Jeffery M. Carrico, Pharm.D., B.C.P.S.

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EXPERIENCE:

Lead, Operations and Investigational Drug/Device Research — 3/29/20 to Present
National Institutes of Health (NIH), National Cancer Institute (NCI), Center for Cancer Research (CCR), Office of Sponsor and Regulatory Oversight (OSRO)
Rockville, Maryland

Member, Institutional Review Board (IRB) — 6/5/20 to Present
National Institutes of Health (NIH) — 1/19/18 to 12/1/19
Bethesda, Maryland

Member, Government Liaison, Expert Committee — 6/1/20 to Present (5/31/25, 5 year term)
General Chapters–Packaging and Distribution — 6/1/15 to 5/31/20 (5 year term)
U.S. Pharmacopeial Convention (USP)
Rockville, Maryland

Member, Advisory Committee — 11/1/18 to Present(10/31/22,4 year term)
Pharmaceutical Science and Clinical Pharmacology — 1/1/16 to 10/31/18 (4 year term)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)
Silver Spring, Maryland

Consultant, Advisory Committee — 10/1/21 to Present
Oncologic Drugs (ODAC)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)
Silver Spring, Maryland

Service Chief, Clinical Pharmacy and Investigational Drug Research — 10/2/17 to 3/28/20
National Institutes of Health (NIH), Clinical Center
Bethesda, Maryland

Director of Pharmacy, Investigational Drug Service — 2/2/15 to 9/22/17
Director of Research , Pharmacy Services — 6/20/16 to 9/22/17
Member, Institutional Review Board (IRB) — 9/8/15 to 9/22/17
Florida Hospital System Department of Pharmacy
Orlando, Florida

Associate Director of Inpatient Pharmacy Services 8/6/12 to 2/1/15
Director of the Investigational Drug Service 7/11/11 to 2/1/15
Chair, Institutional Review Board (IRB) 9/9/13 to 2/1/15
University of Kentucky HealthCare
Lexington, Kentucky

Investigational Drug Service Coordinator 11/25/09 to 5/8/15
The University of Chicago Medicine (Off-Site)
Chicago, Illinois

Clinical Staff Pharmacist 12/7/09 to 7/11/11
University of Kentucky HealthCare
Lexington, Kentucky

Hospice of the Bluegrass Staff Pharmacist 03/16/09 to 12/7/09
Long Term Care Staff Pharmacist 11/6/00 to 12/7/09
D & R Pharmacare, Omnicare
Lexington and Louisville, Kentucky

Director of Research, Clinical Research Center 3/19/06 to 9/16/08
Director of Research, Lexington Cardiac Research Foundation
Central Baptist Hospital, Inc.
Lexington, Kentucky

Research Center Manager 3/13/01 to 3/17/06
SJHC Research Center
Saint Joseph HealthCare, Inc.
Lexington, Kentucky

Clinical Research Pharmacist Coordinator 6/19/00 to 3/10/01
University of Kentucky Surgery Research Program
University of Kentucky HealthCare
Lexington, Kentucky

EDUCATION:

University of Kentucky, **College of Pharmacy** 1996 to 2000
Lexington, Kentucky
Doctor of Pharmacy

University of Kentucky 1991 to 1996
Lexington, Kentucky
Bachelor of Science in Biology with Departmental Honors

University of Kentucky 1987 to 1991
Lexington, Kentucky
Bachelor of Health Sciences in Health Administration

RESPONSIBILITIES OF POSITIONS:

Lead, Operations and Investigational Drug/Device Research (3/30/20 to Present) National Institutes of Health (NIH), National Cancer Institute (NCI), Center for Cancer Research (CCR), Office of Sponsor and Regulatory Oversight (OSRO)

- Provide pharmaceutical expertise, drug product development expertise, manufacturing support, clinical trial oversight, clinical supply operations support, regulatory compliance and other support and safety oversight, consulting, guidance and training for all investigational products (drugs/devices) for trials in which CCR is the sponsor
- Ensure and lead regulatory compliance with sponsor obligations for Investigational New Drugs (IND) and Investigational Device Exemptions (IDE) as they relate to pharmaceutical and operational support
- Lead the pharmacovigilance program, provide analytic support and serve as the subject matter expert regarding FDA regulations and international regulations; maintain regulatory compliance and ensure programs are consistent with current standards of practice, NIH and NCI policies, all applicable standards and regulations including those of the HHS, OHRP, NIH, FDA, USP, ICH and The Joint Commission, including cGMP, GCP and human subjects protection
- Supervise study agent management for novel and individualized, investigational products and intermediate products; provide oversight over CCR manufacturing facilities and CCR contracted manufacturing products
- Guide, lead, train and mentor pharmacists, medical monitors, and other CCR and Clinical Center (CC) staff on pharmacy issues, product issues and procedures for regulatory compliance
- Serve as the Contracting Office Representative (COR II) for all CCR contracted manufactured product; engage in the management of the Sponsor and Regulatory Oversight Support (SORS) contract which supports the manufacturing process of final and intermediary products for CCR clinical trials (including novel cell therapy products)
- Coordinate, develop and administer managerial, technical, fiscal, manufacturing, and pharmaceutical activities accompanying contracts and relationships with the CC manufacturing facilities, CC pharmacy, pharmaceutical companies, and CCR investigators
- Meet important study product delivery and supply chain requirements; develop the statement of work, request for proposal, and all other related documents required for developing and soliciting product contracts
- Provide senior level professional pharmaceutical expertise and leadership in the development, oversight and implementation of pharmacy and manufacturing policies and SOPs for OSRO and CCR; provide oversight of the pharmacy and manufacturing policies and procedures for functions at CCR-sponsored clinical sites including: appropriate management of study products, maintenance of study related pharmacy records, internal quality assurance programs, product manufacturing quality assurance and development of quality assurance plans
- Oversee, develop and coordinate all pharmacy-specific and quality assurance training activities for CCR staff as well as clinical site pharmacy staff and clinical site monitors
- Exercise responsibility for the oversight of the procurement and supply chain for investigational agents, CCR manufactured intermediate products and other agents used in all CCR-sponsored clinical trials including identification of the pharmaceutical manufacturer, negotiation with company representatives, estimation of study product requirements and arrangement for shipment including review of data for agents received prior to distribution to clinical sites
- Confirm that sites meet appropriate guidelines and standards regarding investigational product ordering, storage, dispensing, inventory management and quality assurance
- Communicate and coordinate frequently with CC pharmacy and manufacturing personnel as well as representatives of the clinical site monitoring group

