



**Date:** 03/22/2021

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Clinical Research  
occurring at BMC

Hello Research Community,

This communication applies to clinical research occurring at BMC, including BU Principal Investigators performing research within BMC clinical space. *BU or BMC lab space or non-clinical research should still go through applicable departmental review and approval to host research staff safely.*

**A.** Now that the hospital has entered Phase A, we would like to re-confirm the importance of prioritizing research visit types in the following order:

1. Research visits are completed remotely, with no in-person interaction.
2. Research visits involve piggybacking on routine care visits within or outside of the PI's home department, depending on the location of the service. These visits continue to require approval from the clinic to use of the space for research purposes\*.
3. If research visit types described in #1 and #2 above are not possible and a research-only in-person visit must occur, the visit can only be scheduled after the clinic has granted approval for use of the space\*.

\*Clinic approval may include a review from: section chiefs, clinical operations, or department administrators. Please, confirm your section or department's requirements to confirm clinical volume. The GCRU also requires review and approval, please contact the GCRU directly for further information.

We continue to ask study teams to implement this visit type prioritization even for patients who are 2-weeks post their 2nd vaccination (Pfizer or Moderna) or who have received a single dose of the J&J vaccine.

**BMC Research Re-start is no longer required to submit for on-going or new clinical research as of 3/22/21. Instead, please follow the guidance above.**

**B.** Research monitor, and auditor, visits should be treated with the same level of priority as above and also require departmental approval if a fully remote monitoring visit is not possible. If on-campus monitoring is the only option, the department is responsible for providing a visitor exemption for the study team and must confirm the following guidelines are met: <https://www.bmc.org/visiting-us/visitor-policies>. Please, consider all options before a monitor comes to campus, such as but not limited to, a hybrid monitoring experience involving some work completed remotely via ChartLink or scanned secure records, followed by an in-person review if unavoidable.

Maintaining low volume, coming to and around campus, preserves our community's safety.

C. We welcome you to visit “[Remote Study Design Optimization](#)” documentation for additional guidance. Please, also review the “[Remote Monitoring Charklink Access Workflow](#)” to provide monitors or auditors access to BMC’s EHR.

Please email: [ClinicalTrialOffice@bmc.org](mailto:ClinicalTrialOffice@bmc.org) with any questions or comments.

Thank you,

Matt and Johanna

Matt Ogrodnik, MS, CIP  
Director, Office of Human Research Affairs  
Boston Medical Center and Boston  
University Medical Campus  
Robinson 414I  
72 East Concord Street  
Boston, MA 02118  
phone: (617)358-6559  
email: [maogrodn@bu.edu](mailto:maogrodn@bu.edu)

Johanna C. Chesley, MPH  
Director, Clinical Trial Office  
P. 617-414-2861  
C. 617-549-3367  
[Johanna.chesley@bmc.org](mailto:Johanna.chesley@bmc.org)  
[CDA/NDA Intake Form](#)



**Date:** 10/13/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** OMB Memo 20-26

Expired 9/30/2020

---

Good afternoon,

OMB released several memos earlier this year providing administrative relief for recipients and applicants of federal award in response to the COVID-19 public health crisis. The last of these memos [OMB Memo 20-26](#) providing relief **expired on 9/30/2020**. Additional BMC specific details to follow.

Please reach out if you have any questions.

Thank you,  
Research Operations



**Date:** 07/29/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** BU PAR Period January to June 2020

Good afternoon,

BU recently sent out the memo below announcing the next PAR certification period. As most BMC principal investigators have BU faculty appointments, they will certify their time and effort through the BU process.

BMC received a finding in FY19 on its Uniform Guidance audit for having multiple investigators misreport cost share on their PARs. As you work on completing this period's PARs please note the following about **Cost Sharing:**

- **Cost Sharing is required for all personnel paid a base salary greater than the DHHS Cap (\$197,300) on DHHS awards – BU Researchers' PARs will be marked "Faculty – Over DHHS Cap" in such cases.**  
**NOTE: BMC RESEARCHERS' PARs WILL NOT ALWAYS HAVE THIS LABEL, BUT THEY ARE STILL REQUIRED TO REPORT COST SHARE IF THEY ARE OVER THE CAP.**

Pers Num Faculty- Over DHHS Cap		<b>BOSTON UNIVERSITY PERSONNEL ACTIVITY REPORT Professional Employee</b>	PAR Org Unit/Dept Mail Code
------------------------------------	---	--	-----------------------------------

- Cost Sharing must be reported in Category II. Section B. Cost Sharing Activity. All cost sharing details must be completed, including the Sponsored Program Number, Title and the percentage of effort expended on each sponsored agreement.
- Cost Sharing is required for all Sponsored Agreements with Mandatory or Voluntary Committed Cost Share in the proposal

If you have questions about reporting cost share for BMC grants on PARs please reach out to [Stephanie.Wasserman@bmc.org](mailto:Stephanie.Wasserman@bmc.org) or [Tyler.Flack@bmc.org](mailto:Tyler.Flack@bmc.org).

Thank you,  
Research Operations



[Effort@bu.edu](mailto:Effort@bu.edu)

25 Buick Street, Suite 200

Boston, MA 02215

T 617-353-4555 F 617-353-6740

To comply with Federal Regulations under Uniform Guidance 2 CFR 200, 200.430 Compensation – personnel services, all Boston University employees who are paid from Sponsored Research funds receive a personnel activity report (PAR) on a semi-annual basis to review and certify their salary and effort.

