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Newsletters

9-2021

Volume 2 Issue 5

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Research Matters



Elevating care through discovery.

September 2021, Vol. 2, Iss. 5

Message from Mark Coticchia, M.S.

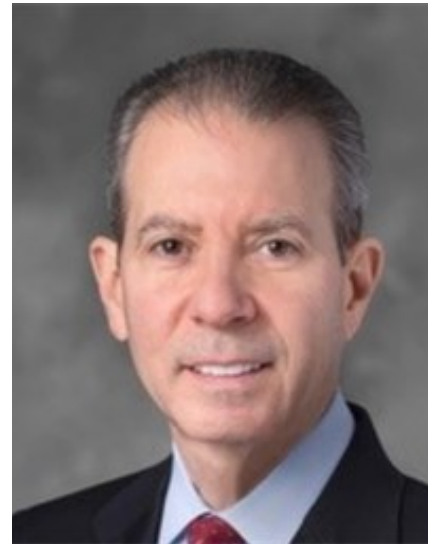
Vice President for Innovation, Baptist Health Innovations

Baptist Health Innovations is pleased to partner with Dr. Lipkin, as the Corporate Vice President for Research, in supporting Baptist Health's journey toward the top echelon of health system innovators.

Innovation is more than a buzzword. It is a driver of patient, physician and other professionals' satisfaction and is a well-recognized metric in evaluating an Institution's status. It is no coincidence that institutions which are recognized as the top healthcare institutions are also viewed as preeminent innovators. See the below chart.

Immediate Correlation among hospital rankings and perceived innovation capacity

Newsweek 2021 Best Hospitals	Becker's 8 Most Innovative Hospitals
1. Mayo Clinic	Mayo Clinic (#1)
2. Cleveland Clinic	Cleveland Clinic (#2)
3. Mass General	Mass General (#7)
4. Johns Hopkins	Johns Hopkins (#4)



"Everything is theoretically impossible, until it is done."

~Robert Heinlein~

At Baptist Health, we are on the journey. On May 1, 2020, we adopted our first Intellectual Property Policy. Establishing clear ownership of Intellectual Property (IP) is the building block in any successful commercialization program and Baptist adopted a sharing program with its contributors, which is as generous as any that the Baptist Health Innovations is familiar with. **One-half of Net Proceeds from licensing, after expenses and charges, is shared with the creators** of new IP, as described in more precise detail in the [BHSF Intellectual Property Policy](#).

In addition, of the remaining 50%, 20% is directed toward the **needs of the business unit where the creators generated the intellectual property.**

Since adoption of that Policy, Baptist Health Innovations has negotiated a number of major licensing deals which have their genesis in past and future research. In this issue, take a look at some of these projects as well as other innovative strategies used in clinical research.

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COTA is a healthcare technology firm founded in 2011 by oncologists, engineers, and data scientists, with the **goal of transforming cancer care** so that treatment is benefited by relevant prior data.

Baptist Health Innovations first negotiated a noteworthy license to COTA for cancer treatment data and a separate license for intellectual property generated by Dr. Leonard Kalman, the Executive Deputy Director and Chief Medical Officer at the Miami Cancer Institute (MCI), with regard to

the **means of analyzing treatment information for improved outcomes**. Both licenses are royalty bearing.

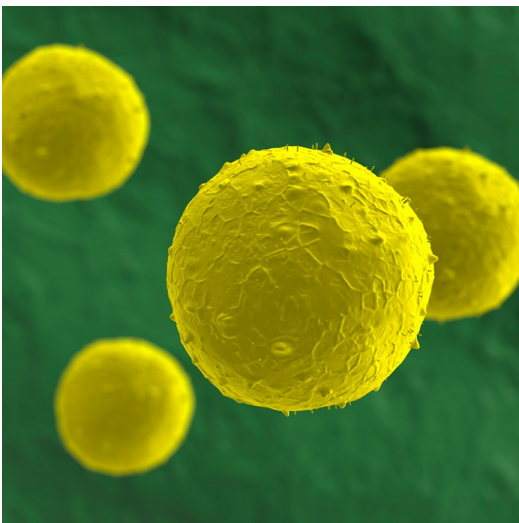
Subsequently, as part of Baptist Health Innovation's mission to diversify Baptist Health's revenue streams, **Baptist Health Innovations co-led a Series D round capital investment in COTA**. Dr. Kalman joined the board of COTA as part of the investment round.

