

Memo

To: Advocate Health Research Faculty and Staff

From: Jamy Ard, MD, Vice Dean for Clinical Research

Subject: Charlotte Region Research Resources

As we look to support research activities across the Advocate Health enterprise, the Wake Forest School of Medicine Dean's Office and the Office of Clinical Research have collated a list of research resources in the Charlotte region. The goal of this list is to provide faculty and staff with an easy reference for identifying resources in the Charlotte region that may be necessary to plan research projects and complete research objectives. This list includes key contacts within various departments that can assist with establishing collaborations, gaining access to specific equipment and expertise, and providing on-the-ground insight that can help get things accomplished. The list also includes key facilities and services that might be utilized for clinical research activities. There is also reference to what is required to set up use of ancillary services like imaging and pathology.

This document will be regularly updated as new resources are added or as information changes. As we expand our research capacity in the Charlotte region with the addition of new faculty and services like a Clinical Research Unit, this living document will be updated and disseminated through a variety of communication channels. If there are resources that you are aware of that have not been included in this list, please share this information with Christine Becker, PhD (Christine.Becker@atriumhealth.org).

### Facilities and Resources for Clinical Research: Atrium Health Greater Charlotte Region (AHGCR)

[Please note: if using this as a boilerplate text on a grant proposal, URLs and hyperlinks are not allowed for NIH (and other sponsors) applications. URLs and hyperlinks included here are for your reference only. Please remove those for your grant application and delete this instruction text. Also, please note that this boilerplate is also available as a Word document.]

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## Cannon Research Building, Room 425

Research Coordinators have common lab space available in the Cannon Research Building Room 425. This space is equipped with a centrifuge for processing specimens and a centrally monitored -80°C freezer for short term storage of specimens. For badge access to this space and for access to the JCI Metasys system for temperature logs, please contact Kay Snider <a href="mailto:kay.snider@atriumhealth.org">kay.snider@atriumhealth.org</a>

The Cannon Research building contains various laboratory equipment such as containment hoods, histology equipment, centrifuges, an electron microscopy lab and more. To coordinate use, please contact Kay Snider <a href="mailto:kay.snider@atriumhealth.org">kay.snider@atriumhealth.org</a>

Flow Cytometry is available by contacting Dr. David Foureau David.foureau@atriumhealth.org

Molecular Biology with Next Generation Sequencing (NGS) Instrument is available by contacting Dr. Nury Steuerwald nury.steuerwald@atriumhealth.org

#### **Clinical Research Services**

The Coordinator Float Pool in Charlotte Office provides a centralized infrastructure to enhance patient safety, promote quality research, and ultimately increase the volume of clinical research for the benefit of Atrium Health's patients. The Float Pool employs Research Nurses and Research Coordinators assist in the day-to-day management of clinical research studies. Support includes:

- preparation and submission of IRB applications and consent forms;
- preparation and maintenance of regulatory binders;
- development of study documents;
- · preparation of subject recruitment materials;
- assistance in the negotiation and preparation of budgets;
- recruitment and screening of participants;
- · conduct of research study visits;
- collection of data;
- drawing and processing of specimens;
- tracking study finances; and
- acting as a liaison between study teams and sponsors.

Requests for Coodinator assistance should be done via the online eForm at <a href="CTSI Service Request Form">CTSI Service Request Form</a> (wakehealth.edu). Please indicate the location for the request.

#### Clinical Research Study Administration: Office of Clinical Research

The Office of Clinical Research (OCR) facilitates the conduct of clinical research across the North Central/Western North Carolina region (including Winston-Salem) and Greater Charlotte region of Atrium Health. It provides a centralized infrastructure to promote quality research, ensure fiscal and regulatory compliance, encourage collaborations, and ultimately increase the volume of clinical research for the benefit of Atrium Health's patients. The OCR supports the initiation and administration of clinical research studies and compliance with all fiscal regulations and requirements, including budget development, Medicare Coverage Analysis (MCA), and billing to industry sponsors. The OCR supports two clinical research systems (OnCore and ClinCard). The OCR also includes a Special (Research) Billing Team, a Recruitment Unit, and provides support for participant recruitment through Be Involved.

