

CURRICULUM VITAE

Kristin JoAnn Wainwright, BSN, BA, RN, PhD Candidate
NINR F31 Fellow, Jonas V Veterans Healthcare Scholar

Duke University School of Nursing
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Nursing License: North Carolina, #231283, since June 2, 2009

Maiden Name: Masel
Date of Birth: July 11, 1981
Place: Bradenton, Florida, USA
Citizen: USA

Areas of Research Interest

- Symptom Science
- Genetics/genomics
- Neurological symptoms
- Disability
- Biostatistics
- Patient reported outcomes
- Applied neuroscience
- Multiple Sclerosis

Education

<u>Level of Education</u>	<u>Institution</u>	<u>Date</u>	<u>Degree</u>
Secondary School	NC School of Science & Mathematics, Durham, NC	1997 – 1999	High School Diploma
College/University	New College, Sarasota, FL	2000 – 2004	BA, Natural Sciences
College/University	East Carolina University College of Nursing, Greenville, NC	2007 – 2009	BSN, Summa Cum Laude
Graduate or Professional School(s)	Duke University School of Nursing, Durham, NC	08/2014 – 05/2021	PhD, Nursing • Certificate in College Teaching

<u>Level of Education</u>	<u>Institution</u>	<u>Date</u>	<u>Degree</u> • Certificate in Cognitive Neuroscience
Additional Training/Education	National Institutes of Health, National Institute of Nursing Research, Summer Genetics Institute, Bethesda, MD	06/2013	NA
Additional Training/Education	SPINE Institute, Basel, Switzerland, Genomics and Symptom Science Management, Christine Miaskowski, Yvette Conley	08/2016	NA
Additional Training/Education	Structural Equation Modeling, Curran-Bauer Analytics	05/2017	NA
Additional Training/Education	Longitudinal Structural Equation Modeling, Curran-Bauer Analytics	05/2017	NA
Additional Training/Education	Mixture Modeling and Cluster Analysis, Curran-Bauer Analytics	06/2017	NA

Scholarly Societies

<u>Society</u>	<u>Date</u>
Association of Clinical Research Professionals (ACRP)	2011– 2015
American Association of Neuroscience Nurses (AANN)	2011– 2015
American Nurses Association (ANA)	2009 – Present
North Carolina Nurses Association (NCNA)	2009 – Present
Sigma Theta Tau International Honor Society of Nursing (STTI), Beta Nu & Beta Epsilon	2008 – Present
International Society of Nurses in Genetics (ISONG)	2020 – Present

Professional & Academic Career

<u>Institution</u>	<u>Position/Title</u>	<u>Date</u>
NINR Center of Excellence, ADAPT Center-Adaptive Leadership for Cognitive/Affective Symptom Science, Duke University School of Nursing	Research Assistant	06/2016 – 07/2017
East Carolina University, ECU Physicians/Brody School of Medicine, Greenville, NC	Clinical Research Nurse Specialist, Dept. of Surgery, Division of Neurosurgery	06/2011 – 12/2014
Carolina East Medical Center, New Bern, NC	Registered Nurse, Orthopedics, Cardiac Intermediate Care	2009 – 2011
U.S. Peace Corps, Environmental Sector, Jamaica, West Indies	Volunteer, Ocho Rios Marine Park & Sturge	2005 – 2006

<u>Institution</u>	<u>Position/Title</u>	<u>Date</u>
	Town Community Development Council	
Mote Marine Laboratory, Department of Environmental Health & Ecotoxicology, Sarasota, FL	Subcontractor, Data Collection & Entry, Research Intern, Florida Red Tide toxin exposure for people with asthma and COPD (NIEHS funded)	2002 – 2004
Chatteris Educational Foundation, Hong Kong, China	English Language Teaching Assistant, Heep Woh Primary School	1999 – 2000
American Heart Association Internship, East Carolina University	Research Intern, Human Performance Laboratory	1999
University of North Carolina at Chapel Hill, Department of Pathology and Laboratory Medicine	Research Intern, Division of Laboratory and Animal Medicine	1998

Selected Publications & Presentations

Wainwright KJ, Docherty S, Dungan JR, Merwin E, Yang Q, Gregory S, & Hartsell FL. (Nov 6-10, 2021). Multiple Sclerosis Diagnosis Experience: A Literature Review [Virtual Poster Presentation]. 46th Biennial Convention. Sigma Theta Tau International: Indianapolis, Indiana, USA.

