



LifeExtensionSM

CLINICAL RESEARCH, INC.

1100 W. Commercial Boulevard ■ Fort Lauderdale, FL 33309
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www.LifeExtension.com/clinicalresearch
clinicalresearch@LifeExtension.com

Life Extension Clinical Research, Inc. is a full service clinical research site located in a large modern facility. We provide a complete range of services to pharmaceutical, cosmeceutical, nutraceutical, and device companies. Our services include:

- managing & conducting clinical trials
- product development strategies
- study design
- protocol and informed consent development
- case report form (CRF) design
- Institutional Review Board document preparation & submissions
- recruitment of healthy volunteers and special populations
- regulatory management
- data collection & management
- preparation of completed study data for peer review publication

We believe that the key to success is the desire to meet and exceed client expectations. The quality of communication and successful relationships developed with our clients is a vital and an integral core focus. Our operational flexibility allows us to respond quickly to sponsor and regulatory requirements and modifications.

Life Extension Clinical Research understands the clinical development process to bring your product to market and recognizes the critical nature of accurate and timely data collection.

Operating a successful research center requires highly skilled and experienced personnel. Life Extension Clinical Research personnel are well-versed in clinical research methodology and applicable regulations and guidelines. Our database of over 10,000 local active members further strengthens our ability to rapidly recruit and enroll appropriate study subjects.

Please contact us if we can be of any service to you,

Sincerely,

Jovianna DiCarlo, President
Life Extension Clinical Research, Inc.



LifeExtensionSM

CLINICAL RESEARCH, INC.

Jovianna DiCarlo, NRCMA, CCRA, CCRC

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Professional Achievements and Experience

Knowledge of Clinical Development Process

Twelve years diverse experience in pharmaceutical, device, biotechnology and bio IT research and development, including roles in corporate operations, clinical research organizations (CRO), monitoring, project management and conducting **clinical** research. **Specializes** in change management and **corporate processes** reorganization. Experienced in designing, leading and executing comprehensive change management programs in **support of adoption and implementation of informatics** systems, process redesigns and transformational business strategy initiatives. In depth knowledge of the pharmaceutical, biotechnology and healthcare industries. **Understands** organizational structures and cultures within employee populations. Core expertise in **development** and **implementation of** project communication strategies, **collaborative workspace programs**, organizational readiness assessments and overall change program design. **Successful** consultant **for corporations** needing to **identify and implement** organizational change elements to **support business expansion and business** process improvements. Experienced in organizational design, including overall organization structure, impact analysis, role design and performance metrics design. **Experienced** in contract and **budget negotiations** and tracking, **clinical trial, CRA and IRB** regulatory management, in addition to timeline management and internal approval cycles. Excellent record of accomplishment with **clinical trial site business development for private practitioners and clinical research centers**, accruing and conducting clinical trials, **identifying and** monitoring investigational sites. Possesses diverse clinical experience and understands the research and clinical development processes and **clinical trial designs** needed to bring drugs, devices, **cosmeceuticals or nutritional supplements to market**. Provides core marketing strategies by **expanding, creating and implementing new** program designs **for electronic data capture and** data management systems. Provides strategic planning of information systems and electronic data capturing applications for *eClinically* run trials. Understands clinical trial monitoring, regulatory compliance, clinical research methodology and all applicable regulations and guidelines. Strong organizational and time management skills with the ability to work independently. Ability to understand complex protocols and monitoring plans, Strong knowledge of laser device systems, computers, electronic data capture applications, electronic medical records and standard computer applications.

Life Extension Clinical Research, Inc.

