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# AAHRPP®

Association for the Accreditation of  
Human Research Protection Programs, Inc.®

## **SITE VISIT FOR RE-ACCREDITATION**

The William Beaumont Hospital Human Research Protection Program (HRPP) has been accredited by The Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011 and has recently submitted for re-accreditation. AAHRPP is a non-profit organization founded in 2001 to ensure research compliance and rigorous standards for the protection of human research participants.

The William Beaumont Hospital HRPP includes not only the Beaumont Institutional Review Board (IRB), but those involved in human subject research across our institution, including investigators, clinical trial office staff, the Vice President of Research/Institutional Official, the Senior Director of Research Administration, and staff working in research compliance, sponsored program administration, general counsel and research education and quality improvement.

The re-accreditation process includes a virtual site visit which is scheduled to occur September 26-27, 2023. During the site visit, the AAHRPP team will review records to assure policies and procedures have been implemented effectively and are consistently applied throughout the HRPP. The AAHRPP team has selected many HRPP stakeholders for interviews! Research administration is in the process of notifying those selected. A research administration team member will contact you to help you prepare should the visit team have selected you for an interview.

For questions, please contact Research Administration at [barbara.higgins@corewellhealth.org](mailto:barbara.higgins@corewellhealth.org)

### Research Slated for Integration Activation

The Corewell Health Integration Management Office (IMO) is preparing to launch Wave 3 integration activities in September. Research is one of the 8 Functional Areas of focus in Wave 3. Chad Tuttle, Sr. VP, Clinical Shared Services, will be responsible for the strategy, integration and performance of the clinical departments (including research) that will be integrated and operated across all care delivery regions.

Research will be identifying opportunities, setting goals, and creating a roadmap of activities to complete in order to become an aligned system function. The IMO will support the integration planning that will take place September through November this year. A kick-off meeting is scheduled for September 11 to describe and define success for a Functional Area. Following that meeting, Research leaders (director level and above from East/West & South) will meet to begin work on next steps. The overall goal is to move from a region based model to a system model inclusive of systemwide best practices and resources to support Corewell Health research.



***Please join us in welcoming....***

**Ghulam Mohammad, PhD**, Research Scientist,  
Radiation Oncology.

### Innovative Research in ID Clinical Trials

The Infectious Disease Clinical Trials Office under the leadership of Maureen Cooney, RN, as Associate Nurse Manager and Matt Sims, MD, PhD as Medical Director, is frequently selected as a study site by sponsors conducting truly innovative research. Their participation in multiple studies of SER-109, a product by Seres Therapeutics for the prevention of recurrent *C. difficile* infection (CDI), resulted in publications in the *New England Journal of Medicine* and the *Journal of the American Medical Association*. The product was approved by the FDA in April of this year and is now marketed as VOWST. Clinicians are excited to have another option for treatment, which may greatly impact a person's quality of life.

The ID Research team is currently working with Prenosis Inc. a precision medicine company, on the study *Early Stratification of Septic Patients*. The timing of appropriate medical treatment is critical in sepsis and Prenosis' first such tool, the Sepsis ImmunoScore™, is a Software-as-a-Medical Device (SaMD) digital diagnostic designed to aid in the risk assessment for progression to sepsis of patients admitted in the emergency department or hospital. Prenosis is seeking FDA clearance for the tool, which interfaces with hospital Electronic Medical Records. Prenosis was recently funded by Biomedical Advanced Research and Development Authority (BARDA), a division of HHS which "promotes the advanced development of medical countermeasures to protect Americans and respond to 21st century health security threats" to study the implementation and impact of their ImmunoScore™. Beaumont is one of only three sites where the research will take place.

Recruitment for a new study by Adaptive Phage Therapeutics' *A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of APT Phage Bank Phage Therapy versus Placebo in Conjunction with*

*Debridement, Antibiotics, and Implant Retention in Subjects with Chronic Prosthetic Joint Infection (PJI)* is now underway. Phage therapy is a method of treatment that uses viruses (phages) specific to bacteria to treat bacterial infections. Phages are viruses that only target bacteria and do not infect people. This is the first Phase III study of phage for PJI. Most studies up to this point using phage therapy for infection, have been compassionate use.

Additional research in microbiome therapy for CDI, sponsored by Vedanta Biosciences, Inc., and by Novozymes A/S, are ongoing. Dr. Matt Sims is the lead PI for the Novozymes A/S study overall.



