Rose Research Center

Pioneers in Nicotine and Smoking Cessation Research

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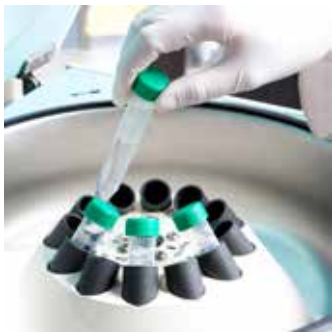


The Rose Research Center

A state-of-the-art research facility with two locations in North Carolina

The Rose Research Center (RRC) is a state-of-the-art research facility with two locations in North Carolina. Each office is specially equipped with staff, technology, and services to conduct the broadest spectrum of study protocols. The Center specializes in tobacco dependence research including research on smokers, addiction, smoking cessation, tobacco harm reduction and the use of other tobacco products.

RRC employs highly qualified individuals and focuses on a safety-centric approach to all clinical trials. Members of our staff have extensive experience in statistically valid study design, clinical trials, data management, and participant recruitment and retention. Rose Research Center ensures that sponsors receive the highest quality experience.

Rose Research Center also maintains a proprietary database of potential research participants in addition to contractual relationships with industry partners to ensure an optimal recruitment process.

"In establishing the Rose Research Center, my goal was to create a unique organization that can skillfully and efficiently conduct clinical evaluations of products designed to promote smoking cessation and tobacco harm reduction. This Center represents an exciting outgrowth of my 35 years of research into nicotine and tobacco dependence and smoking cessation treatment. We stress innovation in device and pharmaceutical development, and we offer the capability to conduct phase I, II and III trials of novel therapeutic approaches. The Center's key leadership has a long history and unique expertise in clinical study design, assessment of cigarette smoking behavior and smoking cessation treatment. By furthering the development of alternatives to cigarette smoking, our long range goal is the elimination of tobacco related disease."

Jed E. Rose

Jed E. Rose, Ph.D.

Study Experience, Design and Services

Staff are trained in mindfulness behavioral counseling

24-hour on-call medical staff

High throughput sample processing

Investigational device prototyping and testing

Protocol Development

Ability to work with a variety of centralized and local Institutional Review Boards (IRBs)

Advanced patient recruitment strategies

On-site CPR certified staff

On-site Phlebotomy certified staff

Integrated community volunteer network

Early-stage study design and project management are offered by our team of Principal Investigators. These investigators have over 50 years of experience in executing phase I-IV trials in smoking cessation, nicotine research, pharmacotherapy, imaging and drug development.

The Rose Research Center is staffed with qualified personnel experienced with conducting smoking cessation studies involving nicotine replacement therapies involving varenicline and bupropion, behavioral counseling and tobacco related investigational devices, Investigational New Drugs and laboratory studies.

State-Of-The-Art Facilities

Data Collection

RCC staff members are trained in data collection, biological sample collection, processing and shipping, and data analysis. Our staff are experienced in maintaining both paper and electronic case report forms (CRF) and source documentation. Additionally, we are familiar with industry software including REDCap, Teleform, Qualtrics, Liquid Office, Medidata Rave, OnCore, NCI AdEERS (CTEP-AERS), eRDE's and RDE, Advantage EDC, GlobalTrace and FormsNet. We are also experienced with reading and navigating electronic medical records such as Webcis and EPIC.

Compliance

Our team of professionals, with extensive experience in government and industry trials, ensures we are always audit-ready and fully compliant. Audits are conducted as indicated by study protocols; internal informal audits are conducted as described in our standard operating procedures. All staff are required to complete Collaborative Institutional Training Initiative (CITI) modules, complete center standard operating procedure training and adhere to Good Clinical Practices at all times.