Wainwright KJ, Yang Q, Docherty S, Dungan JR, Merwin E, Gregory S, & Hartsell FL. (Feb 24-26, 2021). Symptoms of the First Multiple Sclerosis Attack, An Exploratory Factor Analysis [Virtual Podium Presentation]. Annual Conference. Southern Nursing Research Society: Overland Park, Kansas, USA.

David-Berholz J, Smith C, Wainwright K, Wang Z. (2020, July 29). What Mentees Really Think of Mentors, and More. *Professional Development Blog*. Duke University Graduate School: Durham, NC. <https://gradschool.duke.edu/professional-development/blog/what-mentees-really-think-mentors-and-more>

David-Berholz J, Smith C, Wainwright K, Wang Z. (2020, Mar 20). Mentoring Relationships Among Graduate Students and Postdoctoral Trainees at Duke University. *2020 Emerging Leaders Institute*. Duke University Graduate School: Durham, NC.

Wainwright KJ. (2020). Neurological symptoms in Multiple Sclerosis. Duke GradX Talks. *Society of Duke Fellows* [Abstract submitted, cancelled for COVID]. Duke University: Durham, NC.

Docherty SL, Wainwright K, Kayle M, Kreider KE, Padilla BI, Pereira K, Vorderstrasse A, Silva S, Corazzini K, Lin Y, Iversen MM, Wojack R, Cao J, Bailey DE. (2019, July 29). Type 2 Diabetes Self-

Management Interventions: Does the Rubber Meet the Road? [Podium Presentation]. *Sigma Theta Tau International (STTI) 30th International Nursing Research Congress, Theory-to-Practice: Catalyzing Collaborations to Connect Globally*. Sigma Theta Tau International: Calgary, Alberta, Canada.

Dardas LA, Xu H, Shawashreh A, Franklin MS, Wainwright K, Pan W. (2019, May). Psychometric Properties and Factor Structure of the Center for Epidemiologic Studies Depression Scale in a National Sample of Arab Adolescents. *Issues in Mental Health Nursing*, 40(5), 437-443. doi: 10.1080/01612840.2018.1534912. PMID: 30794470. Epub 2019 Feb 22.

Wainwright KJ. (2019, Feb 18). A Study of Symptoms in People with Multiple Sclerosis Using Existing Data [Presentation]. *Center for Cognitive Neuroscience (CCN) Spring 2019 Graduate Student Journal Club and Talk Series*. Duke University Institute for Brain Sciences: Durham, NC.

Bailey D, Wainwright K, Kayle M, Kreider K, Padilla I, Pereira K, Vorderstrasse A, Silva S, Corazzini K, Cao J, Lin Y, Iversen M, Docherty S, ADAPT Symptom Science Workgroup. (2018, Sept 14) Precision Health and Self-Management of Type II Diabetes [Podium Presentation]. *Council for the Advancement of Nursing Science (CANS) 2018 State of the Science Congress on Nursing Research - Precision Health*. The Council for the Advancement of Nursing Science: Washington, DC. Work supported in part by Center for Excellence in Adaptive Leadership for Cognitive/Affective Symptom Science (ADAPT Center), National Institute of Nursing Research, 1P30NR014139-01, PIs: Docherty S, Bailey D.

Wainwright KJ, Dungan JR, Yang Q, Gregory S, Docherty S, Merwin E. (2018, Mar 22). Specific and Pervasive Symptoms in Adults with Multiple Sclerosis Using the MURDOCK-MS Dataset: A Secondary Analysis [Poster, Control ID 2796379]. *Southern Nursing Research Society (SNRS) Annual Conference: Expanding Nursing Science in Population and Global Health*. Sheraton, Atlanta, GA.

