# **GENERAL HELP**

#### **eRoundup Newsletter**

The Georgia CTSA eRoundup newsletter is published every Friday at 10:00 AM ET. Each issue contains featured news, funding, education, research resources, innovation & translation, and community announcements and events.

Contact: GeorgiaCTSA@emory.edu to subscribe

# **Consult Offerings**

#### **Coordinating Center**

The Georgia Clinical & Translational Science Alliance (Georgia CTSA) Coordinating Center is a virtual "front door" for research facilitation in Georgia. The center expedites discovery of the vast Georgia CTSA resources. We offer support with navigation to existing resources within and external to the Georgia CTSA.

Contact: Karen Lindsley klindsl@emory.edu

Request the types of assistance you need for your project: bitl.ly/GeorgiaCTSARequest

#### Level 1 - Direct Referral

Examples: We need help with <u>biostatistics</u>, <u>recruiting</u>, or to find <u>partners</u> in the community

## Level 2 - Ask a Navigator for Help

- Example: I need help navigating the regulatory and approval processes at a Georgia CTSA institution
- Example: We would like to connect with other Georgia CTSA partners
- Examples: I would like to connect with other (national) CTSA partners through the Trial Innovations Network

## Level 3 - Studio Referral

Example: Georgia CTSA will facilitate a group consultation with experts regarding

- Hypothesis generation
- Study design
- Implementation approach
- Analysis and interpretation
- Translation of my basic science work
- Manuscript development

#### **Biostatistical Epidemiology & Research Design (BERD)**

BERD offers assistance with crucial elements of clinical and translational research, such as study design, data collection, data management and development, and application of statistical methodology. The program also provides comprehensive biostatistical and epidemiological support.

Contact: John Hanfelt jhanfel@emory.edu

Submit a Request

#### GeorgiaCTSA.org











The following biostatistical services are available to junior faculty, fellows, and <u>MSCR</u> students:

- Rapid response to statistical questions via email
- Review of proposals
- Sample size and statistical power calculations
- Study design consultation
- Review of questionnaire/data collection form statistical analysis design
- Pre-submission critique of statistical methods
- Statistical genetics, genomics, and high-throughput data analysis

## Data and Safety Monitoring Plan and/or Board (DSMP/DSMB)

The DSMB workgroup provides information and training for Principal Investigators, DSMB members, IRB members, biostatisticians, and research staff on how to work effectively with DSMBs. They provide guidance, training and resources in DSMB practices for investigator-initiated research studies. Other aids include: <a href="NIH guided DSMB charter template">NIH guided DSMB charter template</a>, <a href="charter outline template">charter outline template</a>, and the <a href="Emory IRB guidance">Emory IRB guidance</a> document.

Contact: DSMBmanual@gmail.com

Submit a Request

#### **Ethics**

The Georgia CTSA research ethics consultation service helps researchers including faculty, staff, and students to navigate ethical dilemmas at all stages of research including protocol design, informed consent, dilemmas that arise during research, and publication issues. Confidential discussions and non-binding advice are available by emailing:

**Contact**: Rebecca Pentz <a href="mailto:rpentz@emory.edu">rpentz@emory.edu</a>; Neal Dickert <a href="mailto:njr@emory.edu">njr@emory.edu</a>; Justin Biddle <a href="mailto:justin.biddle@pubpolicy.gatech.edu">justin.biddle@pubpolicy.gatech.edu</a>; John Banja <a href="mailto:jbanja@emory.edu">jbanja@emory.edu</a>;

#### **Informatics**

The Medical Imaging, Informatics, and AI Cores support the Georgia CTSA by obtaining access, curating data, analyzing data, and creating novel informatics and AI/ML solutions for single or multi-center studies. The Informatics group also provides support for informatics architecture design, the processing of data, real-time data flows, grant generation, machine learning model development, and more.

Contact: ci.core@dbmi.emory.edu

#### Community Engagement (CE)

The CE program is made up of community-university research partnerships and works to obtain community input into university research to increase health research in community settings. This program connects existing academic community research programs across the Georgia CTSA, transforms research from a scientist-subject













interaction to an equitable partnership, and trains investigators in principles of community-based participatory research.

