

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
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NAME Peter Doyle Higgins	POSITION TITLE Assistant Professor Department of Internal Medicine		
eRA COMMONS USER NAME (credential, e.g., agency login) PDHIGGINS			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Duke University, Durham, NC	B.S.	1983-87	Chemistry, Molecular
Duke University, Durham, NC	Ph.D.	1987-98	Molecular Cancer
Duke University, Durham, NC	M.D.	1987-98	Medicine
Duke University Hospital		1998-01	Internal Medicine
University of Michigan, Ann Arbor, MI		2001-04	Gastroenterology
University of Michigan, Ann Arbor, MI	M.Sc.	2003-05	Clinical Research Design and Statistical Analysis

A. Positions and Honors

Positions

1998-2001 Resident in Internal Medicine, Duke University Hospital
 2001-2004 Fellow in Gastroenterology, University of Michigan Medical School
 2003 Chief Fellow in Gastroenterology, University of Michigan Medical School
 2004-2005 Lecturer in Gastroenterology, University of Michigan Medical School
 2006- Assistant Professor, University of Michigan Medical School

Honors

1983-4 National Merit Scholarship, Duke University
 1983-87 Angier B. Duke Scholarship, Duke University
 1986 Phi Beta Kappa Honor Society, Duke University
 1987 *Summa Cum Laude*, Duke University
 1987-1998 NIH Medical Scientist Training Program Fellowship
 2001 Eugene Stead Award for Senior Resident Presentation
 2004 Selected research presenter at ASGE, AGA, AASLD Young Investigators' Conference on Digestive Diseases
 2004 AGA Centocor Excellence in IBD Clinical Research Award
 2005-6 Selected for Emerging Leaders in Gastroenterology Conference
 2008 Endoscopic Research Award, ASGE

Other Experience and Professional Memberships

2009-2012 Associate Editor for IBD
 2009-2012 Associate Editor, American Journal of Gastroenterology
 2009-2012 Reviewer, CCFA Senior Research Award Grants
 2008-2011 Associate Editor, Inflammatory Bowel Diseases
 2006-7 Section Editor for Clinical Research, Inflammatory Bowel Diseases
 2006-2008 Member, Professional Education Advisory Committee of the Crohn's and Colitis Foundation of America
 2001-Present Member, AGA, CCFA, ACG, ASGE

B. Peer-reviewed publications (in chronological order).

1. Udvardia, A.J., Rogers, K.T., **Higgins, P.D.R.**, Murata, Y., Martin, K.H., Humphrey, P.A., Horowitz, J.M. Sp-1 binds promoter elements regulated by the RB protein and Sp-1 mediated

transcription is stimulated by RB coexpression. *Proceedings of the National Academy of Sciences*, 90: 3265-3269, 1993.

