under cyclosporine and FK506 for hemolytic uremic syndrome. **Transplantation Proceedings** 27:842-843, 1995.
37. Shapiro R, Jordan M, Scantlebury V, Vivas C, Fung JJ, McCauley J, Randhawa P, Demetris AJ, Irish W, Jain A, et al. A prospective, randomized trial of FK506/prednisone vs FK506/azathioprine/prednisone. **Transplantation Proceedings** 27:814-817, 1995.

38. Tanabe M, Todo S, Murase N, Irish W, Miyazawa H, Fujisaki S, Starzl TE: Therapeutic synergism between low-dose FK 506 and antimetabolites in rat allogeneic heart transplantation. **Transplantation Proceedings** 27:364-365, 1995.
39. Jain A, Fung JJ, Todo S, Reyes J, Selby R, Irish W, Doyle H, Abu-Elmagd K, Casavilla A, Nour B, *et al.* One thousand consecutive primary orthotopic liver transplants under FK 506: survival and adverse events. **Transplantation Proceedings** 27:1099-1104, 1995.
40. Takaya S, Doyle H, Todo S, Irish W, Fung JJ, Starzl TE: Reduction of primary nonfunction with prostaglandin E1 after clinical liver transplantation. **Transplantation Proceedings** 27:1862-1867, 1995.
41. Manez R, Kusne S, Green M, Abu-Elmagd K, Irish W, Reyes J, Furukawa H, Tzakis A, Fung JJ, Todo S, *et al.* Incidence and risk factors associated with the development of cytomegalovirus disease after intestinal transplantation. **Transplantation** 59:1010-1014, 1995.
42. Shapiro R, Jordan ML, Scantlebury VP, Vivas C, Fung JJ, McCauley J, Randhawa P, Demetris AJ, Irish W, Mitchell S, Hakala T, Simmons RL, Starzl TE: A prospective randomized trial of FK506-based immunosuppression after renal transplantation. **Transplantation** 59:485-90, 1995.
43. Grossi P, Minoli L, Percivalle E, Irish W, Vigano M, Gerna G: Clinical and virological monitoring of human cytomegalovirus (CMV) infection in 294 heart transplant recipients. **Transplantation** 59:847-851, 1995.
44. Van Thiel DH, Carroll P, Abu-Elmagd K, Rodriguez-Rilo H, Irish W, McMichael J, Starzl TE: Tacrolimus (FK506), a treatment for primary sclerosing cholangitis: results of an open-label preliminary trial. **American Journal of Gastroenterology** 90:455-459, 1995.
45. Bronshter O, Manez R, Kusne S, Irish W, Roland W, Jain A, llull R, Demetris AJ, Starzl TE: Posttransplant B, non-A non-B, and cytomegalovirus hepatitis increase the risk of developing chronic rejection after liver transplantation . **Transplantation Proceedings** 27:1206-1207, 1995.
46. Kirby S, Brothers M, Irish W, Florell R, Macdonald D, Schold C, Cairncross G. Evaluating glioma therapies: Modeling treatments and predicting outcomes. **Journal of the National Cancer Institute** 87:1884-1888, 1995.
47. Van Thiel DH, Wright H, Carroll P, Abu-Elmagd K, Rodriguez-Rilo H, McMichael J, Irish W, Starzl TE: Tacrolimus - A potential new treatment for autoimmune chronic active hepatitis: Results of an open-label preliminary trial. **American Journal of Gastroenterology** 90:771-776, 1995.

