

Baptist Health South Florida

Scholarly Commons @ Baptist Health South Florida

BHSF Research Matters

Newsletters

7-2021

Volume 2 Issue 4

Center for Research

Follow this and additional works at: <https://scholarlycommons.baptisthealth.net/bg-bhsf-research-matters>

Recommended Citation

Center for Research, "Volume 2 Issue 4" (2021). *BHSF Research Matters*. 11.
<https://scholarlycommons.baptisthealth.net/bg-bhsf-research-matters/11>

This Newsletter - Open is brought to you for free and open access by the Newsletters at Scholarly Commons @ Baptist Health South Florida. It has been accepted for inclusion in BHSF Research Matters by an authorized administrator of Scholarly Commons @ Baptist Health South Florida. For more information, please contact Carrief@baptisthealth.net.

Research Matters



Elevating care through discovery.

July 2021, Vol. 2, Iss. 4

Message from Amy K. Starosciak, Ph.D.

Director of Outcomes Research, Center for Research

How much research does Baptist Health South Florida do? Baptist Health comprises 11 hospitals and 10 institutes as well as several other departments and centers that conduct research. As of right now, each institute and department tracks their own studies and self-reports their information. As you can see from the self-report figures and chart below, we have over 400 retrospective and prospective (therapeutic and non-therapeutic) studies taking place with over 10,000 participants (5K in the VIRUS registry and 2.5K in the Miami Heart Study). That doesn't include the studies currently taking place with independent investigators who are not part of a designated center



68 New patients enrolled in prospective trials during May 2021

Total patients currently participating in prospective studies as of May 31st **10K+**

or institute conducting research. You may be thinking, how do we get a handle on it all? What is the source of truth? One of the ways the BHSF research community is doing that is by transitioning all clinical research to OnCore. From OnCore and the analytics program Insights, research leadership easily can run reports to see how many studies are open, how many participants are enrolled, how many are on active treatment, and how many are in follow-up. We are excited to share more as the transition continues!

"Every brilliant experiment, like every great work of art, starts with an act of imagination."
~Jonah Lehrer~

Number of Retrospective and Prospective Studies as of 5/31/21

Department	Retrospective	Prospective	Total
MCI	35	114	149
Boca Raton	5	95	100
MCVI	4	42	46
NHSR	11	17	28
Pharmacy	20	0	20
MNI South	9	5	14
MOSMI*	8	5	13
CWI/NICU	3	4	7
CAA	3	2	5
Surgery	2	3	5
BHMG	1	0	1

401
Total Studies

*includes Sports Medicine and Total Joint Programs

Inside this issue

- New Staff Updates.....2
- IRB Retiree Reflections.....3
- Boca Pandemic Reflections...4
- Decentralized Trials.....5
- Study Blinding.....6
- New Article Alcove.....7
- Education.....8
- Compliance Corner.....9

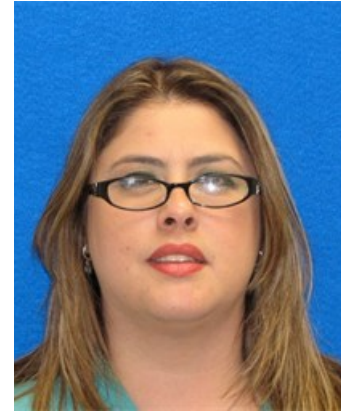
New & Transferred Staff Updates



**Andres Alvarez Pinzon,
M.D., Ph.D.**
Clinical Research
Administrator
Center for Research/MOSMI



Terry Conyers
Supervisor, Library
Coordinators
Center for Research
Library Services



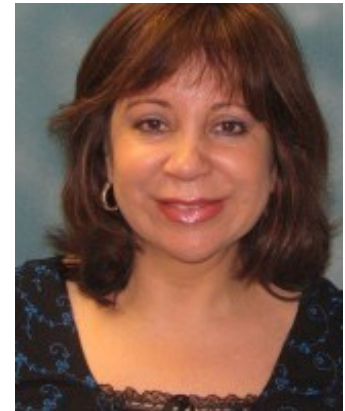
Jetsenea Coto
Clinical Research
Coordinator
Miami Cardiac & Vascular
Institute



Jacqueline Grass
Research Compliance
Coordinator
Center for Research
Research Administration



Karina Rico-Arango
Clinical Research Nurse
Lynn Cancer Institute
Boca Raton Regional
Hospital



Claudia Rivera
Administrative Assistant
Center for Research



REFLECTIONS

BITTERSWEET RETIREMENT – ROSE ALLEN, DNP

After 37 years as a nurse at BHSF and 18 years as a member of BHSF IRB, I have retired as of June 25, 2021. I feel very fortunate to have had this opportunity to fulfill my amazing career first as a Critical Care nurse, then educator, researcher, and nurse ethicist.