Contact: Tabia Akintobi takintobi@msm.edu; Rowena Elliot

rowena.wade.elliott@emory.edu; Allisen Penn allisen.penn@uga.edu

Submit a Request

**Tier 1:** Presentation to CE Steering Board (bi-monthly)

Schedule a meeting to discuss/present your community-engaged research or health initiative concept with the Georgia CTSA's Community Steering Board

Tier 2: Community Engaged Research Committee (quarterly)

Offers on-going, project-specific support (4 times a year x 2 hour meetings or 8 hours per year) over the course of an initiative

**Tier 3:** Formal CE Faculty/Community Partnership - project specific Learn how to include the Georgia CTSA's community steering board as the advisory/governance board for your research grant or health initiative

## **BizGrants**

This service helps entrepreneurial investigators who seek advice and financial support as they navigate the commercialization path to the market. BizGrants offers academic investigators expert advice on how to effectively write applications for two types of specialized small business grants offered through the federal government: the <a href="Small Business Innovation Research (SBIR)">Small Business Innovation Research (SBIR)</a> and <a href="Small Business Technology Transfer">Small Business Technology Transfer</a> (STTR).

# CLINICAL/TRANSLATIONAL RESEARCH & CLINICAL TRIALS

#### **Trial Innovation Network (TIN)**

The TIN is a collaborative national network that features a single IRB system, master contracting agreements, quality by design approaches, and a focus on evidence-based strategies for recruitment and patient engagement in clinical trials. Find out how the TIN can enhance your research.

**Contact**: Kimberly Schmitz <a href="mailto:schmitzk@uga.edu">schmitzk@uga.edu</a>; Priscilla Johnson <a href="mailto:pjohnson@msm.edu">pjohnson@msm.edu</a>; Delta Humphries <a href="mailto:delta.s.humphries@emory.edu">delta.s.humphries@emory.edu</a>

#### **Recruitment Services**

Recruitment Services are a strategic tool for local recruitment in clinical trials across the Georgia CTSA. Consultations provide targeted support across several Georgia CTSA programs for all aspects of a trial. The Recruitment Center will create, launch, and manage ad campaigns for research study on social media sites, primarily Facebook and Instagram.

Contact: Mugisha Niyibizi mugisha.niyibizi@emory.edu

Submit a Request











# Georgia CTSA Clinical Research Centers (GCRCs)

The GCRCs provide seamless support in launching groundbreaking clinical trials. The multifaceted facilities encompass both inpatient and outpatient research units, tailored to accommodate diverse study needs. Backed by a specialized team and comprehensive services spanning study inception to budgeting and beyond, the GCRCs help streamline the entire research process. The GCRC uses a pay-as-you-go approach, schedule that aims to alleviate the financial burden of conducting studies.

Contact: gcrc@emory.edu

Offerings include:

- Nursing services
- Phlebotomy services
- Coordinator pool/regulatory services
- Laboratory services
- Bio-nutrition services
- Administrative support (including study startup & CR-Assist)

## Rapid Response Team (RRT)

RRT is an emergency aid that works to streamline and facilitate the pre-award approval process for NIH and/or other Federally Funded Network Studies needing fast-track approvals. Examples include research on public health emergencies, bioterrorist attacks, a significant or catastrophic event, and high priority events requiring emergency approval for survival.

Contact: MYRESEARCHNAVIGATOR@LISTSERV.CC.EMORY.EDU

Submit a Request

## **SlicerDicer**

Epic SlicerDicer is a self-service reporting tool that enables clinicians to parse local populations of patient data stored in Epic Caboodle. Users can find the data they need to investigate and explore ideas, and then refine or reformulate their searches on the fly to better understand their populations. Beyond a broad patient data model there are models for billing, decision support, Emergency Department encounters, imaging, and laboratory data.

## **Cosmos**

Cosmos is a community collaboration that allows health systems using Epic to gain insights and make discoveries from their combined data, which was created by providing care to over 200 million patients. Cosmos includes tools for researchers as well as the ability to provide information directly to clinicians that are tailored to the patients they are treating.

