



CLINICAL RESEARCH UNITS (CRU)

ROLE OF OFFICE

The role of the clinical research units (CRUs) is to provide space and resources (specialized personnel and equipment) that allow investigators to conduct innovative, high quality, safe, efficient, and cost-effective clinical and translational research across the age spectrum.

The JH CRUs are a coordinated network of 4 facilities across the East Baltimore and Bayview campuses where outpatient and inpatient research visits are conducted. More than one of these units can be used for a single study depending on the protocol (e.g., the need for both inpatient and outpatient visits).

Over the last 4 years, the CRUs supported >400 protocols for >200 individual PIs. Of these PIs, 63% were funded by the NIH, including 14 of the 27 NIH Institutes and Centers. Other research sponsors include other Federal agencies (DOD, CDC), the Bill and Melinda Gates Foundation and Cystic Fibrosis Foundation. The CRUs also support industry-sponsored research protocols and phase I-IV clinical trials. Multiple federally funded clinical trial networks and cohort studies use JH CRU resources to conduct their visits, such as the AIDS Clinical Trial Group, the Multiethnic Study of Atherosclerosis, and the Multicenter AIDS Cohort Study.

CRU-supported studies have resulted in many high impact publications including publications in the New England Journal of Medicine and JAMA. Investigators have used CRU resources to develop novel treatments for peanut allergy (1,2), identify predictors of asthma and morbidity in children living in urban environments (3,4).), test new therapeutics for genetic bone diseases (5, 6), and characterize the cardiac effects of preclampsia (7).

Overview of Clinical Research Units

- 1) Pediatric Clinical Research Unit: This is a state-of-the art inpatient and outpatient facility located in the Charlotte R. Bloomberg Children's Building. The inpatient unit is 20 beds, of which seven can be reserved for ICTR-approved research. The outpatient unit, which includes seven clinical exam rooms, an infusion facility, 2 procedure rooms, pediatric phlebotomy room, and formula and research kitchen is available to

investigators Monday through Friday 7 AM to 6 PM. The services are supported by 1 RN, 1 Research Assistant and 1 Phlebotomist. Sleep studies are conducted at the domiciliary unit with pediatric competent PSG technician support and on-site pediatrician oversight.

- 2) Bayview Clinical Research Unit: This is a domiciliary unit for adult overnight and outpatient visits located in the 301 Building on the Bayview campus. The unit is open 24 hours a day/7 days a week for investigator use. The Unit is a 14,300 square foot space comprised of 8 overnight rooms with private bathrooms, 4 infusion/phlebotomy bays, interview rooms, procedure rooms, a gynecologic exam room, a dental exam room, a sample processing lab with a -70 freezer, echocardiography and vascular function testing lab, metabolic stress testing resources, DXA, and Biodex for muscle strength testing. A staff of 8 nurses, 1 technician, 1 phlebotomist, 1 patient care manager and 1 patient service coordinator provide the research services and support research protocols. Nurses administer protocol-guided medications, including infusions, IVGTT, and pharmacokinetic studies. Support beyond the walls of the CRU include off-site nursing or phlebotomy for protocols at community centers to assist investigators enrolling elderly or minority participants.
- 3) JHH Outpatient Research Unit: Located in the Carnegie Building, this unit includes 11 full-service exam rooms, 2 interview rooms, a phlebotomy room, sample processing lab, -70 freezer, infusion center, and DXA scanner. Full-time staff includes 3 research nurses, a phlebotomist and technicians who assist investigators with protocol specific evaluations (e.g., vital signs, collection/processing of specimens, administration of questionnaires.) Qualified nurses administer medications for approved protocols.
- 4) JHH Inpatient Research Unit: This unit, located on Osler 5, provides inpatient-nursing services for investigators who require hospital-level care, including around the clock nursing coverage, cardiac monitoring, and code-team access. It is well suited for research participants who require intensive monitoring after research procedures or whose underlying medical condition necessitates a higher level of care than can be offered in a domiciliary unit.

