

**Curriculum Vitae**  
**Walter Karl Kraft , MD, MS, FACP**

Date: August 30, 2018

**Office Address:**

Clinical Pharmacology (primary)	Office of Human Research (secondary)
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**Education:**

1986-90      BA      The American University  
1991-95      MD      University of Pittsburgh  
2001-06      MS      Thomas Jefferson University (Pharmacology)

**Postgraduate Training and Fellowship Appointments:**

1995-96      Intern in Medicine, Thomas Jefferson University Hospital  
1996-98      Resident in Medicine, Thomas Jefferson University Hospital  
1998-99      Chief Medical Resident, Thomas Jefferson University Hospital,  
1999-01      Research Fellow in Clinical Pharmacology, Thomas Jefferson University

**Uniformed Service:**

1993      Ensign, U.S. Public Health Service, Junior Commissioned Officer Student  
Training and Extern Program, Dover, Delaware (2 month service in migrant  
health clinic)

**Faculty Appointments:**

Thomas Jefferson University, Philadelphia, PA  
2014      Professor (tenure-track) of Pharmacology and Experimental Therapeutics,  
Department of Pharmacology and Experimental Therapeutics  
2014      Professor of Medicine, Department of Medicine (secondary appointment)  
2014      Professor of Surgery, Department of Surgery (secondary appointment)  
2011-2014      Associate Professor of Surgery  
2008-2014      Associate Professor of Pharmacology and Experimental Therapeutics  
2008-2014      Associate Professor of Medicine  
2008-2014      Faculty of the College of Biomedical Sciences  
2005-2008      Assistant Professor of Pharmacology and Experimental Therapeutics,  
2001-2008      Assistant Professor of Medicine

**Administrative Appointments:**

Clinical Research Unit, Thomas Jefferson University  
2001-06      Associate Medical Director  
2006-      Director

Division of Clinical Pharmacology, Department of Pharmacology and Experimental  
Therapeutics  
2006-      Director,

Office of Human Research, Thomas Jefferson University  
2012-15      Associate Director  
2015-      Director

**Hospital Appointments**

1999-03 Staff Physician and Admitting Officer, VA Medical Center, Wilmington, DE  
2001-05 Medical Consulting Staff, Wills Eye Hospital, Philadelphia, PA  
2001- Admitting Staff, Thomas Jefferson University Hospital, Philadelphia, PA  
2005-08 Medical Consulting Staff, Jefferson Hospital for Neuroscience, Philadelphia, PA  
2009 Interim Director, Antithrombotic Service, Thomas Jefferson University Hospital  
2010- Attending, Jefferson Vascular Center  
2010- Admitting Staff, Methodist Hospital, Philadelphia, PA

**Specialty Certification:**

American Board of Internal Medicine, Diplomate # 185409  
1998-2020 Continuously Certified

American Board of Clinical Pharmacology  
2003 Certification, Diplomate # 03113

**Licensure:**

Pennsylvania, MD063087-L

**Awards, Honors and Membership in Honorary Societies:**

2006- Fellow, American College of Physicians  
2007- United States Pharmacopeia, Thomas Jefferson University Representative  
2007 Member of the Month, December 2007, American Society For Clinical  
Pharmacology and Therapeutics  
2008 Golden Apple Teaching Award, Thomas Jefferson University Hospital Internal  
Medicine Residency  
2008 Top 25 Most Highly Rated Teachers, Thomas Jefferson University Hospital  
Internal Medicine Residency  
2009 Dedicated Member, October 2009, American Society For Clinical Pharmacology  
and Therapeutics  
2010 Jefferson Medical College Early Career Investigator Award for Distinguished  
Achievement in Biomedical Research  
2014 Dean's Award for Excellence in Education, Jefferson Medical College

**NIH Committee Service**

2007-08 NIH Special Emphasis Panel/Scientific Review Group 2007 and 2008 ZGM1  
BRT-5 (PG) T32 Mechanism  
2010 NIH/NICHD ZHD1 DSR-A: K23 Review Committee  
2010 NIH/NICHD ZHD1 DSR-K: Pediatric Clinical Trials Network Review Committee  
2010 NIH ZRG1 Special Emphasis Panel EMNR-P (50) R: RFA Panel: Translational  
Research in Pediatric and Obstetric Pharmacology  
2011 NIH/NICHD ZRG1 EMNR-K (55) R RFA Panel: Translational Research in  
Pediatric and Obstetric Pharmacology  
2011 Special Emphasis Panel/SRG 2011/08 ZHD1 DSR-A (50) 2  
2012 NIDA Multisite Medications Development for SUD, ZDA1 GXM-A (08)  
2014 NIH/NICHD PAR 13-309/310/311: Translational Research in Pediatric and  
Obstetric Pharmacology  
2014 ZHL1 CSR-G (S1), NIH Special Emphasis Panel: RFA HL-14-019: Low-Cost,  
Pragmatic, Patient-Centered Randomized Controlled Intervention Trials  
(UH2/UH3) and the RFA-HL-14-020: Evaluation and Administration Coordinating  
Center  
2014-16 Xenobiotic and Nutrient Disposition and Action (XNDA) Study Section ad hoc  
member  
2015 Special Emphasis Panel: PAR13-309-311: Translational Research in Pediatric  
and Obstetric Pharmacology and Therapeutics, ZRG1 EMNR-D (55)

2015 Special Emphasis Panel: PAR13-309-311: Translational Research in Pediatric and Obstetric Pharmacology and Therapeutics ZRG1 EMNR-W (55)  
 2016 SBIR contract review, NIDA Topic 158, N43DA-16-1210, "Development of Primer and Reference Tool to Assess Neonatal Abstinence Syndrome."  
 2017 Special Emphasis Panel ZRG1 EMNR-S 55: Translational Research in Pediatric and Obstetric Pharmacology and Therapeutics  
 2018 PO1 PAR-16-393 Review, NIDA

