

List for website: Last Updated 5/1/2012

BREAST CANCER

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

Neoadjuvant (Before Surgery)

C40603: Randomized phase II 2x2 factorial trial of the addition of carboplatin +/- bevacizumab to neoadjuvant weekly paclitaxel followed by dose-dense AC in hormone receptor poor/Her-2 negative resectable breast cancer One standard way to treat triple-negative breast cancer is to give chemotherapy before surgery. This is called “pre-operative” or “neoadjuvant” chemotherapy. The goal of neoadjuvant chemotherapy is to shrink the breast cancer and make it easier for a surgeon to completely remove it. Sometimes neoadjuvant chemotherapy works so well that no cancer is found in the breast at surgery. When this happens, it is called a pathologic complete response (pCR) which means there is no left-over cancer in the breast or lymph nodes. This study is being done to find out what happens, good and bad, when experimental drugs called bevacizumab and carboplatin are added to the regular neoadjuvant chemotherapy treatment to see if it can help shrink triple-negative breast cancer faster, and lower the risk of the cancer coming back in other part of the body. These drugs are approved by the Food and Drug Administration (FDA) for other uses but not for treatment of the type cancer you have. This means the way we are using them in the study is experimental.
Principal Investigator: Barbara Craft, M.D.

Inflammatory or Her-2 Neu Negative; Stage IIB or IIIA/B judged unresectable SWOG S0800: A randomized phase II trial of weekly nanoparticle albumin bound paclitaxel with or without bevacizumab, either preceded by or followed by q two-week doxorubicin and cyclophosphamide plus pegfilgrastim as neoadjuvant therapy for inflammatory and locally advanced her2-neu negative breast cancer The purpose of this study is to compare three different drug combinations for breast cancer before surgery to see if one works better than the other. The first drug combination is bevacizumab and nab-paclitaxel followed by doxorubicin, cyclophosphamide, and pegfilgratstim. The second and third drug combinations include the drug nab-paclitaxel, given either before or after doxorubicin, cyclophosphamide, and pegfilgrastim. Bevacizumab is approved for other uses but is not for breast cancer. This means the way we are using it in this study is experimental. All of the other drugs are approved for breast cancer. The other purpose of this study is to compare the type and severity of the side effects of each of the combinations.
Principal Investigator: Barbara Craft, MD

VICC BRE 0904; Stage II or III: A phase II neo-adjuvant study of cisplatin, paclitaxel with or without RAD 001 in patients with triple-negative locally advanced breast cancer

The purpose of this study is to try to find out if Everolimus (RAD001), Paclitaxel (Taxol ®) and Cisplatin (Platinol ®), shrinks the tumor better than Paclitaxel (Taxol ®) and Cisplatin (Platinol ®). Paclitaxel and Cisplatin are both approved by the Food and Drug Administration (FDA) to treat breast cancer. Everolimus is approved by the FDA for the treatment of advanced kidney cancer but it is not FDA approved for breast cancer treatment. This means its use in this study is experimental. Everolimus attacks a part of cancer cells that helps them live and grow. Non-human studies and early studies done in human beings suggest that Everolimus could make a difference in how well treatment works in triple-negative breast cancers.

Principal Investigator: Barbara Craft, M.D.

Recurrence and Survival in Early Stage Breast Cancer

NCIC MA.32: A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer

The purpose of this study is to find out whether it is better to receive the drug Metformin, with the usual treatment for breast cancer, or not.

Metformin is a drug that is commonly used to treat diabetes. We want to see if Metformin can decrease or affect the ability of breast cancer cells to grow and whether it will work with other therapy to keep cancer from returning. Previous laboratory work has shown that Metformin may decrease the growth of different types of cancer cells, including breast cancer cells. Research has also shown that Metformin lowers the level of insulin, a hormone found in the blood that can negatively affect breast cancer. **Principal Investigator:** Barbara Craft, M.D.

Breast Cancer with Metastatic Disease

E2108: A randomized phase III trial of the value of early local therapy for the intact primary tumor in patients with metastatic breast cancer

The standard treatment for metastatic breast cancer is the use of chemotherapy, anti-hormone pills, or other medication. For most people, the tumor in the breast is controlled with medicine and does not cause problems. We are doing this study to see if surgery and/or radiation used early in the course of treatment of the breast cancer will help people with metastatic breast cancer live longer or not. When the cancer has spread to other areas of the body, surgery and/or radiation for the tumor in the breast cannot control the other areas of the cancer and are only used if the breast tumor is causing skin breakdown or pain. In this study, you will get either surgery plus radiation, or continue with the usual treatment. **Principal Investigator:** Barbara Craft, M.D.

S0500: A randomized phase III trial to test the strategy of changing therapy versus maintaining therapy for metastatic breast cancer patients who have elevated circulating tumor cell levels at first follow-up assessment The purpose of this study is to find out if a new blood test called the CellSearch blood test can help predict survival outcome in people with breast cancer that has spread to other parts of the body. The CellSearch blood test identifies circulating tumor cells (CTCs) in the blood. The test may help doctors to tell if chemotherapy is not working before a person shows signs that the cancer is getting worse. This study will test whether switching to another treatment based upon the results of the CellSearch blood test helps people live longer. In addition, this study will also be used to further back up results of a prior study, which showed that people with less than five CTCs before they begin treatment are more likely to live longer than those with five or more CTCs.

Principal Investigator: Barbara Craft, M.D.

SWOG S0702: a prospective observational multicenter cohort study to assess the incidence of osteonecrosis of the jaw (ONJ) in cancer patients with bone metastases starting zoledronic acid treatment The purpose of this study is to learn how often osteonecrosis of the jaw (ONJ) which is death of the jaw bone caused by poor blood flow, occurs in people who are being treated with zoledronic acid. This study will also help us identify risk factors associated with ONJ.

Zoledronic acid falls under a category of drugs called bisphosphonates. Bisphosphonates are sometimes given to people who have cancer that has spread to their bones because it can lower the chances of getting fractures and reduces bone pain. Usually, zoledronic acid does not cause serious problems, but there has been an increase in the number of reported cases of ONJ and we want to see if this is caused by bisphosphonate therapy. Symptoms associated with ONJ are swelling of the soft tissue around the jaw, infection, loosening of teeth, drainage, and exposed jaw bone. **Principal Investigator:** Louis Punecky, M.D.

Adjuvant Studies (After surgery):

Ductal Carcinoma in Situ (DCIS): NSABP B-43: A phase III clinical trial comparing trastuzumab given concurrently with radiation therapy and radiation therapy alone for women with Her-2 positive ductal carcinoma in situ resected by lumpectomy Radiation therapy is the standard treatment for DCIS. This study is being done to find out what effects, good and/or bad, adding the experimental drug, Trastuzumab (Herceptin®), has on breast cancer. This drug is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental. Trastuzumab has been shown to block the HER2 protein and to slow down or stop the growth of HER2-positive “invasive” breast cancers. (“Invasive” means the cancer has spread outside the milk ducts into other parts of the breast or to other parts of the body.) Also, there is early information that suggests trastuzumab may be a “radiosensitizer”. This means that trastuzumab may help radiation therapy work better in HER2-positive breast cancer. More research is needed to prove this. **Principal Investigator:** Barbara Craft, M.D.

NSABP B-39/RTOG 0413: A randomized phase III study of conventional whole breast irradiation (WBI) versus partial breast irradiation (PBI) for women with stage 0, I, or II breast cancer who have had lumpectomies only The purpose of this study is to see if partial breast irradiation (PBI) is as good as or better than whole breast irradiation (WBI) in keeping cancer from coming back in the breast. WBI is a standard treatment after a lumpectomy. WBI is radiation therapy given five days a week for five to seven weeks to the whole breast. PBI is radiation therapy given only to the area of the breast where the cancer was removed. PBI is given two times a day on five days. PBI may be given over a period of five to ten days.
Principal Investigator: Sirinivasan Vijayakumar, M.D.

NSABP B-47: Randomized phase III trial of adjuvant therapy comparing chemotherapy alone (6 cycles of AC or 4 cycles of AC+T) to chemotherapy + herceptin in women with node-positive or high-risk negative HER-2 breast cancer This study is being done to find out if adding a targeted therapy, trastuzumab (Herceptin®), to standard treatment with chemotherapy for early stage, HER2-low breast cancer, will prevent breast cancer from returning and help women live longer. Trastuzumab is called a targeted therapy because it targets the tumor cells by blocking the HER2 protein on the surface of the cancer cell to slow down or stop cancer growth. This drug is approved for treatment of HER2-positive breast cancer but not for HER2-low breast cancer, which is the type of cancer you have. This means the way we are using it in the study is experimental.
Principal Investigator: Barbara Craft, M.D.

SWOG S1007: A phase III randomized clinical trial of standard adjuvant endocrine therapy +/- chemotherapy in patients with 1-3 positive nodes hormone receptor positive and HER-2 negative breast cancer with recurrence score of 25 or less This study is being done to find out if the Oncotype DX® Recurrence Score can help decide whether some people should receive chemotherapy or not. Currently most women who have this type of breast cancer are treated with endocrine therapy (treatment that works with hormones) or chemotherapy. No one knows which breast cancer patients with lower recurrence scores need to get chemotherapy. Some women may be getting chemotherapy who do not need it. These women may be exposed to side effects that are not a necessary risk to the benefit they receive. If the results of this study show that the benefit for getting chemotherapy is dependent on the recurrence score, we might be able to identify a recurrence score level where chemotherapy should be considered and a recurrence score level where chemotherapy may not be needed.
Principal Investigator: Barbara Craft, M.D.

GASTROINTESTINAL

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

Carcinoid

S0518: Phase III prospective randomized comparison of depot octreotide plus interferon alpha versus depot octreotide plus bevacizumab in advanced poor-prognosis carcinoid patients

This study is being done to see which works better, octreotide plus bevacizumab or octreotide plus interferon, and what effects, good and/or bad, they have on the tumor.

Interferon is considered an accepted treatment for carcinoid tumors. Octreotide is an accepted treatment and standard treatment for carcinoid syndrome. The combination of octreotide and interferon is considered a standard option even for people who have progressed on octreotide alone. Bevacizumab is the common name for the commercial drug Avastin. Bevacizumab is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental. Bevacizumab is thought to work by blocking the effect of a protein. This protein can make tumors and the blood vessels around it grow. By blocking the protein, we are trying to stop the tumor from growing.

Principal Investigator: Louis Punecky, M.D.

Extrahepatic Cholangiocarcinoma- Adjuvant

S0809: A phase II trial of adjuvant capecitabine/gemcitabine chemotherapy followed by concurrent capecitabine and radiotherapy in extrahepatic cholangiocarcinoma

The purpose of this study is to find out what effects, good or bad, capecitabine, gemcitabine and radiation have on you and your cholangiocarcinoma.

Principal Investigator: Louis Punecky, M.D.

COLON: Stage III

C80702: A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer

This study is being done to find out what effects, good or bad, an experimental drug called celecoxib, which is not yet approved by the Food and Drug Administration, has on colon cancer when given in combination with FOLFOX chemotherapy [FOLFOX] 5-fluorouracil (also called 5-FU), leucovorin and oxaliplatin, is standard treatment used to prevent colon cancer from coming back. This drug is approved for other uses such as arthritis and prevention of colon polyps but not for treatment of colon cancer. This study will help us determine if celecoxib plus chemotherapy decreases the risk of colon cancer coming back. This study will also look at whether receiving FOLFOX chemotherapy for six cycles (12 weeks) is as good as 12 cycles (24 weeks) in keeping the colon cancer from coming back with fewer side effects. Currently, the standard of care for your stage of colon cancer is 12 treatments with FOLFOX. **Principal Investigator:** Louis Punecky, M.D.

