



COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

BIOSAFETY CONSIDERATIONS AT COLUMBIA UNIVERSITY WHEN ESTABLISHING BIOSAFETY LEVEL-3 LABORATORIES FOR SARS-CoV-2 RESEARCH AND A BIOSAFETY LEVEL-2 COVID-19 BIOREPOSITORY

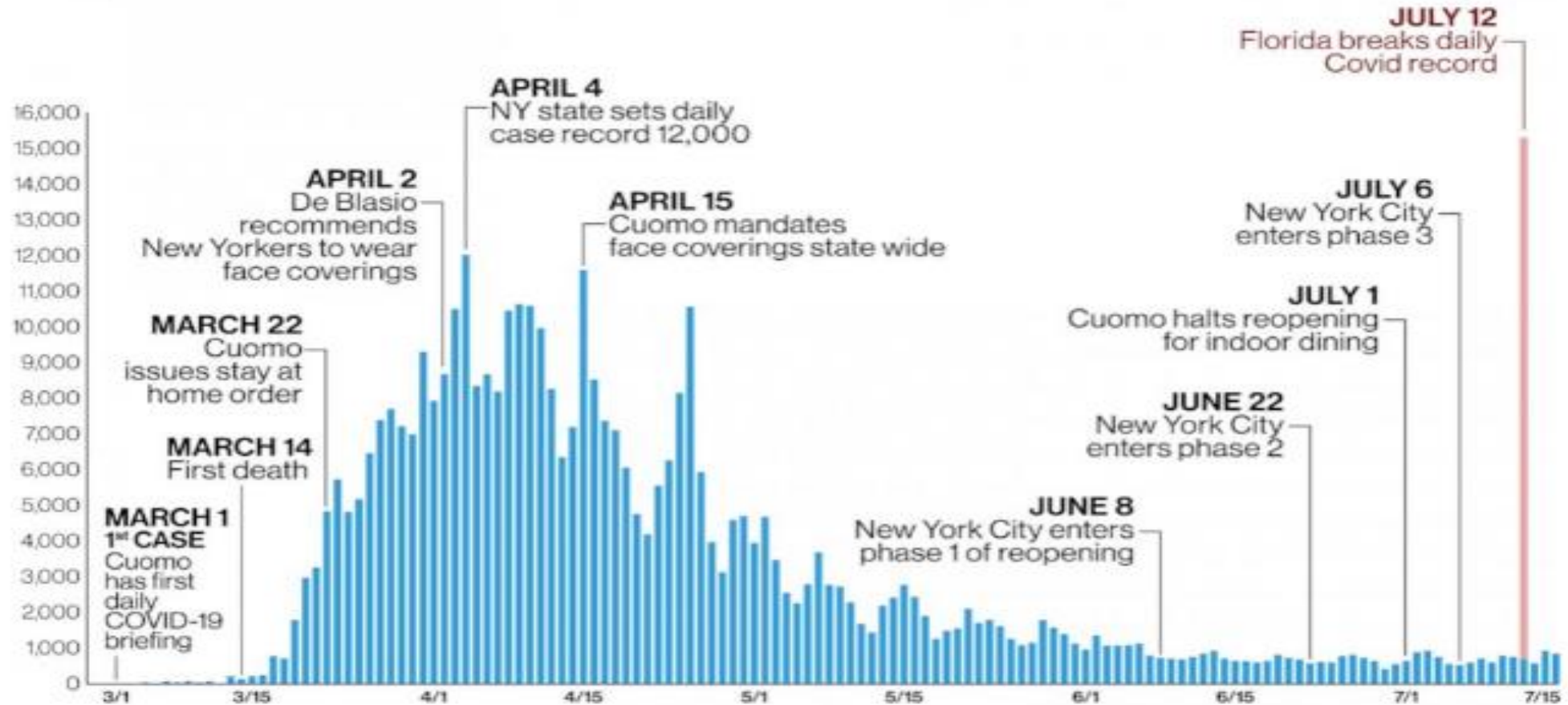
Aderemi Dosunmu, PhD, CBSP (ABSA)
(Biosafety Manager, formerly Columbia University,
currently Memorial Sloan Kettering Cancer Center)

Topics

- ✓ COVID-19 Timeline
- ✓ Notifications of Research Plans
- ✓ Institutional Approvals and Workflows
- ✓ Research: Biosafety Level 3
- ✓ Research: COVID-19 Biorepository for Clinical Specimens
- ✓ Enhanced Biosafety Level 2 Precautions
- ✓ Acknowledgments



New York's Covid Timeline



SOURCE: THE COVID TRACKING PROJECT

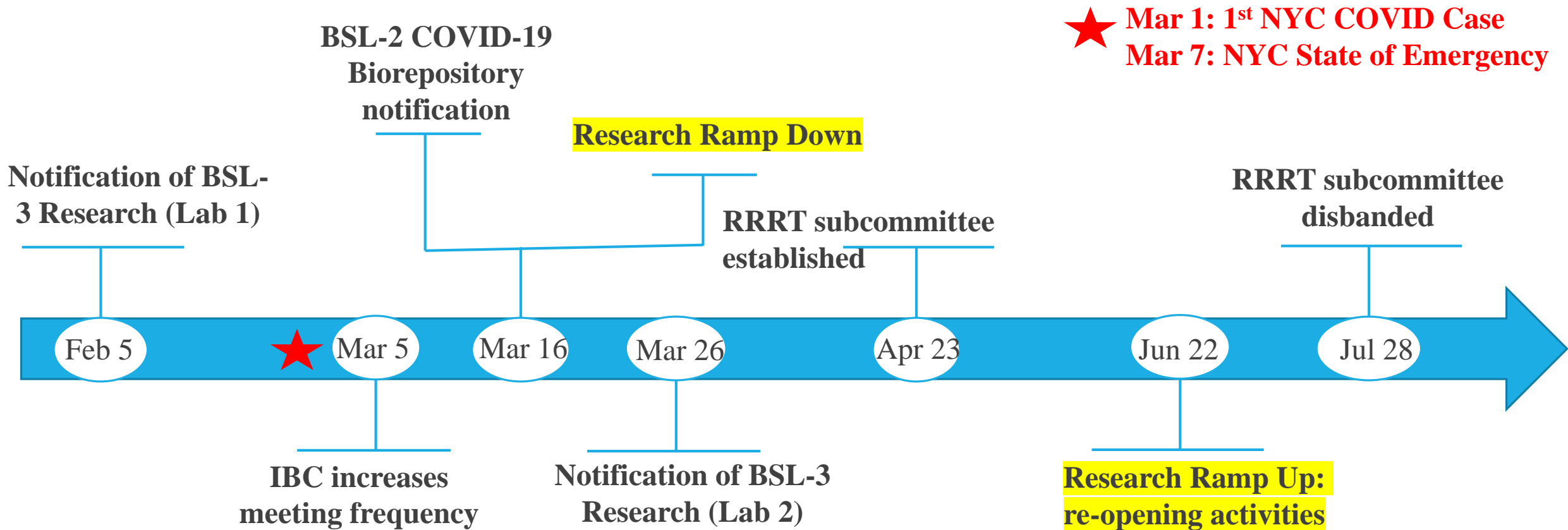
abc NEWS

ABC News

New York's Covid Timeline



Timeline of COVID-19 Pandemic at Columbia



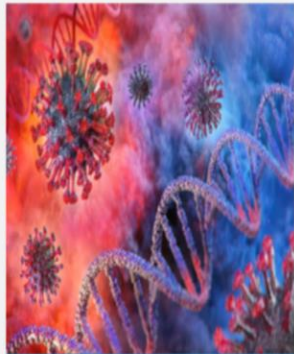


How was the Biosafety Office Notified of SARS-CoV-2 Related Research?



