COVID-19 Response within NIH
June 11-12, 2020
Agenda

- Human Resources COVID-19 Response
- COVID-19 Testing
- COVID-19 Safety
- Covid-19 Facilities Tracker
- Physical Barriers
- Personal Protective Equipment (PPE)
- Travel and Financial Management
- NIH Framework to Return to the Physical Workspaces
Human Resources COVID-19 Response

Early Days of the COVID-19 Outbreak

• Supported the return of NIH employees working or traveling overseas as the pandemic began overseas and travel restrictions were put in place
• Coordinated civilian volunteer deployments of NIH workforce to FEMA, ASPR, and the USPHS Commissioned Corps to respond across the nation

Shifted to Maximum Telework

Navigating Pay, Leave, and Hiring Guidance and Flexibilities

• Developed tools and guidance to implement of the Emergency Paid Sick Leave Act (EPSLA) portion of the Families First Coronavirus Response Act (FFCRA)
• Developed COVID-19 RASOW authority guidance
• Temporarily redelegated all HR authorities to balance demands on NIH leadership
• Prepared Hazardous Duty Pay, Environmental Differential Pay, and Evacuation Pay guidance, to ensure fair compensation for NIH employees for hazards and different work schedules associated with the work environment during NIH’s COVID-19 response
## COVID-19 Testing

### Testing symptomatic NIH staff since mid-March
- Questionnaire and call center assisted in identifying symptomatic staff
- Established capability to conduct sampling outdoors via car line
- Developed SOP and training plan for nasopharyngeal sampling, PPE logistics and decontamination

### OMS contact investigations
- Developed procedure and staffing plan to initiate contact tracing for workers at high risk of exposure to colleagues who tested positive

### Clinical Staff Return to physical work determinations
- Clinical positions must have 2 negative tests within a 48 hr. period to be cleared; administrative positions require 1 negative test.
- Wide variability in individual experiences--some staff have had up to 9 consecutive positive tests before testing negative
## COVID-19 Safety

<table>
<thead>
<tr>
<th>DOHS Partnership with ORF on COVID-19 space remediation procedures</th>
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<td>• Developed procedure for cleaning areas which could not wait for natural environmental dissipation.</td>
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<th>Return to Physical Workspace Parameters to promote safety and source control</th>
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<td>• Developed safety procedures for those in the first phase of return</td>
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<td>• Includes “culture of responsibility” pledge signed by employee and supervisor to promote safety and source control</td>
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<th>Contemplating wider asymptomatic testing for non-clinical areas</th>
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<td>• All NIH campuses</td>
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<tr>
<td>• Challenges with contract staff and sampling capability at geographically separated sites.</td>
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Developed an SOP outlining communications procedures concerning the closure, ventilation, disinfection and reopening of NIH space that may be contaminated by COVID-19.

Developed a tracking tool (COVID-19 Tracker) within NIH’s Facility Information Management System for reporting, securing, disinfecting and returning to service spaces where a staff member recently worked and has since tested positive for SARS-CoV-2. The system was launched April 13th.
Physical Barriers

- Designed, fabricated and installed numerous plexiglass barriers by in-house technicians in coordination with building occupants.
- Locations include hospital, research and security
The NIH Supply Center serves as the supply chain manager for Personal Protective Equipment (PPE) logistics allowing NIH to effectively respond to the coronavirus pandemic

- Identified reliable sources for PPE in an extremely tight market

Program Office coordinating and developing the list of Required Critical Supplies (RCS) that serve as the NIH agency inventory for:

- Mask (N95- Respirator, Ear Loop, Procedural)
- Gloves
- Hand Sanitizer & Disinfectant

Fulfill requiring activity duties for bulk-buys of PPE.

- Working directly with manufacturers. Faster lead times and reduced cost.

The RCS supports Campus and leased facilities (Off-Campus).
Mission Critical Travel: Mission critical travel requests must be submitted directly to DDM for approval.

Non-NIH Hosted Conference Travel: Conference hosts have changed in-person meetings to either cancelled, postponed, rescheduled or virtual meetings. Adopted new processes and procedures for the purpose of tracking and updating the conference tracking system.

Electronic Invoice Receipt Business Need: Ensured vendors/contractors continue to be paid in a timely manner during COVID-19 limiting contact and physical mail processing.