#### ClinicalTrials.gov

<u>ClinicalTrials.gov</u> is a web-based resource that provides patients/research subjects, their family members, health care professionals, researchers, and the public with easy access to information on federally and privately supported clinical studies on a wide













range of diseases and conditions in the United States and across the world. Clinical studies are registered on ClinicalTrials.gov via a web-based data entry system called the Protocol Registration System (PRS).

## **INNOVATION & ENTREPRENEURSHIP**

#### **Innovation Catalyst**

Innovation Catalyst is the jumping off point for all Georgia CTSA commercialization services. This program helps investigators and entrepreneurs with concept articulation; customer definition and benefit description; design thinking methodology and customer needs identification; market considerations; low to mid-fidelity prototyping; and pitch deck development for early-stage funding.

Contact: Morgan Greenleaf morgan.greenleaf@emory.edu

#### **Bench2Market Talks**

The Bench2Market Talks are a series of seminars addressing key issues/topics related to entrepreneurship and commercialization of medical technologies and services. They help to bridge the gap from university innovation to commercialization.

- Topics designed for entrepreneurs in the life sciences
- Panel discussions with industry experts and investors
- Tools to communicate the potential of one's research

## RegRoadmap

The RegRoadmap is an initiative that provide investigators with the knowledge and tools to reduce friction with the FDA and increase speed to market. This initiative offers Georgia investigators expert advice on how to design a strategic plan that effectively navigates the FDA regulatory requirements and launches an innovation to market. To address varying levels of investigator regulatory fluency, the RegRoadmap service offers 2-tier regulatory strategy support:

Tier 1: Self-Guided Intro via Learning Modules

Tier 2: Regulatory "Readiness" Consultation

#### **AppHatchery**

The AppHatchery is a mobile app consulting and development service offered by the Georgia CTSA. Georgia investigators interested in evaluating or leveraging existing mobile applications, or developing new mobile tools for their research, are invited to chat with consultants at the AppHatchery. Mobile app development is a resource-intensive process that requires significant engagement from the investigator and the AppHatchery can help navigate that process.

This service assists investigators with:

- Defining their app goals, functionality, and feasibility
- Researching and recommending existing tools that may meet their needs
- Establishing a realistic feature set, development budget, and timeline













- Designing the user experience and integrating clinical data
- Building a functional "Minimum Viable Product" to test in the field
- Developing an app launch and support plan

## **EDUCATION & CAREER DEVELOPMENT**

# **Degree & Certificate Programs**

# **Master of Science in Clinical Research (MSCR)**

The MSCR is a degree program designed for predoctoral trainees (medical students or PhD students), postdoctoral trainees (resident and fellow physicians or PhD postdocs), and junior faculty (physicians, PhD-level scientists) from the Georgia CTSA partner institutions. MSCR programs are available through Emory University and Morehouse School of Medicine.

Contact: Cheryl Sroka <a href="mailto:csroka@emory.edu">csroka@emory.edu</a>

## **Certificate Program in Translational Science (CPTS)**

CPTS is a formal 16-credit Emory Laney Graduate School program for trainees who seek to conduct research at the interface between basic and translational science and clinical medicine. Predoctoral PhD students, postdoctoral fellows (PhD or MD) and junior faculty at Georgia CTSA partner institutions are eligible.

Contact: Rachel Hardison <u>rachel.hardison@emory.edu</u>

# **Career Development Programs**

# KL2

The Georgia CTSA KL2 is a training program that aims to support and enhance career development for junior faculty (MD, PhD, MD/PhD, or PharmD) interested in a career that encompasses clinical and translational science (CTS) and clinical and translational research (CTR). The KL2 Program supports career development for junior faculty from a wide variety of disciplines at the Georgia CTSA partner institutions.

Contact: Cheryl Sroka <a href="mailto:csroka@emory.edu">csroka@emory.edu</a>

# TL1

The Georgia CTSA TL1 is a program that provides clinical and translational science (CTS) training for predoctoral and postdoctoral trainees at the Georgia CTSA partner institutions. The TL1 is focused on providing didactic and mentored research training for predoctoral (medical students, PhD students, PharmD students) and postdoctoral (resident and fellow physicians, PhD postdocs, PharmD residents) trainees interested in a career focused on clinical and/or translational research relevant to human health.

