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<th>Breast</th>
<th>On Study Dr.:</th>
<th>Call SJH Cancer Services at (856) 641-8670 for further assistance.</th>
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<tr>
<td>NSABP B-43 CTSU</td>
<td>Joseph Fanelle, MD &amp; Kush Sachdeva, MD</td>
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**A Phase III Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy.**

**RATIONALE:** Monoclonal antibodies, such as trastuzumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Radiation therapy uses high-energy x-rays to kill tumor cells. It is not yet known whether radiation therapy is more effective with or without trastuzumab in treating ductal carcinoma in situ.

**PURPOSE:** This randomized phase III trial is studying radiation therapy to see how well it works compared with or without trastuzumab in treating women with ductal carcinoma in situ who have undergone lumpectomy.

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<td>FCCC FER BR 034</td>
<td>Kush Sachdeva, MD</td>
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**PARP Inhibition After Preoperative Chemotherapy in Patients With Triple Negative Breast Cancer or ER/PR+, HER2 Negative With Known BRCA1/2 Mutations**

**RATIONALE:** This study is for patients with Triple Negative Breast Cancer, or patients that are ER/PR+, HER2- and have known BRAC1/2 mutations. PF-01367338, the investigational drug in this study, is a PARP inhibitor. PARP is an enzyme that plays a role in telling DNA to repair a damaged cell. A PARP inhibitor blocks this action so the cancerous cell has less of a chance to repair itself after receiving treatment with chemotherapy.

**PURPOSE:** The purpose of this trial is to evaluate 2-year disease-free survival in this patient population treated with single agent cisplatin and patients treated with cisplatin in combination with PF 01367338 following preoperative chemotherapy. Side effects and tolerability of this treatment in patients with residual disease following preoperative chemotherapy will also be observed and characterized.
**Breast**

**NSABP B-47 CIRB**

A Randomized Phase III Trial of Adjuvant Therapy Comparing
Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer

**RATIONALE:** Drugs used in chemotherapy work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) and giving chemotherapy after surgery may kill more tumor cells. Monoclonal antibodies, such as trastuzumab, can block cancer growth in different ways. Some block the ability of cancer cells to grow and spread. Others find cancer cells and help kill them or carry cancer-killing substances to them. It is not yet known whether combination chemotherapy is more effective with trastuzumab in treating breast cancer.

**PURPOSE:** This randomized phase III clinical trial is studying chemotherapy with or without trastuzumab after surgery to see how well they work in treating women with invasive breast cancer.

**On Study Dr.:**
Benjamin Negin, MD

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**

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**Breast**

**SCUSF 0806 CTSU**

Phase II placebo-controlled trial of lisinopril and Coreg CR® to reduce cardiotoxicity in patients with breast cancer receiving (neo)adjuvant chemotherapy with trastuzumab (Herceptin®)

**RATIONALE:** Lisinopril or carvedilol phosphate may help reduce side effects caused by trastuzumab. It is not yet known whether lisinopril or carvedilol phosphate are more effective than a placebo in reducing side effects caused by trastuzumab.

**PURPOSE:** This phase II trial is studying lisinopril and carvedilol phosphate to see how well they work compared with a placebo in reducing side effects in women with HER2-positive breast cancer receiving trastuzumab.

**On Study Dr.:**
Shailja Roy, MD

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**
## Breast

**Impact of Genomics and Exposures on Disparities in Breast Cancer Radiosensitivity**

**RATIONALE:** Radiation therapy uses high-energy x rays to kill tumor cells. Radiation therapy may cause skin reactions when patients are exposed to high-energy x rays. Studying the genetic pattern of patients before and after radiation therapy may help doctors prevent toxicity and plan the best treatment.

**PURPOSE:** This clinical trial studies genetic susceptibility to radiation-induced skin reactions in racial/ethnic groups of patients with breast cancer.

**On Study Dr.:** Glenda Smith, MD

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**

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## Genetics

**The "Virtual Cancer Genetics Clinic" II: A pilot study of telemedicine delivery of cancer genetic services in community clinics**

**RATIONALE:** Preliminary studies identified burdens associated with the current delivery model for genetic services requiring two in-person visits. Both patients and providers reported perceived advantages to modifications that minimize travel, time and cost burdens for patients receiving genetic services.

**PURPOSE:** The overall objective is to develop a protocol for, and evaluate the feasibility of implementing telemedicine (i.e. videoconferencing) delivery of cancer genetic services in community clinical practices with limited or no access to on-site genetic services, with the ultimate goal of expanding the availability of personalized cancer risk assessment to populations where access to services has been limited or is associated with significant barriers to utilization.

**On Study Dr.:** Melanie Pirollo, MS, RN, AOCN

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**

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## GI Lower - Colon

**Statin Polyp Prevention Trial in Patients with Resected Colon Cancer**

**RATIONALE:** Rosuvastatin may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Giving rosvustatin after surgery may kill any tumor cells that remain after surgery. It may also keep polyps from forming or colon cancer from coming back. It is not yet known whether rosvustatin is more effective than a placebo in treating colon cancer that was removed by surgery.

