



An Introduction to BMC's New Clinical Research Unit

Re-thinking the advancement of medicine with and for all people



Clinical Research Unit Team



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Medical Director



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Clinical Director



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Dean Robinson
Financial Analyst



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Director, Research Lab
Services Core



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Together, the Center for Clinical Research Advancement accelerates inclusive and high-performing clinical trial growth at BMC

Comprehensive core model comprised of staffing & clinical trial infrastructure

Provide innovative clinical trial staffing solutions that incorporate traditional CT metrics of high performance with inclusive methods to engage all people in every phase of the clinical research lifecycle



Forging ahead efficient clinical trials administration

Build life science partnerships, oversee industry-initiated clinical trial negotiations and financials, ensure compliant billing, meanwhile, develop supportive environment for hospital and university colleagues to perform clinical research at BMC



Offering leading-edge research in our patient's trusted environment

High-quality, service-centered, compliant, code response ready, research-skilled and clinically experienced staff

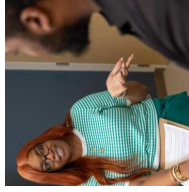
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Inclusive Science Model, building a local framework for national influence



Accelerate BMC Scientific discovery through infrastructure building

- Investments in Research and Sponsored Programs Department, expert administrators seeking efficiency and effectiveness
- Opening of Clinical Research Unit Nov 2024
- Identify partners who share our vision to advance medicine for all



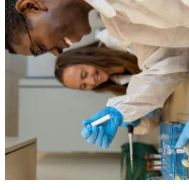
Re-think community engagement and research practices

- Incorporate community engaged methods into standardized approaches to CT operations
- Developed nationwide interpreter services research training
- Collaborate with BMC and BU Community Engagement teams
- Cultivate authentic relationships with community partners



Reflect richness of BMC community in research workforce

- Partner with African Bridge Network to support career development of the skilled immigrant workforce in key Clinical Research Professional roles
- Build multi-lingual, multicultural workforce that strengthens trusted relationships with our patients



Participate and drive clinical trial innovation

- Offer cutting-edge research as part of our clinical care model for the betterment of science and all communities
- Experience builds upon itself, supporting portfolio growth in areas of focus
- Widen BMC brand awareness around clinical therapies we offer through our research participation

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Clinical Research Unit, a welcoming environment in our pt's medical home

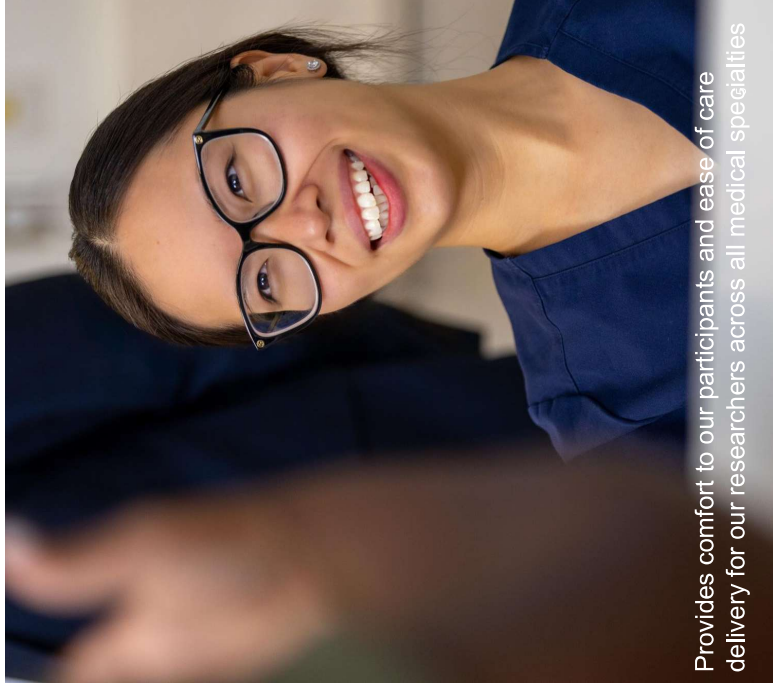
3,000 sq. ft. state-of-the-art clinic located on Yawkey 6

Safe, high-quality, compliant, code response ready, service excellence-focused, skilled and experienced staff

Supports **phase I-IV trials**, permitting portfolio growth across all indications and ages

Unit Capabilities

- Highly trained inpatient nurses for adult and pediatric participants
- Research Clinical Coordinators to support visits
- Potential for the conduct of 24-hour studies, such as pharmacokinetic studies
- Access to emergency response teams facilitating the conduct of higher risk studies
- Clinic exam rooms
- Medication and nutrition stations
- Phlebotomy and lab processing



Provides comfort to our participants and ease of care delivery for our researchers across all medical specialties



BMC CRU and BU CTSI

- We are excited to announce BMC's most recent research infrastructure expansion with the opening of the Clinical Research Unit (CRU) on the 6th floor of the Yawkey Building, welcoming our first patients on Nov. 5, 2024.
- The CRU will focus on higher-risk studies, complementing the existing General Clinical Research Unit (GCRU) at the BU Clinical & Translational Science Institute (CTSI), which handles lower-risk studies.
- Both units are staffed by highly trained professionals, the CRU offers overnight observation and advanced care. This collaboration enhances access to services that prioritize safety and clinical efficiency for researchers and participants.



