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BHSF Research Matters

Newsletters

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Volume 1 Issue 6

Center for Research

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Research Matters



Elevating care through discovery.

September 2020, Vol. 1, Iss. 6

Message from Viviana Bonorat, M.D., MBA, CCRC

Director of Research, Office of Research Administration
Boca Raton Regional Hospital

Boca Raton Regional Hospital has been engaged in research for over 20 years, bringing cutting edge therapies to our community. Being part of Baptist Health South Florida family will open more opportunities to expand our research efforts to Palm Beach County. I am pleased to introduce to you, our BHSF family members, our research team.



We are very proud of our core physician faculty that is very engaged in research and enables access to clinical trials in oncology, cardiovascular, women’s health, neuroscience, and neurosurgery.

Through these difficult months, our research physicians and research staff have been committed to providing continued access to clinical trials for patients. Just last month, we started a patient in a trial that was introduced to us in 2018. Nationwide, there are 20 sites participating in this study and we are very proud to be the first center to successfully recruit and start a patient on this study. This study is a collaborative effort with Radiation Oncology, Medical Oncology, Radiology and our Research Department.

I will end with special recognition for our research physicians, research nurses, and study coordinators who integrate research into the daily clinic workflow. They promote teamwork by engaging many departments, which makes it possible to offer complex and cutting edge clinical trials to our patients. Above all, our patients experience the personalized care.

“When you have completed 95% of your journey, you are halfway there.”

—Proverb—

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New Staff Updates



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Enterprise Systems
Administrator
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NEW COVID STUDY LED BY CAA

Prospective Evaluation of COVID-19 in South Florida

As our healthcare community continues to rise to the challenge of screening and treating COVID-19 patients, scientists and clinicians have begun to understand the prevention (e.g., masks, social distancing) and clinical consequences (e.g., lung and vascular complications) of this novel virus. **However, little to none is known about the psychosocial and socioeconomic consequences of a positive COVID-19 diagnosis.** For example, does screening positive for COVID-19 affect one's quality of life, financial stability, or mental health? Further, do these effects last over time? Hence, the purpose of our study is to explore the psychosocial, medical, and socio-economic consequences of inpatients and

outpatients who tested positive for COVID-19 within Baptist Health South Florida (BHSF).

Three-, six-, and twelve-months post a positive screening result, participants are asked about their health-related quality of life, respiratory quality of life, sleep quality, psychological distress, measures of hardship, demographics, and medical history. BHSF employees and volunteers call potential participants to explain the study and obtain verbal consent and HIPAA authorization. Once consent is obtained, the participant has the option to respond to survey questions over the telephone or be sent a link to the survey via email. All survey responses are captured on REDCap. Descriptive analyses

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NEW COVID STUDY LED BY CAA

Prospective Evaluation of COVID-19 in South Florida

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will be conducted to understand trends over time and disparities within participants. If a participant was hospitalized for COVID-19 within our system, we also will analyze their medical record data. The data collectors on this study include Center for Research staff, front-line nurses, and Florida International University (FIU) students.

To obtain a more accurate representation of the South Florida community, we are collaborating with University of Miami (UM) and Broward Health (BH) to aggregate data across health systems. The study originated from Shirin Shafazand, M.D, M.S., at the UM Miller School of Medicine. Dr. Shafazand contacted Don Parris, Ph.D., MPH (Assitant Vice President, Center for Advanced Analytics, BHSF) and Noella Dietz, Ph.D. (BH). The Center for Advanced Analytics and Center for Research partnered to operationalize this study at BHSF: the

principal investigator is Lourdes M. Rojas, Ph.D., MPH, and the co-investigators are Dr. Parris, William Arguelles, Ph.D., MSPH, Amy K. Starosciak, Ph.D., and Susan Golembeski, Ph.D., RN, CHRC The BHSF team is working closely with the FIU Nicole Wertheim College of Nursing and Health Sciences.

“This important study is a great example of the South Florida community coming together to respond to this pandemic. It’s great to see the region’s major academic and healthcare systems collaborating to better understand this disease and its impacts,” says Dr. Parris.

In summary, long-term follow-up of inpatients and outpatients diagnosed with COVID-19 will not only help us discover social sequelae of this disease, but also enhance our understanding of health disparities within our South Florida community. Results from this study will be informative to healthcare systems’ leaders and clinicians and to the scientific and clinical communities at large. We anticipate being able to supplement the clinical knowledge of this disease with important information related to its impact on a patient’s quality of life. The internal and external collaboration of this study is a testament to how we can band together to understand, and, ultimately, better serve, our COVID-19 patients now and in the future.