Baptist Health Innovations will continue to strengthen its collaboration with COTA as the company **uses real-world data to improve outcomes in cancer care and oncology drug development**.

Cleerly is a healthcare company with a **mission to create a new standard of care for coronary artery disease** to help prevent the millions of heart attacks that occur worldwide every year. The company aims to create innovative strategies toward the prevention of heart attacks, including the **application of artificial intelligence and analytics**.



Cleerly has executed a royalty bearing license to utilize Baptist Health's deidentified data on cardiovascular disease, which will lead to the construction of an analytical tool, aimed at benchmarking the degree of a patient's cardiac disease against others who have had coronary disease treatment. **The tool will benefit greatly from the Miami Heart Study data gathered by Baptist Health**. Dr. Jonathan Fialkow and others are working to present that data in the most useful form.



Stem Cell Provider

Earlier this year, a Master Sponsored Research and License Agreement was entered with a **globally-recognized source of stem cells for clinical research** by Dr. Guenther Koehne, Deputy Director, MCI.

While there is still much to be done and the efficacy as a therapeutic treatment still must be established, we are excited by the potential of this market. Only three years ago, the global cell therapy market was estimated at \$2 billion. By 2025, it is expected to exceed \$8 billion.

Electron micrograph of stem cells, color-enhanced for clarity. Photo from FDA.

For many years Baptist Health has had a relationship with [Philips](#), principally through Miami Cardiac & Vascular Institute (MCVI), which has been beneficial to both parties in various ways. However, that relationship had not previously provided an avenue for direct participation by BHSF and its employee creators of IP in the proceeds of Philips' commercialization of said IP generated at BHSF. Part of the reason for this had been the absence of an IP Policy at BHSF. With the staffing of Baptist Health Innovations and the enactment of a system-wide IP Policy, **BHSF has both the legal capability of holding title to and licensing the IP created by its employees AND the personnel able to devote the time needed to develop the commercial potential of the IP assets of Baptist Health.**



At the encouragement and with the considerable assistance of Dr. Barry Katzen, MCVI Chief Medical Executive, and Carol Melvin, MCVI Chief Operating Officer, Innovations undertook the mission of formalizing, expanding to the entire system, and harmonizing with our new IP Policy the research and development relationship with Philips. An initial Memorandum of Understanding (MOU) was executed with Philips, effective March 12, 2020, and the parties commenced negotiations in earnest, which produced the Master Research Collaboration Agreement, signed April 2, 2021. **We anticipate multiple research and development projects under this Agreement, potentially involving all operational units of Baptist Health.**



With Dr. Scott Lipkin's and my signatures, and Dr. Michael Chuong's (Radiation Oncologist, MCI) assistance, BHSF has entered a new Master Research and License Agreement with [ViewRay](#), under which **BHSF clinicians will have a broader opportunity to share in monetization of the fruits of their research.**

In addition, the Master Research and License Agreement enables collaborative projects to be developed under appropriate statements of work, which should be signed by both Dr. Lipkin and me to assure that both the research and the IP aspects are covered consistently with this new Master Research and License Agreement.

Baptist Health Innovations has completed a collaboration and license agreement with [QurHealth Solutions, Inc.](#) (a spinout of Ventech Solutions). The collaboration centers around IP developed at MCI called the NAVCISE Call Center Algorithm (patent pending, know how, trade secrets) which was developed by Matthew Baumann, MBA, MCI's Assistant Vice President of Operations. Matt applied his knowledge of patient experience strategy in developing the NAVCISE algorithm. NAVCISE incorporates patient language identification to route calls.



Baptist Health Innovations is funding, through the generous philanthropic support of a donor, the **creation of a prototype for NAVCISE** and combining the expertise and resources of both Baptist and QurHealth in the technology and healthcare space. **QurHealth will work with MCI to develop a minimal viable product or a proof of concept** that will be tested and integrated into the MCI call center. At that point, the call center can be integrated into Salesforce and physician conversations can be integrated into the electronic health record.

QurHealth will have a license to implement and license the NAVCISE technology to other institutions in the US and abroad.