Timely Invoice Payment: Supported the goal of paying small business vendors 15 days after receipt of proper invoice through timely submission via Treasury payment schedules.
NIH Framework to Return to the Physical Workspaces
Path to Full Return and the New Normal

“You don’t make the timeline. The virus makes the timeline.” - Dr. Anthony Fauci

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<tr>
<th>INDICATORS</th>
<th>Current State &amp; Baseline for Planning</th>
<th>GROUP A Onsite Specific Work</th>
<th>GROUP B Increasing Onsite Specific Work</th>
<th>GROUP C Integration of Teleworkers</th>
<th>GROUP D Full Return</th>
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<td></td>
<td>Developing agency plan; increased need for patient care</td>
<td>Data supports moving forward</td>
<td>At least 3 weeks &amp; data supports moving forward</td>
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<th>PRINCIPLES</th>
<th>Assess Environmental State and Prep IC Workforce Plans</th>
<th>Work that Cannot be Completed Remotely</th>
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<th>Integration of Teleworkers</th>
<th>Full Return to Workspace</th>
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<td>Current State: IRP exceptions, employees supporting increasing CC patient census</td>
<td>Staff whose work must be done onsite (i.e. campus support, intramural research)</td>
<td>Staff whose work is best done onsite and Tier 3 staff on weather/safety leave</td>
<td>Staff who can successfully telework but are willing and able to return on site</td>
<td>All staff</td>
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| HEALTH & SAFETY | Present | PRINCIPLES | TIMELINE |
| HEALTH & SAFETY | Work that Cannot be Completed Remotely | PRINCIPLES | TIMELINE |
| HEALTH & SAFETY | Work that is Difficult to Complete Remotely | PRINCIPLES | TIMELINE |
| HEALTH & SAFETY | Integration of Teleworkers | PRINCIPLES | TIMELINE |
| HEALTH & SAFETY | Full Return to Workspace | PRINCIPLES | TIMELINE |

| TIMELINE | Present | Earliest - June | Earliest - July | TBD | TBD | TBD |
| TIMELINE | Earliest - June | Earliest - July | TBD | TBD | TBD |
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Intramural Oversight and Organization of COVID-19 Research at the NIH

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH
Advisory Committee to the Director
June 12, 2020
Oversight and Organization of COVID-19 Research at the NIH

- Establishment of a COVID-19 scientific interest group (SIG) led by Pam Schwartzberg, NIAID, with 6 other subject matter experts from NIAID, NCI, NIBIB, NIDDK, NIEHS
- Dashboard of all COVID-19 research projects (currently 357 projects with approx. 250 PIs of 1100 total PIs at the NIH)
- Website (https://oir.nih.gov/sourcebook/intramural-covid-19-guidance-resources) including reagents, repository access, and a weekly seminar series
- COVID-19 listserve with over 2000 participants
- Intramural targeted anti-COVID-19 (ITAC) grant program
- Central review of COVID-19 proposals to assure priority access and safe use of clinical and lab resources at the NIH (Holland committee)
Maintaining Clinical and Animal Research at the NIH

- All essential clinical activities have continued at the NIH Clinical Center maintaining a 60 bed hospital. Currently, increasing capacity to 90-100 beds.
- All staff, patients, and visitors being tested weekly by RT-PCR for viral RNA; current testing capacity is 1000/day, but should be increasing by a factor of 10 soon with arrival of new high-throughput instrumentation.
- The CC has cared for patients with COVID-19 on two different protocols (remdesivir alone and remdesivir +/- baracitinib).
- Animal colonies have been maintained to assure well-being of animals, mission critical and COVID-19 research, and availability for research when fully reopened.
QUESTIONS?
Timeline of Key Events in the NIH Response

Jan 31
Travel bans go into effect & several NIH employees caught overseas

Mar ??
First patient admitted to CC

March 18
Car line testing symptomatic staff

March 11
First COVID-19 positive case among NIH community

Mar 16
Start Maximum Telework

May 15
Framework for Return to Physical Workspaces launched

May 21
Clinical Center Testing asymptomatic employees with patient care responsibilities
Navigating Pay, Leave, and Hiring Guidance and Flexibilities