**FDA Service**

2018-21 SGE consultant to the Pharmaceutical Science and Clinical Pharmacology Advisory Committee  
 2018 Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. Senseonics Eversense Continuous Glucose Monitoring System, March 29, 2018

**State Department Service**

2014-16 Faculty Expert, Guideline generation for treatment of drug abuse in children under 12 years

**FDA Investigational New Drug Approval (IND) Grantees as Sponsor**

# 68,403 Buprenorphine in the Treatment of the Neonatal Abstinence Syndrome  
 # 75,012 Capsaicin Inhalation for Induction of Cough (inactive)  
 #116,387 Exploration of Early Renal Injury Biomarkers Using Tenofovir Disoproxil Fumarate (inactive)  
 # 123,173 Apixaban anticoagulation reversal using KCENTRA (Human 4 Factor Prothrombin Complex Concentrate) (inactive)

**Memberships in Professional and Scientific Societies:**

American College of Clinical Pharmacology (2003- )  
 American College of Physicians  
     1997-06 Member  
     2006- Fellow  
 American Society for Clinical Pharmacology and Therapeutics (2001- )  
 Association of Clinical Pharmacology Units (2010-14)  
 Association for Clinical Research Training (2006-08)  
 Public Responsibility in Medicine and Research (2008-09, 2012)

**National Professional and Scientific Committee Leadership**

American Society for Clinical Pharmacology and Therapeutics  
     2006-09 Scientific Program Committee  
     2009- Finance Committee  
     2014-15 Vice Chair  
     2014-18 Board of Directors  
     2015-18 Treasurer  
  
 American College of Clinical Pharmacology  
     2014 Co-chair, Program Committee, Scientific Meeting  
     2015 Member, Program Committee, Scientific Meeting  
  
 American Board of Clinical Pharmacology  
     2007-12 Governing Board Member,  
             -Chair By-Laws Committee

-Member, Executive Committee

United States Pharmacopeia  
2007-15 Medical School Representative

Association of Clinical Pharmacology Units  
2010-12 Board of Directors  
2013 Annual Meeting Program Chair

National Board of Medical Examiners  
2009 Member, Standards Setting Panel for USLME Step 1

Critical Path Initiative  
2015 Member, INC Clinical Pharmacology Workgroup

**Data Safety Monitoring Board**

2006-07 Member, Wyeth Pharmaceuticals, Neuroscience Clinical Trial  
2007-09 Chair, Repros Therapeutics, Gynecologic Trial  
2007- Member, TJU Kimmel Cancer Center, Multiple Investigator Initiated Cancer Trials  
2013-17 Member, "Improving Outcomes in Neonatal Abstinence Syndrome", multicenter trial ([NCT 01958476](#))

**Ad Hoc Reviewer:**

Advances in Therapy	Neuropsychopharmacology
American Journal of Perinatology	New England Journal of Medicine
Annals of Internal Medicine	Journal of Addiction Medicine
Archives of Disease in Childhood,	Journal of Clinical Pharmacology
BMC Clinical Pharmacology	Journal of Pediatrics
BMC Pediatrics	Journal of Perinatology
British Journal of Clinical Pharmacology	Journal of Pharmacy and Pharmacology
Canadian Medical Association Journal	Journal of Thrombosis and Haemostasis
Clinical and Experimental Gastroenterology.	Journal of Maternal-Fetal & Neonatal Medicine
<a href="#">Clinical and Translational Science</a>	Pediatrics
Clinical Pharmacology and Therapeutics	Pharmacogenomics
Clinical Pharmacology in Drug Development	Pharmacotherapy
Contemporary Clinical Trials	Substance Abuse: Research & Treatment
Current Pharmaceutical Design	The Pharmacogenomics Journal
Drug and Alcohol Dependence	Therapeutics and Clinical Risk Management
Human Psychopharmacology	Therapeutic Delivery

**Editorial Positions:**

2002-06 Editorial Review Board, Journal of Applied Research  
2006-08 Associate Editor, Waldman SA, Terzic A, Eds., Pharmacology and Therapeutics: Principles to Practice, 1st. Ed., Saunders Elsevier; 2008  
2013-15 Associate Editor, [Current Therapeutic Research](#)  
2018- Editorial Board, Clinical and Translational Science

**Academic Committees at the Thomas Jefferson University/ Sidney Kimmel Medical College and Affiliated Hospitals:**

*Present Committee Membership*

Institutional Review Board

1999- Full board member  
2003-10 Serious adverse event reviewer  
2006 Association for Accreditation of Human Research Protection Programs Advisory Committee  
2007 Ad hoc SOP reviewer, Leadership Council of Clinical Coordinators  
2008-15 Vice Chair, Weinstein Committee  
2010- Gene Transfer Review Committee  
2013-15 Associate Director, Office of Human Research  
2015- Director, Office of Human Research

Kimmel Cancer Center

2007- Data and Safety Monitoring Board

Department of Pharmacology and Experimental Therapeutics

2006- Promotion Committee

Sidney Kimmel Medical College (current)

Scholarly Inquiry (formerly College within a College), Clinical and Translational Science Track  
2010-15 Founding Director  
2015-16 Co-Director  
2017- Associate Director  
2014- Student Research Awards Director  
2014- SKMC Council for Diversity and Inclusion  
2017- Clinical Research Leadership Council