All of these transactions **emanate from the highly valuable, world-class research that our clinicians and other professionals are performing.** Baptist Health Innovations, along with Dr. Lipkin and the General Counsel's Office, seeks to find homes for the valuable intellectual property that our clinicians and other professionals generate. And that is the true spirit of what we are attempting to do, i.e., **taking the results of our research and clinical development efforts out into practice** both inside and outside the walls of Baptist Health while at the same time sharing in the fruits of the commercialization of such intellectual property with our commercial licensees and collaborators. **But you, who generate the intellectual property, are the wellspring of Innovation. Keep it coming.**

—Mark Coticchia, M.S., Vice President for Innovation, Baptist Health Innovations

INTRODUCTION

DR. QAMMER BOKHARI, VP AND CHIEF CLINICAL TRANSFORMATION AND MEDICAL INFORMATICS OFFICER



To piggyback off the discussion of innovation at Baptist Health, we are excited to introduce you to another executive who is leading the charge in innovation through informatics and analytics. **Qammer Bokhari, MD, MBA, MHSA, CPHIMS** is a seasoned physician executive, IT strategist, medical informaticist, and population health specialist who recently joined Baptist Health in May as **Corporate Vice President and Chief Clinical Transformation & Medical Informatics Officer.**

Dr. Bokhari came to us from a large and high-performing multi-state health system, [Advent Health](#), where he served as Corporate Vice President and Chief Medical Informatics Officer. There, he was responsible for planning, organization, and coordination of the EHR digital technology implementation, “Big Data” analytics governance and strategy, decision support integration, medical operations support, patient safety, quality improvement, population health, and evidence- and practice-based medical innovations using six sigma and lean methodologies.

At Baptist Health, Dr. Bokhari will focus on clinical systems functionality, enhancing clinical outcomes and efficiency, and the clinician-patient experience. He will play a lead role in driving improved functionality supporting medical and clinical activities, enabled by applying technology and digital systems. **He will spearhead the use of analytics and informatics** to improve clinical efficiency and outcomes across the care continuum. He also will **support research at BHSF via the services offered by the Center for Advanced Analytics.** He has hit the ground running and is currently getting to know the people and teams at Baptist Health, understanding our company culture and building the clinical transformation roadmap.

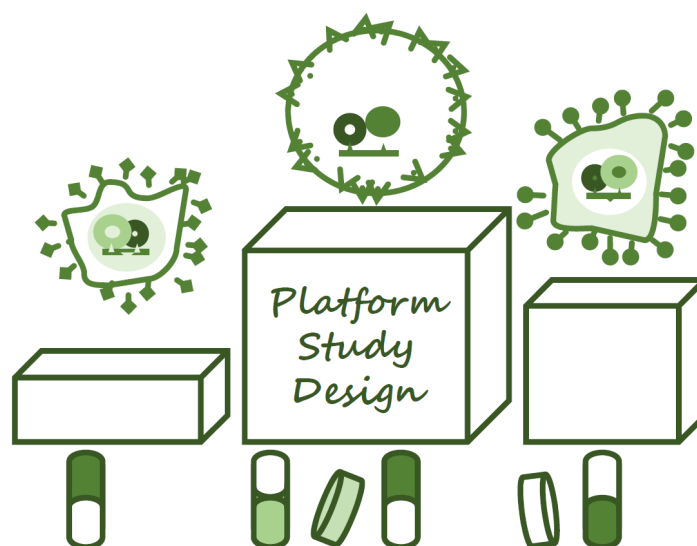
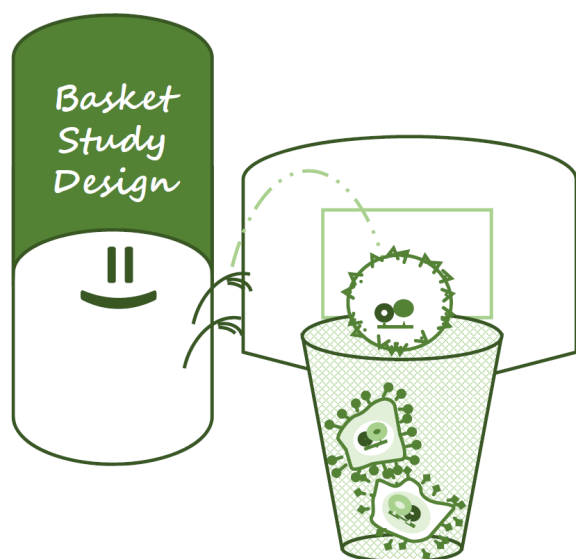
Dr. Bokhari completed his medical and surgical training at Rawalpindi Medical College at the University of Punjab, Pakistan, and obtained a Master of Business Administration (MBA) at Preston University in Pakistan and a Master of Health Services Administration (MHSA) at The George Washington University in Washington, DC.

