



# RESEARCH DEVELOPMENTS at Englewood Hospital and Medical Center

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The EHMC Clinical Research Center provides the resources needed for our investigators to conduct the research shaping the future of patient care. The consistent increase in research activity at EHMC is evidence of our drive to expand the treatment options available to our patients and improve overall patient outcomes. The growing infrastructure both facilitates the research process and ensures compliance with all necessary regulations. Below are the details on some of our new clinical research projects:

NEW CLINICAL RESEARCH STUDIES

## ATRIAL FIBRILLATION

### “RE-CIRCUIT”

Principal Investigator:  
Dr. David Feigenblum

Catheter ablation is currently recommended as an interventional alternative for patients with the abnormal heart rhythm known as atrial fibrillation (AF). During an ablation, there is a measurable risk of stroke, which requires optimal anticoagulation to prevent clot formation and ensure the safety of the procedure. The standard of care is to anticoagulate patients with a vitamin K antagonist (VKA) for 1 month pre-ablation and for 2-3 months post-procedure. The VKA is stopped prior to the procedure and the patient is bridged with heparin. Recently, that standard of care has started shifting towards



using an uninterrupted oral anticoagulation regimen throughout the procedural period. This trial will assess the safety of an uninterrupted dabigatran (Pradaxa) anticoagulation regimen compared to an uninterrupted warfarin (Coumadin) regimen in AF patients undergoing AF ablation.

## CLOSTRIDIUM DIFFICILE

### “ECOSPOR”

Principal Investigator:  
Dr. Mitchell Spinnell

With the ever-increasing use of antibiotics, the incidence of *Clostridium difficile* infection (CDI) continues to rise. The frequency of recurrent CDI has paralleled the growing rate of primary infection. There is no approved therapy to prevent recurrent CDI, but many facilities, including EHMC, offer fecal microbiota transplants (FMTs). The principle behind FMT is to restore the normal gut bacteria of a CDI patient by ‘transplanting’ stool from a healthy donor via a colonoscopy. This ECOSPOR study is based on the same principle as FMT, but tests a new capsule preparation of healthy bacterial spores that is taken as one



oral dose. All participants first receive standard antibiotics to treat their CDI and then are randomized to receive either the study drug or a placebo in an attempt to prevent CDI recurrence. Participants who do have a recurrence may ‘rollover’ to an open-label study to receive the study drug.

## DIABETES

### “Education for the Korean Community”

Principal Investigator:  
Dr. Esther Lee

The purpose of this study is to evaluate the effect of a culturally-tailored education program designed to prevent diabetes in the local Korean community. Korean patients living in Bergen County, who are identified as “at-risk” for diabetes, will be invited to one diabetes prevention session provided in both English and Korean. Eligible patients will then be randomized to receive either no additional intervention (Control Group) or to attend five additional diabetes prevention sessions (Intervention Group). For comparison, both groups will have their diabetes risk factors measured and quality of life data collected before the first session and at 6 and 12 months after the last session.



## MYOCARDIAL INFARCTION

### “ARTEMIS”

Principal Investigator:  
Dr. Richard Goldweit

In observational studies, increased out-of-pocket medication expenses have been associated with lower rates of treatment, delays to treatment, and lower medication adherence. This study will evaluate whether a copay reduction influences antiplatelet medication adherence or clinical outcomes after an acute myocardial infarction (AMI). Sites are randomized as either ‘intervention’ or ‘control.’ EHMC is an intervention site, so all participants enrolled here receive either clopidogrel or ticagrelor (at the provider’s discretion) without copay for 12 months after AMI discharge. The objective of this study is to determine if the copay reduction leads to a lower risk of MACE (composite of death, AMI, and stroke) at one year post-discharge.



# NEW CANCER STUDIES

Cancer is a major focus of research here at EHMC, as evidenced by the growing number of clinical trials ongoing in the Cancer Treatment and Wellness Center. In addition to providing state-of-the-art cancer treatment, our physician-investigators are conducting clinical research studies to evaluate new ways to prevent, diagnose, and treat cancer. The ability to offer these investigational options to our patients is integral to making continued improvement in the treatment of this disease, which so closely affects our community. Details on just a few of the recently activated cancer studies are listed below:

## LUNG CANCER

### “PD-L1 Antibody”

Principal Investigator:  
Dr. Lewis Attas

Non-Small Cell Lung Cancer (NSCLC) is the most common form of lung cancer, accounting for approximately 85% of all cases. For patients with NSCLC tumor types that are not sensitive to currently available targeted therapies, the first line of treatment is a platinum-based chemotherapy regimen. This study will evaluate the effect of adding an investigational anti-PD-L1 antibody to a standard platinum-based chemotherapy regimen as an upfront treatment. Subjects enrolled on this study will first have their tumor tissue tested for the PD-L1 mutation. If the mutation is detected, then subjects are randomized to receive either: (1) MPDL3280A, the anti-PD-L1 antibody, plus standard chemotherapy, or (2) standard chemotherapy alone.



