Current Clinical and Translational Science Award (CTSA) sites: Funded by NIH/NCATS

CTSA Consortium:
Class of 2006 12 awards
Class of 2007 12 awards
Class of 2008 14 awards
Class of 2009 8 awards
Class of 2010 9 awards
Class of 2011 5 awards
Class of 2012 1 award
Class of 2013 1 award
Total 62 awards
Atlanta Clinical & Translational Science Institute

Translating scientific discoveries to impact the Atlanta community, Georgia, &
ACTSI Leadership Council
**ACTSI Specific Aims**

**Aim 1.** Promote **discovery** through inter-disciplinary collaboration, the development of novel and emerging technologies, drugs, devices, diagnostics and biologics, and the efficient translation of these discoveries to benefit human health

**Aim 2.** Expand and improve outstanding programs to **educate and train** a growing cadre of ethnically diverse, transformative clinician scientists, and increase the capacity and infrastructure to foster multidisciplinary translational research teams

**Aim 3.** Actively engage the **community** in research to engender public trust in scientific discovery and in the translation of new knowledge that ultimately enhances the health of the diverse communities we serve
Communications

- ACTSI Weekly eRoundup
  - Funding Opportunities
  - Research Resources
  - Educational Opportunities
  - Events
  - News

Go to [www.actsi.org](http://www.actsi.org) and select “Submit a Request” to sign-up to receive the Weekly eRoundup
Clinical Research Network (CRN)

The **CRN supports clinical and translational research by supporting** the needs of ACTSI investigators at hospital, medical office, and community-based sites across Atlanta. The CRN supports investigators by offering:

- Studio Consultations (CRN, with BIP and BERD reps to discuss new potential protocols, feasibility, resources etc).
- Clinical Data Extraction Service for recruitment and feasibility
- Patient scheduling and tracking
- REDCap – A secure, web-based, electronic data capture tool
- Atlanta Hospital Hospitality House
- Inpatient and outpatient facilities for subject visits and procedures
- Research nursing services
- Biological sample processing, aliquoting, short- and long-term storage
- Bionutrition and exercise physiology expertise
Enabling Discovery

Clinical Research Network including Pediatrics

ACTSI Clinical Research Sites

Tier 1: Hospital Based Clinical Research Sites
1. Emory University Hospital
2. MSM Clinical Research Center*
3. Grady Memorial Hospital*
4. Emory University Hospital Midtown
5. Atlanta VA Medical Center
6. South Fulton Medical Center
7. Wesley Woods Geriatrics Center and Sleep Disorders Unit
8. Emory-Georgia Tech Center for Health Discovery & Well Being
9. Winship Cancer Institute Phase 1 Unit
10. St. Joseph’s Hospital, Cardiovascular Research Institute
11. Emory Emergency Department Research Program

Tier 2: Medical Office Based Clinical Research Sites
12. Mason Outpatient Transplant Unit
13. Emory-Children’s Cystic Fibrosis Center of Excellence
14. Emory ALS Center
15. Emory Ophthalmology Research Program
16. Grady Ponce Center
17. Morehouse Medical Associates
18. Community Physician’s Network
19. Hope Clinic
20. Kaiser Permanente Georgia
21. Grady Diabetes Clinic
22. Emory Autism Center
23. Georgia Tech Research Institute

Tier 3: Community Based Clinical Research Sites
24. Southside Community Health Center
25. Grady East Point Neighborhood Clinic
26. West End Medical Center
27. Oakhurst Community Health Center
29. VA Community Based Outpatient Centers

*also pediatric sites
Distribution of CRN supported studies in 2013

Studies by Type
- Clinical Trials: 161 (59%)
- Observational: 68 (25%)
- Registry: 17 (6%)
- Other: 27 (10%)

Clinical Trials by Phase
- Phase I: 14 (9%)
- Phase I/II: 2 (1%)
- Phase II: 56 (35%)
- Phase II/III: 9 (6%)
- Phase III: 49 (30%)
- Phase IV: 31 (19%)

Studies by Funding Type
- Federal: 151 (55%)
- Foundation/Association: 25 (9%)
- Industry Sponsored: 64 (23%)
- Unfunded: 4 (2%)
- Other: 29 (11%)
# Annual CRN Statistics