—Don Parris, Ph.D., Assistant Vice President, Center for Advanced Analytics

UMBRELLAS, BASKETS AND PLATFORMS

The New Masters of Design

The fast-paced nature of the competitive pharmaceutical industry and the public pressure to make medical advances rapidly available (e.g., COVID-19) have forced clinical trial designers to re-think the simplified approach of testing a single drug for a single disease. Collectively known as **Master Protocol** designs – basket, umbrella and platform study designs are being used to help expedite the drug testing process. These are designed either to let multiple different drugs get an attempt to treat a single disease (**umbrella design**) or use a single drug to catch multiple different types/sub-sets of a condition (**basket design**). In combination, **platform designs** do both and test multiple drugs against multiple conditions at various starting/stopping points. Overall, these innovative, new designs minimize the cost (both money and resources) it takes to test multiple drugs that otherwise would be needed for multiple clinical trials while also helping to bring opportunities to difficult to recruit or treat populations (e.g., rare diseases or cancers with very specific mutation types).



Article and images by Nicholas Chow, Pharm.D., BCOP, Clinical Pharmacy Supervisor, Miami Cancer Institute

Reference: J Woodcock and M LaVange. Master Protocols to Study Multiple Therapies, Multiple Diseases, or Both. *N Engl J Med* 2017; 377:62-70. [DOI: 10.1056/NEJMra1510062](https://doi.org/10.1056/NEJMra1510062)

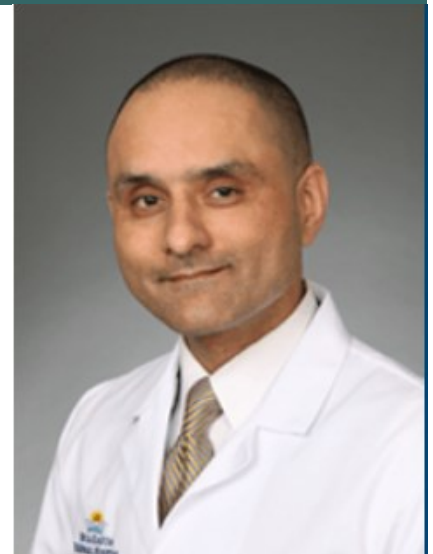
SPOTLIGHT ON BOCA

Neuro-Oncology Research at Boca Raton Regional Hospital

The Neuro-Oncology team at [Boca Raton Regional Hospital](#) (BRRH) comprises a multidisciplinary team of physicians, including medical and radiation oncology, neurosurgery, neuroradiology and neuropathology. Research administration provides support to conduct clinical trials. The Neuro-Oncology research program is part of the [Marcus Neuroscience Institute](#) (MNI) and [Lynn Cancer Institute](#) (LCI) and is led by [Sajeel Chowdhary, M.D.](#) The dedicated research nurse, Veronica Kerr, RN and the research coordinator, Maria Pilar Zuniga work closely with the physician team to enroll patients in studies.

The clinical trial portfolio include trials for primary brain tumor and brain metastasis. Two trials are open for enrollment for those with newly diagnosed glioblastoma:

[TRIDENT EF-32](#): “Randomized, open label study of Optune (TT Fields, 200 KHz) concomitant with radiation therapy and TMZ”



Dr. Sajeel Chowdhary

- Use of the Optune device [tumor treating (TT fields)] which delivers low intensity (1-3 V/cm), intermediate frequency (200 KHz), alternating electric fields to the tumor using non-invasive transducer arrays placed on the skin, in this case the scalp
- Optune Device >18 hr/d for maximal effectiveness
- Patients are randomized to use this device concomitant to radiation therapy and temozolomide (TMZ) vs. to use the device during adjuvant TMZ

[DENOVO DB102-01](#): “A randomized, double blind, placebo controlled Phase 3 Study of enzastaurin added to temozolomide during and following radiation therapy in newly diagnosed GBM patients who possess the novel genomic biomarker DGM1”

- Patients are randomized to receive enzastaurin vs. placebo concomitant to standard care (radiation therapy & TMZ)

Our neuro-oncology program also offers clinical trials for brain metastasis:

- **[A071701](#):** Genomically guided treatment trial in brain metastasis
- **[CE.7](#):** Stereotactic radiosurgery (SRS) compared with hippocampal avoidant whole brain radiotherapy plus memantine for 5-15 brain metastases
- **[A071801](#):** Single fraction SRS compared with fractionated SRS for resected metastatic brain disease

Patients with glioblastoma face many challenges, such as impairments in cognition, social skills, and emotional wellbeing. Our research team works closely with patients and their families to support them throughout the trial and they often establish long lasting relations beyond the duration of their participation in the trial.