Contact: Cheryl Sroka <a href="mailto:csroka@emory.edu">csroka@emory.edu</a>











## Translational Education and Mentoring in Science Mentoring Program (TEAMS)

The Georgia CTSA TEAMS Program provides faculty, postdocs, and clinical fellows from our member institutions the opportunity to join a mentoring program to develop professional skills in the areas of translational and clinical research, with special emphasis on multidisciplinary teams. This innovative, cohort-based model takes a three-pillared approach to mentoring and includes learning communities, 1:1 mentoring, as well as training and resources.

Contact: Lauren James <u>lauren.james@emory.edu</u>

# **Career Navigation**

#### **eMPACT**

eMPACT is a free career navigation service to support research professionals' individual career growth by assessing their professional attributes and experience and linking them with educational courses and programs from the Translational Workforce Development (TWD) catalog to meet their learning needs. Based on their profile, eMPACT also connects them to currently available clinical research coordinator job opportunities that fit their skill set.

Contact: empacthelp@uga.edu

# **eLearning**

## **Introduction to Clinical and Translational Research**

This freely available introductory eLearning module introduces clinical and translational concepts with the goal of educating researchers on clinical and translational opportunities through the Georgia CTSA.

**Contact**: Rachel Hardison <u>rachel.hardison@emory.edu</u>; Cheryl Sroka <u>csroka@emory.edu</u>

This digital <u>exploration</u> is organized into 4 parts that each take 1-2 hours to complete:

Part 1: Understanding the Translational Science Research Ecosystem

Part 2: Basic Concepts Defining the Analytic Approach to Research

Part 3: Elements of Clinical and Translational Research Studies

Part 4: Clinical and Translational Research Study Design Types

At the end of each part is a 10-question multiple choice assessment meant to reinforce the learning objectives and provide some real-world examples of the concepts in the CTR literature.

#### **Translational Workforce Development (TWD) Catalog**

The TWD Catalog is an online database of e-learning courses. These courses aim to advance research professionals' knowledge and skills provide a flexible and convenient way to grow. The TWD Catalog provides continuing education (CE) / contact hours from an approved accreditor.

Contact: empacthelp@uga.edu











## **IRB Webinars**

The Emory IRB presents a new webinar on the second Thursday of every month during the academic calendar year. These webinars are held to help investigators and staff on an NIH-funded study that meets the definition of "clinical trial" (even if not FDA-regulated) complete current GCP training, regardless of their role on the study, per NIH policy.

Contact: Shara Karlebach <a href="mailto:swilli7@emory.edu">swilli7@emory.edu</a>

## **Kauffman FastTrac**

The Kauffman FastTrac is a six-week course given by successful entrepreneurs that teaches aspiring and current entrepreneurs the nuts and bolts of running a business. The course is designed to help science-based entrepreneurs transform grand ideas into flourishing businesses. Participants will explore market research analysis, financial planning, team building, intellectual property, and business management, among other topics. Each topic is taught by a different startup executive or an experienced entrepreneur.

#### **AUTM Webinars**

The AUTMN Webinars focus on the anatomy of a license agreement, what different open-source licenses mean, and how innovative ideas and technologies are commercialized. AUTM is an organization that aims to educate professionals to support the development of academic research, driving innovation forward.

## **Integrating Special Populations**

The ISP Roundtables are a bi-monthly series of discussions on maternal healthcare and maternal health disparities. ISP also offers quarterly webinars regarding broader topics in regards to integrating special populations. The goal of the webinars is to facilitate engagement and collaboration among clinical and translational research investigators with a focus on maternal health inequities.

