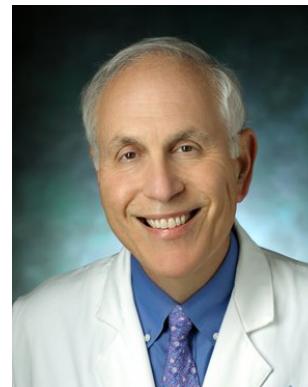




JHM IRB Experience with Emergency IRB Review

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



COVID-19 Steering Committee

Capital Region
Research @
Sibley, Suburban,
and HCGH

Recruitment
Innovation Unit

Research
Coordinator
Support Service

ICTR COVID-19 Clinical Research Center

<https://ictr.johnshopkins.edu/covid-research-center>

COVID-19 Outpatient Clinical Research Units

COVID-19 And Data Research Evaluation Committee (CADRE)

COVID-19 Clinical Research Coordinating Committee (CRCC)

COVID-19 Biospecimen Repository Committee

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