COVERED PROJECT KICKOFF MEETING

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Agenda

- Welcome!!
- Sites
- Key personnel
- Obtain Approvals
- Identify Study Staff
- Identify potentially eligible participants
- Site Budgets
- Central Laboratory testing
- To Do TODAY please!
- Site Readiness Calls

Site	City	Site PIs
Allegheny General Hospital	Pittsburgh, PA	Jestin Carlson, MD
Baystate Medical Center	Springfield, MA	Howard Smithline, MD
Denver Health	Denver, CO	Stacey Trent, MD, MPH
Detroit Receiving Hospital	Detroit, MI	James Paxton, MD
Hennepin County	Minneapolis, MN	Brian Driver, MD and Johanna Moore, MD
Jackson Memorial Hospital	Miami, FL	Lilly Lee, MD
Johns Hopkins Medical Institute	Baltimore, MD	Richard Rothman, MD PhD
Louisiana State University	New Orleans, LA	Steve Lim, MD
Mount Sinai Hospital Manhattan/Elmhurst Hospital Center	New York, NY	Lynne Richardson, MD, Makini Chisolm-Straker, MD, and Kimberly Souffrant
Orlando Regional Medical Center	Orlando, FL	Phil Giordano, MD and Kurt Weber, MD
UAB Hospital	Birmingham, AL	Walter Schrading, MD, Michael Kurz, MD MS
Ronald Reagan-UCLA Medical Center/ Olive View-UCLA Medical Center	Los Angeles, CA	William Mower, MD, PhD and Gregory Moran, MD
University of Iowa	Iowa City, IA	Brett Faine, PharmD, Nicholas Mohr, MD
UMass Memorial Medical Center	Worcester, MA	Greg Volturo, MD
University of Mississippi Medical Center	Jackson, MS	James Galbraith, MD
UCSF Zuckerberg San Francisco General	San Francisco, CA	Robert Rodriguez, MD
UT Southwestern Medical Center	Dallas, TX	Ahamed Idris, MD
Truman Medical Center	Kansas City, MO	Mark Steele, MD and Amy Stubbs, MD
Thomas Jefferson University	Philadelphia, PA	Elizabeth Krebs, MD
Washington University	St. Louis, MO	Stephen Liang, MD and Brian Fuller, MD

Key personnel

Los Angeles Team	Iowa City Team	CDC team
David Talan, MD Co-principal Investigator, COVERED Principal Investigator, EMERGEncy ID NET University of California, Los Angeles Olive View-UCLA Education and Research Institute (ERI) dtalan@ucla.edu	Nicholas Mohr, MD Co-principal Investigator, COVERED Co-investigator, EMERGEncy ID NET University of Iowa Nicholas-mohr@uiowa.edu	Cliff McDonald, MD Department of Healthcare Quality National Center for Emerging and Zoonotic Infectious Diseases
Anusha Krishnadasan, PhD Project Director, EMERGEncy ID NET and COVERED Olive View-UCLA ERI idnet@ucla.edu	Data Coordinating Center, COVERED Kari Harland, PhD Kelli Wallace, MS University of Iowa Emergencyidnet-covered@iowa.edu	Preeta Kutty, MD, MPH Department of Healthcare Quality National Center for Emerging and Zoonotic Infectious Diseases
Denise Tritt Business Manager/Contracts official Olive View-UCLA ERI denisetritt@ovuclaeri.com		Scott Santibañez MD MPHTM CAPT US Public Health Service Associate Director for Science Division of Preparedness and Emerging Infections CDC/OID/NCEZID

Obtain necessary approvals

- IRB Determination
- Obtain Approvals from
  - Chair/Chief Approval
  - Nurse Manager Approval
  - ED Clerk/Social Work/Other Nonclinical Worker Supervisor Approval
  - Other institutional approvals, e.g., hospital administration, etc.

Identify your study team

- Site-PI
- Study Coordinator(s)
- Study phlebotomist(s) or nurse(s) to collect blood on appropriate schedule.
  - Work with local Clinical Research Unit for study-related visits, including phlebotomy.
  - Arrange to pay ED nurses, phlebotomists, paramedics, or technicians to draw blood (likely before or after standard clinical shifts)
  - Collect blood off-site, in a clinic, or on an inpatient service where capacity exists to safely draw and process blood.

Identify potential participants

- Stratify Attending and Resident Physicians
  a. #1 Intubation Likely *
  b. #2 Intubation Unlikely *
  c. Intubation Uncertain
  d. Little Clinical Exposure
- #3 Nurses*
- #4 Non-Clinical Controls*

***THESE ARE THE ONES WE WANT!**

Aim for 20 in each of the 4 groups

- Confirm Presence/Absence of Intubation Team

Site Budgets

- $60,000 in Direct costs for 6 month study period
  - Site PI for 6 months
  - Study coordinator(s) for 6 months
  - Phlebotomist, research nurse or equivalent for 12 weeks
  - Specimen shipping costs on dry ice – twice a week for 12 weeks (24 shipments*$100/shipment= ~$2,400)
  - Fridge space
- ***PLUS Indirect Costs*** Based on Institutional Federally Negotiated Indirect Cost Rate

Site Payment Schedule

Sites will be reimbursed as follows for their participation in the study:

Startup Fees (paid upon subcontract execution)	$10,000
Enrollment Fees ($400/enrolled participant per site – up to 80 participants)	$32,000
Final Fee (paid after final Facility Survey is complete)	$18,000

Budget – other items

- Subcontracts will be with Olive View-UCLA ERI (main coordinating site of *EMERGE*ncy ID NET)

- Participant compensation will be distributed by main site

Central Lab Testing

- Collecting Blood Specimens and self-collected Nasal Swabs
- Blood specimens - Serum-separating tubes, so no processing required at sites. Store tubes in a fridge until shipment.
- Nasal specimens – self collected. Store tubes in freezer until shipment.
- Shipments twice a week (e.g., Mondays and Thursdays)
- Ship specimens on dry ice overnight (site budget covers dry ice cost and overnight shipping costs)
- Blood and nasal specimen collection, storage, labeling, and shipping materials will be purchased by main site or central lab and distributed to sites.

Send TODAY

- Confirm your participation if you haven't already
- Send Contracting contact information
- Provide Site PI and study coordinator (s) Contact Information to Data Coordinating Center
  1. Name
  2. E-mail Address
  3. Job Title
  4. Institution/Employer
  5. Department
  6. College/University
  7. Phone Number

- **SEND ALL THE ABOVE INFORMATION TO emergencyidnet-covered@uiowa.edu**

Site Readiness Calls

- Call will be scheduled with Dave or Nick and Anusha when you have completed the following:
  - IRB determination obtained
  - Identified your study staff and phlebotomy
  - Identified potential participants (gathered email lists)
  - Subcontract draft submitted to your contracts office (sending these out Thursday)
  - Completed review and sent feedback of data collection forms (sending these out today)

Send an email to **emergencyidnet-covered@uiowa.edu** when you have done all of the above (please attach a copy of your IRB determination)

Questions?