- Create, develop or provide guidance for the investigational product section of clinical protocols including drug dosage, drug interactions and potential toxicities
- Advise OSRO staff, clinical investigators and site pharmacists on investigational agent (drugs, devices, vaccines, microbicides, cell therapy products and other IV/injectables) properties, handling and storage, preclinical and toxicity data and issues with supply chain and distribution
- Collaborate and serve as a liaison to the CC central resources (cell manufacturing facilities, pharmacy, etc.) for regulatory processes, study oversight, study implementation, product support and associated processes and procedures
- Review pharmacy site audits and ensure all issues are resolved
- Exhibit leadership, oversight, and direction for all aspects of the OSRO operations and drug/device research program; supervise and direct subordinate staff
- Represent CCR and NCI at FDA meetings, meetings with drug sponsors, and meetings with contract manufacturers

Service Chief, Clinical Pharmacy and Investigational Drug Research (10/2/17 to 3/29/20)
National Institutes of Health (NIH), Clinical Center

- Developed budget and strategic plans to support and achieve the strategic direction, goals and objectives of the department and ensured optimum economic and budgetary performance
- Established a climate that promoted excellent quality and procurement processes for all investigational pharmaceutical products dispensed in clinical trials and patient care
- Assessed, planned, implemented and evaluated unique and complex programs associated with clinical pharmacy and investigational drug services
- Maintained regulatory compliance and ensured programs are consistent with current standards of practice, NIH and Clinical Center policies, all applicable standards and regulations including those of the HHS, OHRP, NIH, FDA, USP, ICH and The Joint Commission, including cGMP, GCP and human subjects protection
- Provided pharmaceutical expertise, leadership and consultation for clinical research protocols Phases I through IV of the drug development/approval process including NDA and IND processes as well as protocol design, implementation, coordination and evaluation
- Served as expert consultant within the Department of Pharmacy and the institution for USP General Chapters-Packaging and Distribution, USP <795>, USP <797> and USP <800>
- Ensured programs were consistent with research protocols to include receipt, distribution, dispensing, handling, storage and return of investigational pharmaceutical products
- Led procurement and supply chain of investigational and standard of care medications
- Provided guidance and training for manufacturing support
- Interfaced with clinicians and nurses to develop patient care initiatives in the context of clinical trials and research methodologies, protocol design and trial implementation that contributed to the discovery and development of new drugs and therapies, reduced the risk of investigational drug-related problems, and ensured the use of cost-effective pharmacotherapy
- Developed and implemented policies and standard operating procedures for the Clinical Pharmacy, Investigational Drug Service and contract manufacturers; established medication-handling procedures for the storage and preservation of medications
- Led appropriate functions of the planning and movement of all operations into a new space
- Represented Department of Pharmacy in the Scientific Review Process for new protocols
- Directed the assessment and analysis of the clinical pharmacy and investigational drug service processes to improve operational efficiency and effectiveness
- Identified inappropriate investigational drug utilization and led efforts to modify practices to improve medication management; utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties, dispensed medications prescribed by physicians and other health practitioners, provided information to

health practitioners and patients about proper usage of medications and side effects, evaluated medication use patterns and outcomes for patients in the hospital
- Utilized technology-enabled medication management data to capture and report pharmacy metrics and drive improvements in patient care and outcomes
- Represented the Clinical Center to other agencies, accrediting organizations, and other external organizations such as CDC, FDA, USP, contract manufacturers and The Joint Commission
- Fostered staff and resident research, managed student and residency educational programs and participated in organizational grant funding applications
- Served as Contracting Office Representative (COR II)
- Led, directed, oversaw and supervised a team of 35, including subordinate supervisors and leaders and ensured that supervisors were properly trained to execute human resource management responsibilities in accordance with NIH, HHS and OPM policies and regulations; managed hiring processes

Director of Pharmacy, Investigational Drug Service (2/2/15 to 9/22/17)
Director of Research, Pharmacy Services (6/20/16 to 9/22/17)
Florida Hospital System Department of Pharmacy

- Provided pharmaceutical expertise and leadership for the Investigational Drug Service (IDS) for an eight campus, 2800 bed system to ensure the provision of quality services, excellence in patient care and procurement of investigational products
- Led, directed, oversaw and supervised a team of 10
- Managed and coordinated operations in a complex hospital Pharmacy setting
- Integrated program goals and objectives of the IDS and pharmacy program including design of short and long term range strategic plans for workforce development, and staff professional development, to assure the availability of a highly specialized and high performing pharmaceutical staff and support staff
- Developed and implemented policies and standard operating procedures for the Investigational Drug Service and contract manufacturers
- Maintained regulatory compliance and ensured programs were consistent with all applicable standards and regulations including those of the HHS, OHRP, FDA, USP, ICH and DNV, contract manufacturers including cGMP, GCP and human subjects protection
- Provided leadership and consultation for clinical research protocols Phases I through IV of the drug development/approval process including NDA and IND processes as well as protocol design, implementation, coordination and evaluation
- Served as expert consultant within the Department of Pharmacy and the institution for USP General Chapters-Packaging and Distribution, USP <795>, USP <797> and USP <800>
- Led procurement and supply chain process of investigational medications and standard of care medications
- Provided guidance and training for manufacturing support
- Identified program goals and designed plans for the implementation of strategic goals within the framework of the service and organizational strategic plan of the pharmacy program
- Ensured clinical research with investigational medications was conducted according to the highest standards of patient safety, ethics and responsible professional practice
- Developed, initiated, reviewed, monitored and provided input for grants
- Collaborated with physicians, pharmacists and research staff to ensure appropriate training and education was available regarding investigational medications
- Promoted an environment of service, collaboration and continuous performance improvement within the IDS as well as to all departments throughout the institution

