Institutional Support and Resources for Human Subjects Research: Lightning Talks

June 14th, 2023

Intro and Expectations

- Will have a Q&A at the end – please hold all questions during the presentations.

Objectives

- Identify basic institutional resources for research at BU Medical Campus and BMC
- Learn best practices and recommendations on a variety of topics

- Clinical Trial Office (CTO)
- Clinical Research Network (CRN)
- General Clinical Research Unit (GCRU)
- Clinical Data Warehouse for Research (CDW)
- Investigational Pharmacy Services (IPS)
- ClinicalTrials.gov
- Medical Licensure
- Institutional Review Board (IRB)
- Standard Operating Procedures
- CRRO Services and Resources
- Question and Answer Period

Lightning Talks

CTO/CRN roles & responsibilities

Clinical Trial Financial Support

Pre and post-award financial support industry initiated Clinical Trials

- Clinical Trial Office (CTO)
  - Contract support and execution: CDA/NDA/CTA
  - Pre-award financial support: budget, coverage analysis, ancillary services, sponsor negotiations, OGC
  - Post-award financial support: Invoicing, AR, RNA, Expenses, Infor, departmental reporting, amendments

Clinical Research Operational Engagement

Led with community engaged values, driven by scientific outcomes

- CTO system oversight: Velos (CTMS), ClinCard (Pt reimbursement), Research Billing (Epic), Research Fee Schedule
- Collaborate with leadership: CTSI, CRRO, SPH, IRB, BMC, BU, Research Compliance, OGC, Chiefs/Chairs/PIs, Department, Administrators, VP Community Relations
- CR space requests
- Scientifically driven decision making to challenge best practices

Inclusive Clinical Research in Practice

Advancement of Science with and for all people

- Clinical Research Network (CRN)
  - Management of clinical trials for under-resourced, high-priority research
  - Community engagement centered around research

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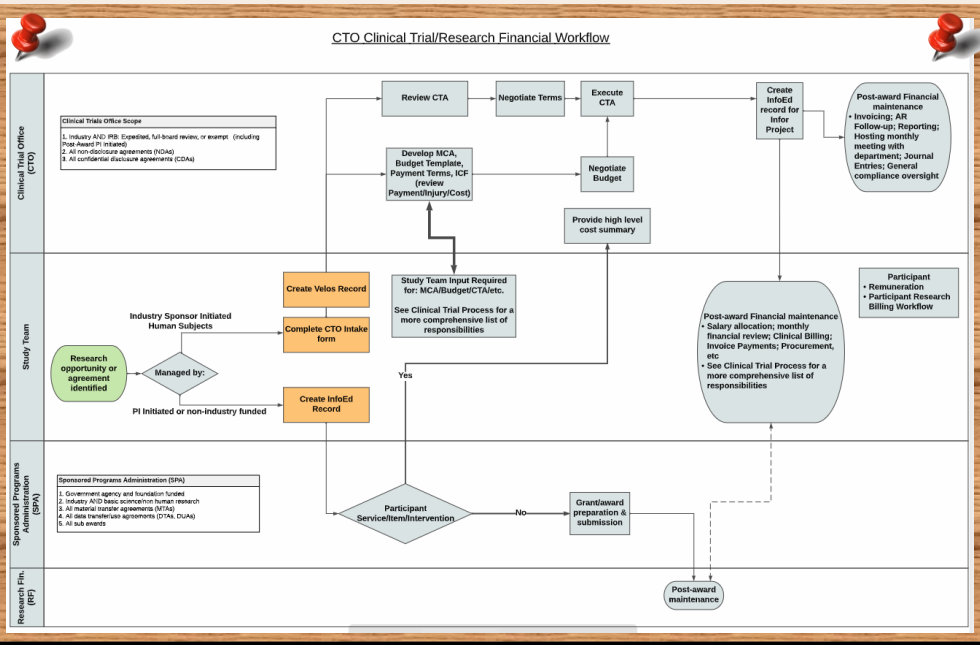
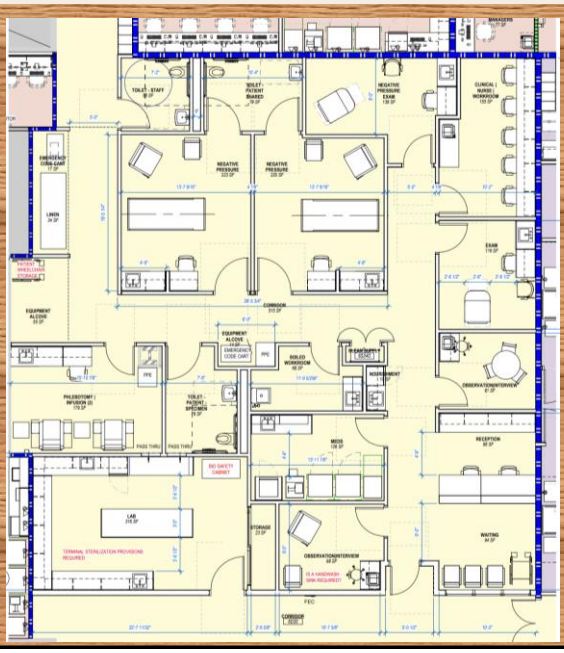
Community Artist, Cedric "Vise 1" Douglas