Fort Lauderdale, FL ■ July-2005 - Present

PRESIDENT / DIRECTOR OF RESEARCH / IRB CHAIR

Responsible for development and operational oversight for a full service multi therapeutic clinical research site. Ensures research facility continually meets all applicable sponsor, FDA, HIPAA, GCP & ICH regulations and guidelines. Developed and maintains clinical research business development and marketing materials. Drives business development initiatives at industry events and symposia's. Conducts and develops clinical research trials for pharmaceutical, biotechnology, nutraceutical product development, cosmeceutical, device and laser device companies. Develops and conducts clinical research trial projects to support Life Extension's product development activities with nutraceutical and supplement formulations by developing protocols, CRF's and informed consents. Developed and maintains online study subject recruitment, study registration & study subject eDatabase. Develops strategic marketing protocols, and conducts post marketing research trials providing marketing materials to cosmeceutical, device, pharmaceutical, nutraceutical and biotechnology companies. Establishes collaborative business networking relationships to fund clinical trial informatics systems to support clinical research activities. Negotiates research contracts, grants, study budgets and tracks sponsor and client payments. Develops and maintains research site standard operating procedures. Develops and maintains quality assurance & quality control standards for research center. Oversees staff and training of research personnel by providing regulations, guidelines, compliance training by developing maintaining online tutorial training with certification. Re-established and Chair's in-house eIRB. Developed IRB policies and procedures, IRB reporting forms. Responsible for preparation of clinical trial documents and IRB submissions, communications documentation, safety reporting and approvals. Ensures the integrity of clinical data with respect to accuracy and accountability of documentation and data capture. Responsible for regulatory oversight and document management, data management, data collection, eResult electronic lab result development and maintenance, case report form completion, query resolution, electronic data capture, remote data entry, electronic imaging management, and transmission of electronic data.

New York Dermatology Group/Clinical Research Dynamics

New York, NY ■ 2004 – May 2005

DIRECTOR OF RESEARCH / CLINICIAN

Responsible for business development in multi therapeutic areas in research for Clinical Research Dynamics and the New York Dermatology Group. Conducted clinical research trials for pharmaceutical, biotechnology, cosmeceutical, device and laser device companies. Provided core marketing strategies and marketing materials to cosmeceutical, device, pharmaceutical, nutraceutical and biotechnology companies by developing protocols, funding and conducting market research trials. Provided strategic direction to identify and secure grant funding to bring in new medical devices for Clinical Research Dynamics and the New York Dermatology Group. Actively developed protocols and successfully funded investigator initiated trials. Excelled in negotiating research contracts, grants and study budgets. Responsible for grant payment tracking. Developed and maintained research centers standard operating procedures. Provided quality assurance & quality control standards for research center. Oversaw staff and training of research personnel by providing regulations, guidelines and compliance training with certification. Developed online research tutorial training for research staff. Responsible for all regulatory document management, IRB submissions, communications documentation and safety reporting. Ensured the integrity of clinical data with respect to accuracy and accountability of documentation and data capture. Ensured research facility meets all applicable sponsor, FDA, HIPAA, GCP & ICH regulations and Guidelines. Excelled in identifying potential study candidates, recruitment, retention meeting or exceeding study population requirements of subjects for ongoing trials. Responsible for regulatory management data management, data collection, electronic data capture, case report form completion and maintenance, query resolution, electronic data capture, remote data entry, electronic imaging, and transmission of electronic data. Configured and managed electronic medical records in accordance with research source documentation. Worked closely with sponsors, CRO's and monitors to ensure quality and integrity of data ensuring research compliance. Secured funding for electronic medical record systems. Clinician during dermatology clinics, procedures and laser procedures. Developed unique and novel cosmetic and dermatology treatment regimens for Medi-spa featured in major publications of VOGUE, ELLE, American Spa, Cosmopolitan and Instyle.

Medidata Solutions, Inc.

New York, NY ■ November 10, 2003 – May 1, 2004

SENIOR TRAINING SPECIALIST

Responsible for development and maintenance of education services curriculum, which includes providing strategic direction to pharmaceutical, biotechnology and device companies throughout the clinical trials arena for adoption of EDC (Electronic Data Capture) and eClinically run trials. Developed and maintained course content for product related training courses. Provided major research and development companies with successful enterprise implementation strategies providing detailed process maps of proven best practices. Identified and delivered internal change management strategies and process improvement strategies for successful implementation of electronically run trials. Managed transition of course content and curricula for new/updated product releases. Developed and delivered customized client training. Responsibilities included development and maintenance of new hire orientation program for rapidly expanding global organization. Provided consulting for pharmaceutical and biotechnology companies, providing industry direction in designing, leading and executing comprehensive change management programs for successful adoption on new technologies to capture and report clinical trial data. Provided direction with process redesigns and transformational business strategy initiatives. Responsible for development of organizational readiness assessments and overall change design including change management methodologies for overcoming resistance and identifying roadblocks.