### “Afatinib”

Principal Investigator:  
Dr. Lewis Attas

Approximately 15% of all Non-Small Cell Lung Cancers (NSCLC) have a mutation in the Epidermal Growth Factor Receptor (EGFR). There are two classes of targeted agents with distinct mechanisms of action: antibodies against the EGFR receptor, and small molecule tyrosine kinase inhibitors (TKIs). EGFR TKIs have revolutionized the way in which NSCLC is treated, as they are extremely effective in treating patients with EGFR-mutated cancers, especially compared to chemotherapy. However, tumors develop resistance to the currently available TKIs after about one year. This study will evaluate the use of afatinib, a second generation TKI. Subjects with NSCLC and an EGFR mutation will be randomized to receive either: (1) afatinib plus cetuximab, an EGFR antibody, or (2) afatinib alone.

## BREAST CANCER

### “B52”

Principal Investigator:  
Dr. Jill Morrison

In women with large but operable breast tumors, neoadjuvant (pre-surgery) therapy may be given to allow for better breast conservation and to potentially decrease the extent and morbidity of axillary surgery and postoperative radiotherapy. Hormone therapy has not traditionally been part of the neoadjuvant regimen. The purpose of this study is to determine whether or not the addition of hormone therapy (an aromatase inhibitor) to neoadjuvant chemotherapy yields a greater rate of ‘pathologic complete response’ than neoadjuvant chemotherapy alone.



### “Triple Negative”

Principal Investigator:  
Dr. Michael Schleider

Triple negative breast cancer (TNBC) is associated with worse outcomes than other subtypes of breast cancer. As TNBC tumors do not express hormone receptors, the available targeted therapies are not effective. More and better treatment options are needed for this population. This study is evaluating two different adjuvant (after surgery) chemotherapy regimens. Subjects enrolled on this study will be randomized to receive either: (1) a standard chemotherapy regimen plus carboplatin, or (2) a standard chemotherapy regimen alone.



# TRANSLATIONAL RESEARCH

EHMC has entered into an exciting research collaboration with senior scientists from the National Cancer Institute (NCI). **Miguel Sanchez, MD** is the EHMC Principal Investigator for two new research projects (details below) where he will be working with **Thomas Ried, MD**, Senior Investigator, Genetics Branch Head, Cancer Genomics Section, NCI and **Kerstin Heselmeyer-Haddad, PhD**, Staff Scientist, Genetics Branch., NCI. The goal of translational research is to 'translate' findings from basic science/bench research into meaningful clinical outcomes. Drs. Sanchez, Ried, and Heselmeyer-Haddad are working together to develop new molecular pathology assays capable of making highly sensitive, specific, and objective diagnoses of breast cancers from small tissue samples obtained through minimally-invasive fine needle aspirations.



## Archived Tissue - PI: Miguel Sanchez, MD

By analyzing tissue samples first collected ten years ago, investigators are able to correlate the results from this new molecular analysis with the interim ten years of outcomes data. The goal is to identify molecular characteristics that can better predict the aggressiveness of a specific tumor and serve as a guide for treatment decisions.

## FNA Waste Tissue - PI: Miguel Sanchez, MD

This study will expand upon the findings from the archived tissue study and look to prospectively collect tumor samples and clinical data. Investigators will evaluate the ability to perform this new lab analysis on very small tumor samples - just the cells leftover in the syringe after a fine needle aspiration - and correlate the lab results with actual clinical outcomes.

# RECENT EHMC PUBLICATIONS

Case Reports in Medicine. 2015;2015:154678.

**Stress Induced Cardiomyopathy with Midventricular Ballooning: A Rare Variant.**

[Siddiqui MU](#), Desiderio MC, Ricculi N, Rusovici A.

American Journal of Nursing. 2015 Jul;115(7):50-4.

