Boston Medical Center
HEALTH SYSTEM

October 11th Research Admin Meeting

Boston Medical Center
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Agenda

9:00am – 10:00am

Welcome

Research Operations updates

10:00am – 10:30am

Research Policy Socialization

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Welcome!

BOSTON MEDICAL CENTER

Research Operations Updates

Oct 11, 2022

FY22: Reflection

Recruit! Recruit! Recruit!

- Focused on filling vacancies across the team
- Develop and retain talent
- Invest in workforce
- Kicked off onboarding comprehensive plan
  - Started pilot with new hires

FY22: Reflection

Discovery! Discovery! Discovery!

- Focused on learning BMC's culture, practice, and research infrastructure capabilities
- Kicked off Website re-design project
  - Expected launch, Dec 2022
- Standardized document repository

FY22: Reflection

Challenges and Opportunities

- Systems Integration
- Policies and Procedures
- Training and Education
- Workflow Silos
- Backlog Management
- Compromised Service Levels

FY22: Reflection

Where are we Heading?

- Systems Optimization
- Process Improvement
- Eliminate manual workflows that contribute to silos and backlogs
- Data governance
- Research Metrics Dashboard
- Optimize Service Levels
- Communication
- Targeted Training and Education
- Establish Best Practice
- Strengthen Infrastructure

Coming up – Dec Meeting

Overview of Research Portfolio

Sponsored Programs Administration

Mahara R. Pinheiro, Director, Sponsored Programs Administration
Vanessa Rubin, Team Lead, Sponsored Programs Administration

Sponsored Programs Administration Updates

Staffing Updates

- Vanessa Rubin, Team Lead, Sponsored Programs Administration
- Maria Chitsaz, Senior Grants and Contracts Administration
- Sarah Pearce, Grants and Contracts Administration

***Revised* Subcontracts Workflow**

- SPA will be releasing information regarding the revised subcontract workflow in October 2022.
- SPA will be offering a drop-in session in October 2022.

Data Management and Sharing Policy

- SPA will be offering drop-in sessions in November and December of 2022.

NIH Policy for Data Management and Sharing (DMS Policy) – FORMS H

- **Submission** of Data Management & Sharing Plan with all applications for funding beginning January 25, 2023.
- NOT-OD-22-189

- **Compliance** with the Data Management and Sharing Plan approved by the funding NIH Institute, Center, or Office.
- **DMS Policy:** Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of "**scientific data**"
- "**Scientific data**" is defined as:
  - ***"The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."***

Activities Subject to the DMS Policy

APPLIES TO…

All research generating scientific data, including but not limited to:

- Research Projects
- Certain Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers

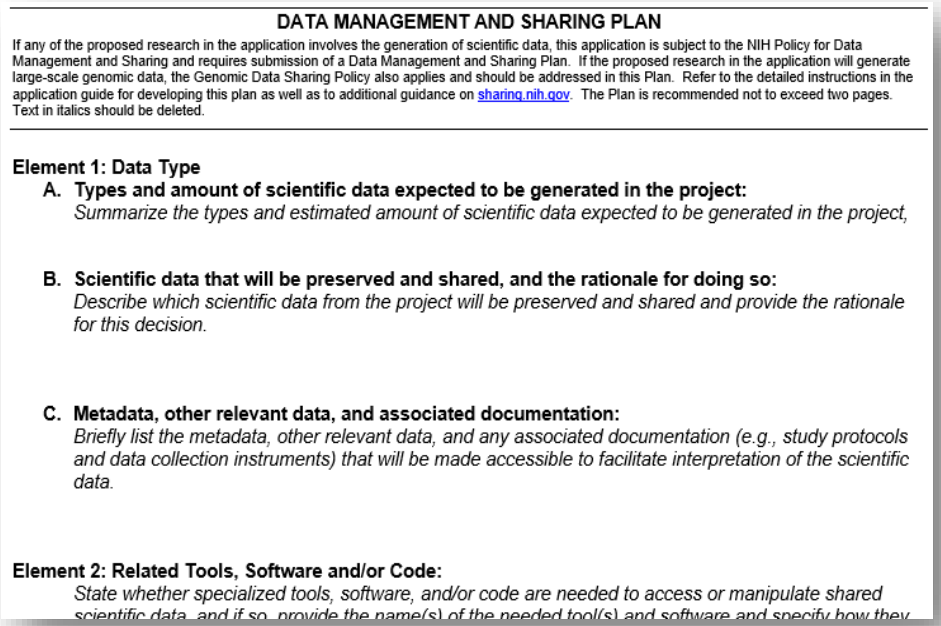
DOES NOT APPLY TO…

Research projects <u>not</u> generating scientific data or non-research projects, including but **<u>not</u>** limited to:

- Training (Ts)
- Fellowships (Fs)
- Certain non-research Career Awards (e.g., KM1)
- Construction (C06)
- Conference Grants (R13)
- Resources (Gs)
- Research-Related Infrastructure Programs (e.g., S06)

Format of a DMS Plan

- ✓ Plans should be no more than **2 pages** in length.
- ✓ Optional format page will be available.
- ✓ A preview of this format page is available now, with a final fillable format version available by Fall 2022.



DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. The Plan is recommended not to exceed two pages. Text in italics should be deleted.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project,

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

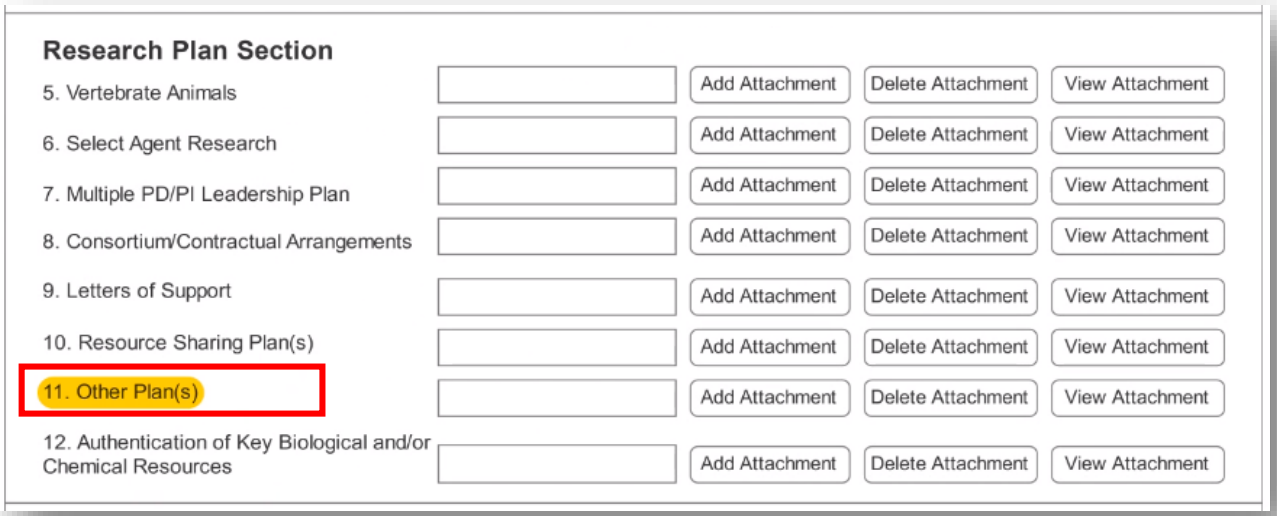
C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Element 2: Related Tools, Software and/or Code:
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they

DMS Plan format page will be added to list of Format Pages and incorporated into FORMS-H application instructions by Fall 2022

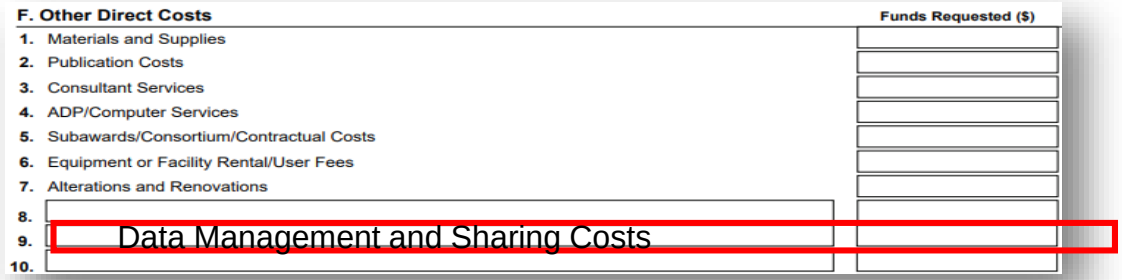
DMS Plan Submission

- A new "**Other Plan(s)**" field will be added to the PHS 398 form to collect a single PDF attachment.
- Data Sharing Plans and Genomic Data Sharing Plans (GDS) will no longer be submitted to the "Resource Sharing Plan(s)" field.