Clinical Trial Office (CTO) high-level workflow



Join Clinical Research Unit- DRAFT

- Leading co-drafting of JCRU space design on Yawkey 6
- Inpatient/outpatient centered in flexible unit design
- Grateful to departmental partners for valuable input
- Collaborating with CTSI on staffing and organization structure
- GCRU space will remain and space assignment workflow to be created



Seeking Research Community Advisement and Participation

Equitable Participant Reimbursement Working Group

Aimed as designing equitable research reimbursement processes

A interdisciplinary team gathers and divides high-priority projects into sub-committees

Welcome departmental representation, please contact for more information:

Bryant.Shields@bmc.org

Duncan.Shulte@bmc.org

Research Operations Advisory Committee

Research Operations will host their first researcher advisory meetings by the end of Q4

Intended to advise on Research Operation's decision making, and create a forum to listen to the needs of the community

Please, keep an eye out in the Research Operations Newsletter: *Research Matters* for more information

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Clinical Research Network Team & Responsibilities

The **Clinical Research Network** (CRN) represents BMC's commitment to community-engaged research values and innovative staffing solutions for institutionally prioritized and under resourced trials. The CRN is a centralized team serving BMC's researchers and our surrounding communities by re-thinking clinical research engagement practices and co-designing appropriate interventions. CRN offers services in the following areas:

Clinical Research Staffing: Providing BMC's researchers, sponsors, and the broader BMC community with high-quality staffing solutions to rapidly activate and manage our most complex and clinically important studies.

- ☑ Clinical Research Coordinator
- ☑ Regulatory/IRB Management
- ☑ Budget/Financial Management
- ☑ Community Engagement Planning & Deployment

Community Engagement: CRN is engaging with our community members and partners to understand their needs, interests, and beliefs to build trust in research, provide education and resources, and establish hospital infrastructure that supports inclusivity and community-guided research.

Inclusive Infrastructure Building: As an incubator for inclusive, high quality clinical trial practices at BMC, the CRN's goal is to improve diverse participation in research by building inclusive infrastructure within BMC and our communities.

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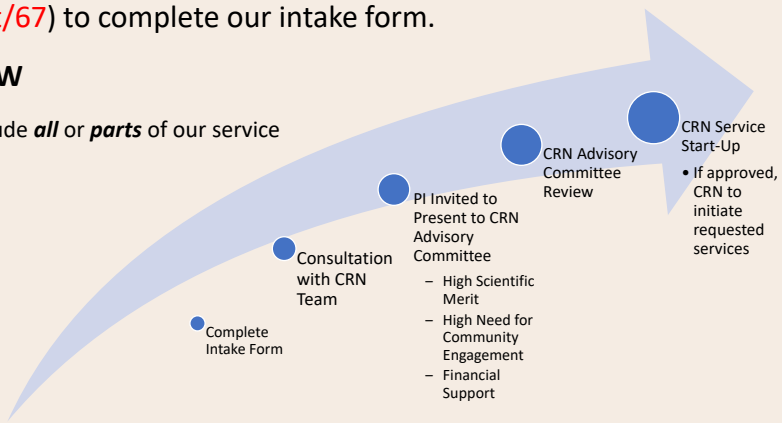
HOW TO PARTNER WITH THE CRN

If you are interested in requesting CRN research staffing, please click here (https://bmc.tfaforms.net/67) to complete our intake form.

CRN INTAKE WORKFLOW

- Note: CRN Services may include ***all*** or ***parts*** of our service capabilities



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GCRU Services & Training

GCRU services Within and Without Walls-BMC inpatient and ambulatory, BU Charles River Campus

- Research Navigator Team-IRB, recruitment, regulatory support, lab processing, visit support, consenting, data entry etc.
- Clinical services-Administration of investigational product, physical measurements and assessment, sample collection etc.
- Laboratory services – biological sample processing, handling, shipping, and storage long or short term
- Training-CPR, Phlebotomy with or without national certification, EKG

