

# The Research Unit Network (RUN) as a Learning Research System

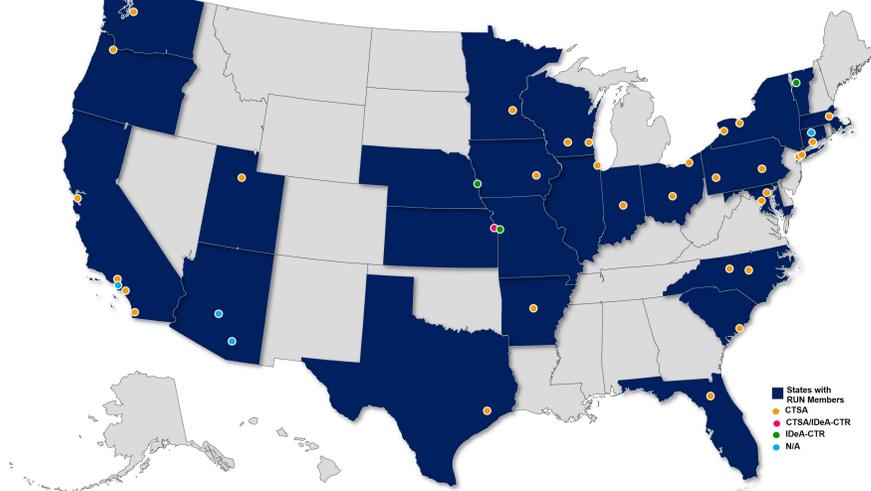
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## The Research Unit Network (RUN) Background & Goals

- RUN was created with the purpose to enable direct communication and collaboration among clinical and translational research units (CTRU).
- The intermediate goal of RUN is to identify best practices CTRUs are establishing, implementing, and following with the goal of sharing these experiences and try to adopt them in different CTRUs.
- The network's long-term goal is to establish standard benchmarks that can be used for evaluating the performance of an individual CTRU as well as comparing the performance of units around the nation.

### RUN Members



RUN Membership by Current CTSA/IDeA-CTR Status (FY-2021)

- RUN held its first meeting on July 25th, 2018, with 8 institutes.
- Within 4 years, the network grew to 50 individual institutes around the nation (79 members, 42 CTSA, 6 IDeA States)
- RUN has had a total of 30 conference calls.

## RUN Discussion Forum & Monthly Meeting Topics



Scan here to join the forum!

- General budget guidelines
- Clinical Research Unit Price List
- Order sets in EMR (Epic)
- Staff recruitment and retainment
- Calibration and equipment maintenance
- Verification of doses
- Sponsor attendance during study visits
- PPE for investigational drugs in context of USP800 requirements
- Recruiting under-represented minority participants
- Development and implementation of Standard Operating Procedures (SOPs)
- Delegation of authority logs
- Scheduling practices of CTRUs
- Use of electronic medical records and electronic orders
- Processes to request services in CTRUs
- Benchmarks in CTRUs
- Pediatric research in CTRUs
- Compliance on CTRU orders

### Protocol Deviation & Participant Safety

- This descriptive mixed method study identified and documented common practices implemented by Clinical Research Units (CRUs) when addressing the challenges posed by the COVID-19 pandemic.
- The findings gathered from 43 CRUs show that challenges faced from the COVID-19 pandemic, changes made to daily operations, and lessons learned are very similar across CRUs.
- Most CRUs never stopped performing essential clinical research, they adapted to the pandemic by engaging in virtual visits, played key roles in conduction of COVID-19 therapeutic and vaccine trials.

- RUN is currently conducting a survey on research service charges among members with the goal of establishing a market fairness analysis and the development of future benchmarks.
- Preliminary data from 17 CTRUs around the country shows the heterogeneity in prices as well as the classification of services.
- Sites charge by item, hours, or hybrid.

- We have developed and pilot tested a protocol deviation survey at a RUN institution to identify areas of improvement to better support clinical trials.
- A total of 55 deviations were reported during the pilot period with most incidents reported in the infusion bay, and during the nursing processes (date of deviation: Jan. 2016 – Oct. 2021).
- RUN members continue to collaborate to reduce protocol deviations and elevate the caliber of research within their institute and across the network.

## Selected Translational Science Initiatives & Results

Table 2. Institutional and research sponsor reaction to initial COVID-19 shutdowns

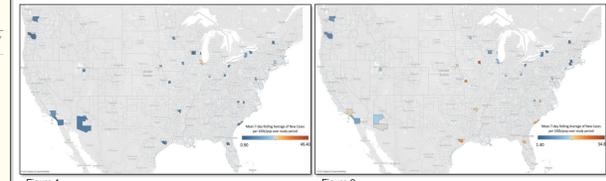
Item test, response options	Frequency (%)
How has the COVID-19 pandemic impacted research activities at your unit?	
Stopping of all nonessential research	25 (64.2%)
Continuing to provide essential clinical research	23 (79.3%)
Reduced hours of operations for essential research	17 (41.4%)
Stopped all research	1 (2.4%)
There have been no changes to research activities	0 (0%)
How have sponsors influenced your research activities?	
Paused enrollment	27 (81.3%)
Virtual visits	23 (79.3%)
Paused visits	19 (46.5%)
Closed studies	7 (19.1%)
Other	3 (10.3%)
No changes have occurred	1 (3.4%)

Participants could choose multiple response options for both items.