Esophageal (No Surgery)

RTOG 0436: A phase III trial of the addition of cetuximab to paclitaxel, cisplatin, and radiation for patients with esophageal cancer who are treated without surgery The purpose of this study is to compare the effects, good and bad, of radiation therapy plus paclitaxel and cisplatin to radiation therapy plus paclitaxel, cisplatin, and cetuximab, to see which works better. Cetuximab may delay or prevent tumor growth by stopping chemicals that help the tumor grow. Cetuximab is approved for the treatment of colorectal and head and neck cancers but is experimental for esophageal cancer.

Principal Investigator: Shankar Giri, M.D.

Esophageal (Resectable)

RTOG 1010: A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma

This study is being done to compare the effects, good and/or bad, of the addition of trastuzumab to standard chemotherapy, radiation and surgery for patients with HER2 positive esophageal adenocarcinoma.

The standard treatment for esophageal adenocarcinoma is radiation therapy and chemotherapy treatment with the drugs paclitaxel and carboplatin, followed by surgery to remove the esophagus. This study will test whether the addition of the drug trastuzumab can help prevent esophageal adenocarcinoma from coming back.

Trastuzumab is a drug that can only be effective in cancers that are HER2 positive. HER2 positive means that cancer cells have an increased amount of a protein called human epidermal growth factor receptor 2 (HER2), which is known to promote the growth of cancer cells.

Trastuzumab attaches to the HER2 proteins and interferes with the reproduction of cancer cells. In patients with HER2 positive breast cancer, trastuzumab has been proven to reduce cancer from growing back but it is considered experimental for use in esophageal adenocarcinoma.

Principal Investigator: Pierre de Delva, M.D.

Pancreas (Resectable)

ACOSOG Z5041: Phase II study of preoperative gemcitabine and erlotinib + pancreatectomy and postoperative gemcitabine and erlotinib for patients with operable pancreatic adenocarcinoma This study is being done to find out what effects, good and/or bad, the experimental drugs, gemcitabine and erlotinib, have on you and on pancreatic cancer when given before surgery. This study is also trying to answer whether the same combination of chemotherapy can be given safely after surgery and reduce the chances of cancer returning. Both of these drugs are approved for pancreatic cancer but not when given before surgery. This means the way we are using them in this study is experimental.

Principal Investigator: Thomas Helling, M.D.

Rectal (Stage II and III)

S0713: A phase II study of oxaliplatin, capecitabine, cetuximab, and radiation in pre-operative therapy of rectal cancer The purpose of this study is to find out what effects, good and/or bad, the combination of the chemotherapy drugs oxaliplatin, capecitabine, and cetuximab, plus radiation therapy and surgery has on you and your rectal cancer.

Principal Investigator: Louis Punecky, M.D.

Liver/ Hepatocellular

E1208: A phase III randomized trial of chemoembolization with or without sorafenib in unresectable hepatocellular carcinoma in patients with and without vascular invasion

The purpose of this study is to see if adding the oral chemotherapy pill, sorafenib (Nexavar), to localized chemotherapy (chemoembolization) to the liver will help people live longer than localized chemotherapy alone. Both chemoembolization and sorafenib are standard treatments that can be used to treat your type of liver cancer, but they are not used together. This study will attempt to determine if the combination is better than chemoembolization alone.

Principal Investigator: Louis Punecky, M.D.

CALGB 80802: Phase III randomized study of sorafenib (IND 69896, NSC 724772) plus doxorubicin versus sorafenib in patients with advanced hepatocellular carcinoma (HCC)

This study is being done to compare the effects, good or bad, of Sorafenib to the combination of sorafenib plus doxorubicin on you and your advanced primary liver cancer to find out which is better. Participants will get either the combination of sorafenib plus doxorubicin or you will receive sorafenib alone. Sorafenib is approved by the Food and Drug Administration (FDA) for the treatment of hepatocellular carcinoma.

Doxorubicin has been used in the treatment of different cancers, including hepatocellular cancer, but is not FDA approved for hepatocellular cancer. The use of the combination of sorafenib and doxorubicin is also not approved by the FDA for hepatocellular carcinoma. This means the way we are using it in the study is experimental.

Principal Investigator: Louis Punecky, M.D.

GENITOURINARY

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

NEOADJUVANT: High-risk Clinically-localized Prostate

CALGB 90203: A randomized phase III study of neo-adjuvant docetaxel and androgen deprivation prior to radical prostatectomy versus immediate radical prostatectomy in patients with high-risk clinically localized prostate cancer The purpose of this study is to compare the effects, good and bad, of the combination of chemotherapy and hormone therapy followed by radical prostatectomy (surgery to remove your prostate) to radical prostatectomy alone on prostate cancer to see which is better. **Principal Investigator:** Charles Pound, M.D.

RTOG 0924: Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial This study is being done to compare the effects of hormone therapy (androgen deprivation) and radiation therapy to the prostate gland and seminal vesicles to hormone therapy and radiation therapy to the whole pelvic body area to find out which is better. **Principal Investigator:** Srinivasan Vijayakumar, M.D.

S1014: Abiraterone Acetate Treatment for Prostate Cancer Patients with a PSA of More Than Four Following Initial Androgen Deprivation Therapy, Phase II This study is being done to find out what effects, good or bad, an experimental drug called abiraterone acetate has on you and on your prostate cancer. The prostate specific antigen (PSA) is a blood test used in prostate cancer screening and also to follow prostate cancer. In this study, we will follow your PSA level to help determine if abiraterone acetate is beneficial and reduces PSA. We will be looking to see if abiraterone acetate improves the effectiveness of standard hormonal shots or injections.

Abiraterone acetate is a hormonal pill that has been approved by the Food and Drug Administration (FDA) for people with more advanced prostate cancer who have received chemotherapy. It is considered experimental for your type of prostate cancer.

Principal Investigator: R. Darryl Hamilton, M.D.

Metastatic Prostate

E3805: CHARTED: Chemohormonal therapy versus androgen ablation randomized trial for extensive disease in prostate cancer This study is being done to find out what effects, good or bad, an experimental drug, not yet approved by the Food and Drug Administration, called Docetaxel, has on you and on your prostate cancer. Hormonal therapy refers to drugs or surgical procedures such as an orchiectomy (removal of testicles) which lowers your testosterone. The hormonal therapy puts prostate cancer into remission in most people as the testosterone is like a fuel for the cancer. It is the standard to give this as the only treatment for this type of cancer. Normally chemotherapy is not given until a person's cancer starts to grow

again despite having a low testosterone level. The purpose of this study is to determine whether getting docetaxel early, when you start hormone therapy (or within 120 days of beginning it) is better than getting it later, only if your disease gets worse. This drug is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental. **Principal Investigator:** Charles Pound, M.D.

SWOG S0702: a prospective observational multicenter cohort study to assess the incidence of osteonecrosis of the jaw (ONJ) in cancer patients with bone metastases starting zoledronic acid treatment The purpose of this study is to learn how often osteonecrosis of the jaw (ONJ) which is death of the jaw bone caused by poor blood flow, occurs in people who are being treated with zoledronic acid. This study will also help us identify risk factors associated with ONJ. Zoledronic acid falls under a category of drugs called bisphosphonates. Bisphosphonates are sometimes given to people who have cancer that has spread to their bones because it can lower the chances of getting fractures and reduces bone pain. Usually, zoledronic acid does not cause serious problems, but there has been an increase in the number of reported cases of ONJ and we want to see if this is caused by bisphosphonate therapy. Symptoms associated with ONJ are swelling of the soft tissue around the jaw, infection, loosening of teeth, drainage, and exposed jaw bone.
Principal Investigator: Louis Punecky, M.D.

Kidney/Renal (After Nephrectomy)

S0931: EVEREST: Everolimus for renal cancer ensuing surgical therapy, a phase III study. The standard of care after kidney cancer surgery is careful monitoring with no immediate treatment. Studies suggest that one way kidney cancer may grow is through chemical signaling of a protein named “mTOR”. The purpose of this study is to see whether treatment with everolimus after surgery for kidney cancer will increase the time without cancer returning. Everolimus is a drug that stops signaling through mTOR and may stop the growth of kidney cancer. Everolimus is approved for people with advanced or metastatic kidney cancer. However, it is not approved for use after surgery. This means the way we are using it in the study is experimental. **Principal Investigator:** Louis Punecky, M.D.

Advanced Kidney/Renal (not a candidate for surgery)

CALGB 90601: A randomized double-blinded phase III study comparing gemcitabine, cisplatin, and bevacizumab to gemcitabine, cisplatin, and placebo in patients with advanced transitional cell carcinoma This study is being done to compare the effects, good and/or bad, of gemcitabine and cisplatin to gemcitabine, cisplatin and the experimental drug, bevacizumab (Avastin), on you and on transitional cell carcinoma. The combination of gemcitabine and cisplatin is a standard treatment for people with transitional cell carcinoma. We think Bevacizumab can block a protein called VEGF and inhibit the growth of new blood vessels. It has been approved by the Food and Drug Administration (FDA) for the treatment of metastatic colorectal, lung, and breast cancer but not for use in transitional cell carcinoma. This

research is also being done to see if adding bevacizumab to gemcitabine and cisplatin will delay the growth of cancer and allow people to live longer than standard treatment.

Principal Investigator: Louis Punecky, M.D.

GYNECOLOGIC CANCER

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

Cervix

GOG 227G: A Phase II Evaluation of Brivanib (BMS582664, IND #108417) in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (BMS Study CA 182-048)

This study is being done to find out how the study drug, Brivanib, works in treating your type of cancer and to find out what side effects, good or bad, are caused by the treatment.

Brivanib is an experimental drug, not approved by the Food and Drug Administration (FDA) that works by blocking proteins that help the tumor grow. Vascular endothelial growth factor receptor 2 (VEGFR2) is a protein that causes tumor cells to grow and stimulates the growth of tumor blood vessels. Fibroblast growth factor receptor (FGFR) is another protein that causes the growth of tumor cells. By stopping VEGFR2 and FGFR from working, Brivanib may cause the tumor to shrink. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 263: A 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

Cervical cancer is classified as low, intermediate, or high risk of recurrence based on what the tumor looks like. Women who are high risk are given radiation therapy and chemotherapy. Women who are intermediate risk are given radiation therapy alone.

The purpose of this study is to determine if weekly chemotherapy with Cisplatin and radiation therapy works better than radiation alone for intermediate risk and increases the time before the cancer comes back. The study will also look at side effects good and/or bad of these treatments. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG/RTOG 0724: A phase III randomized study of concurrent chemotherapy and pelvic radiation therapy with or without adjuvant chemotherapy in high risk patients with early stage cervical carcinoma following radical hysterectomy

The purpose of this study is to compare the effects, good and/or bad, of giving the additional chemotherapy medicines carboplatin and paclitaxel to you after the standard treatment of cisplatin and radiation therapy.

The study drugs carboplatin and paclitaxel are approved for other uses but not for treatment of the type of cancer you have. This means the way we are using them in the study is experimental. This study will also look at biologic factors that may help predict and treat cervical cancer and will gather information about the effects of radiation therapy and chemotherapy on the overall quality of life. One of the standard treatments for your stage and type of cervical cancer is external beam radiation therapy. Both three dimensional radiation therapy and IMRT allow the radiation beam to treat an area that is shaped like your tumor and also to penetrate as deeply as your tumor is located. By treating this way, the dose of radiation to the health areas near your tumor is minimized, and the dose to your tumor is maximized.

Principal Investigator: J. Tate Thigpen, M.D.