PERFORMANCE IN THE PAST YEAR

Units	Outpatient Visits	Inpatient Visits	Protocols	Investigators
Pediatric CRU	2428	72	90	32
Bayview CRU	1830	547	85	55

JH CRU	3483	NA	119	75
--------	------	----	-----	----

Research Coordinator Clinical Skills Training: CRU staff provide various clinical skills training to research staff working on research studies at the institution. Over the past year, 31 study staff members have received training through the program.

CHANGES IN THE PAST YEAR

CTSA Grant that funds the Johns Hopkins Institute for Clinical and Translational Research is Awarded Funding for 5 Years: The CTSA program helps support high-quality translational clinical research locally, regionally, and nationally and fosters innovation in research methods, training, and career development. Johns Hopkins was awarded \$9.8 million per year over 5 years. These important resources support the CRU in its mission to enhance clinical research by providing comprehensive participant and clinical interactions, advising and training investigators and study staff, and developing a robust research workforce.

Successful Transition to a Service-Center Model: Since May 2018, the JH CRUs have transitioned to a Service-Center Model in which services that were previously provided free of charge are now available for a fee. To smooth the transition for protocols that were approved prior to the implementation of the Service-Center Model, we used no-cost extension funds in the previous CTSA grant to award over \$700,000 in CRU services in the past year. For those protocols approved for resources before May 2018, we were awarded additional funds as part of our CTSA grant to support commitments that were made in the previous grant funding cycle. This means that we will be awarding funds for the continuation of these projects with the new CTSA grant.

The following clinical services are now fee-for-service Service Centers.

- JHBV Core: Adult Out-Patient Johns Hopkins East Baltimore Campus and Bayview Adult Outpatient & Overnights
- PCRU: Pediatric Outpatient Clinical Research Unit
- CV Core: Cardiovascular & Exercise & Body Composition (Bayview Campus)
- Research Nutrition
- Core Laboratory

Nicole Cooper, our Senior Administrative Manager, has successfully implemented the Service Center Model using iLabs and monthly invoicing. She is available to answer any questions about the Service Center Model (ncooper2@ihmi.edu) and what costs should be budgeted in grant applications. The fee schedule is available on the ICTR website (<https://ictr.johnshopkins.edu/wp-content/uploads/2016/01/ICTR-Clinical-Research-Unit-Charge-Master-7-2018.pdf>).

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

BOOST and PROPEL Awards: Access to clinical research resources and highly trained research personnel is consistently identified by researchers as an effective way to accelerate their clinical and translational research. BOOST and PROPEL awards are clinical research grants that award CRU resources such as research space, specialized research nursing, imaging assistance (DXA, CV core), and research nutrition resources to ICTR investigators, based on merit and willingness to be actively monitored by the Translational Research Evaluation Committee (TREC) for study specific milestones. The goal of the BOOST and PROPEL awards is to accelerate meritorious protocols to produce efficient, high quality, safe research and to disseminate the results. **BOOST** awards are for junior investigators, first-time R01 awardees, K awardees, and KL2 scholars to generate pilot data for a larger grant submission or to supplement research funds for the K project. **PROPEL** awards are intended for established investigators who are performing early stage clinical trials, deep phenotyping studies, or studies that address Maryland health priorities. PROPEL can augment resources of a funded project or provide resources for small pilot and feasibility studies. PROPEL and BOOST awards are unique within the ICTR in that: 1) awards are for CRU resources; 2) applicants undergo a rigorous, NIH-style, multidisciplinary review process via the TREC with monitoring on a quarterly basis for attainment of milestones; 3) priority is given for collaboration with Hub partners, diverse study populations and Maryland health priorities. BOOST and PROPEL grant programs will be launched in October 2019 with a competitive application process.

Move of the JHH Outpatient Clinical Research Unit: Clinical space on Blalock 3 is currently being renovated to accommodate the East Baltimore Outpatient CRU. The new space will be 40% bigger than the current space on Carnegie 3 and will provide investigators and their teams enhanced facilities to conduct research, such as on-site nutrition services.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

For investigators who are submitting a grant application and plan to use CRU services, Ms. Nicole Cooper is available to help develop a budget for CRU services and guide you in accessing CRU resources. It is recommended that she be contacted at least 6-8 weeks before submission.

