TOWN HALL

Resumption of Research

Virtual Town Hall
September 11, 2020
# Where Are We with Return to Campus?

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<th>Pause Research Ramp Down</th>
<th>Wave 1 Research Ramp Up</th>
<th>Wave 2: Continue Research Ramp-up, with IRB-approved</th>
<th>Wave 3 &amp; Future: Focus on education and academic programs</th>
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<td><strong>Timing:</strong> March 13, 2020</td>
<td><strong>Timing:</strong> June 22, 2020</td>
<td><strong>Timing:</strong> July 20, 2020</td>
<td><strong>Timing:</strong> Mid/Late August 2020-current</td>
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| **Scope:**  
  - The University implemented the Research Ramp Down when only essential employee were allowed to be onsite. | **Scope:**  
  - Began CU’s Research Ramp up for return to campus  
  - Included critical research faculty/staff whose work dependent on access to laboratories and other core research related efforts | **Scope:**  
  - Includes research teams whose projects are IRB-approved and involve human subject research  
  - Wave 2 return have occurred | **Scope:**  
  - Emphasis will turn to education and resuming academic programs  
  - Expanded reopening including select admin. staff  
  - Wave 3 planning continues |

[https://covid19.columbia.edu/content/important-details-about-recovery-planning-and-ramping-site-activity](https://covid19.columbia.edu/content/important-details-about-recovery-planning-and-ramping-site-activity)
Important

Our Gateway testing has shown an extremely low rate of infection (<0.5%) and we are well below the allowable occupancy rate.

Thus, it is now possible for more members of our teams to return to campus. Managers are encouraged to speak with their teams to identify those who could be more effective by spending 1-2 (or more) days per week on campus.

Even for those who can do their work remotely, we know that it can be more effective to interact in person with colleagues.
Requirements for All Returning Employees

1. **Before Arriving On Campus**
   - **COVID-19 Testing** – **New:** Effective July 20, 2020, all employees are required to be tested prior to arrival on campus. [https://health.columbia.edu/content/make-appointment](https://health.columbia.edu/content/make-appointment) To arrange for a test call: (212)-854-7426 *note new number*
   - **COVID-19 Training** – All faculty, staff and students must complete the online training program on Safe Practices at Columbia
   - **ReOpenCU Symptom Self-Check** – All faculty, staff, and students will be required to complete a symptom self-check **every day** before entering campus premises

2. **New: Columbia Community Health Compact** – Faculty and staff must affirm the Compact as part of return-to-campus training and certification.

3. **New: Enforcement Plan for Enhanced Health and Safety Policy** – Complaints and concerns about non-adherence can be reported in a variety of ways:
   - Staff can report concerns to their supervisors
   - Faculty can report concerns to their dept chair/dean of faculty affairs
   - Students can report concerns to student affairs staff

4. **Face covering required** to enter the building and whenever you are in company of others
New Messaging from the University

**EFFECTIVE SEPTEMBER 14 (MONDAY)**

New enhancements to the ReOpen CU COVID-19 Symptom Self-check App have been made to fully integrate training, testing, daily symptom checker and CU Health Compact.

**BEFORE ARRIVING ON CAMPUS FOR WORK:**

- Read the Enhanced University Health and Safety Policy
- Take the required Safety Training
- Get Tested
- Use the ReOpen CU app to complete the daily symptom self-check
  - Sign CU’s Health Compact

Failure to complete any of the steps listed below before arriving on campus, will result in you receiving a ‘red pass’ and access to the building will be denied. In order to reduce any disruption to your schedule, please take this time to ensure that the following has been completed:

If you have any questions, please contact your immediate supervisor, department administrator or the Office of Faculty Affairs and Human Resources.
Return to Campus – Research Information

• Definition of IRB Priorities-paused/unpaused-notifications
  
  • **Priority I** – Direct benefit to patients, in patient, planned outpatient, COVID-19 clinical trials were prioritized
  
  • **Priority II** – Direct benefit to patients, federal or foundation funded
  
  • **Priority III** – Industry sponsored
  
  • **Priority IV** – Observational studies with no direct benefit (PBPK)

• **Process** – we must assure that the facilities can handle human subjects research, developing rapid process to determine this. Nothing in IRB applications address the logistics of working within a pandemic.

• **As of now, all studies are eligible to continue, provided the re-opening process is followed. IRB approval for restarting studies is NOT required but please keep copies of all correspondence.**
Procedures Applicable to All Studies

• Separate requirements for studies where participants are recruited/evaluated at MSPH locations, other CUIMC locations, locally, and nationally/internationally.