Advanced, Persistent or Recurrent Cervix

GOG 76HH: A Limited Access Phase I/II Trial of Paclitaxel, Cisplatin and CTEP Supplied Agent ABT-888 (Veliparib) (IND #77840, NSC #737664) in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix

This study has two parts with different purposes. The first part, called Phase 1, is being done to determine the safest dose of ABT-888 (Veliparib) to be given in the pill form with cisplatin and paclitaxel. Phase 1 has eight different dose amounts for ABT-888. Level 1 is a dose of 50mg twice a day, then each subsequent dose is 50 mg higher, up to Level 8, which is 400 mg twice a day. The dose for cisplatin and paclitaxel does not increase. There will be 3 to 6 participants enrolled at each dose level until the safest, highest dose level of ABT-888 is found. At each dose level, the side effects will be monitored and when it is determined that a dose level is the most that ABT-888 can be given without causing bad side effects, Phase I will close and the second part of the study will open.

The second part of the study, Phase 2, will try to determine how ABT-888, given with paclitaxel and cisplatin, works in treating cervical cancer and what type of side effects, good or bad, are caused by treatment with ABT-888. Participants in Phase 2 will be treated with the highest dose of ABT-888 that is found to not cause significant problems in the Phase I portion. The dose of all three drugs will remain the same for the entire Phase 2 portion.

Because the findings from Phase I will determine the safest dose of ABT-888 to give, Phase 1 must be finished before we can enroll participants into Phase 2. At this time, we are only accepting participants into the Phase I study.

ABT-888 is an experimental drug, not approved by the Food and Drug Administration (FDA). ABT-888 kills cancer cells by interfering with the cells ability to repair itself when damaged, which can lead to a decrease in cancer cell activity.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 127W: A phase II evaluation of ABT-888, topotecan and filgrastim or pegfilgrastim in squamous or non-squamous cell carcinoma of the cervix

This study is being done to find out how the study drug ABT-888, given with the chemotherapy drug Topotecan, works in treating your type of cancer and to find out what side effects, good or bad, are caused by treatment with ABT-888.

ABT-888 is an experimental drug, not approved by the Food and Drug Administration (FDA) that kills cancer cells by interfering with the cells ability to repair itself when damaged. Topotecan is approved by the FDA and also kills cancer cells by preventing the cell from repairing itself.

These two drugs may act together to kill an even greater number of cancer cells.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 274: A PHASE III TRIAL OF ADJUVANT CHEMOTHERAPY AS PRIMARY TREATMENT FOR LOCALLY ADVANCED CERVICAL CANCER COMPARED TO CHEMORADIATION ALONE: THE OUTBACK TRIAL (ANZGOG 0902/GOG-0274/RTOG 1174)

This study will try to determine which of two treatments improves the overall survival rate of cervical cancer and best reduces the chance of the cancer coming back, if it disappears as a result of study treatment. The study will also look at how the treatments affect you and your quality of life, good and/or bad.

The two treatments being compared on this study are:

- Standard treatment - Radiation therapy and cisplatin chemotherapy given at the same time (chemo-radiation).
- Standard chemo-radiation treatment, then additional treatments of carboplatin and paclitaxel chemotherapy (adjuvant chemotherapy).

Adjuvant chemotherapy is considered experimental for this study but has been shown to reduce the risk of other types of cancer from coming back in other places of the body.

Principal Investigator: J. Tate Thigpen, M.D.

Ovary

Advanced Ovarian

GOG 186H: Phase II study of weekly taxol versus weekly taxol with oncolytic reovirus in treatment of recurrent or persistent ovarian This study is being done to find out what effects, good or bad, the drug REOLYSIN has on you and your type of cancer and to find out if REOLYSIN with another chemotherapy drug, paclitaxel, works better than paclitaxel alone. REOLYSIN is a virus that is present throughout the environment and can cause flu-like symptoms, but it is not known to have any long term effects. Previous research has shown that this virus targets cancer cells more than normal cells, and can shrink some solid tumors. This drug is not approved for treatment of your type of cancer. This means the way we are using it in the study is experimental. **Principal Investigator:** J. Tate Thigpen, M.D.

Ovarian, Primary Peritoneal, or Fallopian Tube Cancer

GOG-0170P: A PHASE II EVALUATION OF AMG 102 (RILOTUMUMAB) (IND # 107579, NSC #750009) IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CARCINOMA (AMGEN STUDY #20070612)

This study is being done to find out what effects, good or bad, an experimental drug, not approved by the Food and Drug Administration, called AMG 102 (rilotumumab) (IND #107579, NSC #750009), has on you and on your cancer. AMG 102 (rilotumumab) works to block and interrupt HGF, hepatocyte growth factor, which is found in tumor cells and is thought to help the growth and spread of cancer cells. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 170Q: A phase II evaluation of intraperitoneal EGEN-001 in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer This study is being done to find out what effects, good or bad, an experimental drug, not yet approved by the Food and Drug Administration, called EGEN-001, has on you and on your type of cancer. EGEN-001 has a type of protein called IL-12 that is used to fight cancer. EGEN-001 is given directly into the belly through a tube (intraperitoneal catheter). EGEN-001 is designed to enter cells and start making IL-12, which will help the immune system fight cancer cells in the belly. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 186I: A RANDOMIZED PHASE II EVALUATION OF SINGLE-AGENT BEVACIZUMAB (IND #7921) (NSC #704865) AND COMBINATION BEVACIZUMAB WITH FOSBRETABULIN TROMETHAMINE (CA4P) (NSC #752293) IN THE TREATMENT OF RECURRENT OR PERSISTENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CARCINOMA

This study is being done to compare the effectiveness, good or bad, of the drug bevacizumab to the combination of bevacizumab and the drug fosbretabulin tromethamine (CA4P) in treating your type of cancer and to determine the types and severity of side effects caused by these drugs. These drugs are approved for other uses but not for treatment of the type of cancer you have. This means the way we are using them in the study is experimental.

Bevacizumab has been studied in ovarian cancer and shown to be effective at shrinking tumors. It is thought to work by blocking the effect of Vascular Endothelial Growth Factor (VEGF), a protein made by tumors which can stimulate growth of tumor cells as well as blood vessels in and around tumors in some patients.

Fosbretabulin tromethamine (CA4P), is able to recognize the abnormal blood vessels in the cancer and “stick” to the inside walls of the abnormal blood vessels. When fosbretabulin tromethamine “sticks” to the abnormal blood vessels, the shape of the blood vessels that connect to the cancer cells change. This change can stop the blood flow to the cancer cells, which causes the cancer cells to die.

Bevacizumab prevents new blood vessels from growing. The theory is that if we can destroy the existing cancer-related blood vessels with fosbretabulin tromethamine and prevent new ones from growing with bevacizumab, we might be able to completely eradicate the cancer. However, the combination of the two drugs could also increase the side effects although this has not been seen in lung cancer patients treated with fosbretabulin tromethamine and bevacizumab together. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 212: A randomized phase II trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or xyotax versus no treatment until documented relapse in women with advanced ovarian or primary peritoneal cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy

Standard chemotherapy for your cancer is effective, but a long-term cure is uncommon. Many patients will eventually develop recurrent disease and need additional treatment. We are trying to see if new chemotherapy combinations will improve on the success achieved with current standard treatment programs. Primary peritoneal and fallopian tube cancers are considered identical to ovarian cancers in terms of microscopic appearance and treatment; they differ only

by the initial body site of cancer development. In this study we wish to learn whether women with advanced ovarian, primary peritoneal, or fallopian tube cancer who have no evidence of disease after the completion of initial chemotherapy live longer if chemotherapy is continued once a month for 12 months. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 213: Phase III study randomized controlled trial of carboplatin and paclitaxel alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer

One purpose of this study is to compare treatment with the combination of carboplatin, paclitaxel and bevacizumab to the standard combination of carboplatin and paclitaxel alone. To see if the treatment works, we will look at survival, time without evidence of cancer growth, and quality of life. A second purpose of this study is to determine if a second surgery to remove tumor before starting the chemotherapy can increase the time that you remain without cancer. A second surgery will only be done if you are a good candidate for the surgery. Another purpose of this study is to test blood and tissue samples to see if we can learn how to predict who may respond to treatment, have side effects, or have a better chance of recovery. This part of the study is optional and you do not have to be in the optional part of the study to be in the main study. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 229K: A Phase II Evaluation of BIBF 1120 (IND# 113086) in the treatment of recurrent or persistent endometrial carcinoma

This study is being done to find out the effects, good or bad, of the experimental drug BIBF 1120 in treating your type of cancer and to determine the types and severity of side effects caused by this treatment. BIBF 1120 is not an FDA approved drug, which means it is experimental for endometrial cancer. The reason this drug is being looked at in endometrial cancer is that it has demonstrated being able to stop three proteins from working: vascular endothelial growth factor (VEGFR), platelet-derived growth factor receptor (PDGFR) and fibroblast growth factor receptor (FGFR). These three proteins work by turning on (stimulating) the growth of tumor cells. If BIBF 1120 can stop the three proteins from working it may cause the cancer to shrink by stopping the growth of tumor blood vessels and tumor cells.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 235: A prospective, longitudinal study of YKL-40 in patients with FIGO stage III or IV invasive epithelial ovarian, primary peritoneal, or fallopian tube cancer undergoing primary chemotherapy

This study is being done to find out if an experimental blood test, called YKL-40 works better than the CA-125 blood test, which is the test that is currently used to detect ovarian cancer. Researchers hope that this test will provide more accurate results than the current test and help us know earlier when a cancer treatment is not working, if the cancer has come back, or if the cancer has spread. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 241: GCIG intergroup multicenter phase III trial of open label carboplatin and paclitaxel +/- bevacizumab compared with oxaliplatin and capecitabine +/- bevacizumab as first-line chemotherapy in patients with mucinous epithelial ovarian or fallopian tube

This study is being done to compare four treatments and to see how they work in treating your type of cancer and to find out what side effects, good or bad, they cause. The four treatments are:

- 1) Carboplatin and paclitaxel
- 2) Oxaliplatin and capecitabine
- 3) Carboplatin, paclitaxel and bevacizumab
- 4) Oxaliplatin, capecitabine and bevacizumab

Carboplatin and paclitaxel are the current standard treatment for ovarian or fallopian tube cancer and oxaliplatin and capecitabine are the standard treatment for gastrointestinal cancer. Some research has shown that mucinous carcinoma may act the same as some gastrointestinal cancers, which might mean that the drugs used to treat gastrointestinal cancer may be effective on your type of cancer. Bevacizumab is approved by the U.S. Food and Drug Administration (FDA) for use in people with colon, lung, and breast cancer, but not for ovarian or fallopian tube cancer. Bevacizumab blocks a protein called Vascular Endothelial Growth Factor (VEGF) that is made by tumors. VEGF helps tumor cells to make blood vessels. By blocking VEGF, Bevacizumab can block the blood flow to the tumor and make the tumor shrink.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 254 : Phase II evaluation of sunitinib in persistent or recurrent clear cell ovarian carcinoma

The purpose of this study is to find out if SU11248 (sunitinib malate) works in treating your type of cancer and to learn about its side effects. This drug is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental. Sunitinib blocks a mechanism that controls the growth of cancer cells. It stops a hormone called vascular endothelial growth factor (VEGF) from working.

Principal Investigator: J. Tate Thigpen, M.D

GOG 260: A phase II evaluation of elesclomol sodium and weekly paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer

This study is being done to find out what effects, good or bad, the combination of Paclitaxel and Elesclomol sodium have on your type of cancer.

