**Who we are...**

Genesis Health System Office of Research and Grants Administration is here to help you. If you need assistance please contact us.

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**Genesis Health System Research Promotion Fund**

To make a request to use the monies in the Research Promotion Fund, go to www.genesishealth.com/research and fill out the online application. You can also contact the Office of Research and Grants Administration for a copy of the application.

Once the Research Promotion Fund Committee receives a completed form, the committee does it’s best to respond to applications within two weeks.

If you have questions about the Genesis Health System Research Promotion Fund, please direct them to Sarah Castro at CastroS@genesishealth.com.

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**Coming Soon - Genesis IRB Audits**

The Genesis Institutional Review Board (IRB) is committed to continually improving its practices to ensure the highest quality of ethical research at Genesis. A best practice for IRBs is to conduct routine audits to verify the ethical conduct of human subjects research and compliance with regulations. The Genesis IRB will begin utilizing routine audits in its new Quality Assurance Program.

The purpose of the Quality Assurance Program is to ensure proper documentation, record keeping, data management and adherence to federal regulations and IRB standard operating procedures. This audit process will monitor, measure and improve the effectiveness of the human research protection program at Genesis. Audits will assess study procedures, identify errors and/or omissions and provide investigators with recommendations for corrections and improvements. This will be a learning opportunity for investigators, and training will be offered, as needed.

The Research and Grants Administration Office (RGA) and Genesis Compliance Department will be responsible for conducting IRB audits, on behalf of the Genesis IRB.

**Inclusion Criteria**
1. Investigator-Initiated studies
2. Prospective and retrospective studies
3. Industry- or government-funded studies that are not being routinely monitored on-site

**Exclusion Criteria**
1. Industry-funded studies that are being routinely monitored on-site
2. Government-funded studies that are being routinely monitored on-site

The Genesis IRB will continue to conduct “for cause” audits in response to particular concerns, as outlined in its Standard Operating Procedures.

Additional details will be sent directly to Principal Investigators and Clinical Research Coordinators regarding specific audit procedures.

**The Research Office anticipates that routine IRB audits will begin in the Fall of 2016.**
Study Touted As Most Exhaustive Study on Readmission Root Causes To-Date

A recent study published in The Journal of the American Medical Association (JAMA) Internal Medicine in March 2016 examined the likelihood that a hospital 30-day readmission could have been prevented. What makes this study unique is that it is the first large, nationwide study to incorporate the viewpoints of patients and health care professionals to determine readmission preventability.

The study was an observational study of 1,000 general medicine patients readmitted within 30 days of discharge to 12 US academic medical centers between April 1, 2012 and March 31, 2013. The study surveyed patients and physicians, reviewed documentation and performed 2-physician case review to determine preventability of and factors contributing to readmission.

26.9% of readmissions reviewed were considered potentially preventable. In multivariable models, the factors most strongly associated with potential preventability included the following:

- Emergency department decision making regarding the readmission (aOR, 9.13; 95%CI, 5.23-15.95)
- Failure to relay important information to outpatient health care professionals (aOR, 4.19; 95%CI, 2.17-8.09)
- Discharge of patients too soon (aOR, 3.88; 95%CI, 2.44-6.17), and
- Lack of discussions about care goals among patients with serious illnesses (aOR, 3.84; 95%CI, 1.39-10.64).

The most common factors associated with potentially preventable readmissions included:

- Emergency department decision making (affecting 9.0%; 95%CI, 7.1%-10.3%),
- Inability to keep appointments after discharge (affecting 8.3%; 95%CI, 4.1%-12.0%),
- Premature discharge from the hospital (affecting 8.7%; 95%CI, 5.8%-11.3%), and
- Patient lack of awareness of whom to contact after discharge (affecting 6.2%; 95%CI, 3.5%-8.7%).

This study was an observational study, and therefore, cannot assign causality to the factors identified above. Additional studies are needed to determine whether eliminating the factors found in this study would reduce readmissions. However, the study does provide information to help prioritize local efforts to reduce readmissions.

The full article can be found here— http://archinte.jamanetwork.com/article.aspx?articleid=2498846

Upcoming Presentations!

Two Genesis staff members will be presenting their evidence-based practice and research projects at upcoming events across the country. Congratulations to the following individuals for being accepted for presentation!

Deb Stockdale will be presenting a poster for her project entitled, “Preventing Catheter Associated Urinary Tract Infections on an Inpatient Rehabilitation Unit” at the Association of Rehabilitation Nurses Education Conference in Philadelphia, PA in September.