- Developed tools and guidance to implement of the Emergency Paid Sick Leave Act (EPSLA) portion of the Families First Coronavirus Response Act (FFCRA)
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Framework for Return to Physical Workspaces

• NIH has remained largely operational during the last three months
• Developed a framework with a phased approach to slowly return our workforce, in line with White House, OMB, OPM, CDC and HHS guidance and in review of how universities and other institutions are approaching this
• Underwent thorough vetting by our NIH Coronavirus Response Team and all NIH IC leadership stakeholders before launch
• Four groups that start with bringing back intramural and campus support staff that cannot complete their full responsibilities remotely and end, eventually, in the ability to return all staff
• Three weeks will pass between each group, along with additional indicators that inform decision making based on the current status of COVID-19 in the local area and availability of necessary supplies (cleaning, hygiene, testing)
• Staff will be provided ongoing scheduling and leave flexibility based on challenges such as being at higher risk of severe illness, lack of dependent care, transportation, or general concerns about the virus
NIH Facility Needs

- Conducted electrical and architectural work to house Roche Cobas 6800 testing apparatus in Building 10 on schedule.
  - Can run up to 384 molecular tests in 8 hours
  - Integrates sample prep and real-time PCR
- Conducted electrical work to house a Panther Fusion testing apparatus in Building 10 on schedule.
  - Joins PCR and TMA capabilities and can run 32 different assays simultaneously
- Restroom Manual Faucet Survey on NIH Bethesda Campus, MD
  - On May 15, 2020, completed survey of 933 restrooms
  - Identified 627 manual faucets in 378 restrooms need to be replaced with automatic touchless faucets
- Concerns of stagnant water and associated bacteria growth due to increased telework prompted a comprehensive flushing initiative in all leased and owned buildings. Installed hand sanitizer stations throughout campus
  - Over 450 stand and wall-mounted sanitizer stations in common spaces such as building entrances and elevator lobbies
- Responded to specialized cleaning requests to include CDC-defined wet-wipe and mop procedures and hydrogen peroxide mist procedures in areas where infected persons were known to have been:
  - 47 requests
  - 2,273 rooms
  - Average response time was three hours
Central Utility Plant Resiliency

- One of the largest Central Utility Plants (CUP) in the United States, the CUP provides steam, chilled water and compressed air to the Bethesda Campus.

- Data
  - Artificial Intelligence is used to consider 12,500 variables and collect 40 million data points per day to assist plant technicians with optimizing plant strategies.
  - Data servers have primary and secondary administrators who are cross trained on each server.

- Social Distancing
  - Remote data access by plant staff allows for social distancing.
  - On site CUP staff have been reduced to allow for social distancing.

- Back up plans
  - A remote alternate control room was established, tested and made ready in case the main control room becomes unavailable.
  - Separate back up operations staff are on standby if necessary. Enhanced training using the CUP simulator is underway to keep crews trained on emergency scenarios and to add operations crews.

- On hand: 90 day supply of
  - Boiler and chiller plant treatment chemicals, another 90 days worth are on order.
  - Consumable parts, parts orders for up to 180 days are being initiated.
Division of Facilities Maintenance and Operations (DFOM) continues to be on-site 24/7 with trained technicians monitoring, operating and repairing all campus facilities.

To enable such a large workforce who use centralized spaces and work itself that requires close-working conditions, DFOM had to rethink how to support and maintain safety for technicians:

- Utilizing 12-hour shifts that stretch seven days a week instead of five to platoon over 250 technicians, which decreased the concentration of onsite personnel at one time, leading to improved social distancing and maintaining the NIH mission and other safety needs.
- Established new social distancing sign-in/sign-out procedures.
- Maintaining adequate supply of PPE.
ORF Construction Projects

- Roughly 80% of ORF’s construction projects are moving forward with some minimal to moderate impact.
  - Critical projects including Expansion of IVAU, Renovation of Pharmacy, Renovation of Building 10 E Wing, TIL, CCE Modular cGMP Units and others continue construction.
    - COVID 19 has caused minor delays in large projects with large workforces.
    - Smaller projects have had minimal delays. In some ways, it’s a great time to execute construction while facilities are empty and traffic is minimal.
  - Some projects have been stopped
    - at the request of the end user and
    - where social distancing precautions are problematic.