48. Van Thiel DH, Friedlander L, Malloy P, Wright HI, Gurakar A, Fagioli S, Irish W: gamma-Glutamyl transpeptidase as a response predictor when using alpha-interferon to treat hepatitis C. **Hepato-Gastroenterology** 42:888-892, 1995.
49. Nieto-Rodriguez JA, Kusne S, Manez R, Irish W, Linden P, Magnone M, Wing EJ, Fung JJ, Starzl TE: Factors associated with the development of candidemia and candidemia-related mortality in liver transplant recipients. **Annals of Surgery** 223:70-76, 1996.
50. Shapiro R, Vivas C, Scantlebury V, Jordan M, Gritsch HA, Neugarten J, McCauley J, Randhawa, Irish W, Fung JJ, Hakala T, Simmons RL, Starzl TE: "Suboptimal" kidney donors - The experience with tacrolimus-based immunosuppression. **Transplantation** 62:1242-1246, 1996.
51. Shapiro R, Scantlebury V, Jordan M, Vivas C, Gritsch HA, Ellis D, Gilboa N, Lombardozzi-Lane S, Irish W, Fung JJ, Hakala T, Simmons RL, Starzl TE: Tacrolimus in pediatric renal transplantation. **Transplantation** 62:1752-1758, 1996.
52. Jabbour N, Zajko AB, Orons PD, Irish W, Bartoli F, Marsh WJ, Dodd GD III, Aldreghitti L, Colangelo J, Rakela J, Fung, JJ: Transjugular intrahepatic portosystemic shunt in patients with end-stage liver disease: Results in 85 patients. **Liver Transplantation and Surgery** 2:139-147, 1996.
53. McMichael J, Lieberman R, McCauley J, Irish W, Marino I, Doyle H: Computer-guided randomized concentration-controlled trials of tacrolimus in autoimmunity: Multiple sclerosis and primary biliary cirrhosis. **Therapeutic Drug Monitoring** 18:435- 437, 1996.
54. Kusne S, Furukawa H, Abu-Elmagd K, Irish W, Rakela J, Fung J, Starzl TE, Todo S: Infectious complications after small bowel transplantation in adults: An update. **Transplantation Proceedings** 28:2761- 2762, 1996.
55. Shapiro R, Jordan ML, Scantlebury VP, Vivas C, Gritsch HA, McCauley J, Ellis D, Gilboa N, Lombardozzi-Lane S, Randhawa P, Demetris AJ, Irish W, Hakala TR, Simmons RL, Fung JJ, Starzl TE: Tacrolimus in renal transplantation. **Transplantation Proceedings** 28:2117- 2118, 1996.
56. Minguillan-Tabasco J, Jain A, Naik M, Weber K, Irish W, Fung J, Rakela J, Starzl TE: Gastrointestinal bleeding after liver transplantation. **Transplantation** 63:60-67, 1997.
57. Irish W, Macdonald DR, Cairncross G: Measuring bias in uncontrolled brain tumor trials – to randomize or not to randomize? **Canadian Journal of Neurological Sciences** 24:307- 312, 1997.

58. Mazariegos G, Reyes J, Marino I, Demetris A, Flynn B, Irish W, McMichael J, Fung JJ, Starzl TE: Weaning of immunosuppression in liver transplant recipients. **Transplantation** 63:243-249, 1997.
59. Furukawa H, Smith S, Lee R, Knisely AS, Irish W, Reyes J, Abu-Elmagd K, Starzl TE, Todo S: Influence of donor criteria on early outcome after intestinal transplantation. **Transplantation Proceedings** 29:690, 1997.
60. McCauley J, Irish W, Thompson L, Stevenson J, Lockett R, Bussard R, Washington M: Factors determining the rates of referral, transplantation, and survival on dialysis in women with ESRD. **American Journal of Kidney Diseases** 30:739-748, 1997.
61. Scantlebury VP, Shapiro R, Irish W, Jordan ML, Vivas C, Gritsch HA, Fung JJ, McCauley J, Simmons RL, Starzl TE: Outcome of kidney transplantation in African-Americans using tacrolimus. **Transplantation Proceedings** 29:3731-3732, 1997.
62. Bueno J, Green M, Kocoshis S, Furukawa H, Abu-Elmagd K, Yunis E, Irish W, Todo S, Reyes J, Starzl TE: Cytomegalovirus infection after intestinal transplantation in children. **Clinical Infectious Disease** 25:1078- 1083, 1997.
63. Madariaga J, Iwatsuki S, Todo S, Lee R, Irish W, Starzl TE: Liver resection for hilar and peripheral cholangiocarcinomas: A study of 62 cases. **Annals of Surgery** 227:70-79, 1998.
64. Abu-Elmagd K, Reyes J, Todo S, Rao A, Lee R, Irish W, Furukawa H, Bueno H, McMichael J, Fawzy A, Murase N, Demetris J, Rakela J, Fung J, Starzl TE. Clinical Intestinal Transplantation: New perspectives and immunologic considerations. **Journal of the American College of Surgeons** 186:512-525, 1998.
65. Reyes J, Bueno J, Kocoshis S, Green M, Abu-Elmagd K, Furukawa H, Barksdale E, Strom S, Fung J, Todo S, Irish W, Starzl TE. Clinical status of intestinal transplantation in children. **Journal of Pediatric Surgery** 33:243-254, 1998.
66. Shapiro R, Jordan ML, Scantlebury VP, Vivas C, Gritsch HA, McCauley J, McQuitty D, Randhawa P, Irish W, McMichael J, Hakala TR, Simmons RL, Fung JJ, Starzl TE: Outcome after steroid withdrawal in renal transplant patients receiving tacrolimus-based immunosuppression. **Transplantation Proceedings** 30:1375-1377, 1998.
67. Jain AB, Yee LD, Nalesnik MA, Youk A, Marsh G, Reyes J, Zak M, Rakela J, Irish W, Fung JJ: Comparative incidence of *de novo* non-lymphoid malignancies following liver transplantation under tacrolimus using surveillance epidemiologic end result data. **Transplantation** 66:1193-1200, 1998.
68. Shapiro R, Jordan ML, Scantlebury VP, Vivas C, Gritsch HA, Casavilla FA, McCauley J, Johnston J, Randhawa P, Irish W, Hakala TR, Fung JJ, Starzl TE: A prospective,