### Publications:

**Abbas AE, Khalili H, Madanat L, Elmariah S, Shannon F, Al-Azizi K, et al.** echocardiographic versus invasive aortic valve gradients in different clinical scenarios. *J Am Soc Echocardiogr* 2023 Jul 26; POnline ahead of print. PMID:37507058.

**Babu KC, Fritz CG, Choi JS, Casale GG, Fan CJ, Lucas JC, et al, [Babu SC].** Does labyrinthectomy have an impact on hearing in the contralateral ear during long-term follow-up? *Am J Otolaryngol* 2023 Jul 8;44(6):103989. PMID:37459738.

**Franklin BA.** Interpreting the impact of cardiac rehabilitation without a "true" control group? proceed with caution. *J Cardiopulm Rehabil Prev* 2023 Jul 1;43(4):233-236. PMID: 37343241.

Fritz CG, **Choi JS, Conway RM, Casale GG, Bojrab DI2, Babu SC.** Characterizing the most popular tinnitus inquiries: Is tinnitus incidence on

the rise since COVID-19? *Otol Neurotol* 2023 Jul 1;44(6):e435-e442. PMID:37205864.

**Hawkins K, Coffey M, Cooper M, Markwell A, Boyd P, Zuk K, et al.** The Use of lavender aromatherapy for pain after total hip and total knee arthroplasty: A Randomized trial. *Orthop Nurs* 2023;42(4):230-242. PMID:37494903.

**Knill C, Sandhu R, Loughery B, Lin L, Halford R, Drake D, et al, [Snyder M].** Commissioning and validation of a Monte Carlo algorithm for spine stereotactic radiosurgery. *J Appl Clin Med Phys* 2023 Jul 11:e14092. PMID:37431696.

**Levitin R, Salari K, Squires BS, Hazy AJ, Maywood MJ, Thrasher P, et al, [Delise AP, Almahariq MF, Dekhne N, Oliver L, Chen PY, Walters KJ, Dudley D, Dilworth JT].** Near-surface dose correlates with moist desquamation and unplanned reconstructive surgery in patients with implant-based reconstruction receiving postmastectomy radiation therapy. *Adv Radiat Oncol* 2023 Jun 5;8(6):101283. PMID:37492779.

**Park D, Arveschoug A, Wahlmeier S, Petersen-Fitts G, Zakko P.** The Effect of plate thickness on fusion, complications, and outcomes in anterior cervical spine surgery. *Cureus* 2023 Jun 27;15(6):e41048. PMID: 37519557.


**Park JG, Chen XD, Clontz M, Begaj T, Runner MM, Wolfe JD.** Coding of geographic atrophy and exudative age-related macular degeneration. *Ophthalmol Retina* 2023 Jul;7(7):644-645. PMID:36966949.

**Saiyed N, Yilmaz A, Vishweswariah S, Maiti AK, Ustun I, Bartolone S, et al, [Osentoski T, Ruff S, Pai A, Maddens M, Imam K, Graham SF].** Urinary cytokines as potential biomarkers of mild cognitive impairment and Alzheimer's disease: A Pilot study. *J Alzheimers Dis Rep* 2023 Jun 27;7(1):649-657. PMID:37483327.

**Schukow C, Smith SC, Landgrebe E, Parasuraman S, Folaranmi OO, Paner GP, et al.** Application of ChatGPT in routine diagnostic pathology: Promises, pitfalls, and potential future directions. *Adv Anat Pathol* 2023 Jul 27; Online ahead of print. PMID:37501529.

# BEAUMONT RESEARCH INSTITUTE NEWSLETTER

August 2023



**metabolites**  
an Open Access Journal by MDPI

Metabolomics in Neurodegenerative Diseases

**Guest Editors**  
Dr. Stewart Francis Graham, Dr. Nazia M. Saiyed, Dr. Ali Yilmaz

**Deadline**  
01 April 2024

**Special Issue**  
Invitation to submit

mdpi.com/si/182700

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Indexed in: PubMed  
CITESCORE 5.3



REDCap is a web-based database application specifically designed for clinical research. It is provided to Beaumont Investigators at no cost. Contact our REDCap Administrator Donna McIntyre, (248.551.7599) for more information on how REDCap can support your study.

## Special Issue "Metabolomics in Neurodegenerative Diseases"

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 U.S. National Library of Medicine

## ClinicalTrials.gov

### The Clinicaltrials.gov Corner

#### Did you know?

When entering your study on clinicaltrials.gov, you will be asked to list the primary disease or condition and keywords that best describe the protocol. This allows users, both the public and other researchers, to easily find studies in the database.

Source: <https://clinicaltrials.gov/ct2/manage-recs/how-report#ScientificInformation>

