

# CCTS/COERE/SCOR COVID-19 Forum

March 26<sup>th</sup>, 2020

# Forum Overview

Kenneth Saag, MD, MSc

Professor of Medicine and Epidemiology

Vice Chair for Outcomes and Effectiveness Research, Department of Medicine

Director, Center for Outcomes Effectiveness Research and Education

# Purpose and Goals

- ▶ Summarize many recent communications and hear from leadership on how to continue to best & most safely facilitate clinical and translational research at UAB
- ▶ Learn what others are doing regionally/nationally & what are key Federal policies
- ▶ Provide an opportunity to hear from research community
  - ▶ Discuss timely questions
  - ▶ Share success stories/creative solutions

# What this is not

- ▶ The end of the discussion

This is the beginning of a series of dialogues and remote meetings surrounding this topic

# Speakers

- ▶ ***“General Perspectives from UAB and Response to COVID-19”***; Robert Kimberly, MD; Director, Center for Clinical and Translational Science;
- ▶ ***“Office of the IRB: COVID-19 Crisis”***; Adam McClintock, MBA, CIP; Director, Institutional Review Board
- ▶ ***“Clinical Research Update”***; Cindy Joiner, PhD; Assistant Vice Chair for Research, School of Medicine
- ▶ ***“SOPH research in a time of COVID-19”***; Paul Munter, PhD; Associate Dean of Research, School of Public Health
- ▶ ***“Graduate Student & Postdoc Training Updates”***; Lisa Schwiebert, PhD, Associate Dean for Post-Doctoral Education; David Schneider, PhD, Associate Dean for Graduate Biomedical Sciences;

# Panelists

- ▶ *Anupam Agarwal, MD; Executive Vice Dean; Director, Division of Nephrology, Department of Medicine; Professor of Medicine*
- ▶ *Tika Benveniste, PhD; Senior Vice Dean Basic Sciences; Professor, Department of Cell, Developmental and Integrative Biology; Associate Director for Basic Science Research, Comprehensive Cancer Center*
- ▶ *Chris Brown, PHD; Vice President for Research, Professor of Biology*
- ▶ *Melinda Cotten; Associate Vice President, Research Business Operations; Director, Office of Sponsored Programs*
- ▶ *Emily Levitan, ScD; Associate Professor of Epidemiology; co-Director of COERE*

# Format

- ▶ Short Presentations ~5 minutes
- ▶ Following presentation -panel discussion that will include additional experts to discuss questions already received via email
- ▶ Following panel discussion -moderated Q/A session with panel
  - ▶ All participants will be muted to allow for efficient use of time We ask all participants remain muted throughout the forum
  - ▶ Real time questions can be asked via the **ZOOM Chat Feature to Ken Saag and Jeff Foster** and will be directed to the panel

# Asking Questions

The image is a screenshot of a Zoom meeting interface. At the top left, it shows 'Zoom Participant ID: 48 Meeting ID: 518-092-883'. The main content is a slide titled 'CCTS Covid-19 Panel: Overview' by Kenneth Saag, MD, MSc, with his title and affiliations listed below. A red arrow points from the bottom of the slide to the Zoom chat window. The chat window is titled 'Zoom Group Chat' and contains a text input field with the placeholder 'Type your question(s) here'. The Zoom control bar at the bottom includes buttons for 'Join Audio', 'Stop Video', 'Invite', 'Manage Participants', 'Share Screen', 'Chat', and 'Reactions'. The system tray at the bottom right shows the time as 11:31 AM on 3/23/2020.

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## CCTS Covid-19 Panel: Overview

Kenneth Saag, MD, MSc  
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Zoom Group Chat

To: Everyone  
Type your question(s) here

Jeff Foster

Join Audio Stop Video Invite Manage Participants Share Screen Chat Reactions End Meeting

Type here to search

11:31 AM 3/23/2020





# Clinical and Translational Research in the time of COVID-19

## Changing the work paradigm

- Limited business model
  - Work remotely from home
- Essential activities continue
  - Laboratory setting
    - Complete essential research experiments currently underway
    - No new experiments initiated
    - Limited staffing, mindful of public health precautions
  - Clinical study setting
    - Clinically essential visits continue with appropriate precautions
    - New enrollment on hold
    - Remote monitor visits, site initiation visits; no on-site visits





# Clinical and Translational Research in the time of COVID-19

## Changing the educational paradigm

- Limited business model
  - Learn and explore remotely from home
- On-line meetings / activities
  - Forums, courses (eg, CTS-TP), groups (eg, Friday Fellows)
  - Study team learning activities (eg, RTP)
  - Laboratory setting
    - Team meetings ...
  - Clinical study setting
    - Team meetings ...