Environmental Health & Safety

COVID-19 EH&S GUIDANCE



Click to visit the COVID-19 EH&S
Guidance page

EH&S Service Updates

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- [Research with SARS CoV-2 / COVID-19](#)
- [Ongoing Services](#)
- [Research Ramp Down \(3/19/20\)](#)

Resources

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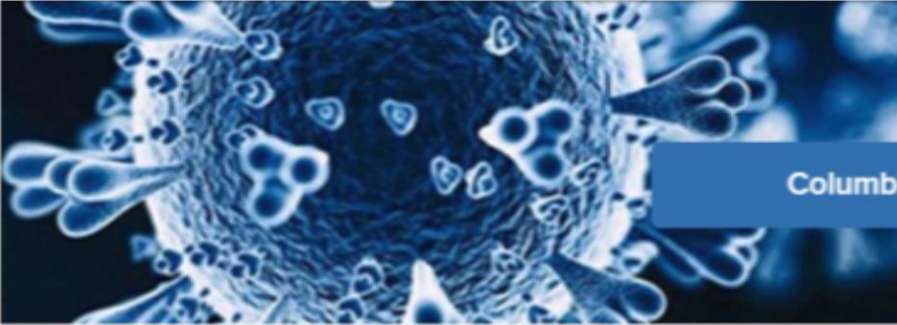
▼ [Advisories](#)

- [Inactivation methods guidance for SARS-CoV-2 materials, May 18, 2020](#)
- [Biosafety Precautions with Clinical Specimens from COVID-19 Patients, Updated May 17, 2020](#)
- [Submission of Proposals for COVID-19-Related Research, Updated May 8, 2020](#)
- [BSL-2 Enhanced Work Practices for Specimen Processing and Cell Culture, April 20, 2020](#)
- [Advisory for Work in Public Safety #1: March 29, 2020](#)
- [Advisory for Essential Work in a University Research Lab: March 21, 2020](#)



Priority Lab Spreadsheet





MOBILIZING RESEARCH AGAINST COVID-19





Columbia COVID Hub 

Virtual Symposium

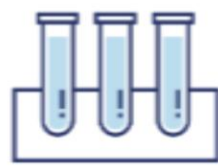
Like research communities around the world, Columbia researchers have mobilized to address all aspects of COVID-19 and the human experience. Our contributions below reveal the virus' composition and spread, address the potential impact on our social and political institutions, and pioneer clinical trials to test new treatment options.

This page features highlights of Columbia's ongoing and proposed research, reported and described by our faculty. They illustrate the breadth of ongoing efforts across the University's research enterprise.

Please visit Columbia's [COVID-19 Resource Guide](#)  for all University communications regarding the current pandemic.

Members of the press media are invited to visit the University's [Press Room](#) .

COLUMBIA'S COVID-19 RESEARCH



Diagnostics and Testing



Vaccines and Treatment



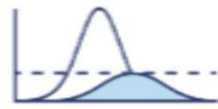
Mapping and Analysis



Medical Devices and Equipment



Community Impact



Flattening the Curve



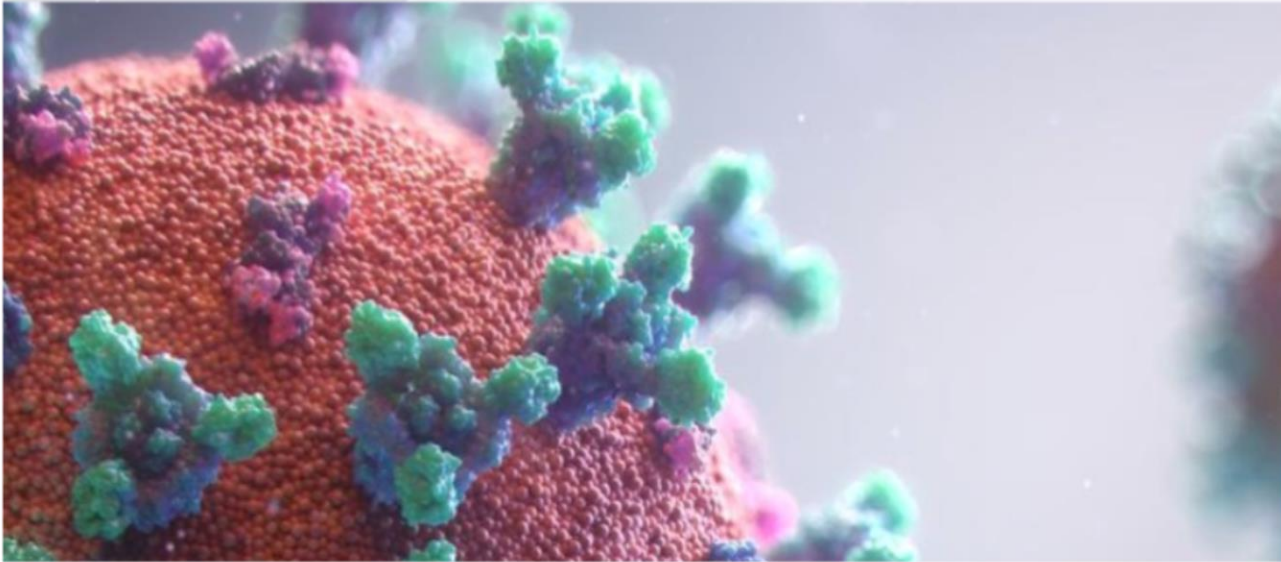
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Home ▾ Mobilizing Research Against COVID-19 ▾ COVID-19 Hub



The COVID-19 Hub is a central information resource for members of the Columbia Community. The Hub is a searchable database of on-going projects and people who are currently working on COVID-19.

The COVID-19 Hub is under development, and relies solely on users to enter and update their information. To keep the Hub up-to-date, please fill out an [investigator survey](#), if you have not already, and a [project survey](#) (one per project). Submit feedback on the functionality of this resource, and share your ideas [here](#).

Please note that this beta version, under development, is available only to officers. Coming soon will be a way to match talent to expertise needed.



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Home ▾ Mobilizing Research Against COVID-19 ▾ COVID-19 Virtual Symposia Archive

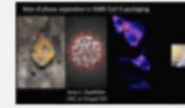
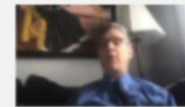
COVID-19 Virtual Symposia Archive

This page is an archive of the COVID-19 Virtual Symposium Series presentations. This page will be updated with the previous week's videos once they are readily available. Click [here](#) to view the upcoming COVID-19 Virtual Symposium registration and agenda.

Please contact covid_symp_support@columbia.edu with any questions or comments.



Alex Butler - June 10

Alex Chavez and
Rodney Rothstein -
April 1Allison A. Norful - April
22Ambassador Lawrence
Butler - April 29Amy Gladfelter -
August 12Andrea Califano - April
1Andres Bendesky -
May 13Andrew Gelman - May
6Andrew Rundle - April
29

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Video Category 1



Antibodies

Clinical

Diversity

Economic

Engineering

Molecular Biology

Societal

Therapeutics

Treatment

Vaccine

Apply Now!



Once Notification
Happened -
What Approvals are
Required?