The next PAR reports will be generated for the January to June 2020 time period and will include all Professional, Non-Professional, and Student employees.\*

\*PARs are not generated for students who are paid on a weekly basis using timesheets

❖ **Important Dates:**

<b>Thursday, July 30<sup>th</sup></b>	Salary Adjustment approval deadline. Any Salary Adjustment not approved by this day will not be picked up on the PAR.
<b>Monday, August 10<sup>th</sup></b>	Effort Reporting distributes PARs and Control Logs by email to Department Administrators and Effort Coordinators.
<b>Friday, October 9<sup>th</sup></b>	<b>PAR return date. All PARs must be submitted to <a href="mailto:effort@bu.edu">effort@bu.edu</a>.</b> Any PAR received after this date runs the risk of disallowance (salary plus corresponding fringe and indirect) so <i>do not wait until the last minute</i> .

❖ **Certification eligibility: Who may sign?**

<b>Faculty and non-faculty PIs</b>	Must certify their own PARs
<b>Non-faculty personnel (i.e. professional staff and lab techs)</b>	Employee or the PI/Supervisor may certify
<b>Students</b>	Employee or the PI/Supervisor may certify

❖ **Acceptable Signature**

Scanned handwritten signatures	Yes, always acceptable
Digital signatures	Yes, always acceptable
Email approval with completed PAR**	Yes, to accommodate those working remotely due to COVID-19.

\*\* Email must be from the BU employee or the PI/Supervisor on behalf of any non-faculty or Student BU employee. The “% of Effort Expended” column on the PAR must still be completed.

❖ **Impact of Covid-19**

The Idle Salary Project that I have been coordinating since March is completely separate from the PAR process. The PAR process has not changed, in that individuals are certifying their Effort for the months of January to June, including any idle time reported. Our only change on the PAR due to COVID is the attestation employees are signing; this has been updated to include references of **consistent with University policy** and **emergency excused absences**. Please process all PARs as you normally would in any given PAR period. Please click [here](#) for information concerning salary and idle time FAQs.

❖ **Return Completed PARs to [effort@bu.edu](mailto:effort@bu.edu):**

<b><u>If single PDF</u></b>	Label file name with <u>Last Name</u> , <u>First Name</u> , and <u>Employee Type</u> (e.g., "Pro" for Professional; "Student" for Student; "NP" or "Non-Pro" for Non-Professional)
<b><u>If multipage PDF</u></b>	<ol style="list-style-type: none"><li>1. Send a separate .PDF for each Employee Type ("Professional," "Non-Professional," or "Student"); and</li><li>2. The .PDF name should include the Employee Type and Mail Code.</li></ol>

If you have further questions, please do not hesitate to reach out to myself, Craig Gerome, or Anne DiNoto.

Thank you!

**PLEASE READ THE IMPORTANT PAR PROCESSING GUIDELINES LISTED BELOW:**

**A PAR is considered certified when the following criteria are met:**

- "% of Effort Expended" column is completed
- The column adds up to 100% (Whole numbers only... no decimals)
- The appropriate certifier has signed, dated, and printed his/her name. If certifier is not the employee, the PI or Supervisor box must be checked on the form for verification.

**Sponsored Program Effort Certification Policy:**

- Faculty and administrators should refer to this policy which was developed and implemented to provide clear guidance on the PAR process. The policy can be viewed on our website at: <http://www.bu.edu/researchsupport/forms-policies/sponsored-program-effort-certification-policy/>
- Signatures must be accompanied by the date and employee's printed name. If the PI or supervisor certifies for the employee then check the appropriate box (PI or Supervisor). Generally Department Research Administrators will not have after-the-fact knowledge of an individual's total work effort and should not certify the effort of research staff unless they have such written after-the-fact confirmation from an individual having direct knowledge and possessing suitable means of verification.

- PAR Certifiers must comply with this statement: "I certify that I am either the covered individual, PI or supervisor using suitable means of verification to confirm that the percentages shown in the Percent of Effort Expended column reasonably reflect the actual effort devoted to the sponsored agreement(s) during the period of the effort report; in the instance that I, as a Faculty member, certified 100% of my time to sponsored activities, my certification as a Faculty member confirms that I did not write proposals, attend committee meetings, participate in teaching, mentoring or any other educational activities for the PAR period attached"

**Cost Sharing:**

- Cost Sharing must be reported in Category II. Section B. Cost Sharing Activity. All cost sharing details must be completed, including the Sponsored Program Number, Title and the percentage of effort expended on each sponsored agreement.
- Cost Sharing is required for all Sponsored Agreements with Mandatory or Voluntary Committed Cost Share in the proposal
- Cost Sharing is required for all PARs marked "Faculty – Over DHHS Cap"

**Cost Sharing Calculation:**

- A CAP worksheet has been created to assist you in calculating the appropriate cost share percentages for sponsors who impose a limit or "cap" on the annual rate of salary reimbursement. You can find the form on our website: <http://www.bu.edu/researchsupport/project-lifecycle/managing-an-award/> ("Effort Reporting - DHHS Salary Cap" section). Please use the appropriate Cap Cheat Sheet for the faculty member (either 9 month or 12 month). The percentage of effort should not be less than that committed to the sponsor for each award on which the employee is the PI or key personnel. Also, be mindful of PAR-eligible wage types.

**Salary Adjustments:**

- If any retroactive salary adjustments are required, refer to the Salary Adjustment Policy located here: <http://www.bu.edu/researchsupport/forms-policies/sponsored-program-salary-adjustment-policy/>
- All payroll adjustments must be made within ninety (90) calendar days of the actual payroll period. Any adjustments beyond 90 days are subject to approval and must be signed by the PI explaining the extenuating circumstances that caused the delay and what procedures will be put in place to ensure that this will not happen in the future. If a Personnel Action is being submitted that affects an original transaction date for which a PAR has been printed and distributed, the certified PAR must be submitted with the Salary Adjustment.
- Once a PAR has been certified, only in rare circumstances will subsequent salary adjustments be permitted. Please refer to section H, "Salary Reallocation & Recertification" of the Sponsored Program Effort Certification Policy for additional information.  
<http://www.bu.edu/researchsupport/forms-policies/sponsored-program-effort-certification/>

Gretchen KM Hartigan, Assistant Vice President, PAFO

PAFO is working remotely and is available to assist you. Best way to reach me is via Microsoft Teams.