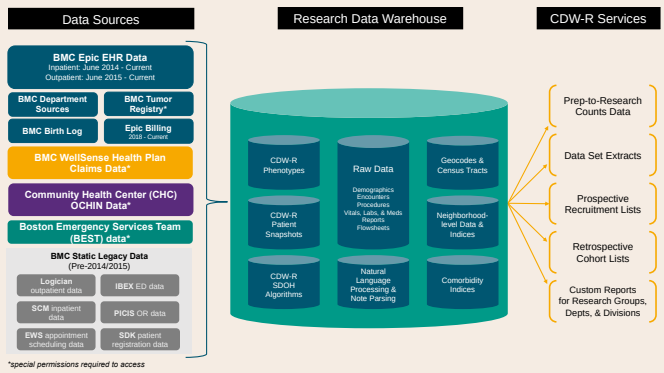
GCRU Updates

- Webcamp application process and timeline
- “A la Carte” scheduling fee
- Scheduling system changing from Access to Webcamp
- Billing and invoicing process change
  - BMC – Purchase Order process (cost center number and detail account number)
  - BU- currently journal upload, possibility of using ISR in the future

Information and training sessions and videos

BMC Clinical Data Warehouse for Research (CDW-R)

- Centralized resource to **access patient-level and population-level data for research.**
- CDW-R analysts **extract and link data** from various health system data streams:
  - BMC Epic electronic health record (EHR) data.
  - Historical data from legacy clinical systems.
  - Community Health Center (CHC) OCHIN EHR data.
  - BMC WellSense Health Plan claims data.
- CDW-R develops **algorithms and phenotypes for identifying patients, characteristics, and conditions** – improving data capture and consistency.
- CDW-R collaborates with Departments, Divisions, and research groups to **increase research infrastructure** and **better leverage data for research.**



CDW-R Recruitment Services: Medical Record Pre-Screens & Study Recruitment Lists

CDW-R recruitment services assist research teams in identifying cohorts of patients that meet study eligibility criteria and provides recurring, prospective patient lists to facilitate study screening, recruitment, and enrollment.

- CDW-R queries the data warehouse to apply study inclusion/exclusion criteria and identify patients who may be eligible for study enrollment.
  - Efficiently identify patients eligible for targeted recruitment – potentially mitigating need for manual chart review.
- Recruitment lists provided by the CDW-R to study teams can include*:
  - Patient demographics (age, race, ethnicity, insurance information)
  - Patient inclusion criterion values (e.g., specific diagnoses, conditions, circumstances; lab values; health care utilization and/or provider information)
  - Patient (and/or parent/guardian) contact information, such as:
    - Mailing address for opt-out letters
    - MyChart status
    - Phone numbers
    - Upcoming clinical appointment schedule and information, including date/time, location, department/clinic, provider
  - Other basic inclusion criteria as available in the data warehouse
- CDW-R aims to begin providing prospective recruitment lists to study teams within 2-3 weeks of data request finalization.
- Recruitment lists provided weekly, monthly, bi-monthly, or quarterly – depending on study team's goals and needs.

**As permitted by study's IRB*

What is the Role of IPS at BMC?

- Provide support for all clinical drug studies conducted at BU/BMC.
- Responsible for the Receipt, Storage, Accountability, Dispensing and Disposition of all research-related drug products.
- Ensure the investigational products are used appropriately to maximize study human subject protection.
- Ensure compliance with applicable regulatory and protocol requirements regarding the use of investigational products.

What Services Does IPS Offer?

- Study Start-Up/Close-Out
- Inventory Control/Storage
- Assist with database maintenance (Vestigo, EPIC)
- Regulatory Documentation
- Dispensing and Accountability
- Randomization
- Blinding
- Compounding/Repackaging (if feasible)
- Collaborating with monitors and auditors for site and remote visits.
- Providing tours for site qualification visits
- IRB membership
- Protocol Training

A New Look and Enhanced Enforcement for ClinicalTrials.gov

CTgov Modernization Initiative (2019-24)

- NLM is modernizing ClinicalTrials.gov and the components of the information submission system/the Protocol Registration and Results System (PRS) to:
  - Introduce users to the new technology platforms and evaluate their real-world performance; and
  - Provide foundational features that will be expanded over time; and
  - Provide PRS users with improved functionality to manage their record portfolios and workflows, and;
  - Collect user input to inform future development activities.
- The modernized CTgov website will go live in June 2023, and the PRS in 2024.
- Look for 3-part CR TIMES series in Fall 2023

CTgov Enhanced Enforcement (ACT & NIH)

- As of Apr 2021, Applicable Clinical Trials (ACTs-studying an FDA regulated drug or device) that are not kept updated receive a Notice of Noncompliance.
  - If results are not posted within 30 days, civil penalties of $13,237/day can be imposed.
- As of Oct 2021, enhanced checks on non-compliance with CTgov registration, updating, and reporting, and harmonization of information between CTgov and the eRA Human Subjects System/ASSIST system.
  - NIH/POs email PIs if information is late or not harmonized between the two databases and until resolved the RPPR submission could be delayed and NIH funds withheld (see the NIH guide notice NOT-OD-22-008 for additional details).