Institutional Biosafety Committee

Charge: Facilitating University compliance with the NIH Office of Science Policy's Guidelines for Research Involving Recombinant DNA Molecules ... The IBC must vote to approve all protocol renewals, or modifications that include significant changes/additions to the hazardous materials appendices or to procedures involving the use of recombinant DNA or potentially infectious materials

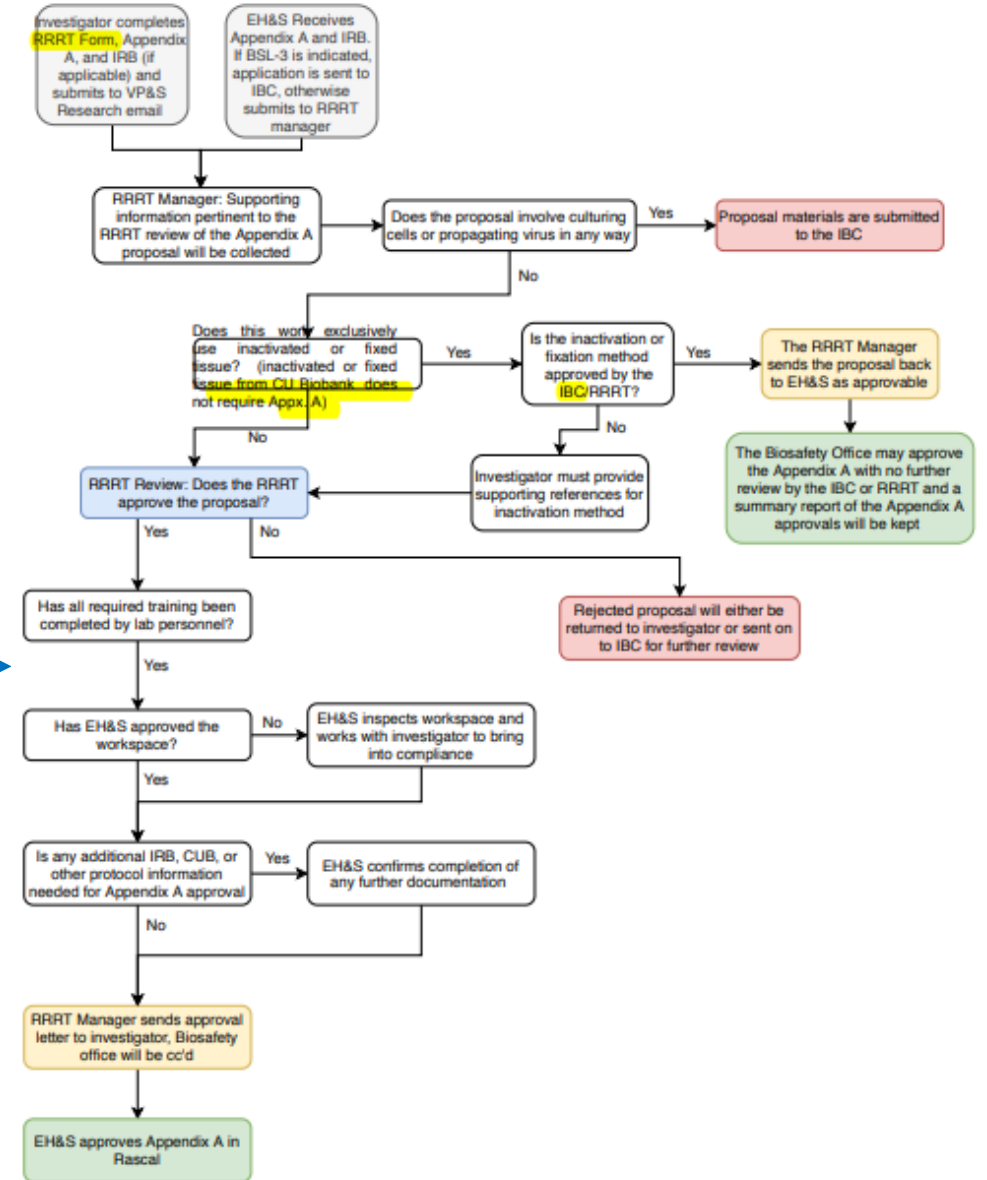
Goal: Register all research activities with SARS-CoV-2 or Clinical Specimen used in Research



IBC Activities

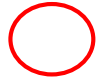
- rDNA/infectious agent reviews and approvals
- Updates on the University's COVID-19 Response
- Inactivation Procedures and Methods
- Transport Protocols
- Human Gene Therapy Protocols
- **Research Activities with COVID-19 Clinical Specimens**

COVID-19 Rapid Research Review Team Workflow



IBC Monthly → Weekly/Bi-Weekly
 Rapid Research Review Team (RRRT):
 Daily Subcommittee





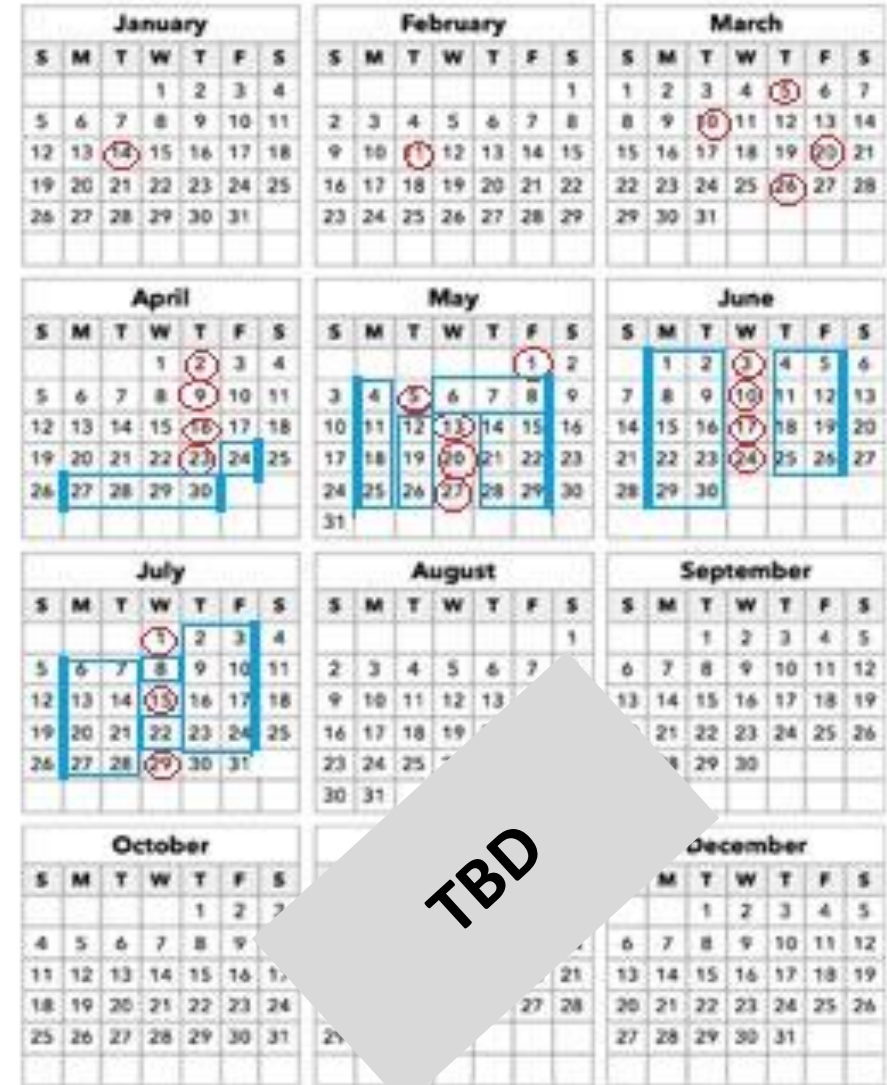
IBC Meetings



RRRT Meetings-daily availability, only met if urgent protocols needed review/approval