**Effective Collaboration Among Magnet Hospitals: A Win-Win for Nurses and Institutions.**

Centrella-Nigro AM, Faber K, [Wiklinski B](#), Bognar L, Flynn DL, LaForgia M.

British Journal of Anaesthesia. 2015 Jul;115(1):15-24.

**'Fit to fly': overcoming barriers to preoperative haemoglobin optimization in surgical patients.**

Muñoz M, Gómez-Ramírez S, Kozek-Langenecker S, [Shander A](#), et al.

Obstetrical & Gynecological Survey. 2015 May;70(5):342-53.

**Iron deficiency anemia in women: a practical guide to detection, diagnosis, and treatment.**

Friedman AJ, [Shander A](#), Martin SR, Calabrese RK, Ashton ME, Lew I, Seid MH, Goodnough LT.

BMC Anesthesiology. 2015 May 9;15:75.

**Should we restrict erythrocyte transfusion in early goal directed protocols?**

Meybohm P, [Shander A](#), Zacharowski K.

Applied Nurse Research. 2015 May;28(2):78-82.

**Factors associated with falls in hospitalized adult patients.**

[Cox J](#), Thomas-Hawkins C, Pajarillo E, [DeGennaro S](#), Cadmus E, Martinez M.

Annals of Vascular Surgery. 2015 Jul;29(5):1022-1028.

**Update on the Role of the Distal Arteriovenous Fistula as an Adjunct for Improving Graft Patency and Limb Salvage Rates after Crural Revascularization.**

[Dardik H](#).

Journal of Blood Medicine. 2014 Dec 24;6:17-23.

**Responses of advanced directives by Jehovah's Witnesses on a gynecologic oncology service.**

[Nagarsheth NP](#), Gupta N, Gupta A, Moshier E, Gretz H, [Shander A](#).



# THE EHM CLINICAL RESEARCH CENTER

The EHM Clinical Research Center welcomes the following new members:

• Mohemmed Abbas, MD	• Jonathan Infeld
• Andrew Brunnquell	• Lorna B. Pazziuagan, RN
• Lauren Boutillier, MD	• Hee Jung Park, MD
• Damon Ceylan	• Jessica Roth
• Woojin Chong, MD	• Tracy Scheller, MD
• Tamara Friedman	• Linda F. Sta. Maria, RN
• Jennifer Guzman, RN	

If you are interested in registering with the Clinical Research Center, please email [Jamie.Ketas@ehmhealth.org](mailto:Jamie.Ketas@ehmhealth.org) or [Renee.Lockwood@ehmhealth.org](mailto:Renee.Lockwood@ehmhealth.org) for information on the required documentation and training.

## RESEARCH 101

The EHM Institutional Review Board (IRB) is charged with protecting the rights of all human research participants. Federal regulations allow for different levels of IRB review, depending on the level of risk to participants. The IRB can determine that a proposed research project: (a) is Exempt from Review, (b) qualifies for Expedited Review, or (c) must receive Full Board Review. IRB paperwork is required for all three types of review, and the necessary forms can be found on the [ePortal: Document Center/Public Documents and Forms/Institutional Review Board](#).

(a) Exempt from Review	(b) Expedited Review	(c) Full Board Review
There are 6 specific categories of exempt research outlined in the regulations. All are minimal risk. Example: A survey where the data obtained is recorded so that human subjects cannot be identified, either directly or through linked identifiers.	Projects that are minimal risk, do not qualify as exempt, and fit into one of the 9 specific research categories outlined as eligible for expedited review. Example: A retrospective chart review to collect data that was previously recorded for non-research purposes.	Proposals that do not qualify as exempt, are not eligible for expedited review, and/or involve more than minimal risk. Example: A clinical trial testing a new investigational drug or device.
The IRB Office determines if a project qualifies for an exemption. An official 'IRB exemption' letter is issued stating that no further action is necessary <i>unless the research is changed</i> (as the change may affect the exemption status).	One qualified IRB member performs the review and can: approve "as-is," request modifications, or send for Full Board Review. (One member cannot disapprove a study.) Expedited review at EHM usually takes about 10 business days.	Must go to a convened IRB meeting for review/vote by the entire committee. The committee can approve, approve pending modifications, defer, or disapprove a study. The EHM IRB meets every other month.

If you are interested in learning more about the clinical research opportunities and resources available at Englewood Hospital and Medical Center, please contact the Clinical Research Center at 201.894.3418.



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