Thomas Jefferson University Hospital

2011- Pharmacy and Therapeutics subcommittee, Cardiology/Thrombosis

*Past Committee Membership*

Thomas Jefferson University and Hospital

1999-2010 Curriculum Committee  
2001- 10 Internal Medicine Residency Competency Committee (Member)  
2007- 10 Competency Committee (Chair)  
2001-02 Educational Task Force, Department of Medicine  
2001-03 Jefferson University Physicians Advisory Board  
2008 4<sup>th</sup> Year Advanced Basic Science Curriculum Working Group  
2008 Committee on Student Affairs  
2010 Fourth Year Elective Working Group  
2008-10 Thomas Jefferson University Intellectual Property Policy Committee  
2010-11 Search Committee Member, Chairperson of Department of Obstetrics and Gynecology  
2010-14 Pharmacy and Therapeutics subcommittee, Medication Events and Drug Safety  
2010-14 Living Donor Organ Transplant Independent Advocate  
2011 Internal Review Committee, Department of Emergency Medicine Residency Program  
2011 Internal Review Committee, Department of Family and Community Medicine  
2011-12 Critical Thinking Task Force  
2011-12 Faculty Research Awards Task Force  
2011-15 Committee on Research

Internal Awards Subcommittee  
Student Awards Subcommittee Chair

2011-17 Curriculum Committee  
2012 Dean's Advisory Council on Research  
2013 Internal Review Committee, Department of Ophthalmology  
2014 Internal Review Committee, Department of Neurosurgery  
2013-14 Admissions Day Keynote Speaker  
2013-14 LCME Taskforce on Faculty  
2014 Clinical Research Planning Oversight Committee Team Leader, Program, Service and Regulatory Model  
2015 Search Committee, Associate Dean for UME/AA  
2015-16 CME Committee  
2015-16 JeffMD Curriculum Redesign Steering Committee  
Scholarly Activity Subcommittee Chair  
2015-17 Jefferson Clinical Research Institute Advisory Board Member  
2015-17 EPIC Implementation Team, Co-Chair of the Academic Advisory Committee  
2017 Internal Review Committee, Department of Medicine

**Major Teaching and Clinical Responsibilities at the Thomas Jefferson University and Affiliated Hospitals:**

*Educational Leadership (at Thomas Jefferson University)*

2001-02 Educational Task Force, Department of Medicine  
2001- House staff rotation coordinator, Department of Pharmacology and Experimental Therapeutics  
2004-10 Associate Director, K30 Program in Human Investigation  
2005 Faculty Development Program presentation, "Evidence-based bedside teaching"  
2006- Associate Program Director, Clinical Pharmacology Fellowship program  
2006- Coordinator, "Seminars in Human Investigation", Department of Pharmacology and Experimental Therapeutics  
2007-12 Section leader (Medical Reading) for 4<sup>th</sup> year JMC elective, Scientific Foundations of Clinical Medicine  
2007- Coordinator, "Gruber Lecture", Endowed lectureship in Pharmacology  
2007-14 Course Director, Pharm 401, Principals of Clinical Pharmacology/Advanced Basic Science  
2008 4<sup>th</sup> Year Advanced Basic Science Curriculum Working Group  
2010 College within a College, Clinical and Translational Subcommittee  
2010 Fourth Year Elective Working Group  
2010- Director, College within a College, Clinical and Translational Science  
2011- Director, K30 Program in Human Investigation  
2012 Coordinator, Summer Student Research Seminars  
2015- Course Director, PR 525, Clinical Pharmacology  
2015- Course Co-Director, CG 960, Regulatory Issues In Scientific Affairs

*Educational Activities*

1999-03	PR 760	Case Studies in Clinical Pharmacology
1999-12 2015-17	PR 522	General Pharmacology
2000-18	PR 525	Clinical Pharmacology*
2001-14	GC 630	Fundamentals of Clinical Trials
2017	GC 640	Research Ethics
2002-17	CG 690	Regulatory Issues In Scientific Affairs*
2016	LS 603	Research Design
1997-99		Physical Diagnosis (2 <sup>nd</sup> year)
2001-06		Ward Attending, Medical Service, TJUH

2001-03		Practical History and Physical examinations (3 <sup>rd</sup> year)
2000-14	PR 401	Clinical Pharmacology*
2001-18	PR 200	Foundations of Clinical Medicine
2007-18		Foundations of Clinical Pharmacology
2002-08		Residency Core Curriculum Lectures
2008-10		Residency Journal Club Facilitator
2002-18		Jefferson Antithrombotic Service Consult Attending, TJUH
2003-14		Scientific Foundations of Clinical Medicine Journal Review (4 <sup>th</sup> year)
2012-17		Summer research student seminar
2018		JeffMD Core Pharmacology lectures