randomized trial to compare tacrolimus and prednisone with or without mycophenolate mofetil in patients undergoing renal transplantation. **Journal of Urology** 160:1992-1985, 1998.

69. Jabbour N, Zajko A, Orons P, Irish W, Fung JJ, Selby RR: Does transjugular intrahepatic portosystemic shunt (TIPS) resolve thrombocytopenia associated with cirrhosis? **Digestive Diseases and Sciences** 43:2459-2462, 1998.
70. Casavilla FA, Rakela J, Kapur S, Irish W, McMichael J, Demetris AJ, Starzl TE, Fung JJ: Clinical outcome of patients infected with hepatitis C virus infection on survival after primary liver transplantation under tacrolimus. **Liver Transplantation and Surgery** 4:448-454, 1998.
71. Samimi F, Irish WD, Eghtesad B, Demetris AJ, Starzl TE, Fung JJ: Role of splenectomy in human liver transplantation under modern-day immunosuppression. **Digestive Diseases and Sciences** 43:1931-1937, 1998.
72. DiMartini A, Jain A, Irish W, Fitzgerald MG, Fung J: Outcome of liver transplantation in critically ill patients with alcoholic cirrhosis: survival according to medical variables and sobriety. **Transplantation** 66:298-302, 1998.
73. Tkatch LS, Kusne S, Irish WD, Krystofiak S, Wing E: Epidemiology of legionella pneumonia and factors associated with legionella-related mortality at a tertiary care center. **Clinical Infectious Diseases** 27: 1479- 1486, 1998.
74. Fisher RA, Pan S-H, Rossi SJ, Schroeder TJ, Irish WD, Canafax DM, Lopez RR: Pharmacokinetic comparison of two cyclosporine A formulations, SangCyA (Sang-35) and Neoral, in stable adult liver transplant recipients. **Transplantation Proceedings** 31: 394-395, 1999.
75. Gaston R, Alloway RR, Gaber AO, Rossi SJ, Schroeder TJ, Irish WD, Canafax DM, First MR: Pharmacokinetic and safety evaluation of SangCyA vs. Neoral or Sandimmune in stable renal transplant recipients. **Transplantation Proceedings** 31: 326-327, 1999.
76. Shapiro R, Jordan ML, Scantlebury VP, Vivas C, Marsh WJ, McCauley J, Johnston J, Randhawa P, Irish W, Gritsch HA, Naraghi R, Hakala TR, Fung JJ, Starzl TE: A prospective, randomized trial of tacrolimus/prednisone versus tacrolimus/prednisone/mycophenolate mofetil in renal transplant recipients. **Transplantation** 67: 411-415, 1999.
77. Shapiro R, Scantlebury VP, Jordan ML, Vivas C, Ellis D, Lombardozzi-Lane S, Gilboa N, Gritsch HA, Irish W, McCauley J, Fung JJ, Hakala TR, Simmons RL, Starzl TE: Pediatric renal transplantation under tacrolimus-based immunosuppression. **Transplantation** 67: 299-303, 1999.