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</thead>
<tbody>
<tr>
<td>Investigators</td>
<td>265 (95%)</td>
<td>326 (92%)</td>
<td>416 (95%)</td>
<td>650 (98%)</td>
<td>654 (84%)</td>
<td>677 (64%)</td>
<td>718 (58%)*</td>
</tr>
<tr>
<td>Publications</td>
<td>0</td>
<td>103 (87%)</td>
<td>104 (85%)</td>
<td>84 (82%)</td>
<td>257 (73%)</td>
<td>154 (58%)</td>
<td>27 (56%)</td>
</tr>
<tr>
<td>Grants (Count)</td>
<td>57 (69%)</td>
<td>58 (65%)</td>
<td>70 (68%)</td>
<td>77 (65%)</td>
<td>69 (53%)</td>
<td>71 (76%)</td>
<td>65 (63%)*</td>
</tr>
<tr>
<td>Grants (Dollars)</td>
<td>$54,675,015 (75%)</td>
<td>$61,839,375 (80%)</td>
<td>$72,797,451 (86%)</td>
<td>$104,349,970 (87%)</td>
<td>$56,481,293 (60%)</td>
<td>$88,112,264 (69%)</td>
<td>$70,237,889 (64%)*</td>
</tr>
<tr>
<td>Patents</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>8 (44%)</td>
<td>4 (22%)</td>
<td>10 (32%)</td>
</tr>
<tr>
<td>INDs</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>28 (100%)</td>
<td>48 (100%)</td>
<td>39 (100%)</td>
</tr>
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* Data from RAPID, all other data from Annual reports to NIH
CRN Nursing Services - Scope of Services

- Nursing resources include:
- Protocol feasibility and roundtable assessments (physician order review and editing for clarity)
  - Participant registration, patient assessment, pre, during and post procedural assistance
  - Accurate and reliable completion of all research protocols
  - Medication administration including research drugs
  - IV access and intravenous infusions
  - Routine and complex vital sign monitoring
  - Phlebotomy, timed specimen collections, PK sampling
  - Telemetry monitoring
Emory University Hospital
CRN Unit: HG wing

- **INPATIENT**: 11-bed Medical/Surgical unit with a per diem research capacity with 4 dedicated research beds
- Inpatient clinical research nurses available
- **OUTPATIENT**: 4-5 full time research nurses; 1 medical assistant; Six study subject bays, procedure rooms
- Human Performance Lab (treadmill, indirect calorimeter, PFTs, ultrasound for vascular function and CIMT, infusions)
- CRN Administrative offices (GG)
- Nursing services provided at EUH; EUHM; Grady; Winship; Genetics; VA and greater inpatient units at EUH & Grady
- Nurses can float between study sites on campus if scheduled
Grady Memorial Hospital
CRN Unit: 12A

- 12A Grady Memorial Hospital, with an outpatient and inpatient unit.
- Staffed by 2-3 clinical research nurses
- Procedures requiring overnight stays also are done at Grady
  - Inpatient care area of 3 beds
  - Outpatient care area with 4 patient contact units
  - Research coordinators office
  - Waiting area
  - Laboratory (-80° freezer, centrifuges, sample processing)
  - Administrative offices
Emory University Hospital
Midtown
CRN Unit

• The CRN facilities (Davis-Fisher Bldg):
  – Outpatient care area with 3 patient contact units
  – Waiting area
  – Laboratory (-80° freezer, centrifuges, sample processing)
CRN Lab Resources for Investigators

- Consultation for laboratory processing protocols:
  - Planning
  - Set-up, appropriate tubes, etc
  - Initiation

- Sample processing (centrifugation, aliquoting, etc...)
  - Urine
  - Serum/Plasma
  - Buffy Coat
  - RNA isolation

- Sample barcoding and tracking using state-of-art laboratory information management (LIMS) software

- Labs have CLIA certificate of waiver
  - Point-of-care testing (drugs of abuse, glucose, etc...)

- Short- and long-term sample storage
  - 4°C, -20°C and -80°C
CRN Bionutrition Unit - Resources

Assist investigators in planning and conducting research as it relates to nutrition and exercise

- Protocol Development
- Metabolic kitchen for research meal preparation; e.g. food challenges
- Nutrient Analysis
  - Food Records (24-hour recalls, 3-day food records, food frequency questionnaires)
  - Nutrition Data System for Research (NDS-R) software
- Nutrition Assessments
  - DXA Scanner
  - Indirect Calorimetry, Bioelectrical Impedance Analysis (BIA)
  - Anthropometric measures of muscle and fat compartments
Other Bionutrition Services & Exercise Testing

- Diet education and counseling
- Nutrition and exercise classes
- VO\textsuperscript{2} Max Testing
  - Uses metabolic cart to predict peak oxygen uptake
  - Reflects physical fitness of individual
- Sub-max test
  - Subject taken to 85% of age-predicted maximum heart rate
The ACTSI is pleased to announce a new resource for investigators called Studio Consultations to aid in the successful design and implementation of clinical and translational science research proposals. The Studio Consultation concept involves a clinical investigator presenting their proposal to representatives of the ACTSI’s Biostatistics, Epidemiology, & Research Design (BERD) program, Biomedical Informatics Program (BIP), and Clinical Interaction Network (CIN) who in turn give the investigator their expert feedback. In short, a studio consultation is a pre-review by a panel of experts designed to improve your chances of success.