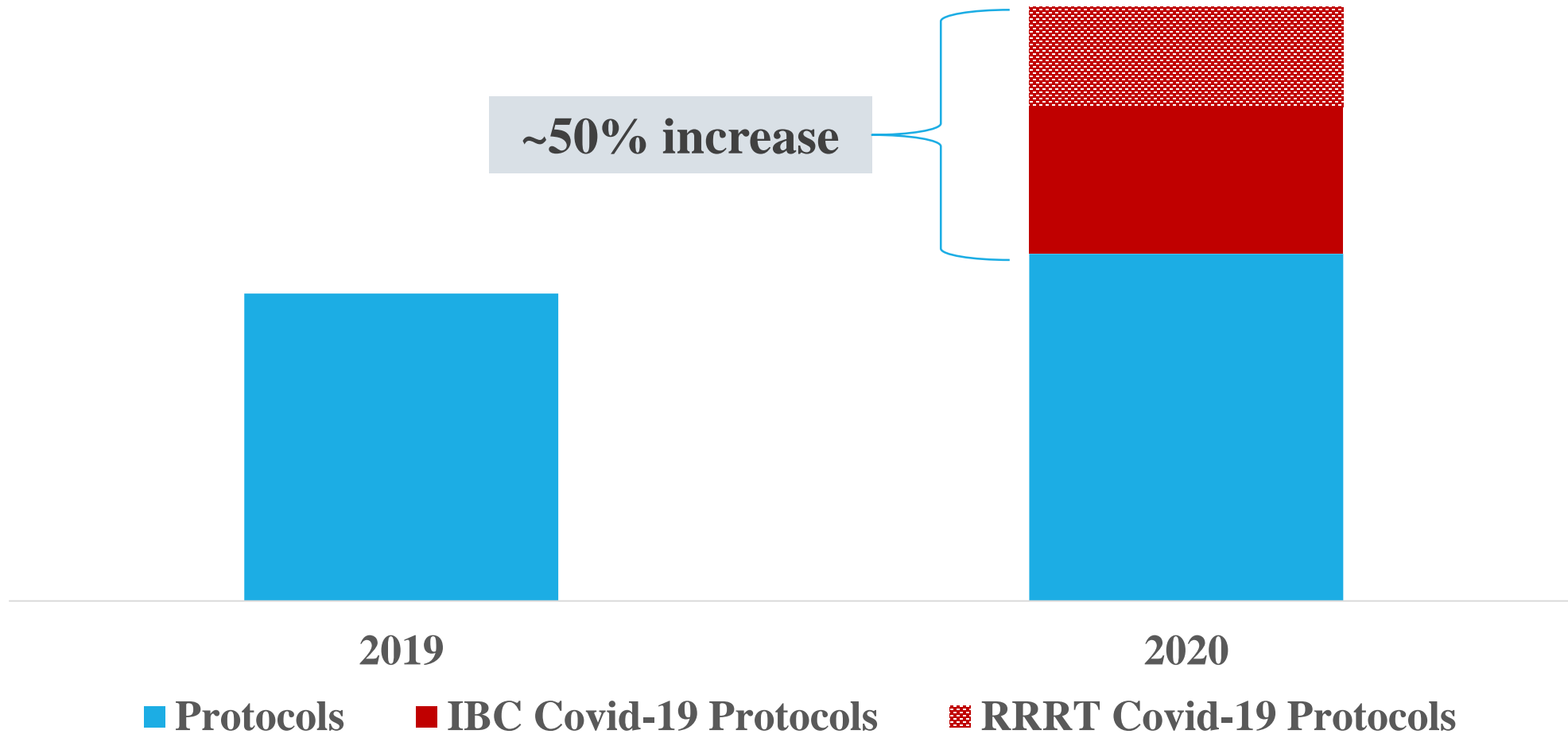
2019

2020



TBD

2019 vs 2020 IBC Reviews (January-July)



Topics

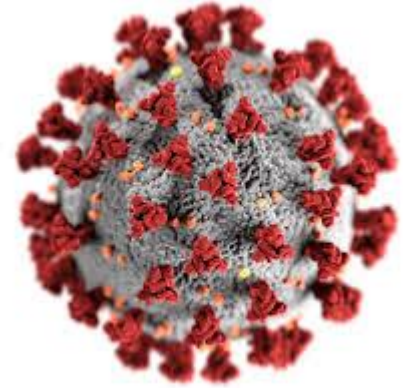
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Biosafety Level 3

Will proposal consist of any of the following BSL-3 experiments?

- Storage and laboratory work with seed stocks, working stocks or specimens with the intent to grow or use infectious SARS-CoV-2.
- SARS-CoV-2 isolation, characterization and/or expansion
- Use of infectious SARS-CoV-2 virus in functional assays:
 - Plaque/Focus Forming Unit assays
 - Serologic virus capture/binding assays
 - Therapeutic MIC assays
 - Live cell sorting with intact virus
- Infectious SARS-CoV-2 *in vivo* models



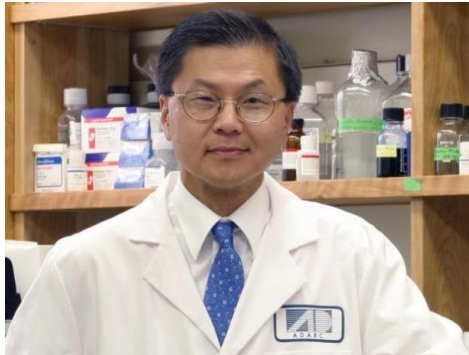
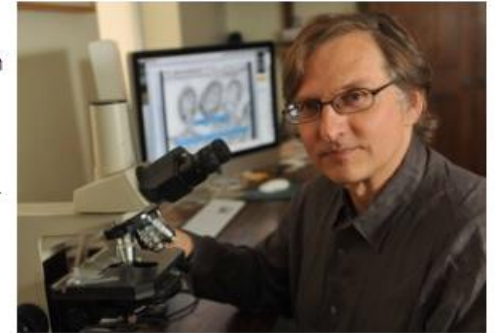
Biosafety Level 3 Laboratories

About



Center for
Infection and
Immunity

The Center for Infection and Immunity has been committed to research and service in global public health since moving from the University of California to Columbia in 2001. The CII is directed by W. Ian Lipkin, MD, John Snow Professor of Epidemiology and Professor of Neurology and Pathology who has been named the “World’s Most Celebrated Virus Hunter”.



Aaron Diamond AIDS Research Center



About Us

ADARC's mission is to develop scientific solutions to end AIDS and COVID-19

ADARC and CUIMC will combine their scientific strengths in discovery to advance the treatment and prevention of both HIV/AIDS and COVID-19.



Research

Learn about ADARC research labs and core facilities

We have adopted a multidisciplinary approach virology, immunology, molecular biology, and clinical medicine—to pursue a number of projects in AIDS research.



Biosafety Measures for BSL-3 Laboratories

- ✓ Approvals
- ✓ Risk Assessments
- ✓ Facilities and Biosecurity
- ✓ Disinfection and Decontamination
- ✓ Incident Response
- ✓ Medical Surveillance Plan
- ✓ Training and Documented Competency
- ✓ Personal Protective Equipment
- ✓ Assurances



Approvals

- Biosafety Office received and reviewed the BSL-3 research proposals and protocols
- Preparation for review by the IBC
- Senior University Leadership approvals