- Managed financial responsibilities of the IDS including budgetary analysis of services related to specific protocols; developed and monitored the departmental operating budget and managed human resources and capital
- Marketed the services of the IDS and recruited new studies
- Managed and coordinated daily operations in the IDS pharmacy as an alternate IDS pharmacist; utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties, dispensed medications prescribed by physicians and other health practitioners, provided information to health practitioners and patients about proper usage of medications and side effects, evaluated medication use patterns and outcomes for patients in hospitals or managed care organizations

Associate Director of Inpatient Pharmacy Services (8/6/12 to 2/1/15)

University of Kentucky HealthCare

- Directed, led, oversaw and coordinated the complex operations of Inpatient Services (Central Pharmacy and IV room/Sterile Compounding, Pediatric Services, Operating Room Services and Clinical Operations) in a cost-effective manner, including planning for new services, directing day-to-day operations (24/7), delegating responsibility and authority for providing services, continuously improving services to meet customer needs, assuring adequate resources are available and integrating services with other professional services within and outside the medical center to assure continuity of care, supervised a team of 101
- Managed the program goals and objectives process for planning and implementing annual departmental goals and objectives by coordinating assigned objectives and assisting in the accomplishment of others; developed and implemented streamlined methods and procedures to improve the Pharmacy department's goals and objectives
- Built and designed short and long term range strategic plans for workforce development, and staff professional development, to assure the availability of a highly specialized and high performing pharmaceutical staff and support staff; identified program goals and designed plans for the implementation of goals within the framework of the service, and organizational strategic plan of the pharmacy program
- Led appropriate portions of the planning and movement of all operations into a new space
- Prepared and revised policies and procedures; implemented approved changes
- Led procurement and supply chain process
- Served as expert consultant within the Department of Pharmacy and the institution for USP <795>, USP <797> and USP <800>
- Interpreted hospital and departmental policies and procedures for pharmacy personnel and assured compliance
- Recruited, hired, trained, developed, scheduled, and supervised assigned staff, developed performance standards; conducted performance appraisals and recommended salary increases consistent with hospital policy and procedures
- Participated in tracking medication errors as appropriate and developed and implemented improved procedures to minimize and prevent medication errors
- Provided pharmaceutical expertise and utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties, dispensed medications prescribed by physicians and other health practitioners, provided information to health practitioners and patients about proper usage of medications and side effects, evaluated medication use patterns and outcomes for patients in hospitals or managed care organizations
- Performed administrative, consultative and staff advisory work for the pharmacy program
- Coordinated services in assigned areas with other pharmacy areas, nursing areas, other hospital departments and external agencies to facilitate a smooth continuity of care

- Prepared, monitored, and operated within the departmental budget for operations, personnel, and capital equipment; prepared budget variance reports as required
- Coordinated planning, development and maintenance of both clinical and operational information systems
- Planned, monitored and evaluated medication programs and regimens
- Researched medical literature and/or clinical medication information to provide accurate responses to inquiries
- Assured accuracy and completeness of pharmacy billing in cooperation with hospital finance; assured that appropriate charge capture and billing systems for pharmacy charges were developed and maintained by staff
- Developed, coordinated, and monitored the departmental productivity monitoring system; produced timely reports as required; reassigned staff as required to most effectively match staffing to workload

Director of the Investigational Drug Service (7/11/11 to 2/1/15)

University of Kentucky HealthCare

- Provided pharmaceutical expertise and leadership for the Investigational Drug Service (IDS) to ensure the provision of quality services and excellence in patient care, led, directed, oversaw and supervised a team of 6
- Contributed to and provided input for processes leading to National Cancer Institute (NCI) cancer center designation and receipt of the Center for Clinical and Translational Science (CCTS) grant
- Ensured programs were consistent with all applicable standards and regulations including those of the HHS, OHRP, FDA, USP, ICH, contract manufacturers and The Joint Commission, including cGMP, GCP and human subjects protection
- Provided leadership and consultation for clinical research protocols Phases I through IV of the drug development/approval process including NDA and IND processes as well as protocol design, implementation, coordination and evaluation
- Led procurement and supply chain process of investigational medications and standard of care medications; facilitated investigational medication supply for other state institutions; ensured quality of procurement processes for investigational products
- Utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties, dispensed medications prescribed by physicians and other health practitioners, provided information to health practitioners and patients about proper usage of medications and side effects, evaluated medication use patterns and outcomes for patients in hospitals or managed care organizations
- Planned, monitored and evaluated medication programs and regimens
- Researched medical literature and/or clinical medication information to provide accurate responses to inquiries
- Maintained regulatory compliance and ensured compliance with all requirements of appropriate regulatory agencies
- Provided guidance and training for manufacturing support
- Developed, initiated, reviewed, monitored and provided input for research protocols and/or grants
- Collaborated with physicians, pharmacists and research staff to ensure appropriate training and education was available regarding investigational medications
- Developed and implemented policies and standard operating procedures for the Investigational Drug Service and contract manufacturers
- Promoted an environment of service, collaboration and continuous performance improvement within the IDS as well as to all departments throughout the institution

- Managed financial responsibilities of the IDS including budgetary analysis of services related to specific protocols; developed and monitored the departmental operating budget and managed human resources and capital
- Worked with contract manufacturing centers to meet cGMP for protocols as needed
- Managed and coordinated daily operations in the IDS pharmacy as an alternate IDS pharmacist

Investigational Drug Service Coordinator (11/25/09 to 5/8/15)
University of Chicago Medical Center (Off-Site)

- Coordinated IDS reimbursement for protocols in accordance with the IDS Fee Policy
- Assisted with preparation of the budget for IDS Center to include new protocols and renewals
- Coordinated IDS charges and oversaw submission process for reimbursement
- Reviewed and updated all IDS standard operating procedures and policies related to the control, packaging, dispensing, and monitoring of investigational medications
- Served as a liaison to others involved with research including the Office of Clinical Research, Institutional Review Board, the Associate Dean of Clinical Research, study coordinators and investigators
- Supported principal investigators by serving as a liaison to the study sponsor and assisting in the development of study protocols
- Provided leadership and consultation for clinical research protocols Phases II through IV of the drug development/approval process including NDA and IND processes as well as protocol design, implementation, coordination and evaluation
- Participated in protocol development, budget preparation and other requirements of the study sponsor, hospital or investigator
- Prepared pharmacy information sheets and related protocol information; utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties
- Developed and reviewed proper recording and documentation methods to be used by all personnel involved with investigational medication studies