Wainwright KJ. (2017, Sept 26). Symptoms in People with Multiple Sclerosis: A Secondary Data Analysis. [Presentation]. *PhD and Postdoctoral Research Conference Series*. Duke University School of Nursing: Durham, NC.

Wainwright KJ. (2017, Sept 21). The Adaptive Leadership Framework [Presentation]. *Course N483 Professional Nursing: Evolution as a Leader*. Duke University School of Nursing. Durham, NC.

Landis BO, Anderson SL, Wainwright KJ, Briggs FB, Das S, Newby LK, Gregory SG. (2017, Aug 26). Development of a REDCap-Based Instrument for Investigating Environmental and Genetic Risk Factors of Multiple Sclerosis [Poster]. *2017 Carolinas Research Day*. Durham, NC.

Dail RB, Lewinski AA, Wainwright KJ, Bailey DE. (2016, April 23). Leadership and Career Development Series for PhD Students [Presentation]. *2016 Radical Transformation in Nursing Education Conference*. Durham, NC: Duke University School of Nursing.

Lewinski A, Wainwright KJ, Gordon H, Derouin A. (2016, April 17-20). Exploring the Impact of a Student-Faculty Program to Increase Mentoring and Build an Environment of Civility in a Nursing School [Poster]. *ATI National Nurse Educator Summit*. Nashville, TN.

Wainwright KJ. (2016, April 20). Working with Multiple Sclerosis [TED Talk]. *Duke/UNC Networking Event*. Durham, NC.

Lewinski A, Wainwright KJ, Gordon H, Derouin A. (2016). Student-Faculty Lunch Program to Increase Mentoring and Facilitate Cross-Program Relationships in School of Nursing. *Nurse Educator*, 41(3), 143-146. doi: 10.1097/NNE.0000000000000220, PMID: 26465347

- James RF, Wainwright KJ, Kanaan HA, Hudson S, Wainwright ME, Hightower J, Delaney JJ. (2015). Analysis of Occupational Radiation Exposure During Cerebral Angiography Utilizing a Real-Time Radiation Dose Meter System. *Journal of Neurointerventional Surgery*, 7(7), 503-508. doi: 10.1136/neurintsurg-2014-011215. PMID: 24827064. Epub 2014 May 14.
- James RF, Wainwright KJ. (2014, May 16). Heparin Infusion for Aneurysmal Subarachnoid Treatment [Poster]. *Eastern Regional Stroke Conference*. Greenville, NC.
- Wainwright KJ. (2014, March 31). Biomedical Research Training Opportunities at the National Institutes of Health for Students, Faculty, Clinicians, and Staff: A General Overview with a Focus on the National Institutes of Nursing Research Summer Genetics Institute [Podium Presentation]. *East Carolina University Research and Creative Achievements Week*. Greenville, NC.
- James RF, Shao E, Martin L, O'Brien K, Chaudry MI, Gaughen JR, Wainwright KJ, Kanaan HA, Everhart DK, Simard JM. (2014, Feb 28). Low-dose IV heparin infusion improves cognitive function in aneurysmal SAH patients [Poster]. *Nursing Collaborative Research Day*. Greenville, NC.
- Wainwright KJ, Kanaan HA, Hudson S, Wainwright ME, Hightower J, James RF. (2014, Feb 28). Analysis of Occupational Radiation Exposure During Cerebral Angiography Utilizing a Real-Time Radiation Dose Meter System: A Prospective Two-Phase Behavior Modification Study [Poster]. *Nursing Collaborative Research Day*. Greenville, NC.
- James RF, Lukosius EZ, Wainwright K, Kanaan HA. (2013). E-069 Intentional Partial Embolization for Dome Protection of Ruptured Complex Bifurcation Cerebral Aneurysms with Onyx HD500 is Feasible Prior to Delayed Definitive Treatment [Electronic Poster]. *Journal of Neurointerventional Surgery*, 5(Suppl 2), A64-A65.
- James RF, Wainwright KJ. (2013, April 26). PHAST Update: Prophylactic Heparin Infusion for Aneurysmal Subarachnoid Hemorrhage Trial [Poster]. Greenville, NC: Eastern Regional Stroke Conference.
- Acknowledgement in James RF, Palys V, Lomboy JR, Lamm RJ, Simond SD. (2013). The Role of Anticoagulants, Antiplatelet Agents, and Their Reversal Strategies in the Management of Intracerebral Hemorrhage. *Neurosurgery Focus*, 34(5), E6. doi: 10.3171/2013.2.FOCUS1328
- James RF, Wainwright KJ. (2012, Sept 14). PHAST Prophylactic Heparin Infusion for Aneurysmal Subarachnoid Hemorrhage Trial [Poster]. *Vidant Medical Center Neurosciences Growth Fair*. Greenville, NC.

