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Newsletters

6-2020

Volume 1 Issue 5

Center for Research

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Research Matters



Elevating care through discovery.

June 2020, Vol. 1, Iss. 5

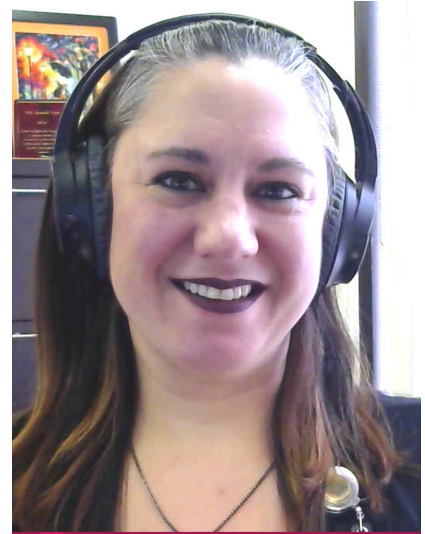
Message from Amy K. Starosciak, Ph.D.

Director of Outcomes Research, Center for Research
Editor-in-Chief, *Research Matters*

The “new normal” is upon us, even as cases of COVID-19 have continued to increase in Florida (especially in the last few weeks), hitting over 152 thousand cases as of this writing (6/30/20). Florida’s virus epicenter still comprises Miami-Dade, Broward, and Palm Beach Counties, with 36 thousand total cases in Miami-Dade and over 14 thousand each in Broward and Palm Beach. The next most affected counties are Hillsborough and Orange, with just over 10 thousand case each—so not too far below our volume. That means that as we recover clinical and research operations, we need to be ever-diligent in preventing the spread of COVID-19, including wearing masks, washing and sanitizing hands often, interviewing and temperature checking each person as they enter buildings, wiping down frequently used surfaces with a bleach or alcohol-based cleaner, minimizing in-person meetings (hence the Zoom™ picture on the right!), and continuing to work remotely when possible.

In this issue, the editors wanted to give our readers an idea of how research has been affected across the Baptist Health system since the pandemic began in March. We have included some vignettes and dashboards that we hope you will find interesting and important.

As we take our first steps towards research recovery, remember that this is a learning process for all of us. We can prepare as best as possible, but there may be missteps, miscommunications, and unintended delays. Please be kind to your colleagues, participants, principal investigators (PIs), and sponsor representatives. Keep the lines of communication open and give regular feedback on how the recovery process is going. We may need to make adjustments to our recovery plan as we go. Most importantly—stay safe!



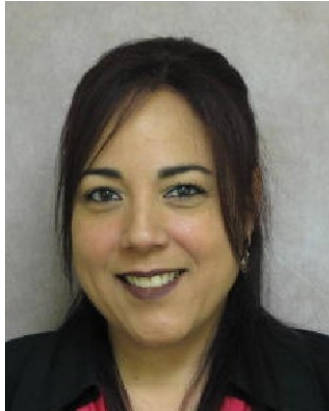
“It is better to ask some of the questions than know all of the answers.”
—James Thurber

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Quote from short story, “The Scotty Who Knew Too Much” in The Thurber Carnival (1945)

New Staff Updates



Carol Pantoja
Grants Administrator
MCI CTO



Tiffany Rozo
Research Support
Coordinator



Daylen Santana
Pharmacokinetic
Technician
MCI PSL & BRF



CONVALESCENT PLASMA

Expanded Access Protocol (EAP) for Treatment of COVID-19

Responding to the unprecedented challenge of fighting coronavirus disease 2019 (COVID-19), the U.S. Government is supporting a national Expanded Access Program (EAP) to collect and provide convalescent plasma to patients in need across the country. Plasma from recovered COVID-19 patients contains antibodies that may help fight the disease.

<https://www.uscovidplasma.org/>

Working collaboratively with industry, academic, and government partners, Mayo Clinic serves as the lead institution for the program and BHSF is a site. Coordination of this effort is led by Center for Research, nurse navigators Edwina Brathwaite, Ph.D., MSN/Ed, MS/HSA, RN-BC and Maureen Avella, RN, and Principal Investigator Guenther Koehne, M.D. See the next page for a snapshot of our dashboard.