Institutional Review Board and Regulatory Submissions

Our dedicated regulatory staff is capable of working with any centralized institutional review board and contracts IRBs independently when necessary. We are experienced with both paper and electronic IRB submissions for central and local IRBs. RRC staff have experience with preparation, submission and maintenance of Investigational New Drug applications (INDs) and Investigational Device Exemptions (IDEs) with the Food and Drug Administration.

"Hopefully it's a wave of the future that inhaling combusted, burning tobacco will someday be a thing of the past." - Jed E. Rose, Ph.D.

Recruitment and Retention

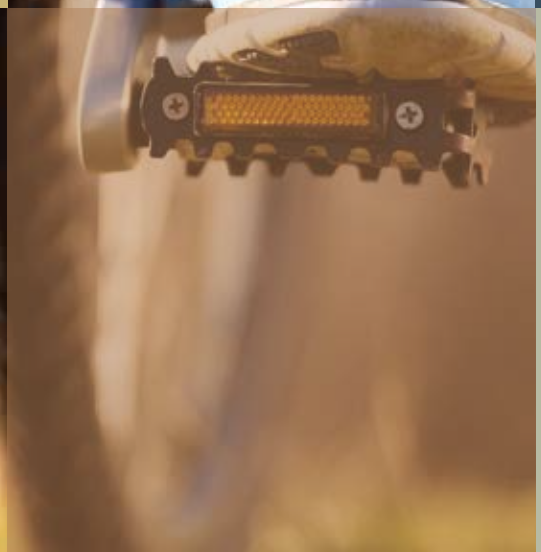
RRC utilizes advanced in-house marketing techniques to recruit at a maximum return on investment. Successful recruitment strategies are formulated and executed by our marketing department using television commercials, print advertising, social media, and a powerful set of recruitment websites.

Participant information is maintained in a volunteer database system and retained for future studies as they become available. Pertinent information is confidentially kept on file to aid in selecting highly qualified candidates for research studies.

In-House Marketing



Thousands of Interested Volunteers


Professional Staff

Both Raleigh and Charlotte offices are managed by teams with years of experience in government and industry sponsored research. Under the direction of Dr. Jed Rose, the Rose Research Center employs expert staff with backgrounds at leading medical research centers and experience conducting studies that have paved the way for modern smoking cessation medications and treatments.

Over 50 Years of Research Experience

Tanaia Loeback
Vice President of
Research and Compliance

Jed E. Rose, Ph.D.
President and CEO

David Botts
Vice President of
Marketing and Technology

Technology and Security

RRC maintains the latest in technological resources to aid in study design and coordination, recruitment, and operations. Each site is equipped with electronic data collection capabilities, video conferencing, and electronic data storage with loss prevention.

Capabilities

- Experienced with electronic data capture systems
- Interactive voice response (IVR) telephony systems for the recruitment of subjects
- Highly automated online pre-screening and capture system
- Industry leading software for the storage, maintenance, and communication management of potential volunteers
- Cloud software utilized for subject scheduling, call, text, and voice reminders
- Telemedicine capabilities with on-site technology
- International video conferencing
- Site-to-site internal Lync communication network
- Firewall secured data storage with real-time off-site backup
- Video and two-way audio monitoring and recording

The Rose Research Center utilizes the latest technology to conduct cutting edge research.

Rose Research Center
Corporate Office
7920 ACC Boulevard
Suite 110
Raleigh, NC 27617

Corporate Office
Raleigh, North Carolina

The corporate office is a privately owned research space in a centrally located office complex near Research Triangle Park. Staff members include President and CEO, Dr. Jed Rose, Vice President of Research and Compliance, Tanaia Loeback, Vice President of Marketing and Technology, David Botts, a Supervising Physician, and full-time research staff. This 2,300 sq. ft. custom designed facility includes two exam rooms, two private form completion rooms, two ventilated smoking rooms (one with negative pressure), a phlebotomy room and laboratory space.