In Preparation

Wainwright KJ. Phenotyping Complex Symptoms in Adults with Multiple Sclerosis [Dissertation, in progress]. Duke University: Durham, NC. Committee Members/Consultants: Sharron Docherty, Jennifer Dungan, Simon Gregory, Elizabeth Merwin, Qing Yang, & F. Lee Hartsell.

Wainwright KJ, Docherty S, Dungan J, Merwin E, Yang Q, Gregory S. (Manuscript in preparation). Symptoms of First Multiple Sclerosis Attack, An Exploratory Factor Analysis.

Wainwright KJ, Docherty S, Dungan J, Merwin E, Yang Q, Gregory S. (Manuscript in preparation). Trajectory Typologies of Pervasive Symptom in Adults with Multiple Sclerosis, A Latent Class Growth Analysis.

Wainwright KJ, Docherty S, Dungan J, Merwin E, Yang Q, Gregory S. (Manuscript in preparation). A Literature Review of the Symptom Experience in Adults with Multiple Sclerosis.

Wainwright KJ, Docherty S, Dungan J, Merwin E, Yang Q, Gregory S. (Manuscript in preparation). Creating symptom phenotypes from Latent Classes and Trajectory Typologies, Exploring Relationships with Individual Characteristics for Adults with Multiple Sclerosis.

Other

Masel KJ. (2004). Puffer Fish Poisoning [Undergraduate thesis]. *New College of Florida*. Sarasota, FL. Committee Members: Alfred Beulig, Paul Scudder, Amy Clore, & Barbara Kirkpatrick.

Consultant Appointments

<u>Appointment</u>	<u>Date</u>
HIPAA/Security Administrator for Neurosurgery Research, East Carolina University Brody School of Medicine, Greenville, NC	2013 – 2014
University & Medical Center Institutional Review Board's (UMCIRB) Biomedical Committee, Scientist, full-time voting member, East Carolina University & Vidant Medical Center, Greenville, NC	2012 – 2015
North Carolina Association of Nursing Students (NCANS), Special Consultant NC Northeast Regional Science & Engineering Fair, Judge	2012 – 2014 2013

Professional Awards & Special Recognitions

<u>Award</u>	<u>Date</u>
COVID-19 Funding Extension, Duke University Graduate School	2020, 2021
Duke University Graduate Young Trustee Finalist	2018
Jonas V Veterans Healthcare Scholar	2016 – 2018
Summer Fellowship, Duke University Graduate School	2015, 2016, 2017
Sigma Theta Tau, Beta Nu, Research and Creativity Award	2014
ECU Alumni Association Scholarship	2009
University Book Exchange Scholarship	2009
Honorable Mention ECU Elite Pirate	2008
North Carolina Nurse Scholar	2007 – 2009

Tylenol Scholarship Recipient	2007 – 2009
Sarasota Garden Club Scholarship	2003
Craven Regional Medical Center Auxiliary Scholarship	2000
National Merit Special Scholarship	1999
NC State & National Keyboarding (Typing) Competitor, Future Business Leaders of America	1997