\*Course Director

## Bibliography:

### Publications, peer reviewed:

1. Kraft W, Greenberg H, Waldman S. Paradoxical Hypotension and Bradycardia after Intravenous Arginine Vasopressin. *Journal of Clinical Pharmacology*. 1998; 38:283-286 [PMID 11522118]
2. Kraft WK, Waldman SA. Manufacturer's drug interaction and post-market adverse event data: What are appropriate uses? *Drug Safety*. 2001; 24:637-643 [PMID 11522118]
3. Hastie AT, Kraft WK, Nyce KE, Zangrilli JG, Fish JP, Peters SP. Kinetics of Airway Epithelial Cell Proliferation And Stimulation of Collagen After Segmental Allergen Challenge. *American Journal of Respiratory and Critical Care Medicine*. 2002; 165:266-272 [PMID 11790666]  
<http://ajrccm.atsjournals.org/content/165/2/266.long>
4. Blum RA, Majumdar A, McCrea J, Busillo J, Orlowski LH, Panebianco D, Hesney M, Petty KJ, Goldberg MR, Murphy MG, Gottesdiener KM, Hustad CM, Lates C, Kraft WK, VanBuren S, Waldman SA, Greenberg HE. Effects of Aprepitant on the Pharmacokinetics of Ondansetron and Granisetron in Healthy Subjects. *Clinical Therapeutics*. 2003; 25:1407-19 [PMID 12867217]
5. Burke J, Kraft WK, Greenberg HE, Gleave M, Pitari GM, VanBuren S, Wagner J, Waldman SA. Relationship of Arachidonic Acid Concentration to Cyclooxygenase-Dependent Human Platelet Aggregation. *Journal of Clinical Pharmacology*. 2003; 43:983-989 [PMID 12971030]
6. Kraft WK, Steiger B, Beussink D, Quiring JN, Fitzgerald N, Greenberg HE, Waldman SA. The Pharmacokinetics of Nebulized Nanocrystal Budesonide Suspension in Healthy Volunteers. *Journal of Clinical Pharmacology*. 2004; 44:67-72 [PMID 14681343]
7. Kraft WK, McCrea JB, Winchell GA, Carides A, Lowry R, Woolf EJ, Kusma SE, Deutsch PJ, Greenberg HE, Waldman SA. Indinavir and Rifabutin Drug Interactions in Healthy Volunteers. *Journal of Clinical Pharmacology*. 2004; 44:305-13 [PMID 14973305]
8. Agrawal NG, Matthews CZ, Mazenko RS, Woolf EJ, Porras AG, Chen X, Miller JL, Michiels N, Wehling M, Schultz A, Gottlieb AB, Kraft WK, Greenberg HE, Waldman SA, Curtis SP, Gottesdiener KM. The Effects of Modifying In-Vivo Cytochrome P450 3A (CYP3A) Activity on Etoricoxib Pharmacokinetics and of Etoricoxib Administration on CYP3A Activity. *Journal of Clinical Pharmacology*. 2004, 44:1125-1131 [PMID 15342613]
9. Stone JA, Migoya EM, Hickey L, Winchell GA, Deutsch PJ, Ghosh K, Freeman A, Bi S, Desai R, Dilzer SC, Lasseter KC, Kraft WK, Greenberg HE, Waldman SA. Potential for Drug Interactions

between Caspofungin and Nelfinavir or Rifampin. *Antimicrobial Agents and Chemotherapy*. 2004; 48(11):4306-14 [PMID 15504857]

10. Filicko J, Kakhniashvili I, Kraft WK, Flomenberg N. Heterogeneous Clearance of Anti-Thymocyte Globulin (ATG) Following CD34+ Selected Allogeneic Hematopoietic Progenitor Cell Transplantation (HPCT). *Biology of Blood and Bone Marrow Transplantation*. 2005, 11(8):609-18 [PMID 16041311]
11. Bergman AJ, Burke J, Larson P, Johnson-Levonas AO, Reyderman L, Statkevich P, Kosoglou T, Greenberg HE, Kraft WK, Frick G, Murphy G, Gottesdiener K, Paolini JF. Effects of Ezetimibe on Cyclosporine Pharmacokinetics in Healthy Subjects. *Journal of Clinical Pharmacology*. 2006;46:321-327 [PMID 16490808]
12. Patel T, Pequignot E, Parker SH, Leavit MC, Greenberg HE, Kraft WK. Transgenic Avian Derived Glycosylated Recombinant Human Interferon Alpha-2b (AVI-005): An Open Label, Controlled, Single Dose Study in Healthy Subjects. *International Journal of Clinical Pharmacology and Therapeutics*. 2007;45(3):161-68 [PMID 17416111] <http://jdc.jefferson.edu/petfp/29/>
13. Gong L, Greenberg HE, Perhach JL, Waldman SA, Kraft WK. The Pharmacokinetics of Taurolidine Metabolites in Healthy Volunteers. *Journal of Clinical Pharmacology*. 2007;47:697-703 [PMID 17395893] <http://jdc.jefferson.edu/petfp/26/>
14. Majumdar AK, Yan KX, Selverian DV, Barlas S, Constanzer M, Dru J, McCrea JB, Ahmed T, Frick GS, Kraft WK, Petty KJ, Greenberg HE. Effect of Aprepitant on the Pharmacokinetics of IV Midazolam. *Journal of Clinical Pharmacology*. 2007;47:744-750 [PMID 17463213]
15. Ghanim AJ, Daskalakis C, Eschelmann EJ, Kraft WK. A Five-Year Retrospective, Comparison Review of Survival in Neurosurgical Patients Diagnosed with Venous Thromboembolism and Treated with Either Inferior Vena Cava Filters or Anticoagulants. *Journal of Thrombosis and Thrombolysis*. 2007; 24(3):247-54 [PMID 17385008]
16. Kraft WK, Gibson E, Dysart K, Damle V, LaRusso J, Greenspan J, Moody D, Kaltenbach K, Ehrlich M. Sublingual Buprenorphine for Treatment of the Neonatal Abstinence Syndrome: A Randomized Trial. *Pediatrics*. 2008; 122:e601-7 [PMID 18694901] <http://pediatrics.aappublications.org/content/122/3/e601.long>
17. Varki R, Pequignot E, Leavitt MC, Ferber A, Kraft WK. A Glycosylated Recombinant Human Granulocyte Colony Stimulating Factor Produced in a Novel Protein Production System (AVI-014) in Healthy Subjects: A First-in Human, Single Dose, Controlled Study. *BMC Clinical Pharmacology* 2009, 9(1):2 [PMID 19175929] <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2639539/?tool=pubmed>
18. Loboda A\*, Kraft WK\*, Joseph J, Fine B, Nebozhyn M, Zhang C, He Y, Yang X, Wright C, Morris M, Chalikhonda I, Ferguson M, Dai H, Emilsson V, Schadt E, Greenberg HE, Lum PY. Diurnal variation in human adipose and its link to metabolic diseases and mTOR signaling. *BMC Medical Genomics* 2009, 2:7 [PMID 19203388] \*contributed equally to this manuscript <http://www.biomedcentral.com/1755-8794/2/7>
19. Kim DH, Daskalakis C, Whellan DJ, Whitman IR, Hohmann S, Medvedev S, Kraft WK. Safety of Selective Serotonin Reuptake Inhibitor in Adults Undergoing Coronary Artery Bypass Grafting. *American Journal of Cardiology*. 2009; 103:1391-5 [PMID 19427434]
20. Lai E, Schwartz JI, Dallob A, Jumes P, Liu F, Kraft WK, Royalty J, Chodakewitz J, Sisk CM, Radziszewski W, Wagner JA. Effects of Extended Release Niacin/Laropiprant, Laropiprant, Extended Release Niacin, and Placebo on Platelet Aggregation and Bleeding Time in Healthy Subjects. *Platelets*. 2010; 21(3):191-8 [PMID: 20163197]