To arrange for a Studio Consultation please visit [http://www.actsi.org/actsirequest/request1.cfm](http://www.actsi.org/actsirequest/request1.cfm).

A Studio Consultation will assist researchers in any of the following areas:
1. Biostatistics
2. Bioinformatics
3. Database development
4. Project generation planning
5. Research design
6. Protocol planning and implementation
Studio Consultations

The Studio:

- A fully integrated consultative model
- A member from each of bioinformatics (BIP), biostatistics (BERD) and the clinical research network (CRN) are available for input
- Formal consultative environment and outcomes
  - Technical input
  - Professional advice and guidance
To arrange for a studio consultation, please complete the ‘Submit a Request' form on the main ACTSI website.

A Studio Consultation will assist researchers in any of the following areas:

1. Biostatistics
2. Bioinformatics
3. Database development
4. Project generation planning
5. Research design
6. Protocol planning and implementation

Schedule: Reserve a 30 or 60 minute time block. Duration will depend on the perceived needs of the researcher and of the proposal complexity. Be sure to provide as much detail as possible when filling out the "Submit a Request form”

Hours: Blocks scheduled between 1:00 p.m. and 3:00 p.m. on the first Friday of each month

Location: Emory University, Woodruff Health Sciences Center Administration Building, Room 102, 1440 Clifton Road NE, Atlanta, GA 30322
Additional Resources

Access to extensively characterized diverse patient populations in the metropolitan Atlanta CTSI community.

1) Clinical Data Extraction Service: Investigators may request support for data extraction from the Clinical Data Warehouse

2) REDCap: Research Electronic Data Capture (REDCap), a Research and Health Sciences supported resource for ACTSI investigators that allows electronic capture of data for research ($300/year/protocol cost can be covered)

3) Atlanta Hospital Hospitality House: The CRN is now partnering with AHHH to offer accommodations for research participants who are either traveling from distant sites to any CIN site or those who are undergoing evaluation for multiple days for outpatient studies where inpatient stays are not necessary.

4) Inter-Institutional Recruitment Core: Under development a multi-institutional (with appropriate IRB review and approval for online consent processes) recruitment database and expansion of selected registries of eligible and interested participants for clinical studies
How can the CRN Help You?

- Inpatient Studies
- Outpatient Studies
- NIH
- Foundations
- Investigator-initiated
- Industry
- Study Design
- IT & Statistical Support
- Networking
- Funding
- Nursing Support
- Vascular Lab
- Bionutrition
- Metabolic Studies
- Exam rooms
- Conference rooms
- Laboratory
- Sample storage
How to contact program directors to either help find a mentor or help start a project

- Arlene Chapman, MD, CIN Program Director (abchapm@emory.edu)
- Thomas Ziegler, MD, Emory University Hospital CIN Site Program Director (tzieg01@emory.edu)
- Guillermo Umpierrez, MD, Grady Hospital CIN Site Program Director (geumpie@emory.edu)
- Greg Martin, MD, MS, Emory University Hospital Midtown CIN Site Program Director (greg.martin@emoryhealthcare.org)
- Debora Clem, CIN Administrative Director (dclem@emory.edu, 404-712-1993)
Atlanta Clinical & Translational Science Institute (ACTSI)
(Established September 2007)

Mission: Through ethical community engagement, focused education and training, and innovative support of discovery, the collaborative partners of the ACTSI rapidly and efficiently translate scientific discoveries to impact all populations of the Atlanta community.

David S. Stephens, MD
Principal Investigator
A-CTSI – CRN

• Investigator-initiated research: (supported by NIH, American Heart, etc., or pilot studies supported by the PI, etc.) ➔ FREE space and research support*

• Industry-sponsored research: (supported by pharmaceutical company) ➔ LOW-COST space and support

* Under review
What is the process to get a project supported?