Professional Organizations & Participation

<u>Professional Organization</u>	<u>Office Held and/or Committee Assignment</u>	<u>Dates</u>
Duke GradParents	President	2020 – 2021
American Association of College of Nursing (AACN) Policy Summit	Duke Nursing PhD Student Representative	2018
Duke University School of Nursing Student Council	President	2018
Duke Health Academic Affairs Committee (DHAAC), Duke University Board of Trustees	Graduate Student Representative	2017 - 2018
Duke University School of Nursing Student Council	PhD Representative	2017, 2020, 2021
Duke University Judicial Board	School of Nursing Student Representative	2016 – 2018
Internal Action Caucus, Duke Graduate & Professional Student Council	Chair	2016 – 2017
Duke University Graduate & Professional Student Council (GPSC)	Executive Secretary	2015 – 2016, 2017 – 2018
Duke University Graduate & Professional Student Council (GPSC)	Nursing PhD Representative	2015, 2017, 2020
Integrity Caucus, Duke Graduate & Professional Student Council	Member	2015 – 2016
Duke Medicine Orchestra	French Horn, 4 th Chair	2014 – 2016
Duke University School of Nursing Student Council	Secretary	2014 – 2016
North Carolina Nurses Association	2015 NCNA Convention Task Force	2014 – 2015
North Carolina Nurses Association	Nurse of the Day at the NC General Assembly	July 2014
North Carolina Nurses Association	Reference Committee & Delegate	2012 – 2013
East Carolina University/ Vidant Medical Center Bariatric Consortium	Member	2011 – 2014
East Carolina University Medical Readers' Theater Company	Cast/Reader	2008 – 2014
East Carolina University Human Library Event	Human Library "Book"	2014
Sigma Theta Tau International, Beta Nu	Leadership Intern, Committee Chair for "Scout-Out Nursing Day"	2012 – 2013
NC Association of Nursing Students	Secretary, Executive Board; Chair, Convention Planning Committee (4 state conventions); Resolutions & By-Laws Committee Member, wrote and presented Resolution at NSNA	2007 – 2010

Professional OrganizationOffice Held and/orCommittee Assignment

Convention in support of Evidence-Based Practice

Dates**Training and Certifications**Training and CertificationsDate

Certificate in Cognitive Neuroscience, Duke University	2017 – 2019
Certificate in College Teaching, Duke University	2015 – 2021
Collaborative IRB Training Initiative (CITI) Modules	2011 – Present
CITI Program, Biomedical Research – Basic/Refresher	09/14/2014
CITI Program Vulnerable Subjects (Prisoners, Children, Pregnant Women, Fetuses, Neonates)	2014
CITI Program Good Clinical Practice	02/17/2017
NIH Stroke Scale Certified	2011 – 2018
Association of Clinical Research Professionals Project Management Course	2012
Grant writing workshop	2012
National Council of University Research Administrators (NCURA), Primer on Clinical Trials	2011
Association of Clinical Research Professionals Fundamentals of Clinical Research	2011

Teaching ResponsibilitiesResponsibilityDate

Guest Lecturer, Adaptive Leadership Framework, N483 Professional Nursing: Evolution as a Leader	Sept 2017
Guest lecturer, N911 Introductory Statistics Laboratory, Duke University School of Nursing PhD Program	Fall 2017
Teaching Assistant for Dr. Qing Yang, N911 Introductory Statistics Class & Laboratory, Duke University School of Nursing PhD Program	Fall 2016
Mentor for undergraduate student researcher, Exercise and Nutrition for Multiple Sclerosis, UMCIRB #14-000178	Spring 2014
Tutor, Pitt Community College Tutoring and Academic Success Center (Biology, Pre-Algebra, College Algebra, Physics, Microbiology, Chemistry, Drug Calculations, Anatomy & Physiology)	2006 – 2007
English Language Teaching Assistant, CCC Heep Woh Primary School, Hong Kong	1999 – 2000

Research SupportProject Number: 5 F31 NR017121-02, F31NR017121, Duke IRB #Pro00073408Status on Grant: Fellow/PI, PhD StudentApproved Project Period: Sept 1, 2017 to July 13, 2020Sponsor: Sharron Docherty, Jennifer DunganSource: NRSA, NIH NINRAnnual Direct Costs: \$35,493Title of Project: Specific and Pervasive Symptoms in Adults with Multiple Sclerosis Using the MURDOCK-MS Dataset: A Secondary Analysis