21. Vasu TS, Doghramji K, Cavallazzi R, Grewal R, Hiraini A, Leiby B, Markov D, Reiter D, Kraft WK, Witkowski T. Obstructive Sleep Apnea Syndrome and Postoperative Complications: Clinical Utility of the STOP-BANG Questionnaire. Archives of Otolaryngology - Head & Neck Surgery. 2010;136(10):1020-1024 [PMID: 20956751]  
  
<http://archotol.ama-assn.org/cgi/content/full/136/10/1020>
22. Stoch AS, Gargano C, Valentine J, Braun MP, Murphy MP, Fedgchin M, Majumdar A, Pequignot E, Gottesdiener KM, Petty KJ, Panebianco D, Dean D, Evans JK, Kraft WK, Greenberg HE. Double-Blind Crossover Study to Assess Potential Differences in Cytochrome P450 3A4 Activity in Healthy Subjects Receiving Ondansetron Plus Dexamethasone, With and Without Aprepitant. Cancer Chemotherapy and Pharmacology. 2011; 67(6):1313-21 [PMID: 20734049]
23. Kraft WK, Dysart K, Greenspan J, Gibson E, Kaltenbach K, Ehrlich M. Revised Dose Schema of Sublingual Buprenorphine in the Treatment of the Neonatal Opioid Abstinence Syndrome. Addiction. 2011; 106(3):574-80 [PMID: 20925688] <http://jdc.jefferson.edu/petfp/7/>
24. Dallob A, Luo WL Mabalot J, Ratcliffe L, Johnson-Levonas A, Schwartz JI, Dishy V, Kraft WK, de Hoon JN, Van Hecken A, de Lepeleire I, Radziszewski W, Wagner JA, Lai E. The Effects of Laropiprant, a Selective Prostaglandin D2 Receptor 1 Antagonist, on the Antiplatelet Activity of Clopidogrel or Aspirin. Platelets. 2011; 22(7):495-503. [PMID: 21526889]  
<http://jdc.jefferson.edu/petfp/14/>
25. Henwood PC, Kennedy KM, Thomson L, Galanis T, Tzanis G, Merli GJ, Kraft WK. The Incidence of Deep Vein Thrombosis Detected by Routine Surveillance Ultrasound in Neurosurgery Patients Receiving Dual Modality Prophylaxis. Journal of Thrombosis and Thrombolysis. 2011; 32(2):209-14. [PMID: 21505787] <http://jdc.jefferson.edu/petfp/25>
26. Hiraini A, Cavallazzi R, Vasu TS, Pachinburavan M, Kraft WK, Leiby B, Desimone J, Squires KE, Weibel S, Kane GK. Prevalence of Obstructive Lung Disease in HIV population: A Cross Sectional Study. Respiratory Medicine. 2011; 105(11):1655-61. [PMID: 21703841]
27. Anagnostis EA, Sadaka RE, Sailor LA, Moody DE, Dysart KC, Kraft WK. Formulation of Buprenorphine for Sublingual Use in Neonates. Journal of Pediatric Pharmacology & Therapeutics. 2011;16(4):281-4. [PMID: 22768012] <http://jdc.jefferson.edu/petfp/38/>
28. Reitman M, Dishy V, Moreau A, Denney W, Liu, C, Kraft WK, Mejia A, Matson M, Stoch A, Wagner J, Lai E. Pharmacokinetics and Pharmacodynamics of MK-5046, a Bombesin Receptor Subtype-3 (BRS-3) Agonist, in Healthy Subjects. Journal of Clinical Pharmacology. 2012;52 1306-1316 [PMID:22162541]
29. Cavallazzi R, Awe OO, Vasu TS, Hiraini A, Vaid U, Leiby B, Kraft WK, Kane GK. MELD Score for Predicting Outcome In Critically Ill Patients with Liver Cirrhosis. Journal of Critical Care. 2012; 27(4):424.e1-6 [PMID: 22227088]
30. Pasquinelli C, McPhee F, Eley T, Villegas C, Sandy K, Wendelburg P, Persson A, Hernandez D, Sheaffer A, Scola P, Marbury T, Lawitz E, Goldwater R, Rodriguez-Torres M, DeMicco M, Wright D, Charlton M, Kraft WK, Lopez-Talavera J, Grasela DM. Single and Multiple Ascending Dose Studies of the NS3 Protease Inhibitor Asunaprevir in Subjects With or Without Chronic Hepatitis C. Antimicrobial Agents and Chemotherapy. 2012; 56(4):1838-44. [PMID: 22290978]
31. Stroh M, Palcza J, McCrea J, Marsilio S, Breidinger S, Panebianco D, Johnson-Levonas A, Kraft WK, Orford K, Murphy G, Agrawal N, Trucksis M, Wagner JA. The Effect of Multiple Doses of Rifampin and Ketoconazole on the Single Dose Pharmacokinetics of Ridaforolimus. Cancer Chemotherapy and Pharmacology. 2012; 69(5):1247-53 [PMID: 22290273]