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85. Basar H, Soran A, Shapiro R, Vivas C, Scantlebury VP, Jordan ML, Gritsch HA, McCauley J, Randhawa P, Irish W, Hakala TR, Fung JJ: Renal transplantation in recipients over the age of 60: the impact of donor age. **Transplantation** 27:1191-1193, 1999.
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84. Romine M., Wong J., Burch A., Landry A., Black M., Jones H., Leeser D., Irish W. Access to the Kidney Transplant Waiting List is Socioeconomically Driven **Am J Transplant**, 24:6,s1 Abstr#B93, 2024

85. Romine M., Overman A., Irish W., Subramanium A., Black M., Jones H., Leeser D. Righting the Wrong of Race Based EGFR Calculations: Results of the eGFR Modification Program **Am J Transplant**, 24:6,s1 Abstr#B107, 2024
86. Barefoot N., Evangelous T., Leeser D., Haisch C., Jones H., Irish W., Rebellato-deVente L., Black M., Romine M. Kidney Transplantation in Patients with a History of Prostate Cancer: Application of Recent Guidelines **Am J Transplant**, 24:6,s1 Abstr#C335, 2024

### **PROFESSIONAL ACTIVITIES**

#### **TEACHING:**

**Carlow College** (Mathematics and Natural Science), Pittsburgh, PA

Adjunct Lecturer:

Introduction to Statistics. An introductory statistics course designed to introduce to students basic concepts of statistics and the use of these concepts to make inferences from experimental and survey data.

Introduction to Applied Finite Mathematics. An introductory course designed to introduce to students basic concepts of elementary algebra, set theory and combinatorics. The student is also introduced to basic concepts in statistics and probability commonly encountered in the liberal arts, business and the health professions.

Introduction to College Algebra. An introductory course designed to introduce to students basic concepts of elementary algebra and algebraic functions.

**University of Pittsburgh** (School of Medicine), Pittsburgh, PA

Faculty Facilitator:

Clinical Epidemiology and Biostatistics. An introductory course designed to introduce to first year medical students the concepts of epidemiology and biostatistics, and the use of these concepts to design and make inferences from epidemiologic studies. (Course Director: James Schlesselman, Ph.D., Professor, Family Medicine and Clinical Epidemiology).

**Xavier University** (College of Social Sciences, Health, and Education), Cincinnati, OH

Adjunct Professor:

Health Economics and Outcomes Research Advanced Statistical Method (On-line course): The goal of this course is to (1) to understand and (2) to confidently apply a variety of statistical methods that are essential for health services and public policy research. This class provides a survey of more advanced statistical methods with a focus on causal inference, i.e. methods designed to address research questions that concern the impact of some potential cause (e.g., a medical intervention, a change in treatment, economic conditions, or policies) on some outcome (e.g., comorbidity, healthcare utilization and expenditures).

**East Carolina University** (Department of Public Health, Brody School of Medicine), Greenville, NC

Professor:

Introduction to Public Health Data Analysis. This course provides basic instruction in public health data analysis using core features of the SAS Software system (SAS Institute, Cary, NC). In this course, the student will learn the basics of SAS programming and analysis utilizing SAS/Basic and SAS/Stat software. This course focuses on the use of the SAS programming language to manipulate, organize, summarize, and analyze public health data.

#### **INVITED/CONFERENCE LECTURES:**

1. McMaster University, Hamilton, Ontario, Canada. May 1995. "**The changing epidemiology of orthotopic liver transplantation**"
2. Queen's University, Kingston, Ontario, Canada. October 1996. "**The analysis of multivariate failure time data: A counting process approach**"
3. ESRD Medical Review Board, Philadelphia, PA. February 1997. "**Study Design and Data Analysis: Considerations in Health-Outcome Research**"
4. SangStat Medical Corporation, Menlo Park, CA. July 1997. "**Some statistical approaches to the analysis of multivariate failure time data**"
5. Stanford University, Department of Statistics, Industrial Affiliates Program, Stanford, CA. April 1999. "**Statistical issues related to bioequivalence testing**"
6. Delayed Graft Function Expert Panel, Grapevine, TX.  
April 2000. "**Impact of delayed graft function on renal allograft survival**"
7. American Society of Transplantation, Chicago, IL. May 2000. "**Results of the ANTILFA randomized, double-blind, placebo-controlled clinical trial**"
8. Stanford University, Biostatistics Seminar, Stanford, CA. October 2000.      "**Risk factor analyses of delayed graft function in adult renal transplant recipients**"
9. United Network for Organ Sharing, Chicago, IL. April 2001. "**Impact of delayed and slow graft function on outcome following orthotopic renal transplantation**"
10. American Society of Transplantation, Chicago, IL. May 2001. "**A nomogram for predicting the likelihood of delayed graft function in adult cadaveric renal transplant**"
11. American Society of Transplant Surgeons, Alexandria, VA. June 2001. "**Lessons of a failed clinical trial**"