FAQ(s)

Where are the research units located? The CRU at BMC is located on the 6th floor of the Yawkey Building. The GCRU at BU CTSI is housed on the 8th floor of the Evans Building.

If I have an existing study at the GCRU, what will happen to my study? The CRU at BMC and GCRU at BU CTSI teams are collaborating to transition all higher-risk studies to the new unit. If your study is affected, you will be notified in advance of the move to the CRU. You will receive relevant information about the transition and have the opportunity to ask questions to ensure a smooth process with minimal impact on research participants. The expanded hours at the new CRU will offer more scheduling options, including overnight observation. Additional details on scheduling options will be provided for impacted studies.



What are the costs for CRU services? For contracts negotiated before Jan. 1, 2025, studies will continue to be charged the current GCRU at BU rates for the course of their study. Starting Jan. 1, 2025, any studies using CRU at BMC space or services being negotiated will be subject to the new rates for services associated with the CRU at BMC.

Single Intake Form



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FAQ(s) - Continued

Do I get to choose where my study is conducted and/or how is the decision made about which unit is best for my study?

If you are initiating a new clinical study, please complete the [Intake Form](#), which will be reviewed by clinical staff from both the CRU at BMC and the GCRU at BU CTSI teams. A location determination will be made based on the protocol's risk level. Once a decision is reached, you and your study team will be notified and provided with further details. Scan the QR code below to view the intake form.

Single Intake Form



Contact information

CRU at BMC, contact Anh Tran, Clinical Director, Anh.Tran@bmc.org

GCRU at BU CTSI, contact Ridiane Denis, Director of Clinical Research Operations, ridianed@bu.edu

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- Continue to schedule through WebCAMP.
 - Please enter ALL requests under “YCRU”

- Our long-term plan is to streamline systems and migrate scheduling into Epic.





DOA and training logs

Represent CRU on DOA and Training Logs by listing CRU Medical Director only

- Obtain the signature of managerial or supervisory staff member(s) who takes accountability for training and performance within the department
- Extend this to IPS and other departments as viable
 - Allow study teams to use the DOA template of their choosing

Track clinical skills/competencies internally at CRU so 'delegated tasks' are appropriate

- Maintain Research Activity Profile for each CRU staff member
- Lists clinical skills/competencies for each individual member
 - Signed by CRU Medical Director and resigned if any changes or updates
 - Documents appropriateness of that staff member to complete the study tasks they are performing in the unit

Document CRU staff assignments and training to specific studies internally

- Maintain CRU Study Delegation Grid and Training Logs
- Documents which studies CRU staff have been deemed appropriate to contribute to
 - Training Logs allow for updates with new protocol amendments
 - Accompanied by revision history to track changes and approval from CRU Medical Director



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Study supplies maintenance

- We ask the study team to drop off supplies (i.e., specimen collection kit, shipping box, nursing flowsheet) at latest 2pm the business day before the scheduled visit to allow time for visit preparation.
- CRU can accommodate supply storage of clinical and lab supplies of up to 2 days of scheduled visits at a time.
- Please indicate the following information upon drop off:
 - Visit date
 - BU IRB#
 - PI name
 - Participant ID
 - Visit ID



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Sample handling and processing

Local POC testing available in CRU (i.e., urine pregnancy, urinalysis, blood glucose) if indicated by the study protocol.

Other samples:

- CRU lab will be fully functional by the end of March 2025 and will be processing samples in the CRU space.



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Budgeting and Billing Oversight

The CRU FA will perform budget development and billing oversight of clinical trials flowing through the CRU. The CRU Financial Analyst (Dean Robinson) will:

- Conduct CRU core service price analysis, develop and support sponsor budget negotiations as needed.
- Generate monthly invoice that will be sent to the study teams for review and approval.
- Study team will be provided 5 business days to respond with any questions. After 5 business days (without additional question/query), the CRU will process charges.
- For any general budget or billing related question/concern you may have, feel free to reach out to Dean Robinson, CRU Financial Analyst (dean.robinson@bmc.org).



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Badge Access to CRU

Study teams will be provided access to the following badge readers in the CRU:

- Elevators to Yawkey 6
- The 2 doors to the unit
- Clinical Workroom
- Staff Breakroom

If you only have a BU ID, please complete the BMC Visiting Personnel Registration Form and follow the instructions to obtain BMC badge access. Once you have a BMC ID, contact Anh and Ryan to request CRU badge access.

Addendum