CONVALESCENT PLASMA

Expanded Access Protocol (EAP) for Treatment of COVID-19

“As the lead clinical research coordinator entering data for the EAP, it has been enlightening to see how awful the virus can progress in some patients; it definitely puts the social distancing and mask wearing guidelines into perspective. I am so proud to work for an organization that recognizes the importance of being able to provide as many treatment options as possible to our patients. I am happy to be able to contribute to such an important effort.”

—Jacquie Landrian, LPN, CCRC, CCRP, Center for Research

Convalescent Plasma EAP Enrollment Dashboard



BHSF System PI: Guenther Koehne, M.D.

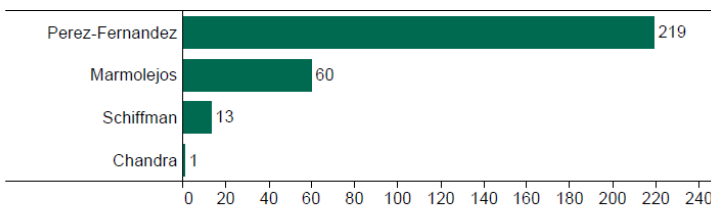
N Enrolled
293

N Received Plasma
226

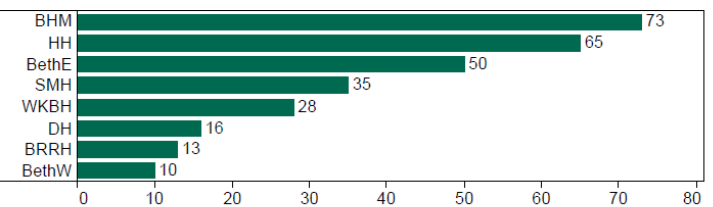
% Received Plasma
78%

Cost Savings w/ EAP vs. eIND
\$170K

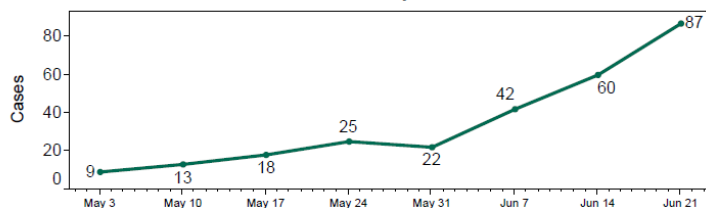
Number of Cases by Physician



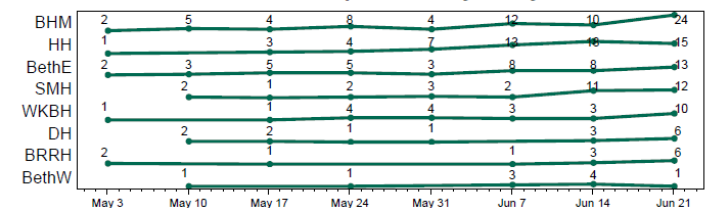
Number of Cases by Entity



Number of Cases per Week



Number of Cases per Week by Entity



The bottom two charts only show up to the last completed week. The rest of the dashboard shows data through current (updated 6/29/2020 @ 19:30).

“Research Compliance, while administrative, has still felt the effects of COVID-19. We have aided compliance matters of the Expanded Access Program (EAP) that provides convalescent plasma to affected patients. This EAP has presented its share of new compliance challenges and required the creation of new processes such as unique consent processes as the coordinators are unable to enter the room with the patients and unique bill reviews for specific codes that are required to be listed for compliance purposes. Research Compliance also has seen an uptick in compliance reviews as BHSF has opened up for elective services and sites eagerly re-open their clinical trials that were previously halted.”