• All investigators MUST complete the restarting research survey so we can track the restarts
  • https://cumc.co1.qualtrics.com/jfe/form/SV_3ZVrNGSJy7qmyqh
  • One survey for each project please.

• WHY??
  • We need to keep track of ongoing projects for: contact tracing purposes (should they be necessary) and space considerations (as the buildings are not yet at full capacity)
  • All projects need to have approval from the department chair.
  • R2 sends a confirmation note when the survey is complete and you may proceed. Note that for studies in MSPH buildings, Sepi is coordinating space requirements she is copied on those requests.
Of Special Concern to MSPH Researchers

- Research where participants are recruited/seen in MSPH space.
  - All such studies must have a plan in place to ensure that the minimal number of people (participants/staff) are in the building, that proper PPE will be provided, and that after each visit, the space will be adequately cleaned.

- Research where participants are being recruited/seen at CUIMC facilities.
  - All such studies must conform to the rules of the space (e.g. CTSA, PI clinics) that they are using.

- Domestic Research, where participants are being recruited at sites other than CUIMC, and where the local IRBs are permitting research to occur.
  - Do the local IRBs have precedence? Yes, and we require a copy of the local IRB approval.
  - Will the CUIMC IRB automatically unpause this work? If not, what is the appropriate documentation to present to the CUIMC IRB? Yes, the CUIMC is automatically unpause all research. But please keep copies of all documents as they may want to see them later.
Of Special Concern to MSPH Researchers

• Research conducted in the local Washington Heights/Harlem/South Bronx communities (as well as other places in NYC)

  • What if recruitment and all study procedures takes place remotely?
    
    • You will need approval from the local IRB, if applicable to restart this work.
    
    • You will also need to fill out the survey, get departmental approval and send to msph_research@cumc.columbia.edu, and keep copies of all documents.

  • Protocols for investigators wishing to migrate from in person research to remote research

    • The IRB is allowing this without requiring approval. However, you should file a modification at the earliest convenience.
Of Special Concern to MSPH Researchers

• International Studies
  
  • What is the role of the local IRB and local regulations regarding continuation of these projects? That is, does the CUIMC IRB or the local IRB take precedence?

  • The local IRB takes precedence regarding whether can resume. We will need the clearance letter from the local IRB, and the plans to provide adequate PPE and social distancing for staff and participants.

  • **We are also required to inform the provost that this research will be restarted (not for approval, just notification).** There is a form that must be completed and sent (with the other documentation) to msph_research@cumc.Columbia.edu. We will send the form to the provost’s office.

  • The link to the downloadable form can be found here.
Of Special Concern to MSPH Researchers

- What are the IRB response times to queries, and does it vary by priority of the study?
  - You should follow the usual procedures for IRB questions and responses.

- Does all research continuation need to be approved by MSPH, including that which does not require MSPH space?
  - We need to be informed, that is the purpose of the survey.
MSPH Survey to Faculty

• We are primarily concerned with occupancy rates in MSPH facilities and will use the results to assist investigators in scheduling visits that keep within the university stated occupancy.

• If your protocol does not require MSPH space please complete the survey anyway, as we would like to know the volume of research that is underway.

• Thank you.
Questions?
REMINDER: Building Updates: Access

• Building Access
  • ARB, Haven and our spaces in Black and P&S are open for returnees. Building 600 remains closed.
  • All employees are required to swipe their CUIMC ID to enter a building on campus, in addition to fulfilling health-related requirements – testing, training, symptom checker.

• Process for Guests / Visitors
  • All visitors and vendors must be registered by emailing Ps-mc-guestaccessrequests@columbia.edu at least 24 hours in advance, and copy Brian Byrne, bb2502@cumc.columbia.edu

ARB lobby extra ID scanning station will reduce the chance of lobby crowding during rush hour.
A Look Forward

- **Communications**
  - A “Return to Campus” email bulletin has been created and will be going out on an as-needed basis to keep everyone up-to-date
  - A dedicated email box: msph_covidsupport@cumc.columbia.edu to address questions. The mailbox is being monitored to ensure that emails are routed to the appropriate parties for a response.
  - Please continue to address **confidential** matters to the Office of Faculty Affairs/HR msph-hr-fac-affairs@cumc.columbia.edu
  - Visit the MSPH “Covid-19 Resource” Webpages for updated information
  - We will continue to have Town Halls

- **Planning underway** with departments/centers future