12. International Society for Pharmacoeconomics and Outcomes Research, Cannes, FR. November 2001. “**Using propensity scores to adjust for treatment selection bias: Review of methods plus an extension for use in studies with three or more treatment groups**”
13. Thymoglobulin Faculty Training Meeting, Leesburg, VA. March 2002. “**A predictive model for identifying patients at risk for delayed graft function: Delayed graft function nomogram**”
14. Drug Information Association, Hilton Head, SC. March 2003. “**Statistical modeling and decision tools**”
15. International Society for Pharmacoeconomics and Outcomes Research, Arlington, VA. May 2003. “**An economic approach to generating population cost estimates for event-time data: An example using renal transplant graft failure data**”
16. International Society for Pharmacoepidemiology, Philadelphia, PA. August 2003. “**Chronic renal allograft failure: Comparison of Tacrolimus vs. Neoral-based regimens using the U.S. Renal Data System**”
18. International Society for Pharmacoeconomics and Outcomes Research, Arlington, VA. May 2004. “**Therapeutic expansion of the classical Q-TWiST approach**”
19. American Transplant Congress, Seattle, WA. May 2005. “**An economic evaluation of all-cause renal allograft failure: A population-based approach**”
20. International Society for Pharmacoeconomics and Outcomes Research, Florence, IT. November 2005. “**Unconditional power for secondary objectives in a clinical trial**”
21. International Society for Pharmacoeconomics and Outcomes Research, Florence, IT. November 2005. “**Evaluating cost associated with event-censored data: Application to all-cause graft failure following kidney transplantation**”
22. University of North Carolina, School of Medicine, Chapel Hill, NC. January 2008. “**Parametric model for analysis of graft failure following kidney transplantation: Implications for survival prediction and clinical trial design**”
23. American Transplant Congress, Toronto, ON, CA. May 2008. “**Updated nomogram for predicting the likelihood of delayed graft function in the current ERA of deceased donor renal transplantation**”
24. International Society for Pharmacoeconomics and Outcomes Research, Athens, GR. October 2008. “**Statistical measures of treatment effect in oncology: What are we missing?**”

25. International Society for Pharmacoeconomics and Outcomes Research, Paris, FR. October 2009. **“Statistical methods to handle incomplete longitudinal patient-reported outcomes data in advanced disease stage trials”**
26. Transplant Symposium, Wake Forest University, Winston-Salem, NC. September 2010. **“Risk prediction model for delayed graft function in the current era of deceased donor renal transplantation”**
27. UC Pharmacy Practice and Administrative Sciences, University of Cincinnati, Cincinnati, OH. November 2010. **“Marginal structural models – evaluating drug effectiveness when patient health is declining”**
28. Pharma Research and Exploratory Development, Roche, Nutley, NJ. October 2010. **“Non-inferiority concept in clinical trials”**
29. Outcomes Research, Evidence-based Medicine, Novartis, East Hanover, NJ. February 2010. **“Marginal structural models”**
30. Infections and Organ Transplantation, Verese, IT. March 2011. **“Statistical tools for data analysis in organ transplantation”**
31. Transplant Symposium, Duke University, Durham, NC. April 2011. **“A risk prediction model for delayed graft function in the current era of deceased donor renal transplantation”**
32. BHOPS, Genentech, South San Francisco, CA. July 2011. **“Marginal structural models”**
33. FDA Workshop on Ischemia/Reperfusion Injury, Silver Springs, MD. September 2011 **“Cold machine perfusion versus static cold storage for SCD, ECD and DCD kidneys”.**
34. Transplant Academia, Duke University, Durham, NC. November 2012. **“Impact of donor and recipient BMI and donor renal function on graft failure after deceased donor renal transplantation”**
35. Novartis, East Hanover, NJ. March 2012. **“Regression models for correlated responses”**
36. Scientific Registry of Transplant Recipients (SRTR), Arlington, VA. February 2012. **“Consensus conference on transplant program quality and surveillance – Methods review”.**
37. Drug Information Association (DIA) Annual Meeting, Boston, MA. July 2013. **“The Use of Electronic Medical Record for Medical Research”.**