**PURPOSE:** This randomized phase III trial is studying rosvustatin to see how well it works compared with placebo in treating patients with stage I or stage II colon cancer that was removed by surgery.

**On Study Dr.:** Rama Sudhindra, MD

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**
### GI Lower - Colon

**CALGB 80702 CTSU**

**RATIONALE:** Drugs used in chemotherapy, such as oxaliplatin, leucovorin calcium, and fluorouracil, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Celecoxib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether giving oxaliplatin, leucovorin calcium, and fluorouracil is more effective with or without celecoxib in treating colon cancer.

**PURPOSE:** This randomized phase III trial is studying giving oxaliplatin, leucovorin calcium, and fluorouracil together to compare how well they work when given together with or without celecoxib in treating patients with stage III colon cancer previously treated with surgery.

**On Study Dr.:**
Carl Minniti, Jr., MD

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**

### GU - Bladder

**RTOG 0524**

**RATIONALE:** Drugs used in chemotherapy, such as paclitaxel, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Radiation therapy uses high-energy x-rays to kill tumor cells. Paclitaxel may also make tumor cells more sensitive to radiation therapy. Monoclonal antibodies, such as trastuzumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Giving paclitaxel together with radiation therapy and trastuzumab may kill more tumor cells. Giving these treatments after surgery may kill any remaining tumor cells.

**PURPOSE:** This phase I/II trial is studying the side effects of giving paclitaxel together with radiation therapy with or without trastuzumab and to see how well it works to kill any remaining tumor cells in patients who have undergone surgery for bladder cancer.

**On Study Dr.:**
Joseph Fanelle, MD

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**
**GU - Prostate**

**RTOG 0534**

A phase III trial of short term androgen deprivation with pelvic lymph node or prostate bed only radiotherapy (SPPORT) in prostate cancer patients with a rising PSA after radical prostatectomy.

**RATIONALE:** Radiation therapy uses high-energy x-rays to kill tumor cells. Androgens can cause the growth of prostate cancer cells. Antihormone therapy, such as flutamide, bicalutamide, and luteinizing hormone-releasing hormone agonist, may lessen the amount of androgens made by the body. It is not yet known which regimen of radiation therapy with or without androgen deprivation therapy is more effective for prostate cancer.

**PURPOSE:** This randomized phase III trial is studying prostate radiation therapy to see how well it works compared with short-term androgen deprivation therapy given together with pelvic lymph node radiation therapy with or without prostate radiation therapy in treating patients with a rising PSA after surgery for prostate cancer.

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**GYN Cervical**

**GOG 0263 NCI CIRB**

Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated With Initial Radical Hysterectomy and Pelvic Lymphadenectomy

**RATIONALE:** Radiation therapy uses high-energy x-rays to kill tumor cells. Drugs used in chemotherapy, such as cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether giving radiation therapy together with chemotherapy is more effective than radiation therapy alone in treating patients with cervical cancer.

**PURPOSE:** This trial is studying giving radiation therapy together with chemotherapy to see how well it works compared to radiation therapy alone in treating patients with stage I or stage II cervical cancer who previously underwent surgery.
**GYN Endometrial**

**GOG 0249 NCI CIRB**

A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed By Paclitaxel/Carboplatin Chemotherapy in Patients With High Risk, Early Stage Endometrial Carcinoma.

**RATIONALE:** Radiation therapy uses high-energy x-rays to kill tumor cells. Implant radiation therapy uses radioactive material placed directly into or near a tumor to kill tumor cells. Drugs used in chemotherapy, such as paclitaxel and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether pelvic radiation therapy is more effective than vaginal implant radiation therapy, paclitaxel, and carboplatin in treating patients with endometrial cancer.

**PURPOSE:** This trial is studying pelvic radiation therapy to see how well it works compared with vaginal implant radiation therapy, paclitaxel, and carboplatin in treating patients with high-risk stage I or stage II endometrial cancer.

**On Study Dr.:**

Glenda Smith, MD and Robin Wilson-Smith, DO

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**

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**Hematology**

**ECOG E2905 CIRB**

A Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia

**RATIONALE:** Lenalidomide may stop the growth of myelodysplastic syndrome by blocking blood flow to the cell. Colony stimulating factors, such as epoetin alfa, may increase the number of immune cells found in bone marrow or peripheral blood. It is not yet known whether lenalidomide is more effective with or without epoetin alfa in treating patients with myelodysplastic syndrome and anemia.

**PURPOSE:** This randomized phase III trial is studying lenalidomide to see how well it works with or without epoetin alfa in treating patients with myelodysplastic syndrome and anemia.