Submitting DMS Budgets

- Direct costs to support the activities proposed in the DMS Plan must be indicated as "**Data Management and Sharing Costs**"
  - **R&R Budget Form:** line item in section F. Other Direct Costs.
  - Brief summary of DMS Plan and description of DMS costs must be **included within the budget justification attachment.**

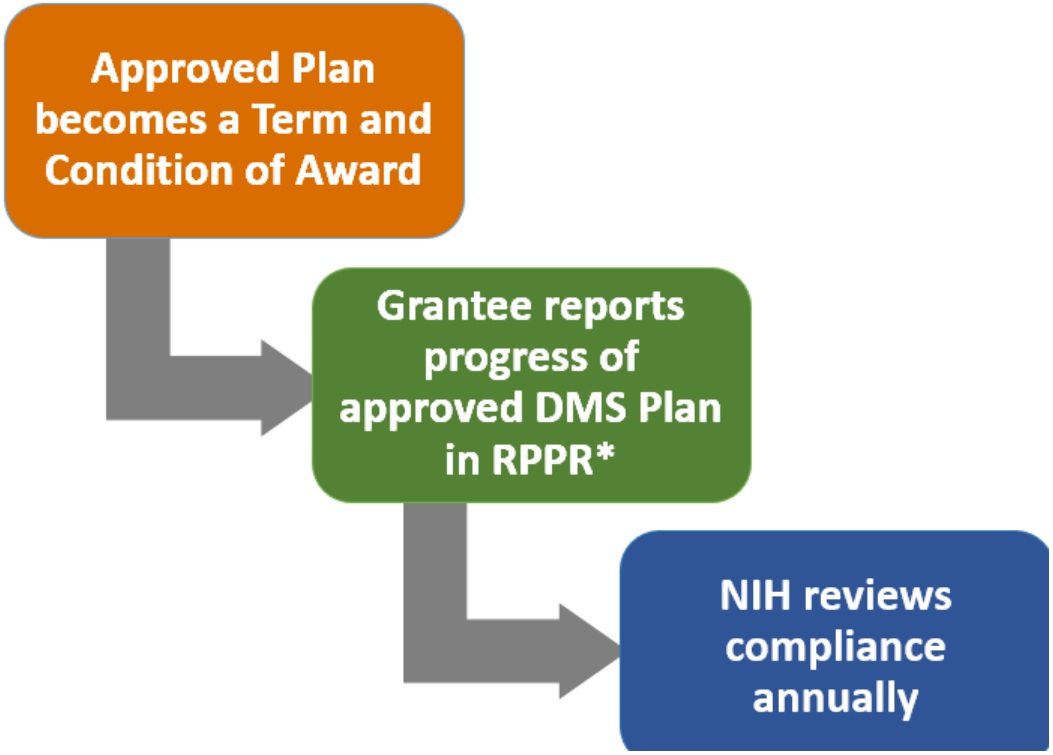


  - **PHS 398 Modular Budget Form:** within Additional Narrative Justification

DMS Plan Assessment

- NIH Institute, Center, or Office determine **if DMS Plan** is acceptable or unacceptable.
- Peer reviewers ONLY consider if **budget** is reasonable.
- DMS Plan must be approved prior to award.
- If additional details are needed, it may be necessary to communicate with NIH staff to resolve issues with DMS Plan.
  - Will occur through standard Just-In-Time (JIT) process.
- **When should I share my data?**
  - No later than the time of a **publication of findings** in a peer-reviewed journal OR at the **end of the award**, whichever comes first.

Monitoring Compliance



Failure to comply…. may result in an enforcement action, including additional special terms and conditions or termination of award, and may affect future funding decisions.

Resources

- **NIH Scientific Data Sharing**
- **Email Box:** Sharing@nih.gov
- FAQs
- NOT-OD-22-189
- Budgeting for Data Management & Sharing
- Writing a Data Management & Sharing Plan | Data Sharing (nih.gov)
- Which Policies Apply to My Research? | Data Sharing (nih.gov)
- NIH Institute and Center Data Sharing Policies | Data Sharing
- Repositories for Sharing Scientific Data | Data Sharing (nih.gov)
- FAQ on Noncompliance: Frequently Asked Questions (FAQs) | Data Sharing (nih.gov)