Project Goal: To characterize—or phenotype—symptom experiences, using both MS-specific symptoms from the first MS-attack, five years of pervasive symptom data, to describe their relationship with each other, and to describe their relationship with individuals' characteristics, such as age, biological sex, and employment status. This will be the first study to use symptom data from the Duke MURDOCK-MS dataset of 958 adults with MS, as well as the first study to describe the relationship between early MS-specific symptoms, and subsequent pervasive

symptom trajectories. Guided by the NIH Symptom Science Model and the Adaptive Leadership Framework in Chronic Illness, this study will:

Aim 1) Develop MS-specific symptom clusters for adults with MS using symptoms from the first MS-attack

Aim 2) Classify adults with MS into trajectory typologies based on pervasive symptom severity over five years

Aim 3) Create MS symptom phenotypes that describe the relationship between MS-specific symptom clusters (from Aim 1) and:

(a) Pervasive symptom trajectory typologies (from Aim 2)

(b) Individual characteristics (demographic variables and covariates).

Project Number: Duke IRB #Pro000880802

Status on Grant: Study Coordinator (I am presently inactive in this project but still on the IRB)

Approved Project Period: Jan 18, 2018 – present

PI: Simon Gregory

Source: Duke Molecular Physiology Institute (DMPI), Duke Medicine

Title of Project: Health and medical history survey to investigate associations between genetic and environmental factors of multiple sclerosis (MS) and MS origins, expression, and progression

Project Goal: Collect a health history questionnaire from active Duke Clinical & Translational Science Institute (CTSI) MURDOCK study participants with MS and matched healthy control participants to facilitate collaborative studies combining participant health history with 'omic datasets to investigate relationships between genetic and environmental risk factors of multiple sclerosis (MS) and MS origins, expression, and progression. 'omic data sets are generated from biospecimens previously collected by the MURDOCK study.

Project Number: East Carolina University, UMCIRB #14-00018

Status on Grant: Principal Investigator

Approved Project Period: 2014

Source: Sigma Theta Tau International (STTI), Beta Nu

Title of Project: Inter-Departmental Reliability of the NIH Stroke Scale

Project Goal: Determine reliability of NIHSS across multiple disciplines in a stroke simulation setting. Applied for \$1,000 grant from Sigma Theta Tau, Beta Nu. Grant awarded, moved institutions before completed.

Project Number: East Carolina University, UMCIRB # 13-001735

ClinicalTrials.gov Identifier: NCT01827046

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2013 – 2014 (study completed Sept 2018)

Site PI: Robert F. James, MD

Sponsor: Johns Hopkins University

Study Chair: Daniel F. Hanley, MD, Johns Hopkins University

Collaborators: National Institute of Neurological Disorders and Stroke (NINDS), Genentech, Inc., and Emissary International LLC

Title of Project: Minimally Invasive Surgery Plus Rt-PA for ICH Evaluation Phase III (MISTIE III)

Project Goal: A Phase III, randomized, open-label, 500-subject clinical trial of minimally invasive surgery plus rt-PA in the treatment of intracerebral hemorrhage (ICH). Primary Objectives: Efficacy: Demonstrate that minimally invasive surgery (MIS) plus recombinant tissue plasminogen activator (rt-PA) for three days improves functional outcome by a 12% increase in the modified Rankin Scale (mRS) score 0-3 compared to medically treated subjects assessed at 365 days. Secondary Objective: Demonstrate that the end of treatment volume and percent of ICH reduction from MIS+rt-PA is related to improved functional outcome, as compared to medically treated subjects.

Safety: Demonstrate that early use of MIS+rt-PA for three days is safe for the treatment of ICH relative to rates of mortality, rebleeding, and infection in the medically treated subject at 30 days. Interpretation of results: For moderate to large ICH MISTIE did not improve the proportion of patients who achieved a good response 365 days after ICH. Procedure was safely adopted by sample of surgeons.