Paclitaxel is a drug that has been shown useful in treating ovarian, uterine and cervical cancer. Elesclomol sodium is an experimental drug, not approved by the Food and Drug Administration (FDA) that is thought to make cancer cells react better to paclitaxel. Combining paclitaxel and elesclomol may be more effective than paclitaxel alone in shrinking tumors and slowing cancer cell growth and progression. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 262: A randomized phase III trial of every 3 weeks paclitaxel with carboplatin versus dose dense weekly paclitaxel combined with carboplatin with or without concurrent and consolidation bevacizumab in the treatment of primary stage III with or greater than 1 centimeter residual disease or IV epithelial ovarian, peritoneal or fallopian tube cancer The current standard treatment for ovarian, fallopian tube, and primary peritoneal

cancer is carboplatin and paclitaxel, given every three weeks. Recent studies have shown that giving paclitaxel every week can increase the length of time without disease, but it caused more anemia (low red blood cell count) and more problems, including tingling and numbness. The purpose of this study is to compare the effectiveness and side effects of carboplatin plus paclitaxel every three weeks to carboplatin every three weeks plus paclitaxel once a week, with or without bevacizumab. In this study you will choose if you take bevacizumab. Bevacizumab is approved by the U.S. Food and Drug Administration (FDA) for use in people with colon, lung, and breast cancer, but not for ovarian, fallopian tube or peritoneal cancer. Studies have shown that people with colon cancer live longer if they get bevacizumab. Studies have also shown that people with lung and breast cancer had more time without cancer growth if they got bevacizumab. Bevacizumab is another name for the drug Avastin. It is a type of drug that blocks a protein that is made by tumors called Vascular Endothelial Growth Factor (VEGF). VEGF helps tumor cells to make blood vessels. By blocking VEGF, Bevacizumab can block the blood flow to the tumor and make the tumor shrink. Bevacizumab might cause people to have more side effects. These risks are listed later in the document.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 267: Quality of life and care needs in patients with persistent or recurrent platinum-resistant ovarian, fallopian tube, and peritoneal cancer

The purpose of this study is to assess the quality of life and needs of women with advanced ovarian cancer, fallopian tube, or peritoneal cancer, as well as the support available to them. The study will look at how patients' symptoms and needs affect their health and their quality of life. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 268: A phase II evaluation of temsirolimus in combination with carboplatin and paclitaxel followed by temsirolimus consolidation as consolidation as first-line therapy in the treatment of stage III-IV clear cell carcinoma of the ovary

This study is being done to find out the effects, good or bad, an experimental drug, called Temsirolimus (CCI-779) plus paclitaxel and carboplatin has on your type of cancer.

This drug is approved by the Food and Drug Administration (FDA) for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental. **Principal Investigator:** J. Tate Thigpen, M.D.

Ovary: Stromal

GOG 0251- A Phase II Trial of Bevacizumab (rhuMAB VEGF) for Recurrent Sex Cord-Stromal Tumors of the Ovary

The purpose of this study is to find out the effects, good or bad, Bevacizumab has on you and your type of cancer. This drug is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental.

Principal Investigator: J. Tate Thigpen

GOG 187 - Phase II study of paclitaxel for ovarian stromal tumors as second-line therapy

You have a malignant stromal tumor of the ovary. The purpose of this study is to see if paclitaxel will reduce or get rid of your cancer. This study will evaluate how effective the drug

will be on your type of cancer and evaluate side effects of the drug paclitaxel. This is considered new treatment for your disease and is an attempt to see how successful this drug will be in treating the disease that you have. Radiation therapy is not effective for this stage of your disease and further surgery is usually not helpful.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 264: A randomized phase II trial of paclitaxel and carboplatin versus bleomycin, etoposide and cisplatin for newly diagnosed advanced stage and recurrent chemo-naïve stage sex cord-stromal tumors of the ovary The purpose of this study is to compare treatment with the drugs carboplatin and paclitaxel to standard treatment (paclitaxel, ifosfamide, and mesna). Based on other studies, researchers think that the combination of carboplatin and paclitaxel may work as well as the standard treatment, but have less side effects.

Principal Investigator: J. Tate Thigpen, M.D.

Ovary: Carcinosarcoma

GOG 261: Phase III trial of paclitaxel plus carboplatin versus ifosfamide plus paclitaxel in chemotherapy naïve patients with newly diagnosed stage I-IV or persistent or recurrent carcinosarcoma of the uterus and ovary The purpose of this study is to compare treatment with the drugs carboplatin and paclitaxel to standard treatment (paclitaxel, ifosfamide, and mesna). Based on other studies, researchers think that the combination of carboplatin and paclitaxel may work as well as the standard treatment, but have fewer side effects.

Principal Investigator: J. Tate Thigpen, M.D.

Uterus – Endometrial

GOG 0229J- A phase II Evaluation of Cediranib (Recentin: AZD2171, IND #72740, NSC#732208) in the treatment of recurrent or persistent endometrial carcinoma

This study is being done to find out what effects, good or bad, an experimental drug, called Cediranib (Recentin), has on you and on your cancer.

This drug is approved for prostate, brain, breast and kidney tumors but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental.

Cediranib seems to work by blocking proteins that are thought to help cancer cells grow.

Principal Investigator: J. Tate Thigpen, MD

GOG 229L: A Phase II Trial of AMG 386 (IND #111071), A Selective Angiopoietin ½ Neutralizing Peptibody, in Patients with Persistent/Recurrent Carcinoma of the Endometrium

This study is being done to find out if the study drug, AMG 386, works in treating your type of endometrial cancer and to find out what side effects the drug causes.

AMG 386 is an experimental drug not approved by the Food and Drug Administration (FDA) that is designed to stop the formation of blood vessels and block the growth of tumors.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 238: Randomized trial of pelvic irradiation with or without concurrent weekly cisplatin with pelvic only recurrence of uterine carcinoma The purpose of this study is to compare radiation therapy plus weekly treatment with the chemotherapy drug cisplatin to radiation therapy alone, which is the standard treatment for this type of cancer. Radiation therapy is a cancer treatment that uses radiation beams from outside your body, or radioactive seeds or pellets placed directly into the tissue to kill cancer cells. Another purpose of the study is to evaluate the side effects of the combination of radiation therapy and cisplatin.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 249 : 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 This study is being done to find out if vaginal radiation therapy plus the chemotherapy drugs carboplatin and paclitaxel works better than radiation therapy to the pelvis to reduce the chance that the cancer could come back. Radiation therapy to the pelvis alone is the standard of care in your type of cancer. Vaginal radiation therapy plus chemotherapy is experimental. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 258: A Randomized phase III trial of cisplatin and tumor volume directed irradiation followed by carboplatin and paclitaxel versus carboplatin and paclitaxel for optimally debulked, advanced endometrial carcinoma This study is being done to find out if radiation therapy plus chemotherapy given for 4 cycles works better than standard treatment, chemotherapy for 6 cycles. **Principal Investigator:** J. Tate Thigpen, M.D.

Uterine Sarcoma

130F:A phase II evaluation of ixabepilone in the treatment of recurrent or persistent carcinosarcoma of the uterus This study is being done to find out what effects, good or bad, an experimental drug, called Ixabepilone, has on uterine cancer and to find out what side effects it causes. This drug is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental.

Ixabepilone is a type of drug called an epothilone. Epothilones are similar to paclitaxel (a common chemotherapy drug), but have the potential to work in cells that are resistant to paclitaxel. Ixabepilone has caused tumors to shrink or stop growing for a period of time in previous studies. **Principal Investigator:** J. Tate Thigpen, M.D.

GOG 250 : Phase III of docetaxel and gemcitabine plus G-CSF with bevacizumab versus docetaxel and gemcitabine plus G-CSF with placebo in recurrent or advanced leiomyosarcoma of the uterus We are doing this study to try and find out if adding bevacizumab to gemcitabine and docetaxel will help treat your type of cancer and the side effects it may cause. Gemcitabine and docetaxel are standard of care for leiomyosarcoma. Bevacizumab is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental.

Principal Investigator: J. Tate Thigpen, M.D.

GOG 261: Phase III trial of paclitaxel plus carboplatin versus ifosfamide plus paclitaxel in chemotherapy naïve patients with newly diagnosed stage I-IV or persistent or recurrent carcinosarcoma of the uterus and ovary

The purpose of this study is to compare treatment with the drugs carboplatin and paclitaxel to standard treatment (paclitaxel, ifosfamide, and mesna). Based on other studies, researchers think that the combination of carboplatin and paclitaxel may work as well as the standard treatment, but have fewer side effects.

Principal Investigator: J. Tate Thigpen, M.D.

HEAD AND NECK

For further information regarding these studies, contact: **Cancer Research & Registry 601-984-1095**

Thyroid and Parathyroid

University Thyroid and Parathyroid Tumors Tissue Bank The purpose of this tissue bank is to collect leftover thyroid and/ or parathyroid tissue from surgical procedures and take blood and saliva samples to keep and use for future research. This research may include things like testing the samples to look for things that might affect thyroid and/ or parathyroid tumors.

Principal Investigator: Karen Pitman, MD

RTOG 0912: A Randomized Phase II Study of Concurrent Intensity Modulated Radiation Therapy (IMRT), Paclitaxel and Pazopanib (NSC 737754)/Placebo, for the Treatment of Anaplastic Thyroid Carcinoma Chemotherapy and radiation therapy to the neck is the standard treatment for anaplastic thyroid cancer. The purpose of this study is to determine whether adding pazopanib to paclitaxel and radiation (chemoradiotherapy) is safe and tolerable. The study also will compare the effects, good and/or bad, of chemoradiotherapy and pazopanib to chemoradiotherapy and a placebo to find out which is better. A placebo looks like the experimental drug but does not have any drug in it. The standard treatment of surgery followed by radiation therapy can stop thyroid tumors from growing in most people, but the cancer can come back or spread to other parts of the body. Pazopanib is an experimental drug that may reduce the size of the tumor and delay the growth of the tumor. Pazopanib is approved by Food and Drug Administration (FDA) for treatment of kidney cancer, but the way we are using it in this study is experimental. Paclitaxel is a chemotherapy drug that may slow down or stop the tumor from growing by blocking chemical pathways that allow it to grow. Paclitaxel is approved by the FDA for treatment of ovarian, lung and breast cancer. Research has shown it to have good effect on thyroid cancer, but it is not approved for that use.

Principal Investigator: Shankar Giri, MD

Pharynx

RTOG 1016: Phase III trial of radiotherapy plus cetuximab versus chemoradiotherapy in HPV associated oropharynx cancer The purpose of this study is to compare the effects, good and/or bad of two standard treatments for head and neck cancer: radiation therapy and cisplatin or radiation therapy and cetuximab. The two treatments may be comparable in treating your cancer, but radiation and cetuximab may cause less severe side effects.

Cisplatin is a classic chemotherapy drug. Cetuximab is a drug that blocks the epidermal growth factor receptor, a protein that affects cancer growth and many other functions. Both are approved by the Food and Drug Administration. **Principal Investigator:** Shankar Giri, M.D.

Peripheral CD4+ regulatory T-cell in head and neck squamous cell carcinoma study The purpose of this study is to study the relationships between head and neck squamous cell cancer

and its risk factors to body's immune system. The immune system is the human body's way of staying healthy by keeping cancer cells from growing inside our body. We will look for differences in the immune system in people with this type of cancer. This might help us better understand cancer's relationship to the immune system, and may lead to new and better treatments for this type of cancer. **Principal Investigator:** Alan R. Grimm, MD

Validation of Biomarkers for Head and Neck Squamous Cell Carcinoma We are doing this study to learn how patients with different types of proteins in cancer cells respond to standard treatments in head and neck cancer. **Principal Investigator:** Sharon Lobert, PhD

Lip & Oral Cavity

A Phase 3, Prospective, Open-Label, Multicenter Study of LYMPHOSEEK®-Identified Sentinel Lymph Node (SLNs) Relative to the Pathological Status of Non Sentinel Lymph Nodes in an Elective Neck Dissection (END) in Cutaneous Head and Neck and Intraoral Squamous Cell Carcinoma During your surgery, we will remove the tumor and look for possible spread of cancer to the lymph nodes in your neck. We are doing this study to see if an experimental radioactive substance called LYMPHOSEEK® can help us find the first lymph node that cancer cells may go to from the cancerous tumor.