—*Maria Pilar Zuniga, Clinical Research Coordinator, and Viviana Boronat, M.D., MBA, Director of Research, Boca Raton Regional Hospital*

New & Transferred Staff Updates



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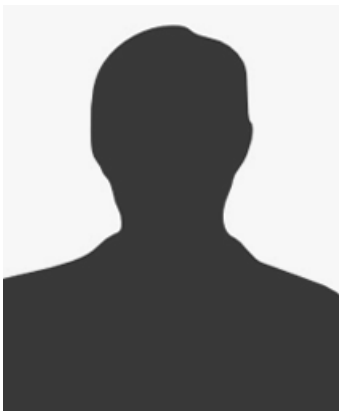
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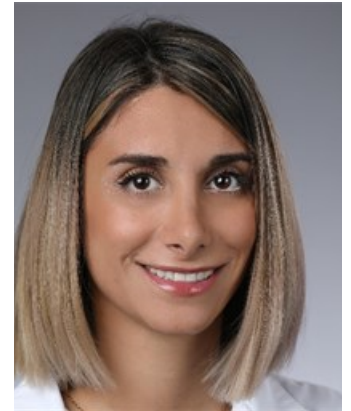
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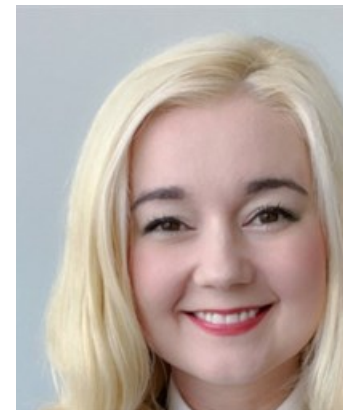
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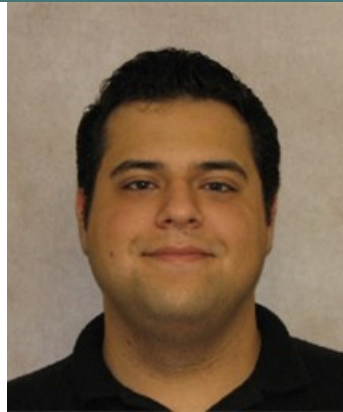
New & Transferred Staff Updates



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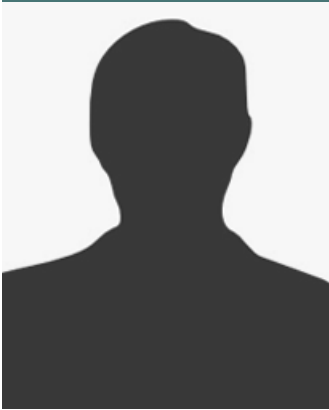


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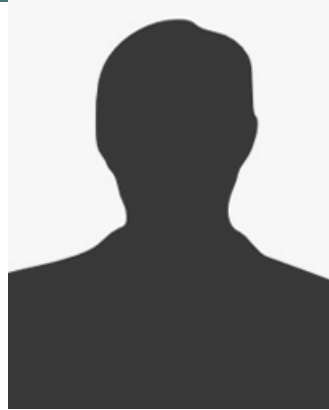


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New & Transferred Staff Updates



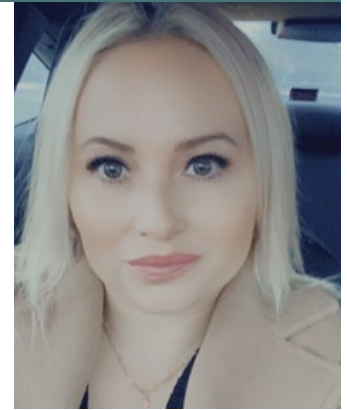
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Austin Pourmoussa
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New & Transferred Staff Updates