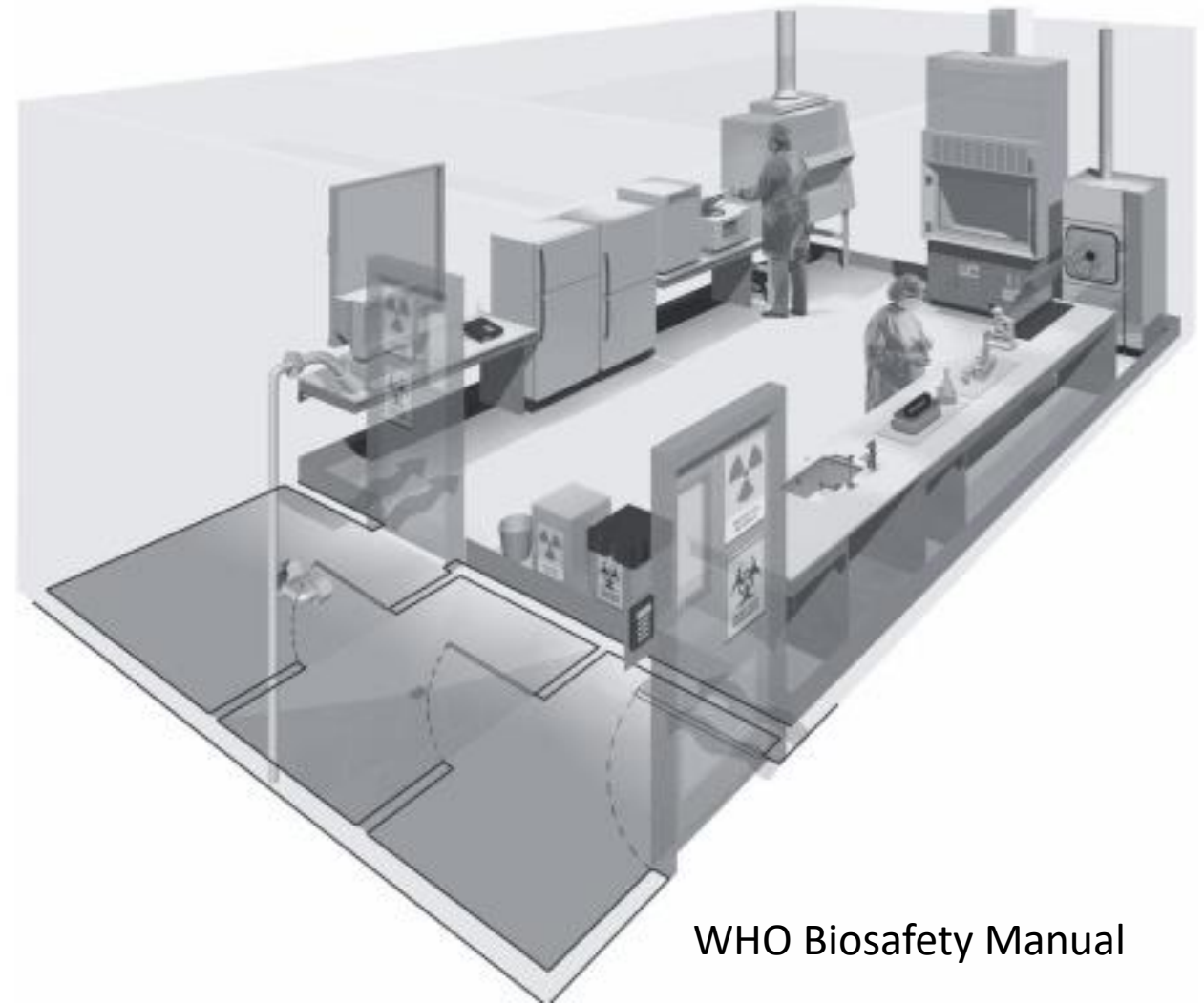
Risk Assessment

Biosafety Officer worked with the laboratories to perform a site-specific and activity-specific risk assessment to identify and mitigate risks:

- Sources of the samples and/or specimens
- Specific experiments parameters for SARS-CoV-2 and identification of the hazards involved in the process and/or procedures.
- Engineering and administrative controls and work practices
- Personal Protective Equipment
- Virus inactivation methods
- Containment levels for active and inactivated materials
- Disinfection and Decontamination and Waste Disposal
- The competency level of the personnel who perform the procedures
- Incident Response
- Occupational Health and Medical Surveillance
- Resources and supplies available



Facilities and Biosecurity



WHO Biosafety Manual



Disinfection and Decontamination



Incident Response

Reviewed procedures in place for emergency situations:

- Breach of containment
- Spill response
- Alarms
- Fire
- Power Outage



Experience with Select Agent
Incident Response SOPs and
Drills and Exercises



Medical Surveillance Plan



- Expansion of the general Occupational Safety Program to be specific for SARS-CoV-2 BSL-3 work.
- The plan was peer Reviewed by Clinicians from Workforce Health and Safety, Infectious Disease, New York-Presbyterian Infection Control, and Student Health Services.
- Serum Banking
- Contingency Plans should a researcher become ill with COVID-19
 - Determinations on if community acquired or a laboratory acquired infection
 - Protocols in place for general illnesses
- Fever Diary/Log: Keeping track of constitutional symptoms



Training and Documented Competency



- Pathogen Specific Training for SARS-CoV-2 BSL-3 research
- Assessor/Trainer: Advises and observes microbiological techniques.
- Biosafety Officer: Observes and advises on safety, security, and incident response procedures.
- Trainees: Must pass the assessment and take a Test/Quiz to ensure comprehension of policies and procedures.



Personal Protection Equipment PPE)

BSL-3 Personal Protective Equipment		
Tyvek Coveralls	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Double Gloves	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Eye protection	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Respiratory protection PAPR or N95 respirator	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Face protection (face shield)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Other? (Please list) Disposable sleeves, disposable shoe covers		
Remove and discard sleeves immediately upon completion of work in BSC.		



EH&S Occupational Safety Team to the Rescue:

- Evaluation of supply donations both internal and external
- Fit Testing of N95 and KN95 respirators
- PAPR trainings



Assurances for Virus Procurement



be i RESOURCES
SUPPORTING INFECTIOUS DISEASE RESEARCH

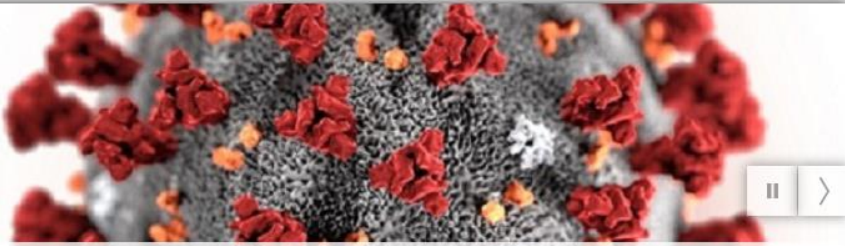
Home Catalog Deposits Register MR4 About

Catalog Search Choose a Resource

Update 9/5/2020: 2019 SARS-CoV-2 and currently available Coronavirus strains and reagents

Click [here](#) for available products, information and FAQs regarding the 2019 SARS-CoV-2. For any questions regarding materials, please contact contact@beiresources.org.

BEI Resources is prioritizing and fast tracking all SARS-CoV-2 registrations and orders. We anticipate a 12-72 hour turn-around time on approved orders and a 24-48 hour turn-around time on related registrations and a 24-48 hour turn-around time on approved orders. Please indicate SARS-CoV-2 in your scope of work paperwork.



2019 SARS-CoV-2 and currently available Coronavirus strains and reagents

Click [here](#) for available products, information and FAQs regarding the 2019 SARS-CoV-2. For any questions regarding BEI Resources and SARS-CoV-2 materials, please contact contact@beiresources.org.

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Schedule of Events Coming Soon



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BSL-2 Biorepository Background

[COVID-19 Updates and Information](#)

[COVID-19 Studies](#)

[Columbia Researchers against COVID-19 Biorepository Volunteer Opportunities](#)

[Basic Research](#)

[Clinical and Translational Research](#)

[Center for Advanced Laboratory Medicine \(CALM\)](#)

[Laboratory of Transfusion Biology](#)

[Digital Pathology Resources](#)

[Pathology Research Administration](#)

[Research Directory](#)

[Graduate Teaching Faculty](#)

Center for Advanced Laboratory Medicine (CALM)



We are staffed by ASCP licensed medical technologists who strive for accuracy in results, attention to detail, and a quick turn-around-time. Our director, [Dr. Eldad Hod](#), is a board-certified clinical pathologist, assistant director of the Core Laboratory, and has expertise in blood banking, clinical chemistry and hematology testing. CALM medical technologists and staff have extensive access to, and actively collaborate with, the entire faculty of the Columbia University Department of Pathology. We are a knowledgeable, creative group who will carefully develop solutions for your research needs.