BEST WAY TO WORK WITH PROGRAM

More information about the CRUs is available on the ICTR website (https://ictr.johnshopkins.edu/programs_resources/programs-resources/clinical-research-units/).

Applications to use the CRUs can be obtained during eIRB submission or directly through the online portal CRUonline (<http://ictrweb.johnshopkins.edu/cruonline>).

A link to detailed instructions for applying to the CRUs can be found here: (https://ictr.johnshopkins.edu/programs_resources/programs-resources/clinical-research-units/applying-to-use-the-crus/)

Administrator:

Nicole Cooper, Senior Administrative Manager, ncooper2@jhmi.edu

PCRU:

Robert Wood, MD, Director of Pediatric CRU, rwood@jhmi.edu

Corinne Keet, MD, PhD, Associate Director of Pediatric CRU, ckeet1@jhmi.edu

Bayview CRU:

Suzanne Jan de Beur, MD, Director of Bayview CRU, sjandebe@jhmi.edu

Pamela Ouyang, MBBS, Associate Director of Bayview CRU, pouyang1@jhmi.edu

JH CRU:

Charles Flexner, MD, Director of Human Subjects Core, flex@jhmi.edu

Todd Brown, MD, PhD, Director of JH Outpatient CRU, tbrown27@jhmi.edu

REFERENCES

1. PALISADE Group of Clinical Investigators, Vickery BP, Vereda A, Casale TB, et al. AR101 Oral Immunotherapy for Peanut Allergy. N Engl J Med. 2018 PMID: 304492342.
2. Fleischer DM, Greenhawt M, Sussman G, et al. Effect of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Ingestion Among Children with Children With Peanut Allergy: The PEPITES Randomized Clinical Trial. JAMA. 2019. PMID: 30794314
3. [Bacharier LB](#), [Beigelman A](#), [Calatroni A](#), et al. NIAID sponsored Inner-City Asthma Consortium. Longitudinal Phenotypes of Respiratory Health in a High-Risk Urban Birth Cohort. Am J Respir Crit Care Med. 2018 PMID: 30079758

4. Wu TD, Brigham EP, Peng R, et al. Overweight/obesity enhances associations between secondhand smoke exposure and asthma morbidity in children. *J Allergy Clin Immunol Pract.* 2018 6:2157-2159, 2018. PMID: 29730453
5. Savarirayan R, Irving M, Bacino CA, Bostwick B, Charrow J, Cormier-Daire V, Le Quan Sang KH, Dickson P, Harmatz P, Phillips J, Owen N, Cherukuri A, Jayaram K, Jeha GS, Larimore K, Chan ML, Huntsman Labeled A, Day J, Hoover-Fong J. C-Type Natriuretic Peptide Analogue Therapy in Children with Achondroplasia. *N Engl J Med.* 2019; 381:25-35. PMID: 31269546
6. Insogna KL, Briot K, Imel EA, Kamenický P, Ruppe MD, Portale AA, Weber T, Pitukcheewanont P, Cheong HI, Jan de Beur S, Imanishi Y, Ito N, Lachmann RH, Tanaka H, Perwad F, Zhang L, Chen CY, Theodore-Oklota C, Mealiffe M, San Martin J, Carpenter TO; AXLES 1 Investigators. A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial Evaluating the Efficacy of Burosumab, an Anti-FGF23 Antibody, in Adults With X-Linked Hypophosphatemia: Week 24 Primary Analysis. *J Bone Miner Res.* 2018; 33(8):1383-1393. PMID: 2994708
7. Vaught AJ, Kovell LC, Szymanski LM, Mayer SA, Seifert SM, Vaidya D, Murphy JD, Argani C, O'Kelly A, York S, Ouyang P, Mukherjee M, Zakaria S. Acute Cardiac Effects of Severe Pre-Eclampsia. *J Am Coll Cardiol.* 2018; 72(1):1-11. PMID29957219

”