Please be sure to check the [Research COVID-19](#) website for regular daily updates.

[Fundamentals of Research Administration courses](#) now available online – access them all on Terrier eDevelopment.



**Date:** 07/15/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Research restart  
summary

---

Hello Research Community,

We appreciate your patience as we finalize the BU and BMC Medical campus in-person research re-start workflow. We have provided a reminder of the High Level phase determination and Research re-start workflow [here](#). We are currently reviewing the submitted material and will be focusing first on those projects that piggyback on routine care, have seasonal or funding implications. Today, we are sending the Departments of Medicine and Psychiatry lists the of projects requested to re-start review, which covers the bulk of requests received. For those requests not in those department, please see the attached [workflow](#) for expected next steps. Research Operations has been and will continue to send individual protocol communications.

As a reminder, if you have approval from the IRB and sponsor to complete 100% remote visits, fell into an exempt category to continue research during the pandemic, or complete your research 100% outside of the BUMC medical campus, then there is no need to submit re-start forms and you may continue your research.

If you would like to submit an in-person restart request, please review the 6/15/20 communication: [https://www.bmc.org/sites/default/files/Research/documents/Communications\\_COVID-19.pdf](https://www.bmc.org/sites/default/files/Research/documents/Communications_COVID-19.pdf)

If you have any questions or comments, please send them to: [BMCResearchRestart@bmc.org](mailto:BMCResearchRestart@bmc.org)

Thank you,

Research Operations



**Date:** 06/26/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Human Research Restart

---

Hello Clinical Research BUMC community,

Please, see the attached [Research Restart phased approach and approval process](#) designed by the Research Restart Task Force. This document outlines how protocols will be prioritized to have in-person research restart within BMC and BU Medical Campus.

If you have already submitted a previous version of the BU or BMC return to campus form with your Personnel Template and Recovery Plan, you do not need to submit a new form, but you must complete [Resuming In-Person Subject Interactions](#) templates for your studies and email them to [BMCResearchRestart@bmc.org](mailto:BMCResearchRestart@bmc.org).

If you have not submitted you must complete the [Return to Campus Form](#) and attach the 3 templates:

1. Recovery Planning Template
2. Research Personnel Template
3. Resuming In-Person Interactions (if applicable)

Please contact the BMC Research Operations at [BMCResearchRestart@bmc.org](mailto:BMCResearchRestart@bmc.org) if you have any questions.

Thank you,  
Research Operations



**Date:** 06/15/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Forms for restarting in-person human subjects research at BMC and BU Medical Campus

Good Afternoon,

The institutions are gathering information about plans for resuming in-person human subjects research at BMC and BU Medical Campus.

Any project that requires one or more member of the study team to interact with subjects in BMC or BU Medical Campus space must fill out the following form:

BMC: [Returning Research Staff to BMC or BU Medical Campus](#)

This form has basic questions about the research and requires the preparation of three attachments:

- [Research Recovery Plan](#) (describes the space where staff will work)
- [Research Personnel Template](#) (identifies the staff members)
- [Resuming In-Person Subject Interactions](#) (lists expected interactions with human subjects per project)

All research (both already IRB-approved and preparing for IRB review) that requires in-person recruitment, consent, or study visits in BMC or BU Medical Campus space must upload the form. The data obtained will contribute to decisions regarding when and how to bring research back to campus safely and effectively. As these discussions progress, more concrete information on this timeline will be disseminated widely to the research community.

If you have already submitted the previous version of the form, called "Resuming In-Person Research - Human Subjects", you do not need to submit the new form, but you must complete [Resuming In-Person Subject Interactions](#) templates for your studies and email them to [BMCResearchRestart@bmc.org](mailto:BMCResearchRestart@bmc.org)

Please contact the BMC Research Operations at [BMCResearchRestart@bmc.org](mailto:BMCResearchRestart@bmc.org) if you have any questions.

Thank you,  
Research Operations



**Date:** 06/2/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** BMC/BU COVID-19  
Biorepository

---

## The BMC/BU COVID-19 Biorepository is Accepting Requests for Samples

A biorepository has been established to gather biospecimens from both ambulatory and inpatient COVID-19 patients at BMC. A centralized COVID-19 Biorepository Scientific Review Committee (SRC) will review sample requests from BU/BMC researchers. The biorepository includes two components:

1. Biorepository of discarded clinical samples from inpatient and outpatient Boston Medical Center patients (PI Stephen Pelton)
2. Biorepository of prospectively collected samples from an inpatient COVID-19 cohort (PIs Nahid Bhadelia, Karen Jacobson, and Nina Lin)

### **Biorepository Sample Requests:**

The SRC will review all research requests for access to samples. Investigators will submit a request via an online form. Requests will be assessed for: completeness, feasibility, overlap with existing research efforts, scientific rigor and reproducibility, and scientific merit of research aims. To begin, requests for discarded samples will be prioritized. Prospective cohort sample requests will be given contingent approvals until samples accumulate. All investigators submitting requests should understand that there will be a formalized cost structure for accessing biorepository specimens. Approvals will be contingent upon finalization of this cost structure and confirmation from the investigator that they will have funding available to cover biorepository fees.