Columbia Researchers approached CALM for discarded specimens to study Seroprevalence in NYC before the first case: Dumpster diving for specimens



COVID-19 Biobank: A Collaboration between New York-Presbyterian and Columbia University Irving Medical Center



VAGELOS COLLEGE OF
PHYSICIANS AND SURGEONS

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[Cancer Center Resources](#)

[Clinical & Translational](#)

[Columbia Genome Center](#)

[Columbia University Biobank](#)

[Cryo-Electron Microscopy Center](#)

[Emergency Backup Freezers](#)

Columbia University Biobank

The purpose of the Columbia University Biobank (CUB) is to create a centralized resource to collect, process, store and disseminate biological specimens, biomarkers, and health data for Columbia University investigators for use in biomedical research.

The CUB functions under standard operating procedures (SOPs), quality assurance and quality control measures for sample collection and

COVID-19 Biobank

To assist with the scientific response to the coronavirus, the Columbia University Biobank is currently focused on the collection and distribution of biospecimens that may enable COVID-19 research. If you are interested in contributing samples, or would like to request samples for your research, please use the links provided below.



Biosafety Measures for the BSL-2 Biorepository

- ✓ Approvals
- ✓ Specimens
- ✓ Workflow
- ✓ Facilities
- ✓ Disinfection and Decontamination
- ✓ Personal Protective Equipment
- ✓ Personnel Training and Volunteer Efforts



Approvals



Institutional Biosafety Committee approval and Institutional Review Board approval:

- Collection of residual samples from COVID-19 patients for research
- Collection of clinical data from Electronic Health Record (EHR) for observational studies of COVID-19 and its clinical outcomes
- Genomic and clinical studies

For researchers requesting materials from the Biobank:

- All protocols were reviewed by the IBC or Rapid Research Review Team (RRRT)
- Inactivated specimens reviewed/approved by Biosafety Officer



Specimens

Specimens (with consent) were collected from patients evaluated for COVID-19 in outpatient “cough and fever” clinics, antibody testing, patients evaluated in the emergency department, and all inpatients, including adult and pediatric patients. Autopsy tissue was also collected.

The COVID-19 Biobank stored and distributed residual de-identified specimens from all patients with confirmed SARS-CoV-2 infection:

- Nasopharyngeal swabs
- Serum
- Plasma
- Buffy coats
- Urine
- CSF
- Stool samples
- Cord blood
- Autopsy samples: all organs with special emphasis on lung, liver, kidney, and heart. In addition, frozen sections (OCT snap frozen) of lung, heart, kidney, liver and GI tract (esophagus, stomach, small bowel and colon), and frozen samples of brain and nasal and olfactory mucosa



The COVID-19 Biobank Workflow



- Biosafety Officers reviewed the workflows, inactivation procedures, and evaluated specimens needed as informed by the IBC protocols.
- Recommended limited spaces for certain activities e.g., flow cytometry or tissue cutting



Facilities

- Clinical Laboratory Space – CLIA Labs
- Additional Space required
- Biosafety Office and EH&S provided walkthroughs and recommendations



Disinfection and Decontamination

- Sealed tubes wiped down with bleach wipe or ethanol prior to leaving BSC
- All waste generated considered biohazardous
- Waste in RMW and Sharps containers
- 10% bleach for decontamination
- Spill Kit inside the Lab



Personal Protective Equipment



Personnel Training

Name	UNI	Lab Safety (TC0950/TC4951)	Biosafety (TC0509/TC4850)	Biosafety (TC3550/TC4950)	Shipping Bio Materials (TC0507)	Shipping w. Dry Ice (TC0076)	C-14 (Yes/No/In Progress)
xxx	xxx	1/8/2021	3/23/2021	1/8/2021			No, is not a C-14 card holder and needs to complete training and submit paperwork
xxx	xxx	1/31/2022	02/21/2021	03/18/2022			Yes, is a C-14 card holder
xxx	xxx	07/05/2021	7/5/2020	07/03/2021			No, is not a C-14 card holder and needs to complete training and submit paperwork
xxx	xxx		11/09/2017	4/7/2022		4/7/2022	Yes, is a C-14 card holder
xxx	xxx	10/15/2021	12/26/2019	10/10/2020	02/20/2021		Yes, is a C-14 card holder
xxx	xxx	08/14/2020	02/26/2021	08/14/2020			Yes, is a C-14 card holder
xxx	xxx	07/08/2021	07/08/2020	4/3/2022	4/3/2022	4/3/2022	No, is not a C-14 card holder and needs to complete training and submit paperwork
xxx	xxx	03/25/2021	02/26/2021	03/19/2021			No, is not a C-14 card holder and needs to complete training and submit paperwork
xxx	xxx	10/03/2021	09/17/2020	09/17/2021			Yes, is a C-14 card holder
xxx	xxx	04/11/2018	04/05/2011				Yes, is a C-14 card holder



Volunteers

The Clinical Lab staff had to prioritize their clinical responsibilities, so volunteers were needed to provide specimens for research.

The Columbia Researchers Against COVID-19 (CRAC) team were Post-Doctoral Researchers whose work was put on hold and wanted to contribute to the University's COVID-19 Response:

- From March to June they volunteered 4-hour shifts in the Biobank.
- Started with 8 volunteers, gradually expanded to a total of 18 volunteers.
- Assisted in processing ~35,000 specimens.



Photos by Dr. Álvaro Cuesta-Domínguez

Source:

<https://columbiacovid.weebly.com/>



In the end....

Collection of over 30,000 biospecimens and clinical data from over 2,000 COVID-19 patients for the Columbia University research community and beyond.



For active specimens that were distributed by the Biobank to the research community or other direct specimens collected by researchers...

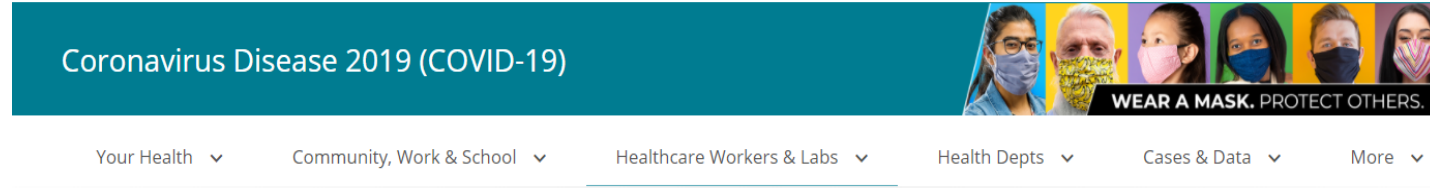


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Enhanced Biosafety Level 2 Precautions



CDC provided recommendations. How to practically apply guidelines to research?