Kansas University Medical Center, Department of Neurology

Kansas City, KS ■ 2000 – 2003

CLINICAL RESEARCH PROJECT MANAGER/ CLINICIAN/ PATIENT EDUCATION AND RESOURCE COORDINATOR

Conducted clinical research trials with investigational new drugs, devices and biotechnology products for management and treatment of symptoms in multiple therapeutic areas pertaining to neurological disorders. Provided staff training, developed and deployed motivational strategies for site personnel to accomplish study objectives by possessing a proactive management strategy of applying the ability to anticipate issues that may impact successful project outcome and managing these issues until resolution. Demonstrated proficiency managing teams with effective, proactive communication, considering even the most remote perspectives of team members. Identified opportunities for the development of new programs and services that ensures successful project outcome. Executed all aspects of management in conducting clinical trials including but not limited to advertising, subject recruitment and retention, IRB submissions and regulatory document management. Performed clinical assessments, electrocardiograms, holter monitoring, vital signs, global assessments and quality of life assessments. Developed and maintained patient education and resource information. Frequent guest speaker educating health professionals in care settings, providing standards of care for end stage Parkinson's patients. Frequent speaker at caregiver support meetings and neurology grand rounds. Responsible for data management, data collection, case report form completion and maintenance, query resolution, electronic data capture, remote data entry, electronic imaging, and transmission of electronic electrocardiograms. Worked closely with sponsor/monitor to ensure highest quality and integrity of data, ensuring research compliance. Responsible for implementing and maintaining records in regulation with CLIA and OSHA.

MP Clinical Research

Kansas City, MO ■ 1998 - 2000

DIRECTOR OF CLINICAL RESEARCH/ PROJECT MANAGER/ IN HOUSE MONITOR

Executed all aspects of monitoring clinical research pharmaceutical, biotechnology and device trials. Ensured integrity of clinical data with respect to accuracy, accountability and documentation by reviewing electronic case report forms, remote data capturing systems, case report forms, source documentation and regulatory documents. Completed monitoring reports to document efficiencies and corrective action required. Conducted periodic audits of site files. Performed all aspects of managing a research center including procurement of investigational trials, negotiated grant proposals, submissions, IRB submissions, negotiating budgets and contracts, regulation and development of compliance

training and certification of staff. Created and implemented company standard operating procedures. Managed and maintained regulatory documents for entire research facility. Conducted in-patient and out-patient clinical trials with antibiotic therapies, asthma therapies, antiviral therapies, Cox II inhibitors, anticoagulant therapies, pulmonary therapies for treatment and management of asthma, exercise induced asthma, allergies, COPD, emphysema, chronic bronchitis, community acquired pneumonia, hospital acquired pneumonia, hospital acquired skin infections, wound care, sinusitis, MRSA, SEPSIS, ARDS, IBS and pain management. Responsible for orchestrating various hospital departments per protocol for in-patient clinical trials usually microbiology, lab, pharmacy, MICU, ICU, SICU and CCU. Provided direction to residents and hospital staff to adhere to protocol. Responsible for writing orders for procedures and medication management of hospital charts per protocol. Responsible for data collection, case report form management and maintenance and query resolution. Responsible for integrity of data and ensured research compliance.

Provided patients with education/resource information and materials. Extensive use of electronic data capturing applications, remote data entry applications, electronic imaging and electronic electrocardiograms. Created informed consent forms and study specific source documents which were implemented post submission and IRB approval. Responsible for advertising, study subject recruitment and retention.

Leawood Family Physicians

Overland Park, KS ■ 1996 -1998

FAMILY PRACTICE CLINICIAN/ RESEARCHER

Executed all aspects of clinical nursing for busy multi-physician family practice. Responsible for administering immunizations, injections, IV's, medications, administering and regulating immunotherapy, X-rays, phlebotomy, scheduling and assisting surgeries, sigmoidoscopies, vasectomies, excisions and biopsies.

Provided patient education and resource information and materials. Responsible for lab collection and processing. Performed UA's, urine cultures, ESR, beta strep tests and pregnancy tests. Responsible for inventory and ordering of all medical supplies, casting materials, injectables, x-ray films, sutures, surgical instruments. Fostered relationships with pharmaceutical representatives and managed sample control. Conducted open label hypertension clinical research trials. Responsible for study subject recruitment and retention, regulatory management, IRB communications and submissions. Responsible for data collection, query resolution, management and completion of case report forms.