**The BMC/BU COVID-19 Biorepository SRC is currently accepting online applications [here](#).**

To learn more about the current inventory of the Biorepository and for any other questions regarding the process outlined above, email [COVIDBiorepository@bmc.org](mailto:COVIDBiorepository@bmc.org).

### **The Massachusetts Consortium on Pathogen Readiness (MassCPR) COVID-19 Biorepository**

BMC/BU Investigators should also be aware that MassCPR is working to make samples from patients infected with COVID-19 available for investigators at all member institutions, including BMC and BU. **Investigators are invited to use [this form](#)** (link to DropBox file) **to request samples for studies that are funded, IRB-approved, and ready to get underway.** Requests for samples will be reviewed by the MassCPR Sample Access Accelerator Committee, which has representation from the Consortium's member institutions. When requests are approved and deemed feasible, the investigator will be provided with the information necessary to access the biorepository and request the samples.



**Date:** 05/22/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Reminder for Upcoming  
NIH Deadlines

Good morning,

We have made a change to clarify some confusing language below in red. To clarify, use of break rooms will be prohibited. Guidance signage will be posted in elevators and common areas, i.e. lobbies and hallways, to direct coming and going. No meetings or congregating is permitted at this time.

Apologies for any confusion. Thank you.

Research Operations

**Corrected Version:**

**From:** BMC Research Operations [<mailto:BMCRsearch.Operations@bmc.org>]

**Sent:** Friday, May 22, 2020 9:28 AM

**To:** DG-BMC Research Administrators <[bmc\\_research\\_administrators@mailinglist.bmc.org](mailto:bmc_research_administrators@mailinglist.bmc.org)>

**Subject:** RE: Research Restart

Good Afternoon,

Research leadership has been working with Boston University and our clinical teams, Facilities, and Environmental Health and Safety to coordinate a phased plan for the return of research activity to the BMC campus. We appreciate your patience and understanding as the institution first focuses on ramping back up our normal non-COVID clinical activities. Below we have outlined plans and information for Phase 1 for Basic Research. Research occurring in clinical space or in buildings connected to clinical space will likely be phased in over a longer period of time as we have to align with BMC Hospital access procedures.

**Boston Medical Center (BMC) Basic Research Phase 1 Reopening**

**Important Notes:**

- **This email describes our overall re-opening plans for basic laboratories but DOES NOT include a specific date that we will re-open. An official re-opening date will be communicated separately.**
- For any employee that has concerns about returning to work or extenuating circumstances, we encourage you speak with your supervisor or Human Resources to address them. Those who are able to work remotely will continue to do so.
- The guidance document aligns with state and federal public health requirements and recommendations. Procedures are consistent with hospital policy, regulatory compliance, scientific efficacy, and operational support. The health and safety of the BMC community is our highest priority.

Supported by this framework, PIs should develop and implement laboratory-specific plans to restart their basic research programs. Each Department/Section/Program will need to develop and address the specific personnel, areas, equipment use, and other concerns they foresee under these guidelines. They should work collaboratively with the individual investigators in their areas to resolve issues at the local level whenever possible. Research Operations personnel are available to assist and advise when requested. We welcome and encourage, Department, Section and Program online meetings with Research Operations leadership to handle specific issues and questions. We have established a dedicated inbox to manage your inquires and concerns:

[BMCResearchRestart@bmc.org](mailto:BMCResearchRestart@bmc.org)

Links to the BMC forms are below. Please complete and submit the Recovery Plan and Personnel Listing if you have not done so already. If you have already completed a BU form you do not need to resubmit to BMC. We have access to the plans submitted to BU and we will follow up with questions, if necessary.

<https://www.bmc.org/resumption-in-person-research-human-subjects>

<https://www.bmc.org/resumption-in-person-research-not-involving-human-subjects>

### **Phase 1 Reentry group**

Those whose research is dependent on the use of facilities — and cannot be performed remotely — will be first to return. This applies to basic research activities in 650 Albany (EBRC) and 670 Albany.

### **Employee responsibilities**

- Wear a mask in BMC Facility
- Adhere to all requirements for maintaining physical distancing.
- Comply with Working Well policies for reporting and contact-tracing of any individuals with confirmed or suspected COVID-19 diagnosis.
- Follow all required health and safety measures. Additional information regarding health and safety:
- [EHS Home](#) | [EHS COVID-19 Resources](#)
- [Department of Public Health Mandatory Safety Standards for Workplaces \(5/18/20\)](#)
- [Standards for Responsible Laboratories in Massachusetts \(5/18/20\)](#)
- Observe all Department/Division/Program operating parameters

Laboratory floor plans will be made available to investigators. These plans show how many people are allowed in specific areas at one time. Cell Culture, procedure and microscope rooms will be limited to one person at a time. Signage will be installed by BU throughout the facilities, including directional arrows for traffic flow where appropriate.

Workflow, layout, personnel, and shared instrumentation are determined by departments/divisions/programs in coordination with Research Operations. Ultimately, laboratory lead investigators will determine specific personnel schedules and laboratory-space assignments.

### **Basic Research Facilities**

- All personnel working on-site must comply with EHS policies for entry, personal protective equipment (PPE), cleaning, scheduling, and reporting concerns.
  - o Please contact Supply Chain regarding acquisition of PPE
- Use of research conference rooms for meetings is prohibited.
- Use of break rooms be will prohibited.
- No training activities should be taking place.
- Floor plans will be available for procedure, cell culture, and microscope rooms, showing the maximum number of people allowed at a given time.

- Staggered shifts are recommended to support 6-foot distancing mandates.
- Lab workers will adhere to proper disinfection and hygiene procedures for space they are working in, as outlined in EHS documentation.
- No visitors, including minors under 18, will be allowed.
- Contracted external service and maintenance personnel must be scheduled and escorted while on site.
- Badge access is required for research facilities.