2. Rogers, K.T.*, **Higgins, P.D.R.***, Milla, M.M., Phillips, R.S., and Horowitz, J.H. DP-2, a heterodimeric partner of E2F: Identification and characterization of DP-2 proteins expressed in vivo. *Proceedings of the National Academy of Sciences*, 93: 7594-7599, 1996.
3. **Higgins, P.D.R.** and Askari, FK. Barrett's Esophagus: Diagnosis and Therapy. *The National Organization of Rare Diseases Guide to Rare Diseases*, Lippincott, 2001.
4. **Higgins, P.D.R.** and Fontana, R. Transplantation in Acute Liver Failure. *Panminerva Medica*, 52: 93-7, 2002.
5. **Higgins, P.D.R.**, Russo, C.A., Scheurer, M. and Duvall, W.L. How Well Do We Treat Elevated Lipids? *North Carolina Medical Journal*, 63: 247-52, 2002.
6. **Higgins, P.D.R.**, and Rockey, D.C. Iron Deficiency Anemia. *Techniques in Gastrointestinal Endoscopy*, 5: 134-141, 2003.
7. **Higgins, P.D.R.**, and Laine, L. Ischemic Colitis: A Systematic Review. *Alimentary Pharmacology and Therapeutics*, 19:729-38, 2004.
8. **Higgins, P.D.R.**, and Johanson, J. A Systematic Review of the Epidemiology of Constipation. *American Journal of Gastroenterology*, 99: 750-759, 2004.
9. **Higgins, P.D.R.**, and Zimmermann, E.M. Inflammatory Bowel Disease Diagnosis and Therapy. *Clinics in Family Practice*, 6: 671-692, 2004.
10. **Higgins, P.D.R.**, Schwartz, M., Mapili, J. and Zimmermann, E.M. Endoscopy is Not Necessary for the Measurement of Disease Activity in Ulcerative Colitis. *American Journal of Gastroenterology*, 100: 355-361, 2005.
11. **Higgins, P.D.R.**, Mapili, J., Schwartz, M., Krokos, I., and Zimmermann, E.M. Endpoints for Patient-Defined Dichotomous Endpoints for Remission and for Clinical Improvement in Ulcerative Colitis. *Gut*, 54: 782-788, 2005.
12. Poynter, J.N., Gruber, S.B., **Higgins, P.D.R.**, Almog, R., Bonner, J.D., Rennert, H.S., Low, M., Greenson, J.K., Rennert, G. Statins and the Risk of Colorectal Cancer. *New England Journal of Medicine*, 352: 2184-2192, 2005.
13. **Higgins, P.D.R.**, Umar, R. Parker, J.W., and DiMagno, M. Massive Lower Gastrointestinal Bleeding after Rejection of Pancreatic Transplants. *Nature Clinical Practice Gastroenterology and Hepatology*, 2: 240-244, 2005.
14. Harris, R. E., Jeter, J., Chan, P., **Higgins, P.D.R.**, Kong, F-M., Fazel, R., Bramson, C., Gillespie, B., and Cohort 11 of the UM CRDSA. Using Accupressure to Modify Alertness in the Classroom: A Single-Blind, Randomized, Crossover Trial. *The Journal of Alternative and Complementary Medicine* 11: 673-679, 2005.
15. Demierre, Marie-France*, **Higgins, P.D.R.***, Gruber, Stephen B., Hawk, Ernest, and Lippmann, Scott. Statins and Cancer Prevention, *Nature Reviews Cancer*, 5: 930-942, 2005.
16. Waljee, A. and **Higgins, P.D.R.** Statins Reduce Inflammation, DVT, Osteoporosis, and Colon Cancer: Could they Be of Benefit in IBD? *Practical Gastroenterology*, 30: 34-46, 2006.
17. Waljee, A., Waljee, J., Morris, A., and **Higgins, P.D.R.** Three-Fold Increased Risk of Infertility: A Meta-Analysis of Infertility after Ileal Pouch Anal Anastomosis in Ulcerative Colitis. *Gut*, 55: 1575-80, 2006.
18. Bhuket, T.P., and **Higgins, P.D.R.** Statins and Gastrointestinal Cancer. *Nature Clinical Practice Gastroenterology and Hepatology*, 3: 552-562, 2006.
19. Menees, S., Korsnes, S., **Higgins, P.D.R.**, and Elta, G. Does Colonoscopy Cause Increased Ulcerative Colitis Symptoms? *Inflammatory Bowel Diseases*, 13: 12-18, 2007.
20. **Higgins, P.D.R.**, Caoili, E., Zimmermann, M., Bhuket, T. P., Sonda, P., Manoogian, B., Platt, J., and Zimmermann, E.M. Computed Tomographic Enterography (CTE) Adds Information to Clinical Management in Small Bowel Crohn's Disease, *Inflammatory Bowel Diseases*, 13: 262-268, 2007.
21. **Higgins, P.D.R.**, Leung, J., Schwartz, M., Mapili, J., Wren, P.A., Zimmermann, E.M. The Quantitative Validation of Non-Endoscopic Disease Activity Indices in Ulcerative Colitis, *Alimentary Pharmacology and Therapeutics*, 25: 333-42, 2007.
22. **Higgins, P.D.R.**, Katz, S., Wolf, D.C., and Present, D.H. Clinical Trial Designs in Ulcerative Colitis. *Gastroenterology and Hepatology*, 3(3) S10: 1-7, 2007.