Clinical Staff Pharmacist (12/7/09 to 7/11/11)
University of Kentucky HealthCare

- Provided pharmaceutical care by collaborating with physicians, nurses and other members of the healthcare team
- Maintained chemotherapy certification in order to provide service to outpatients and inpatients being treated for cancer
- Monitored drug therapy to evaluate appropriateness of use, dose, dosage form, regimen, route, therapeutic duplication and drug interaction; utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties, dispensed medications prescribed by physicians and other health practitioners, provided information to health practitioners and patients about proper usage of medications and side effects, evaluated medication use patterns and outcomes for patients in hospitals or managed care organizations
- Maintained compliance with prescribing criteria, guidelines and protocols
- Conducted target drug programs and drug usage evaluations as needed and reported results to the Pharmacy and Therapeutics Committee
- Detected, monitored, documented and reported adverse drug reactions and medication errors
- Performed medication histories, medication reconciliations and discharge counseling
- Clarified medication orders with the prescriber, documented any pharmacy records and informed others of medication order changes
- Reconciled pharmacy and nursing medication records daily
- Planned, monitored and evaluated medication programs and regimens

- Researched medical literature and/or clinical medication information to provide accurate responses to inquiries
- Maintained all medication records required by law
- Supported cost avoidance measures in drug therapy by promoting more cost effective regimens, drugs and by reducing waste
- Ensured proper technique and accurate preparation of all pharmaceutical products, including oral, IV admixtures, chemotherapeutic and investigational agents
- Reviewed physician orders for possible therapeutic problems, contraindications, interactions, allergies and formulary status of the medication

Hospice of the Bluegrass Staff Pharmacist (03/16/09 to 12/7/09) and Long Term Care Staff Pharmacist (11/6/00 to 12/7/09)
D & R Pharmacare, Omnicare

- Processed all medication orders for patients receiving care in inpatient and outpatient areas of hospitals, nursing homes, hospice and rehabilitation facilities
- Provided pharmaceutical services with consideration to medication selection, route, dose, frequency, safety and formulary alternatives; utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties, dispensed medications prescribed by physicians and other health practitioners, provided information to health practitioners and patients about proper usage of medications and side effects, evaluated medication use patterns and outcomes for patients in hospitals or managed care organizations
- Performed administrative, consultative and staff advisory work for the pharmacy program
- Initiated appropriate evidence-based medication therapy and offered suggestions to healthcare providers to prevent adverse events
- Planned, monitored and evaluated medication programs and regimens
- Researched medical literature and/or clinical medication information to provide accurate responses to inquiries
- Maintained all medication records required by law
- Supplied accurate and timely drug information to healthcare providers
- Led operations of pharmacy as appropriate for shift worked
- Provided clinical services as requested and recommended therapy including appropriate vancomycin and aminoglycoside dosing and monitoring
- Maintained current, evidence-based knowledge of medication therapy by reviewing literature
- Supported quality assurance programs

Director of Research, Clinical Research Center (3/19/06 to 9/16/08)
Director of Research, Lexington Cardiac Research Foundation
Central Baptist Hospital, Inc.

- Managed the departments to ensure the provision of quality research services and excellence in patient care, led, directed, oversaw and supervised a team of 16
- Ensured clinical research was conducted according to the highest standards of patient safety, ethics and responsible professional practice
- Provided leadership and consultation for clinical research protocols Phases II through IV of the drug development/approval process including NDA and IND processes as well as protocol design, implementation, coordination and evaluation
- Coordinated research chemotherapy through an outpatient clinic including the flow and management of the clinic with regard to research patients
- Attended tumor board meetings and participated in ACoS certification of oncology program
- Ensured compliance with all requirements of appropriate regulatory agencies

- Initiated a centralized Investigational Drug Service that met the needs of investigators and pharmacy operations
- Developed, initiated, wrote and monitored research protocols and/or grants
- Collaborated with physicians and staff to make clinical research studies available that met the clinical, strategic and operational goals of the organization
- Promoted an environment of service, collaboration and continuous performance improvement within the Research Department as well as to all departments throughout the hospital
- Managed financial responsibilities of the Research Department including budgetary analysis of clinical research studies; developed and monitored the departmental operating budgets and managed human resources and capital
- Reviewed all clinical trial agreements
- Marketed clinical research and recruited new studies
- Managed and coordinated research protocols as an alternate research coordinator

Research Center Manager (3/13/01 to 3/17/06)
Saint Joseph HealthCare, Inc.

- Coordinated Research Center activities with sponsors, physicians and staff wishing to conduct research, led, directed, oversaw and supervised a team of 5
- Led the creation and development of a centralized research service
- Negotiated study agreements and budgets with sponsors of clinical trials
- Developed the Research Center budget; maintained a system for tracking financial progress of the Research Center
- Provided leadership and consultation for clinical research protocols Phases II through IV of the drug development/approval process including NDA and IND processes as well as protocol design, implementation, coordination and evaluation
- Worked closely with the Cancer Center to incorporate research trials into line of therapy offered to patients
- Attended tumor board meetings as needed and participated in ACoS certification of oncology program
- Served as the primary departmental liaison to other departments for problem solving with relation to research-related issues and assured that other departments received adequate research services
- Participated in departmental strategic planning activities with administration to define yearly goals, objectives and appropriate timelines for accomplishment
- Provided adequate training and resources for pharmacy staff involved with research studies
- Managed and coordinated research protocols as alternate research coordinator
- Coordinated mixing, storing, dosing and administration of research pharmaceuticals as the Investigational Drug Service Pharmacist; utilized knowledge of the use, clinical effects, and composition of medications, including their chemical, biological, and physical properties, dispensed medications prescribed by physicians and other health practitioners, provided information to health practitioners and patients about proper usage of medications and side effects, evaluated medication use patterns and outcomes for patients in hospitals or managed care organizations
- Performed administrative, consultative and staff advisory work for the pharmacy program
- Maintained the operational aspects of the pharmacy department with regards to the interaction of research in all aspects of pharmacy operations
- Marketed the research service and recruited new studies for the Research Center
- Participated in the precepting of pharmacy students, externs, interns and technicians
- Developed and implemented investigator and staff orientation and training