Principal Investigator: Karen Pitman, M.D

Larynx

Observational Study of Swallowing Function after Treatment of Advanced Laryngeal Cancer We are doing this study to understand the long-term effects of surgery and chemotherapy/radiation treatment in regards to swallowing function. We would like to understand how swallowing is affected by treatment, and how swallowing and related symptoms change over time. **Principal Investigator:** Karen Pitman, M.D

Recurrent or Metastatic

CTSU E1305: A phase III randomized trial of chemotherapy with or without bevacizumab in patients with recurrent or metastatic head and neck cancer The purpose of this study is to compare the effects (good and bad) of adding a drug called bevacizumab to standard chemotherapy to see which works better and if adding bevacizumab gives us results that are better than those we expected. Bevacizumab stops the growth of blood vessels that feed the tumor. It can starve the tumor and prevent it from growing. Bevacizumab has been shown to improve the effect of chemotherapy against cancer in some other cancer types. This drug is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental.

Principal Investigator: R. Darryl Hamilton, M.D.

Intermediate Risk (Locally Advanced)

RTOG 0920: A phase III study of postoperative radiation therapy +/- cetuximab for locally advanced resected head and neck Cancer The purpose of this study is to compare the effects, good and/or bad, of radiation therapy to radiation therapy and Cetuximab to find out which is better. The standard treatment of surgery followed by radiation therapy can stop tumors from growing in the head and neck area in most people, but the cancer can come back or spread to other parts of the body. Cetuximab is a drug that may slow down or stop the tumor from growing by blocking chemical pathways that allow it to grow. Cetuximab is approved by the FDA for treatment of head and neck cancer.

Principal Investigator: Shankar Giri, M.D.

Randomized double-blind phase II trial of Everolimus versus placebo as adjuvant therapy in patients with locally advanced squamous cell cancer of the head and neck (SCCHN)

We are doing this study to learn about an experimental drug called Everolimus. We want to see if Everolimus helps keep cancer from coming back after surgery and/or radiation therapy treatment. **Principal Investigator:** Karen Pitman, M.D

Salivary Gland

RTOG 1008: A randomized phase II study of adjuvant concurrent radiation and chemotherapy versus radiation and chemotherapy versus radiation alone in resected high-risk malignant salivary gland tumors For salivary gland cancer that is at high risk for coming back, radiation therapy to the head and neck is usually recommended after surgery. The purpose of this study is to test whether the use of chemotherapy with radiation is better than using radiation alone to try and keep the cancer from coming back.

Cisplatin is a drug that may slow down or stop the tumor from growing by blocking chemical pathways that allow it to grow. Cisplatin is approved by the Food and Drug Administration (FDA) for treatment of head and neck cancer, but not for the way we are using it in this study.

Principal Investigator: Shankar Giri, M.D.

Salivary Gland Tumor Biorepository The purpose of this tissue bank is to collect leftover tissue from surgical procedures and take blood and saliva samples to keep and use for future research on salivary tumors. **Principal Investigator:** Karen Pitman, MD

LEUKEMIA

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

Acute Myelogenous Leukemia/AML

SWOG S0919: A phase II study of idarubicin and ara-c in combination with pravastatin for relapsed acute myelogenous leukemia The purpose of this study is to find out what effects, good and/or bad, the combination of regular chemotherapy plus pravastatin has on you and your leukemia. The chemotherapy is made up of two drugs which are commonly used to treat your type of leukemia, idarubicin and AraC. Pravastatin is a drug that is usually used to treat high cholesterol. We would like to see whether adding pravastatin to the chemotherapy will have an effect on you and your leukemia. Since pravastatin is not normally used to treat leukemia, the way we are using it in this study is experimental.

Principal Investigator: Stephanie Elkins, M.D.

SWOG S0703: A phase II trial of azacitidine (NSC 102816) plus gemtuzumab ozogamicin on induction and post remission patients age 60 and older with previously untreated nonM3 acute myeloid leukemia

The purpose of this study is to find out what effects, good and/or bad, the experimental drug combination hydroxyurea, azacitidine, and gemtuzumab ozogamicin has on you and your leukemia. Hydroxyurea, gemtuzumab ozogamicin, and azacitidine are approved by the Food and Drug Administration for other uses but not for the type of cancer you have. This combination has not been given before and is considered experimental.

Principal Investigator: Stephanie Elkins, M.D.

Acute Promyelocytic Leukemia/APL

SWOG S0535: A phase II study of ATRA, arsenic trioxide and gemtuzumab ozogamicin in patients with previously untreated high-risk acute promyelocytic leukemia

The purpose of this study is to see what effects, good and bad, the drugs ATRA, arsenic trioxide and gemtuzumab ozogamicin have on people with high risk APL. The chemotherapy for APL has three parts: induction therapy, consolidation therapy, and maintenance therapy. The purpose of the induction therapy is to eliminate the signs and symptoms of the APL from your body. If this happens, your APL will be in "remission." Consolidation therapy and maintenance therapy are intended to make your remission last as long as possible. All of the drugs used in this study are approved for APL that comes back, but not for newly diagnosed APL, which means the way we are using it is experimental. Your bone marrow aspirate or biopsy will be sent to a special lab located at UMMC to confirm your diagnosis of APL and to see how the study treatment is affecting your body. **Principal Investigator:** Carolyn Bigelow, M.D.

Acute Lymphocytic Leukemia/ALL

SWOG S0910: A phase II study of epratuzumab in combination with cytarabine and clofarabine for patients with relapsed or refractory ph-negative precursor b-cell acute lymphoblastic leukemia This study is being done to find out what effects, good or bad, clofarabine, cytarabine and an experimental drug called epratuzumab has on you and on precursor B-Cell acute lymphoblastic Leukemia that has come back after previous treatment or that has not responded to previous treatment. Epratuzumab is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental. Cytarabine is a chemotherapy drug that is used as part of standard treatment for ALL. Clofarabine is approved for treating ALL in children whose disease comes back. Researchers think that adding epratuzumab to regular chemotherapy with cytarabine and clofarabine may help get rid of leukemia, and any cells that might not be killed by regular chemotherapy alone. B-cell ALL cells have a molecule on them called CD22. Epratuzumab is an antibody that can find the CD22 and use it to target leukemia cells.

Principal Investigator: Stephanie Elkins, M.D.

Other Related Studies:

Untreated Patients with Systemic Light-chain (AL) Amyloidosis Ineligible for Autologous Stem-cell Transplantation

E4A08: A Randomized Phase III Trial of Melphalan and Dexamethasone (MDex) versus Bortezomib, Melphalan, and Dexamethasone (BMDex) for Untreated Patients with Systemic Light-chain (AL) Amyloidosis Ineligible for Autologous Stem-cell

Transplantation This research study is being done to compare two possible treatments for immunoglobulin light chain amyloidosis, a disease in which a type of protein collects in multiple organs and tissues in your body, often including the kidneys. The two drug combination: melphalan plus dexamethason, will be compared to the experimental three drug combination of melphalan, dexamethason and bortezomib.

Bortezomib is considered experimental for immunoglobulin light chain amyloidosis and is not a standard treatment for your disease. Bortezomib interferes with the protein processing in cells. The plasma cells (bone marrow cells) are responsible for making the amyloid building-block proteins that cause amyloidosis and are thought to be sensitive to this type of drug. Bortezomib has been shown to reduce the level of the amyloid building blocks (immunoglobulin light chains) in the blood stream. **Principal Investigator:** Stephanie Elkins, M.D.

LUNG

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

Non-small cell lung/NSCL Stage I-IIIa/ Resectable

E1505: A phase III randomized trial of adjuvant chemotherapy with or without bevacizumab for patients with completely resected stage IB (>4cm)- IIIa non small-cell lung cancer (NSCLC) Even with the most aggressive after-surgery treatment with chemotherapy, many people still have the lung cancer come back. The purpose of this study is to see if adding the drug bevacizumab to chemotherapy improves the chance of a cure for people who have had their lung cancer removed. We will compare the effects (good and bad) of bevacizumab plus standard chemotherapy to standard chemotherapy to see which is better at preventing the cancer from coming back. Bevacizumab has not yet been approved by the Food and Drug Administration for the treatment of lung cancer. This means the way we are using it in the study is experimental. **Principal Investigator:** R. Darryl Hamilton, M.D.

RTOG 0839: Randomized Phase II Study of Pre-operative Chemoradiotherapy +/- Panitumumab (IND #110152) Followed by Consolidation Chemotherapy in Potentially Operable Locally Advanced (Stage IIIa, N2+) Non-Small Cell Lung Cancer This study is being done to find out what effects, good or bad, adding an experimental drug called Panitumumab (not yet approved by the Food and Drug Administration) to chemotherapy and radiation therapy has on you and on your lung cancer. Panitumumab is a drug that may delay or prevent tumor growth by blocking certain cellular chemical pathways that lead to tumor development. It has been approved by the FDA as a single agent for the treatment of epidermal growth factor receptor (EGFR) expression in people with colorectal cancer whose disease has progressed after prior chemotherapy. However, it is not approved for treatment in the type of cancer you have. This means the way we are using it in the study is experimental. **Principal Investigator:** Shankar Giri, M.D.

Non-small cell lung/NSCL Stage IV

SWOG S0819: A randomized phase III study comparing carboplatin/paclitaxel or carboplatin/paclitaxel/bevacizumab with or without concurrent cetuximab in patients with advanced non-small cell lung cancer This study is being done to find out what effects, good or bad, the experimental drug, Cetuximab, has on you and on your lung cancer. This drug is approved by the Food and Drug Administration (FDA) for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental. **Principal Investigator:** Louis Punecky, M.D.

CALGB 30801: A Randomized Phase III Double Blind Trial Evaluating Selective COX-2 Inhibition in COX-2 Expressing Advanced Non-Small Cell Lung Cancer

This study is being done to compare the effects, good or bad, of adding an experimental drug called celecoxib, to chemotherapy.

Current standard treatments for your type of lung cancer are usually not effective in preventing the cancer from growing. In this study we will test a sample of your cancer to see if it has an enzyme called COX-2. Recent studies have shown that people who have high levels of COX-2 in tumor tissue appear to benefit from treatment with celecoxib or other similar drugs.

This drug is approved for other uses but not for treatment of the type of cancer you have. This means the way we are using it in the study is experimental.

Principal Investigator: Louis Puneky, M.D.

Small Cell Limited Disease

CTSU/CALGB 30610: Phase III comparison of thoracic radiotherapy regimens in patients with limited small cell lung cancer also receiving cisplatin and etoposide

This study is being done to compare the effects, good or bad, of three different ways to give radiation therapy. Two of the ways are experimental, and one of them is standard.

- Experimental - Once a day with a high dose of radiation for 7 weeks
- Experimental - Once a day for 16 days of treatment (about 3 weeks), followed by twice a day for the remaining 9 days of treatment (about 2 weeks), for a total of 5 weeks.
- Standard - Twice a day for 3 weeks.

Everyone will get chemotherapy with cisplatin and etoposide, which are standard drugs (chemotherapy) for your type of cancer. The exact doses of the chemotherapy have not been completely standardized and you will be receiving a commonly used dosing schedule. Using this dose of chemotherapy with any of the three radiotherapy regimens may cause additional side effects. **Principal Investigator:** Louis Puneky, M.D.

Small Cell Extensive Disease

RTOG 0937: Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small Cell Lung Cancer

The standard treatment for extensive disease small cell lung cancer is chemotherapy without radiation. In many people, even those who respond well to chemotherapy, the cancer can grow back in the chest or grow in the brain or other places after chemotherapy. One study found that radiation to the brain improves survival in people with extensive disease small cell lung cancer. Based on that study and due to the high risk of cancer growth in the brain, radiation to the brain is often recommended. It is not known if radiation therapy to the chest or other sites of disease that do not completely respond to chemotherapy improves survival. This study will compare the effects, good and/or bad, of radiation given to the brain versus radiation to the brain, chest and up to 4 other sites, to find out which is better. **Principal Investigator:** Shankar Giri, MD

LYMPHOMA

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

Untreated Non-Hodgkin's CD20+DLBCL- STAGE II, III, OR IV

C50303: Phase III randomized study of R-CHOP versus dose-adjusted EPOCH-R with molecular untreated denovo diffuse large B-cell lymphoma The purpose of this study is to compare the effects good and/or bad of R-CHOP treatment with dose adjusted EPOCH-R (DA-EPOCH-R) on you and your lymphoma to find out which is better. R-CHOP is the standard treatment for your type of lymphoma. The study will also analyze your tumor using new scientific laboratory studies to better understand your type of lymphoma. This will allow doctors to perform important scientific research studies that may help determine if one of these treatments is more effective in certain types of lymphomas. **Principal Investigator:** Vincent Herrin, M.D.