23. Bandarenko, N., and **Higgins, P.D.R.** Treatment of Inflammatory Bowel Disease: An Overview of Pharmacologics, Biologics, and Selective Leukocyte Apheresis. CME Monograph. MediCine, Inc., New York, NY. June, 2007.
24. Awais, D., and **Higgins, P.D.R.** Should we be CHARMed?, *Inflammatory Bowel Diseases*, Oct;13:1308-9, 2007.
25. Elmunzer, B. J., **Higgins, P.D.R.**, Kwok, Y., and Elta, G. Jumbo forceps are superior to standard large-capacity forceps in obtaining diagnostically adequate inflammatory bowel disease surveillance biopsies. *Gastrointestinal Endoscopy*, 68: 273-8, 2008.
26. Kim, K., Rangwalla, S., Congxian, J., **Higgins, P.D.R.**, and Rubin, J. Non-Invasive Ultrasound Elasticity Imaging (UEI) On Crohn's Disease: Animal Model. *Ultrasound in Medicine and Biology*, 34: 902-12, 2008.
27. Elmunzer, B.J., Waljee, A.K., Elta, G.H., Taylor, J.R., Fehmi, S.M.A., **Higgins, P.D.R.** A meta-analysis of rectal NSAIDs in the prevention of post-ERCP pancreatitis. *Gut*, 57: 1262-7, 2008.
28. Bruce E. Sands, William J. Sandborn, Brian Feagan, Robert Löfberg, Toshifumi Hibi, Tao Wang, Lisa-Marie Gustofson, Cindy J. Wong, Margaret K. Vandervoort, Stephen Hanauer, and the **Adacolumn Study Group**. A Randomized, Double-Blind, Sham-Controlled Study of Granulocyte/Monocyte Apheresis for Active Ulcerative Colitis. *Gastroenterology*, 135: 400-409, 2008.
29. Stenson, W.F., Snapper, Scott B., and the **Research Challenges Work Groups**. Challenges in IBD Research: Assessing Progress and Rethinking the Research Agenda. *Inflammatory Bowel Diseases*, 2008; 14: 687-708.
30. Joyce, J.C., Waljee, A.K., Khan, T.A., Wren, P.A., Dave, M., Zimmermann, E.M., Wang, S., Zhu, J., **Higgins, P.D.R.** Identification of Symptom Domains in Ulcerative Colitis that Occur Frequently During Flares and are Responsive to Changes in Disease Activity. *Health and Quality of Life Outcomes*, 6:69, 2008.
31. Irvine, E.J., Yeh, C-H, Ramsey, D., Stirling, A.L., **Higgins, P.D.R.** The effect of mesalamine therapy on quality of life in patients with mildly to moderately active ulcerative colitis. *Alimentary Pharmacology and Therapeutics*, 28: 1278-86, 2008.
32. Spiegel, B., Ho, W., Esrailian, E., Targan, S., **Higgins, P.D.R.**, Siegel, C., Dubinsky, M., Melmed, G.Y., Controversies in Ulcerative Colitis: A National Survey Comparing Decision-Making of Experts versus Community Gastroenterologists. *Clinical Gastroenterology and Hepatology*, 7: 168-174, 2009.
33. Rangwalla, S.R., Waljee, A.K., **Higgins, P.D.R.** The Voting With their Feet (VWF) Endpoint: A Meta-Analysis of an Alternative Endpoint in Clinical Trials, Using 5-ASA Induction Studies in Ulcerative Colitis. *Inflammatory Bowel Diseases*, 15: 422-428, 2009.
34. **Higgins, P.D.R.**, Rubin, D.T., Kaulback, K., Schoenfeld, P.S., Kane, S.V. Systematic Review: Impact of Non-Adherence to 5-ASA Products on the Frequency and Cost of Ulcerative Colitis Flares. *Alimentary Pharmacology and Therapeutics*, 29: 247-57, 2009.
35. Kane S, Lu F, Kornbluth A, Awais D, **Higgins P.D.R.** Controversies in mucosal healing in ulcerative colitis. *Inflammatory Bowel Diseases*, 2009, 15: 796-800.
36. Waljee, A.K., Joyce, J.C., Wren, P.A., Khan, T.M., **Higgins, P.D.R.** Patient reported symptoms during an ulcerative colitis flare: A Qualitative Focus Group Study. *European Journal of Gastroenterology & Hepatology*. 2009, 21: 558-64.
37. Singal A, Volk ML, Waljee A, Salgia R, **Higgins P.D.R.**, Rogers MA, Marrero JA. Meta Analysis: Surveillance with Ultrasound for Early Stage Hepatocellular Carcinoma in Patients with Cirrhosis. *Alimentary Pharmacology and Therapeutics*. 2009, 30: 37-47.
38. Rubenstein, J.H., Waljee, A.K., Jeter, J., Velayos, F., Ladabaum, U., **Higgins, P.D.R.** Cost-Effectiveness of Ulcerative Colitis Surveillance in the Setting of 5-Aminosalicylates. *American Journal of Gastroenterology*, 2009, in press.
39. Awais, D., Seigel, C.A., **Higgins, P.D.R.**, Modeling Dysplasia Detection in Ulcerative Colitis: Clinical Implications of Surveillance Intensity. *Gut*. 2009, in press.
40. Luther, J., **Higgins, P.D.R.**, Schoenfeld, P., Moayyedi, P., Vakil, N., Chey, W. Empiric Quadruple vs. Triple Therapy for Primary Treatment of Helicobacter pylori Infection: Systematic Review and Meta-Analysis of Efficacy and Tolerability. *American Journal of Gastroenterology*, 2009, in press.