#### **Animal Facilities**

- Animal facilities are still working under emergency-care protocols.
- All animal activities must be coordinated with IACUC, additional questions are included in the planning document.
- Additional measures will be reviewed by IACUC for all animal work.

#### **Elevators and distancing signage**

- Elevators will be used in accordance with EHS guidelines and protocols. A limited number of people will be allowed to ride an elevator at once.
- Distancing signage will be used in lobby areas, common areas, ~~lunch areas~~, and other critical locations.

We also need to be prepared to ramp down quickly. If you suspect you or a close contact may be ill, please self-quarantine and notify Working Well immediately. In this event, you will work with the administration and Working Well to decide whether we need to partially or fully shut down temporarily.

Further guidance around the dates and approval for return will be forthcoming.

Thank you,  
Research Operations



**Date:** 05/21/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Reminder for Upcoming NIH Deadlines

Good Afternoon,

Research leadership has been working with Boston University and our clinical teams, Facilities, and Environmental Health and Safety to coordinate a phased plan for the return of research activity to the BMC campus. We appreciate your patience and understanding as the institution first focuses on ramping back up our normal non-COVID clinical activities. Below we have outlined plans and information for Phase 1 for Basic Research. Research occurring in clinical space or in buildings connected to clinical space will likely be phased in over a longer period of time as we have to align with BMC Hospital access procedures.

### **Boston Medical Center (BMC) Basic Research Phase 1 Reopening**

#### **Important Notes:**

- **This email describes our overall re-opening plans for basic laboratories but DOES NOT include a specific date that we will re-open. An official re-opening date will be communicated separately.**
- For any employee that has concerns about returning to work or extenuating circumstances, we encourage you speak with your supervisor or Human Resources to address them. Those who are able to work remotely will continue to do so.
- The guidance document aligns with state and federal public health requirements and recommendations. Procedures are consistent with hospital policy, regulatory compliance, scientific efficacy, and operational support. The health and safety of the BMC community is our highest priority.

Supported by this framework, PIs should develop and implement laboratory-specific plans to restart their basic research programs. Each Department/Section/Program will need to develop and address the specific personnel, areas, equipment use, and other concerns they foresee under these guidelines. They should work collaboratively with the individual investigators in their areas to resolve issues at the local level whenever possible. Research Operations personnel are available to assist and advise when requested. We welcome and encourage, Department, Section and Program online meetings with Research Operations leadership to handle specific issues and questions. We have established a dedicated inbox to manage your inquires and concerns:

**[BMCResearchRestart@bmc.org](mailto:BMCResearchRestart@bmc.org)**

Links to the BMC forms are below. Please complete and submit the Recovery Plan and Personnel Listing if you have not done so already. If you have already completed a BU form you do not need to resubmit to BMC. We have access to the plans submitted to BU and we will follow up with questions, if necessary.

**<https://www.bmc.org/resumption-in-person-research-human-subjects>**

**<https://www.bmc.org/resumption-in-person-research-not-involving-human-subjects>**

#### **Phase 1 Reentry group**

Those whose research is dependent on the use of facilities — and cannot be performed remotely — will be first to return. This applies to basic research activities in 650 Albany (EBRC) and 670 Albany.

#### **Employee responsibilities**

- Adhere to all requirements for maintaining physical distancing.
- Comply with Working Well policies for reporting and contact-tracing of any individuals with confirmed or suspected COVID-19 diagnosis.

- Comply with Working Well policies for reporting and contact-tracing of any individuals with confirmed or suspected COVID-19 diagnosis.
- Follow all required health and safety measures. Additional information regarding health and safety: [EHS Home](#) | [EHS COVID-19 Resources](#)  
[Department of Public Health Mandatory Safety Standards for Workplaces \(5/18/20\)](#)  
[Standards for Responsible Laboratories in Massachusetts \(5/18/20\)](#)
- Observe all Department/Division/Program operating parameters

Laboratory floor plans will be made available to investigators. These plans show how many people are allowed in specific areas at one time. Cell Culture, procedure and microscope rooms will be limited to one person at a time. Signage will be installed by BU throughout the facilities, including directional arrows for traffic flow where appropriate.

Workflow, layout, personnel, and shared instrumentation are determined by departments/divisions/programs in coordination with Research Operations. Ultimately, laboratory lead investigators will determine specific personnel schedules and laboratory-space assignments.

#### Basic Research Facilities

- All personnel working on-site must comply with EHS policies for entry, personal protective equipment (PPE), cleaning, scheduling, and reporting concerns.
- Please contact Supply Chain regarding acquisition of PPE
- Use of research conference rooms for meetings is prohibited.
- Use of break rooms will be prohibited.
- No training activities should be taking place.
- Floor plans will be available for procedure, cell culture, and microscope rooms, showing the maximum number of people allowed at a given time.
- Staggered shifts are recommended to support 6-foot distancing mandates.
- Lab workers will adhere to proper disinfection and hygiene procedures for space they are working in, as outlined in EHS documentation.
- No visitors, including minors under 18, will be allowed.
- Contracted external service and maintenance personnel must be scheduled and escorted while on site.
- Badge access is required for research facilities.

#### Animal Facilities

- Animal facilities are still working under emergency-care protocols.
- All animal activities must be coordinated with IACUC, additional questions are included in the planning document.
- Additional measures will be reviewed by IACUC for all animal work.

#### Elevators and distancing signage

- Elevators will be used in accordance with EHS guidelines and protocols. A limited number of people will be allowed to ride an elevator at once.
- Distancing signage will be used in lobby areas, common areas, lunch areas, and other critical locations.