32. Kosoglou T, Kraft WK, Kumar B, Statkevich P, Xuan F, Ma L, Jennings LK, Schiller JE, Langdon RB, Cutler DL. Pharmacokinetics and Pharmacodynamics of the Novel PAR-1 Antagonist Vorapaxar in patients with End-Stage Renal Disease. *The European Journal of Clinical Pharmacology*. 2012; 68(7):1049-56 [PMID: 22315147]
33. Pavri BD, Greenberg HE, Kraft WK, Lazarus N, Lynch JJ, Salata J, Bilodeau M, Regan CP, Stump G, Fan L, Larson P, Mehta A, Wagner JA, Gutstein DE, Bloomfield D. MK-0448, a Specific Kv1.5 Inhibitor, Safety, Pharmacokinetics and Pharmacodynamic Electrophysiology Results in Experimental Animal Models and Humans. *Circulation: Arrhythmias & Electrophysiology*. 2012; 5(6):1193-201 [PMID: 23060423] <http://jdc.jefferson.edu/petfp/40>
34. Halegoua-De Marzio D, Kraft WK, Daskalakis C, Ying X, Hawke RL, Navarro VJ. Limited Sampling Estimates of Epigallocatechin Gallate Exposures in Cirrhotic and Non-cirrhotic Hepatitis C Subjects After Single Oral Doses of Green Tea Extract. *Clinical Therapeutics*. 2012; 34:2279-2285 [PMID 23153661] [http://jdc.jefferson.edu/gastro\\_hepfp/17/](http://jdc.jefferson.edu/gastro_hepfp/17/)
35. Vaid U, Singer E, Marhefka GD, Kraft WK, Baram M. Poor Positive Predictive Value of McConnell's Sign on Transthoracic Echocardiography for Diagnosis of Acute Pulmonary Embolism. *Hospital Practice*. 2013;3(41)23-7 [PMID 23948618] <http://jdc.jefferson.edu/petfp/46>
36. Lawitz E, Sulkowski M, Jacobson I, Faruqi S, Kraft WK, Maliakkal B, Al-Ibrahim M, Ghalib R, Gordon S, Kwo P, Rockstroh J, Panorchan P, Miller M, Caro L, Barnard R, Hwang PM, Gress J, Quirk E, Mobashery N. Safety, Antiviral and PK activity of Vaniprevir, a Hepatitis C Virus NS3/4A Protease Inhibitor, in Patients with HCV Genotype 1 Infection. *Antiviral Research*. 2013;99(3):214-20. [PMID 23747481]
37. Kraft WK, Chang P, van Iersel MLPS, Waskin H, Krishna G, Kersemaekers W. Posaconazole Tablet Pharmacokinetics: Lack of Effect of Concomitant Medications Altering Gastric pH and Gastric Motility in Healthy Subjects. *Antimicrobial Agents and Chemotherapy*. 2014;58(7):4020-4025. [PMID: 24798274] <http://jdc.jefferson.edu/petfp/52>
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**Lectures by Invitation (Thomas Jefferson University or Hospital):**

- 6/10/99 Department of Medical Grand Rounds, "Bioterrorism"
- 6/13/03 Current Trends in Antithrombotic Therapy CME Symposium, "Duration of Anticoagulation"
- 9/16/03 Division of Hematology (Cardeza Foundation) Grand Rounds, "Duration of Anticoagulation"
- 11/22/04 Thomas Jefferson University Faculty Development Seminar, "Teaching Evidence Based Medicine at the Bedside"
- 6/9/06 Preoperative Evaluation and Post-Operative Care CME Symposium, "Preoperative Medications: Management Strategies"
- 1/25/07 Division of Rheumatology Grand Rounds, "Current Issues in Anticoagulation"
- 6/12/09 Department of Neurosurgery Grand Rounds, "Venous Thromboembolism Prophylaxis in the Neurosurgical Patient"
- 1/10/12 Faculty Development Lecture, "Obtaining Industry Support of Investigator Initiated Research Proposals" (workshop organizer)
- 9/19/13 Faculty Development Lecture, "How to Build a Career in Clinical Research" (workshop organizer)
- 9/28/13 MD/PhD Retreat, Panelist, "Challenges Facing Physician Scientists in the 21st Century" (speaker)
- 3/13/14 Medical Education Research Interest Group, "How the IRB Looks at Medical Education Projects".
- 2/2/15 Faculty Development Lecture, "The Five Things You Need to Know Before You Do Clinical Research" (workshop organizer)
- 2/13/15 Faculty Development Lecture, "Conducting Clinical Research: How to Navigate the IRB" (workshop organizer)
- 9/22/15 Faculty Development Lecture, "How JCRI Can Help You Conduct Clinical Research"
- 3/2/18 Learning Collaborative Speaker, "Neonatal Abstinence Syndrome", Division of Substance Abuse Programs