# Clinical and Translational Research in the time of COVID-19

Working collaboratively together

- **Biorepository initiative**
  - Paul Goepfert, lead
    - Peripheral blood: BSL2+
    - Viral cultures: BSL3 (Seblab)
- **Registry initiative**
  - Matt Wyatt, Jim Cimino, leads
    - Cerner Millenium – local UAB data
    - CTSA ACT Network (16 AMCs)
- **Clinical trial proposals initiative**
  - Cindy Joiner, Jennifer Croker, Bob Kimberly
    - Jeanne Marrazzo: clinical lead



# OFFICE OF THE IRB: COVID-19 CRISIS

Adam J. McClintock

Director, Office of the Institution Review Board

March 26, 2020

# HIGHLIGHTS & OVERVIEW

- Brief Introduction
- Ongoing Study Procedures
- Amendments & Safety Reporting
- New COVID-19 Related Projects

# BRIEF INTRODUCTION

- Is the OIRB Still working?
  - Yes, we are working remotely
  - Managing emails and phone calls
  - Conducting normal reviews
  - Expedited reviews remotely
  - Weekly IRB meeting via Zoom
- Special Thanks to OIRB staff!
  - Flexibility and diligence, and
  - Commitment to research at UAB



- Where can I get answers?
  - Office of Research Business Continuity Plan: <https://www.uab.edu/research/home/business-continuity-plan>
  - IRB Business Continuity FAQs: <https://www.uab.edu/research/home/business-continuity-plan/irb-faqs>
  - Specific Questions:
    - Email: [irb@uab.edu](mailto:irb@uab.edu)
    - Cc: [amclint@uab.edu](mailto:amclint@uab.edu)



# ONGOING STUDY PROCEDURES

- Essential v. Non-Essential Visits
  - Conduct visits remotely to the extent possible
  - Delay or reschedule non-essential visits that cannot be conducted remotely
- Social Distancing of In-Person Visits
  - Minimize participant contact during unavoidable, essential in-person study visits
  - Develop and follow appropriate procedures to prevent transmission between study personnel and research participants

# AMENDMENTS & SAFETY REPORTING

- Changes to Approved Protocol Procedures
  - Must be approved by IRB in advance of change, unless to prevent immediate harm to participants
    - Implement change and disclose unapproved change when submitting amendment submission
    - Include reason for change and the immediate harm that was prevented via change
  - Consider if changes are temporary or permanent
- Problem Reporting Requirements
  - Currently, no changes to reporting requirements
  - 5-day, 10-day, or continuing review summary



# NEW COVID-19 RELATED PROJECTS

- COVID-19 Projects are Prioritized Accordingly
  - Treatment/Interventional Projects
  - Expedited, Exempt, and Not Human Subjects
- Emergency Use / Expanded Access
- New Projects Unrelated to COVID-19
  - Consider risks/benefits of current environment
  - May need to delay or adjust implementation
  - Must follow recommendations for ongoing studies (i.e., remote visits, essential v. non-essential visits)

# Clinical Research Update

Cynthia Joiner, PhD, MPH, RN

Associate Vice Chair

Department of Medicine

# Contingency plan

- ▶ Communication with the sponsor, investigator and research team is critical during this time.
- ▶ The research team should create and implement a contingency plan.
  - ▶ <https://www.uab.edu/research/home/business-continuity-plan>
- ▶ Consider your response and management of:
  - ▶ Enrollment
  - ▶ Study visits (essential and non-essential)
  - ▶ Dispensing of investigational product
  - ▶ Oversight and review of study results (labs, procedures, tests)
  - ▶ Protection of participants and research team members
  - ▶ Long term goals of new studies, recruitment and financial stability

# Study management

## ▶ Study Enrollment

- ▶ Highly encourage suspending enrollment
- ▶ If enrollment is to continue....
  - ▶ Does the patient screen negative to COVID-19?
    - ▶ Use the most current UAB clinical screening tool (attachment)
  - ▶ Is the participation in the study essential to the participant's health/well-being?
  - ▶ Can the enrollment and longitudinal participant management be conducted remotely for the duration of the COVID-19 outbreak?

