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BHSF Research Matters

Newsletters

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Research Matters



Elevating care through discovery.

May 2021, Vol. 2, Iss. 3

Message from Don Parris, Ph.D., MPH, CCRC

Assistant Vice President, Center for Advanced Analytics
Executive Sponsor, Corporate Diversity & Inclusion Committee

Baptist Health values and respects the diverse experiences, backgrounds and cultures of its patients and employees. So far this year we came together to celebrate World Religions Day, Black History, Women's History, and Autism Awareness. This summer we will celebrate World Cultural Diversity Day and Pride Month. From here on, *Research Matters* will have an article focusing on diversity and inclusion as it pertains to research, such as the importance of including diverse populations in clinical trials and considerations and implications for enrolling those individuals. In this issue, we highlight the Christine E. Lynn Women's Health & Wellness Institute and the high impact trials it delivers.

From a research perspective, it is important to understand the implications of diversity in study enrollment as it could have serious consequences. Differences between people can lead to different responses to the same medication. Age, genetics, sex, weight, ethnic origin, and geographic location may play a role in how treatments work. For example, African Americans sometimes need a different dosage (or a different drug altogether) for certain asthma, blood pressure, and heart conditions than do white, Asian, or Hispanic patients with the same diagnoses. For this reason, diversity in clinical trial populations is critical to being able to generalize and interpret study results.

To address the lack of adequate diversity in clinical trials, the NIH adopted a policy in 1993 mandating all federal grants for clinical research to include women and minorities. The Revitalization Act of 1993 states, "since a **primary aim** of research **is to provide scientific evidence leading to a change** in health policy or standard of care, **it is imperative** to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently."

The FDA also instituted policies to understand the barriers to participation and increase enrollment of more diverse participants. In 2014, the FDA launched a website called [Drug Trials Snapshots](#) to provide the public with the demographic composition of participants in clinical trials of newly approved medications.

Even with these efforts by the federal government, populations underrepresented in health care tend to be underrepresented in clinical research. Barriers to research participation may be economic, linguistic, cultural, religious, physical (such as a lack of access to a nearby healthcare center) or historical because of scientific wrongs like the Tuskegee Syphilis Study.

By taking a comprehensive view of patient and public health needs, efforts in reaching underrepresented populations by clinicians and research staff can be integral to diversify clinical trial participants. Patient education and outreach efforts such as establishing Community Advisory Boards and creating patient centered policies for research have proven to be effective tools as well. Lastly, new approaches to getting the word out — such as outreach and education programs in churches, schools, town hall meetings, and community centers — can help bring better awareness of clinical trials to all communities.

For more information on resources to increase diversity in clinical trials, visit the [FDA website](#) for an informative webinar (approved by ACRP for continuing education in clinical research). We hope you enjoy this edition of *Research Matters*.



"Now is the time
to understand
more, so that we
may fear less."
~Marie Curie~

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New & Transferred Staff Updates



Emily Anchia
Research Assistant
Miami Cancer Institute
Office of Clinical Research



Mikaela Bearham
Regulatory Coordinator
Miami Cardiac &
Vascular Institute



Juan Carvajal
Research Assistant
Miami Cancer Institute
Protocol Support/
Biorepository



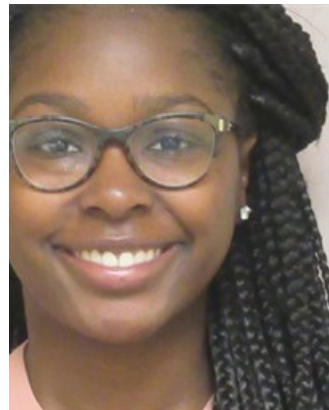
Brandon Galloway
Research Assistant
Miami Cancer Institute
Protocol Support/
Biorepository



**Yenny Giraldo, BSN,
RN, CMSRN**
Clinical Data Analyst
Center for Research &
MNI



Ashley Jiron
Clinical Research
Coordinator
Miami Cancer Institute
Office of Clinical Research



Alexis Lawrence
Patient Scheduler
Miami Cancer Institute
Protocol Support/
Biorepository