Clinical Research Pharmacist Coordinator (6/19/00 to 3/10/01)
University of Kentucky Surgery Research Program

- Coordinated cardiothoracic and transplant surgery research protocols
- Managed research study protocols
- Assessed clinical status of patients for protocol eligibility
- Acted as patient and family liaison for protocol presentation and informed consent
- Educated and counseled patients and family members
- Initiated the research process including selection of studies and contract issues
- Processed laboratory specimens
- Prepared and dispensed research medications
- Evaluated procedures and patient progression throughout the treatment process
- Provided documentation of patient narratives and adverse events
- Completed case report forms
- Prepared Institutional Review Board documents
- Educated clinicians: physicians, nurses, pharmacists, respiratory therapists and other staff pertaining to research-related patient care

CONSULTING POSITIONS:

Carrico Clinical Research Consulting, LLC

etectRx, Orlando, FL 03/17 to 09/17
This project focused on the clinical trials and regulatory landscape of getting a product approved to market

Wheaton Franciscan Healthcare-St. Joseph, Milwaukee, WI 06/12 to 9/12
This project focused on the provision of IDS services without a dedicated IDS pharmacist or with the addition of an IDS pharmacist. Relationships with the research community were evaluated. Recommendations were made for financial management of IDS services

University of Chicago Medical Center, Chicago, IL 03/09 to 11/09
This project was an overview of the current Investigational Drug Service (IDS) organizational structure and Clinical Research Center (CRC) relationships in order to develop strategy recommendations to position the IDS to provide maximum value to the research and clinical missions of the organization

PROFESSIONAL LICENSURE / CERTIFICATIONS:

Board Certified Pharmacotherapy Specialist (BCPS)	2011 to Present
Pharmacist, Kentucky (Preceptor)	2000 to Present
Consultant Pharmacist, Florida	2015 to 2019
Pharmacist, Florida	2015 to 2017
Pharmacy-Based Immunization Delivery American Pharmacists Association	1999

ACADEMIC APPOINTMENTS:

Assistant Professor, Adjunct Series The George Washington University School of Medicine and Health Sciences	2016 to Present
Assistant Professor, Adjunct Series University of Kentucky College of Pharmacy Course Director / Instructor: PPS 895-002 Introduction to Clinical Research and the Investigational Drug Service	2019 to Present 2012 to 2015
Community Based Faculty Advanced Pharmacy Practice Experience and/or Introductory Pharmacy Practice Experience Preceptor University of Kentucky HealthCare University of Kentucky College of Pharmacy	2011 to 2012
Community Based Faculty Advanced Pharmacy Practice Experience Preceptor Saint Joseph HealthCare/University of Kentucky University of Kentucky College of Pharmacy	2004 to 2006

APPOINTMENTS:

Advisory Group on Emerging Sciences American Society of Health-System Pharmacists	2016 to 2019
Chair, Institutional Review Board (IRB) University of Kentucky	2013 to 2015
Board of Directors Kentucky Society of Health-System Pharmacists	2013 to 2015
Data Safety Monitoring Board (DSMB) Center for Clinical and Translational Science (CCTS) University of Kentucky	2012 to 2015
Data Safety Monitoring Committee (DSMC) Markey Cancer Center University of Kentucky	2011 to 2015
Residency Research Coordinator PGY1 Pharmacy Residency Program PGY2 Pharmacy Residency Program University of Kentucky HealthCare	2011 to 2015
Institutional Animal Care and Use Committee (IACUC) University of Kentucky	2011 to 2015

Board of Directors Faith Pharmacy (a charity organization that provides necessary medications to indigent clients, provides pharmaceutical related counseling and monitoring of disease and helps clients enroll in Patient Assistance Programs)	2011 to 2015
Institutional Review Board (IRB) University of Kentucky	2010 to 2015
Data Monitoring Committee Kentucky Lung Cancer Research Program	2007 to 2015
Network Committee, Clinical Trials Network Kentucky Lung Cancer Research Program	2005 to 2015
Vice-Chair, Institutional Review Board (IRB) University of Kentucky	2012 to 2013
House of Delegates Kentucky Society of Health-System Pharmacists	2012 to 2013
Scientific Advisory Committee (SAC) Center for Clinical and Translational Science (CCTS) University of Kentucky	2011 to 2012
Bioethics and Research Integrity Committee Center for Clinical and Translational Sciences University of Kentucky	2006 to 2008
CBH Nursing Research Council Central Baptist Hospital	2006 to 2008
LCRF Research Committee Central Baptist Hospital	2006 to 2008
SJHC Pharmacy Practice Residency Committee Saint Joseph HealthCare	2004 to 2006
SJHC Institutional Review Board Saint Joseph HealthCare	2002 to 2006
SJHC Departments of Cardiology, Cardiothoracic Surgery, Emergency Medicine, Executive Team, Heart Institute, Oncology, Pharmacy, Psychiatry: Research Representative Saint Joseph HealthCare	2001 to 2006
SJHC Institutional Review Board, Associate Member Saint Joseph HealthCare	2001 to 2002

Research Director of Residency Programs — 2004 to 2006
PGY1 Pharmacy Residency Program
PGY2 Cardiology Pharmacy Residency Program
Saint Joseph HealthCare - Lexington, KY
ASHP Accredited (#52107)

Delegate — 2001 to 2002
Kentucky Society of Health-System Pharmacists

Chair, Points Committee — 1998 to 1999
Kentucky Academy of Students of Pharmacy (KASP)

Vice-President — 1998 to 1999
University of Kentucky Phi Lambda Sigma
Honorary Leadership Society