Relapsed or Refractory Diffuse Large B-Cell/DLBCL

GlaxoSmithKline: Ofatumumab versus rituximab salvage chemoimmunotherapy followed by ASCT in relapsed or refractory diffuse large B-cell lymphoma: CD20 + DLBCL We are doing this study to try to find out if ofatumumab plus DHAP works better and how safe it is than rituximab plus DHAP. Ofatumumab is approved in some countries for doctors to prescribe to patients with a type of leukemia (a cancer of white blood cells). This study is testing a new use of this drug. This use is not approved by the Food and Drug Administration for the way we are using it in this study. It must be studied first to see if it safe and that if it works against your type of lymphoma. Ofatumumab has been tested in another type of lymphoma. Ofatumumab did work against this lymphoma and it was also safe. **Principal Investigator:** Stephanie Elkins, M.D.

Non-Hodgkins in Complete or Partial Remission

Genzyme MOZ11809: A phase IV multicenter, randomized, comparator trial evaluating the standard weight-based dose (0.24 mg/kg) compared to a fixed dose (20 mg) of plerixafor injection in combination with G-CSF to mobilize and collect $\geq 5 \times 10^6$ CD34+ cells/kg in greater than or equal to 4 days and to evaluate the difference in total systemic exposure in patients with non-hodgkin's lymphoma weighing less than or equal to 70 kg The purpose of this study is to compare the responses to 2 different doses of a drug called plerixafor in participants with NHL who will receive an autologous stem cell transplant. Plerixafor has been approved by the US Food and Drug Administration (FDA) to increase the number of stem cells in people with NHL. This process is called mobilization. Plerixafor is given in addition to a standard drug, G-CSF, a "growth factor". G-CSF causes the bone marrow to make extra stem cells that are released into the blood stream where they can be collected and used at a later time for transplant. G-CSF is approved by the FDA for mobilizing stem cells. This study will

compare a standard dose of plerixafor based on body weight to a specific dose (20 milligrams) that is set in advance (fixed dose). The fixed dose in people who weigh less than 154 pounds has not been previously studied. **Principal Investigator:** Stephanie Elkins, M.D.

Non-Hodgkin's Lymphoma Beyond First Complete Response

BMT CTN 0701: Phase II Trial of Non-Myeloablative Allogenic Hematopoietic Cell Transplantation for Patients with Relapsed Follicular Non-Hodgkin's Lymphoma Beyond First Complete Response This study is being done to measure progression free survival at 2 years after non-myeloablative HSCT with a pre-transplant conditioning regimen of fludarabine, cyclophosphamide, and rituximab (FCR). This study is being done to determine how effective non-myeloablative transplant will control and possibly cure your lymphoma. Non-myeloablative SCT (also sometimes called a mini transplant or reduced intensity transplant), has been shown to control your kind of lymphoma. **Principal Investigator:** Stephanie Elkins, M.D.

MELANOMA No trials for melanoma are being conducted at UMMC/UMHC.

MYELOMA

For further information regarding these studies, contact: Cancer Research & Registry 601-984-1095

Myeloma with Bone Metastasis

SWOG S0702: a prospective observational multicenter cohort study to assess the incidence of osteonecrosis of the jaw (ONJ) in cancer patients with bone metastases starting zoledronic acid treatment The purpose of this study is to learn how often osteonecrosis of the jaw (ONJ) which is death of the jaw bone caused by poor blood flow, occurs in people who are being treated with zoledronic acid. This study will also help us identify risk factors associated with ONJ. Zoledronic acid falls under a category of drugs called bisphosphonates. Bisphosphonates are sometimes given to people who have cancer that has spread to their bones because it can lower the chances of getting fractures and reduces bone pain. Usually, zoledronic acid does not cause serious problems, but there has been an increase in the number of reported cases of ONJ and we want to see if this is caused by bisphosphonate therapy. Symptoms associated with ONJ are swelling of the soft tissue around the jaw, infection, loosening of teeth, drainage, and exposed jaw bone.

Principal Investigator: Louis Punecky, M.D.

Asymptomatic High-Risk Smoldering Multiple Myeloma

E3A06: Randomized Phase III Trial of Lenalidomide versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma Asymptomatic high-risk myeloma is a type of blood cell cancer that has not yet damaged body tissue and organs to the point where symptoms are noticeable. The current accepted treatment for asymptomatic high-risk myeloma is to receive no therapy. This study is being done to find out what effects, good or bad, an experimental drug, called lenalidomide, has on you and on your asymptomatic high-risk multiple myeloma and to compare this with participants that receive no therapy. Lenalidomide is a drug that has shown benefit and is approved for use in people whose myeloma has been resistant to other therapies. The mechanism by which lenalidomide works in myeloma is still unclear, but it is felt that the drug works by making the immune system (your body's natural defense against disease) work better against the myeloma cells. It may also have additional direct effects on the myeloma cells. This drug is approved for symptomatic myeloma and myelodysplastic syndrome (disease of blood and bone) and other uses but not for treatment of the type of myeloma you have. This means the way we are using it in the study is experimental.

Principal Investigator: Stephanie Elkins, M.D.

ADULT NEUROLOGICAL AND BRAIN

No trials for neurological or brain cancer are being conducted at UMMC/UMHC. Please check the NIH clinical trials web site:

<http://clinicaltrials.gov/ct2/results?term=neurologic+cancer> or

<http://clinicaltrials.gov/ct2/results?term=brain>

ADULT SARCOMA No trials for sarcoma are being conducted at

UMMC/UMHC. Please check the NIH clinical web site:

<http://clinicaltrials.gov/ct2/results?term=sarcoma>

Young Adult Studies

ACUTE LYMPHOBLASTIC LEUKEMIA (for ages 0-21)

For more information on these studies, please call 601-984-5220.

AALL0433: Intensive treatment for intermediate risk relapse of childhood acute lymphoblastic leukemia The purpose of this study is to find out about the effectiveness and side effects of the combination of high dose chemotherapy drugs for all participants on this study. **Principal Investigator:** Gail Megason, M.D.

AALL0434 : Intensified methotrexate, nelarabine, and augmented BFM therapy for children and young adults with newly diagnosed T-cell acute lymphoblastic leukemia or T-cell lymphoblastic lymphoma The purpose of this study is: 1) to compare the effects, good or bad, of two different treatment plans for low-risk T-cell ALL; 2) to compare the effects, good or bad, of four different treatment plans for intermediate and high-risk T-cell ALL; 3) to see if the experimental drug, nelarabine, helps improve the chances of survival for children with intermediate or high-risk T-cell leukemia and for those patients who still have T-cell leukemia at the end of Induction therapy. **Principal Investigator:** Gail Megason, M.D.

AALL07P1: Phase II pilot of bortezomib in combination with intensive re-induction therapy for children with relapsed acute lymphoblastic leukemia The purpose is: 1) to find out if bortezomib can be safely added to the standard COG re-Induction therapy for relapsed ALL and lymphoblastic lymphoma (LL); 2) to see how well adding bortezomib to standard chemotherapy drugs works at treating children and young adults with relapsed ALL and LL; 3) to find out what effects (good or bad) bortezomib, given with standard chemotherapy drugs, has on children and young adults with relapsed ALL or LL. **Principal Investigator:** Gail Megason, M.D.

AALL1122: A Phase 2 Multi-Center Historically - Controlled Study of Dasatinib Added to Standard Chemotherapy in Pediatric Patients with Newly Diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ ALL) The main goal of this study is to find out what the survival rate is when dasatinib is added to a standard chemotherapy. Additional goals of the study are to evaluate the side effects of dasatinib added to a standard chemotherapy, to compare the survival

rate in this study to that seen with a similar but less potent drug called imatinib when added to this same chemotherapy and other treatments and to monitor the response of your disease to this treatment with disease specific tests (minimal residual disease).

Principal Investigator: Gail Megason, M.D.

AALL1131: A Phase III Randomized Trial for Newly Diagnosed High Risk B-precursor ALL Testing Clofarabine in the Very High Risk Stratum

For High Risks Patients: The overall goals of this study are to find out if using chemotherapy with ITT improves survival rates better than using chemotherapy with IT MTX for HR-ALL; to compare the effects, good and/or bad, of chemotherapy with ITT to chemotherapy with IT MTX for HR-ALL to find out which is better; to better understand the effects of cancer treatment in people with HR-ALL.

For Very High Risk Patients: The overall goals of this study are to find out if using Experimental Arm 1 or Experimental Arm 2 improves survival rates better than using the Control Arm for VHR-ALL; to find out if using Experimental Arm 2 improves survival rates better than Experimental Arm 1 for VHR-ALL; to compare the effects, good and/or bad, of using either Experimental Arm 1 or Experimental Arm 2 to the standard treatment (Control Arm) for VHR-ALL; to better understand the effects of cancer treatment in people with VHR-ALL. **Principal Investigator:** Gail Megason, M.D.

ACUTE MYELOID LEUKEMIA

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

AAML05P1: Killer immunoglobulin receptor (KIR) incompatible unrelated donor hematopoietic stem cell transplantation for AML with monosomy 7, -5/5q-, high FLT3-ITD AR, or refractory or relapsed acute myelogenous leukemia in children

The primary goal of this study is to see whether specific bone marrow mismatches (KIR receptor-ligand) may improve bone marrow transplant results. **Principal Investigator:** Gail Megason, M.D.

AAML1031: A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib for Patients with High Allelic Ratio FLT3/ITD The main goals of this study are 1) to see if an experimental drug, called bortezomib, is tolerated when added to the standard AML treatment without causing too many serious side effects; 2) to compare the effects, good and/or bad, of adding bortezomib to the standard AML treatment to find out which is better; 3) to determine the dose of sorafenib that is safe when added to standard AML treatment; 4) to compare the effects, good and/or bad, of adding sorafenib to standard AML treatment to find out which is better; 5) to determine how effective the combination of sorafenib and chemotherapy will be at killing cancer cells.

Principal Investigator: Gail Megason, M.D.

AAML0631: Risk adapted treatment of newly diagnosed childhood acute promyelocytic leukemia (APL) using arsenic trioxide during consolidation

The goal of this study is to see if using less anthracycline than what is normally used in standard APL treatment, and adding arsenic, will work as well as standard treatment and decrease some of the long term side effects without affecting the cure rate.

Principal Investigator: Gail Megason, M.D.

BRAIN TUMORS

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

ACNS02B3: A Children's Oncology Group protocol for collecting and banking pediatric brain tumor research specimens The purpose of this study is to collect blood and tumor samples from children diagnosed with a brain tumor. The samples will be stored (banked) and used as needed by qualified researchers. **Principal Investigator:** Betsy Herrington, M.D.

ACNS0331: A study evaluating limited target volume boost irradiation and reduced craniospinal radiotherapy 18.00 gy and chemotherapy in children with newly diagnosed standard risk medulloblastoma: A phase III double randomized trial The purpose of this study is to find out if the overall dose of radiation to the brain and spine can be reduced without decreasing rates of survival in children with medulloblastoma. The study will also look at whether the volume of radiation given during the boost can be reduced without decreasing survival rates in children with medulloblastoma. **Principal Investigator:** Betsy Herrington, M.D.