Daniel Leon Ariza
Medical Writer
Miami Cancer Institute
Research Administration



Ryan Lopez
Research Assistant
Miami Cancer Institute
Office of Clinical Research



Margarita Mederos
Clinical Research
Coordinator, Center for
Research & MNI



Allison Miller
Research Assistant
Miami Cancer Institute
²Office of Clinical Research



David Mitchell
Clinical Research
Coordinator
Miami Cancer Institute
Office of Clinical Research

New & Transferred Staff Updates



Juliana Montoya
Clinical Research
Coordinator
Miami Cancer Institute
Office of Clinical Research



Kristina Nieves
Clinical Research
Coordinator
Miami Cancer Institute
Office of Clinical Research



Luciana Ortecho
Research Assistant
Miami Cancer Institute
Office of Clinical
Research



Xiaou Pan
Clinical Research
Coordinator
Miami Cancer Institute
Office of Clinical Research



Ashley Pena
Research Finance
Specialist
Miami Cancer Institute
Research Administration



Marietsy Pujol
Regulatory Coordinator
Miami Cardiac &
Vascular Institute



**Venkataraghavan "Ram"
Ramamoorthy, Ph.D.**
Data Scientist
Center for Advanced
Analytics



Nicolas Rojas
Research Assistant
Miami Cancer Institute
Office of Clinical
Research



Juliet Rivero
Research Assistant
Miami Cancer Institute
Office of Clinical
Research



Ana Santos
Research Assistant
Nursing & Health Sciences
Research



Cathy Schilero, RN
Mgr, Clinical Operations
Miami Cancer Institute
Office of Clinical
Research

CHRISTINE E. LYNN WOMEN'S HEALTH & WELLNESS INSTITUTE

Spotlight on Boca Raton Regional Hospital's Research Programs

Research is an integral part of the [Women's Institute](#) and gives women in our community and the region an opportunity to participate in cutting-edge breast imaging technology. Breast imaging has expanded and evolved over the years to include mammography, MRI, ultrasound, nuclear medicine, and X-ray. These imaging tools, coupled with advanced, computer-aided detection software, have improved early breast cancer detection and diagnosis. With these tools, care is personalized for each patient and surveillance plans are created based on an individual's level of breast cancer risk. This personalization allows for earlier cancer detection, which then increases treatment options and improves overall quality of life and survival outcomes for research patients.

This program is a hub for research and testing of new imaging technologies. Medical Director [Kathy Schilling, M.D.](#) collaborates with researchers around the world and contributes to national research enterprises. The variety of clinical trials has led the scientific community and industry leaders to recognize the Women's Institute as a flagship site for rolling out cutting-edge breast imaging technology that enhances patient experience and device usability and comfort in a state-of-the-art facility.

The Institute has been a pioneer in researching new mammography techniques to improve breast cancer screening rates. In particular, research led to the implementation of a sensory suite in the mammography rooms that brings dimensional experiences during the procedure, including pleasant visual and olfactory sensations and self-compression to help maximize imaging accuracy. Furthermore, the Women's Institute participates in [National Cancer Institute](#) (NCI) sponsored trials. In fact, the Institute contributed 41 patients to an NCI study that examined whether abbreviated MRI could overcome the limitations of mammography in women with dense breast—this study was recently published in JAMA!

Boca Raton Regional Hospital Women's Institute is a world class facility dedicated to women's health and their unique medical needs, from young adult to menopause and beyond. Its comprehensive model of services includes wellness programs, such as



lectures, support groups, acupuncture and massage therapy, the latest technology, and renowned physicians, making it one of the most advanced screening, diagnostic, and clinical women's programs in the country.

—Stephanie A. Boodram, Research Data Analyst and Ileana M. Vargas, Regulatory Coordinator, BRRH Office of Research Administration and Lynn Cancer Institute

RESEARCH VOLUNTEERS

The Onboarding Process

Principal Investigators often request to have research volunteers assist in various areas of their research. In particular, FIU and FAU medical students are encouraged to conduct extracurricular research as part of their training. Research volunteers include medical, nursing, allied health, and undergraduate students, as well as unpaid volunteers wishing to conduct research.