The Massachusetts Controlled Substances Registration (MCSR) Research License Application System is Now Online

- In MA, any drug used as an intervention in a research study is considered a 'controlled substance' and per MA law, the PI of that research must be covered by an active MCSR Research License.
  - If the drug research involves an IND -*no matter who holds the IND- the PI must have an active individual MCSR Research License;* there are still 2 umbrella/institutional MCSR Licenses to cover non-IND drug research studies
  - IPS will not release the study drug/s unless there is an active MCSR Research License
- In March 2023, the MCSR Research licensing system, that was previously paper-based, transitioned to an online licensing system. PIs are now required to apply, renew, and amend all MCSR Research licenses online through the MDPH eLicensing System.
  - No documents should be mailed or delivered to the MDPH
  - Payment of the $150 annual fee must be made online by credit/debit card or ACH/electronic check
  - Verification of any license can be done online
- BMC/BUMC OHRA provides support, maintains oversight, and monitors compliance

Measure Twice, Cut Once:
Tips for a successful IRB submission

- Submissions to the IRB can be challenging
- The IRB team and panels are wholeheartedly dedicated to approving your study as fast as possible – once it is ready!
- Common issues appear in every type of submission
- Before your next submission, read this CR Times article:
  - *Avoiding & Responding to the Most Common IRB Application Stipulations*
  - January/February 2023 Issue
  - bit.ly/CommonStips

Before you submit to the IRB... **CREMATE** your study

C - consistent (make sure all parts of the submission are harmonized)
R - reread (take a thorough look at everything before you submit)
E - engage with instructions (read the entire question before answering and make sure you've addressed every part of the question)
M - missing information (make sure there are no blank sections, unattached documents, or details missing that we would need to assess the study)
A - allow time for routing & reviewing (submit early because it takes time to obtain signoffs from stakeholders and for us to review it)
T - templates (make sure you're using our templates for consents, protocols, scripts, etc – coming soon: opt-out letter!)
E - elementary (write your application so we can understand it - don't copy from your grant; write your ICF so an 8th grader can read it with ease).

Standard Operating Procedures (SOPs)

- Cross-institutional collaboration between Boston Medical Center and Boston University Medical Campus
- Set of written instructions
  - Documents routine activity
  - Used by an organization to ensure compliance with regulations/policies, etc.
- Guidance for a research team
  - How to complete some of the daily activities
  - How to complete structural activities

Adverse Event Monitoring, Assessing, and Reporting
Case Report Form Completion
Delegation of Authority and Responsibilities
Essential Research Documents
External Audit Preparation
Informed Consent Process
Institutional Research Policies and Guidance Documents
Participant Withdrawal
Protocol Deviation Reporting
Quality Management
Research Team Competency
Research Training
Site Monitoring Visits
SOP Management
Subject Recruitment

SOPs – Importance and Value

- Framework for excellence in research
- Part of a successful quality system
  - provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of work performed
- Promotes consistency/reproducibility in conducting the study
- Reduce errors/reduce non-compliance
- Protects safety and rights of participants,
- Ensures quality/reliability of the data

- Provides – overall foundational learning and context
- Provide less experienced research teams or staff learning in best practices
  - Information that can be referenced continually when questions or new situations come up
- Enhanced performance, confidence, efficiency of staff
- Provides external teams (industry sponsors and lead teams) with assurance of the high-quality work and written documentation of procedures

Institutional requirement – Effective as of January 1st, 2023 (based on scope)

SOP – Scope and Format

Scope

Specifically guide clinical research studies that target BMC patients, use BMC patient data, or utilize BMC facilities and/or services

- BMC patient: any individual with a clinical encounter generating a BMC-specific medical record
- BMC patient data: patient data that is derived from BMC medical records and/or systems
- BMC facilities: clinical or non-clinical space owned or operated by BMC
- BMC services: a unit or group operated or managed primarily by BMC staff