ACNS0332: Efficacy of carboplatin administered concomitantly with radiation and isotretinoin as a pro-apoptotic agent in other than average risk Medulloblastoma or PNET patients The purpose is: 1) to find out if giving the drug carboplatin along with radiation therapy works better than giving radiation therapy alone; 2) to find out if the drug isotretinoin can improve the survival of participants with high-risk medulloblastoma. **Principal Investigator:** Betsy Herrington, M.D.

ACNS0333: Treatment of atypical teratoidrhabdoid tumors of the central nervous system with surgery, intensive chemotherapy, and 3-D conformal radiation The purpose is: 1) to find out what effects (good and bad) surgery, intense chemotherapy with stem cell rescue, and radiation therapy have on people with AT/RT; 2) to look at the tumor tissue taken out during surgery and a blood sample to see if there are any features of the tumor cells such as proteins, and/or any genetic features. **Principal Investigator:** Betsy Herrington, M.D.

ACNS0821: Temozolomide with Irinotecan versus Temozolomide , Irinotecan, plus Bevacizumab for Refractory/Recurrent Medulloblastoma/CNS PNET of Childhood, A COG Randomized Phase II Screening Trial The purpose of this study is to compare two experimental treatments to see if one is better than the other for

treatment of recurrent/refractory medulloblastoma/CNS PNET of childhood. **Principal Investigator:** Betsy Herrington, M.D.

ACNS0822 : A Randomized Phase II/III Study of Vorinostat and Local Irradiation OR Temozolomide and Local Irradiation OR Bevacizumab and Local Irradiation Followed by Maintenance Bevacizumab and Temozolomide in Newly Diagnosed High Grade Glioma The purpose of this study is: 1) to identify a safe, feasible dose of vorinostat when given in combination with radiation therapy in patients with newly diagnosed high grade glioma; 2) phase II portion :to compare three experimental treatment arms to see if one is better than the other for treatment of newly diagnosed high grade glioma; 3) phase III portion: using the findings from the phase II portion of the study, to compare two experimental treatments to see if one is better than the other when given in combination with radiation therapy followed by maintenance chemotherapy in patients with newly diagnosed high grade glioma. **Principal Investigator:** Betsy Herrington, M.D.

ACNS0831: Phase III randomized trial of post-radiation chemotherapy in patients with newly diagnosed ependymoma ages 1 to 21 years

The purpose is: 1) to look at the progress of participants whose entire tumor is successfully removed during surgery and will be carefully observed after surgery, to see if they can avoid the side effects of radiation therapy without having the tumor grow back; 2) to see if giving chemotherapy after surgery and radiation therapy will work better to get rid of the tumor and/or keep it from coming back than treatment with standard therapy; 3) To see if giving a short course of chemotherapy can kill any remaining tumor that the surgeons were unable to remove during the initial surgery and increase the number of participants whose remaining tumor can be completely removed by a second surgery. Other goals of this study are to: 1) study the effects of surgery on learning, thinking, hearing and the production of hormones (substances made in the brain that affect growth and development); 2) study tumor tissue and blood samples for possible genetic and biologic factors related to ependymoma. **Principal Investigator:** Betsy Herrington, M.D.

EWING'S SARCOMA

(for ages 0-30)

For more information on these studies, please call 601-984-5220.

AEWS0331: European Ewing tumor working initiative of national groups Ewing tumor studies 1999 (Euro – EWING 99) The purpose of this study is to compare survival in a randomized study of standard drug therapy and whole lung irradiation *versus* high dose, intense drug therapy followed by replacement of peripheral blood stem cells (transplant). Also to see if there is genetic information in the tumor cells that may help researchers predict how a patient will respond to therapy and to see if there are any microscopic disease cells left in the bone marrow after treatment and to find out if this has any effect on the outcome of the treatment. **Principal Investigator:** Gail Megason, M.D.

AEWS07B1: A Children's Oncology Group protocol for collecting and banking Ewing sarcoma specimens The goal of this study is to collect Ewing sarcoma tumor specimens and blood and bone marrow samples. These specimens will be used by researchers in future research to increase our knowledge about how to diagnose and treat Ewing sarcoma. **Principal Investigator:** Gail Megason, M.D.

AEWS1031: Phase III randomized trial of adding vincristine-topotecan-cyclophosphamide to standard chemotherapy in initial treatment of non-metastatic Ewing sarcoma The overall goal of this study is to find if adding a new drug combination to the standard five-drug chemotherapy for Ewing sarcoma will get rid of the cancer better than the standard five-drug chemotherapy by itself. Researchers want to find out if we can improve the treatment for Ewing sarcoma by adding the drug topotecan to the 5 drugs used in standard treatment. **Principal Investigator:** Gail Megason, M.D.

OSTEOSARCOMA

(for ages 0-30)

For more information on these studies, please call 601-984-5220.

AOST06B1: A Children's Oncology Group protocol for collecting and banking osteosarcoma specimens The goal of this study is to collect osteosarcoma tumor specimens and blood samples. These specimens will be used by researchers in future research to learn more about how to diagnose and treat osteosarcoma. **Principal Investigator:** Gail Megason, M.D.

GERM CELL TUMORS

we have no open studies for germ cell tumors at this time.

HEPATOBLASTOMA

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

AHEP0731: Treatment of children with all stages of hepatoblastoma The purpose is: 1) to find out if using a rating system called Pretreatment Extent of Disease (or PRETEXT) can be used to decide if a tumor can be removed by surgery. (PRETEXT ratings will be based on CT and/or MRI scans to see how much of your child's liver is involved by the tumor). We will also try to find out if different doctors give the same or different PRETEXT ratings when looking at the same participant's tumor on a CT/MRI scan; 2) to find out if there are other factors present in children with hepatoblastoma that can be used to develop better treatments.

For Low Risk Participants: To find out if giving only 2 cycles of C5V (cisplatin, 5-fluorouracil, vincristine) in addition to taking the tumor out with surgery works as well as the standard therapy with 4 cycles; For Intermediate Risk Participants: To find out if adding doxorubicin can be given with C5V without causing too many side effects; For Intermediate and High-risk Participants: To find out if it is possible for participants to be referred by their study doctor to a center with experts in liver transplant surgery by the end of 2 cycles of chemotherapy and to find out if it is possible for these participants to have their liver transplant done at the end of 4 cycles of chemotherapy; For High-risk Participants: To find out if adding vincristine and irinotecan (chemotherapy known as VI) work well in treating participants with high-risk hepatoblastoma. Irinotecan is not a standard drug used to treat hepatoblastoma. **Principal Investigator:** Gail Megason, M.D.

HODGKIN LYMPHOMA

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

AHOD04B1: Hodgkin disease banking study The goal of this study is to collect samples from people with Hodgkin Disease and send them to a central COG lab where COG researchers will be able to study them. This study is a registry (a collection of information to help study Hodgkin disease) and collection study designed to allow us to better understand why some people get Hodgkin Disease, how different people respond to therapy and how to look for problems caused by the treatment. **Principal Investigator:** Rathi Iyer, M.D.

NON-HODGKIN LYMPHOMA

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

AALL0434: Intensified methotrexate, nelarabine, and augmented BFM therapy for children and young adults with newly diagnosed T-cell acute lymphoblastic leukemia or T-cell lymphoblastic lymphoma

The purpose of this study is: 1) to compare the effects, good and/or bad, of two different treatment plans for Low Risk T-cell ALL; 2) to compare the effects, good and/or bad, of four different treatment plans for Intermediate and High-risk T-cell ALL; 3) to see if the experimental drug, Nelarabine, helps improve the chances of survival for children with Intermediate or High-risk T-cell leukemia, for those patients who still have T-cell leukemia at the end of Induction therapy, and for those patients with High-risk T-cell lymphoblastic lymphoma. **Principal Investigator:** Gail Megason, M.D.

ANHL04B1: Rare and cutaneous nonHodgkin's lymphoma registry The goals of this tissue bank are 1) to learn more about the rare types of lymphoma/LD, how they present, and whether they behave differently from the same lymphoma/LD in adult 2)to find out what treatment is being used for these rare diseases 3)to register all patients under age 21 years who present with an uncommon type of lymphoma/LD or a lymphoma/LD at an uncommon site such as the brain or skin. **Principal Investigator:** Rathi Iyer, M.D.

NEUROBLASTOMA

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

ANBL0032: Phase III randomized study of chimeric antibody 14.18 (Ch14.18) in high-risk neuroblastoma following myeloablative therapy with autologous stem cell rescue This study is being done to try and improve the likelihood that the cancer will not come back in children with high-risk neuroblastoma. This study involves the experimental use of the drugs ch14.18 and aldesleukin (IL-2). We wish to study whether aldesleukin (IL-2), when given with Ch 14.18 will help kill cancer cells. **Principal Investigator:** Rathi Iyer, M.D.

ANBL00B1: Neuroblastoma biology studies The central purpose of this study is to define the characteristics of your/your child's neuroblastoma and to predict the best therapy for you/your child. We will use some of the tumor tissue that is not needed for diagnosis for some specialized laboratory tests. These studies will determine the amount of DNA (genetic material) in the tumor cells, as well as whether multiple copies of a gene called "MYCN" are present in the tumor cells. The results of these tests may be used by your/your child's study doctor to find the best therapy for you/your child and will be a part of your/your child's medical record. **Principal Investigator:** Mary Gail Smith, M.D.

ANBL00P3: Phase III randomized trial of intravenous gammaglobulin therapy for patients with neuroblastoma associated opsoclonus-myooclonus-ataxia syndrome treated with chemotherapy and prednisone We are doing this study to try and learn whether the use of intravenous gammaglobulin (IVIG) improves the abnormal motor coordination (ataxia), improves abnormal eye movements (opsoclonus), and muscle twitching (myoclonus) of children diagnosed with neuroblastoma associated OMA. This study will also look at the long-term effects OMA may have on your child, and will try to find out if chemotherapy and prednisone is a reasonable treatment for neuroblastoma associated OMA. **Principal Investigator:** Mary Gail Smith, M.D.

ANBL1021: Feasibility/Phase II Study of hu14.18-IL2 Immunocytokine + GM-CSF and Isotretinoin in Patients with Relapsed and Refractory Neuroblastoma The overall goal of this study is to find out what effects, good and/or bad, the combination of hu14.18-IL2, GM-CSF, and isotretinoin has on people with relapsed or resistant neuroblastoma. **Principal Investigator:** Gail Megason, M.D.

KIDNEY TUMORS

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

AREN0321: Treatment of high-risk renal tumors The purpose is: 1) to see if most participants with renal cell carcinoma can be cured with surgery alone and to collect information about participants whose renal cell carcinoma cannot be removed by surgery or has spread to other areas of the body so that we can learn more about the disease; 2) to find out if adding a third drug (doxorubicin) plus giving radiation therapy, will improve the chance for cure for participants with Stage I focal or diffuse anaplastic Wilms tumor; 3) to find out if participants with Stage I clear cell sarcoma of the kidney will have excellent outcomes if they do not get radiation therapy to the abdomen; 4) to see if a different combination of five standard drugs (called Revised Regimen UH-1) decreases the chance of the tumor returning compared to the currently used treatment regimens that use only 3 or 4 drugs. ; 5) to see if an experimental pair of drugs, irinotecan and vincristine, are effective in treating the tumor and to see if a different combination of five standard drugs (called Revised Regimen UH-1) lessens the chance of the tumor returning (this is called recurrence) compared to the currently used treatment regimens that use three or four drugs. **Principal Investigator:** Rathi Iyer, M.D.

AREN03B2: Renal tumors classification, biology, and banking study The purpose is to find out information about the participants' renal tumor to help the doctor know which is the best treatment for the tumor with the least side effects, to study kidney tumors so that we may learn more about them and find out more about how to treat participants who have these tumors, and to store tumor tissue, normal kidney tissue, samples of blood and urine from participants with kidney tumors so that researchers can do more studies in the future. **Principal Investigator:** Gail Megason, M.D.

