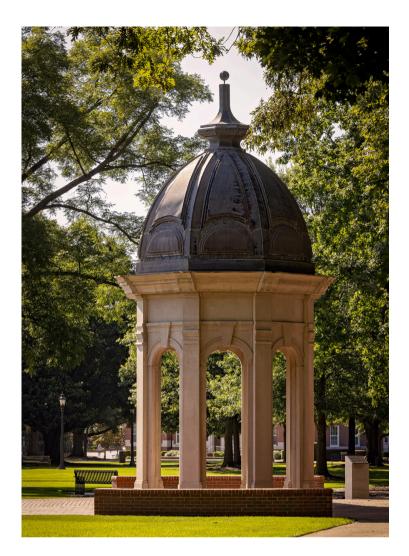
WELCOME TO THE CLINICAL RESEARCH CORE



East Carolina Heart Institute 115 Heart Drive Greenville, NC 27834



The Clinical Research Core, located in the East Carolina® Heart Institute since 2014, supports investigators by providing trained research staff to assist with the start-up, implementation, and closeout phases of clinical studies.

The Clinical Core study coordinator services offer a model in which our study coordinator effort is recharged to the sponsor or study budget. Using a study coordinator from the pool can provide continuity during study team turnover and cushion faculty from carrying full personnel expenses when they only need fractional support. Enclosed you will find information about our staff, facilities, and the various services we provide. J J \leq Τ



MEET OUR TEAM

Our multidisciplinary team consists of three clinical research coordinators and one clinical research nurse coordinator. With over 20 years of experience, the Clinical Research Core excels in all aspects of research. We have the ability to work with all ECU departments and have previously worked with Anatomy & Cell Biology, Biology, Endocrinology, Family Medicine, Internal Medicine, Kinesiology, Microbiology & Immunology, Pediatrics, Physical Therapy, Physiology, Psychology, and Public Health.

Patricia Brophy, MA, CCRC

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Angela Clark, RN

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Elizabeth Gates, MPH, REHS

Clinical Research Coordinator ☐ gatese21@ecu.edu

(252) 744-1917



CORE SERVICES

Whether you are an experienced researcher or just beginning your journey into human subject research, we are here to support you every step of the way. Our mission is to help streamline the complexities of your study by reducing administrative burdens to allow you to focus on the essential aspects of your research. With our extensive database of eager, qualified participants, we make the recruitment process faster and more efficient, ensuring that your studies are enrolled in a timely manner and with participants who meet your specific criteria.

If you are planning a new pilot project or looking to collect preliminary data for a larger study, we offer the tools, expertise, and resources to help you get started with ease. We understand the challenges that researchers face, and our goal is to make clinical research more accessible and efficient for investigators of all experience levels. By partnering with us, you can maximize the potential of your research, reduce the time it takes to gather valuable data, and ensure that your resources are used in the most effective way possible.

IRB & REGULATORY

- Create IRB applications in ePIRATE after the finalized protocol is received
- Customize consent form templates by individualizing subject, parental, and minor assent forms
- Prepare subject recruitment materials
- Respond to IRB concerns
- Prepare and submit regulatory documents
- Prepare and submit amendments to the IRB
- Assemble Regulatory Binder
- Prepare study documents

CLINICAL COORDINATION

- Subject prescreening, recruitment, and scheduling
- Obtain informed consent
- Data collection and Case Report Form completion
- Specimen collection and processing
- Process participant payments through Greenphire
- Complete study visits and perform or assist with required procedures
- Adverse Event and Significant Adverse Event reporting
- Ongoing liaison for all subject-related communications with PI/study team and external sponsors
- Schedule and implement monitoring visits
- Receive and inventory study supplies



NURSE-SPECIFIC SERVICES

- IV placement
- Blood draws
- Oral Glucose Tolerance Tests (OGTT)
- Intravenous Glucose Tolerance Tests (IVGTT)
- Infusions
- Muscle and fat tissue collection

ASSESSMENTS

- Anthropometric measurements
- Resting and Exercise EKGs (Interpretation for another fee)
- Bioelectrical Impedance Analysis
- Resting Metabolic Rate/Indirect Calorimetry
- Near-Infrared Spectroscopy
- VO2 Max Testing



FACILITIES & EQUIPMENT

Second Floor

O2

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- Private exam rooms with beds
- Parvo Medics TrueOne® 2400 Metabolic Cart
- Specimen processing room equipped with centrifuges, hood, and fridge/ freezer space
- TANITA for Bioelectrical Impedance Analysis

Third Floor

- Exercise training and testing facility
- Parvo Medics TrueOne® 2400 Metabolic Cart
- Quinton Q-Stress Testing System
- Near-Infrared Spectrometer (NIRS)
- Private exam rooms with beds

Fourth Floor

- -80°C and -20°C freezers for temporary sample storage
- Conference rooms



BUDGETING

We will work with you to determine your needs for nursing and/or coordinator services. For small scale projects, staff services are available at an hourly rate. Staff rates can also be calculated on a percent of effort for larger projects.

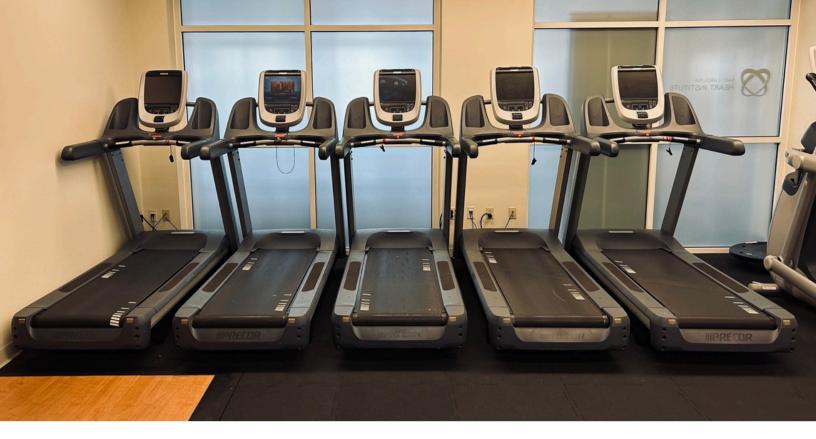
PROCEDURE		
Procedure	Cost	Staf
Blood Draw	\$3.10	C
IV Placement with Blood Draw	\$6.72	N
OGTT	\$15.17	
IVGTT	\$66.86	
Adipose Biopsy	\$12.94	
Muscle Biopsy	\$23.75	
Microdialysis	\$25.38	Inte
Clamp	\$26.34	Re
Resting EKG Testing	\$7.65	12
12 Lead Exercise Testing	\$18.25	

STAFF HOURLY RATES

Staff	Cost	
Coordinator	\$44.43	
Nurse	\$54.92	

EKG INTERPRETATION

Interpretation	Cost
Resting EKG	\$10.00
12 Lead Exercise EKG	\$30.00



NEXT STEPS

In order to get started, contact Patricia Brophy at <u>brophyp@ecu.edu</u> or visit us online by scanning the QR Code.

We look forward to working with you.