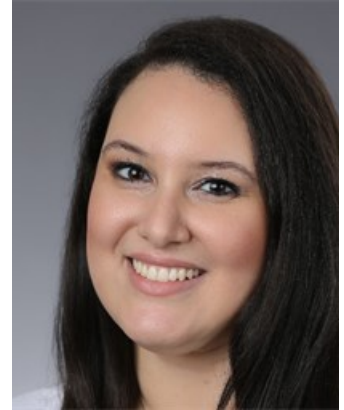
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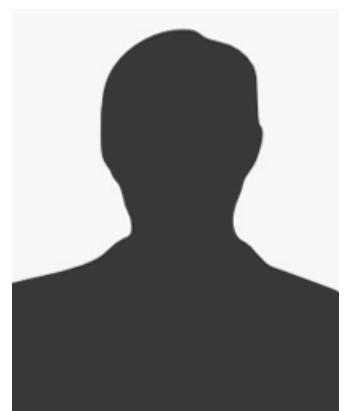
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Zhenwei Zhang, Ph.D.
Biostatistician
Center for Advanced
Analytics





New Article Alcove

Explore some of our recent publications!

Dmytriw AA, Dibas M, Schirmer CM, Settecase F, Heran MKS, Efendizade A...**Linfante I, Dabus G** et al. (2021) Age and acute ischemic stroke outcome in North American patients with COVID-19. *J Am Heart Assoc* 10:e021046. [Find it here!](#)

Valero-Elizondo J, Chouairi F, Khera R, Granghi GR, **Saxena A**, et. Al (2021) Atherosclerotic cardiovascular disease, cancer, and financial toxicity among adults in the United States. *JACC: CardioOncol* 3(2): 236-246. [Find it here!](#)

Greenwood J, Belnap S, Dabus G, Linfante I, De Los Rios La Rosa F (2021) Risk of contracting SARS-CoV-2 (COVID-19) from hospital admission and the impact of protection efforts on acute stroke treatment. *Clin Neurol Neurosurg* 207:106793. [Find it here!](#)

Kim H, **Lee YC**, Benedict SH, Dyer B, Price M, Rong Y et al. (2021) Dose summation strategies for external beam radiation therapy and brachytherapy in gynecologic malignancy: a review from the NRG Oncology and NCTN medical physics subcommittees. *Int J Radiat Oncol Biol Phys* S0360-3016 (21):00737-9. [Find it here!](#)

Manchanda K, Nakonezy P, Sathy AK, Sanders DT, Starr AJ, Wukich DK (2021) A systematic review of ankle fracture treatment modalities in diabetic patients. *J Clin Orthop Trauma* 16:7-15. [Find it here!](#)

Renshaw A (2021) Updating the Papanicolaou Society cytologic criteria for invasive adenocarcinoma in cystic pancreaticobiliary specimens. *Cancer Cytopathol* 129 (8):579-580. [Find it here!](#)

Sucharew H, Kleindorfer D, Khoury JC, Alwell K, Haverbusch M, Stanton R...**De Los Rios La Rosa F** et al. (in press) Deriving place of residence, modified Rankin Scale, and EuroQol-5D scores from the medical record for stroke survivors. *Cerebrovasc Dis* [Find it here!](#)

REMINDER: Backissues of the *Research Matters* newsletter can be found on the Scholarly Commons in addition to all our published research. [Find them 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, September 14th	Principles of Good Clinical Practice
Tuesday, October 12th	Preventing Noncompliance
Tuesday, November 9th	Participant Recruitment
Tuesday, December 14th	Study Documentation

Look out for the new 2022 Schedule in the next newsletter!

UPCOMING CONFERENCES

by Pharmacy, Nursing & Clinical Research Organizations



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.acrpnet.org/regulatory-trends-compliance>

Onsemble Conference—October 5-8, 2021, **Virtual**
<https://conference.onsemble.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

Research Compliance would like to take the time to thank everyone who promptly completed the CCOI form during the 2021 Annual Disclosure period! As of the 9th of September, 2021, we are tracking a total of 948 research personnel with only 250 personnel (26%) that are non-compliant. Our office is working with study teams to get the remaining investigators compliant and providing department compliant status reports.

With the expansion of the team, our Research Compliance Coordinator (Jacqueline Grass) is conducting the initial compliance reviews, in the order they are submitted, via IRBNet. In order to conduct these reviews, it is required that Jackie and myself are provided "Read-Only" access to all studies and Compliance Requests via IRBNet. In addition, we recommend that all Research Compliance related communication is sent to our shared inbox, ResearchCompliance@baptisthealth.net, to ensure a speedier response.

Stay tuned for upcoming process improvements!



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, September 28th**

Submission Deadline for October Meeting: **Monday, September 27th**

MCI IRB

Full Board Committee Meeting: **Tuesday, September 14th**

EDITORIAL STAFF

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

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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