

**TIERNEY L. NORSTED, PH.D., M.P.H.**

Dr. Terry Norsted is a Founder of RCRI, Inc. and a Principal consultant in worldwide regulatory and clinical affairs. She holds a Ph.D. and an M.P.H. in Epidemiology along with a B.A. in Biostatistics and has been responsible for the design, conduct and analysis of clinical trials since 1981. Terry has held clinical and regulatory management positions for medical device companies since 1987 where she has been responsible for domestic and international regulatory strategies, regulatory product submissions, and the design, implementation, and analysis of clinical trials of medical devices.

Terry is actively networked throughout the medical device community; she has served as Co-Chairperson of the Clinical Studies Committee. She regularly presents at seminars on the design and management of clinical trials and regulatory affairs for medical devices.

**EDUCATION:**

Ph.D.	1989	Epidemiology, University of Washington, Seattle, WA
M.P.H.	1983	Epidemiology, University of Minnesota, Minneapolis, MN
B.A.	1980	Biostatistics, University of Minnesota, Minneapolis, MN

**PROFESSIONAL ACTIVITIES, HONORS AND DISTINCTIONS:**

Regulatory Affairs Professionals Society; Past Chairperson, International Harmonization of Medical Device Regulation. Regulatory Affairs Professionals Society, Washington D.C.  
Member: Medical Alley; Past Co-Chairperson, Clinical Studies Committee  
Medtronic Customer Focused Quality (CFQ) Award, Cardiac Pacing Business, Medtronic, Inc., 1994  
Minnesota 100, 1994-1995

**LECTURES:**

"The Art and Science of Designing Successful Medical Device Clinical Trials Workshop", September 13, 2001, Medical Devices & Diagnostics, San Diego, CA

"Regulatory Considerations in Technical Manual Development", April 13, 1999, Society for Technical Communication, Medical Writer's Special Interest Group, Minneapolis, MN.

"Planning and Protocols for Preclinical and Clinical Testing", March 10, 1999, Medical Alley Clinical Studies Subcommittee, Minneapolis, MN.

"The Art and Science of Designing Successful Medical Device Clinical Trials", June 22, 1998, Institute for International Research, Minneapolis, MN.

"Recent Advances in the Regulations of Medical Devices and the Opportunity they Provide for Professional Growth", June 13, 1998, Sigma Delta Epsilon Graduate Women in Science, St. Paul, MN.

"Considerations in: Choosing, Negotiating, and Managing a Contract Clinical or Regulatory Organization", June 21, 1995, Medical Alley Clinical Studies Committee, Minneapolis, MN.

"Current Challenges in Designing Clinical Studies for Life Supporting and Life Sustaining Medical Devices", October 11-13, 1994, Applied Clinical Trials, Annual Meeting, East Brunswick, NJ.

"Current Challenges in Designing Clinical Studies for Medical Devices", December 7, 1993, Medical Alley, Annual Meeting, Minneapolis, MN.

"Current Challenges in Designing Clinical Studies for Medical Devices", November 16-17, 1993, Regulatory Affairs Professional Society, Bethesda, MD.

"Current Challenges in Designing Clinical Studies for Medical Devices," July 26-28, 1993, American Society for Quality Control, Biomedical Focus, Minneapolis, MN.

#### **PUBLICATIONS:**

Norsted TL, Norsted SW. Current Challenges in Designing Clinical Studies of Medical Devices. In preparation by invitation of Regulatory Affairs Professional Society (RAPS).

Norsted, SW, Norsted TL. Bias Management in Clinical Studies of Medical Devices. In preparation.

White E, Daling JR, Norsted TL, Chu J. Rising incidence of breast cancer among young women in Washington State. J Nat Cancer Inst 1987,79:239-243.

Strong LC, Stine M, Norsted TL. Cancer in survivors of childhood soft tissue sarcoma and their relatives. J Nat Cancer Inst 1987,79:1213-1220.

Norsted TL, White JE, Daling JR. Cancer incidence among Native Americans in western Washington. Int J Epi 1987.

Norsted TL, White JE, Daling JR. Proportional cancer incidence in western Washington by demographic, temporal and socioeconomic characteristics. Cancer Prevention Research Unit Report, Fred Hutchinson Cancer Research Center, Seattle, Washington, 1986.

White JE, Norsted TL, Daling JR. Proportional cancer incidence in western Washington: Time trends by median household income. Cancer Prevention Research Unit Report, Fred Hutchinson Cancer Research Center, Seattle, Washington, 1986.

Norsted TL, White JE, Daling JR. Cancer incidence in western Washington by county of residence and by year of diagnosis. Cancer Prevention Research Unit Report, Fred Hutchinson Cancer Research Center, Seattle, Washington, 1985.

White JE, Norsted TL, Daling JR. Avoidable mortality from cancer: Predictors of late stage of diagnosis and poor survival. Cancer Prevention Research Unit Report, Fred Hutchinson Cancer Research Center, Seattle, Washington, 1985.

Williams WR, Strong LC, Norsted TL. The Genetic Epidemiology of childhood soft tissue sarcomas. Proceedings for the American Association for Cancer Research 1985,26:208.

Williams WR, Strong LC, Norsted TL. Identification of cancer-prone families ascertained through childhood sarcoma by segregation analysis. American Journal of Human Genetics (Suppl) 1984, 36(4):39s.

Norsted TL. The efficacy of frequent dental visit in reducing oral cancer mortality. University of Washington, 1989.

Norsted TL. The concurrence of autoimmune disease and B-cell lymphoreticular malignancies in humans: A common genetic predisposing factor? University of Minnesota, 1983.

#### **INDEPENDENT RESEARCH:**

"La Securite' Sociale, et elle en triste? (Social Security, is it in trouble?) ". Independently conducted analysis of the social, political and economic issues influencing the organizational structure and future of the socialized health care system of France, 1980. Study performed in Paris, France. Department of Foreign Studies, University of Minnesota, Minneapolis, Minnesota. Foreign language: French

#### **VOLUNTEER ACTIVITIES:**

Hospice volunteer, Allina Hospice and Healthcare, 1999-present