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SUMMARY of QUALIFICATIONS

Established Regulatory Affairs and Compliance Specialist since 2005 at the University of Texas MD Anderson Cancer Center. Experience exceeds coordination and management of clinical Psycho-Social studies, Phase I, II and III clinical trials.

Additional regulatory compliance responsibilities and experience is summarized below in addition to detailed working history.

- Established clinical trial management for over 14 years
- History of collaborative relationships with MD Anderson Institutional Compliance Offices, Pharmaceutical Industry and National Cancer Institute Regulatory Affairs divisions
- Three years' experience as consumer protocol reviewer for Department of Defense Breast Cancer Research Programs
- Part-time Adjunct College Professor of Sociology
- Effective communication, conflict and problem-solving skills obtained as Employee Assistance Professional during employment years 2002-2005
- Detailed-oriented writing skills
- Extensive conflict and problem-solving skills
- Solid and structured work ethic

EDUCATION

SoCRA – Certified Clinical Research Professional – Since November 2014

Texas Woman's University, Houston, Texas
Executive Masters in Business Administrative – August 2009

Texas Southern University, Houston, Texas
Masters of Arts Degree in Clinical Sociology – May 1995

Texas Tech University, Lubbock, Texas
Bachelors of Art Degree in Psychology – August 1991

WORK EXPERIENCE

09/2019-Present **The University of Texas MD Anderson Cancer Center**
Manager of Clinical Protocol Administration
Department of Breast Medical Oncology

- Responsible for the development of department audit processes
- Manage regulatory compliance processes
- Continue efforts as indicated in Regulatory Compliance Coordination of clinical Trials

08/2019-Present **Houston Community College-Central Campus**
Adjunct Professor of Sociology

Adjunct Sociology Professor currently providing instruction at Houston Community College. Inspiring lectures include use of sociology research methods, field observations, theoretical essays, cultural arts and a structured curriculum. Focused teaching on society's impact of the human existence and its experience influenced by social institution. Past Adjunct teaching experience during years 2007-2013, not consecutively, with Houston Community College as well.

03/2015-08/2019 **The University of Texas MD Anderson Cancer Center**

Lead Regulatory Compliance Coordinator – 06/ 2017-Present
Regulatory Compliance Coordinator- 03/2015-06/2017

- Lead regulatory affairs compliance specialist for the Department of Breast Medical Oncology
- Daily management of over 100+ trials
- Responsible for submissions of new protocols, amendments, protocol documents, Informed Consents to the MD Anderson Cancer Center regulatory authorities
- Lead regulatory staff in over 15 audits conducted by clinical trial financial supporters, Cooperative Groups (SWOG) and Food and Drug Administration since 2012
- In 2017, selected to participate and complete the Office of Clinical Research Support institution's audit class
- Successful audit track record with no FDA 483 memorandum issued (findings) nor SWOG major or minor regulatory queries
- In 2017, implemented the department's internal audit process of aging clinical trials activated 10+ years with current focus on clinical trials activated from 1-5 years.
- Lead staff responsible for archiving and storage of terminated clinical trials; recently archived and stored over 30+ trials.
- Established regulatory compliance specialist recognized as by industry regulatory authorities as knowledgeable to the compliance process
- MDACC lead regulatory staff responsible for submission of new protocols, amendments and supporting protocol documents for MDACC main campus and Houston Area Locations including Lyndon B. Johnson Hospital participating in SWOG studies 1207, 1007,

1418 and NRG-BR003. In addition, responsible for distributing training and clinical trial updates to locations referenced above.

- MDACC lead regulatory staff that submit MDACC IRB Approvals to the NCI regulatory administrative site (CTSU) for SWOGS 1207, 1007 and 1418. MDACC Administrator that create and maintain the NCI Delegation of Authority Log on CTSU site for all MDACC locations including Lyndon B. Johnson Hospital participating on SWOGS1418
- Facilitate staff trainings regarding new Protocols and Amendments, Informed Consent Updates
- Assist faculty with completion of NCI Annual Reports and recertification of NCI credentials
- Facilitate and assist other departments in the training of new compliance coordinators across the institution
- Regulatory lead for MDACC clinical trial collaborations with other departments or within alliance studies
- One of regulatory staff responsible for the development of the Breast Medical Oncology Department Training Standard Operating Procedures and IND Safety Reporting
- Provide administrative support to Principal Investigators in writing and revising clinical and laboratory trials

01/16-12/16 **Lone Star Community College-University Park Campus**
Adjunct Professor of Sociology

Inspiring lecturer and instructor who taught Sociology to students attending community college. Lectures included use of media, field observations, cultural arts and a structured curriculum. Focused teaching on society's impact of the human existence and its experience influenced by social institution. Past Adjunct teaching experience during years 2007-2013, not consecutively, with Houston Community College as well.

01/2012-03/2015 **The University of Texas MD Anderson Cancer Center**
Clinical Program Coordinator

- Created the Department of Breast Medical Oncology Protocol Monitoring Plan for Investigator Initiative Clinical Trials
- Responsible for managing the entire protocol process from study start-up to termination: complete clinical trial feasibility questionnaires, site selection forms and coordinate the sponsor Pre-site, Site Initiation, and Close-Out visits.
- Responsible for the submission of study start-up packets to the sponsor or, its sponsor representatives of new clinical trials (managing faculty credentials, financial conflict of interest forms, privacy consent data forms and delegation of authority logs)
- Create Informed Consent Documents for sponsored, Investigator Initiative Trials and National Cancer Institute studies
- Actively negotiate the finalization of Informed Consent Documents with sponsors, financial supporters and Office of Human Research Protection ICF Editors
- Respond to all protocol compliance and ethic queries cited from sponsor monitoring visits
- Prepare and assist BMO faculty in the submission of Investigator Initiative Studies to the MDACC Investigational New Drug Office and Federal Drug Administration
- Responsible for assisting department leadership in determining the prioritization of new clinical trials

- Responsible for developing and maintaining regulatory study binders

07/05 – 12/11 <u>The University of Texas MD Anderson Cancer Center</u>
Senior Behavioral Research Coordinator

- Managed clinical psychosocial studies in the Department of Behavioral Sciences
- Responsibilities included the entire program management of Dr. Leslie Schover clinical trials that recruited through the Department of Breast Medical Oncology and Gynecological Oncology
- Actively recruited all patients from clinical departments indicated above, completed patient screenings, study visits, obtained patient questionnaires, data collection and entered data in CORe and PDMS.
- Managed the clinical trial relationships with contract IT Firms, department IT and statisticians in the development of program databases
- Maintained study documents
- Completed protocol submissions to the IRB
- Responsible for submitting expenditure billing reports and ensuring funds are appropriately allocated to patients participating on studies
- Managed two national clinical trials that employed 41 breast cancer advocates and counselors across the country for the SPIRIT Study.
- Completed breast cancer survivor interviews of over 50 women to assist in the publication of psychosocial research
- Co-author of two published psychosocial research journal articles
- Counseled both breast and gynecological survivors for quality of life study

03/07 – 1/10- <u>Department of Defense CDMRP Breast Cancer Review Panels</u>
Consumer Reviewer and Mentor-Contract

- Responsible for reviewing and completing written critiques of scientific breast cancer research proposals submitted for DOD funding regarding impact and innovation in oncology clinical research. Responsibilities also included review of submitted budgets and proposed research designs to ensure research cost were justified according to funding source requirements.
- Highly requested to attend the Department of Defense Era of Hope Conference for 2011 for outstanding work as consumer reviewer.

References

Available upon request