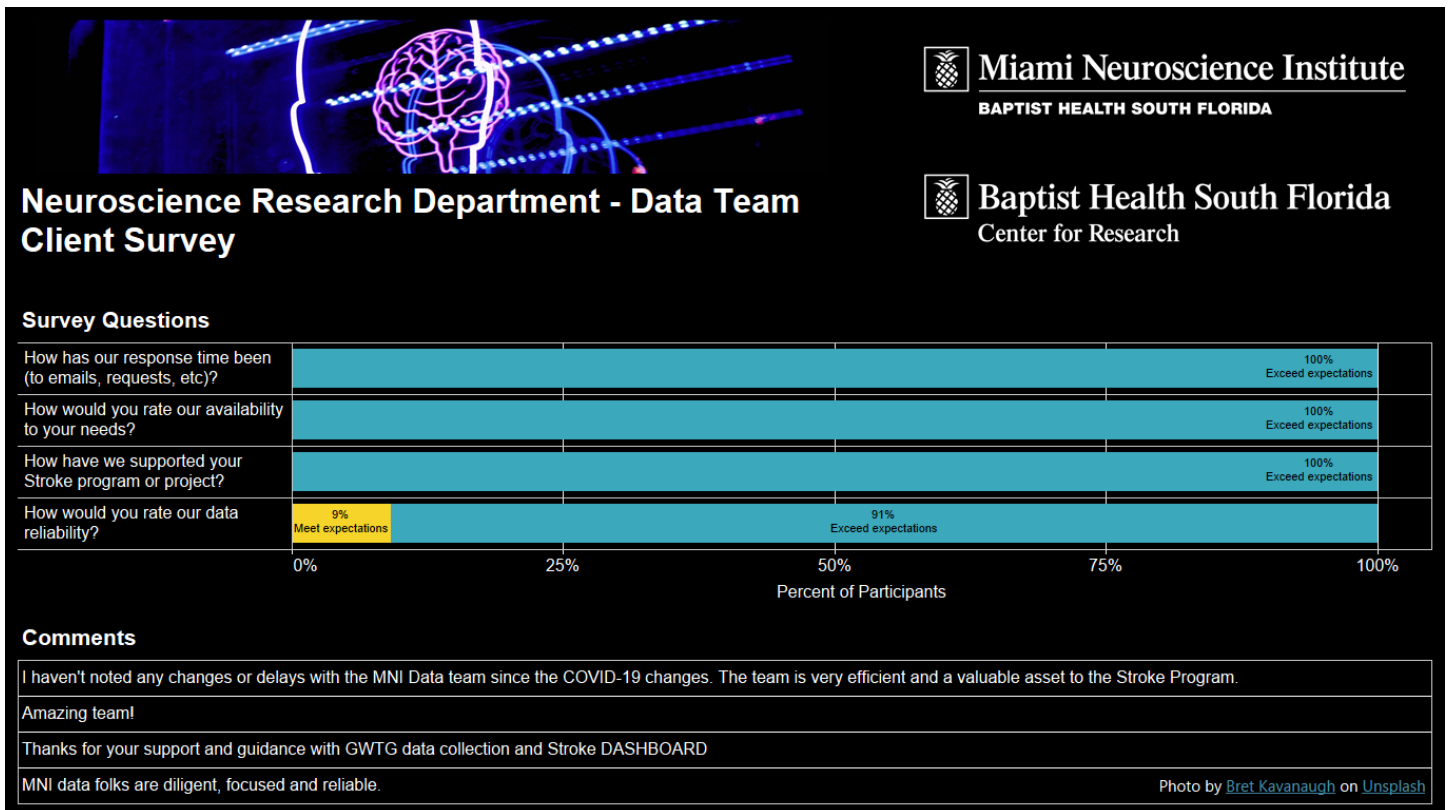
—Heather Osorio, MBP, Center for Research

MNI RESEARCH CLIENT SURVEY

During the COVID-19 Pandemic

“MNI Research data team collaborates with several of the Baptist Health entities to provide essential stroke data used for performance measures, improvement, and outcomes. Our department is based out of Baptist Hospital. When COVID-19 presented, as with other departments, the safest option was to work remotely. The thought of remote work created doubt and hesitancy at first, especially for those who had no experience with off-site work. The idea of solitary work created apprehension, as our team is used to office collaboration and sharing of tasks. However, since mid-March, we have been working remotely, and our operations have been just as productive and the performance of our team collaboration has only strengthened during this experience. Our leaders and colleagues are well aware of the team’s responsibilities and expectations, and it shows in our team results. We are grateful our job responsibilities are 100% compatible with remote work, so that we may continue to provide our entities with patient care metrics and health outcomes. Our goal is to continue to provide the most accurate data in a timely manner while remote, so we created a client survey to ensure we met or exceeded expectations. The results speak for themselves.”