## ▶ Sponsor visits

- ▶ Defer all in person monitor visits and site initiation visits.
- ▶ Consider remote monitor
  - ▶ Use of UAB Box for regulatory files
  - ▶ Do not share patient data via email

# Participant study visits

- ▶ Conduct visits remotely or defer whenever possible.
- ▶ Conduct only essential (vital to the health of a participant) visits in person.
  - ▶ Screen participant for COVID-19 by phone 24 hours prior to visit and again onsite the day of visit (see attachment)
  - ▶ Conduct in a patient care area.
    - ▶ JT 15 is a resource for essential visits
  - ▶ No visitors or guests with the participant (caregiver allowed).
  - ▶ Know the steps in reporting a participant with COVID-19 symptoms (see attachment).
  - ▶ Know the available COVID-19 resources to share with participants.
    - ▶ <https://www.uab.edu/news/coronavirus/patients>

# Stay current

- ▶ Utilizing project management software (e.g. Trello or Microsoft Teams) can facilitate communication and progress tracking with the research team.
  - ▶ <https://www.uab.edu/it/home/remote-work>
- ▶ Stay up to date UAB Medicine guidelines and communications regarding hospital and ambulatory processes.
  - ▶ <https://www.oneuabmedicine.org/coronavirus>
- ▶ Be aware of emerging FDA guidance
  - ▶ FDA's new guidance for industry, investigators, and institutional review boards is aimed at ensuring the safety of trial participants as well as the integrity of clinical trials.
  - ▶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic>
- ▶ NIH guidance
  - ▶ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>

# UAB Basic COVID-19 Symptom Check

- ▶ Are you having any of the following?
  - ▶ Fever ( $\geq 100.5$ )
  - ▶ New or worsened cough
  - ▶ New or worsened shortness of breath
- ▶ If yes to any of the 3 symptoms, discuss with the study physician immediately.
- ▶ Alabama COVID -19 Hotline at 888-264-2256 or the Jefferson County Department of Health / UAB Appointment-based testing center at 205-975-1881.
- ▶ They will screen them again to verify if they need to make an appointment.

# SOPH RESEARCH IN A TIME OF COVID-19

Paul Muntner, PhD  
Associate Dean for Research  
UAB School of Public Health

March 26, 2020



# FACILITATING RESEARCH PROGRESS & CONTINUITY

- Continuing regularly scheduled activities – virtually
  - Some projects are simply on hold
  - If data collection, interventions are stopped: papers? ancillary grants? new grants? revised grants? online trainings? thesis and dissertation progress?
- Develop plans for computer access
- Enabling the Survey Research Unit to function remotely
- Participate on the SOPH continuity of operations committee/Emergency management Team

# COMMUNICATIONS

- One daily email with a research update
- Thrice weekly emergency management team phone calls
- Regular check-in with faculty – especially Assistant Professors

# NATIONALLY - INTERNATIONALLY

- ASPPH Associate Deans for Research message board
  - Communication of planning of COVID-19 research
  - Discussions of managing research given current restrictions
  - Discussions of future research/administrative supplements
- Limited interaction with NIH project officers (e.g., NHLBI COVID-19 task-force)

# NEW (COVID-19) RESEARCH ACTIVITIES

- Identify public health research needs for covid-19
- “Question bank”
- Assistance with IRB submissions
- Grant writing groups
- Paper writing groups
- Facilitate research groups:
  - Societal- Pia Sen
  - Community- Suzanne Judd, Eric Ford
  - Relationship- Robin Lanzi, Faith Fletcher
  - Individual- Emily Levitan, Andrzej Kulczycki
  - Genetics/genomics – Hemant Tiwari, Sadeep Shrestha

# Graduate Student & Postdoc Training Updates

David Schneider, PhD, Associate Dean for Graduate Biomedical Sciences

Lisa Schwiebert, PhD, Senior Associate Dean for Graduate and  
Postdoctoral Affairs

# FAQs and Mental Health Resources for Graduate Students and Postdocs

- ▶ Graduate School:

- ▶ <https://www.uab.edu/graduate/about/faqs>

- ▶ Office of Postdoc Education:

- ▶ <https://www.uab.edu/postdocs/123-students/535-covid-19>

- ▶ Mental Health Resources:

- ▶ <https://www.uab.edu/students/counseling/resources/covid-19-services-and-resources>

# Guidance for Mentored Research Under Limited Operations Model

- ▶ It is expected that research mentors articulate a plan for their trainees and allow flexibility and curtail all studies that are not immediately necessary
- ▶ **No new experiments should be started**
- ▶ All trainees and lab personnel not involved in the most crucial studies should be instructed to read, analyze data, and write AT HOME
- ▶ **Labs should stay connected via zoom meetings to review data, manuscripts and review articles in preparation, journals, etc**

# Guidance for Postdoc Administrators, T32 Program Directors

- ▶ New hires will be honored if Letters of Offer have been signed, but not if the recruitment is only at the discussion stage
  - ▶ Recruitments are on hold based on University policy issued 03/25/2020
  - ▶ J-1 visas have been delayed until at least June 1<sup>st</sup>
- ▶ NIH advises that award recipients will continue to receive stipends
  - ▶ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-086.html>



# Contact Info

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<https://www.uab.edu/gbs/home/>

<https://www.uab.edu/graduate/>

<https://www.uab.edu/postdocs/>

# Reminder --- Use *Zoom Chat Feature* to Ask Questions

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