## Clinical Research Management Systems (OnCore and ClinCard)

#### **OnCore**

OnCore is the enterprise-wide Clinical Research Management System. This system is used to address all areas of clinical research management, including regulatory, subject, and protocol management; data management and study design; billing and financial management; reporting; and biobanking and specimen management.

OnCore can be used for clinical research that is considered non-human subjects research (e.g., retrospective chart reviews or registries, etc.) for the purposes of managing the regulatory, study data, and/or invoicing and receipt of payment from a sponsor, but its use is not required in those cases.

Study teams across all departments and clinics are required to use OnCore for any clinical research studies that are considered human subjects research by our IRB, and which will prospectively enroll or consent subjects, or for which the Office of Clinical Research (OCR) is responsible for managing the study financials. OnCore is used by the Clinical and Translational Science Institute (CTSI) as the repository and reporting of enrollment on all clinical research. The Recruitment Unit within CTSI utilizes OnCore to monitor enterprise clinical research accrual, tracking progress to enrollment goals, and will intervene as needed to support study teams in meeting enrollment for their studies.

#### **ClinCard**

ClinCard is the enterprise-wide participant reimbursement system. ClinCard is similar to a Visa or MasterCard debit card, and it is used by departments to provide research participants with compensation or reimbursement. ClinCard use is mandatory for Investigators and study teams in the Charlotte region.

ClinCards are provided directly to research participants by the study teams and the study teams will utilize the web-based system, to electronically issue payments onto the card. The OCR, within the CTSI, will build the participant payment schedule in the system, dispense ClinCards to study teams, track and monitor payments issued, and will intervene as needed to support study teams in remaining compliant.

#### Be Involved (available in AHGCR Q2, CY 2023)

<u>Be Involved</u> is a community-facing website that outlines actively enrolling clinical studies conducted by Wake Forest University School of Medicine (WFUSM). Created and maintained by the CTSI, *Be Involved* offers an easy-to-use search tool for Atrium Health Wake Forest Baptist (AHWFB) patients, community members, and healthy volunteers to find WFUSM study opportunities in the region.

Study outlines include high-level information such as what the study is investigating, key eligibility criteria, basic information on what may be involved as a participant, and the principal investigator identity. All study outlines go through a health literacy review to an eighth-grade reading level, and study teams can have their studies posted in English on the *Be Involved* site and in Spanish on the *Be Involved En Español* site, which was launched in 2019.

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Volunteers have 2 ways to gain more information and ascertain potential eligibility for a given study: (1) they can call or email the study team contact provided in the study outline, or (2) they can click on the "sign up to learn more" button in the outline, enter their name and phone number, and receive a call from the study team contact.

## Electronic Health Record (EHR) System (Encompass)

In 2021, AH began transitioning the hybrid EMR system to a consolidated medical record and financials EMR-Epic, branded Encompass. Encompass is a single, enterprise-wide platform that supports integrated clinical, billing and ancillary applications. Data, such as medication lists and treatment history, flow between providers/departments, eliminating the need for multiple data entries. Features include myAtriumHealth, a patient portal that allows patients to establish accounts to view their laboratory and other test results online, contact their providers electronically, and make or change appointments. Encompass includes an interface with OnCore Clinical Trials Management System to flag the records of patients who are active on research studies and has features to help with research patient documentation and reporting used in various study-specific workflows such as screening. Encompass will continue to be rolled out to AH facilities through 2022, with Cerner (branded Canopy) will be archived in March 2023.

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### **List of Key Contacts**

# Department Contacts and External Ancillary Subcontractors supporting Anesthesia, Ophthalmology, Pathology, and Radiology

Researchers conducting clinical trials in Charlotte and requiring collaboration from other disciplines should initiate the process by contacting the designated Department contact provided below. Additionally, Carolinas HealthCare Anesthesia Service Group, Carolinas Pathology Group, and Charlotte Radiology, as external Atrium Health facilities, are responsible for providing the professional component of clinical services in Anesthesia, Surgical Pathology, and Radiology. Furthermore, Charlotte Eye, Ear, Nose, and Throat Associates, along with Carolinas Imaging, offer comprehensive technical and professional clinical services for research studies conducted in Charlotte.