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Clinical Trial Office

Johanna Chesley & Michael Porreca

CTO Updates

- Introducing Cissy Ayebi, Research Operations Intern!
- Preparing CTO FY22 metrics – Dec 13th meeting
- VelosCT updates:
  - Epic interface issues and misbilling of research participant charges
  - VelosCT upgrade Oct 17th (tentative date)
    - Interface stability
    - Ability to use latest browsers
    - Enhanced user interface
  - No workflow changes with upgrade

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Clinical Research Network

Ryan Schroeder

CRN Updates

- Introducing Olanike (Nike “Knee-Kay”) Asupoto, Clinical Research Coordinator II
- Announcements/Updates:
  - Institutional Clinical Research SOPs Approved on 10/1
    - Next Steps:
      - Socializing with Departments
      - Training Infrastructure
      - BMC/BU Hosting of SOPs
  - Interpreter Research Training Series Launching 10/12

Boston Medical Center

Research Operations

Update: Policy, Education, and Communications

Kaye Mottola

Bi-monthly Meeting
11 October 2022

Policy, education, communications intersect in multiple initiatives

Eg, policy programming includes training and communications

- **Socialize** new and updated policy drafts, pre- and post-submission to committee
  - FY2022: benchmarking; draft updates to SMEs **– 1st communication**
  - Q1 FY2023 : add one general departmental reviewer per draft policy **– 2nd communication**
    - Track to ensure: all departments are invited to participate as policy drafts are prepared
  - Bi-monthly policy spotlights: **RO-departmental communication**
  - Under discussion: **communication methods** to share new and updated policies between **bi-monthlies**
  - **Website re-launch, Q1**: updated library of active policies

- Goal, FY 2023: provide multiple **job aids/trainings** for understanding policy
  - Q1 pilot: launch **Research Operations General Education (ROGE) trainings** on targeted policies
  - Future: assign **policy modules through Workday**

Policy, education, communications intersect in multiple initiatives

Eg, onboarding initiative, conceived in 2021, evolves

- Originally conceived as a **general research education curriculum** for NE
  - Common training for all roles: **~35% policy reviews**
  - Subsequent specialty trainings by role
- Q4 FY2022: onboarding **plan expands** and RO pilot commences:
  - Tracker adds business/tech needs, job-specific structures, **HM-NE reviews** to training curriculum
  - Common training for all roles (ROGE); job-specific by HM for individual NE
  - New RO employees (11) and HMs (4) test-drive draft template, provide feedback
  - RO directors confer on draft design for consensus improvements
- Q1 FY2023: **pilot adds two DRA NEs**: a grants administrator and research director
  - Draft template shared – to be customized as needed
  - NEs join orientation and basic classes
  - Department focus spotlights needed specifics: eg, robust InfoEd, Infor trainings

Onboarding plan aims at community building and job training

Multifold goals include:

1. Tear down silos, strengthen research **community and communications**
   - Acknowledges that job performance needs more than job-specifics
   - Builds **collegial relations** among and between teams and departments
   - Creates **shared general knowledge**: background, context, big-picture RA awareness
2. Enlighten RO and departments on crucial job-specific needs
   - Fosters collaboration and mutual responsibility to develop **role-specific training**
   - Identifies **training gaps** and works to fill them
3. Provide a multi-purpose onboarding template for department customization
   - Maps a multitude of tasks from pre-start through 13 weeks
   - Documents onboarding task completion
   - Suggests a model for ongoing **collaborative manager-employee job review**
4. Introduce salient **policies** to new employees
5. Suggest **training**, provide drafts for **ongoing employees**

Policy, education, communications intersections, continued

Eg, website redesign

- Website itself is a primary **communications tool**
  - RO teams rework content for **user ease** and **relevance**
  - Outdated materials to be replaced; new material added
    - Focus on **educating** and communicating
  - **Multiple routes** to individual items
- Team pages to provide team-specific, community-wide content
  - Primary content to **inform** and direct
  - **User-based** features
  - Prominent links to **policy, trainings, forms, resources** (eg, systems, SOPs)
- Separate systems page directs users to **electronic tools** for quick access
- **Policy, education, communications** page houses multiple **libraries**
  - Access directly or through team pages
  - Content available through **multiple means** (eg, RO team ownership, user role, general look-up)

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Research Technology Program (RTP) Updates