International Medical Technical Consultants, INC. (CRO)

Prairie Village, KS ■ 1994 - 1996

IN HOUSE MONITOR/ PROJECT MANAGER

Performed in house monitoring, quality assurance, project management and coordinated Phase I to IV clinical research trials for pharmaceutical, biotechnology and device companies in multiple therapeutic areas including cardiopulmonary and respiratory diseases, allergies, asthma, COPD, pediatric allergies and asthma, methocholine challenges, exercise induced asthma and hypertension. Implemented statistical analysis. Responsible for project management and managing multiple projects simultaneously, providing team guidance and support for the design and execution of project outcome.

Identified which applications and resources were experiencing performance issues, prioritizing and managing resolution. Provided instruction and training to clinical research coordinators. Responsible for review of case report forms, source documentation, medical records and regulatory documents. Completed monitoring reports documenting results, listing deficiencies and corrective action required. Performed global evaluations, evaluated and tracked regulatory processing, IRB submissions. Performed periodic audits of site files. Responsible for grant tracking, grant proposals and contract negotiations. Created and implemented informed consent forms and study specific source documents for submission to IRB for review and approval. Responsible for regulation and compliance.

Concord Career Institute

Kansas City, MO ■ 1992 - 1993

EXTERN COORDINATOR / MEDICAL INSTRUCTOR

Responsible for implementation, coordination and maintenance of externship program for medical, dental and respiratory therapy students their respective fields prior to graduation and certification. Responsible for tracking, grading and assessment of student skills, attendance, professionalism and appearance. Responsible for recruiting hospitals, physicians, medical centers and research centers for participation in the externship program. Responsible for onsite visits and documentation for compliance and ensuring requirements were met for students to obtain certification. Medical instructor in medical office management, human anatomy and physiology, medical terminology and medical lab procedures.

EDUCATION

Mesa College, San Diego, CA	Associate Degree Medical Assisting
Miramar College, San Diego, CA	Emergency Medical Technician

CERTIFICATIONS

National Registered Certified Medical Assistant 1993 – Current # 2974-528715100193
Certified in Conducting Clinical Research Trials, Kansas University Medical Center 2000 - Current
Certified Clinical Research Coordinator, Associates of Clinical Pharmacology 1996

PROFESSIONAL AFFILIATIONS

American Academy of Dermatology	Clinical Data Interchange Standards Consortium
CenterWatch	Drug Information Association

CRITICAL TECHNICAL AND BEHAVIORAL SKILLS

Excellent record of accomplishment with project management, monitoring investigational sites, sales and marketing while continually bearing in mind project goals and objectives while considering even the most remote perspectives of colleagues and staff. Possesses diverse clinical experience with understanding of research and development process. Successful business consultant in all aspects of market research, marketing, sales and business plan initiatives. Provides core-marketing strategies, creating and implementing program designs, provides strategic planning of information systems. Strong in organizational skills, Utilizes strong analytical and critical thinking skills. Possesses strong oral and written communication skills. Ability to separate performance issues from those with no business impact. Passionate about actively contributing to the process of clinical research trials adopting highly efficient, intelligent electronic data capturing systems enabling vast improvements in data quality and subject safety. Excels in public speaking presentations.



Joel Roskind M.D., FACS

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Date of Birth ■ December 5, 1944

Place of Birth ■ New York, New York

EDUCATION

University of Louisville School of Medicine Louisville, Kentucky	1966 - 1970	M.D. 1970
Hofstra University Hempstead, New York	1964 - 1966	A.B. 1966
Franklin & Marshall College Lancaster, Pennsylvania	1962 - 1964	

INTERNSHIP

Montefiore Hospital Bronx, New York	Chief - <i>T. Lawyer, M.D.</i>	Rotating Medicine	07/1970 - 06/1971
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RESIDENCY

Montefiore Hospital Bronx, New York	Chief - <i>M. Gleidman</i>	M.D.General Surgery	07/1971 - 06/1974
St. Louis University Hospitals St. Louis, Missouri	Chief - <i>F. X. Paletta, M.D.</i>	Plastic Surgery	07/1974 - 06/1976

FELLOWSHIP

Christine Kleinert Institute of Hand and Microsurgery Louisville, Kentucky	Chief - <i>H. Kleinert M.D.</i>	Hand Surgery	1976 - 1977
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PRACTICE