Dr. Jon Lemke will be presenting his research project entitled, “The Impact of Untreated Sleep Apnea on Elective Surgery Complication, Mortality, Length of Stay and Readmissions” at the Genesis Continuing Medical Education Conference in Victoria, British Columbia in October.

These trips were made possible through the use of Research Promotion Funds. Please visit http://www.genesishealth.com/about/research_grants/information-for-researchers/ to learn more about the Research Promotion Fund and to apply!
Nursing Residency Program
Research Component Added

In an effort to create greater awareness and interest among nurses regarding the Genesis Research Program, the Research department will begin participating in the Nursing Residency Program.

Information will be provided to nurses regarding the types of research being conducted at Genesis, the role research plays in nursing, its benefits on quality/safety and opportunities for research at Genesis.

Research starts with a question, so nurses will get the opportunity to brainstorm potential research questions that pertain to their everyday work. They will also get the opportunity to sign-up for greater involvement in research at Genesis.

Remember to Complete Your Conflicts of Interest Disclosure

If you are an active principal investigator, research team member or IRB member you are required to complete a conflicts of interest disclosure questionnaire annually.

You would have received an e-mail from Genesis COI Smart. This e-mail provided you with the link to access the questionnaire (https://genesis.coi-smart.com) and your specific user ID. If you have not already completed the questionnaire, please do so as soon as possible!

Thank you to those that have already completed the 2016 questionnaire.

If you need assistance accessing the questionnaire, please contact Sherri Brown at 421-8522, e-mail: brownsh@genesishealth.com. Research-related questions should be directed to Sarah Castro, (563) 421-7957, email: castros@genesishealth.com.

Summary of Genesis Health System IRB Activity
July - August, 2016

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<th>New Project</th>
<th>Adverse Event</th>
<th>Amendment</th>
<th>Closure</th>
<th>Continuing Review</th>
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IRB Approved New Projects: July - August, 2016

2 New Studies Approved

**EA1131: A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy**
Principal Investigator: George Kovach, MD

Rationale and Purpose: The purpose of this study is to compare getting more treatment with capecitabine (i.e. one of the usual approaches), to any good and bad effects of getting more treatment with a platinum-based chemotherapy (cisplatin or carboplatin), after surgery.

**Can the FitBit Wearable Activity Tracker Measure Caloric Expenditure in an Inpatient Ischemic Stroke Population?**
Principal Investigator: Joseph Brooks, DO

Rationale and Purpose: The primary objective of this study is to learn more about the use of FitBits in measuring calories burned in the inpatient therapy setting. The study also would like to know whether the amount of calories patients burn is related to their ability to carry out activities of daily living and discharge location (e.g., home, skilled care) after the therapy program.

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Research Highlights—Seven Studies were Completed in July - August, 2016

**NSABP B-38: A Phase III Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node-Positive Breast Cancer:**
- Docetaxel/Doxorubicin/ Cyclophosphamide (TAC),
- Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel; DD AC Followed by DD Paclitaxel Plus Gemcitabine
Principal Investigator: George Kovach, MD and Shobha Chitneni, MD

Results: Adding Gemzar to Dose Dense AC followed by paclitaxel did not improve outcomes. No significant differences in efficacy were identified between Dose dense AC followed by paclitaxel and TAC, although toxicity profiles differed.

**NSABP R-04 Treatment With Two Chemotherapy Drugs Combined With Radiation Therapy for Patients With Rectal Cancer**
Principal Investigator: Shobha Chitneni, MD

Results: Pending

**NSABP B-36 A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-Fluorouracil, Epirubicin and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC), in Patients With Node-Negative Breast Cancer.**
Principal Investigator: Shobha Chitneni, MD

Results: Pending

**S0931 EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study.**
Principal Investigator: Shobha Chitneni, MD

Results: Pending

**E4A03 A Randomized Phase III Study of CC-5013 plus Dexamethasone versus CC-5013 plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide plus Dexamethasone Salvage Therapy for Non-Responders**
Principal Investigator: Shobha Chitneni, MD

Results: Pending

**CTSU E5508: Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC**
Principal Investigator: Shobha Chitneni, MD

Results: Pending

**S1304—A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-756640) with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease**
Principal Investigator: Shobha Chitneni, MD

Results: Pending

For More Information About Any of These Studies, Contact the Research and Grants Office at 421-7955