—Maygret Ramirez, ARNP, MSN, FNP, SCRN , Center for Research, MNI





New Article Alcove

Explore our new publications!

The remote work environment has given our researchers time to focus on publications when those long, frustrating Miami commutes and traveling between entities are removed from the equation!

Askenazi DJ, Heagerty PJ, Schmicker RH, Griffin R, Brophy P, Juul SE, Mayock DE, Goldstein SL, Hingorani S, on behalf of the **PENUT Trial Consortium (includes Perez JE)** (in press) Prevalence of acute kidney injury (AKI) in extremely low gestational age neonates (ELGAN). *Pediatr Nephrol* [Find it here!](#)

Baralt M, **Darcy Mahoney A**, Brito N (in press) Háblame Bebé: A phone application intervention to support Hispanic children’s early language environments and bilingualism. *Child Lang Teach Ther* [Find it here!](#)

Fraser JF, Arthur AS, Chrn M, Levitt M, Mocco J, Albuquerque FC, Ansari SA, **Dabus G**, et al. (2020) Society of NeuroInterventional Surgery recommendations for the care of emergent neurointerventional patients in the setting of COVID-19. *J Neurointerv* 12 (6): 539-541. [Find it here!](#)

Linfante I, Andreone V, Ravelo N, **Starosciak AK ... McDermott M, Dabus G** (2020) Endovascular Treatment of Giant Intracranial Aneurysms: Real-Life Experience in Three Medical Centers. *Cureus* 12(5): e8290. [Find it here!](#)

Linfante I, Ravipati K, **Starosciak AK, Reyes D, Dabus G** (in press) Intravenous Cangrelor and Oral Ticagrelor as Alternative to Clopidogrel in Acute Intervention. *J Neurointerv Surg* [Find it here!](#)

Madsen TE, Khoury JC, Leppert M ... **De Los Rios La Rosa F**, et al. (2020) Temporal trends in stroke incidence over time by sex and age in the GCNKSS. *Stroke* 51: 1070-1076. [Find it here!](#)

Mistry EA, Dakay K, Peterson N, Jayaraman M, McTaggart R, Furie K, Mistry AM, Mehta T, Arora N, **De Los Rios La Rosa F, Starosciak AK**, et al. (2020) Pre-endovascular therapy change in blood pressure is associated with outcomes in stroke patients. *J Neurol Neurosurg Psychiatry* 91(4): 438-439. [Find it here!](#)

Mistry E, Mehta T, Mistry A, Arora N, **Starosciak AK, De Los Rios La Rosa F**, et al.(2020) Blood pressure variability and neurologic outcome after endovascular thrombectomy: A secondary analysis of the BEST study. *Stroke* 51(2):511-518. [Find it here!](#)

Mistry EA, Mistry AM, Mehta T, Arora N, **Starosciak AK, De Los Rios La Rosa F**, et al. (2020) White matter disease and outcomes of mechanical thrombectomy for acute ischemic stroke. *AJNR Am J Neuroradiol* 41(4): 639-644. [Find it here!](#)

Siegler JE, Messé SR, Sucharew H, Kasner SE, Mehta T, Arora N, **Starosciak AK, De Los Rios La Rosa F**, et al. (2020) Noncontrast CT versus perfusion-based core estimation in large vessel occlusion: The blood pressure after endovascular stroke therapy study. *J Neuroimaging* 30(2): 291-226. [Find it here!](#)

Williams LMS, Walker GR, Loewenherz JW, Gidel LT (2020) Association of contrast and acute kidney injury in the critically ill: A propensity-matched study. *Chest* 157(4): 866-876. [Find it here!](#)

Explore more publications from the Baptist Health Institutional Repository

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[Center for Advanced Analytics](#)

[Miami Cancer Institute](#)

[Miami Cardiac & Vascular Institute](#)

[Miami Neuroscience Institute](#)

[Miami Orthopedics & Sports Medicine Institute](#)

Did we miss your publication?