LABORATORIES

Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)



Biosafety Responsibilities

Biosafety Officer consultation visits of each space:

- Determination if work is at enhanced BSL-2 or must be performed in a BSL-3 Laboratory
- Facilities tours and recommendations
- Evaluated BSC placements and locations
- Housekeeping
- Transport protocols
- Summarize visits back to Rapid Research Review (RRRT) subcommittee or IBC



Resources for Research at Enhanced Biosafety Level-2

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

ENVIRONMENTAL HEALTH AND SAFETY

Biosafety Precautions with Clinical Specimens from COVID-19 Patients

Executive Summary

Columbia University Environmental Health & Safety (EH&S) in conjunction with the Institutional Biological Safety Committee (IBC) has prepared this guidance for laboratories and other groups that are registered to receive or will be receiving unfixed human specimens as part of their research in relation to potential COVID-19 risks. Work with human specimens requires the use of [standard AKA universal precautions](#) and Enhanced biosafety Level 2 (BSL-2) containment and work practices, because all human materials must be treated as potentially infectious. Given the presence of COVID-19 across the world, this update is provided as a reminder to strictly adhere to established biosafety practices (See Appendix 1 Biocontainment levels and training required for research materials).

CDC/ABSA Guidance Information for Laboratories

For those labs who will handle specimens from COVID-19 patients, the CDC has also published interim laboratory biosafety guidelines that can be accessed from the following [website](#) (Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)). The IBC considers the current CDC guidance regarding containment procedures for working with the SARS-CoV-2 virus as a minimum standard. See also Appendix 2; ABSA chart.

1. Procedures/Lab Work Requiring BSL-2 Containment

Specimens that have been inactivated by an established method can be worked on with BSL-2 practices. At BSL-2, aerosol-generating procedures are also performed in a biosafety cabinet.

2. Procedures/Lab Work Requiring Enhanced BSL-2 Containment

Nasal and pharyngeal swabs have been shown to contain high loads of SARS-CoV-2 virus and must be worked on at enhanced BSL-2 containment. Be advised that current data in the literature

Appendix 1. Biocontainment levels and training required for research materials

	Universal / Standard precautions	BSL-2	Enhanced BSL-2	BSL-3	ABSL-2	ABSL-3
Rascal Training	PI attests	TC0509 TC3550 (lab work). TC0025 (specimen collection)	TC0509 TC3550 TC5500	TC0509 TC3550 TC5500	TC0509	TC0509
Other training	WHO Standard Precautions (References)	N/A	Hands-on provided by PI	Contact EH&S		Contact EH&S/ CM
Viral culture from a repository Viral isolation from specimens Culture of cells from clinical specimens	X			X		
Respiratory specimens (swab, BAL, endotracheal wash, lung tissue). Other specimens (blood, urine, fecal)	X		X			
Cadaverous tissue	X	X	X (lung)			
Cutting frozen sections	X	X				
Unfixed cells for Fluorescence-Activated Cell Sorting (FACS)	X		X			
Material subjected to viral inactivation in the University's Biobank		X				
Material subjected to viral inactivation in a Columbia University research laboratory		X				
Material not inactivated, processed for shipping	X		X			
Material subjected to viral inactivation before receiving at Columbia University (non-infectious)		X				
Full length viral RNA		X				
Pseudotyped viral vector (lentiviral, VSV)		X				
Viral genes in plasmids		X				
Introducing SAR-CoV-2 into animals	X					X
Introducing Pseudotyped viral vector into animals					X	





Bench work

- Whole blood, serum and urine
- Rapid respiratory testing performed at the point of care (no nucleic acid isolation)

Laboratory Practices and Technique

- Good (Standard) Microbiological Practices

Primary Barriers and Personal Protective Equipment (PPE)

- PPE: lab coat, single gloves, surgical mask, eye protection, face shield
- Work behind plexiglass screen in an isolated designated area (minimum)
- Notify others in the lab
- Work with samples done over a plastic-backed benchtop pad
- Surface decontamination at every step using EPA List N disinfectants and contact times.
- Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.

Administrative Controls:

Training and competency verification on donning and doffing required PPE

* CDC Guidance for Laboratory <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

** WHO Laboratory Guidance <https://apps.who.int/iris/bitstream/handle/10665/331138/WHO-WPE-GIH-2020.1-eng.pdf>

*** The Lancet [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(20\)30089-3/fulltext](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(20)30089-3/fulltext)

These considerations do not supersede any regulatory or country-specific requirements in your locale.

BSL2

- Using automated instruments and analyzers (if aerosol containment is a feature) some devices might be older and not contained
- Staining and microscopic analysis of fixed smears
- Examination of bacterial cultures
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
 - Inactivation methods should be validated
- Molecular analysis of extracted nucleic acid preparations
- Final packaging of specimens for transport to diagnostic laboratories for additional testing
- Specimens should already be in a sealed, decontaminated primary container
- Using inactivated specimens, such as specimens in
- Nucleic acid extraction buffer
- Performing electron microscopic studies with glutaraldehyde- fixed grids

* CDC Source

Additional procedures

- Cytometry – fixed samples

Laboratory Practices and Technique

- Good (Standard) Microbiological Practices
- Access to the laboratory is restricted when work is being conducted
- All procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.
- Use safety cups whenever possible to avoid exposure to aerosols.

Primary & Secondary Barriers and PPE

- PPE: surgical mask, single gloves, gown/lab coat, eye protection
- BSCs, if available, are properly maintained and certified
- Mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory
- A method for decontaminating all laboratory wastes should be available in the facility

Administrative Controls:

- Training and competency verification for each procedure performed
- Laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures
- Occupational health
- -mandatory reporting of any symptoms, any laboratory exposure

BSL2 with BSL3 practices

- Aliquoting and/or diluting specimens
 - Inoculating bacterial or mycological culture media
 - Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
 - Nucleic acid extraction procedures involving potentially infected specimens
 - Preparation and chemical- or heat-fixing of smears for microscopic analysis
- * CDC Source

Additional procedures

- Respiratory samples and secretions
- Stool***
- Cytometry – non-fixed samples
- Inactivated virus lysate
- Work with ANY sample that may produce an aerosol

Laboratory Practices and Technique

- Good (Standard) Microbiological Practices
- Primary & Secondary Barriers and PPE
- PPE: surgical mask (blood)/N-95 (respiratory secretions), double gloves, impervious gown, eye protection with side shields
- All samples opened inside the BSC in case of spills/leakage. If BSC is not available, don N95 and face shield and work behind plexi-glass screen in an isolated designated area, notify other laboratorians, work with samples done over a plastic-backed benchtop pad
- Surface decontamination at every step using EPA List N disinfectants and contact times.

Administrative Controls:

- Scheduled time for handling SARS-CoV-2 samples (best practice)
- Two-person rule for minimizing withdrawing hands from BSC
- Centrifuging of blood specimens is in safety cups or sealed rotor, loaded and unloaded in a BSC
- Training and competency verification on donning and doffing required PPE
- Specific training on use of N95 respirators, if applicable (includes pulmonary function, medical clearance, and fit testing)

BSL3

Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens

Additional procedures

- FACS/High Speed Cell Sorting
- Transfer of inactivated samples outside BSL3
- Inactivation by validated methods

Laboratory Practices and Technique

- Good (Standard) Microbiological Practices
 - Follow BSL3 practices and procedures according to CDC BMBL 5th ed.
- Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents and must be supervised by scientists competent in handling infectious agents and associated procedures.

Primary & Secondary Barriers and PPE

- All procedures involving the manipulation of infectious materials must be conducted within a BSC, or other physical containment devices.
- Respiratory protection is required (N95 or PAPR/CAPR)
- Autoclave waste before disposal
- Facility exhaust system must have HEPA filtration**

Transfer of samples outside BSL3-based on risk assessment by biosafety officer

- Ensure lids are tight
- Decontaminate outside of tubes
- Wrap sample with absorbent material
- Individually place into zip-lock bag
- Seal zip-lock bag and change gloves
- Add all wrapped samples into second bag
- Wrap bagged samples in ample packaging and place into designated carrier, firmly attach lid



Inactivation methods for SARS-CoV-2

Viral inactivation is an important step prior to reducing the biocontainment level for handling materials that contain SARS-CoV-2. Viral inactivation destroys the ability of the virus to replicate but seeks to preserve viral and host proteins or nucleic acid.