—Lourdes Rojas, Ph.D., MPH, Center for Advanced Analytics



MCI STUDY OPERATIONALIZATION

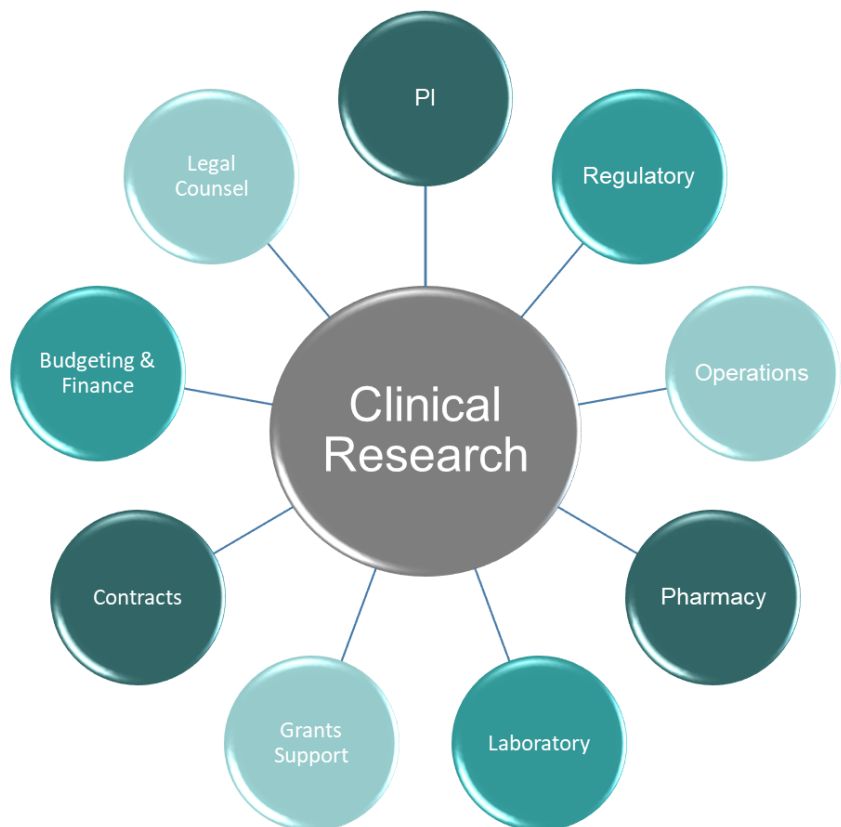
During the Era of COVID-19

There is a pressing interest in BHSF involvement in COVID-19 clinical research to help treat individual patients but also to support a greater societal benefit. As a large healthcare system, we have the catchment to impact a broad community and include a diverse population to identify and test the safety and effectiveness of a potential intervention. A particular infrastructure is needed to conduct scientific inquiries ethically, safely, and with high quality.

To meet clinical research requirements, there are some particular areas of practice in which resources are necessary. A **principal investigator (PI)** who takes responsibility for the oversight and conduct of the research must be designated; ideally, the PI should be experienced and should understand the importance of a well-composed study team who conducts the research. **Regulatory expertise** dedicated to support and track the required documents and information ensures that the research we conduct successfully will pass a review by the FDA or other auditing agency. The regulatory team also can coordinate swiftly with the IRB. An **operations team** who can conduct informed consent, coordinate between the PI and other teams for new patient enrollments, and communicate with the Sponsor is essential. Key teams to loop in early are **pharmacy** and **laboratory** support, if needed, as their expertise is necessary to ensure safe administration of interventions and the collection of specimens in alignment with the protocol's schedule of events and times. Support for **budgeting and finance**, **grants and funding**, **contracts**, and **legal counsel** also are needed for the relationships between the Sponsors and BHSF. In balance with the interests of the providers and patient population, a robust network of teams is imperative to conduct high quality research. At greatest risk for not having adequate research support to conduct clinical trials are our smaller sister hospitals. They will need assigned staff trained to support some of these roles or individuals across the system may need to be resourced in a way to support a multi-site trial.

Leadership's stewardship of the appropriateness of trials, discussion with investigators, and guidance on resourcing all are key to aid in opening clinical trials.