Step 1: It is recommended that investigators contact one of the CRN Program Director(s) and CRN Administrator to discuss their planned protocol and research needs in advance.

Step 2: Plan a studio appointment that involves membership from the Biostatistics, Informatics and CRN to help plan and develop the study design and analysis section.

Step 3: All new submissions are pre-screened by the CRN site specific Program Director and biostatistics (BERD) staff.

Step 4: Submissions that have passed pre-screening are reviewed at the next SAC meeting.

Step 5: Submissions are reviewed for feasibility, scientific merit and safety.

Step 6: SAC letters of approval or requesting clarification are distributed to the investigator, usually within a week of the SAC meeting.
Procedures for Clinical Research at the CRN

1. Initial discussion of protocol with CRN Administrator, Program Director(s)

   - Protocol, data safety monitoring plan, budget, and Scientific Advisory Committee ("SAC") approval
   - Protocol submitted to Emory or Morehouse IRB (can be concurrent with CTSA submission)

2. Review by Grady Research Oversight Committee

3. “Roundtable” discussion of detailed, day-to-day protocol with CRN staff
How to contact program directors or CRN Administrator

- Arlene Chapman, MD, CRN Program Director (abchapm@emory.edu)
- Thomas Ziegler, MD, Emory University Hospital CRN Site Program Director (tzieg01@emory.edu)
- Guillermo Umpierrez, MD, Grady Hospital CRN Site Program Director (geumpie@emory.edu)
- Greg Martin, MD, MS, Emory University Hospital Midtown CIN Site Program Director (greg.martin@emoryhealthcare.org)
- Debora Clem, CRN Administrative Director (dclem@emory.edu, 404-712-1993)
http://www.actsi.org/areas/cin/index.html
Questions?

Thank you!
Current Cost Recovery Policy

Protocols that request research study support from the CRN are subject to payment of all support costs.

This applies to industry-initiated, non-federal studies and may pertain to investigator-initiated industry supported studies as well.

Fee schedules are used for budget development to justify requests for support from sponsors.

The fee schedule is updated annually and investigators will be charged the published rate at the time of service.

It is recommended that investigators include a three percent (3%) annual increase in budgets in anticipation of salary adjustments.

http://www.actsi.org/areas/crn/protocol_submission/index.html
Industry Fee Schedule
• Updated Annually
• Invoiced monthly

http://www.actsi.org/areas/crn/protocol_submission/index.html
How do I budget for CRN services now?

- Contact Debora Clem, 404-712-1993, dclem@emory.edu, in CRN Administration to discuss study requirements
- CRN will develop a budget based on these requirements
- Will work with departmental administration and OCR to ensure CRN costs are covered
- Current fee schedule is available on the ACTSI website
Future Cost Recovery Policy

- The current CTSA RFA, mandates that no CTSA funding may be used to pay for the costs of clinical research services (e.g. nursing and lab services, space and patient care costs)
- Therefore the CRN will implement a cost sharing plan for all studies beginning in June 2017
- A percentage of CRN costs for these services will be charged back to the investigator funding source (federal, foundation, department, etc). Industry sponsored studies will continue to be charged as they are currently.
- The plan and associated fees and charges will be distributed within the next year
CTSA funding can be used to support clinical research staff only for oversight and quality assurance, but not to support actual research activities that are part of studies and trials conducted at the CTSA hub. For example, the CTSA funding may be used to support a limited number of experienced clinical research professionals such as research nurses or coordinators who can facilitate access to resources, can assist study-specific staff, and can provide oversight and help with quality control and assurance. **Support for the study-specific staff conducting the actual research participant evaluations must be included in the per patient fee or other funding provided by the NIH ICs or the private sector supporter of that study or trial.** If a pool of coordinators or research nurses is available to conduct participant evaluations and implement protocols at a CTSA hub, their activities must be charged to the study budget itself.

- Space to conduct research cannot be charged to the CTSA grant.
- Inpatient and outpatient care costs cannot be charged to the CTSA grant.

The only exception is the option of including a "voucher" program. Such a “voucher” program can provide small amounts of support for research evaluations, for instance laboratory testing in pilot studies (e.g. those funded by the CTSA or those that are part of the NCATS K-award program).
How will I budget for CRN services under the new policy?

- Contact Debora Clem, 404-712-1993, dclem@emory.edu, in CRN Administration when planning grant application
- We will work with departmental administrators, RAS units, OCR and OSP to ensure CRN services are appropriately budgeted
- Fee schedules for both federal and non-federal projects will be posted on the ACTSI website