AREN0532: Treatment for very low and standard risk favorable histology Wilms tumor The purpose is: 1) to find out if children less than 2 years old with a small Stage I Wilms tumor can be safely treated with surgery alone followed by careful observation; 2) to confirm that the treatment given for relapse after observation alone works well in participants with very low risk Wilms tumor. **Principal Investigator:** Gail Megason, M.D.

AREN0533: Treatment of newly diagnosed higher risk favorable histology Wilms tumors The purpose is; 1) to find out if genetic information (loss of heterozygosity

[LOH]) about the tumor cells can help us know when to give people more intensive treatment; 2) to find out if participants with Wilms tumor that has spread only to the lungs (and the tumor cells do not have LOH) can be treated without having radiation therapy to the lungs; 3) to find out if participants with Wilms tumor that has spread only to the lungs whose lung tumors do not go away after the first six weeks of standard chemotherapy for Wilms tumor can be treated by using two additional chemotherapy drugs, along with the standard drugs, plus radiation therapy to the lungs; 4) to find out if participants who have Wilms tumor that has spread to other parts of the body in addition to or instead of in the lungs, can be treated by using two additional chemotherapy drugs along with the standard drugs, and radiation therapy to all sites of the disease, including the lungs; 5) to find out if participants with Wilms tumor who have tumor cells with LOH can be successfully treated by using two additional chemotherapy drugs along with standard drugs and radiation to all sites of disease, including the lungs. **Principal Investigator:** Gail Megason, M.D.

AREN0534: Treatment for patients with bilateral, multicentric, or bilaterally-predisposed unilateral Wilms tumor The purpose is: 1) to find out if giving three drugs to treat bilateral Wilms tumor instead of two will help get rid of the tumor cells while saving the largest amount of normal kidney tissue; 2) to try to improve survival for patients with Wilms tumor; 3) to see if having surgery early in the treatment will help identify aggressive cells in the tumor earlier which will lead to beginning a five-drug chemotherapy regimen earlier and to see if the five-drug chemotherapy regimen will improve patient survival and save as much of the normal kidney tissue as possible; 4) to find out if the chemotherapy drugs that are given after surgery should be based on changes that are seen in the tumor cells before surgery; 5) to find out if giving chemotherapy before surgery to treat DHPLNR will save as much normal kidney tissue as possible and prevent a Wilms tumor from developing; 6) to collect information on the natural history of DHPLNR and to determine if response to treatment can be monitored with repeated scans such as CTs and MRIs; 7) to find out if the chemotherapy drugs that are given after surgery should be based on changes that are seen in the tumor cells before surgery; 8) to find out if giving chemotherapy before surgery to treat Wilms tumor with other risk factors (abnormal cells in the other kidney or predisposing syndromes) will shrink the tumor so when surgery is done a portion of the normal kidney can be saved; 9) to see if using a five-drug chemotherapy drug regimen to treat Wilms tumor with very aggressive cells in the tumor will be more effective at killing the tumor cells and improving patient survival; 10) to find out if the chemotherapy drugs that are given after surgery should be based on changes that are seen in the tumor cells before surgery. **Principal Investigator:** Gail Megason, M.D.

RARE SOLID TUMORS

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

ABTR01B1: A Children's Oncology Group protocol for collecting and banking pediatric research specimens including rare pediatric tumors The goals of this study are to 1) collect samples of tumor, blood, and bone marrow from people with cancerous tumors including rare pediatric tumors, 2) keep these samples carefully in long term storage, 3) make these samples available for research studies. We want to find better ways to detect tumors early and to find ways to prevent tumors from starting. **Principal Investigator:** Rathi Iyer, M.D.

ARAR0331: Treatment of childhood nasopharyngeal carcinoma with neoadjuvant chemotherapy and concomitant chemoradiotherapy The goals of this study are as follows: 1) To see if a combination of chemotherapy followed by chemoradiotherapy works better at treating children with advanced NPC than the standard therapy, and 2) To see how well amifostine protects children against dry mouth when given daily before radiation therapy. **Principal Investigator:** Rathi Iyer, M.D.

ARET0321: A trial of intensive multi-modality therapy for extra-ocular retinoblastoma This purpose is: 1) to find out if this multimodality therapy will get rid of the cancer better than treatments used in the past; 2) to find out how well the first phase of the study treatment (called induction) makes the tumor shrink or disappear; 3) to find out what effects good and/or bad the multimodality therapy has on people with retinoblastoma. **Principal Investigator:** Gail Megason, M.D.

RHABDOMYOSARCOMA

(for ages 0-30)

For more information on these studies, please call 601-984-5220.

D9902: A COG Soft tissue sarcoma diagnosis, biology and banking protocol

This study is being done for several reasons. **Central Pathology Review** If your/your child's study doctor plans to treat you/your child on a COG treatment study, one goal of this study is to be sure that you are/your child is treated on the correct COG RMS or NRSTS treatment study. This is done by having additional experts in the diagnosis of RMS and NRSTS look at the tumor biopsy and do some tests with the tumor tissue; this is called "central review". **Biology/Banking** Another goal is to collect tumor, blood, serum, and bone marrow specimens from people with soft tissue sarcoma for biology studies. We hope to learn more about RMS, NRSTS, and the people who have these diseases. A final goal is to collect specimens for the COG soft tissue sarcoma tissue bank for future research. This goal applies no matter how you are/your child is treated.

Principal Investigator: Rathi Iyer, M.D.

ARST0531: Randomized study of vincristine, dactinomycin and cyclophosphamide (VAC) versus VAC alternating with vincristine and irinotecan (VI) for patients with intermediate risk rhabdomyosarcoma

The overall goals of this study are: 1) to see if the combination of VAC plus VI is better than standard chemotherapy (VAC) alone for treating intermediate risk RMS, 2) to compare the effects, good and/or bad, of VAC plus VI to standard chemotherapy, 3) to compare radiation therapy (starting at Week 4) to the standard schedule (starting at Week 13) for side effects (toxicity), and the older schedule (starting at Week 10) for effectiveness, and 4) to compare the side effects of a slightly lower dose of cyclophosphamide to the higher standard dose. **Principal Investigator:** Gail Megason, M.D.

ARST08P1: A pilot study to evaluate novel agents in combination with Intensive multi-agent interval compression therapy for patients with high-risk rhabdomyosarcoma

The 3 sequential pilots proposed in this study assess 3 innovations. The goals of Pilot 1 are: 1) To find out the effects, good and/or bad, of giving the experimental drug IMC-A12 in combination with high intensity chemotherapy (ifosfamide, etoposide, doxorubicin and irinotecan plus standard VAC therapy). 2) To see if giving your child IMC-A12 and high intensity chemotherapy earlier in his/her treatment will get rid of the cancer longer than standard chemotherapy.

The goals of Pilot 2 are: 1) To find out the effects, good and/or bad, of giving temozolomide in combination with high intensity chemotherapy (ifosfamide, etoposide,

doxorubicin and irinotecan plus standard VAC therapy) to people with high-risk rhabdomyosarcoma and ectomesenchymoma. 2) To see if giving your child temozolomide and high intensity chemotherapy earlier in his/her treatment will get rid of the cancer longer than standard chemotherapy.

The goals of Pilot 3 are: 1) To find out the effects, good and/or bad, of giving the experimental drug IMC-A12 in combination with temozolomide and high intensity chemotherapy (ifosfamide, etoposide, doxorubicin and irinotecan plus standard chemotherapy) 2) To see if giving your child IMC-A12, temozolomide, and high intensity chemotherapy earlier in his/her treatment will get rid of the cancer longer than standard chemotherapy **Principal Investigator:** Gail Megason, M.D.

ARST0921: A randomized phase II trial of bevacizumab and temsirolimus in combination with intravenous vinorelbine and cyclophosphamide in patients with recurrent/refractory rhabdomyosarcoma The goals of this study are: 1) To find out what effects (good and/or bad) bevacizumab, given with vinorelbine and cyclophosphamide, has on children and young adults with recurrent or refractory rhabdomyosarcoma 2) To find out what effects (good and/or bad) temsirolimus, given with vinorelbine and cyclophosphamide, has on children and young adults with recurrent or refractory rhabdomyosarcoma 3) To compare the effects of treatment with vinorelbine, cyclophosphamide and bevacizumab against the effects of treatment with vinorelbine, cyclophosphamide and temsirolimus. **Principal Investigator:** Gail Megason, M.D.

ADVL0921: A Phase II Study of MLN8237 , a Selective Aurora A Kinase Inhibitor in Children with Recurrent/Refractory Solid Tumors and Leukemias

The purposes of this study are: 1) to find out if MLN8237 can stop recurrent solid tumors from growing or cause them to get smaller, for a period of time; 2) to find out if MLN8237 can stop leukemia cells from growing or decrease the number of leukemia cells in the body, for a period of time; 3) to learn more about the side effects of MLN8237; 4) to learn more about how your body handles MLN8237; 4) to learn more about how the drug works in the body and in cells. **Principal Investigator:** Gail Megason, M.D.

STEM CELL TRANSPLANT

(for ages 0-21)

For more information on these studies, please call 601-984-5220.

AAML05P1: Killer immunoglobulin receptor (KIR) incompatible unrelated donor hematopoietic stem cell transplantation for AML with monosomy 7, -5/5q-, High FLT3-ITD AR, or refractory or relapsed acute myelogenous leukemia in children

The primary goal of this study is to see whether specific bone marrow mismatches (KIR receptor-ligand) may improve bone marrow transplant results. **Principal Investigator:** Gail Megason, M.D.

AAML1031: A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib for Patients with High Allelic Ration FLT3/ITD

The main goals of this study are 1) to see if an experimental drug, called bortezomib, is tolerated when added to the standard AML treatment without causing too many serious side effects; 2) to compare the effects, good and/or bad, of adding bortezomib to the standard AML treatment to find out which is better; 3) to determine the dose of sorafenib that is safe when added to standard AML treatment; 4) to compare the effects, good and/or bad, of adding sorafenib to standard AML treatment to find out which is better; 5) to determine how effective the combination of sorafenib and chemotherapy will be at killing cancer cells.

Principal Investigator: Gail Megason, M.D.

ACNS0333: Treatment of atypical teratoid/rhabdoid tumors of the central nervous system with surgery, intensive chemotherapy, and 3-D conformal radiation

The purpose is: 1) to find out what effects (good and bad) surgery, intense chemotherapy with stem cell rescue, and radiation therapy have on people with AT/RT; 2) to look at the tumor tissue taken out during surgery and a blood sample to see if there are any features of the tumor cells such as proteins, and/or any genetic features.

Principal Investigator: Betsy Herrington, M.D.

0501: Multi-center, open label, randomized trial comparing single vs double umbilical cord blood (UCB) transplantation in pediatric patients with high-risk leukemia and myelodysplasia

The purpose is to find out if giving two units of cord blood is better than giving one; results in faster bone marrow recovery; and improved survival. **Principal Investigator:** Gail Megason, M.D.

BMT CTN 0802: A multi-center randomized, double blind, phase III trial evaluating corticosteroids with placebo as initial treatment for acute GVHD The purpose is to evaluate the addition of Mycophenolate Mofetil vs Placebo to steroids as initial therapy to graft versus host disease in patients that have had a bone marrow transplant. The primary objective objective is to estimate graft versus host disease free survival at Day 56 after randomization without therapy. **Principal Investigator:** Gail Megason, M.D.

BMT CTN 0601: Unrelated donor hematopoietic cell transplantation for children with severe sickle cell disease using a reduced intensity conditioning regimen The purpose is to determine the safety of transplanting children whose have severe sickle cell disease with unrelated donors using a reduced intensity regimen. **Principal Investigator:** Gail Megason, M.D.