—Nicholas Chow, Pharm.D., BCOP,
MCI Clinical Trials



CONVALESCENT PLASMA

Changes to Expanded Access Protocol with New Emergency Use Authorization

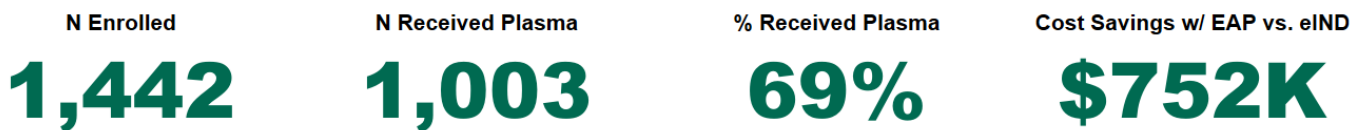
In the last issue, we discussed the Convalescent Plasma Expanded Access Program (EAP), offered through Mayo Clinic, to treat patients with severe COVID-19. Since the last issue, we enrolled over 1,100 more people, of which another 700 were treated with plasma. **Breaking news arrived on Sunday, August 23rd: the FDA announced that convalescent plasma was approved to treat any hospitalized person with COVID-19 under an Emergency Use Authorization.** Monday, August 24th brought a flurry of emails and phone calls between the research coordinators, regulatory coordinators, physicians, leadership, nurse navigators, and the Evidence-Based Clinical Care (EBCC) team. What would we do now? We hadn't yet received any notification from Mayo Clinic, and there were still patients for whom plasma needed to be ordered. We finally received notification that the EAP would continue enrolling until Friday, August 28th and plasma could be administered until Monday, August 31st so that sites could transition off the research EAP. Overnight, EBCC developed a new workflow that then went into effect on Friday, August 28th. Now, the Center for Research team will continue collecting data on enrolled patients and reconciling patient bills until completion. It was a whirlwind journey for the Center for Research team, and we finally can breathe a sigh of relief that the research aspect is over for convalescent plasma. However, we are truly grateful to have been a part of the research that helped so many people during the pandemic.

—Amy K. Starosciak, Ph.D., Center for Research

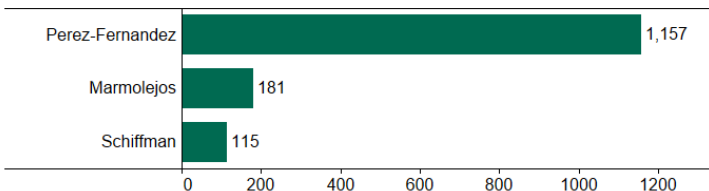
Convalescent Plasma EAP Enrollment Dashboard



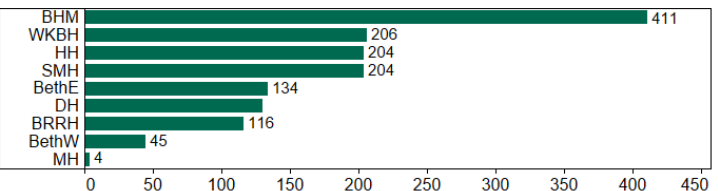
BHSF System PI: Guenther Koehne, M.D.



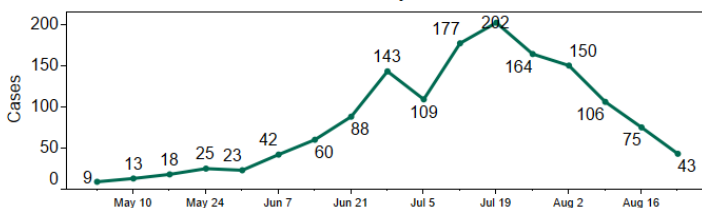
Number of Cases by Physician



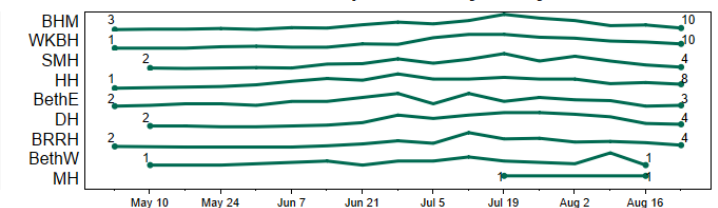
Number of Cases by Entity



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 (last updated 8/31/2020 @13:00).



New Article Alcove

Explore our new publications!