I joined the BHSF IRB in 2003 when appointed as BHSF Director of Bioethics Program, after working for 18-years in the Critical Care Unit at Baptist Hospital. I had very little exposure to research prior to joining the IRB, but was welcomed with open arms by then chair, Dr. Harold Goldstein. The required CITI training prepared me and allowed me to feel more comfortable as a member. By 2004, I was motivated to conduct my first research study on [“Advance Directives Use in Acute Care Hospitals”](#), which was published 2005 in *JONA’s Healthcare Law, Ethics, and Regulations*. Subsequently, I conducted other research over the years.

My 18-year IRB membership taught me so much through all the various protocols presented on a monthly basis, and the research conferences and workshops offered to all members each year. I have also valued the professional expertise of our IRB interdisciplinary members of physicians from different specialties, pharmacists, nurse scientists, legal counsel, clergy, community members, and IRB management staff.



RESEARCH AT BOCA RATON REGIONAL HOSPITAL DURING THE PANDEMIC

Challenges and Opportunities

When I go back to March 2020 and all the uncertainty we faced, the thing that stays in my mind is the **teamwork, collaboration, and support we gave to each other**. With so many decisions in an unprecedented situation, my main goal was to focus on staff and patient safety. On the other hand, we had a great opportunity to bring novel experimental therapies to our patients for the still very much unknown COVID-19 disease.

We held frequent staff meetings and we all were engaged in the decision process and planning. It was **important to be able to maintain most of our enrolled patients under their treatment regimens**, especially our cancer patients, evaluate what procedures and assessments were crucial for patient safety, and coordinate with the clinic's newly established pandemic protocols. Our researchers were on board with the decision and worked with the research nurses and clinical research coordinators to make the adjustments needed. Likewise, all our sponsors, except for one oncology trial, kept the studies ongoing at our site. Back in December 2019 we had worked with Baptist Health legal and compliance departments to align our

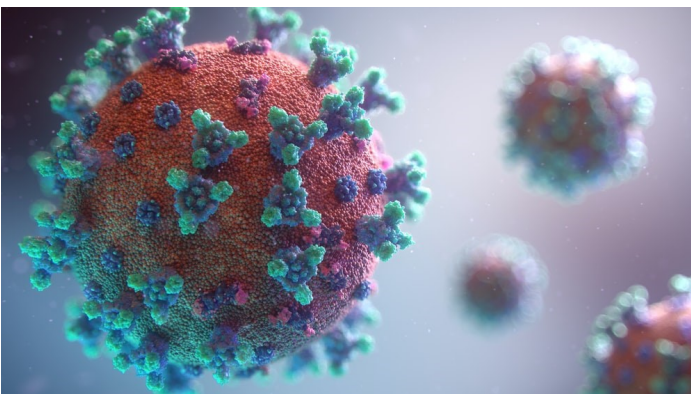
current monitor credentialing process to Baptist Health standards. The final guidelines and new policies were implemented in January 2020. These guidelines allow remote source data verification and regulatory review. **Remote monitoring was one of the key factors the sponsors took into consideration when deciding to keep sites open.**

Staff safety was a priority, so a rotating schedule that included work from home and on site, minimized the number of people in the office at once and allowed staff to maintain appropriate social distancing. The regulatory team continued all IRB activities including the additional reporting of changes in protocols due to the pandemic.

We faced challenges when some hospital procedures were placed on hold, which impacted certain study protocol timelines. After having approval from IRB, we were able to bring the patients back to complete their study visits when the hospital reopened the services. Incredibly, from March to September 2020, we:

- **Enrolled 51 patients** in cancer trials (11 less than the same period in 2019)
- Continued with the research treatment visits and follow-up visits of enrolled patients
- **Performed 30 coronary angiogram CT exams** (7 more than the same period in 2019)
- **Did 8 surgeries with investigational devices** (9 less than the same period in 2019)

Our physicians were very interested in
(continued on next page)



(continued from previous page)