Historian, Member of the Executive Council — 1996 to 1998
KASP

Treasurer — 1989 to 1991
University of Kentucky American College
of Healthcare Executives

Student Activities Council — 1991
University of Kentucky Chandler Medical Center
Representative, College of Allied Health, 1991
Secretary, 1991

CLINICAL/ANALYTICAL RESEARCH (Role, Sub-Investigator):

Jennings HR, **Carrico JM**, Poe KL, Blake RA. Acute Decompensated Heart Failure National Registry (ADHERE LM). (2004 to 2006)

Jennings HR, **Carrico JM**, Harris BH. Strategies to minimize contrast-induced nephropathy following cardiac catheterization. (2004 to 2005)

Jennings HR, Poe KL, **Carrico JM**, Harris BH. Comparison of B-type natriuretic peptide serum levels in samples drawn from intravenous catheters used for nesiritide administration vs. direct venipuncture. (2004 to 2005)

Jennings HR, Poe KL, **Carrico JM**, Blake RA, Sartini JC. Ischemic and hemorrhagic outcomes following percutaneous coronary interventions (PCI): enoxaparin versus heparin. (2003 to 2004)

Jennings HR, Poe KL, **Carrico JM**, Miller EC, Blake RA, Sartini JC. Ischemic and hemorrhagic outcomes following percutaneous coronary interventions (PCI): glycoprotein IIbIIIa-inhibitors (GP IIbIIIa) versus bivalirudin. (2003 to 2004)

Carrico JM, Keedy DL. A Randomized Trial to Evaluate the Relative Protection Against Post-PCI Microvascular Dysfunction and Post-PCI Ischemia Among Anti-Platelet and Anti-Thrombotic Agents PROTECT – TIMI 30. (2003-2004)

Carrico JM, Harris BH. Identification of Heparin-induced Thrombocytopenia and Thrombosis: A Registry of Prolonged Heparin Use and Thrombocytopenia among Hospitalized Patients with and without Cardiovascular Disease: The Complication After Thrombocytopenia Caused by Heparin (CATCH) Registry. (2003-2004)

Carrico JM, Jennings HR, Gochett CG, Short JM, Harris BH. Serum B-type natriuretic peptide (BNP) changes following coronary artery bypass grafting (CABG). (2002 to 2004)

Carrico JM, Blake RA, Sartini JC. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial Comparing the Efficacy and Safety of Reteplase and Abciximab Combination Therapy with Abciximab Alone Administered Early or Just Prior to Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction (FINESSE). (2002-2004)

Carrico JM, Poe KL, Rodrigue DC**.** Efficacy and Safety of Drotrecogin Alfa (Activated) in Adult Patients with Early Stage Severe Sepsis (Address). (2002-2004).

Carrico JM, Parsley BN. Randomized, Open Label, Comparative Study of Zosyn® (Piperacillin/Tazobactam [12g/1.5g]) Administered by Daily 24 hr Continuous Infusion vs. Zosyn® (Piperacillin/Tazobactam [3g/0.375g]) q6h for the Treatment of Hospitalized Patients with Complicated Intra-abdominal Infection. (2002-2003)

Carrico JM, Blake RA, Sartini JC. Randomized Evaluation in Percutaneous Coronary Intervention Linking Angiomax to reduced Clinical Events, Part 2 (REPLACE-2). (2002)

Carrico JM, Parsley BN. A Prospective, Randomized, Open-Label, Multicenter Study In Patients Presenting With Acute Coronary Syndromes (ACS) Protocol ENO.GMA.301 (SYNERGY). (2001 to 2004)

Carrico JM, Parsley BN. Prospective, Randomized, Open-Label, Multicenter Comparison of the Efficacy and Safety of Sequential Treatment with Intravenous (IV)/Oral (PO) Moxifloxacin 400/400 mg QD Versus Ceftriaxone 2 gm IV ± IV/PO Azithromycin ± IV/PO Metronidazole Followed by Cefuroxime axetil PO ± PO Azithromycin ± PO Metronidazole in Patients with Community or Nursing Home Acquired Pneumonia. (2001 to 2002)

PUBLICATIONS:

Carrico JM. The United States Pharmacopeia (USP) New Chapter on the Storage and Distribution of Investigational Drug Product (IDP). *Pharmaceutical Outsourcing*. 2016;17(5):34-36.

Jennings HR, Poe KL, **Carrico JM**, Miller EC, Blake RA, Sartini JC. Ischemic and Hemorrhagic Outcomes Following Percutaneous Coronary Interventions: Glycoprotein IIbIIIa-Inhibitors versus Bivalirudin. Proceedings of the American College of Cardiology Annual Scientific Session 2005 – Abstract #1039-29

Jennings HR, Poe KL, Miller EC, **Carrico JM**, Blake RA, Sartini JC. Comparison of Hemorrhagic Complications Associated with Abciximab, Eptifibatide and Bivalirudin Use for Percutaneous Coronary Interventions (PCI). *Pharmacy World & Science* 2004 April 26(2) – Abstract #PT-021.

Carrico JM. The human genome project: an update. *Medscape, www.medscape .com/viewarticle/408604.* 2001.

Carrico JM. Human genome project and pharmacogenomics-implications for pharmacy. *Medscape, www.medscape.com/viewarticle/406679.* 2000.

Carrico JM. Human genome project and pharmacogenomics-implications for pharmacy. *J Am Pharm Assoc*. 2000;40:115-16.

Carrico J. A day in the life of John Q. Pharmacy student. *Catscripts*. January 1999:13-14.

Carrico J. KASP Corner. *Kentucky Pharmacist*. April 1998:90.

Carrico J. APhA annual meeting to be held in Miami. *Kentucky Pharmacist*. March 1998:62.

Carrico J. KASP Corner. *Kentucky Pharmacist*. January 1998:22.

Carrico J. KASP Corner. *Kentucky Pharmacist*. December 1997:334.

Carrico J. KASP Corner. *Kentucky Pharmacist*. November 1997:306.

Carrico J. KASP Corner. *Kentucky Pharmacist*. October 1997:281.