#### Previous Roundtable Sessions:

- Change Happens at the Speed of Trust: Creating Circles of Care in Our Communities
- Partnering with Cooperative Extension to Engage Communities

# **GRANT WRITING SUPPORT**

#### **Grant Wise**

Grant Wise is a service that offers the opportunity for one-on-one feedback from experienced senior faculty (aka consultants) to junior faculty or fellows on grant writing. Interested faculty and trainees submit an online request for a consultation and are then paired with a senior faculty member from our list of volunteer consultants.

Contact: Gray Messina gemessi@emory.edu













## **Grant Writing Workshops**

The Grant Writing Workshops are offered bi-annually by the Georgia CTSA and Emory School of Medicine. These workshops cover basic strategies to improve the foundation of grant writing. Workshops are recorded and can be viewed on the <a href="CMDTS webpage">CMDTS webpage</a>.

Contact: Lauren James lauren.james@emory.edu

#### K-Club

The K-Club is an educational forum providing support and advice to young investigators on obtaining research career development awards. Researchers, junior faculty, and fellows interested in academic research careers are invited to attend. K-Club meets monthly and provides lunch. RSVP is required.

Contact: Barbara Kilbourne barbara.kilbourne@choa.org

## **Letters of Support**

The Georgia CTSA can supply investigators from member institutions with letters of support describing CTSA resources for grant submissions.

**Contact**: Stephanie Wright <u>stephanie.nicole.wright@emory.edu</u>

## **FUNDING & AWARD OPPORTUNITIES**

# **Pilot Grants**

The Pilot Grant Program solicits and funds proposals that either a) generate preliminary data and refine research strategies for subsequent extramural grant applications; or b) develop the best approaches and methodologies to address complex translational and clinical research problems. The program encourages new networks of inter-institutional research teams.

Contact: Bekeela Davila bekeela.davila@emory.edu

#### Biostatistics, Epidemiology & Research Design Grants

This funding opportunity is provided by the BERD program. Candidates may submit proposals to support novel methodological research in biostatistics, epidemiology, or health services research and related areas to advance clinical and translational research (CTR). Review criteria include: (i) quantitative methodological research to fill gaps in CTR; (ii) innovation; (iii) feasibility; and (iv) plans for dissemination and translation of results. Awardees are encouraged to disseminate any software developed in their research to relevant publicly available software repositories.

Contact: Bekeela Davila <u>bekeela.davila@emory.edu</u>

#### **Blue Sky Groups Mini Grants**

Blue Sky Groups are meetings held to discuss common research areas and identify potential areas of collaboration. Successful new collaborations spawned from these discussions can apply for a pilot grant of \$1,500 to kick-start the collaboration.

Contact: Lauren James lauren.james@emory.edu

GeorgiaCTSA.org











#### **Team Science Awards**

These awards celebrate an outstanding multi-disciplinary research team in recognition of its innovative and impactful research that has advanced, or will likely advance, clinical and translational science and positively impact human health. The Georgia CTSA provides two awards: <a href="Presidents">Presidents</a>' Award of Distinction for Team Science, and Team Science Award of Distinction for Early Stage Research Teams. The recipients of these awards are recognized at the annual Southeast Regional Clinical and Translational Conference.

Contact: Lauren James <u>lauren.james@emory.edu</u>

# **Diversity, Equity and Inclusion in Clinical/Translational Science Awards**

The Georgia CTSA created these awards to ensure a climate of inclusion and organizational equity by leveraging the varied attributes of diversity in our community. The Georgia CTSA offers two awards celebrating DEI in clinical and translational science: Faculty Excellence in Diversity, Equity & Inclusion in Clinical/Translational Science Award and Staff Excellence in Diversity, Equity & Inclusion in Clinical/Translational Science Award

Contact: Lauren James lauren.james@emory.edu

## **COLLABORATION & NETWORKING**

# **Blue Sky Groups**

Blue Sky Groups are meetings convened to discuss common research areas and identify potential areas of collaboration. These groups meet once to discuss a broad topic, and then future meetings are organized based on interests and potential outcomes. Topic submissions are encouraged; the Georgia CTSA will schedule and facilitate the event.

Contact: Lauren James <u>lauren.james@emory.edu</u>

#### **Speed Networking**

Participants are given the opportunity to make a 3-4 minute presentation to potential collaborators from both clinical and basic science backgrounds. If speakers exceed the allotted amount of time, they will be gonged off the stage! Attendees are also welcome to participate as observers rather than presenters.