### Lectures by Invitation (External):

- 1/17/01 Medical Grand Rounds, "Airway Remodeling and Collagen Deposition in Asthma", Veterans Affairs Medical Center, Wilmington, DE
- 12/5/01 Medical Grand Rounds, "Is There an Epidemic Of Primary Hyperaldosteronism", Veterans Affairs Medical Center, Wilmington, DE
- 12/3/03 Medical Grand Rounds, "Duration of Anticoagulation", Veterans Affairs Medical Center, Wilmington, DE
- 9/11/04 Lower Shore Symposium, American College of Physicians, Delaware Chapter, "Idiopathic Deep Vein Thrombosis/Pulmonary Embolus: What the Data Tells Us About the Duration of Anticoagulation", Rehoboth Beach, DE
- 3/8/07 Oral presentation of "Trial of Buprenorphine for the Treatment of Neonatal Abstinence Syndrome", National Institute of Drug Abuse Conference Pharmacotherapy Research for the Treatment of In-Utero Substance Exposed Neonates: Advances and Future Directions. Rockville, MD
- 3/24/07 Co-chair and moderator, Late Breaking Abstract Session, American Society of Clinical Pharmacology and Therapeutics Annual Meeting, Anaheim, CA
- 4/5/08 Co-chair and moderator, Late Breaking Abstract Session, American Society of Clinical Pharmacology and Therapeutics Annual Meeting, Anaheim, CA
- 9/12/08 Visiting FDA lecturer, "Buprenorphine for the Treatment of the Neonatal Abstinence Syndrome", Office of Clinical Pharmacology, CDER, FDA, White Oak, MD
- 3/20/09 Co-chair and moderator, Oral Session "Pharmacodynamic Modeling", American Society of Clinical Pharmacology and Therapeutics Annual Meeting, Washington, DC
- 4/8/09 Association of Clinical Research Professionals Seminar, "Phase 1 Trials in Healthy Volunteers", Lambertville, NJ
- 6/24/10 Featured Speaker, "Future Trends in the Treatment of Neonatal Abstinence Syndrome", 2010 Summit on Substance Exposed Newborns: Collaborative Approaches to a Complex Issue. Alexandria, VA
- 2/24/11 Medical Grand Rounds, "Phase 1 Research and Healthy Volunteers", Cooper University Hospital, Camden, NJ
- 6/1/11 14th Annual Neonatal Advanced Practice Nursing Forum, "New Agents, New Horizons in the Pharmacologic Management of Substance - Exposed Newborns", Washington, D.C.
- 12/20/11 Visiting Speaker, "Buprenorphine for the Treatment of the Neonatal Abstinence Syndrome", Division of Clinical Pharmacology, Indiana University School of Medicine
- 3/16/12 Symposium Chair and Presenter, "Optimizing Pediatric Therapeutics by Applying Lessons from Adult Drug Development", American Society of Clinical Pharmacology and Therapeutics Annual Meeting, Washington, DC
- 4/26/12 Speaker and Discussant, "The Human Research Participant in Today's Early Phase Research & Updates on National Registry Initiatives", Association of Clinical Pharmacology Units Annual Meeting, Bethesda, MD

- 5/3/12 Speaker and Discussant, "Addressing Current Recruitment and Retention Challenges within Pediatric Clinical Trials" and "Optimizing Pediatric Drug Development", at 8th Annual Pediatric Clinical Trials meeting, Philadelphia, PA
- 5/9/12 Division of Hematology Research Conference, "Optimizing Pediatric Drug Development", Thomas Jefferson University
- 9/23/12 Speaker and Discussant, "Safety Challenges and Developing Models for Emergency Response Coverage in First in Human Trials", American College of Clinical Pharmacology Annual Meeting, San Diego, CA
- 11/4/12 Speaker and Discussant, "Bridging Adult and Pediatric Conditions: Biomarkers in Pediatric Drug Development", American Heart Association Scientific Sessions 2012, Los Angeles, CA
- 11/16/12 Speaker, "Best Practices and Resources for Preventing Dual Enrollment in Clinical Trials", GCP Compliance and Quality Oversight Conference, New Brunswick, NJ
- 2/25/13 Speaker, "'Novel Therapies in Treatment of Neonatal Abstinence Syndrome", Translational Science Research Seminar, Nemours/A.I. duPont Hospital for Children, Wilmington, DE
- 5/15/13 Faculty Speaker, "Substance Exposure 101: Frequency and Neonatal Impact by Agent" Vermont Oxford Network Webinar Curriculum, *Controversies in Caring for Infants and Families Affected by Substance Abuse Disorders and Neonatal Abstinence Syndrome* <http://www.vtoxford.org/quality/inicq/nascontroversies.aspx>
- 5/29/13 Speaker, "Pharmacology Review: Risks and Benefits of Methadone, Morphine, Buprenorphine, Clonidine, and/or Phenobarbital". 16th Annual Neonatal Advanced Practice Nursing Forum Preconferences A and B, Washington, DC
- 5/30/13 Speaker, "Controversies in the Treatment of Neonatal Abstinence Syndrome: Methadone, Morphine, Buprenorphine, Clonidine, Phenobarbital or Bust?" 16th Annual Neonatal Advanced Practice Nursing Forum, Washington, DC
- 7/14/13 Faculty Speaker, "Examining the Evidence: Controversies in the Pharmacologic Management" Vermont Oxford Network Webinar Curriculum, *Controversies in Caring for Infants and Families Affected by Substance Abuse Disorders and Neonatal Abstinence Syndrome*
- 1/22/14 Faculty Speaker, "Toxidromes: Making the best treatment decisions" Vermont Oxford Network Webinar Curriculum, *Structuring Success in the Care of Infants and Families Affected by Neonatal Abstinence Syndrome*
- 3/6/14 Speaker, "Pharmacologic Therapies for the Neonatal Abstinence Syndrome". Neofest 2014, Cincinnati Children's Hospital, University of Cincinnati School of Medicine
- 8/26/14 Speaker, "Current Pharmacologic Approaches to the Treatment of Neonatal Abstinence Syndrome" Christiana Hospital Grand Rounds, Newark, DE
- 9/13/14 Workshop organizer and session chair, "Opioid Prescribing: Reducing the Risks", American College of Clinical Pharmacology scientific meeting, Atlanta, GA
- 9/14/14 Symposium organizer and session chair, "Real-world, Large-scale Implementation of Pharmacogenetic-guided Drug Dosing", American College of Clinical Pharmacology scientific meeting, Atlanta, GA