Please send it to:

library@baptisthealth.net



Mondays 12:00 to 1:30 pm

Invite was sent out to Research Operations & Regulatory teams. Certificates provided.

Because of the COVID-19 pandemic, we will be doing Zoom™ meetings only until further notice.

Email Amy at amyst@baptisthealth.net if you are interested and did not receive an invite.



Date	Topic
Monday, July 13 th	FDA Audit Preparation
Monday, August 10 th	Consent Best Practices
Monday, September 14 th	Participant Recruitment
Monday, October 12 th	Reporting Adverse Events
Monday, November 9 th	How to Conduct a Literature Search
Monday, December 14 th	History of Informed Consent and HIPAA Authorization



UPCOMING CONFERENCES

by Nursing & Clinical Research Organizations

SOCRA—September 25-27, 2020, Las Vegas, NV **Virtual**
<https://www.socra.org/annual-conference/2020-conference-information/2020-annual-conference-information/>

Onsemble—October 6-9 2020, Madison, WI **Virtual**
<https://onsemble.net/conference/>

ANCC Pathway & Magnet—October 7-9 2020, Atlanta, GA **Virtual**
<https://www.nursingworld.org/ancc/>

MAGI West—November 15-18, 2020, San Francisco, CA
<https://www.magiworld.org/EventInfo?EVT=49>

ONLINE

Thanks to those who joined!

June 24, 2020 | 12 noon - 1 p.m.

Conversations in Ethics – Ethics and Artificial Intelligence

Amanda Coltes-Rojas, MPH, CIP, CHRC

Director, Human Research Protection Program | BHSF Institutional Review Board

Artificial intelligence (AI) is rapidly growing in healthcare, with the prospect of making the field safer and more efficient. AI will affect almost every area of healthcare in which machines can automate larger volumes of people. There are however unforeseeable risks, such as false positives or negatives, system error, unexplainable results and amplifying biases or unethical behavior.

Center for Research

MISSION

To serve as a research hub for elevating care through discovery for the diverse community we serve by using a shared service model that capitalizes on synergies created through a collaborative intellect.

VISION

In alignment with the strategic goals of Baptist Health South Florida, and within the context of a sustainable business model, the Center facilitates the development and dissemination of knowledge with the goals of providing continued excellence in patient care for the diverse multicultural community of South Florida.

Research Compliance Corner

The annual Conflict of Interest disclosure period will soon begin! On July 1, 2020, the new Clinical Conflict of Interest (CCOI) form will be available via PeopleSoft. BHSF's policy, BHSF 1300, requires all personnel involved with research to disclose all "financial interests or relationships including those that could result in a conflict with their BHSF responsibilities including, in part, their obligations to BHSF patients and to research participants." The CCOI form was updated to distinguish between disclosure periods and improve user experience. Research Compliance requires all personnel listed in the IRB application to complete the CCOI form as part of our study specific compliance review. Non-compliance will result in a compliance review hold on the IRB submission. Please note that while this is the annual disclosure, it is also required to update the CCOI form within 30 days of a change in your financial interests or relationships.

Upon requests, Research Compliance will provide guidance via phone/zoom to all, especially physicians, that may need assistance to complete this requirement. Please send all requests and/or feedback to ResearchCompliance@baptisthealth.net.



Do you have any questions or topics you would like for us to cover regarding conflicts of interest, compliance review, or billing compliance process? If so, contact us directly for all Research Compliance matters!

Heather Osorio, Research Compliance & Billing Administrator, ResearchCompliance@baptisthealth.net

UPCOMING IRB DATES

BHSF IRB

Full Board Committee Meeting: **Tuesday, July 28th**

Submission Deadline for August Meeting: **Monday, July 27th**

MCI IRB

Full Board Committee Meeting: **Monday, July 6th**

To contribute to this newsletter, please contact Dr. Amy Starosciak at amyst@baptisthealth.net or x79546.



Baptist Health South Florida
Center for Research