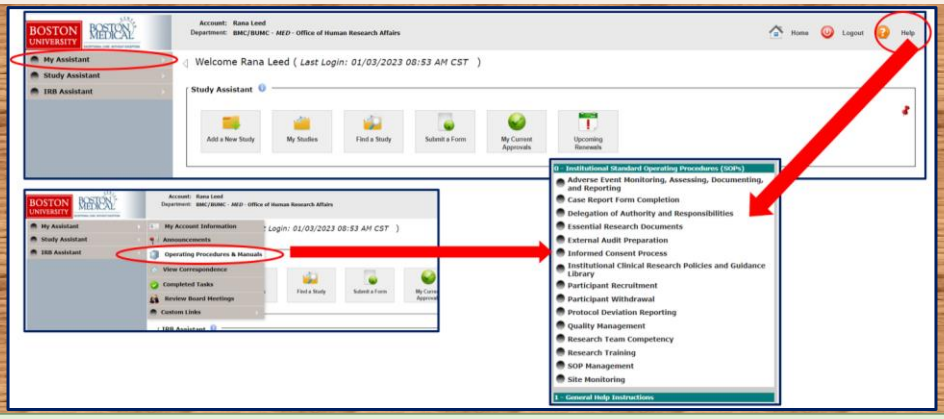
Format

- *Purpose/Objective*: Explains briefly what the SOP will include and the intent
- *Scope*: Includes which studies the SOP applies to as referenced above
- *Responsibility*: Provides information on whose responsibility it is to follow the procedures in the SOP
- *Procedures*: Contains the primary information and details of how to complete the procedure or process
- *Definitions, References, and Resources*: Includes additional details and links, but not all SOPs will have information in these three sections

Recommendation

➢ SOPs provide excellent guidance for studies that are outside of the scope and can be followed/used for any study

SOPs – How to Access Within INSPIR



<u>Two different pathways –</u>

- My Assistant → Operating Procedures & Manuals – only available within the "home screen"
- Help – always available, even within "study screens"
- Recommend NOT downloading and saving – should always use INSPIR pathways to ensure correct version is being used

SOPs – Training

CITI Modules – "Question 10"

- 2 levels
  - Fundamental: all SOPs must be reviewed and acknowledged
  - Abbreviated: Subset of SOPs must be reviewed and acknowledged (for those conducting only studies that are limited to data and/or specimen analysis)
- Training will be required to be completed according to the following time-frames:
  - <u>January 1, 2024</u>: all new studies targeting BMC patients, utilizing BMC facilities and/or services, or using BMC patient data will require completion of training prior to IRB approval
  - <u>January 1, 2024</u>: new BMC employees working on studies within scope are required to complete training within 90-days of employment start date
  - <u>December 31, 2024</u>: existing clinical research investigators and staff are encouraged to complete
- Review the *Research Training* SOP for more details

SOP Resources

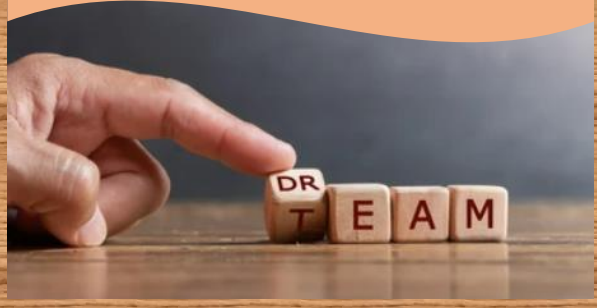
- Institutional Standard Operating Procedures (SOPs) webpage for more info
- Clinical Research Times
  - Feature Article December 2022
  - Monthly Spotlight on SOPs
- Clinical Research Seminar November 2022
- Feedback Intake Form for suggestions and recommendations
- Email CRRO for targeted training on a specific SOP or procedure

Clinical Research Resources Office (CRRO)

- Supported by the BU CTSI and the Office of Human Research Affairs
- Provides a range of services, resources and guidance to support BMC and BU Medical Campus clinical researchers
- Provide guidance on planning, submitting, implementing, and conducting research

Zoom Office Hours: Mondays, 4pm

- Mary-Tara Roth, RN, MSN, MPH – Director
- Rana Leed, MPH – Human Research Education Manager
- Marena Neggers – Regulatory Coordinator



CRRO Clinical Research Resources Office

CRRO Resources → Consultations

- Obtain expert review and guidance for investigators and research staff
- Consultations can be requested at any point during the life of a study and for any reason
- Any member of a study team or research staff member may request a consultation
- For simple questions, consultations will be completed over email but most generally involve at least one meeting or more depending upon the complexity of the request
- For investigators with funding or submission deadlines, it is recommended that consultations are requested early in the process to best meet those deadlines

➢ To request a consultation, complete the Request CRRO Services form

Required Review for Investigator-Initiated Clinical Trials	IRB Submissions	Study Implementation: either before or after start of recruitment and enrollment	BMC SOP Guidance	FDA Guidance
• Per HRPP policy 6.2.1.2, a study meeting the definition of a clinical trial that is initiated by the PI at Boston Medical Center or Boston University Medical Campus must complete a CRRO consultation prior to IRB review	• Could include review of INSPIR application, protocol, consent, or any other study-specific document • Could be an initial submission, CAPA submission, or protocol amendments • Could include review of stipulations from any IRB review	• Recruitment plans either for feasibility or slower than expected enrollment rates • Consenting processes • Eligibility determinations and documentation • Adverse events monitoring, assessing, and reporting • General study documentation include setup of participant or regulatory files	• Implementation and completion of standards set in Quality Management and Research Team Competency SOPs • General review and compliance recommendations for any SOP	• Responsibilities of a Sponsor-Investigators holding an IND or IDE • Review of initial or ongoing submissions

