



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 where outpatient and inpatient research visits are conducted. More than one of these units can be used for a single protocol depending on the study's needs (eg, a protocol with 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 a recent randomized, controlled clinical trial of an integrated pest management system to reduce mouse allergen exposure and asthma symptoms,¹ a randomized trial showing that anti-IgE antibody improves the safety and tolerability of oral immunotherapy for cow's milk allergy², and an observational study demonstrating a higher burden of high-risk, non-calcified coronary artery plaque in older HIV-infected men compared to well-matched HIV-uninfected control men³.

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 7 at any one time can be reserved for ICTR-approved research. The outpatient unit, which includes 7 clinical exam rooms, an infusion facility, 2 procedures 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 which 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 protocols 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

- PCRUCR: There were 3162 outpatient visits and 89 bednights utilized that served 104 different protocols from 36 pediatric investigators. Of these protocols, approximately 30% were industry-sponsored.
- Bayview CRU: There were 2141 outpatient visits and 761 bednights utilized that served 117 protocols.
- JH Outpatient CRU: There were 3535 outpatient visits, serving 134 protocols for 75 investigators.

User Satisfaction

Feedback is essential to tailor CRU services to meet the evolving needs of our investigators. To this end, we conduct periodic user surveys, with the last being in 2015. Of the 76 investigators who responded, 95% agreed with the statement that the “CRUs have been a critical resource for enabling me to conduct clinical research”. In addition, 86% agreed with the statement “The CRUs resources have helped me to obtain (or augment) my NIH or other externally funded research support”. According to investigators the most valuable services offered were Nursing, Phlebotomy, Sample Processing, and Advanced Chemistry Laboratory. We plan to conduct another survey in 2019.

CHANGES IN THE PAST YEAR

Transition to a Service-Center Model: In May 2018, the JH CRUs transitioned to a service center model in which services that were previously provided free of charge are now available for a fee. These changes were mandated by our funding agency the [National Center for Advancing Translational Sciences \(NCATS\)](#) of the NIH and have been implemented at multiple institutions across the country who are supported by the [Clinical and Translational Science Award \(CTSA\)](#) program.

In determining the fee schedule, the JH CRU administration sought to find prices that were fair and affordable to investigators, comparable to our peer institutions and compatible with financially sustaining CRU resources. Nicole Cooper, our Senior Administrative Manager, who was previously in charge of a service center in the Department of Radiology has been instrumental in this transition and is available to answer any questions about these changes (ncooper2@jhmi.edu). 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

Pending funding, we plan to roll out a grant program that awards CRU resources through a competitive application process. More details will be available in the upcoming months.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

For investigators who are submitting a grant application and plan to use JH CRU services, Ms Cooper is available to help develop a budget for CRU services. . 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/)

Questions about the CRUs can be directed towards the faculty administrators.

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