COVID-19 trials. We engaged with Ohio State University (OSU), Duke University and Florida Atlantic University (FAU) to bring some research trials to Boca. Most of these trials were tailored for hospitalized patients, posing a challenge to workflows for the inpatient setting, because our current trial portfolio was mostly in the outpatient setting. Furthermore, the research support staff were not able to be at the bedside for consenting and data collection, which added research responsibilities to the nursing staff that already had an increased burden of care for the COVID-19 patients. Despite these challenges, **we opened the first COVID-19 treatment trial at our site in July and enrolled 13 patients** with the full support of the floor nurses and hospital staff. We were able to provide Convalescent Plasma treatment for COVID-19 under individual patient IND to 15 patients and continued access through the Mayo Clinic Expanded Access protocol. Then we opened two more COVID-19 trials. We would not have been able to open these trials without the **collaboration of the laboratory personnel and radiation oncology staff** because of very specific logistics related to laboratory processing and radiation treatment for these trials.

We have learned to adjust, collaborate, and innovate to ensure we continue to bring the best care to our patients and we will be well prepared to take on whatever challenges the future may hold. —*Viviana Boronat, M.D., MBA, CCRP Director of Research, BRRH Office of Research Administration*

DECENTRALIZED TRIALS

The idea of decentralized clinical trials has been around for several years, but they really skyrocketed in the last year with the pandemic. The Clinical Trials Transformation Initiative (CTTI) published a [white paper](#) on recommendations for decentralized trials in 2018, which they defined as studies that are “executed through telemedicine and mobile/local healthcare providers, using processes and technologies differing from the traditional clinical trial model.” Other names you may have heard for decentralized trials include mobile, virtual, digital, site-less, and remote. Examples of how studies can be decentralized include, but aren’t limited to:

- Remote informed consenting
- Telehealth visits
- Wearable health technologies (e.g., fitness trackers, smart watches, ECG)
- Patient-reported outcomes through online or phone surveys
- Home health providers

- Remote monitoring
- Direct-to-patient distribution of investigational product

These methods allow meaningful connection of participants with study staff, real-time data collection, and faster screening of adverse events for individual trials. More broadly, decentralized trials can improve participant diversity and retention by removing certain barriers. For example, converting some visits to virtual and providing more options for communication increases the chances that a participant will complete a visit on time. Establishing a long-term strategy to incorporate aspects of decentralization on the site side will lead to greater trial success.



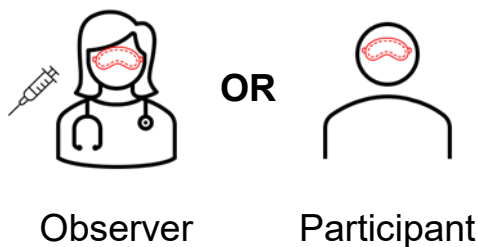
—*Amy K. Starosciak, Ph.D., Director of Outcomes Research, Center for Research*

BLINDING IN CLINICAL TRIALS

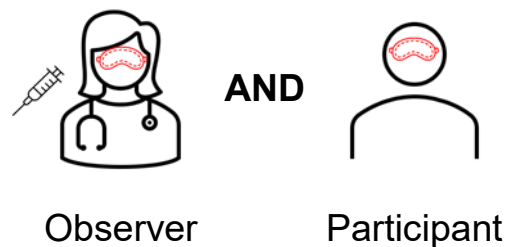
What is Blinding and How is it Used?

Several characteristics make a good randomized, controlled trial (RCT). **Blinding**, sometimes called masking, is one of these key characteristics. There are three primary types of blinding used in RCTs: single, double, and triple. 1) **Single blinding** protects clinical outcomes from observer bias. Simply put, *observer bias* occurs when the treatment administrators “see what they want to see”. By blinding treatment, it protects the study’s results from being influenced by an individual’s conscious, or unconscious, predisposed ideas of whether a treatment will work or not, or cause a side effect. 2) **Double blinding**, on the other hand, blinds both observer and participants to protect against observer bias and something called the Hawthorne effect. The *Hawthorne effect* is a type of bias that occurs when participants of the trial change or improve their behavior only because they know they are being observed by others, and not just because of the treatment’s effects. 3) **Triple blinding** blinds observer, participant, and the individuals performing the analysis of the final outcomes (e.g., statisticians or whomever completes the final analysis of the data) to protect against observer bias, the Hawthorne effect, and exposure suspicion bias. *Exposure suspicion bias* occurs when knowledge of the participant’s disease status influences an individual to more likely connect the outcome to receiving the treatment. In studies where there is a combination of two treatments, another blinding method that is often referred to is **double-blinded, double-dummy** method which blinds both of the treatments simultaneously. —Daylin Barranco am Darian Daniel, Pharmacy Students, Palm Beach Atlantic University and Nova Southeastern University