- The volume of construction requests received over the past two months is about 70% normal for a typical FY third quarter.

- Design projects have continued with little to no impact.
Janitorial Adjustments

- Reduced contractor traffic in most areas to prevent spread of infection
- Increased frequency of disinfection to twice a day of high-traffic areas to include elevator call buttons, stair railings, door handles, restrooms and kitchen areas
- Moved trash collection to communal areas utilizing over 1,500 trash bins and rolling dumpsters
- Provided certain high-traffic locations with specialized cleaning including the badging office in 31B, the NIH police department in 31B, Gateway Center, CVIF and West Drive Patient Entrance, childcare centers in 23 and 64 and NCI building 10 Autopsy
A flood was reported in 5J causing damage to the 2J cell processing area of Building 10 on May 17th

2J remediation started immediately

Within 12 days of the report, the affected areas were remediated and repaired:

• Installed isolation barrier between East and West sides
• Constructed containment barriers and negative air machine
• Protected CCE equipment
• Removed wet ceiling and walls
• Completed above ceiling survey and investigation
  • Survey found multiple vulnerabilities
  • Installed shafts with Acrovyn to prevent leaks
• Restored ceilings and walls
• To be completed the first week of June:
  • Remove barriers
  • Clean areas
  • Turn area back to CCE
Hazardous Waste Risk Reduction Actions

Actions being taken to reduce risk associated with hazardous waste operations post COVID-19:

- **Continued activities:**
  - PPE will be worn to protect the NIH community as well as the waste contractor during pickups
  - Solvent recovery containers and transport carts will be wiped down using an approved EPA disinfectant prior to delivering to the NIH researcher

- **New activities:**
  - Phone calls will be made to the customer prior to collection, to determine if a pickup is required and also to coordinate pickup locations and immediate time to minimize contact between lab personnel and collection staff.
  - Where possible, personnel will be assigned to specific buildings/collection routes to minimize potential transmission
  - Contractors have implemented a program to monitor worker health and to take actions if an employee shows symptoms

- Global Email Addressing Changes disseminated on June 1, 2020
MPW Disposable PPE Collection Sites

- All disposable PPE should be discarded as MPW into properly identified step cans or MPW boxes.
- Step cans will be placed at the exit doors of heavily occupied buildings, parking garages and parking lots.
- Step can locations on the NIH Bethesda campus [https://go.usa.gov/xwgDB](https://go.usa.gov/xwgDB)
Acquisition Policy Response & Results

➢ OALM Response and Leadership
  • **Immediately** initiated COVID related contract portfolio assessment in NIH Offices of Acquisition
  • **Within days**, proactively developed consolidated flexibilities matrix of rarely used and new streamlining authorities to support NIH contracting staff, later adopted by HHS for all OPDIVs
  • **Strategically** developed a SharePoint site to organize rapidly emerging acquisition guidance for contracting professionals to support increased speed of acquisition
  • **Within less than 24 hours of receipt** implemented HHS and OFPP issued emergency related acquisition efficiencies
    - Increased Acquisition thresholds – *Saved days/weeks/months as more actions could be executed with simplified procedures*
    - Streamlined acquisition planning – *Weeks/months eliminated from HHS planning process*
    - Unusual and Compelling urgency HHS Class Justification (J&A) to limited competition - *Market research and approval process streamlined by weeks/months*

➢ Challenges
  • Delay in execution of acquisition streamlining flexibilities triggered by emergency declaration - *HHS and OFPP implementation guidance lagged*
  • Quick action required to align NIH service contracts with the social distancing requirements to maintain operations while combating the virus.
  • Impossible to issue broad contract guidance - *Unique terms and conditions require each contract be addressed case-by-case*
Acquisition and Logistics COVID Support

- Delivery of acquisition policies and guidance for contracts supporting the NIH mission
- Issuing guidance on COVID transactions reporting and tracking
  - Monitoring reporting – ensuring proper reporting
- Reporting COVID transactions to HHS and Federal Reporting Systems
- Rapid awards of major contracts supporting COVID research
- Supporting NIH staff with Personal Protection Equipment (PPE)
- COVID-19 Contract Reporting
NIH Clinical Center and NIAID leveraged the HHS Class J&A:

- Rapidly replenished dwindling or long lead time supply items including isolation gowns, gloves, swabs and face shields while still available (CC)
- Reduced procurement lead time for COVID-19 testing reagents from months to weeks accelerating NIH staff testing (CC)
- Mobilized to procure hospital beds for special studies unit (reserved for highly communicable diseases like Ebola) when the supplies were dwindling (CC)
- $1.5M cutting edge instrument to isolate human monoclonal antibodies against SARS-CoV-2, reducing antibody screening time per donor from 3 weeks to 1-2 days and obtain antibody heavy and light chain sequences within 3-4 days – executed in one week (NIAID)

NIAID utilized Letter Contract authority to initiate trials and establish surveillance on a worldwide basis through critical large dollar awards with the NCI FFRDC, averaging two weeks processing time per action:

- $67M - COVID-19 Randomized Control Trials (RCTs)
- $10M - COVID-19 Observational Study
- $13.4M - COVID19 Remdesivir Study
- $23M - COVID-19 NIAID Clinical Trial “A Multicenter Platform Evaluating Putative Therapeutics for the Treatment of COVID-19 in Hospitalized Adults” (short title, the Big Effect Trial or “BET”)
Contract Awards

- ACTIV program to support Dr. Collins - Contractor provides high level project management expertise to support COVID-19 research and program initiatives

- Operation Warp Speed supporting the White House - Contractor builds governance, prioritizes vaccine candidates and supports research & development

- Supply Chain Control Towers to support the HHS Secretary - Contractor supports the flow of the COVID-19 supply chain and provides operational maintenance and analysis.

- Analytical Support - Contractor analyzes data from testing and diagnostics, and provides program management support

- High level scientific consultants - Contractor supports:
  - The White House in leading Operation Warp Speed
  - FDA-CDER supporting licensure of vaccine candidates
  - ASPR expertise in late stage research & development
COVID-19 Contract Reporting

- Tracking acquisition activities required by OMB and HHS
  - Department-wide coordination of contracting activities
  - Transparency, accountability, and traceability in order to ensure proper internal controls
  - Ensure senior leadership awareness of high priority items
  - Scrutiny like with American Recovery and Reinvestment Act (ARRA) funding

- Budget TASK Numbers created to efficiently identify COVID-19 emergency funding

- Internal controls developed to ensure proper coding and that award descriptions are clear to the public

- Daily COVID-19 contract award report submitted to HHS - 425 Awards to date - $204M
Mission Critical Travel

- Mission critical travel requests must be submitted directly to DDM for approval.

Non-NIH Hosted Conference Travel

Conference hosts have changed in-person meetings to either cancelled, postponed, rescheduled or virtual meetings. These changes have required OFM to adopt new processes and procedures for the purpose of tracking and updating the conference tracking system.

Although virtual meetings no longer require pre-approvals; as travel costs are not incurred; ICs are still required to report any virtual meetings with costs (registration fees) to OFM to comply with the Cures Act reporting requirement.

- Changes were made to the functionality of OFM’s SharePoint site to:
  - Capture the reporting of all cancelled, postponed, rescheduled and virtual meetings.
  - Capture revised attendance numbers and costs for previously reported in-person meetings that are now being held virtually.
Electronic Invoice Receipt and Timely Processing

Electronic Invoice Receipt Business Need: Ensure that vendors/contractors continue to be paid in a timely manner during COVID-19 limiting contact and physical mail processing.

- **Solution:** OFM worked closely with colleagues at OALM, NBS, nVision and ICs to develop an electronic/email invoice receipt process.
- **Effective Date:** Solution developed during March 2020, Implemented April 1, 2020.
- **Results from 4/1/20 – 6/3/20:** Received over 22,000 or 72% invoices via new email solution and just over 6,000 or 28% via physical mail – effectively processed 80% of those invoices into NBS for payment and on target to process remaining 20% into NBS timely. Process efficient and effectiveness continues to improve dramatically.

Timely Invoice Payment: In response to the April 6, 2020 Memo “Class Deviation (2020-02) from the Federal Acquisition Regulation Regarding Accelerated Payments to Small Business Contractors and Subcontractors,” OFM is supporting the goal of paying small business vendors 15 days after receipt of proper invoice through timely submission via Treasury payment schedules.