All external subcontractor services necessitate the creation of a Statement of Work (SOW), which outlines the relationship, responsibilities, and financial arrangement for executing the study. Researchers are required to provide the Office of Clinical Research with the requested service CPT codes, and the OCR will establish an SOW with the appropriate pricing before the study can open to accrual. It is important to note that both Charlotte Radiology and Carolinas Imaging have a request form that requires approval from their respective Administrator for each study prior to the generation of an SOW.

#### List of Department Contacts

Department	Atrium Contact Name	Atrium Contact email
Animal Research	*Lisa Colvin, IACUC & Biosafety Coordinator	Lisa.colvin@atriumhealth.edu
	*Dr. Melissa Stair, Attending Veterinarian	mestair@wakehealth.edu
Bariatric Surgery	Courtney McCoy, Research Analyst	Courtney.mccoy@atriumhealth.org
Behavioral Health (Alzheimers)	Dineen Gardner, Project Manager	Dineen.gardner@atriumhealth.org
Biosafety Coordinator (CLT campus)	Lisa Colvin, IACUC & Biosafety Coordinator	Lisa.colvin@atriumhealth.edu
Cardiology (SHVI)	Melissa Meyers, Research Manager	Melissa.meyers@atriumhealth.org
Community Outreach	Carlene Mayfield, Director, Division of Community & Social Impact	Carlene.Mayfield@atriumhealth.org
Coordinator Float Pool CLT campus	Maria Duncan, Research Manager	Maria.duncan1@atriumhealth.org
Emergency Medicine	Melanie Hogg, Research Director	Melanie.hogg@atriumhealth.org
Family Medicine	Melinda Manning, Research Manager	Melinda.manning@atriumhealth.org
Hepatology	Marybeth Schwallie, Research Manager	Marybeth.schwallie@atriumhealth.org
Internal Medicine	Jessica Kearney-Bryan, Research Director	Jessica.Kearney-bryan@atriumhealth.org
Investigational Drug Services	Ryan Bender, Manager, Pharmacy,	CMCPIDrugSVC@Atriumhealth.org
	Clinical Trial Services	Ryan.bender@atriumhealth.org
Lab Services	Deanna D Franke, Director	Deanna.Franke@atriumhealth.org
Levine Cancer Institute (LCI)	Deborah Lewis, LCI Oncology Research Administrative Director	deborah.lewis@atriumhealth.org
Minimally Invasive Surgery (CLASP)	Gregory Scarola, Research Manager	Gregory.scarola@atriumhealth.org
Neurology (Neurosciences Institute)	Latisha Morgan, Clinical Research Nurse (*interim manager)	Latisha.morgan@atriumhealth.org
Oral Medicine	Jenene Noll, Research Manager	Jenene.noll@atriumhealth.org
Orthopedics (Musculoskeletal Institute)	Christine Churchill, Research Manager	Christine.churchill@atriumhealth.org
Pediatrics	Tonisha Brown, Research Director	Tonisha.brown@atriumhealth.org
Physical Medicine & Rehabilitation	Tami Guerrier, Research Manager	Tami.guerrier@atriumhealth.org
Radiology	Keri Murr, Manager	Keri.Murr@atriumhealth.org
Surgery	Nicole Kaiser, Project Manager	Nicole.kaiser@atriumhealth.org
Trauma	Julia Brake, Research Director	Julia.brake@atriumhealth.org
Women's Health (OB/GYN)	Gretchen Hoelscher, Research Manager	gretchen.hoelscher@atriumhealth.org

#### Ancillary External Subcontractors

External Subcontractor	Contact Name	Contact Email
Charlotte Eye, Ear, Nose, and Throat	Angela Price, Director	Aprice@ceenta.com
Associates (CEENTA)		
Carolinas HealthCare Anesthesia	Scott Moroney, VP	Scott.Moroney@atriumhealth.org
Service Group (CHS ASG)		
Carolinas Imaging Service (CIS)	Abbi Karr, Clinical Research Coordinator	Abbi.Stacherski@charlotteradiology.com
Carolinas Pathology Group (CPG)	Chad Livasy, MD	Chad.Livasy@atriumhealth.org
Charlotte Radiology (CR)	Abbi Karr, Clinical Research Coordinator	Abbi.Stacherski@charlotteradiology.com

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