CRRO Resources → Education and Training

Registrations Open Currently (In-Person and Zoom) → Summer Sessions – July 2023

Multi-Site Studies: Exponentially More Work and More Fun Than Single-Site Studies (7/17)

- Attendees will learn best practices and for successful multi-site study management including staffing and communications, documentation, and IRB review and reliance.
- Using a mix of presentations and case study review, this session will include recommendations for feasibility and site selection, startup, and active enrollment.

Everything You Always Wanted to Know But Were Afraid to Ask: A Focus on Study Documents (7/18)

- Attendees will review the various types of study documents and best practices for developing and managing them in both Word and REDCap.
- Using a mix of presentations and live demonstrations, this session will include recommendations for protocols, consents, and various logs and forms.

CRRO Resources → Education and Training

Schedule and Agenda for Academic Year 2023-2024 being developed currently

Principal Investigator Training

- Offered quarterly, one 3.5 hour session
- Focus on PI's oversight responsibility and current regulations and best practices as well as providing tools and resources for successful study implementation

Fundamentals Training

- Offered quarterly, four 2.5 hour sessions
- Current regulations and best practices as well as providing tools and resources for successful study implementation

Sponsor-Investigator Training

- Upon request only, required for investigators holding their own IND or IDE

Custom or Departmental Training

- Upon request only, based on needs of study teams or other units or groups

Research Professional Network Workshop

- Offered monthly, focused on topics relevant to research staff, peer-led through inter-institutional collaboration
- Library of previous workshops available

Clinical Research Seminar

- Offered monthly, forum to discuss important ethical, regulatory, or operational research topics
- Library of previous seminars available

CRRO Resources → Tools, Templates, and Guidance

eConsent Guidance

- Overview
- Non-Exempt
- Exempt

Self-Assessment Review Tools

- Overview Instructions and Review Plan
- Informed Consent
- Participant Eligibility
- Protocol Adherence

Participant-Related Files

- Research Subject Eligibility Assessment Form
- Documentation of Informed Consent Tool
- Documentation of Pregnancy Testing
- Note to File Template

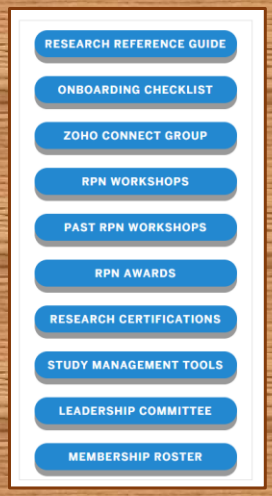
Regulatory-Related Files *(not full list)*

- Regulatory Binder tools (Tabs, FAQ, Using REDCap)
- Logs
  - Delegation of Authority
  - Communications
  - Participant (Study ID, Screening, Enrollment)
  - IRB Submissions
  - Adverse Event Tracking
  - Deviation Tracking
  - Training
- Templates
  - Data and Safety Monitoring Plan
  - Study-Related Standard Operating Procedures

- Tools can help develop the set of "Essential Documents" based on ICH Good Clinical Practice standards
- Tools can help meet protocol and regulatory standards to ensure valid and reliable data
- CRRO can provide training and assistance with editing on any of the templated forms and tools

Research Professionals Network (RPN)

- Primary audience is clinical research staff (coordinators, research assistances, mangers, etc)
  - Provide professional development opportunities including mentoring and networking
  - Increase awareness and communication of best practices to promote overall wellbeing and protection of participant rights as well as successful recruitment and retention
  - Maximize satisfaction and productivity of all members of the research team through sharing of resources
- Main services and resources
  - Workshops
  - Onboarding Checklist
  - Research Reference Guide
- Join the RPN – Become a Member



Wrap-Up

- Contact Information and Additional Resources will be available in full slide set posted to Seminar Library.
- Planning for 2023-2024 seminar calendar is ongoing – provide suggestions on Evaluation Survey.