Principal Investigator	Life Extension Clinical Research, Inc.	10/2005 - present
Consultation	Miami, Florida	08/2003 - present
Private Practice	Miami, Florida	05/1982 - 08/2003
Long Island Plastic Surgery Group	Garden City, New York	08/1979 - 05/1982
U.S. Naval Hospital	San Diego, California	07/1977 - 06/1979
Long Island Plastic Surgical Group	Garden City, New York	03/1977 - 07/1977

LICENSES AND CERTIFICATES

New York State Medical License	#109455	07/1970
Florida Medical License	#ME0039885	05/1982
Kentucky Medical License	#15921	07/01/1971
Missouri Medical License	#R5701	08/10/1974
Drug Enforcement Administration	#AR7512658	1971
National Board of Medical Examiners Diplomate	#113948	07/01/1971
American Board of Plastic Surgery Certificate	#2168	04/79
American Association for Accreditation of Ambulatory Surgical Facilities		11/1998
Former Member and Inspector for above		

MEMBERSHIPS

American Academy of Pain Management
American Society of Plastic Surgeons
American Society for Aesthetic Plastic Surgery
American Society for Laser Medicine and Surgery
Lipoplasty Society of North America
Miami Society of Plastic Surgeons
Fellow of the American College of Surgeons
American Medical Association
Florida Medical Association
Dade County Medical Association
American Association for Hand Surgery
American Cleft Palate Association
American Burn Association
New York Academy of Medicine
New York Regional Society of Plastic and Reconstructive Surgery

PRESENTATIONS

Surgical Park Center - Miami, Florida
National Association of Women Business Owners - Miami, Florida
Neurofibromatosis Society - Miami, Florida
Dave and Mary Alper Jewish Community Center - Miami, Florida
Stroke Club - South Miami Hospital - Miami, Florida
Baptist Hospital Women's Auxiliary - Miami, Florida
Amit Women of Temple Zamora - Coral Gables, Florida
Grand Rounds - South Miami Hospital - Miami, Florida
Dade County Medical Association Auxiliary - Miami, Florida
President's Committee on Total Employment - Miami, Florida
University of Miami School of Nursing - Miami, Florida
South Miami Hospital Plastic Surgery Grand Rounds - Miami, Florida
South Miami Rotary Club - Miami, Florida
Hadassah Women's Group - Miami, Florida
Member, Speaker's Bureau, Department of Public Relations, Baptist Hospital - Miami, Florida
Member, Speaker's Bureau, Dade County Medical Association - Miami, Florida
St. Louis University, Department of Plastic Surgery Grand Rounds - St. Louis, Missouri
Stroke Rehabilitation Group, Baptist Hospital - Miami, Florida
Grand Rounds, Bascom Palmer Eye Institute - Miami, Florida
Hofstra University - Hempstead, New York
Nassau Surgical Society, Westbury - Long Island, New York
Plastic Surgery Research Council - Denver, Colorado
University of Miami School of Medicine - Miami, Florida

CIVIC GROUPS

President's Committee on Total Employment
Partners of America

PUBLICATIONS

"Quantitation of Thermoregulatory Impairment in Patients with Healed Deep Burns"
Annals of Plastic Surgery, March 1978
J.L. Roskind, M.D., J.S. Petrofsky, Ph.D., A.R. Lind, M.D., and F.X. Paletta, M.D.

SPECIALTY BOARD

American Board of Plastic Surgery - Certificate #2168 - April 27, 1979

CERTIFICATIONS

Former Member and Inspector, American Association for Accreditation of Ambulatory Surgery
Facilities
Diplomate, National Board of Medical Examiners

MILITARY SERVICE

Active Duty for Training	U.S. Naval Hospital St. Albans, New York	06/1968 - 09/1968
Active Duty for Training	U.S. Naval Hospital Bethesda, Maryland	06/1969 - 09/1969
LCDR, MC, USNR	Department of Plastic Surgery U.S. Naval Hospital San Diego, California	07/1977 - 06/1979 Honorable Discharge

STAFF APPOINTMENTS

Hospital

Baptist Hospital of Miami
8900 North Kendall Drive
Miami, Florida 33176
Telephone: (305) 596-1960

Status

Honorary

ACADEMIC APPOINTMENTS

Former Voluntary Clinical Assistant Professor of Surgery
University of Miami School of Medicine