Inactivation methods include chemical treatment (detergents, fixatives, denaturants), physical treatment (heat, ionizing radiation, UV light) or a combination of the two. Kit reagents can come with a validated claim that they inactivate enveloped viruses. Freezing will not inactivate virus.

Influence of specimen matrix and reagent combinations

When an investigator seeks EH&S approval for an inactivation method, biosafety officers and subject matter experts on committees review each method and any supporting references or claims that the investigator provides. Each method is reviewed on its own merits for the matrix that the virus is present in. For example chemical fixation times may be different for tissues versus isolated cells. Cells in serum may require more rigorous inactivation conditions than cells in buffered saline. Similarly, ionic and non-ionic detergents plus heat may be more effective at inactivating virus in combination than alone.

Inactivation protocol submission

Investigators submitting protocols as a Rascal Appendix A should specifically describe inactivation reagents, concentrations, length of treatment, temperature and specimen types. EH&S maintains a list of methods that have been reviewed and deemed effective. These include chemical fixatives (histology), guanidinium isothiocyanate (RNA extraction), detergents (protein assays), and methanol (mass spec.)

Kit reagents - acceptable

CDC has published a list of kit lysis buffers for RNA isolation that inactivate SARS-CoV-2 when used according to the manufacturer's instructions (table reproduced on next page).

EH&S has also approved the following nucleic acid isolation kits:

DNA/RNA shield (Zymo Research)

Oragene CP-190 Saliva collection kit (DNAgenotek)

Kit reagents - unacceptable

These nucleic acid preservation kits do not have demonstrated claims to inactivate SARS-CoV-2.

RNA later (Qiagen)

Omnigene Oral OM-501 (DNAgenotek)

RNA Extraction Options

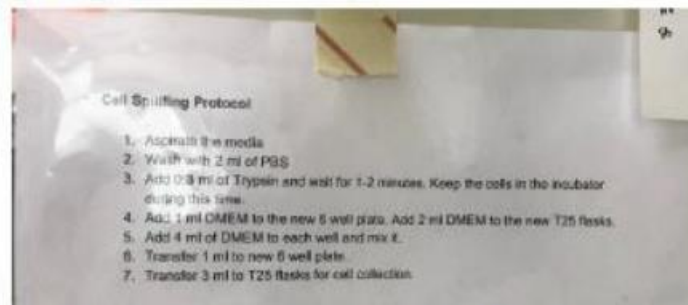
For each of the kits listed below, CDC has confirmed that the external lysis buffer is effective for inactivation of SARS-CoV-2.

Instrument/Manufacturer	Extraction Kit	Catalog No.
QIAGEN	² QIAamp DSP Viral RNA Mini Kit	50 extractions (61904)
	² QIAamp Viral RNA Mini Kit	50 extractions (52904) 250 extractions (52906)
QIAGEN EZ1 Advanced XL	² EZ1 DSP Virus Kit	48 extractions (62724) Buffer AVL (19073) EZ1 Advanced XL DSP Virus Card (9018703)
	² EZ1 Virus Mini Kit v2.0	48 extractions (955134) Buffer AVL (19073) EZ1 Advanced XL Virus Card v2.0 (9018708)
¹ Roche MagNA Pure LC	² Total Nucleic Acid Kit	192 extractions (03 038 505 001)
¹ Roche MagNA Pure Compact	² Nucleic Acid Isolation Kit I	32 extractions (03 730 964 001)
¹ Roche MagNA Pure 96	² DNA and Viral NA Small Volume Kit	576 extractions (06 543 588 001) External Lysis Buffer (06 374 913 001)
¹ QIAGEN QIAcube	² QIAamp DSP Viral RNA Mini Kit	50 extractions (61904)
	² QIAamp Viral RNA Mini Kit	50 extractions (52904) 250 extractions (52906)
^{1,3} bioMérieux NucliSENS® easyMAG® and ^{1,3} bioMérieux EMAG® (Automated magnetic extraction reagents sold separately. Both instruments use the same reagents and disposables, with the exception of tips.)		EasyMAG® Magnetic Silica (280133) EasyMAG® Lysis Buffer (280134) EasyMAG® Lysis Buffer, 2 mL (200292) EasyMAG® Wash Buffers 1,2, and 3 (280130, 280131, 280132) EasyMAG® Disposables (280135) Biohit Pipette Tips (easyMAG® only) (280146) EMAG®1000µL Tips (418922)

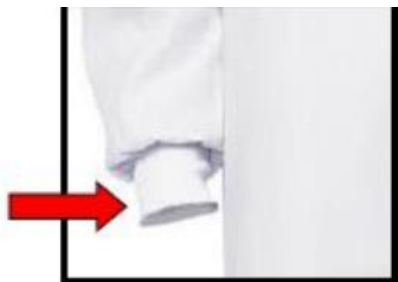
¹Equivalence and performance of these extraction platforms for extraction of viral RNA were demonstrated with the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K190202). Performance characteristics of



THANK YOU YALE!!



Note: Avoid having unnecessary items that you do not need for your experiment inside the BSC; this helps you with the proper decontamination process of the BSC.



Double gloves are recommended for BSL-2 experiments.



BSL-2 ENHANCED WORK PRACTICES FOR SPECIMEN PROCESSING AND CELL CULTURE

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Set up a biohazard bag for solid waste.



4/20/20 [CA]



Thank You Resources

The screenshot shows the CDC website with a search bar containing "COVID-19". Below the search bar is a banner for "Coronavirus Disease 2019 (COVID-19)" with a row of images of people wearing masks and the text "WEAR A MASK. PROTECT OTHERS." The left sidebar includes "Your Health", "Community, Work & School", and "Healthcare Workers". The main content area is titled "Resources for Laboratories (COVID-19)" and lists "Multiplex Assay for Flu and COVID-19 & Supplies" and "Diagnostic Test for COVID-19 Only & Supplies".

The screenshot shows the ABSA International website. The main content area is titled "SARS-CoV-2: What is the 2019 novel coronavirus?" and includes sections for "What are coronaviruses?", "What are the symptoms and complications caused by COVID-19?", and "Updates". The "Updates" section lists several resources: "CDC: Sign Up for CDC.gov Email Updates", "CDC: Global COVID-19", "CDC: CDC COVID-19 Global Response", "WHO: Coronavirus disease (COVID-19) Pandemic", "United Nations Office for the Coordination of Humanitarian Affairs (OCHA): reliefweb.int Updates", "Pan American Health Organization (WHO) Coronavirus Disease (COVID-19)", and "Africa CDC: Coronavirus Disease 2019 (COVID-19) - Latest updates on the COVID-19 crisis from Africa CDC". There are also sections for "Guidance & Regulatory", "Non-Governmental Resources", and "Transmission/Prevention". A sidebar on the right contains instructions on how to use the site's search function and a link to "Emerging Infectious Diseases Toolboxes".

The screenshot shows the NIH website with a search bar and navigation tabs for "Health Information", "Grants & Funding", "News & Events", "Research & Training", "Institutes at NIH", and "About NIH". A prominent red banner reads "COVID-19 is an emerging, rapidly evolving situation." Below this, there are links to "Get the latest public health information from CDC", "Get the latest research information from NIH", and "NIH staff guidance on coronavirus (NIH Only)". The main content area is titled "Coronavirus (COVID-19)" and includes social media icons and a note that the page was last reviewed on June 12, 2020. At the bottom, there are buttons for "Sign up to get COVID-19 updates from NIH" and "Search clinical trials related to COVID-19".



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Office of Executive Vice President for Research

Institutional Review Board

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Facilities Management



Acknowledgments

Institutional Biosafety Committee
&
Environmental Health and Safety



Thank You!