38. Drug Information Association (DIA) Annual Meeting, San Diego, CA. June 2014. “**Pricing, Economic, Reimbursement, Market Share (PERMS) Strategy: An Interactive Holistic Approach for Rare Diseases**”.
39. Transplant Academia, Duke University, Durham, NC. May 2014. “**Risk Prediction Model for Acute Rejection using the OPTN/UNOS Database**”.
40. Department of Health Services Administration, Xavier University, Cincinnati, OH. October 2015. “**Tools of the trade: Secondary Data Collection and Analysis**”.
41. Department of Public Health, Brody School of Medicine, East Carolina University, Greenville, NC. February 2017. “**Sampling Methods in Epidemiology**”.
42. Department of Public Health, Brody School of Medicine, East Carolina University, Greenville, NC. March 2017. “**Intervention Studies in Epidemiology**”.
43. FDA Workshop on Antibody Mediated Rejection in Kidney Transplantation, Silver Springs, MD. April 2017 “**Conducting Clinical Studies in Low Incidence/Rare Conditions: Scientific Challenges and Study Design Considerations**”.
44. Department of Surgery, Ground Rounds, Brody School of Medicine, East Carolina University, Greenville, NC. August 2018 “**Introduction to Research Study Design**”.
45. Department of Surgery, Ground Rounds, Brody School of Medicine, East Carolina University, Greenville, NC. August 2018 “**Summarizing and Displaying Data**”.
46. Department of Surgery, Ground Rounds, Brody School of Medicine, East Carolina University, Greenville, NC. January 2019 “**Estimation and Statistical Inference Basic Concepts**”.
47. Department of Computer Science, East Carolina University, Greenville, NC. February 2019 “**Challenge in Kidney Transplantation where Artificial Intelligence/Machine Learning Could Help**”.
48. Department of Internal Medicine, Brody School of Medicine, East Carolina University, Greenville, NC. March 2019 “**Clinical Utility of Biomarkers in Clinical Research: Potential Application in NASH**”.
49. Department of Medicine, Nephrology Ground Rounds, University of Wisconsin, Madison, WI. March 2019 “**Clinical Trial Endpoints in Kidney Transplantation**”.
50. Duke Center for Health Informatics, Informatic Research Seminar, Duke University, Durham, NC. February 2020 “**Challenge in Kidney Transplantation Where Artificial Intelligence/Machine Learning Could Help**”.

51. Laupus Library, Love Data Week, East Carolina University, Greenville, NC. February 2020  
“**Big Data and Analytics: The Future in Healthcare Decision Making**”.

### **Extramural Activities:**

#### **Present:**

- Associate Editor, Clinical Transplantation
- Member, Brody School of Medicine Research Committee
- Co-director, Big Data and Analytics Research Cluster, East Carolina University
- Academic Positions Search Committees – GeoSpatial Data Science Center and Public Health
- Chair, Surgical Research Committee, Department of Surgery, East Carolina University
- Member, Clinical Research Certificate Committee, Allied Health Sciences, East Carolina University
- Member, Academic Program Review for Department of Computer Science, East Carolina University

#### **Past:**

- Statistical Editor, American Journal of Transplantation
- Member, Clinical Research Advisory Committee, American Society of Transplantation.
- Member, Education Committee, American Society of Transplantation.
- Member, Data Management Committee, Thomas E. Starzl Transplantation Institute, University of Pittsburgh
- Board Member, Protocol Review Committee, Thomas E. Starzl Transplantation Institute, University of Pittsburgh

### **RESEARCH GRANTS:**

#### Current Funded Research Projects in 2020-2023

1. 01/01/2022 – 12/31/2022  
William Irish (Co-I) “: Placental metabolomics and maternal biomarkers: early detection for adverse pregnancy outcomes” Brody Brother Endowment. Goal: To determine which placental metabolites and maternal blood markers are altered in early and late pregnancy.
2. 01/01/2022 – 12/31/2022  
William Irish (PI) “Building a Better Platform to Understand Disparities in Surgical Access through Complex Systems Science” Brody Brother Endowment. Goal: To integrate publicly available structured, semi-structured and unstructured health system data from multiple sources into a single data platform and utilize advance analytic and machine learning approaches to better understand the reasons for disparities in surgical care access.
3. 09/01/2020 – 09/30/2021  
William Irish (Co-I) “Does Empagliflozin reduce cardiovascular risk factors and mortality in Black patients with type 2 diabetes?” Brody Brother Endowment. Goal: To evaluate,