All research volunteers who will participate on an assigned research study at a BHSF facility must be onboarded and receive clearance by the Center for Research (CR) liaison, Research Compliance, and the IRB prior to conducting a research activity. This process begins by contacting the CR liaison at CRGResearch@BaptistHealth.net and requesting to have a research volunteer onboarded. The CR liaison will then contact the research volunteer via email with instructions and forms that need to be completed before clearance is granted.

Requirements for ALL research volunteers:

- CITI certification with BHSF affiliation
 - Group 1 Biomedical
 - BHSF Conflict of Interest
- Note: GCP optional for onboarding but may be required by the study team*
- Clinical Conflict of Interest form (CCOI) on paper until July, then via REDCap
 - Other forms (Acknowledgment of Confidentiality, Safeguards for Non-employed Researchers, HIPAA quiz)
 - Flu vaccine during flu season (Oct – Mar of each year)
 - Current PPD



Other requirements depend on the type of research volunteer:

- FIU/FAU medical students should have their requirements met through the Graduate Medical Education (GME) department
- Nursing and allied health students doing research for credit should have their requirements met through Academic Affairs
- Undergraduate students and unpaid volunteers must provide background checks and proof of immunizations

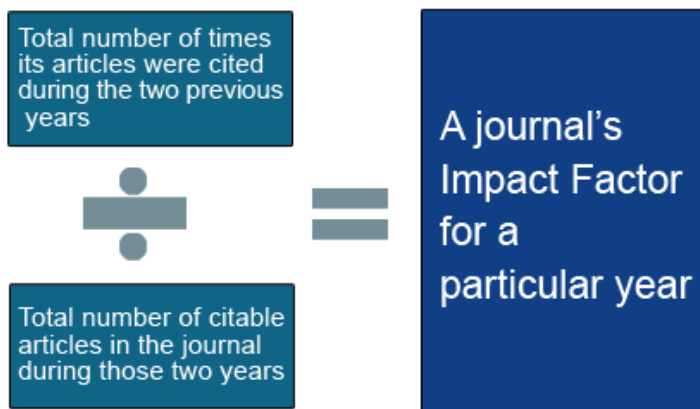
Upon receipt of all documentation, the CR liaison will advise the research volunteer, mentor, and IRB of their clearance via email. Volunteers need to be set up as Persons of Interest (POIs) in PeopleSoft if logical access to the BHSF network or physical access to buildings is required.

For additional information, please contact: **Virginia Mojica** in the Center for Research by phone at 786-527-9892 or by email at VirginiaM@BaptistHealth.net.

JOURNAL IMPACT FACTOR

What Do Impact Factors Mean?

In 1961, linguist Eugene Garfield created the journal impact factor (JIF) to aid researchers in the tedious process of finding high-quality books and journals. This metric calculates the ratio between the numbers of citations received by a journal in a chosen year and the number of publications issued by said journal in the two years prior to the selected year of interest.



For example, [A Cancer Journal for Clinicians](#) had the highest JIF in the oncology category in 2019. Its calculated JIF was 88.192, meaning that, on average, papers published in 2018 and 2017 received around 88 citations each in 2019. In fact, as of this writing, the JIF is 292.278! These results are published annually in [Journal Citation Reports](#) (JCR) by Web of Science, which has become a legitimate authority for ranking scholarly journals and an evaluator of journals' prestige and influence.

That being said, JIF is not a perfect measurement. Its simple calculation allows for certain biases to be introduced. A

common example is attributed to many journals publishing highly cited review articles, which are generally cited more than research reports, therefore skewing JIF to their favor. Additional metrics have been created over the years to overcome these limitations, the [SCImago Journal Rank](#), the journal h-index (similar to the author h-index as discussed in the [previous issue](#) of *Research Matters*), and the [Eigenfactor](#) are just examples of other indicators that calculate impact factor using more complex algorithms that take into consideration the quality of studies. Using multiple indices simultaneously when searching for data can lead to identification of higher quality studies. Narrowing the search to a specific area of interest can also give researchers a more focused picture, allowing them to identify high-quality data, articles, and journals more efficiently.

