

Curriculum Vitae

Full Name: Deborah E. Loope, RMA, CCRC
Address: 1279 Old Eastside Road
Burns, TN 37029
Telephone numbers: (615) 446-5960/Fax (615) 446-5936
Email: debbie@aceresearch.net

THERAPEUTIC EXPERIENCE:

Conducted hundreds of studies, including (Phase I-IV):

- Oncology: 5 studies (Prostate, Melanoma, Breast)
- Gastrointestinal: 132 studies (Ulcerative Colitis, Crohn's, GERD, IBS, Constipation, Diarrhea)
- Nervous System: 10 studies (Migraine, Stroke, Epilepsy)
- Sleep: 6 studies (Narcolepsy, Cataplexy, Apnea)
- Respiratory: 6 studies (Asthma, COPD)
- Genitourinary: 26 studies (Erectile Dysfunction, Urge Incontinence, Prostatitis, Genital Herpes, Overactive Bladder, BPH)
- Cardiology: 112 studies (Hypertension, Irregular Heart beat, Atrial Fibrillation)
- Inflammatory Disease: 12 studies (Rheumatoid Arthritis)
- Metabolic: 2 studies (Obesity)
- Dermatology: 76 studies (Acne, Psoriasis, Onychomycosis, Rosacea, Dermatitis)
- Internal Medicine: 78 studies (Diabetes Type II, Neuropathy, Hypercholesterolemia, Overactive Bladder, Hypertension)
- Women's Health: 43 studies (HPV, Menopause, Post-menopause, Endometriosis, Bone Loss)
- Infectious Diseases: 8 studies (Sinusitis, Chronic Bronchitis, Herpes)
- Nephrology: 2 studies (Vitamin D, kidney failure)
- Gene Therapy-3 studies (HPV)
- Phase I: 6 studies (Nutritional supplement, food preservative, urology, GI, sleep)
- Device: 4 studies (BPH, GI, Cardiac, Bedsore mattress)

PROFESSIONAL EXPERIENCE:

- **Consultant/Contract Clinical Research Coordinator & Research Associate, January 1, 2008 - present**
ACE Research
1279 Old Eastside Road
Burns, TN 37029

Contract Clinical Research Associate for Sponsors. Contract/Consulting specific for site responsibilities and/or support services. Provided Site support services including site recommendations, structuring of SOP's, training, marketing and assistance in coordinating, regulatory, budget, patient and investigator recruitment. Contract Clinical Research Coordinator for St. Thomas Research Institute (cardiology, oncology) assisted with new research acquisitions in take over and setup. Contract Regional Recruitment Manager with Inclinx, Incorporated, Wilmington, NC. Responsible for reviewing each site's potential for participant recruitment and implementing a plan throughout the areas involved at site and community levels, involving the hospital and local referring physicians as well. The Pre-Term Labor study also involved birthing and yoga classes, websites, labor, delivery, triage and community activities with sites in Tennessee and North Carolina. Scheduled luncheon and dinner presentations to hospital staff and managers, residents, physicians, and referring physicians to stimulate and sustain patient recruitment.

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- **Director of Research/Clinical Research Coordinator/Consultant/Contract Clinical Research Coordinator & Clinical Research Associate, - May 1, 2000 - December 31, 2007**
ACE Research Specialists, LLC
300 20th Avenue North, Suite 105
Nashville, TN 37203

Started my own Limited Liability Corporation following the acquisition of Hill Top Research by Radiant Research and completed studies still active at that time. Held the majority ownership of the corporation, sharing membership with premier Investigators. Able to pick up immediate cash flow and continue existing business with its staff. Generated cash flow and growth development, as well as profit at LLC dissolution. Recruited, trained and set up investigator research sites, as well as a central office. Employed and trained coordinators, regulatory, administrative, front office personnel, as well as patient phone-call screeners. Developed, maintained and updated SOPs, investigator and coordinator training, in-house budget-tracking system, patient stipend-release process, payroll, taxes, and overall business development and maintenance. Set marketing strategies for studies and subject recruitment. Prepared, experienced and completed FDA inspection for highest enrolling site in a GI study Aug-Sep 2005. No 483's.