Project Number: East Carolina University, UMCIRB # 12-002308

ClinicalTrials.gov Identifier: NCT01793792

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2013 – 2014, study completed Jan 2016

Site PI: Robert F. James, MD

Overall Study PI: David Fiorella, MD, Stony Brook University Medical Center

Sponsor: Microvention-Terumo, Inc.

Title of Project: Pivotal Study of the MicroVention, Inc. Neurovascular Self-Expanding Retrieable Stent System (LVIS/LVIS Jr.) in the Treatment of Wide-Neck Intracranial Artery Aneurysms

Project Goal: The purpose of this study is to evaluate the safety and efficacy of the Low Profile Visualized Intraluminal Support (LVIS™ and LVIS™ Jr.) devices from MicroVention, Inc. when used to facilitate endovascular coiling of wide-necked intracranial aneurysms with coils. Interpretation of results: the LVIS stent system allows for safe and highly effective coil embolization of wide-neck intracranial artery aneurysms.

Project Number: East Carolina University, UMCIRB #12-000600

Status on Grant: Project Manager (Site Initiated), Clinical Research Coordinator

Approved Project Period: 2012 – 2014

PI: Robert F. James, MD, East Carolina University, Coordinating Center, and J. Marc Simard, MD, PhD, University of Maryland

Sponsors: 2012 East-West Collaboration Program Grant Award, East Carolina University, Division of Research and Graduate studies (\$25,000), Microvention, Inc. (\$115,000, approved 04/2013)

Title of Project: Prophylactic Heparin Infusion for Aneurysmal Subarachnoid Hemorrhage Trial (PHAST-1): Analysis of Myeloperoxidase and Myeloid-Related Protein 8/14 levels and genotypes

Project Number: East Carolina University, UMCIRB #12-001990

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2012 – 2014

PI: Robert F. James, MD

Sponsor: East Carolina University

Title of Project: Retrospective Outcome Analysis of Cerebral Disease Outcomes

Project Goal: Retrospective analysis of outcomes in people with cerebral disease.

Project Number: East Carolina University, UMCIRB #12-001994

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2012 – 2014

PI: Robert F. James, MD

Sponsor: East Carolina University

Title of Project: Utilization of a large diameter compliant balloon during aneurysm remodeling of wide-neck bifurcation aneurysms is safe and effective within small diameter cerebral arteries

Project Number: East Carolina University, UMCIRB #12-000097

ClinicalTrials.gov Identifier: NCT01407952

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2012 – 2014, study completed March 2018

Site PI: Robert F. James, MD

Overall Study PI: Bernard R. Bendock, MD, Mayo Clinic

Sponsor: Northwestern University

Collaborator: MicroVention, Inc.

Title of Project: New Generation Hydrogel Endovascular Aneurysm Treatment Trial (HEAT)

Project Goal: The purpose of this study is to test the effectiveness of a new generation FDA-approved device for treating aneurysms compared to the current standard device for endovascular aneurysm treatment, which is bare platinum coils. Endovascular procedures are a form of minimally invasive surgery performed on blood vessel, the technique involves the introduction of a catheter, which is a long, thin, flexible, hollow plastic tube, through the skin into a large blood vessel. Typically, the chosen blood vessel is the femoral artery found near the groin. The catheter is maneuvered through the body to the location of the aneurysm in the brain using image guidance. Coils are delivered into the aneurysm through the catheters and detached from the catheter. This is repeated until enough coils fill the aneurysm, blocking blood flow to the aneurysm. The body forms a blood clots around the coil(s), which helps block the flow of blood into the aneurysm and keeps the vessel from rupturing or leaking. This study will compare the study device to the standard bare platinum coil to see which is better at preventing future rupturing or leaking. The study device is called the HydroCoil Embolization System and this study is a post-market clinical trial. About 600 subjects from multiple institutions will take part in this study.

