The Georgia CTSA Rapid Response Team (RRT) was created to establish a standard procedure to dramatically streamline the pre-award approval process for NIH studies, Federally Funded Network Studies, as well as Non-Federal studies needing fast-track approvals.

- High priority, requiring emergency approval for survival
- Public health emergency
- Bioterrorist attack
- Significant or catastrophic event

**VISION**

Emory’s first COVID-19 patient began receiving infusion therapy of Remdesivir within 48 hours as a result of Georgia CTSA’s assistance in coordinating the approvals needed. Georgia CTSA utilized its new Standard Operating Procedure (SOP) for its Rapid Response Team process to obtain fast-track approvals across the Emory system.

**SUCCESSES**

The Rapid Response Team expedited and facilitated pre-award approval process for 27 COVID-19 studies through September 2020 and effectively responded to the COVID-19 pandemic at many levels:

- advancing our understanding of how the immune system fights SARS-CoV-2
- providing valuable samples starting with an 80-year-old couple exposed to the disease while on a cruise ship to allow the development of serologic testing
- being the highest enrolling site in the world for the Remdesivir placebo-controlled trial. Remdesivir, an anti-viral agent, was recently granted FDA approval
- testing the first in human coronavirus vaccine and the first site in the world to enroll older adults in a coronavirus vaccine trial with promising results paving the way for a Phase 3 vaccine trial

**RESULTS**

**METHODS**

- Each department completes departmental approval.
- If applicable, external/single IRB is notified of urgency.
- Clinical Research Navigator team facilitates the pre-award approval process through all research administrative offices to completion.
- Each office assigns one person to complete the approval and other tasks in real time, working in parallel with other offices.
- Clinical Research Navigator notifies the investigator when study approvals are complete.

**KEY STATISTICS**

The Georgia CTSA Rapid Response Team expedited high-priority studies of experimental therapeutics and vaccines.

- Representatives from Emory research offices worked together in parallel to expedite 27 COVID-19 studies.
- Median time from Protocol Receipt to First Subject First Visit was 20 Days.

Total number (N = 27) of COVID-19 high-priority studies that met qualifying criteria for expedited review and approval through Rapid Response Team.

**CONCLUSIONS**

- The Georgia CTSA Rapid Response Team expedited high-priority studies of experimental therapeutics and vaccines.

**TIME METRICS FOR COVID-19 STUDIES Days from Rapid Response Team Activation to:**

- RAS Completion: 1 day
- eNOA Issued: 13 days
- CTA Executed: 11 days
- OCR Completed: 3 days
- FSFV: 8 days
- IRB Approval: 10 days

Virginity

"Results of COVID-19 Studies Routed, Approved via Rapid Response Team"

- Federal: 6
- Non-Federal: 9
- Non-Funded: 12

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