Chung DJ, Liounakos J, **Abrams K, Siomin V** (2020) Extreme intracranial hypotension with brain herniation treated with repeat bolus intrathecal infusions. *Cureus* 12(5): e8089. [Find it here!](#)

Dabus G, Kan P, Diaz C, Pabon B, Andres-Mejia J, **Linfante I, McDermott MW** (in press) Endovascular treatment of anterior cranial fossa dural arteriovenous fistula: a multicenter series. *Neuroradiology* [Find it here!](#)

Dabus G, Linfante I, McDermott MW (2020) Angiography and embolization of meningiomas. *Handb Clin Neurol* 169: 193-202. [Find it here!](#)

Fargen KM, Leslie-Mazwi TM, Klucznik RP...**Dabus G**, et al. (in press) The professional and personal impact of the coronavirus pandemic on US neurointerventional practices: a nationwide survey. *J Neurointerv Surg* [Find it here!](#)

Gammon RR, Delk A, Houtz P, **Alvarez H**, Benitez N (in press) A rare cohort of two Rh_{null} individuals. *Lab Med* [Find it here!](#)

Hasegawa Y, Ryherd E, Ryan CS, **Darcy-Mahoney A** (in press) Examining the utility of perceptual noise categorization in pediatric and neonatal hospital units. *HERD* [Find it here!](#)

Juul SE, Vu PT, Comstock BA...**Perez JE**, McKay V, Heagert PC, for the PENUT Consortium (in press) Effect of high-dose erythropoietin on blood transfusions in extremely low gestational age neonates: Post hoc analysis of a randomized clinical trial. *JAMA Pediatrics* [Find it here!](#)

Mokin M, Waqas M, Fifi J,...**Linfante I**, et al. (in press) Clot perviousness is associated with first pass success of aspiration thrombectomy in the COMPASS trial. *J Neurointerv Surg* [Find it here!](#)

Rai AT, Leslie-Mazwi TM, Fargen KM, Pandey AS, **Dabus G**, et al. (in press) Neuroendovascular clinical trials disruptions due to COVID-19: Potential future challenges and opportunities. *J Neurointerv Surg* [Find it here!](#)

Rubens M, Ramamoorthy V, **Saxena A, Bhatt C, Das S, Veledar E, McGranaghan P, Viamonte-Ros A, Odia Y, Chuong M, Kotecha R, Mehta MP** (2020) A risk model for prediction of 30-day readmission rates after surgical treatment for colon cancer. *Int J Colorectal Dis* 35(8): 1529-1535. [Find it here!](#)

*Rynor H, *Levine J, ^Souchak J, ^Shashoua N, **Ramirez M, Gonzalez I, Ramos V, Saxena A, Veledar E, Starosciak AK, De Los Rios La Rosa F** (in press) The effect of a county prehospital FAST-ED initiative on endovascular treatment times. *J Stroke Cerebrovasc Dis* [Find it here!](#)

Santalo O, Farano J, **Igwe J**, Deyim N (2020) Survey of health-system pharmacy administration and leadership residencies. *Am J Health Syst Pharm* 77(6): 449-456. [Find it here!](#)

Vega EA, **Asbun HJ**, Conrad C (in press) ASO author reflections: Laparoscopic pancreatic head preserving total duodenectomy—You can eat your cake and have it too. *Ann Surg Oncol* [Find it here!](#)

*FIU medical student, ^undergraduate student

Explore more publications from the Baptist Health Institutional Repository

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[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, 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/>

Nursing World Conference—October 19-20, 2020, **Virtual**
<https://nursingworldconference.com/>

MAGI West—November 2-12, 2020, San Francisco, CA **Virtual**
<https://www.magiworld.org/EventInfo?EVT=49>

ACRP—May 14-17, 2021, Toronto, Canada
<https://acrpnet.org/event/acrp-2021-annual-conference/>

PASSION LED US HERE

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



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

CALL FOR ABSTRACTS

The **Miami Neuroscience Symposium Online** course planning committee invites interested individuals to submit abstracts for consideration as e-Poster presentations. We are accepting abstracts for e-Posters on research and performance improvement in neuroscience through **Friday, September 25th**.

[Submit Your Abstract Here!](#)

UPCOMING IRB DATES

BHSF IRB

Full Board Committee Meeting: **Tuesday, September 22nd**
Submission Deadline for October Meeting: **Monday, Sept 28th**

MCI IRB

Full Board Committee Meeting: **Monday, September 7th**

EDITORIAL STAFF

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



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Center for Research