- using real world data, the effect of empagliflozin on (SGLT-2i) cardiovascular risk factors in Black versus White patients with Type 2 diabetes. Role: Study design, data collection, statistical analysis, interpretation of results, and scientific communication.
4. 01/01/2020 – 12/31/2022  
William Irish (Co-PI) “Access to Cancer Care for Rural Patients: Developing and Implementing a Validated Measure to Identify Patients at High Risk of Transportation Barriers”.  
Alliance for Clinical Trials in Oncology. Goal: To adapt and validate an instrument to identify patients at high risk of limited access to cancer care due to transportation barriers within a rural population. Role: Study design, data collection, statistical analysis, interpretation of results, and scientific communication.
  5. 04/01/2020 – 12/31/2022  
William Irish (Co-PI) “Use of dd-cfDNA to Detect Renal Allograft Rejection in a Predominantly African American Population”. Natera Inc. Goal: To evaluate the predictive performance and clinical utility of Prospera in measuring donor-derived cell-free DNA in a predominantly African American kidney transplant population. Role: Study design, data collection, statistical analysis, interpretation results, and scientific communication.
  6. 05/1/2020- 04/30/2021  
William Irish (Co-I) “Pitt County Community Prevalence and COVID-19 Testing (ComPACT Study)”.  
NC DHHS Contract. Goal: To assess changes in COVID-19 prevalence, proportion of asymptomatic persons, and adherence to mitigation guidance. Role: Sampling strategy, statistical analysis, interpretation of results, scientific communication.
  7. 01/1/2021- 12/31/2021  
William Irish (Co-PI) “Democratization of bariatric surgery with increased access and efficiency”. United Health Group. Goal: To evaluate the current eligibility rules for bariatric surgery, develop an objective scoring method for staging type 2 diabetes and other expressions of the metabolic syndrome, assess approaches to delivering operative care with greater efficiency but without loss of safety, and improve education of stakeholders (patients, healthcare providers, payers etc.) regarding the advantages and consequences of surgery. Role: Study design, data collection, statistical analysis, reports, interpretation of results, scientific communication.
  8. 01/01/2021 – 01/31/2024  
William Irish (PI) “Early outcomes associated with de novo LCPT vs IR-TAC in a predominantly African American kidney transplant cohort”. Veloxis Pharmaceuticals, Inc. Goal: To evaluate potential trends in tacrolimus trough levels and renal function to determine the appropriate starting dose of LCPT in a predominantly AA kidney transplant population without compromising clinical outcomes. . Role: Study design, data collection, statistical analysis, reports, interpretation of results, scientific communication.
  9. 01/01/2023 – 12/31/2026  
William Irish (PI) “Comparative Before and After Analysis of Outcomes Associated with de Novo LCTP Daily Dose Protocol Change, within a Predominantly African American Kidney Transplant Cohort”. Veloxis Pharmaceuticals, Inc. Goal: To assess the effects of this dosage modification on the patterns of tacrolimus trough levels and renal function, as

well as their correlation with early clinical outcomes following kidney transplantation .  
Role: Study design, data collection, statistical analysis, reports, interpretation of results, scientific communication.

10. 07/01/2024 – 06/30/2025

William Irish (Co-I) “Improving Access to Surgical Cancer Care in Eastern North Carolina”. Sponsored Activities and Research Catalyst (SPARC) Program. Goal: To quantify individual-level factors influencing surgical decision-making for integration into our Data Platform. The rationale for this initiative is rooted in the understanding that contributions from patient-based participatory research are crucial. They play a vital role in capturing the diverse array of factors contributing to disparities in access to surgical cancer care. These contributions are expected to enhance our analytic modeling efforts, ultimately striving for equity in access to surgical cancer care. Role: Study design, data collection, statistical analysis, reports, interpretation of results, scientific communication.

11. 01/01/2025 – 12/31/2025

William Irish (Co-I) “The Effects of Metabolic Surgery on Mitochondrial Genome and its Potential Link to Obesity-Associated Cancers”. Brody Brother Endowment. Goal: To determine: i) The effects of metabolic surgery on mitochondrial dysfunction, and ii) The specific sites of resistance within the mitochondrial energy transduction pathway that may be in common in patients with cancer as well as in patients with obesity. Role: Study design, data collection, statistical analysis, reports, interpretation of results, scientific communication.