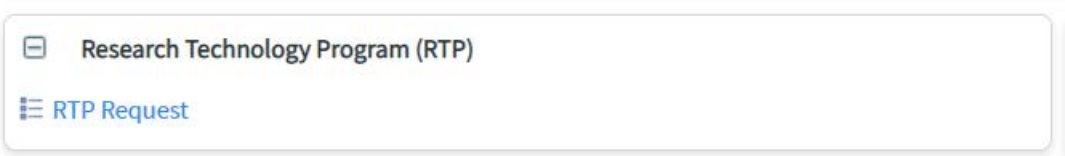
Caitlin Gaudreau

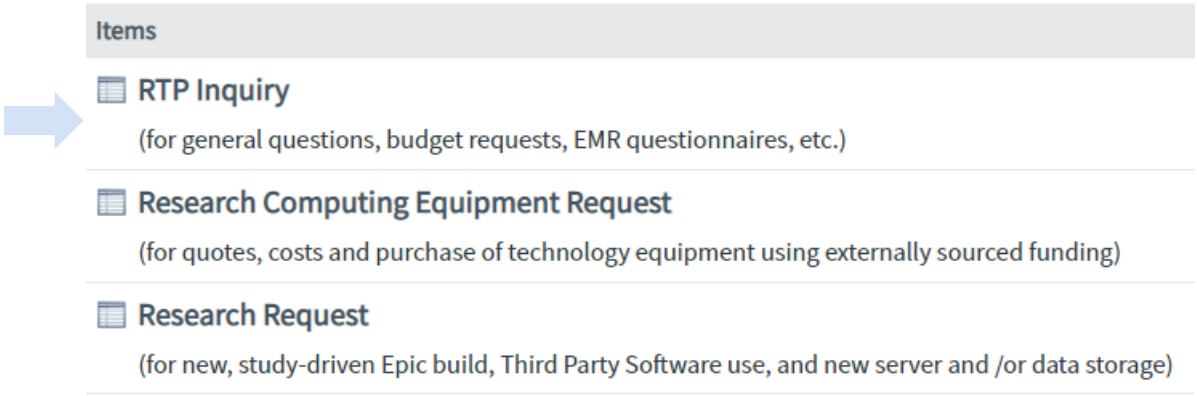
Research Technology Program (RTP) Updates

- **Information Security Review Update:**
  - We are simplifying what is requested of vendors in order for our Information Security team to perform an audit of new software
  - In lieu of the BMCHS Questionnaire, a vendor can provide a SOC 2 certification or a Third Party Assessment report to serve as their initial review
    - The BMCHS Questionnaire is still in use; however, in some circumstances it may be too in-depth (20+ pages)
    - If there are additional questions we may move forward with the questionnaire or meetings

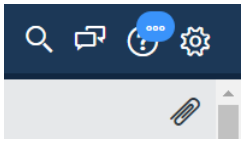
Research Technology Program (RTP) Updates

RTP has an improved presence in the [BMC Service Catalog]:





- 'RTP Inquiry' can be used in lieu of sending an E-Mail
  - Ensures RTP team is aware of the request
  - For EMR questionnaires, the document can be attached to the request to help facilitate the review