We also need to be prepared to ramp down quickly. If you suspect you or a close contact may be ill, please self-quarantine and notify Working Well immediately. In this event, you will work with the administration and [Working Well](#) to decide whether we need to partially or fully shut down temporarily.

Further guidance around the dates and approval for return will be forthcoming.

Thank you,  
Research Operations



**Date:** 05/14/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Reminder for Upcoming  
NIH Deadlines

Good afternoon,

As follow a up to our previous email, please find [attached](#) a guidance document for those interested in doing COVID-19 related research. We will continue to update this guidance with links to online forms and additional items as they become available.

Thank you,  
Research Operations

Hello Dept administrators and Investigators,

We are fast approaching the NIH June and July deadlines which is a high volume proposal time for Research Operations and Foundation Relations and Government Grants. Due to current COVID-19 circumstances, your assistance in notifying us of your intention to submit a proposal for the upcoming deadlines and submitting the final proposal according to the below guidance will help ensure a smooth and successful submission.

- Work with your Grants Officer/Dept Admin to be sure the InfoEd record has been initiated and that the submission deadline listed, is accurate
- Research Operations is expecting heavy proposal volume for the Friday June 5 deadline; server loads increase as we approach the 5 pm deadline
- Early submissions are encouraged, to avoid delays and system errors on the day of the deadline
- Compiled applications may be viewed on eRA Commons and will not be emailed
- Please avoid causing unnecessary rework: withdrawal for corrections/edits and resubmission
- Proposals that do not meet the timeline noted below are at risk for limited review and not meeting the sponsor's deadline

**Research Operations Internal Due Dates (in Advance of Sponsor Deadline)**



Thank you,  
BMC Research Operations



**Date:** 05/11/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** COVID-19 Research

---

Good afternoon,

We understand that many in our research community are developing COVID-19 research projects. Given the current public health crisis and the strain on hospital resources, BMC has been working on establishing formal processes for beginning research on COVID-19 that will prioritize patient and employee safety while maximizing the use of BMC's limited resources.

We hope to communicate more on these processes later this week. We greatly appreciate your patience.

Wishing you the best of health,  
Research Operations



**Date:** 05/08/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** ClinCard Participant  
Information Form Update

---

Good Morning –

In light of the new patient interaction guidelines, we have developed an online version of the ClinCard Participant Information Form (CPIF). This is a PDF form that the participant can fill in, sign electronically, and return by email; Site Coordinators will then be able to mail the ClinCard to the participant's physical address. Links to the new form and instructions are available on our website <https://www.bmc.org/research-operations/forms> as well as linked below. If you have any questions please contact [CTO@bmc.org](mailto:CTO@bmc.org).

[ClinCard Participant Information Form \(CPIF\)](#)

[ClinCard Participant Information Form \(CPIF\): eSign Instructions](#)

Thank you,  
BMC Research Operations



**Date:** 04/14/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** COVID-19 Updates for  
BMC Grant Award Management

---

Hello Investigators and Department Administrators,

We are contacting you regarding COVID-19 updates for BMC grant award management. We have attached additional Award Management FAQs that are BMC focused and Award Management Guidance by sponsor resources. This information and all COVID-19 updates for BMC Research are available on our website <https://www.bmc.org/covid-19/covid-19-research-related-information>.

Please continue to work with your **Post-Award Office** [Research Operations Contact](#) regarding any questions around salary charges and allowability of expenses and for any required contact with sponsors, including any project updates.

Thank you,

Research Operations

Good Morning –

We wanted to share with our research community recent announcement from NIH on COVID-19 Funding and Funding Opportunities.

Our Pre-Award team is preparing FAQs please send along any questions you have to [grants.admin@bmc.org](mailto:grants.admin@bmc.org).

Thank you,

Research Operations

## **COVID-19 Funding and Funding Opportunities**

Posted on [April 13, 2020](#) by [Mike Lauer](#)

As you can imagine, NIH is devoting significant resources to COVID-19. In addition to dedicating regularly appropriated funds, to date NIH has received emergency funding for COVID-19-related activities in two supplemental bills (available from the [NIH Office of Budget website](#)), that together provide:

- \$1.532 billion for NIAID
- \$103.4 million for NHLBI
- \$60 million for NIBIB
- \$36 million for NCATS
- \$30 million for the NIH Office of Director
- \$10 million for NIEHS
- \$10 million for NLM

To get funding as quickly as possible to the research community, we are using Urgent and Emergency competing revisions and administrative supplements to existing grant awards. This approach allows us to leverage resident expertise, getting additional funding to those researchers who are already working with other organisms, models, or tools so that they can quickly shift focus to the novel coronavirus. These Urgent and Emergency competitive revision Funding Opportunity Announcements (FOAs) allow NIH to fund applications quickly, often in under three months, sometimes much quicker than that, because evaluation for scientific and technical merit is done by an internal review panel convened by staff of the NIH awarding institute or center rather than by our traditional peer review process.

The Urgent and Emergency competing revision FOAs sound very similar. And they are, but there is an important distinction.

- The [Emergency Competitive Revision FOA](#) can only be used for funding available for applications based on a presidentially declared disaster under the Stafford Act, a public health emergency declared by the Secretary, HHS, or other local, regional or national disaster. This means that for COVID-19 funding, it can only be used by those NIH Institutes and Centers I listed above that received special emergency funding.
- The [Urgent Competitive Revision FOA](#) can be used to meet immediate needs to help address a specific public health crisis in a timely manner. This vehicle is used to help address a specific public health crisis that was unforeseen when the application or progress report was submitted.

When responding to these types of funding opportunities, it is important that you understand how they work.