Thank you to our Lightning Talk Presenters

CTO	CRN	GCRU	CDW	IPS	ClinicalTrials.gov	MCSR Research License	SOPS	CRRO Resources
Johanna Chesley Michael Porreca	Ryan Schroeder	Ridiane Denis	Erin Ashe	Husam Dennaoui	Matthew Ogrodnik on behalf of Karla Damus	Matthew Ogrodnik on behalf of Karla Damus	Mary-Tara Roth	Rana Leed

CTO Resources and Contacts

Johanna Chesley, MPH
Senior Director, Clinical Trial Office
960 Massachusetts Ave, 2nd floor
Johanna.Chesley@bmc.org

Mike Porreca
Senior Manager, Clinical Trial Office
960 Massachusetts Ave, 2nd floor
Michael.Porreca@bmc.org

CTO Resources

- Email: clinicaltrialoffice@bmc.org
- CDA Intake Form: https://bmc.tfaforms.net/f/forms-research-cda-nda-intake
- CTO Intake Form: https://bmc.tfaforms.net/46
- Research Operations Director & Portfolio Distribution: https://www.bmc.org/sites/default/files/Research/documents/Combined_Assignment_List.xlsx

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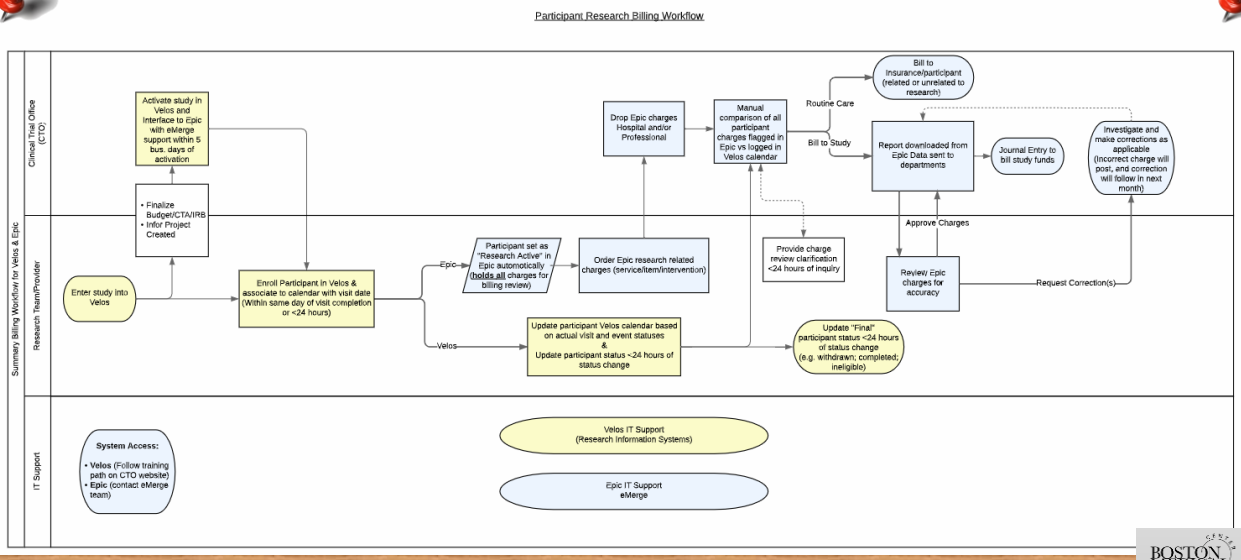
CTO Addendum- Clinical Trial Process