Contact: Lauren James <u>lauren.james@emory.edu</u>

#### **Georgia CTSA Match**

The <u>Georgia CTSA Match electronic platform</u> encourages meaningful collaboration by pairing researchers with similar interests to promote networking opportunities and research.

Contact: Lauren James <u>lauren.james@emory.edu</u>

## **TEAM SCIENCE**













#### **Team Science Toolkit**

This toolkit is designed to promote engagement in team science, which has become crucial to a successful scientific career. The toolkit provides resources, guides, and connections that will help researchers explore the translational impact of their research.

Contact: Gray Messina <a href="mailto:gemessi@emory.edu">gemessi@emory.edu</a>

#### **Team Science Workshops**

This workshop series aims to help participants develop the skills necessary to build and maintain their research team by leveraging evidence-based recommendations. The science of good teamwork is universal, from incorporating graduate students and post-docs into their first research team to crossing boundaries in the creation and maintenance of an interdisciplinary expert team.

**Contact:** Lauren James <u>lauren.james@emory.edu</u>; Chris Wiese chriswiese@gatech.edu

## DATABASES & SUPPORT

## **Community and Academic Partner Database**

This resource is a database of community and university partners across Georgia that is publicly available and designed to facilitate collaborations. Explore this searchable database to find potential partners or connect with those doing work on health topics.

# **Georgia Tech Tool Suite**

This collection of virtual 'tools' serves as first step for the open-source software community, providing health care solutions to encourage interoperability, innovation, and research.

Contact: iclheatdinfo@gtri.gatech.edu

#### ResearchMatch.org

This free resource allows researchers to query and contact a national database of eligible research volunteers for their study.

#### Research Opportunities & Collaboration Support (ROCS) Searchable Database

This searchable database supports exploration of specific cores, courses, collaborative funding opportunities, and programs across the Georgia CTSA institutions.

Contact: Gray Messina gemessi@emory.edu

# **Trial Innovation Network Recruitment & Retention Toolkit**

This toolkit is an online collection of useful tools for recruitment and retention of subjects for clinical trials and multi-site research studies.











# CONFERENCES

## Southeast Regional Clinical and Translational Science Conference

The Southeast Regional Clinical and Translation Science Conference is a 2  $\frac{1}{2}$  -day conference held annually in late February/early March. The goal of the conference is to bring together researchers from across the region to present the best new health-related preclinical, clinical, implementation, and population-based research and build collaborative relationships.

Contact: Lauren James <u>lauren.james@emory.edu</u>

# **Health Services Research Day**

Health Services Research Day is an annual symposium and networking opportunity where researchers learn about ongoing quality, effectiveness, and value-based research activities across the state of Georgia.

Contact: Lauren James lauren.james@emory.edu

## Biostatistics, Epidemiology, & Research Design (BERD) Research Forum

The BERD Research Forum is a yearly meeting to facilitate new collaborations related to important, innovative research topics. It brings together experts and enthusiasts in the fields of biostatistics, epidemiology, and community-based research to share their latest findings and exchange ideas based on an annually-chosen theme.

Contact: Stephanie Wright <a href="mailto:stephanie.nicole.wright@emory.edu">stephanie.nicole.wright@emory.edu</a>

## **Annual Southeast Pediatric Research Conference**

The Southeast Pediatric Research Conference is an annual meeting held each summer. This conference highlights the scope of pediatric research conducted across the southeast, with an emphasis on research from Children's Healthcare of Atlanta and the Georgia CTSA partner institutions.

Contact: PRUTeam@choa.org

#### **Community Health Matters Forum**

The Community Engagement Program looks to creae an exchange between the community and clinical research. This biennial forum, provides participants with the tools necessary to develop and sustain successful and mutually-beneficial community-university partnerships to increase public health in Atlanta and beyond. Each year, experts from academia, non-profits, foundations, and other community partners come together for the program's Community Forum.

Contact: georgiactsa-ce@msm.edu

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