- They require applications to be submitted in response to an Emergency or Urgent Notice of Special Interest (NOSI). We are maintaining a list of COVID-19 specific Notices of Special Interest on our [Coronavirus Disease 2019 \(COVID-19\): Information for NIH Applicants and Recipients of NIH Funding](#) website.
- You need to read the instructions in the NOSI and in the FOA it points to carefully. If the instructions in the NOSI differ from those in the FOA, follow those in the NOSI.
- There are specific review criteria specified in the FOA. Make sure you address those as well as any that might be mentioned in the NOSI. They are how NIH staff will evaluate your application for funding.
- The NOSI will instruct you to include the NOSI number in the Agency Routing Identifier field (Box 4b) of the SF424 (R&R) Form. This information is very important for NIH tracking of spending of emergency award funding. Applications without this information in Box 4b may not be considered for this type of funding.
- Often the due dates are rolling, meaning you should submit the application as soon as it is ready to get it considered for funding as quickly as possible.

NIH is issuing new COVID-19 related NOSIs frequently. Please check back for these and other COVID-19-related information on our [Coronavirus Disease 2019 \(COVID-19\): Information for NIH Applicants and Recipients of NIH Funding](#) website.

You can learn more about NOSI's in this quick 5 minute video.





**Date:** 04/03/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** Webpage: Covid-19  
Research Information

---

Good Morning –

This email is to notify you that all COVID-19 Research Operations information, including email notices, forms, templates, FAQs, and any other relevant materials, has been consolidated and posted to this central location. We will continue to keep this page updated with the information that we communicate to you.

<https://www.bmc.org/covid-19/covid-19-research-related-information>

Thank you,  
BMC Research Operations



**Date:** 03/30/2020

**To:** BMC Research Community

**From:** BMC Research Operations

**Subject:** COVID-19 Updates for BMC Grant Submissions and Award Management

Hello Investigators and Department Administrators,

We are contacting you regarding COVID-19 updates for BMC grant submissions and award management. Pre and Post Award staff are all working and available for anything you need.

Please continue to work with [Research Operations Contact](#) for any required contact with sponsors, including any submission or project updates.

Given the current situation, all grant submissions related to COVID-19 are being prioritized so there may be delays in non-COVID-19 related projects. Please reach out to the **Pre-Award Office** at [Grants.Admin@bmc.org](mailto:Grants.Admin@bmc.org) with any questions, and if there are needs to escalate your request.

We understand that in this current state there may be communications on delays and updates that need to be communicated to sponsors. Please reach out to your **Post-Award Office** [Research Operations Contact](#) to assist with, and send the communication to the sponsor.

Additionally, The Council on Government Relations (COGR) has developed FAQs regarding COVID 19's Impact on Federal Awards [COVID-19's Impact to Federal Awards](#) (3/20/20). These FAQs address the following concerns for award management and allowability of costs:

- Travel Charges, Including Cancellations
- Remote Work Environments
- Project Progress Obligations (addressing delays due to COVID 19)
- Salary Charges
- Allowability of COVID 19 Related Items on Grants

In regards to questions around salary charges and allowability of expenses, please reach out to your post award contact. We are preparing additional FAQs that are BMC focused that will be shared via email and our website.

**Important NIH updates related to application deadlines:**

[NOT-OD-20-091](#) UPDATE: NIH Late Application Policy Due to Public Health Emergency for United States for 2019 Novel Coronavirus (COVID-19)

- **All grant applications submitted late for due dates between March 9, 2020, and May 1, 2020, will be accepted through May 1, 2020.**

[NOT-OD-20-086](#) - Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19

[NOT-OD-20-083](#) - General Frequently Asked Questions (FAQs) - Proposal Submission and Award Management Related to COVID-19

[NOT-OD-20-082](#) - NIH Late Application Policy Due to Public Health Emergency for United States for 2019 Novel Coronavirus (COVID-19)

- Proposals that are submitted after the published deadline will be considered for acceptance on a case-by-case basis.

Good Afternoon -

We hope you are all well.

As a reminder of the emails sent 3/13 by the IRB in regards to [Human Subjects Research](#), and Research Operations on 3/16 asking everyone to minimize laboratory activity to the greatest extent possible, **Boston Medical Center** is asking labs to plan for the potential stoppage of research should a further required shut down of operations occur.

Similar to the request from Boston University, the purpose of this email is:

1. To ask PIs to provide an inventory of work that is continuing on campus
2. To provide information about what activities would be critical to maintaining the capabilities of the lab if it is necessary to cease in-person-in-the-laboratory work.

**Inventory of Ongoing Work:** We are asking all PIs to let their department chairs know by Wednesday, March 25, what activity is still occurring on campus and which personnel are considered essential to the ongoing work. As outlined in our earlier communications, the following principles underlie the designation of activities currently considered essential:

- Long-term experiments and activities that would generate significant financial and data loss if not completed; this includes work to maintain critical samples and animal populations
- Activity that if discontinued would pose a safety hazard
- Activity to maintain critical equipment in facilities and labs
- COVID-19 related activity that has a timeline for deployment that could address the current crisis
- Human Subjects Research: no human subjects should be tested unless there are very special circumstances. Please refer to the FAQs posted here: <http://www.bumc.bu.edu/irb/faqs-impact-of-covid-19-on-human-subjects-research/>

**Non Essential** justifications include:

- It will take substantial time to get the lab up and running again
- Experimental results are needed for a paper submission or another critical deadline

**Please be prepared for these criteria to become more restrictive, depending upon developments.**

**Preparation for stoppage of in-person-in-the-laboratory work.**

- Indicate on the [form](#) what activities they believe are critical to maintaining the capabilities of their lab if in-person-in-the-laboratory work is **required** to cease.
- In the case of stoppage, access to labs would only be available for essential personnel who perform critical procedures, processes or equipment management that require regular personnel attention to maintain laboratory viability (e.g. liquid nitrogen tank filling, animal support, maintaining shared computational equipment).
- Where the activity goes beyond simple equipment or sample maintenance the request should include:
  - A justification of the essential activity
  - A physical distancing plan
  - A contingency plan.