Acted as a contractor as a Clinical Research Associate as well as Consultant for Sponsors and Sites as a "trouble shooter" or "site clean specialist". In 2000 performed a quality assurance investigation with site in Nashville to find possible Investigator Fraud (Dermatology group). Assisted the site with the interview and SOP development to prevent such incidents in the future. Contracted in 2006 by a pharmaceutical regarding sites in Nashville and Los Angeles (Oncology). Hired to evaluate, assist and develop the sites to produce quality data output. Able to evaluate, identify, correct and develop study logistics, training and SOP's to prevent data quality insufficiencies.

- **Site Director/Laboratory Director/Clinical Research Coordinator May 1, 1998 – April 30, 2000**
Hill Top Research, Inc.
Pharmaceutical Clinical Trials Division
Brentwood, TN

Nationally-known Site Management Organization pursued me and acquired my sole proprietorship to establish and manage a site in Tennessee. Recruited, trained and set up the central office as well as other investigator research sites within Tennessee. Employed and trained coordinators, regulatory, administrative, front office personnel, as well as patient phone-call screeners. Developed, maintained and updated SOP's, investigator and coordinator training, in-house budget-tracking system, patient stipend-release process, payroll, taxes, and overall business development and maintenance. Set marketing strategies for studies, subject recruitment and investigators.

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- **Independent Consultant/Coordinator, 1997 - 1998**
Research Management Services
Fairview, TN

Started sole proprietorship home-based contract business. Developed own financing, accounting and business plan. I acted as a Contract Clinical Research Associate for Sponsors, Coordinator and Business Development services. Recruited, trained and set up investigator research sites, as well as the central offices. Assisted sites in coordinator recruitment and training as well Investigator training (GI, urology, Internal Medicine, Dermatology, Nephrology). Developed and trained sites' regulatory, administrative, front office personnel, as well as patient phone-call screeners. Developed, maintained and updated SOP's, investigator and coordinator training, in-house budget-tracking system, patient stipend-release process, payroll, taxes, and overall business development and maintenance. Set marketing strategies for studies and subject recruitment.

- **Director of Research, 1994 -1997**
Tennessee Clinical Trials Inc.
Franklin, TN

Structured, developed and started partnership business. Recruited, trained and set up investigator research sites, as well as a central office. Employed and trained coordinators, regulatory, administrative, front office personnel, as well as patient phone-call screeners. Developed, maintained and updated SOP's, investigator and coordinator training, in-house budget-tracking system, patient stipend-release process, payroll, taxes, and overall business development and maintenance. Set marketing strategies for studies and subject recruitment.

- **Assistant Director of Research, 1991 - 1995**
Nashville Medical Research Institute
Nashville, TN

Recruited, trained and set up investigator research sites, as well as a central office. Employed and trained coordinators, regulatory, administrative, front office personnel, as well as patient phone-call screeners. Developed, maintained and updated SOP's, investigator and coordinator training, in-house budget-tracking system, patient stipend-release process, payroll, taxes, and overall business development and maintenance. Set marketing strategies for studies and subject recruitment.

- **Assistant Office Manager/Study Coordinator, 1987 - 1991**
Nashville Impotence Center
Nashville, TN

Assisted the office manager with filing and correspondence; completed pharmaceutical and IRB submission documents. Worked as Medical Assistant with the physician, performing study procedures, patient recruitment and scheduling.

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- **Billing Manager/Study Coordinator, 1985 - 1986**
Hypertension Center of Nashville
Nashville, TN

Set up and organized study budgets, source documents and study plans throughout private practice. Performed the following tasks; filing, correspondence, completed pharmaceutical and IRB submission documents, etc. Assisted the research nurse with study procedures, patient recruitment and scheduling.

- **Office Manager/Administrator, 1982 - 1985**
Joseph I. Benjamin, M.D./Psychiatry
Phoenix, AZ

Managed a psychiatry practice; performed administrative duties, scheduling, insurance billing, payroll, and staffing.

LICENSURE & CERTIFICATIONS:

- Certified Clinical Research Coordinator – Association of Clinical Research Professionals, Washington, DC 1995 – present
- Registered Medical Assistant – American Registry of Medical Assistants, Boston, MA 1995 - present
- Certified Cardio-Pulmonary Resuscitation – American Heart Association, 2006-present
- IATA Certifications 2003 - present

COMPUTER SKILLS:

- Microsoft – Word, Excel, Inform, Power Point, eCRFs, and similar programs
- Interactive Voice Systems

References available on request