- 9/27/14 Speaker, "Current Pharmacologic Approaches to the Treatment of Neonatal Abstinence Syndrome" at Medical Society of Delaware Symposium, "The Face of Addiction: Across the Ages", Wilmington, DE
- 5/14/15 Speaker, "Changes in Clinical Trials: The PI perspective", ACRP Greater Philadelphia Chapter's annual 2-day meeting, Blue Bell, PA
- 12/8/15 Speaker, "Pharmacologic Management of the Neonatal Abstinence Syndrome". NIDA Webinar Series
- 2/23/16 Speaker, Substance Abuse Treatment Center, University of Pennsylvania, "Pharmacologic Treatment of the Neonatal Abstinence Syndrome"
- 9/12/16 Speaker, "Modeling, simulation and dose selection in NAS", International Neonatal Consortium of the Critical Path Meeting, European Medicines Agency, Canary Warf, London, UK
- 9/19/16 Session Co-Chair, "Award Winning Abstract Selection" American College of Clinical Pharmacology scientific meeting, Bethesda, MD
- 5/7/17 Platform Speaker, "Buprenorphine for the Treatment of the Neonatal Abstinence Syndrome", Pediatric Academic Societies meeting, San Francisco, CA
- 12/12/17 Platform Speaker, "What is new in Neonatal Abstinence Syndrome", at Hot Topics in Neonatology, Washington, DC
- 1/12/2018 Panel Speaker, NIDA Neonatal Opioid Withdrawal Syndrome symposium, Rockville, MD
- 6/6/2018 NIDA CTN Youth Special Interest Group presentation, Webinar
- 6/27/2018 Speaker, "Clinical Dosing and Pharmacokinetics Considerations for Neonatal Abstinence Disease Treatment", HESI joint session at The Teratology Society meeting, Clearwater, FL

## **Research Support**

### ACTIVE

NIH R01 DA029076 (PI: Kraft, Walter)

06/01/11-04/30/19 3.0 calendar

Title: A Comparison of Buprenorphine versus Morphine in the Treatment of the Neonatal Abstinence Syndrome

The goal of this project is directly compare the safety and efficacy of buprenorphine versus morphine in the treatment of neonatal abstinence syndrome in a blinded clinical trial.

Role: PI

Stanford Subaward (PI:Kraft, W.)

09/01/2016-05/31/18 .6 calendar

Prevention of Neonatal Abstinence Syndrome (NAS2)

The goal of this project is directly compare ondansetron to placebo for the prevention of neonatal abstinence syndrome in a blinded clinical trial.

Role: PI

Capillary Biomedical, Inc.Subcontract (PI:Kraft, W.)

09/01/2018-08/31/19 1.2 calendar

Enhanced Bioavailability of Continuous Subcutaneous Insulin Infusion for Extended Seven Day Duration

The goal of this project is to optimize the delivery of subcutaneous insulin using a novel technology

Role: PI

Various Clinical Trials (PI: Kraft, W.)  
Information available upon request

### **Selected Recent Completed Research Support**

NIH Thru Univ of PA (PI: Hand, D PI) 08/01/15-07/31/17\* \*project ongoing/role complete  
Title: Placebo-controlled trial of bupropion for smoking cessation in pregnant women  
The goal of this project is assess effectiveness of bupropion for smoking cessation in pregnancy  
Role: Co-I

BMS (Investigator Initiated). (PI; Kraft, Walter) 10/1/14-10/1/15  
Title: A Phase I, Placebo-Controlled, Open-Label, Crossover Study to Assess the Reversibility of Apixaban Anticoagulation with the Four Factor Prothrombin Complex Concentrate Kcentra in Healthy Volunteers [4PAR]  
Role: PI

R01 CA172336 (Forsberg) 02/01/15-01/31/19 NIH \*project ongoing/role complete  
Contrast Ultrasound Detection of Sentinel Lymph Nodes in Breast Cancer Patients  
The fundamental hypothesis of this project is that contrast enhanced ultrasound can be used to map lymphatic drainage from breast malignancies and localize SLNs in breast cancer patients and that lymphosonography will improve the detection of SLNs compared to isotope mapping leading to improved disease staging.  
Role: Co-Investigator

Commonwealth of Pennsylvania (PI: Kraft W.) 01/01/05-12/31/08  
Program Project  
Title: Buprenorphine Treatment of Neonatal Abstinence Syndrome  
The major goal of this project is to characterize the safety and feasibility of the use of sublingual buprenorphine in the treatment of neonatal abstinence syndrome.  
Role: PI

NIH 5 U01 AT003574-02 (PI: Navarro, V) 08/01/07-07/31/09  
Title: Silymarin for the Treatment of Nonalcoholic Steatohepatitis  
The major goal of this project is to identify silymarin exposure levels in patients with non-cirrhotic liver disease attributable to non-alcohol induced fatty liver disease (NAFLD) and hepatitis C(HCV) that are safe, and to determine if exposures are dose proportional.  
Role: Co-Investigator

NIH/NIDA 1 R21 DA018207-01A1 (PI: Kraft, W.) 09/01/05-08/31/09  
Title: Buprenorphine Treatment of Neonatal Abstinence Syndrome  
The major goal of this project is to model the pharmacokinetics and pharmacodynamics of sublingual buprenorphine in the treatment of neonatal abstinence syndrome.

NIH/NCI 1 R01 CA095026-01 (PI: Waldman, S.A) 08/01/03-05/31/11  
Title: Guanylyl Cyclase C in Blood and Colorectal Cancer  
The major goal of this project is to examine the utility of GCC for post-operative surveillance in blood in patients with colorectal cancer. Role: Collaborator

K30 RR022299 (PI: S. Waldman)

09/30/00-06/30/11

NIH/NCRR

Training Program in Human Investigation

A Master's program that trains clinical investigators in patient-oriented research through integration of relevant coursework in multi-disciplinary topics with practical experience (thesis projects, clerkships, and/or rotations) Role: Co-Investigator

BMS (Investigator Initiated). (PI; Kraft, Walter)

10/1/14-10/1/15

Title: A Phase I, Placebo-Controlled, Open-Label, Crossover Study to Assess the Reversibility of Apixaban Anticoagulation with the Four Factor Prothrombin Complex Concentrate Kcentra in Healthy Volunteers [4PAR]

Role: PI