In conclusion, it is key to recognize that JIF may be significant when assessing a journal's reputation but it should not be indicative of an individual article's quality. The prestige of a journal should not be an absolute standard when determining the quality of its publications. Independent appraisal and examination by researchers are still fundamental in assessing the significance of articles, studies, and publications based on the previous literature, study methods, results, and conclusions.

—Benny Fernandez Lopez, Pharmacy Student, Nova Southeastern University

AUTHOR! AUTHOR!! DAY

42nd Annual Celebration

The 42nd Author! Author!! Event was celebrated pandemic style with a Zoom celebration but still preserved many of our old traditions. The event started with a virtual coffee toast to our 300+ staff authors and transitioned to an update from library team focusing on digital transformation projects. Among the projects highlighted:

- **Chat service** – customers can “chat” with a library team member during operating hours, great for quick questions, submitting a request or help navigating the library’s site.
- **Reservation system** – need a quiet space? Working remote? Need a computer to record a lecture or access SPSS software? Customers can now reserve a space at the library.
- **Updated Search Request form** – request form for reprints and searches has migrated to REDCap (scan QR code for instant access and bookmark for future use); form now includes interactive PICO generator.

To access these enhancements visit [the library’s intranet](#) on PineappleConnect.

Our long-standing tradition of sharing our

publishing stories (good or bad) worked out even better on Zoom! Common themes from those who shared: (1) co-authors are helpful because you can divide the work; (2) just write something down to get started, there will be time for revisions later; and (3) especially lately, don’t give up, perseverance is the key to getting published! Authors should have received their yellow & green recognition ribbons by now, so if you have not received one or if we missed your publication, please submit it to library@baptisthealth.net so that we can add it to our institutional repository at the [Scholarly Commons](#).

Explore 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](#)

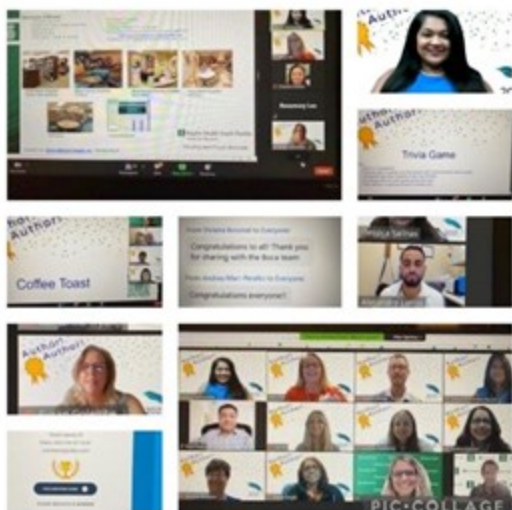
[Miami Neuroscience Institute](#)

[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, May 11th	Clinical Trial Agreement (CTA) Basics by Kelly Willenberg (live)
Tuesday, June 8th	Research Finance Basics by Kelly Willenberg (live)
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



MAGI—April 26-May 6, 2021, **Virtual**
<https://www.magiworld.org/>

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

ACCP 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, Denver, CO
<https://www.socra.org/annual-conference/future-annual-conference-dates/>

Onsemble Conference—October 5-8, 2021, Madison, WI
<https://conference.onsemble.net/>

Nursing World Conference—October 18-21, 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

Research Compliance encourages you to set your reminders as the 2021 Annual Disclosure period is quickly approaching, July 1, 2021. During this disclosure period, all research personnel must complete the Clinical Conflict of Interest (CCOI) form to avoid any lapse in their compliance status. Please note that current compliance confirmations will expire on July 31, 2021, unless a research personnel's requirement(s) expire prior. The month of July provides our research community with a window to complete their annual CCOI form and stay compliant!

All employed research personnel will receive the notice to complete their CCOI form via PeopleSoft, similarly to the previous year. All non-employed research personnel will receive the notice to complete their CCOI form via REDCap.

Research Compliance may provide quick demonstrations for the new non-employee process to any individual or department upon request. Also, this is a great time to start working with the physicians to prepare their financial information!



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, May 25th**

Submission Deadline for June Meeting: **Monday, May 24th**

MCI IRB

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

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