Carrico J. KASP Corner. *Kentucky Pharmacist*. August 1997:242.

Carrico J. KASP Corner. *Kentucky Pharmacist*. July 1997:182.

Carrico J. Reflections of a soon to be second year student. *Kentucky Pharmacist*. June 1997:155.

Carrico J. KASP Corner. *Kentucky Pharmacist*. May 1997:127.

Carrico J. KASP Corner. *Kentucky Pharmacist*. April 1997:90.

ABSTRACTS:

Cai L, Jennings HR, **Carrico JM**, Whitaker MJ, Miller EC. Professional development and practice improvement through international exchange: Kentucky, USA & Beijing, China. Proceedings of 2005 ASHP Midyear Clinical Meeting – Abstract #RP493

Jennings HR, Poe KL, **Carrico JM**, Miller EC, Blake RA, Sartini JC. Ischemic and hemorrhagic outcomes following percutaneous coronary interventions: glycoprotein IIbIIIa-inhibitors versus bivalirudin. Proceedings of the American College of Cardiology Annual Scientific Session 2005 – Abstract #1039-29

Jennings HR, Poe KL, Miller EC, **Carrico JM**, Blake RA, Sartini JC. Comparison of hemorrhagic complications associated with abciximab, eptifibatide and bivalirudin use for percutaneous coronary interventions (PCI). *Pharmacy World & Science* 2004 April 26(2) – Abstract #PT-021

SELECTED PRESENTATIONS:

International

"An Introduction to Clinical Research in the United States." University of Sao Paulo, School of Pharmaceutical Sciences (Virtual, 07/21)

"US Pharmacopeia's New General Chapter on Storage and Distribution of Investigational Drug Product." 15th Cold Chain- GDP & Temperature Management Logistics Summit- Canada (Toronto, Ontario, Canada 02/17)

"US Pharmacopeia Update: The Past, The Present and Future of General Chapters, Packaging and Distribution- The New General Chapter on Storage and Distribution of Investigational Drug Product." Temperature Controlled Logistics, Europe (London, England 02/17)

"United State Pharmacopeia: Good Distribution Practice: General Information Chapters." – platform Temperature Controlled Logistics, Europe (Frankfurt, Germany 01/16)

"Clinical Research and Drug Development in the United States." – platform
First Annual Collaborative HealthCare Symposium, Beijing Friendship Hospital Affiliated to the Capital University of Medical Sciences (Beijing, China 5/05)

"Incorporating Clinical Research Into Graduate Studies." – platform
Medical Research Symposium, Graduate Research Program (Beijing, China 5/05)

"Clinical Research and Drug Development in the United States." – platform
Peking University College of Pharmacy (Beijing, China 5/05)

"Incorporating Clinical Research into Pharmacy Education." – platform
Peking University College of Pharmacy (Beijing, China 5/05)

"Comparison of Hemorrhagic Complications Associated with Abciximab, Eptifibatide and Bivalirudin Use for Percutaneous Coronary Interventions (PCI)." – poster
American College of Clinical Pharmacy/European Society of Clinical Pharmacy - 2nd International Congress on Clinical Pharmacy 2004 (Paris, France 4/04)

National

"Where Pharmacy and Research Intersect, the IDS, IRB and Beyond." University of Maryland, Baltimore School of Pharmacy (Baltimore, MD 4/20)

"Where Pharmacy and Research Intersect, the IDS, IRB and Beyond." University of Maryland, Baltimore School of Pharmacy (Baltimore, MD 4/19)

"USP – GDP <1083> Updates, Clinical Trials and Key Factors with Investigational Drug Product Distribution." Leading Minds Seminars, Philadelphia 2018 (Blue Bell, PA 6/18)

"US Pharmacopeia's New General Chapter on Storage and Distribution of Investigational Drug Product." Global Cold Chain Exchange (Miami, FL 7/17)

"Drug Supply Chain Security Act/Track and Trace, A Panel Discussion." Moderator. Global Cold Chain Exchange (Miami, FL 7/17)

"US Pharmacopeia's New General Chapter on Storage and Distribution of Investigational Drug Product." Cold Chain- GDP & Temperature Management Logistics Global Forum- Spring (San Diego, CA 5/17)

"Exploring an Active Clinical Trial Site in the Southeast, the Florida Hospital System." Cold Chain- GDP & Temperature Management Logistics Global Forum- Spring (San Diego, CA 5/17)

"US Pharmacopeia's New General Chapter on Storage and Distribution of Investigational Drug Product." 14th Cold Chain GDP & Temperature Management Logistics Global Forum (Boston, MA 9/16)

"USP's New General Chapter on Storage and Distribution of Investigational Drug Product." Biologistics Summit (San Francisco, CA 6/16)

"Attitudes Towards Participation in Clinical Trials Before and After an Educational Session (CARES)." - poster. Markey Cancer Center Research Day (Lexington, KY, 5/16)

"The Evolution of Institutional Review Boards and Investigational Drug Services in the United States." Food and Drug Administration (FDA) Research Lecture Series. (Silver Spring, MD 11/15)

"Why We Do What We Do, IDS, Research Ethics and the Drug Approval Process in the United States." Pharmacy Technician Educators Council Annual National Conference. (Charleston, SC 7/12)

"Investigational Drug Service and Clinical Research." Research Day, Wheaton Franciscan Healthcare-St. Joseph. (Milwaukee, WI 6/12)

"The Role of the Institutional Review Board and Investigational Drug Service." University of Chicago Medical Center Research Retreat (Chicago, IL 7/10)

"How the Investigational Drug Service (IDS) assists Investigators in meeting all Federal regulations for Medication Control." University of Chicago Office of Clinical Research Workshop (Chicago, IL 6/10)

"Ischemic and Hemorrhagic Outcomes Following Percutaneous Coronary Interventions: Glycoprotein IIbIIIa-Inhibitors versus Bivalirudin." – poster
American College of Cardiology Annual Scientific Session 2005 (Orlando, FL 3/05)