41. Waljee, A.K., Joyce, J.C., Wang, S., Saxena, A., Hart, M., Zhu, J., **Higgins, P.D.R.** Machine Learning Outperforms Metabolites in Identifying Responders to Thiopurines in Inflammatory Bowel Disease. *Clinical Gastroenterology and Hepatology*, 2009, in press.
42. Luther, J., Dave, M., **Higgins, P.D.R.**, Kao, J.Y. Association Between Helicobacter pylori Infection and Inflammatory Bowel Disease: A Meta-analysis and Systematic Review of the Literature. *Inflammatory Bowel Diseases*, 2009, in press.
43. Adler, J., Stidham, R.J., **Higgins, P.D.R.** Bringing the Inflamed and Fibrotic Bowel into Focus: Imaging in Inflammatory Bowel Disease. *Gastroenterology and Hepatology*, 2009; 5: 1-11.
44. Stidham, R.J., Waljee, A.K., **Higgins, P.D.R.** Evolving Endpoints in IBD Management. *IBD Monitor*, 2009, in press.

C. Research Support

Ongoing Research Support

1 K08 DK080172-01 Higgins (PI) 02/01/2008-01/31/2011
NIH/NIDDK

“Mechanisms and Prevention of TGF-beta-induced intestinal Fibrosis”
Training grant to study the basic mechanisms of intestinal fibrosis in human intestinal myofibroblasts and rodent models of intestinal fibrosis.

1R21DK081123-01A1 Rubin (PI) 04/01/09-03/31/11
NIH

“Non-invasive Ultrasound Elasticity Imaging (UEI) in Crohn's Disease”
Project Director: Kang Kim, Ph.D.
Role: Co-I

This study will investigate the potential of UEI to radically improve the diagnosis and timely management of intestinal fibrosis in Crohns Disease.

Foundation Grant Higgins (PI) 09/01/09-12/31/10
Genentech Investigator-Initiated Grant

“Development of Patient Reported Outcome Measures for Ulcerative Colitis and Crohn’s Disease”
This study collects biological samples in a well-characterized population with IBD to enable biomarker identification and assay development for use in future therapeutic trials in patients with Crohn’s disease and ulcerative colitis.

Novartis Pharmaceuticals Higgins (PI) 03/24/08-11/30/09

”A multicenter, randomized, double-blind, placebo-controlled, parallel-group, proof-of-concept study to assess the efficacy, safety, and tolerability of two single iv infusions of AIN457A 10 mg/kg in patients with moderately to severely active Crohns Disease.”

Centocor Higgins (PI) 07/09/09-12/31/10

“A multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, and safety, and intravenous induction of response and subcutaneous maintenance therapy with ustekinumab in patients with moderately to severely active Crohns Disease who have failed a previous anti-TNF therapy (including remicade, humira, or cimzia)”

The primary objectives of this study are to evaluate the efficacy of ustekinumab in inducing clinical response and to evaluate the safety of ustekinumab.

Completed Research Support

CCFA 01/02/06-06/30/09

Senior Research Award

A Novel, Valid Disease Activity Index for Clinical Research in Ulcerative Colitis

This study will rigorously establish a valid basis for the noninvasive assessment of the many new therapies being developed for ulcerative colitis so that the best therapies will be identified, developed, and made available to patients.