**On Study Dr.:**

Tami Bach MD

**Call SJH Cancer Services at (856) 641-8670 for further assistance.**
### Lung, Non-small Cell

**ECOG E1505 CIRB**

A phase III randomized trial of adjuvant chemotherapy with or without Bevacizumab for patients with completely resected stage IB ( = or > 4 cm) - IIIA non-small cell lung cancer (NSCLC).

**RATIONALE:** Drugs used in chemotherapy work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) may kill more tumor cells. Monoclonal antibodies, such as bevacizumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Bevacizumab also may stop the growth of tumor cells by blocking blood flow to the tumor. Giving chemotherapy together with bevacizumab after surgery may kill any tumor cells that remain after surgery. It is not yet known whether chemotherapy is more effective with or without bevacizumab in treating non-small cell lung cancer.

**PURPOSE:** This randomized phase III trial is studying chemotherapy and bevacizumab to see how well they work compared to chemotherapy alone in treating patients with stage IB, stage II, or stage IIIA non-small cell lung cancer that was removed by surgery.

### Lung, Non-small Cell

**CALGB 30607 CTSU**

Randomized, Phase III, Double-Blind Placebo-Controlled Trial of Sunitinib (NSC #736511, IND #74019) as Maintenance Therapy in Non-Progressing Patients Following an Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB / IV Non-Small Cell Lung Cancer

**RATIONALE:** Sunitinib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth and by blocking blood flow to the tumor. It is not yet known whether sunitinib is more effective than a placebo in treating non-small cell lung cancer.

**PURPOSE:** This randomized phase III trial is studying sunitinib to see how well it works when given as maintenance therapy compared with a placebo in treating patients with stage III or stage IV non-small cell lung cancer previously treated with combination chemotherapy.

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**On Study Dr.:**

**Kush Sachdeva, MD**

**Call SJH Cancer Services at**

(856) 641-8670 for further assistance.

**On Study Dr.:**

**Carl Minniti, Jr, MD**

**Call SJH Cancer Services at**

(856) 641-8670 for further assistance.
### Lung, Non-small Cell

**ECOG E5508 CIRB**

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

**RATIONALE:** Drugs used in chemotherapy, such as paclitaxel and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Monoclonal antibodies, such as bevacizumab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Bevacizumab may also stop the growth of non-small cell lung cancer by blocking blood flow to the tumor. Pemetrexed disodium may stop the growth of tumor cells by blocking some enzymes needed for cell growth.

**PURPOSE:** This randomized phase III trial is studying bevacizumab and pemetrexed disodium alone or in combination after induction therapy to see how well they work in treating patients with advanced non-squamous non-small cell lung cancer.

### Lymphoma

**FCCC FER HM 035**

Phase II Study of Fludarabine, Velcade and Rituximab for Relapsed or Refractory Indolent Non-Hodgkin Lymphoma (HOG LYM08-134)

**RATIONALE:** The three drugs that will be studied are fludarabine, Velcade and rituximab and all subjects will receive the three-drug combination. Fludarabine and Velcade are chemotherapy drugs. They work by causing cancer cells to die and may stop the cancer from growing. Fludarabine has been approved by the Food and Drug Administration (FDA) for use in patients with chronic lymphocytic leukemia. Velcade has been approved by the FDA for use in patients with multiple myeloma and with mantle cell lymphoma. Rituximab is an antibody. Antibodies are proteins that can protect the body from foreign invaders, such as bacteria and viruses. Rituximab fits with specific proteins, like a key fits in a lock. It can stimulate the immune system to attack and destroy cancer cells, allowing new healthy cells to develop. Rituximab has been approved by the FDA for use in patients with low-grade or follicular Non-Hodgkin’s Lymphoma (NHL), diffuse large B-cell Non-Hodgkin’s Lymphoma (NHL) and for certain patients with rheumatoid arthritis.

**PURPOSE:** The purpose of this study is to determine the effectiveness of fludarabine, Velcade, and rituximab treatment regimen with relapsed or refractory follicular non-Hodgkin lymphoma.
Nursing Study: Impact of Exercise on CRF

SJH NURSING STUDY HB-35: Impact of Exercise on Cancer Related Fatigue (CRF)

RATIONALE: Fatigue is one of the most common and distressing symptoms experienced by patients with cancer. The most debilitating effect of CRF is the negative impact on the patient's health, well-being, and quality of life. For most patients, fatigue occurs with a cluster of symptoms such as pain, nausea, insomnia, and depression. Oncology nurses are in an ideal position to design interventions that may help patients maintain their individual primary, secondary, and tertiary roles in life. The oncology nurse can be instrumental in initiating exercise as an effective intervention to reduce CRF and increase quality of life.

PURPOSE: The purpose of this study is to see if a patient’s post-treatment participation in a supervised 60 day exercise program decrease CRF, and in return, improve their quality of life.

On Study Dr.:
Staci Oertle RN, BSN, OCN

Call SJH Cancer Services at (856) 641-8670 for further assistance.