The information you provide will be used to notify your departmental administrator about who these individuals are.

**Research Personnel:**

Unless their presence is required for an essential role, trainees (including PhD students and post-doctoral researchers) should work remotely. Please continue charging personnel salaries to grants as normal. Research Operations is monitoring awarding agency guidance and will be contacting departments where after-the-fact changes may be necessary. We have also been working with research sponsors to ensure that we continue to operate in a compliant and appropriate manner.

Staff in Environmental Health & Safety and the Animal Science Center, who are defined as essential personnel, have robust continuity programs to support the campus during this time. Additionally, the units of the Research Operations, the Institutional Review Board and Research Compliance, are fully functional using remote protocols. Departments, Research Operations, Compliance and Environmental Health & Safety will work together to determine how best to continue the indicated critical activities.

Please do not hesitate to reach out to me directly or any of your [Research Operations](#) contacts for anything you need.

Thank you,

Grace Cashman, Senior Director of Research Administration  
660 Harrison Ave | Gambro Building 235 | Boston, MA 02118  
P. 617.414.2628 | [Grace.Cashman@BMC.org](mailto:Grace.Cashman@BMC.org)

To Our Research Community:

We are writing as a follow-up to our message of March 13<sup>th</sup> in regards to Human subjects Research Human Subjects, and the email from Dean Antman yesterday. Please, start preparing your laboratory and research staff, if you have not already, to minimize the impact of disruptions related to COVID-19,

Given the evolving situation with the COVID-19 pandemic, we are attempting to limit the rate of spread of disease and protect our community as best we can, while limiting the loss of critical research resources and momentum. At this point, we are asking everyone to plan to **minimize lab activity to the greatest extent possible**, and to plan for this level of minimal activity to be ongoing for potentially many weeks. The measures outlined below should be in place by 5:00 pm on **Thursday, March 19**. Our major goal at this time is to minimize social interactions, as well as the density of lab staff in research space where possible.

Obviously, COVID-19 research needs to continue, but please ramp down the number of people in your laboratories, as well. This will require a unit-by unit, project-by-project determination and conversation with your manager. Physical presence should not be required when participation is possible digitally. The goal is to promote social distancing as broadly as possible and we are asking researchers to do the following:

- Ensure that any work that can be done remotely is done off campus
- Delay or stop any work that can be stopped
- Limit the work done on campus to long-term experiments and activities that would generate significant financial and data loss if not completed; this includes work to maintain critical samples and animal populations
- Reduce the density in laboratories to 3 or fewer essential personnel
- Hold lab meetings remotely

For human subjects research and as communicated earlier, no human subjects should be tested unless there are very special circumstances. Please refer to the FAQs posted here:

<http://www.bumc.bu.edu/irb/faqs-impact-of-covid-19-on-human-subjects-research/>

Please make sure to pay particular attention to BMC's COVID-19 Travel Guidance:

<https://www.bmc.org/covid-19-information-employees/travel-guidance>

Please stay up to date on all BMC covid-19 updates <https://www.bmc.org/covid-19-information-employees>

We will continue to keep you updated, and send out updates and FAQs as we have them. Thank you,

Research Operations

Good Morning –

Many of you have received the below email from the IRB. We are including a link to the FAQs that have now been updated. [FAQs](#)

Any study teams that may be impacted, please reach out to your CTO and/or Research Operations contact to coordinate any necessary communication to sponsors and possibly your affected study subjects. (<https://www.bmc.org/research-operations/about-us>)

We know that there will continue to be unexpected and unpredictable changes and we are here to support you please reach out with any questions and concerns.

Thank you,

Research Operations

**From:** "[inspir2@bu.edu](mailto:inspir2@bu.edu)" <[inspir2@bu.edu](mailto:inspir2@bu.edu)>

**Date:** March 12, 2020 at 8:43:39 PM EDT

**Subject:** IMPORTANT NOTICE FROM THE IRB

Dear Colleagues:

Drs. Karen Antman and Ravin Davidoff, the Institutional Officials at Boston University Medical Campus and Boston Medical Center, have determined that most research activities involving in-person interactions with subjects MUST STOP until further notice. The only exceptions are if canceling or postponing the activities would either (A) increase the risk to the subject's safety or wellbeing or (B) deprive the subject of a potential direct benefit. This is being done to protect research subject.

The following expands on the implementation of this:

For Ongoing Research with Enrolled Subjects:

Most research activities that involve face-to-face interaction with subjects must stop.

The exceptions are:

1) The research holds the potential for direct benefit to the subject (e.g., investigational drug, devices or surgical procedure) and the interaction is required to deliver that potential direct benefit

2) Collection of safety data (based on clinical judgment of the importance of the visit to detect potential adverse events)

Research activities that involve no face-to-face interactions with subjects may continue.

New Enrollment into Existing Studies:

Most studies must stop enrolling new subjects.

The exception is studies with the potential for direct benefit, that is, benefits that are not available through standard of care.

Pending IRB applications for human subjects research:

The IRB will continue to review and approve submissions. For studies that are approvable, but do not meet the above New Enrollment exception, the IRB will approve the study but explicitly note that enrollment cannot start until the pause in clinical research activities is lifted.

If you have any questions, please contact [medirb@bu.edu](mailto:medirb@bu.edu) or 617-358-5372

John F. Ennever MD, PhD  
Director, Office of Human Research Affairs