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 its 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.

Common Rule Revisions Delayed...Again

The revisions to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, have been delayed for a second time. The new compliance date is January 21, 2019.

Reason for Delay: There is much needed guidance on how to implement aspects of the new regulations, including but not limited to: Human Subject Regulations Decision Charts, clarification on informed consent, limited IRB review, benign behavioral interventions and continuing review.

In addition to delaying the general compliance date, the rule allows (but does not require) institutions to implement three "burden-reducing provisions" of the revised rule during the delay period:

1) use of the revised definition of "research," which deems four categories of activities not to be research;
2) the allowance for no annual continuing review of certain categories of research; and
3) the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research.

The Genesis IRB has chosen NOT to implement the 3 provisions listed above prior to the January 21, 2018 compliance date. This is because any study that implements the 3 burden-reducing provisions during the delay period must, beginning on January 21, 2019, comply with ALL of the new requirements for the balance of the study’s duration. This would likely require additional consent form changes, and other potentially burdensome changes once the new Common Rule goes into effect. The Genesis IRB believes it will be easier for researchers to wait and implement the new requirements on the official compliance date.

What Does This Mean for Researchers at Genesis?
This means the Genesis IRB will continue to follow the existing Common Rule legislation, as it is stated. Please continue to use the materials listed in IRBNet for your Genesis IRB submissions.

Where Can I Get More Information?
Click here to read the full Interim Final Rule, which outlines the reasons for delay.
Cancer Study Highlight

**Study Title:** Testing MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer

**Principal Investigator:** Dr. George Kovach

**Primary Objective:** To compare invasive disease-free survival of patients with triple-negative breast cancer who have either >1 cm residual invasive breast cancer and/or positive lymph nodes (>ypN+) after neoadjuvant chemotherapy randomized to receive 1 year of MK-3475 (pembrolizumab) adjuvant therapy compared to no MK-3475 (pembrolizumab), in both the entire study population and also in the PD-L1 positive subset.

**Why is this study important?** Triple-negative breast cancer cells do not contain receptors for estrogen, progesterone, or HER2. Therefore, they cannot be treated with hormone therapies or medications that work by blocking HER2. This leaves patients with triple-negative breast cancer with less options for treatment, making clinical trials very important.

This study is using Pembrolizumab, which is an immunotherapy that works with the body’s immune system to help fight cancer. It is a promising new type of treatment, and only available to breast cancer patients through clinical trials.

Patients eligible for this study usually do not receive any more treatment after surgery, but this study will see whether an additional round of drug therapy will be more or less effective at preventing cancer recurrence. This knowledge will help physicians understand the best ways to treat triple-negative breast cancer in the future.

New Genesis IRB Member!

Genesis Research would like to welcome Linda Stewart as a new member of the Genesis Institutional Review Board (IRB). Linda is a social worker in the Care Coordination Department at Genesis, and serves as a non-scientific member on the IRB. The Genesis IRB is required to have one member at each meeting whose primary concerns are in non-scientific areas and Linda will help to meet this requirement. The Genesis IRB has members of varying background and expertise to provide complete and thorough review of research activities conducted by the institution.

StrokeNet Renewed!

University of Iowa wins competitive renewal

The National Institute of Neurological Disorders and Stroke (NINDS) has selected the University of Iowa Regional Coordinating Center to remain in StrokeNet after a competitive renewal! StrokeNet is a research network created by the National Institutes of Health in 2013 to efficiently conduct clinical trials and research studies to advance stroke treatment, stroke prevention and recovery and rehabilitation following a stroke.

Genesis Health System participates in StrokeNet as a satellite site and is currently enrolling patients in The AtRial Cardiopathy and Antithrombotic Drugs In prevention After cryptogentic stroke (ARCADIA) study. This study is led locally by Dr. Rodney Short and aims to test the hypothesis that apixaban is superior to aspirin for reducing the rate of recurrent stroke or death in patients with cryptogenic stroke and evidence of atrial cardiopathy.

Genesis is excited to continue working with the University of Iowa and the rest of the StrokeNet participants on this important collective project!
IRB Audit Results - Food and Drug Administration (FDA)

The Genesis IRB went through a routine FDA audit in March 2018 and were found to have no reportable citations! The auditor had a few suggestions for strengthening our IRB process even more, which we have begun to implement. A couple of suggestions will affect the IRB submission process for researchers. These changes are highlighted below:

1) **For FDA governed studies, the informed consent must state that research records may be specifically shared with the FDA.** In the Confidentiality and HIPAA sections of the informed consent, researchers already must state a list of persons/groups that might have access to research records. The FDA should be named specifically as a party that might have access to these records.

