State-of-the-Art Clinical Research Center Optimized for Metabolic Studies

ProSciento's state-of-the-art clinical research unit (CRU) specializes in metabolic studies and is located in Chula Vista, CA. Since 2003, the CRU has conducted more than 300 clinical research studies in NASH, diabetes, obesity, and related metabolic diseases for small and large molecule therapies, biologics, biosimilars, and medical devices. Research conducted at the CRU has been at the forefront of metabolic clinical research, contributing to the development of advanced methodologies, including imaging and circulating biomarkers, glucose clamp procedures, tracer studies, and glucose monitoring systems.

The CRU is supported by in-house clinical, pharmaceutical, research nutrition, and study recruitment teams that are widely recognized for their deep scientific and operational expertise in metabolic studies. The clinical facility has 30+ treatment beds (all with overnight stay capabilities), CLIA-certified laboratory, USP 797/800 standard clean room, and a dedicated glucose clamp unit.

Specialty Clinical Research Unit

- 30,000 sf. (5,000 sf. of treatment rooms)
- 30+ beds (including 15+ glucose clamp beds)
- Dedicated screening suite with 5 private rooms
- USP 797/800 standard clean room
- CLIA-certified laboratory
- In-house extended stay capabilities of up to 8 weeks

Amenities for Study Participants

- Full wrap-around privacy curtains
- Personal televisions with DirecTV
- High-speed WiFi
- Private shower suites and bathrooms
- Laundry service
- Lounge with computers, video and board games
- On-site dietitian and diverse menu options
- Visiting hours for family members*

* Suspended during COVID-19 impacts

Specialized Methodologies

ProSciento's CRU is renowned for its specialized methodologies to conduct complex metabolic research. Below is an overview of clinical research methods used to investigate disease pathophysiology and therapeutic mechanisms.

Methods for Diabetes Clinical Research

- Automated glucose clamp procedures
  - Euglycemic (assess pharmacodynamics)
  - Hyperinsulinemic (assess insulin sensitivity)
  - Hyperglycemic (assess insulin secretion)
  - Hypoglycemic (assess counter-regulatory responses)
- Stable isotope tracer methods
  - Fasting endogenous glucose production (EGP)
  - Gluconeogenesis and glycogenolysis
  - Hepatic and peripheral insulin sensitivity
  - Postprandial glucose fluxes
- Graded glucose infusion (GGI)
- Glucose-stimulated insulin secretion
- 24-hour continuous glucose monitoring (CGMS)
  - Glucose fluctuations and glycemic variability
  - Average daily glucose and other CGMS-derived endpoints
- Advanced imaging technologies (MRI and PET-MRI)
  - Microcirculation
  - Myocardial and renal metabolism and oxygenation
- Oral glucose (OGTT) and oral lipid (OLTT) tolerance tests
- Mixed-meal (MMTT) tolerance tests
- Tissue biopsies and gene expression

Methods for NASH Clinical Research

- Liver biopsy (liver fat content, inflammation, ballooning, fibrosis)
- Assessment of hepatic and lipid metabolism
  - Hepatic glucose production
  - Hepatic de-novo lipogenesis
- Fibroscan VCTE (CAP/LSM)
- MRI-PDFF (liver fat content)
- MR Elastography (MRE) (stiffness, fibrosis)
- Contrast-enhanced-MRI (hepatobiliary function)
- Circulating biomarkers

Methods for Obesity Clinical Research

- Indirect calorimetry
  - Energy expenditure, metabolic rate
  - Diet-induced thermogenesis, respiratory quotient, substrate oxidation
- Dual energy X-ray absorptiometry (DEXA)
- Adipose and skeletal muscle tissue biopsies
- Nutritional assessments
  - Ad-libitum food intake and food preference
  - Assessment of hunger, satiety, satiation, food cravings
- MRI (visceral and subcutaneous adipose tissue, ectopic fat deposition)
- Cardiac telemetry

cru Clinical Research Unit

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ADVISE • ADVANCE • ACHIEVE

STATE-OF-THE-ART CLINICAL RESEARCH CENTER OPTIMIZED FOR METABOLIC STUDIES

Patient Access at ProSciento's CRU

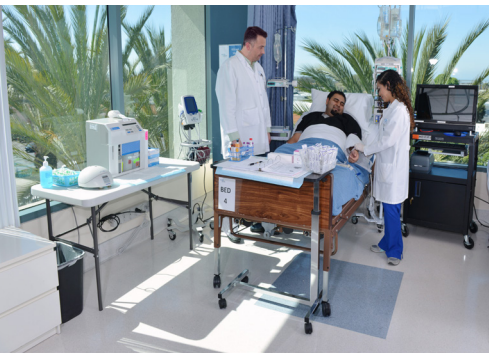
ProSciento's in-house CRU recruitment team specializes in providing robust feasibility analysis of inclusion and exclusion criteria to support study protocol development and design considerations focused on study recruitment viability. With a database of more than 30,000 active study participants and 17+ years of experience in metabolic clinical research, ProSciento's CRU maintains an overall study participant attrition rate of 9.2% (5.9% for T1DM and 6.4% for T2DM) compared to an industry average of > 30%.

ProSciento meets aggressive enrollment timelines for clients and exceeds industry benchmark enrollment rates for NASH, diabetes, and obesity clinical trials.

- Dedicated recruitment team and call-center
- Database of >30,000 active study participants
- Targeted subject engagement campaigns
- Community outreach programs
- Subject referral program
- Routine subject database engagement

ProSciento's recruitment database includes patient and healthy populations to support SAD/MAD, PK/PD, safety and tolerability studies and is categorized by:

- Metabolic disease diagnosis (T1DM, T2DM, NAFLD, or NASH)
- Healthy
- Lean, overweight, or obese (BMI >30)
- Concomitant medical conditions
- Medications and supplements
- Age, gender, and ethnicity



ProSciento's Unparalleled Expertise in Metabolic Clinical Research

325+ diabetes, NASH, and obesity clinical projects completed

130+ clinical trials for biologics

17+ years designing and conducting clinical studies in diabetes and obesity

11+ years designing and conducting clinical studies in NASH and NAFLD

Contributions to **17** approved metabolic drugs and devices

Contact us at bd@prosciento.com to discuss your drug or device clinical development program

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