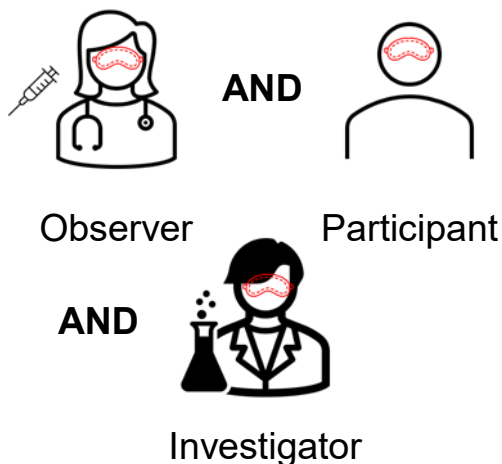
Single Blind



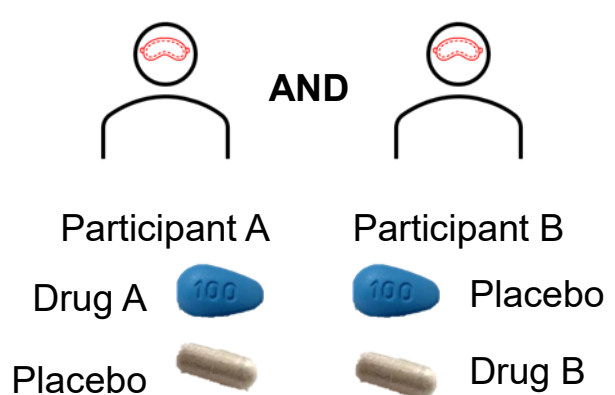
Double Blind



Triple Blind



Double Blind, Double Dummy





New Article Alcove

Explore some of our recent publications!

Addae JK, Genuir T, **Colletta J**, **Schilling K** (2021) Case of second primary breast cancer in ectopic breast tissue and review of the literature. *BMJ Case Rep* 14 (4):e241361. [Find it here!](#)

Asburn HJ, Abu Hilal M, **Kunzler F**, ...**De La Cruz L**, ...**Zinner M**, Francis N (2021) International Delphi Expert Consensus on Safe Return to Surgical and Endoscopic Practice: From the Coronavirus Global Surgical Collaborative. *Ann Surg* 274(1): 50-56. [Find it here!](#)

Cortez GM, Monteiro A, ...**Dabus G**, **Linfaente I**, et al. (2021) The use of cangrelor in neurovascular interventions: a multicenter experience. *Neuroradiology* 63(6): 925-934. [Find it here!](#)

Cury RC, Megyeri I, Lindsey T, **Macedo R**, **Battle J**, et al., (2021) Natural language processing and machine learning for detection of respiratory illness by chest CT imaging and tracking of COVID-19 pandemic in the US. *Radiol Cardiothorac Imaging* 3(1):e200596. [Find it here!](#)

Ekairab, Edwards CS, ...**McDermott MW**, Magill ST (2021) Meningioma surgical outcomes and complications in patients aged 75 years and older. *J Clin Neurosci* 88:88-94. [Find it here!](#)

Ellingson BM, Sampson J, ...**Chowdhary S**, ...**Vrionis F**, et al. (in press) Modified RANO, immunotherapy RANO, and standard RANO response to convection-enhanced delivery of IL4R-targeted immunotoxin MDNA55 in recurrent glioblastoma. *Clin Cancer Res* [Find it here!](#)

LeBlanc KA, **Gonzalez A**, Dickens E, Olsofka J, Ortiz-Ortiz C, **Verdeja J-C**, Pierce R, Propsective Hernia Group (in press) Robotic-assisted, laparoscopic, and open incisional hernia repair: early outcomes from the Propsective Hernia Study. *Hernia* [Find it here!](#)

Nassir K, **Ziffer JA**, Cainzos-Achirica M, **Ali SS**, Feldman DI, **Arias L**, **Saxena A**, **Feldman T**, **Cury R**, Budoff MJ, **Fialkow J** (in press) The Miami heart Study (MiHeart) at Baptist Health South Florida, A prospective study of subclinical cardiovascular disease and emerging cardiovascular riskfactors in asymptomatic young and middle-aged adults: Rationale and Design. *Am J Pre Cardiol* [Find it here!](#)

Rana S, Rosenfeld AB (in press) Impact of errors in spot size and spot position in robustly optimized pencil beam scanning proton-based stereotactic body radiation therapy (SBRT) lung plans. *J Appl Clin Med Phys* [Find it here!](#)