Highlights

Walking distance to the WakeMed Emergency Department

Dual -86°C/-20°C specimen sample freezers capable of holding 8,000+ samples

State-of-the-art conference room facilities

Accessible from three major highways

Telemedicine capabilities

Flexible hours depending upon participant and study needs and 24-hour on-call medical staff

Hours of Operation 9AM-5PM, M-F

Satellite Office
Charlotte, North Carolina

This customized 2000 sq. ft. leased research facility includes two exam rooms, two form completion rooms, a ventilated smoking room, phlebotomy space and laboratory space located in a prominent medical plaza. Our full-time staff members employed here include a Physician Assistant, Research Manager and research staff. The office is situated in the heart of the university area in north Charlotte, located a few miles from University Research Park, UNC Charlotte, Carolinas Medical Center and major highways.

Rose Research Center
Satellite Office
8401 Medical Plaza Drive
Suite 275
Charlotte, NC 28262

Highlights

Located in a prominent medical plaza; minutes from Carolinas Medical Center and UNC Charlotte

Dual -86°C/-20°C specimen sample freezers capable of holding 8,000+ samples

Telemedicine capabilities

Flexible hours depending upon participant and study needs and 24-hour on-call medical staff

Hours of Operation 9AM-5PM, M-F

Smoking Studies

Each site is specially designed and equipped with space for participants to smoke or vape within a controlled laboratory environment. Studies involving inhaled tobacco products can be conducted in an isolated negative pressure room with air purifiers and adjustable telescopic ventilation arms.

Participants in smoking studies are not necessarily ready to quit smoking but their involvement contributes to understanding nicotine addiction. These studies research tobacco products, their addictive properties and their physiological effects, which ultimately contribute to the development of new alternatives to smoking cigarettes.

Rooms are equipped with video and audio monitoring, recording and two-way audio communication for subject interaction.

Cessation Studies

Our team of professionals is trained to conduct clinical trials for people who want to quit smoking. Our trials test medications, behavioral approaches and various combinations of both in an attempt to find the most effective smoking cessation treatment. Staff is also trained to conduct behavioral counseling.

Standard Equipment

- Emergency AED and on-site portable oxygen
- ECG machines
- Carbon monoxide monitors
- Breathalyzer
- Pulse oximeters
- Adult portable sphygmomanometers
- Clinical freezer storage (-86°C/-20°C) with 24-hour power backup and temperature monitoring
- Compact analytical balance
- High-pressure programmable syringe pumps for device and cigarette testing
- Refrigerated centrifuge
- Nebulizer
- CReSS smoking topography device
- Medical exam tables
- Laboratories equipped for clinical trial specimen collection and processing
- Isolation negative pressure room and telescopic ventilation arm for smoking studies adjacent to a second room with a telescopic ventilation arm
- Video recording and two-way audio monitoring of subject sessions

Equipped with modern technology to conduct cutting-edge research.

Facility Compliance

Rose Research Center offices operate under strict internal standard operating procedures for all studies and procedures. These are reviewed biennially or as necessitated. RRC is accustomed to adhering to guidelines as stipulated by industry sponsors and good clinical practices. Compliance, security and subject safety are our top priorities alongside maintaining accuracy, privacy and reliability of data.

Rose Research Center maintains:

- Current medical licenses
- Secure storage for ambient and climate controlled investigational study drug(s)
- DEA licenses for scheduled drugs
- Scheduled equipment inspections and calibration
- 24-hour power generation and backup services for sample storage
- Secure off-site backups of all electronic data

Ethics

We believe in a participant-centric approach to safety and conducting clinical research. We adhere to the highest standards of professionalism and good clinical practice.

Innovation

A team with decades of achievements in smoking cessation and harm reduction including co-inventing the nicotine skin patch and aiding in the development of Chantix.

Partnership

As a partner in research, we believe in promptness, reliability and cohesive relationships. We hold ourselves accountable to these values and to the expectations of our research partners.

Quality

Our commitment is to provide exceptional services and results that exceed the expectations of our study participants and research partners.

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