Table 6. Changes made to CRU operating procedures due to COVID-19

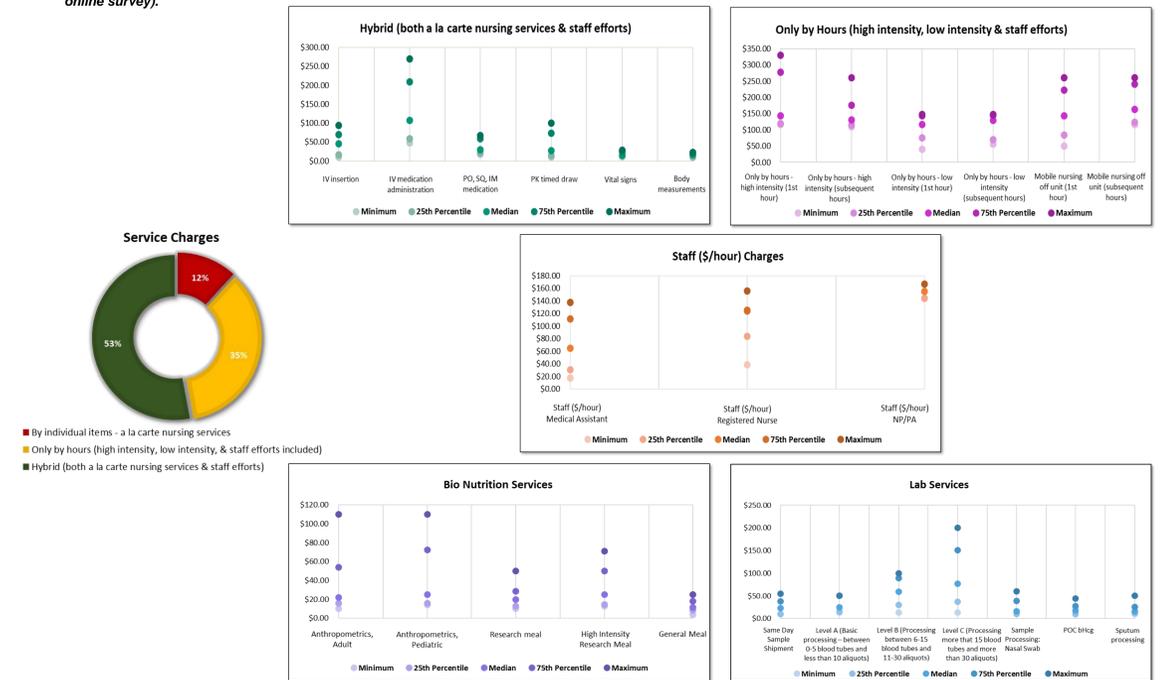
Changes to practice	Frequency (n=79)
1. Study teams were to contact participants within 24 hours prior to the visit for any COVID-19 symptoms and to explain the screening procedures during their visit.	6
2. Limiting participant number allowed in the CRU at the same time	6
3. Continue studies that are essential to a participant's health and/or well-being or consistent with an in-house clinical care	4
4. PIs had to provide plans explaining how they would conduct the studies safely given the pandemic restrictions.	4
5. Subjects and staff following PPE guidelines	4
6. Mandatory use of masks by CRU staff	2
7. Conducting procedures outside the facility (e.g., Sponsorship)	1
8. Arranging for mail-order medications or locally-provided lab work (avoiding travel and exposure)	1
9. Dividing research spaces into "clean" and "dirty" areas	1
10. Designating special areas for immune-compromised individuals to protect them	1
11. Providing special pods for COVID-19-positive participants	1

CRU: Clinical Research Unit; PI: principal investigator; PPE: personal protective equipment.

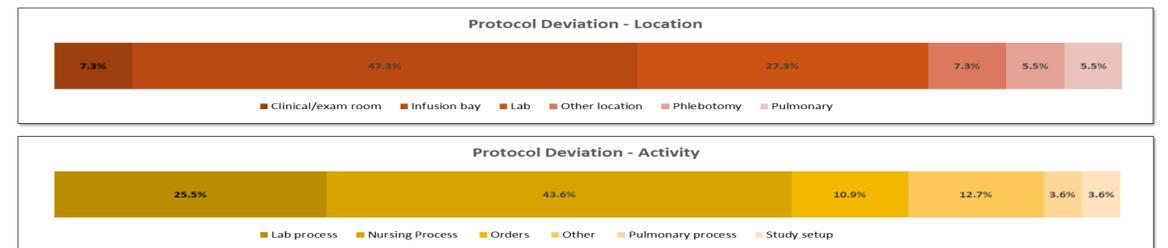


Figures 1 and 2 show the mean 7-day rolling average number of new cases per 100,000 population for each county in which a RUN member institution is located during the survey period (Fig. 1) and interview period (Fig. 2).

The figures below show the ways in which CTRU services are being charged, and distributions of the charges among 17 RUN member institutes (who have completed the online survey).



The figures below show the locations and protocol deviation activities reported in one (pilot tested) RUN member institute.



## Conclusions and Future Directions

- RUN members vary in geographic location (rural vs urban), type of clinical research (outpatient vs inpatient), resources, and research subject volume. They are engaged in an online forum discussion and learning opportunities to improve translational science practices.
- Led by the University of Iowa CTSA, RUN members are currently documenting forum discussions, publishing and disseminating various evaluation results, and developing guidance documents between all RUN members as a source for SOP standardization.
- RUN as a Learning Research System enhances CTRUs capacity and efficiency, encouraging collaboration to contribute with improving public health. This network is aligned with the CTSA's mission of developing innovative solutions to improve translational science.

### References:

Subramain M, Wangui-Verry JM, Sprenger KJ, Comellas AP, Barlow PB. Impact of COVID-19 on Clinical Research Units (CRUs). J Clin Transl Sci. 2021;5(1):e167. Published 2021 Aug 13. doi:10.1017/cts.2021.836.

### ACKNOWLEDGEMENTS

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