Verhoef PA, Kannan S, ...**Armaignac DL**, et al. (2021) Severe Acute Respiratory Syndrome-Associated Coronavirus 2 infection and organ dysfunction in the ICU: Opportunities for translational research. *Crit Care Explor* 3(3):e0374. [Find it here!](#)

Yagnik GP, **Seiler JR**, **Vargas LA**, **Saxena A**, et al. (2021) Outcomes of arthroscopic fixation of unstable distal clavicle fractures: A systematic review. *Orthop J Sports Med* 9(5):23259671211001773. [Find it here!](#)

Explore more publications from the Baptist Health Institutional Repository

[Center for Advanced Analytics](#)

[Center for Research](#)

[Christine E. Lynn Heart & Vascular Institute](#)

[Christine E. Lynn Women's Health & Wellness Institute](#)

[Eugene M. & Christine E. Lynn Cancer Institute](#)

[Marcus Neuroscience Institute](#)

[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

Tuesdays 12:00 to 1:00 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.

[Click here](#) or go to baptisthealth.zoom.us

Meeting ID: 958 8490 1869

Password: 861787



Date	Topic
Tuesday, July 13th	Appraisal of Statistical Methods in Research by Emir Veledar, Ph.D. (live)
Tuesday, August 10th	Principles of Good Clinical Practice
Tuesday, September 14th	Participant Safety
Tuesday, October 12th	Preventing Noncompliance
Tuesday, November 9th	Participant Recruitment
Tuesday, December 14th	Study Documentation

UPCOMING CONFERENCES

by Pharmacy, Nursing & Clinical Research Organizations

AONL—July 13-14, 2021, **Virtual**

<https://www.aonl.org/aonl-virtual-conference>

Global Leadership Summit—August 5-6, 2021, **Virtual**

<https://globalleadership.org/global-leadership-summit/>

CCP Annual Meeting—September 13-17, 2021, **Virtual**

https://accp1.org/Members/Annual_Meeting/ACCP1/3Annual_Meeting/Letter_of_Invitation.aspx

SOCRA—September 24-26, 2021, **Virtual**

<https://www.socra.org/annual-conference/future-annual-conference-dates/>

ACRP Regulatory Trends & Compliance—September 16, 23, 30, 2021, **Virtual**

<https://2021.acrpnnet.org/regulatory-trends-compliance>

Onsemble Conference—October 5-8, 2021, Madison, WI

<https://conference.ensemble.net/>

Nursing World Conference—October 18-21, 2021, **Virtual**

<https://www.mageworld.org/Eventinfo>

MAGI Fall Conference—October 18-28, 2021, **Virtual**

<https://nursingworldconference.com/>

ANCC Magnet & Pathway—November 11-13, 2021, Atlanta, GA

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



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 2021 Annual Disclosure is now open as of July 1, 2021. It is required to complete the Clinical Conflict of Interest (CCOI) Form on an annual basis or prior to participating in research at BHSF. The completion of the form is required even if you have nothing to disclose. For physicians, it is recommended to first visit CMS Open Payments to review the reported data, if any, to ensure a complete disclosure. Research personnel will receive an email with the link to the CCOI form via PeopleSoft (employees) or REDCap (non-employees). The research community has the month of July 2021 to complete the CCOI form. As of August 1, 2021, any study that includes a researcher that has not completed the 2021 CCOI form, along with the required CITI COI and Human Subject training, is non-compliant and will not receive compliance confirmation.

Remember, it is **required** to complete the CCOI Form within 30 days of any changes in financial disclosures.

Announcement: Research Compliance has a new Research Compliance Coordinator, Jacqueline (Jackie) Grass who is providing compliance confirmations. Please share your IRBNet studies with Jackie and provide her with Read-Only access.



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 at ResearchCompliance@baptisthealth.net!

—Heather Osorio, Research Compliance & Billing Administrator

UPCOMING IRB DATES

BHSF IRB

Full Board Committee Meeting: **Tuesday, July 27th**

Submission Deadline for August Meeting: **Monday, July 26th**

MCI IRB

Full Board Committee Meeting: **Monday, August 2nd**

EDITORIAL STAFF

Amy K. Starosciak, Ph.D., Center for Research, Editor-in-Chief

Stephanie Boodram, BRRH Lynn Cancer Institute

Nicholas K. Chow, Pharm.D., BCOP, MCI Pharmacy

Ileana Vargas, BRRH Office of Research Administration

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



Baptist Health South Florida
Center for Research