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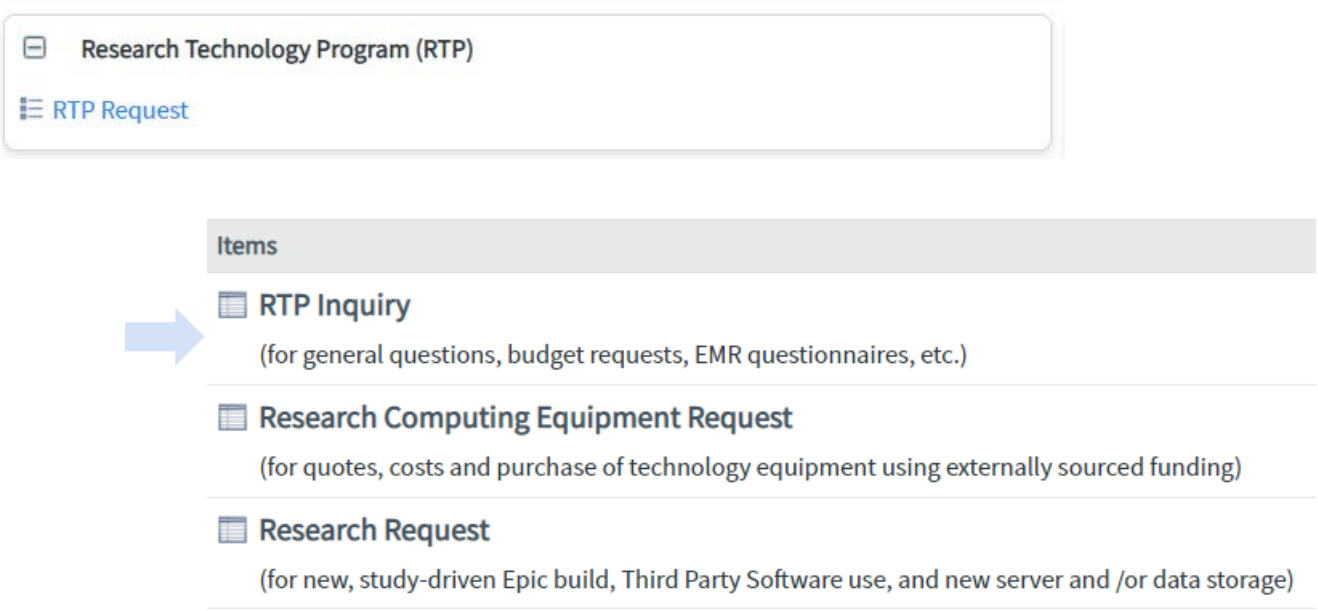
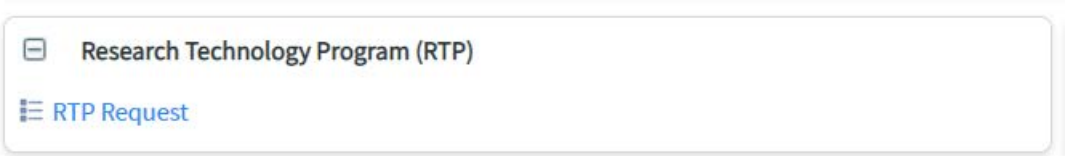
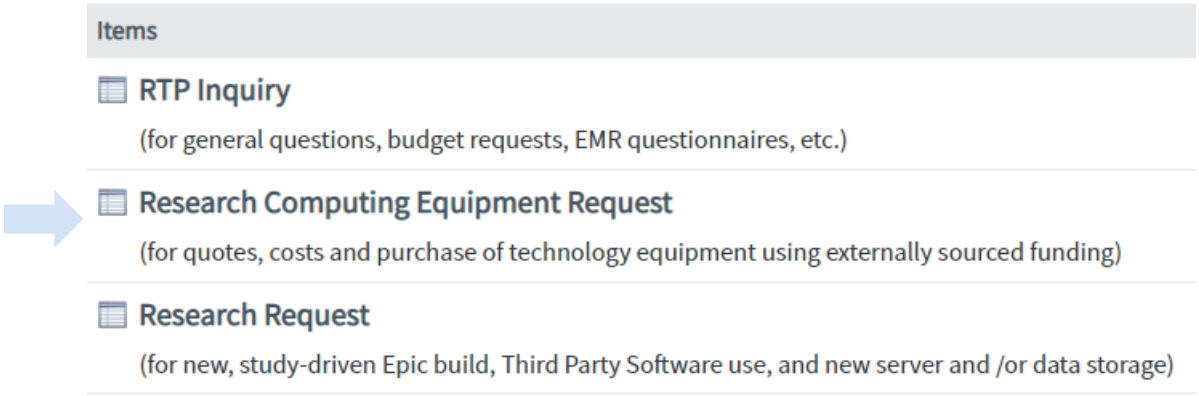


- For all grant proposal and budget estimates, including costs for technology equipment and consultant planning, please use the “RTP Inquiry” form.
- RTP provides costs via REQ and does not publish a price list to help ensure accuracy
- Friendly reminder: please request as early as possible to enable a timely review
  - Collaboration with internal and external teams is sometimes required

Research Technology Program (RTP) Updates

RTP has an improved presence in the **BMC Service Catalog**:



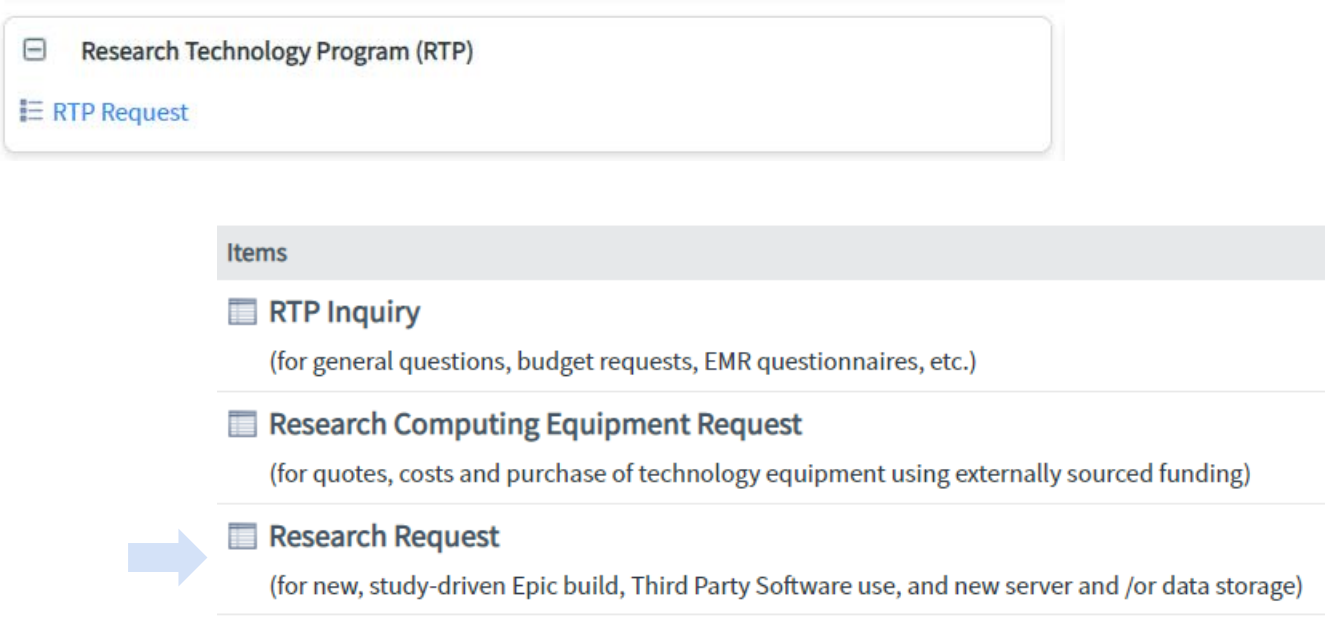


- Research Computing Equipment Request is used to purchase gear with externally sourced funding (grants, etc.)
  - Laptops, Desktops, Monitors, Tablets and Software*
- This form should only be used for initiating purchases

*Note: Software purchases are subject to ITS, Information Security and Compliance review prior to being executed

Research Technology Program (RTP) Updates

RTP has an improved presence in the **BMC Service Catalog**:



- 'Research Request' initiates the RTP review of a new study or project
  - Includes questions around IRB, Funding, IT Involvement, and Study Aims
  - Complete all required fields and provide as much information as possible

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Research Counsel: Alternative IRB Oversight

Patricia Bass, J.D., M.P.H.
Associate General Counsel & Senior Research Counsel

Jurisdiction

- Boston University Medical Campus/Boston Medical Center Institutional Review Board

  All research or clinical investigations involving human subjects in which faculty, staff, or students acting as employees or agents of Boston Medical Center or Boston University Medical Campus are subject to the authority of the HRPP, regardless of funding source or other regulatory requirements.

- The Human Research Protection Program (HRPP) is a shared service activity between BMC and BU

Drives Toward Efficiency

- Originally IRB review one a single institution activity
- NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (2016)
  - all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB)
- Industry use of commercial IRBs for multi-site studies
- Avoidance of delays caused by multiple reviews of the same study

How Does Local IRB Cede Authority?

- Ceding can work either way
  - BUMC/BMC ⇆ Outside IRB
- Core of Ceding is the IRB Authorization Agreement (IAA)
  - For BMC studies agreement is between BMC and outside institution
  - Single study or multiple studies
- OHRA Director or IRB Director determine when to cede and when to accept oversight over another institution's reseatch
  - Factors: risk level, on vs off campus, quality of proposed IRB of record, AAHRPP accreditation, industry-sponsored IND/IDE study

Smart IRB

- Streamlined, Multisite, Accelerated Resources for Trials (SMART IRB) platform
- A fixed set of terms and conditions which Institution adopts by signing the Joinder agreement
- Refer all cede review matters to the IRB for drafting and handling
  - Reviewed by OGC

WIRB Copernicus Group

- Commercial IRB
- Institutional Agreeement

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Research Policy Socialization

Kaye Mottola

Tyler Flack

Boston Medical Center

Research Operations

Allowable Costs of Sponsored Programs

Policy Update 2022

Allowable Costs policy

Trifold purpose

- To comply with federal regulations
- To provide a summary of cost accounting requirements of sponsored programs
- To enumerate common unallowable costs

