Our Response to the COVID-19 Pandemic

Nora Singer, Elaine Borawski, Ruth Farrell, Grace McComsey, Darcy Freedman, Heidi Gullett
Our Response to the COVID-19 Pandemic

SARS-CoV-2 Task Force: Nora Singer
COVID Pilot Program: Elaine Borawski
Pregnancy Project: Ruth Farrell
Clinical Studies and Biorepository: Grace McComsey
Cleveland SARS-CoV-2 Task Force

**March 13, 2020**

- **Initial Concept of the Task Force**
  - Developed by Mark Chance, Dean Davis, and Jonathan Karn

**March 13-28, 2020**

- **Organization of the Task Force**
  - Co-Chairs appointed
  - Working groups and Biosafety Committee assembled

**March 13-30, 2020**

- **Organization of Administrative Infrastructure**
  - Relational database to record research interests
  - Resource sharing (i.e., samples, equipment, animal models, and viral constructs)
  - Administrative support
  - Central repository for funding opportunities

**March 25- April 15, 2020**

- **Committees Formed with Hospital Partners**
  - COVID prioritization committees
  - Combined meetings between Task Force and sites

**March 13- April 30, 2020**

- **Purchase of Equipment**
  - Acceleration BSL2+ and BSL3 construction/equipment purchase
  - Committee SOW’s and subsequently training for access to BSL3
Cleveland SARS-CoV-2 Task Force

Directors
Jonathan Kern
Nora Singer

Steering Committee
Stan Gerson, Cliff Harding, Bob Salata, Mina Chung, Grace McComsey + Michael Konstan + Working Group Pam Davis Mark Chance Ex Office

Administration
Joan Schenkel
Erin Fogerty

6/10 are CTSC Leadership

- Biosafety
- Immunology & Immunotherapeutics
  - T-cell Immunology
  - B-cell Immunology
  - Cell Based Therapies
  - Systems Biology
  - Innate Immunity
- Clinical & Clinical Trials
  - Clinical Trials
  - Biorepository
  - Natural Hx, Disease Progression Co-Morbidities
- Virology & Drug Discovery
  - Life cycle, pseudotyping & screens
  - Drug Design
- Behavioral Health & Population Outcomes
  - Epidemiology & Surveillance
  - Molecular Epidemiology & Surveillance
  - Modeling & Big Data
  - Social & Behavioral Drivers
  - Social & Behavioral Drivers/Impacts
  - Ethics & Regulatory
Fdn/Industry (Jun 2020-Present)

- Multiple proposals and sponsors
- NORD Foundation $430K
- Taskforce reviewed pilots and allocated specialty equipment

Pilot Initiatives (Jun-July 15, 2020)

- 18 pilot awards
- $500K
- NORD Family Foundation
- CTSC
- Cancer Center
- CFAR
- Digestive Health Research Institute (DHRI)
- Cleveland Brain Health Initiative
- Swetland Center

Federal (May-July 2020)

- 4 NIH supplements submitted
- 2 awarded:
  - Jacobson, $600K
  - Canaday/Cameron, $1M
- 2 U01 Serology Centers awarded:
  - King and Zidar
  - $1.3M each over 4 years
Rapid Response COVID-19 Pilot Grant Program

• Desire to support interdisciplinary projects emerging from the Taskforce Working Groups

• CTSC Community and Collaboration Team coordinated the marketing, submission, review, and selection process on behalf of the Taskforce. Also, developed and implementing a performance-based 6 and 12 month progress reporting process

• C&C and Taskforce solicited pilot funds from centers, institutes and programs across the campus and our institutional partners
  • Message was clear: an institution-wide opportunity for interdisciplinary collaboration

• Seven funding groups, funding 1-5 pilots, ranging from $15k to $40k (CTSC)
  • Allowing smaller centers & institutes to participate without bearing administrative burden.