	Feasibility Assessment	Study Start-up	Study Management	Study Closure
Clinical Trial Office (CTO)		**Clinical Trial Office** **Coverage Analysis** • Qualifying CT review • Reimbursement analysis • PI review, sign-off **Budget (Template)** • Patient charge research fee schedule • Protocol billing grid creation • Internal/External Budget • Notice to legal, regulatory • Internal budget • CT terms negotiation • Lead Budget negotiations • Confirm Budget Final **Clinical Trial Agreement (CTA)** • CTA Terms Negotiation • CTA Executed	**Clinical Trial Office** • Internal study setup after execution: ◦ InfoEd record creation ◦ Velos Calendar creation ◦ Epic activation (if applicable) ◦ ClinCard Setup (if applicable) • Post Execution Management: ◦ Comparison of Epic charges and visit log; square issues • See Research Billing Workflow ◦ Invoice Sponsor and Apply Revenue ◦ Track "automatic" payment collection and review ◦ Route approves per study visit record in Velos ◦ QA of first participant's claims ◦ Ensure expected charges are present and none are missing ◦ Identify inaccurate charging and correct ◦ Reconcile study and visit level revenue and expenses ◦ Process expense payments	**Clinical Trial Office** • Confirm with study team that contractual obligations have been met and all outstanding AR are collected • Complete closeout package • Transfer deficit/residual balance if applicable • Close study in Velos/InfoEd/Infor/Epic
Study Team*	**Dept. CT Interest** • Industry initiated (PI initiated or sub-awards with human subject research work with SPA/CTO) • NDA/CDA Form • Feasibility Review • Queue up review teams (legal, regulatory, privacy, CA) • CTO Intake Form • CRN Intake Form when applicable • Dept. Leadership Approval ***Study team may include CRN staff for all or some responsibilities. Please complete the CRN Intake form if you are interested in utilizing their services.**	**Budget (Template)** • Confirm coverage analysis accuracy • Confirm visit and event effort cost accuracy • Provide justifications as necessary • Confirm final Budget #'s • Ancillary service form submission(s) and confirmation of services & pricing • Community engagement costs **Clinical Trial Agreement (CTA)** • Review and provide feedback (e.g. document storage, milestone payments, data entry, etc.) • Confirm final CTA terms **Regulatory, Document Alignment & Billing Prep** • CITI, GCP • IRB Submission • Regulatory Binder • Verify and document alignment of PBG, ICF, CTA • Complete electronic billing assignments • IRB Approval • Study Initiation Visit (SIV) • Study Activation letter • Protocol Training • Internal Training (CRRO, SOP, CITI, etc) • Internal/External System Access & Training	**Study Team*** • Participant reimbursement (see link) ◦ ClinCard Request (if applicable) ◦ Other (Food voucher, Cab voucher, Uber Health) • Pre-Screening • Participant consent • Community engagement • Enroll patient into Velos, triggering Epic Research Flag • Schedule Epic Visit • Track all protocol related visits and status into Velos study visit logging • Complete Participant status updates in Velos • Complete CRF / ECRF • Data Queries • AE Submission • Amendment initiation • Monitoring • FDA/Sponsor Audits • Monthly Financial Review ◦ Salary allocation/Effort tracking ◦ Review Epic Charges (see Research Billing Workflow)	**Study Team*** • Reconcile and confirm that: ◦ All program work has been completed ◦ All payments from the sponsor have been received and posted to the project ◦ All allocable and allowable expenditures have been charged to the project ◦ Residual Balance Form ◦ Residual Balance Policy

Required Completions:
- CTA Executed
- Budget Final
- IRB Approval
- Study Initiation Visit (SIV)
- Study Activation letter

CTO Addendum- Participant Research Billing Workflow



CTO Contacts and Resources

Ryan Schroeder
Director, Clinical Research Network
960 Massachusetts Ave, Boston MA
Ryan.Schroeder@bmc.org
(617) 414-7075

CRN Intake Form:
https://bmc.tfaforms.net/67

CRN Community Partners:

URBAN COLLEGE of Boston

BMA TENPOINT

UNION CAPITAL BOSTON

ABN

VITAL CxNS

the YMCA

EVERYDAY BOSTON

WE GOT US

IPS Contact Information

- IPS@bmc.org
- 617-638-6744

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  → Phone: 617.638.5957
  → Email: Samuel.Bliss@BMC.org

IPS Staff
- Husam Dennaoui, PharmD
- Michael Camuso, PharmD
- Ratna Dodhia, PharmD
- Nisha Verma, CPhT

Contact the BMC Clinical Data Warehouse for Research (CDW-R)

Erin Ashe, MPH

Program Director, CDW for Research

For questions or to schedule a consultation, email: cdw@bmc.org

For more information on CDW-R Services
or to submit a research data request: https://www.bmc.org/research/clinical-data-warehouse-cdw

GCRU Resources and Contacts

- Contact information
  - Ridiane Denis- 617-358-7558 ridianed@bu.edu
  - Nursing-Anh Tran-617-358-7597 anhltran@bu.edu
  - Laboratory-Della Carter-617-358-7579 djcarter@bu.edu
  - Billing/Invoicing Lea Bele-617-358-7563 lcbele@bu.edu

- Main GCRU
  - https://www.bu.edu/ctsi/support-for-research/ctsi-general-clinical-research-unit-gcru/
  - BUMCGCRC@bu.edu, 617-358-7560

OHRA Resources and Contacts for CTgov and MCSR Research Licenses

ClinicalTrials.gov/CTgov

- For questions/assistance to register, update/edit or submit results to CTgov, contact the BUMC/BMC CTgov Administrator, damusk@bu.edu, 358-5337 or the OHRA Director maogrodn@bu.edu, 358-6559
- www.bumc.bu.edu/ohra/clinicaltrials-gov
- CTgov related HRPP policies 6.6.9 Registering, Updating, and Posting Requirements for Clinical Trials
- https://clinicaltrials.gov
- Articles about CTgov in CR Times

MCSR Research Licenses

- For questions/assistance contact the BUMC/BMC MCSR Research Licensure Administrator, damusk@bu.edu, 358-5337 or the OHRA Director maogrodn@bu.edu, 358-6559
- www.bumc.bu.edu/ohra/massachusetts-controlled-substances-research-licenses
- www.mass.gov/mcsr-for-individuals
- www.mass.gov/info-details/health-professions-licensing-system-user-guide
- https://checkahealthlicense.mass.gov