Project Number: East Carolina University, UMCIRB #11-000864

Status on Grant: Sub-Investigator

Approved Project Period: 2011 – 2014

PI: Robert F. James, MD

Source: East Carolina University

Title of Project: DoseAware Radiation Monitoring System in Cerebral Angiography-Prospective Observational Study

Project Goal: Hypothesis: Implementation of real-time radiation monitoring (the DoseAware system) will decrease occupational radiation exposure during diagnostic cerebral angiography. Real-time radiation dose badges were assigned to the roles of physician (2), nurse, scrubbed technician, and circulating technician for two phases, one where participants were blinded to the display showing badge exposure to radiation, and a second phase where they were unblinded to the display. This was done for 120 consecutive cases (30 cases per physician per phase). Data recorded per case (prospectively), with high radiation events (Red Events) recorded for each role. A red event was defined as >2.0 mSv/hr of radiation exposure. The dose area product (DAP) and total radiation exposure (mSv) for each role were also recorded. Results showed that real-time radiation dose monitoring led to a significant reduction in occupational radiation exposure during diagnostic cerebral angiograms. Adoption of this technology or similar technology should be seriously considered by administrators of biplane neuroangiography suites to help protect healthcare workers and patients.

Project Number: East Carolina University, UMCIRB #09-0525

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2011 – 2014

PI: Robert F. James, MD

Source: Codman, Raynham, MA

Title of Project: Enterprise Vascular Reconstruction Device & Delivery System (HUD/HDE)

Project Goal: The ENTERPRISE Vascular Reconstruction Device and Delivery System is authorized by federal law as a Humanitarian Use Device (a designation for devices that will be used to treat fewer than 4,000 people a year) for use with embolic coils for the treatment of wide-necked, intracranial aneurysms. Endovascular coiling of intracranial aneurysms represents an approach to treatment that can reduce morbidity and possibly mortality relative to surgical clipping of the aneurysm neck. The goal of endovascular coiling is to prevent rupture or rebleeding by isolating an aneurysm from the normal blood circulation without narrowing the parent vessel.

Project Number: East Carolina University, UMCIRB #09-0526

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2011 – 2014

PI: Robert F. James, MD

Source: EV3, Irvine, CA

Title of Project: Onyx Liquid Embolic System, Onyx HD-500 (HUD/HDE)

Project Goal: The EV3 Inc. Onyx Liquid Embolic System, Onyx HD-500 is authorized by federal law as a Humanitarian Use Device (a designation for devices that will be used to treat fewer than 4,000 people a year). This device is indicated for treatment of intracranial, saccular, sidewall aneurysms that present with a wide neck (> 4 mm) or with a dome-to-neck ratio < 2 that are not amenable to treatment with surgical clipping.

Project Number: East Carolina University, UMCIRB #09-0977

Status on Grant: Clinical Research Coordinator

Approved Project Period: 2011 – 2014

PI: Robert F. James, MD

Source: Stryker Neurovascular, Fremont, CA

Title of Project: Neuroform Microdelivery Stent System (HUD/HDE)

Project Goal: The neuroform microdelivery stent system is authorized by federal law as a Humanitarian Use Device (a designation for devices that will be used to treat fewer than 4,000 people a year). It is intended for use with embolic coils for the treatment of wide neck, intracranial, saccular aneurysms arising from a parent vessel with a diameter of greater than or equal to 2 mm and less than or equal to 4.5mm that are not amendable to treatment with surgical clipping. Wide neck aneurysms are defined as having a neck of greater than 4mm or a dome-to-neck ratio of less than 2.

Project Number: East Carolina University, UMCIRB #09-0976

Status on Grant: Clinical Research Coordinator

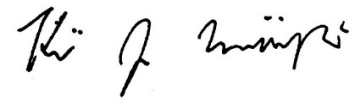
Approved Project Period: 2011 – 2014

PI: Robert F. James, MD

Source: Stryker Corp., Fremont, CA

Title of Project: Wingspan Stent System with Gateway PTA Balloon Catheter (HUD/HDE)

Project Goal: The Wingspan Stent System with Gateway PTA Balloon Catheter is authorized by federal law as a Humanitarian Use Device (a designation for devices that will be used to treat fewer than 4,000 people a year). This device is indicated for improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with greater than or equal to 50% stenosis that are accessible to the system.



Kristin J. Wainwright
January 7, 2021