Policy Statement*

- Specifies the federal cost principles for hospitals
- Points out:
  - A cost of a federal program cannot included on any other federal program
  - Sponsor approval of a proposal budget including unallowable costs does *not* make costs allowable
  - Necessary conditions treating admin effort as direct costs
- Lists common unallowable costs and indicates that the list is not exhaustive

Allowable Costs policy

Length shortened from 6-3 pages

- To render language natural and concise and avoid repetition
- To facilitate understanding of essential requirements
- A training is being prepared

Clarification of concepts, roles and responsibilities, and unallowable costs

- Reconfiguration of cost principles and definitions simplify concepts
- Definition additions and references explicate crucial distinctions
- Addition of “overbase payments” and bonuses on commonly unallowable list
- Approval requirements are explicitly noted for
    - Non-federal cost transfers from one program to another
    - Allocation of administrative/clerical effort as direct cost
    - Any exception to the policy
- ***PI/PDs must review posted expenses quarterly at a minimum***
- ***Department administrators must review posted expenses monthly***

Appendix: cost principles and common unallowable costs

To be assigned to a sponsored program, a cost must be:

- Reasonable for program performance
- Allocable in relation to program performance
- Consistent with other cost-related BMC policies
- Treated consistently as direct or indirect across programs, whenever alike type and circumstance
- Incurred during the approved budget period (exception: pre-award spending **with prior approval**). Large amounts posting at the end or after a project end date will be questioned by Res Ops and Auditors
- Documented adequately, and
- Otherwise determined according to generally accepted accounting principles

In addition:

- A federal program cost may not be charged to or used for cost sharing or matching reqs of any other federal program
- A sponsor-approved proposal that includes non-allowable cost is *not* an indication of allowability

Non-allowable costs include but are not limited to:

- alcohol
- bad debts
- lobbying
- business meals (unless a travel expense)
- fundraising, donations, contributions
- bonuses or “overbase” payments
- first-class airfare
- entertainment, flowers, gifts
- parking tickets, fines, penalties

Resources

BMC policy:
https://bostonmedicalcenter.policytech.com/dotNet/documents/?docid=3205

Federal requirements

- 45 CFR 75 Appendix IX, *Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals*
- NIH Grants Policy Statement

Research Operations

Sponsored Program Equipment Management

Policy Update 2022

SP Equipment Management policy

Twofold purpose

- To comply with federal regulations
- To facilitate inventory control

Policy Statement*

- Provides list of required documentation for equipment record
- Specifies additional requirements for changes, maintenance, safeguard
- Includes the technical meanings of “movement,” “transfer,” “sale,” or “disposal”
  - and associated requirements
- Requires Research Operations approval before purchase

**See appendix, slide 4, for details*

SP Equipment Management policy

Length shortened from 4.5 to 2 pages

- To avoid repetition and facilitate understanding of essential requirements
- A standard operating procedure (SOP) is being prepared
- The associated form has been removed and is being prepared as a web form

Affected equipment and associated requirements and roles are clarified

- All equipment, with a life expectancy of ≥ 1 year and costing ≥$5K, that is/was purchased with ***sponsored-program*** funds
  - (Service programs are held to the same UG requirements as research)
- PI/PDs must provide accurate, timely records to Research Finance (RF)
  - (Administrators may act as designees, but PI/PD is responsible)
- RF maintains a physical inventory and reconcile it with PI/PD records

Outdated references were replaced by current section covering equipment

Appendix: summary of PI/PD requirements

Initial requirement: documentation to be provided to RF	
– Equipment description – Serial or other ID number – Source of funding – Award ID number – Title holder – Acquisition date	– Cost – Location – Percentage of sponsor participation in award costs, as applicable – All additional funder requirements specified (regarding the equipment) – Disposal date and description, sale price, and approver, as applicable
Subsequent requirements	
– Documentation updates, as applicable: ≤ 2 years	
– Adequate upkeep maintenance and controls for prevention of loss, damage, theft	
– Loss, damage, or theft must be investigated	
– Research Finance ***authorization prior*** to movement, transfer, sale, disposal, any other sponsor requirements • See policy for related details, definitions, and limitations	

Resources

BMC policy:
https://bostonmedicalcenter.policytech.com/dotNet/documents/?docid=3269

Federal requirements: 2 CFR 200.313

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Open Discussion and Questions

Thank-you for attending today's meeting!