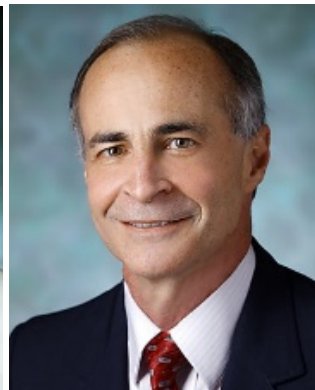
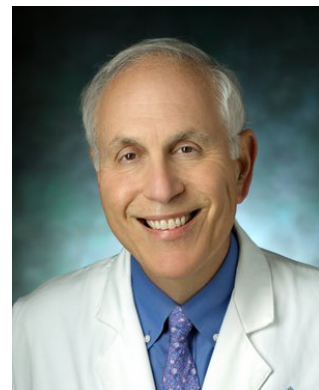
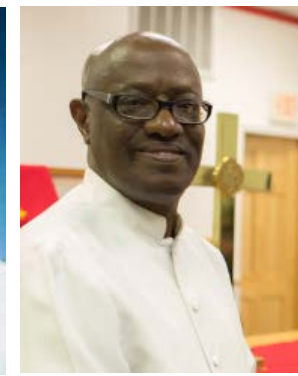




# **JHM IRB Experience with Emergency IRB Review**

Megan Kasimatis Singleton, JD, MBE, CIP  
Associate Dean for Human Research Protections

# The Emergency Response IRB



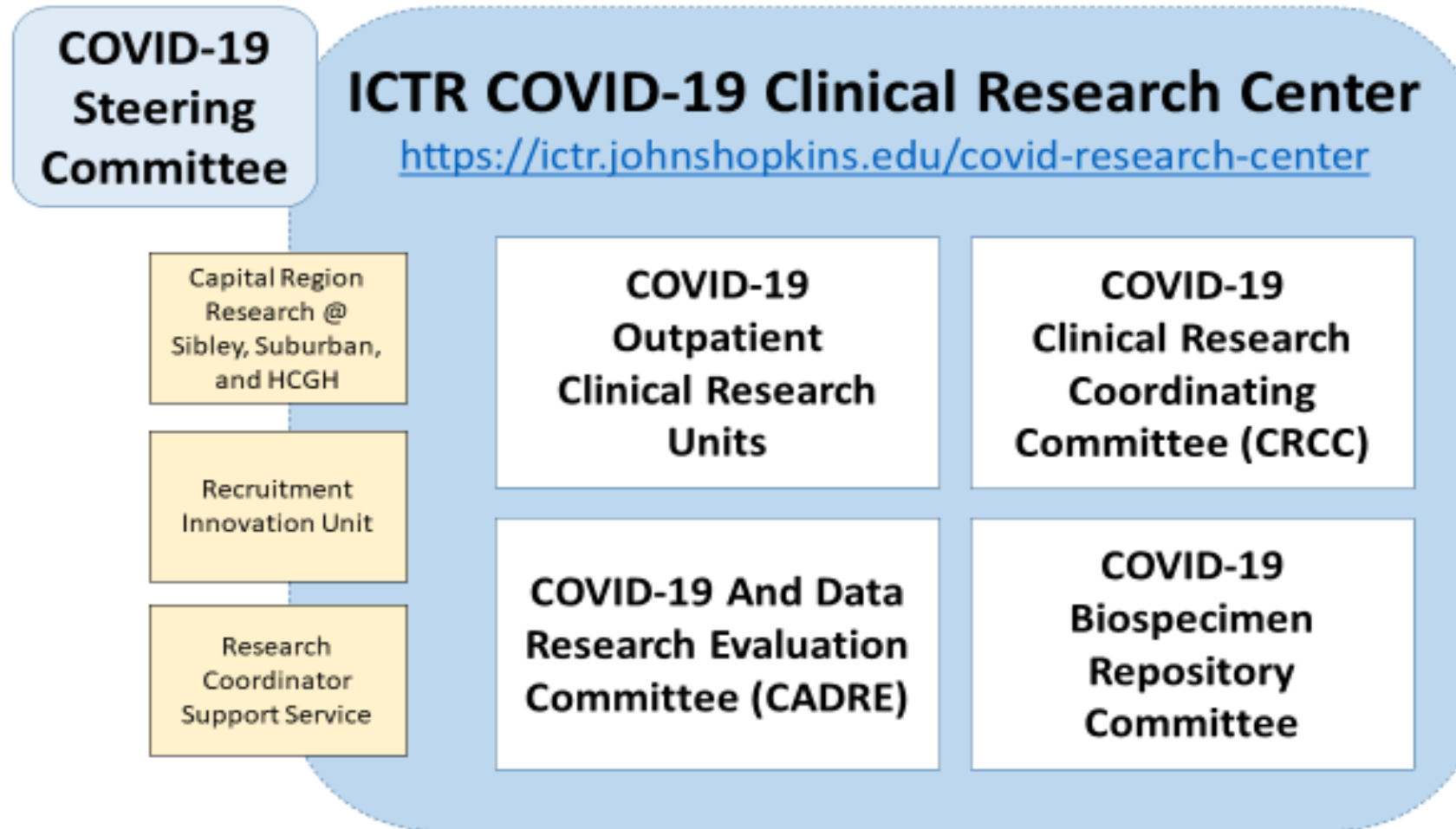
# Composition of the Emergency Response IRB

- “Alternate” structure on IRB roster allowed us to embed this process into an existing IRB Committee
- Drew on expertise across existing IRB committees to bring in members with relevant expertise (Pulmonary, Emergency Medicine, Infectious Disease, Pediatrics)
- Two community representatives on the Emergency Response IRB
- Pulled senior level staff to support the committee (intensive pre-review, senior experts generating minutes, etc)

# Emergency Response IRB Metrics

- Number of meetings held (3/2020-06/30/2022): 156
- New COVID-19 applications: ~650
- Changes in Research (Amendments) ~800

# Close Coordination with COVID Research Oversight Committees



# Lessons Learned from Emergency Review Experience

- Work is substantive and needs to be financially supported
- Close coordination with other required approvals is essential
- Researchers are not always able to be “nimble” in responding to IRB concerns - consider creative mechanisms for support
- IRB will have to get much more in the weeds about operations in order to assess whether risks are minimized- everything is new!
  - Repurposed staff, facilities not designed to treat targeted condition, etc