2) **For each IRB submission (e.g., new project, amendment, continuing review), the principal investigator must sign their own Assurance Statement.** The Assurance Statement states the principal investigator will be responsible for the conduct and ethical performance of the study, and certifies that the information provided in the IRB application is complete and accurate. Currently, the Genesis IRB allows a proxy signer (e.g., clinical research coordinator) to electronically provide this assurance. Per FDA recommendation, moving forward the Assurance Statement must be signed by the principal investigator, either electronically in IRBNet or using a new paper Assurance Statement that is uploaded with the application.

The Research Department is currently in the process of revising its Standard Operating Procedures to reflect these changes. Once the revised policies are approved by the Genesis Board, the above changes will go into effect. An e-mail will be sent out to all investigators and clinical research coordinators providing a start date for the process changes. New application forms will be available in IRBNet.

If you have any questions about these changes, please feel free to contact Sarah in the Research Department at 563-421-7957 or castros@genesishealth.com

Coming Soon—New Educational Opportunities

The Therapy Research Subcommittee is working to develop a number of educational opportunities for Genesis Staff to learn more about research and evidence-based practice. These opportunities will be a combination of online training and in-person workshops depending on the topic. **Free CEUs** will be offered for each training, and trainings will be open to all departments and disciplines. Details regarding the first online training in development are below:

**Topic:** Finding and Evaluating Evidence

**Objectives:**

1) Formulate a plan for searching the literature
2) Identify where to find evidence
3) Identify methods and tools for critically analyzing the evidence

Additional details will be provided once this online training is available to staff, so stay tuned!
IRB New Projects: May - June, 2018

One New Study Under Review

Pharmacist led diabetes management using bi-directional text message reminders
Principal Investigator: Matt Arnold, PharmD
Rationale and Purpose: To see whether text message reminders help prompt people to measure, record, and share their blood sugar readings. These readings will be viewed by pharmacists. The pharmacists will recommend treatment adjustments to help control blood sugar.

Completed Studies — Three Studies in May - June, 2018

CLEE011A2404 ComPLEEment-1: An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment of men and postmenopausal women with hormone receptor-positive (HR+) HER2-negative (HER2-) advanced breast cancer (aBC) with no prior hormonal therapy for advanced disease
Principal Investigator: George Kovach, MD
Rationale and Purpose: To further learn about the safety and how well ribociclib works when added to standard treatment (letrozole) for patients with hormone receptor-positive, HER2 negative, advanced breast cancer with no prior hormonal therapy for advanced disease.
Results: Results pending

Medical device alarm systems: A multi-hospital study of alarm-related events, caregiver alarm response, and their contributing factors
Principal Investigator: Colleen Lindell, RN, PhD(c)
Rationale and Purpose: To compare 3 hospitals’ alarm-related events, alarm configurations, medical device policies and alarm system education and training, and to compare registered nurse perceptions per unit (if applicable) and per hospital.
Results: Medical device alarm systems are expected to improve patient care by alerting clinicians about conditions that require attention. However, due to a variety of circumstances, including inadequate training, muting alarms, alarm fatigue, and staffing shortages, the effectiveness of alarm systems may be questionable. This research looked at the appropriateness of time to respond to alarms, given the alarm system configuration, policies regarding alarms, and the extent of training and education provided about alarms. Using concepts from cognitive systems engineering, organization policy, and organizational learning, a research model was assembled to investigate these relationships.

Alarm survey data was collected from a total of 107 respondents over a 3-month timeframe. Data download of alarms totaled 88,307 alarms. Using a logistic regression approach, partial support for the hypotheses was found across contexts of high, medium, and low priority alarms. The overall prediction of appropriateness of alarm response was good, except on the case of medium priority alarms. Examination of the alarm data revealed that clinician response to medium priority alarms was considerably slower than anticipated.

Xience 90
Principal Investigator: Jon Robken, MD
Rationale and Purpose: To evaluate safety of 3-month dual antiplatelet therapy (DAPT) in subjects at high risk of bleeding (HBR) undergoing percutaneous coronary intervention (PCI) with XIENCE.
Results: Results pending

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

Genesis Research Inquirer May/June 2018