"Comparison of Hemorrhagic Complications Associated with Abciximab, Eptifibatide and Bivalirudin Use for Percutaneous Coronary Interventions." – poster *encore*
Catholic Health Initiatives Annual Clinical Pharmacy Meeting (Chicago, IL 9/04)

Local

"Why We Do What We Do, An Introduction to IDS Operations", University of Central Florida, MCB4912. (Orlando, FL 8/15)

"Why We Do What We Do, An Introduction to IDS Operations", Florida Hospital, Orlando Campus, Research Matters Series. (Orlando, FL 8/15)

"Drug and Device Development." University of Kentucky Clinical Research Development and Operations Center, Clinical Research Coordinator 101 Series. (Lexington, KY 6/14)

"Why We Do What We Do, Clinical Research and Research Ethics in the United States", University of Kentucky College of Pharmacy, PPS 940. (Lexington, KY 4/14)

"Drug and Device Development." University of Kentucky Clinical Research Development and Operations Center, Clinical Research Coordinator 101 Series. (Lexington, KY 12/13)

"Why We Do What We Do, Clinical Research and Research Ethics in the United States", University of Kentucky College of Pharmacy, PPS 972. (Lexington, KY 12/13)

"An Overview of Clinical Research and the Investigational Drug Service from the Pharmacy Perspective." Bluegrass Pharmacists Association. (Lexington, KY 11/13)

"Drug and Device Development." University of Kentucky Clinical Research Development and Operations Center, Clinical Research Coordinator 101 Series. (Lexington, KY 5/13)

"Drug and Device Development." University of Kentucky Clinical Research Development and Operations Center, Clinical Research Coordinator 101 Series. (Lexington, KY 11/12)

"Why We Do What We Do, Clinical Research and Research Ethics in the United States", University of Kentucky College of Pharmacy, PPS 972. (Lexington, KY 10/12)

"Clinical Research and Drug Development in the United States." University of Kentucky Pharmacy Resident Orientation, UK HealthCare. (Lexington, KY 7/12).

"Drug and Device Development." University of Kentucky Clinical Research Development and Operations Center, Clinical Research Coordinator 101 Series. (Lexington, KY 5/12)

"Drug and Device Development." University of Kentucky Clinical Research Development and Operations Center, Clinical Research Coordinator 101 Series. (Lexington, KY 11/11)

"Why We Do What We Do, Clinical Research and Research Ethics in the United States", a two part lecture, University of Kentucky College of Pharmacy, PPS 972. (Lexington, KY 10/11)

"Clinical Research and Drug Development in the United States." University of Kentucky Critical Care Team, UK HealthCare. (Lexington, KY 9/11).

"Why We Do What We Do, IDS, Research Ethics and the Drug Approval Process in the United States." Kentucky Society of Health-System Pharmacists Spring Conference. (Louisville, KY 5/11)

"Drug and Device Development." University of Kentucky Clinical Research Development and Operations Center, Clinical Research Coordinator 101 Series. (Lexington, KY 03/11)

"A Career in Clinical Research." University of Kentucky College of Pharmacy, PPS 910. (Lexington, KY 10/10)

"Why We Do What We Do...Research Ethics, Good Clinical Practice, and How Research Professionals Assist Investigators in Meeting all Federal Regulations for Medication Control." Kentucky Clinical Trials Network Fall Educational Conference: "Fall into Clinical Research: How to Manage the Reins" (Lexington, KY 10/10)

"Clinical Research and Drug Development in the United States." Saint Joseph HealthCare Pharmacy Practice Residency Retreat (Lexington, KY 7/07)

"Clinical Research and Drug Development in the United States." Saint Joseph HealthCare Pharmacy Practice Residency Retreat (Lexington, KY 7/06)

AWARDS/HONORS:

Honorary Faculty — 05/05
Peking University College of Pharmacy

Lilly Achievement Award — 05/00
For scholastic achievement in the professional curriculum, Leadership qualities and professional attitude awarded to a graduating student

Dean's List — 12/98 to 5/00
University of Kentucky

PROFESSIONAL AFFILIATIONS:

Phi Lambda Sigma Honorary Leadership Society	1998 to Present
American Society of Health-System Pharmacists	2000 to 2020
Public Responsibility in Medicine and Research	2011 to 2017
Florida Society of Health-System Pharmacists	2016 to 2017
Kentucky Society of Health-System Pharmacists	2000 to 2015
American College of Clinical Pharmacy	2004 to 2010
Public Responsibility in Medicine and Research	2006 to 2008
Kentucky Pharmacists Association	2000 to 2010
Bluegrass Pharmacists Association	2000 to 2003
American Pharmacists Association	2000 to 2003

COMMUNITY SERVICE AND VOLUNTEER ACTIVITIES:

Faith Pharmacy	2008 to 2015
Habitat for Humanity – Lexington, KY	2004 to 2015
God's Pantry – Lexington, KY	2004 to 2015
Lexington Humane Society – Lexington, KY	2004 to 2015
College of Pharmacy Television Call In Show, "Ask Your Pharmacist." UK College of Pharmacy and WKYT Television - Lexington, KY	1997 to 1999
College of Pharmacy Life Adventure Camp Counseling Sessions – Lexington, KY	1997 to 1999
Kentucky Academy of Students of Pharmacy "Brown Bag" Counseling Session. Lexington Senior Citizen Center - Lexington, KY	1997 to 2000
Habitat for Humanity - Lexington, KY	1995 to 1996
Health Clinic in Brazil	08/90

Member of Volunteer Team of Eleven

- Organized and supervised the flow of patients in two temporary health clinics
- Assisted with clinical duties at times
- Studied the Brazilian health care system briefly

ADDITIONAL SKILLS:

General

- Microsoft Office – PowerPoint, Word, Outlook, Front Page, Publisher
- Public Speaking & Group Communication
- Data Analysis and Database Management

- Vestigo Software
- iMedRIS Research Software
- Structured Query Language (SQL) programming
- Microsoft Access and Excel
- SAS Statistical Software
- Six Sigma Methodology
- Failure Mode and Effects Analysis (FMEA)
- Root Cause Analysis (RCA)
- Institute for Healthcare Improvement (IHI)
- Midas & Data Trend
- Quality and Process Improvement