• Total funds available: $510k
Rapid Response COVID-19 Pilot Grant Program

- Single RFA and submission process (InfoReady; multi-track option) with standardized application but allowing funder-specific requirements.
- Review was standardized by C&C; however, identified a SRO for each funding group and each group recommended reviewers.
- **48 proposals**, representing 7 of the 8 CWRU schools/colleges and 3 of 4 health system partners (UH, Metro, CCF).
- **18 funded projects**
  - 6 of 8 CWRU Schools/Colleges, 3 Health Systems
Rapid Response COVID-19 Pilot Grant Program

CTSC Funded Projects:

• Addressing Ethical, Social, and Regulatory Issues in Research during the COVID-19 Pandemic
• COVID-19 associated Coagulopathy– Developing a Point-of-Care Device for Diagnosis
• Neighborhood context of social vulnerability and perceptions of COVID-specific risk and prevention
• Glycemic Control and COVID-19 Disease Severity among Patients with Chronic Kidney Disease
• Determining the Diagnostic and Prognostic Value of Underlying Cutaneous Disease and Cutaneous Eruptions in Patients with COVID-19

Co-sponsored with the Swetland Center for Environmental Health:

• Understanding the Behaviors of Dental Aerosol Flume and Engineering Effective Capture System for COVID-19 Risk Mitigation

All CTSC funded projects must:

• Complete C&C Interview (to assess team development needs and stakeholder engagement)
• Complete RACI tool (team member roles and responsibilities)
• 6 & 12 month reporting on progress and TS & SE
• Present results at CTSC-supported seminar
• Engage and be responsive to C&C throughout award
Investigating the vertical transmission of COVID-19 from mother to baby

• Does SARS-CoV-2 cross the placenta?
  - The data are not clear
    • Lessons learned from Zika, H1N1, and other viral pathogens
    - If so, when, how, and what is the impact for mother and fetus/baby

• Objective: To identify the rate of vertical transmission of SARS-CoV-2 from mother to fetus/baby
  - Antepartum, intrapartum, and immediate postpartum
  - Target sample size is 100 pregnant women
City-wide collaboration

• Study supported by the CTSC program and each institution

• Investigators:
  • CCF: Farrell (PI)
  • UH: Pope and Ragsdale (PIs)
  • Metro: Gibson (PI)
  • CWRU: Sekaly
  • NIH: McDermott
  • Cuyahoga County Board of Health
Biosample Collection and Analysis

- Screening, enrollment, sample collection: Coordinated by the CTSC HUB Research Capacity at CCF, Metro, and UH
- Samples include: Maternal serum, vaginal secretions, amniotic fluid, cord blood, placenta, umbilical cord segment, colostrum/breastmilk, neonatal serum, possible products of conception
- Samples are shipped to CWRU and NIH for analysis
- Analysis for each of the samples:
  - PCR – virus (CWRU)
  - IgG (NIH)
  - IgM (NIH)
  - Cytokines (CWRU)
REDCap

• We will use data from the EMR to collect data specific to COVID testing, COVID management, and obstetric outcomes

• REDCap
  • Developed with the assistance of the CTSC BERD
  • Bilateral sharing of information across all three sites
    • Universal and static data dictionary used between CCF, UH, and Metro
    • Variables designated as shared and/or calculated fields (e.g., replace date with EGA, PPD#)

• DUAs in place to share a limited data set to combine analysis across the three sites
## COVID-19 Human Studies (IRB Approved)

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* Includes Epidemiologic, Diagnostic, Virologic, and Immunologic studies

NIH Interventional Trials:
- ACTIV-2 (CWRU/UH/MH), -3 (CWRU/UH), -4 (CWRU/MH)
- PassItOn (CC)
- IMPACC (CWRU/UH)
- Network HVTN-AZ (CWRU/UH)
COVID Centralized Biorepository (Data + Biological Samples)

• Ensures the privacy and better Patient Experience for COVID-positive patients
• Allows UH/CWRU/other CTSC city-wide investigators access to de-identified data & biological specimens
• Simple Redcap request form with protocol attached
• Committee vote
• If approved, expedited IRB review
• Thus far, >45 supported projects (including federal grant applications)
• Working with industry and non-profit partners with novel technology for testing blood, saliva, etc.
COVID Centralized Biorepository

• Coming soon (FINALLY!) Mobile Unit:
  Will boost COVID (& non COVID) enrollment and retention in:
  • Interventional outpatient studies
  • COVID Biorepository

• Working with NAACP and Otis Moss (minority enrollment)

• Several local media appearances for Research Education
  • Provided email and phone# to recruitment specialist
  • Patients contacting us when COVID positive or to volunteer for vaccine studies
Developing COVID Testing Strategies to Reach Underserved, Multigenerational Households (Borawski)

SPROUT: Successful Pandemic-Responsive Opportunities for COVID Testing, Contact Tracing, and Vaccination (Farrell, Pope)