The Research Ramp-Up Continuum

Bringing On-Campus Research Activities Back Online as COVID-Restrictions Ease

Presenters

Panelists:

- Karen Hartman, Div. Chair, Shared Services Research Admin., Mayo Clinic
- J.R. Haywood, Assist. Vice Pres., Office of Regulatory Affairs, Michigan State Univ.
- Ara Tahmassian, Chief Research Compliance Officer, Harvard Univ.

Moderator:

• Sara Bible, Assoc. Vice Provost for Research, Stanford Univ.

Presentation Overview

- The Ramp Up Continuum
 - From Just Beginning to Lessons Learned
- Getting Ready for Re-Entry
 - Planning
 - Re-Opening Buildings
 - Ensuring Support Services are in Place
 - Screening & Testing
- Special Considerations for Basic, Animal, and Clinical Research
- Addressing Possible Retrenchment

POLL 1: Where is your Campus on the Ramp Up Continuum?

- Poll Question: What percentage of lab-based research activities on your campus have reopened?
- A. 0-25%
- B. 26-50%
- C. 51-75%
- D. 76-100%



Getting Ready for Re-Entry



Planning

- State lifting "stay at home order"
 - Consistency with any state restrictions
- Planning Team(s)
- Roles and Responsibilities
 - How are decisions for reopening made (e.g. Committee, Deans, Chairs, etc.).
- Populations that Must be Considered
 - Faculty
 - Staff
 - Students
 - High Risk Employees



Planning

- Access to Personal Protective Equipment (PPE)
- Phasing and low-density planning
 - Those who can work remotely should continue to do so
- Coordination between research, teaching, clinical and administrative
- Administrative support (e.g. receiving supplies, building maintenance, housekeeping)
- Arrangements for food services, lunch space, etc.
- Commute to and from work
- Access Control
- Training

Complexity

Safely restarting oncampus research is complex and depends on factors that are outside of our control!



Planning (Operational Issues)

It is complex!

As you plan for the resumption of on-campus research you need to:

Walkthrough the entire *life-cycle of the research process

+

Additional factors related to COVID-19 control

And determine what changes are required to support it!

- *Life Cycle includes: experimental procedures, human subject, animal research, lab supplies, core/shared facility usage, data management, research administration, receiving, break-rooms, etc.
- * Additional factors: staff/student return to campus, social distancing, cleaning and disinfection, health monitoring, isolation, postings, elevator use, break areas, bathrooms, signage, commute, etc.



Reopening Buildings

- Systems
 - HVAC
 - Water
 - Fume hoods, biosafety cabinets, autoclaves

Reopening Buildings

- Preparation
 - Addition of COVID Risks to Risk Assessments
 - Signage
 - Building use conference rooms, break rooms
 - Understanding use of common, shared and individual spaces
 - Repurposing security systems to enforce social distancing
 - Sanitation chemicals to use, frequency, hand sanitizer
 - Supply chain PPE, disinfectants
 - Which buildings open first?

Ensuring Support Services are in Place

- Support Services & Personnel
 - Campus Maintenance, Security & Custodial Services
 - Research Specific Services, e.g., Core Labs, Computing Facilities, Libraries
 - Regulatory Committees (IRB, IACUC, Biosafety)
 - Impact of illness & Furloughs
 - Union Considerations

Special Considerations: Animal Research



Special Considerations: Animal Research

- Assessments
 - Mouse colonies
 - Large animals
 - Staff
- Getting started
 - Scaling the ramp up with attention to reversal
 - Animal ordering, breeding colonies
 - Scheduling access and use of spaces
 - Supply chain animals, PPE
- Remembering the emergency preparedness plan:
 - "Disaster won't follow your plan"

Special Considerations: Human Subjects Research

Coordination with Clinical Practice or Clinic/Hospital

- Numbers of patients on site (any restrictions)
- COVID-19 screening and testing: meeting the requirements of clinic/hospital and/or study
- Conserving PPE
- Limiting onsite activities for specific populations

Participant's (Patient's) Perspective

- Type of trial, and need to be seen for clinical care
- Concern for safety -- masking, social distancing
- Screening & Testing expectations
- Travel to site concerns



Staffing Implications

- Study staff concerns and/or accommodations
- Furloughs or reduced availability of staff in ancillary areas
- Identify work that can be done or continue to be done remotely

Sponsor/Industry Coordination

- Building or on-campus restrictions: how to manage monitoring, qualification visits, study close out requirements
- Communication of expectations and changes critical
- Start thinking new : Creation of video library to meet needs, use of electronic health record for remote monitoring, other ideas

Regulatory Implications



Regulatory Committee requirements



Reporting requirements – deviations, modifications



Documentation and process (e.g., consent)



Executive orders and state/city requirements

Special Considerations: Basic Research

- Open labs
- Shared Space
- Shared Equipment
- PI with labs in multiple buildings
- PI with staff with specialized skills

Special Considerations: Basic Research

- Assignment of Workbench with >6 feet separation
- Mentor/Mentee Interactions
- Shifts
- Disinfection in between shifts
- Movement of researchers within the lab
- Equity!



Retrenchment

Retrenchment

- Monitoring
- Triggers for retrenchment
 - Governmental triggers
 - Institutional triggers
- Full or partial retrenchment

CDC COVID Data Tracker

USA 1,938,823 TOTAL CASES

CDC | Updated: Jun 8 2020 6:17PM

USA 110,375 TOTAL DEATHS CDC | Updated: Jun 8 2020 6:17PM

Retrenchment

- How are you monitoring employee health?
- Who is trending data within the institution to identify clusters?
- How is information reported to decision makers?
- What is the contingency plan for rapid lab/building Closure in the event of:
 - Identified Cluster within a lab/building
 - Local (city/county/state) resurgence and closure orders?

Monitoring Through Screening, Testing & Contact Tracing

- Bringing Personnel Back on Campus
 - Research Personnel
 - Health Screening & COVID Testing
 - Contact Tracing
 - Occupational Health & Risk Assessments

Example of Daily Monitoring

CLEARNACE	
May 15, 2020	
к and may start your sk from your location's	
-	
	May 15, 2020

9:41	A	ull 📚 🗖
harvard.edu		
0	Crimson Clear	=
COVID - Screeni	19 ng	
John Harva	ard, YOU ARE NOT CLEARED FOR	WORK TODAY
enter your manager.	NO CLEA May 15	T RED , 2020
YOU HAVE I If you need your health	INDICATED ONE OR MORE SY I immediate medical assista hcare provider or dial 911	MPTOMS Ince, call

POLL 2: Will your campus require COVID-19 testing for returning employees?

- A. Yes
- B. No
- C. Discussing
- D. Unsure

Take Aways

- Need to include a broad spectrum of stakeholders
- Be flexible!
 - Needs of researchers are different
 - Situation/information changes rapidly



Questions and Answers

Next Session: Tomorrow, June 11 at 12:00 EDT: Federal Legislative and Congressional Update

Thank You

Visit us at www.cogr.edu



Copyright © 2020 by COGR. All Rights Reserved.