

BIOGRAPHICAL SKETCH

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NAME: Sandy Vollstedt

eRA COMMONS USER NAME (credential, e.g., agency login): Sandy Vollstedt, RN, BSN, OCN

POSITION TITLE: Clinical Research Specialist

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Iowa	BSN	05/1991	Nursing

A. Personal Statement

Radiation Oncology research nurses represent experienced, well-trained clinical trials staff specializing in implementing clinical research. This group of clinical researchers has conducted clinical trials since 2012. We initiate, conduct, and complete all aspects of complex human subjects' research, including eligibility determination, the oversight of any infusions (including administration, review of, and contraindications) and adverse event reporting. In addition, we provide expert guidance and resources as well as interface with the Holden Comprehensive Cancer Center. Our involvement in clinical trials over the past decade include: successful completion of imaging and blood studies, several cooperative group trials, studies such as the Ketogenic Diet trial for Lung and Pancreatic cancer (PMCID: [PMC5510645](#)), as well as the Soligenix trial, a pivotal, double-blind, randomized, placebo-controlled, multinational study of SGX942 (dusquetide) for the treatment of oral mucositis in patients being treated with concomitant chemoradiation for the treatment of squamous cell carcinoma of the head and neck.

B. Positions, Scientific Appointments, and Honors:**Positions and Scientific appointments**

2012 - present Clinical Research Specialist, Department of Radiation Oncology, University of Iowa Hospitals and Clinics

2012 - present NRG Oncology group

2006 - present Eastern Iowa Chapter of the Oncology Nursing Society

2004 - 2012 Gynecologic Oncology Clinical Care Coordinator, University of Iowa Hospitals and Clinics

2004 - present Oncology Nursing Society

2001 - 2004 Gynecologic Oncology Clinical Care Coordinator, University of Iowa Hospitals and Clinics

2000 – 2001 Interim Nurse Manager, Gynecology Oncology, Thoracic Oncology, Urologic Oncology, Cardiovascular and benign gynecology inpatient unit. University of Iowa Hospitals and Clinics

1991 - 2001 Staff Nurse, Gynecology Oncology, Thoracic Oncology, Urologic Oncology, Cardiovascular and benign gynecology inpatient unit University of Iowa Hospital and Clinics

C. Contributions to Science:**1. Development of Clinical Trials Structure for Pharmacological Ascorbate**

Ascorbate has demonstrated efficacy in treating a range of tumors and is believed to act as a radiosensitizer enhancing the response to standard-of-care radiation therapy. Our team has sought to provide structure through the development of Clinical Trials **Core C**, which is responsible for providing experienced, well-trained

clinical trial staff specializing in implementing translational, clinical research involving pharmacological ascorbate.

- a. Alexander MS, Wilkes JG, Schroeder SR, Buettner GR, Wagner BA, Du J, Gibson-Corley K, O'Leary BR, Spitz DR, Buatti JM, Berg DJ, Bodeker KL, Vollstedt S, Brown HA, Allen BG, Cullen JJ. Pharmacologic Ascorbate Reduces Radiation-Induced Normal Tissue Toxicity and Enhances Tumor Radiosensitization in Pancreatic Cancer. *Cancer Res.* 2018 Dec 15;78(24):6838-6851. doi: 10.1158/0008-5472.CAN-18-1680. Epub 2018 Sep 25. PMID: 30254147; PMCID: PMC6295907.
- b. Cushing CM, Petronek MS, Bodeker KL, Vollstedt S, Brown HA, Opat E, Hollenbeck NJ, Shanks T, Berg DJ, Smith BJ, Smith MC, Monga V, Furqan M, Howard MA, Greenlee JD, Mapuskar KA, St-Aubin J, Flynn RT, Cullen JJ, Buettner GR, Spitz DR, Buatti JM, Allen BG, Magnotta VA. Magnetic resonance imaging (MRI) of pharmacological ascorbate-induced iron redox state as a biomarker in subjects undergoing radio-chemotherapy. *Redox Biol.* 2021 Jan;38:101804. doi: 10.1016/j.redox.2020.101804. Epub 2020 Nov 19. PMID: 33260088; PMCID: PMC7708874.
- c. Allen BG, Bodeker KL, Smith MC, Monga V, Sandhu S, Hohl R, Carlisle T, Brown H, Hollenbeck N, Vollstedt S, Greenlee JD, Howard MA, Mapuskar KA, Seyedin SN, Caster JM, Jones KA, Cullen JJ, Berg D, Wagner BA, Buettner GR, TenNapel MJ, Smith BJ, Spitz DR, Buatti JM. First-in-Human Phase I Clinical Trial of Pharmacologic Ascorbate Combined with Radiation and Temozolomide for Newly Diagnosed Glioblastoma. *Clin Cancer Res.* 2019 Nov 15;25(22):6590-6597. Epub 2019 Aug 19. PMID: 31427282; PMCID: PMC6858950.
- d. Schoenfeld JD, Sibenaller ZA, Mapuskar KA, Wagner BA, Cramer-Morales KL, Furqan M, Sandhu S, Carlisle TL, Smith MC, Abu Hejleh T, Berg DJ, Zhang J, Keech J, Parekh KR, Bhatia S, Monga V, Bodeker KL, Ahmann L, Vollstedt S, Brown H, Kauffman EPS, Schall ME, Hohl RJ, Clamon GH, Greenlee JD, Howard MA, Schultz MK, Smith BJ, Riley DP, Domann FE, Cullen JJ, Buettner GR, Buatti JM, Spitz DR, Allen BG. O₂- and H₂O₂-Mediated Disruption of Fe Metabolism Causes the Differential Susceptibility of NSCLC and GBM Cancer Cells to Pharmacological Ascorbate. *Cancer Cell.* 2017 Aug 14;32(2):268. doi: 10.1016/j.ccell.2017.07.008. PubMed PMID: 28810149

2. Use of Superoxide Dismutase Mimetics (GC4419 and GC4711) in Partnership with Galera Therapeutics, Inc.

Several studies using the superoxide dismutase mimetic, GC4419, are currently underway to decrease the incidence and severity of radiation-induced severe oral mucositis in subjects receiving chemoradiation for squamous cell carcinoma of the head and neck as well as during lung radiation to decrease the incidence and severity of esophagitis.

There is currently a phase I/II study evaluating GC4711 to be given in combination with stereotactic body radiotherapy (SBRT) to improve efficacy and reduce normal tissue damage of high dose per fraction radiation delivery in early stage non-small cell lung cancer.

- a. Anderson CM, Sonis ST, Lee CM, Adkins D, Allen BG, Sun W, Agarwala SS, Venigalla ML, Chen Y, Zhen W, Mould DR, Holmlund JT, Brill JM, Buatti JM. Phase 1b/2a Trial of the Superoxide Dismutase Mimetic GC4419 to Reduce Chemoradiotherapy-Induced Oral Mucositis in Patients With Oral Cavity or Oropharyngeal Carcinoma. *Int J Radiat Oncol Biol Phys.* 2018 Feb 1;100(2):427-435. doi: 10.1016/j.ijrobp.2017.10.019. Epub 2017 Oct 16. PMID: 29174131; PMCID: PMC6430109.
- b. Anderson CM, Lee CM, Saunders DP, Curtis A, Dunlap N, Nangia C, Lee AS, Gordon SM, Kovoov P, Arevalo-Araujo R, Bar-Ad V, Peddada A, Colvett K, Miller D, Jain AK, Wheeler J, Blakaj D, Bonomi M, Agarwala SS, Garg M, Worden F, Holmlund J, Brill JM, Downs M, Sonis ST, Katz S, Buatti JM. Phase IIb, Randomized, Double-Blind Trial of GC4419 Versus Placebo to Reduce Severe Oral Mucositis Due to Concurrent Radiotherapy and Cisplatin For Head and Neck Cancer. *J Clin Oncol.* 2019 Dec 1;37(34):3256-3265. doi: 10.1200/JCO.19.01507. Epub 2019 Oct 16. Erratum in: *J Clin Oncol.* 2020 Jan 20;38(3):288. PMID: 31618127; PMCID: PMC6881100.

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