

# Enrolling In Clinical Trials

## **CURRENT CLINICAL TRIALS AVAILABLE AT UNIVERSITY HOSPITALS OF CLEVELAND**

Dear Neighbor:

**University Hospitals of Cleveland (UHC)** receives numerous inquiries each month requesting information on Clinical Trials.

A Clinical Trial is a research study to answer specific questions about new therapies or new ways of using established treatments. Clinical Trials are used to determine whether new drugs or treatments are both safe and effective. Most current drug therapies were initially developed in past Clinical Trials.

Participants include men, women and children of all ages, races, religions and ethnic backgrounds, depending on the study guidelines. Protection of the rights, safety and welfare of our research participants is always our primary concern. Clinical Trial participants are seen regularly by the research staff to monitor their health and determine the safety and effectiveness of their treatment. Each Clinical Trial is approved by the Institutional Review Board, consisting of health care professionals as well as lay people

from the community, to ensure that risks are monitored and federal regulations are followed. Informed consent is the process of learning the key facts about a Clinical Trial before deciding to participate. When being considered for a Clinical Trial, the research staff will provide you with an informed consent document that includes the following details: why the research is being done, what will be done during the trial, what risks and benefits can be expected, availability of alternative treatments, contact information, confidentiality, and any costs. What follows is a partial list of the hundreds of Clinical Trials at University Hospitals of Cleveland that are actively recruiting participants. If you would like to participate, please call 216-844-5000, or register online at [www.uhhs.com/clinicaltrials](http://www.uhhs.com/clinicaltrials).

We hope you find this publication useful, and that you will share it with friends and family who may benefit from one of the studies.

**For information or to register for screening in a  
selected trial, call HealthMatch at (216) 844-5000.**

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## ➤ AIDS #1

**OVERVIEW:** This research study is designed to learn whether different anti-HIV medication (“HAART”) combinations work equally well in participants who have never taken anti-HIV medications before. The research study will also look at how easy the medications are to take and their side effects. Each participant will be randomly assigned, like a flip of a coin, to one of four groups (called “Arms”). Participants in each group will take a different set of anti-HIV medications. The medications used in this research study are all commonly used, FDA-approved, anti-HIV medicines. All medicines used in this research study are supplied at no cost to participants.

**CRITERIA:** Participants must be an HIV-positive person, 16 years of age or older, who has never taken anti-HIV medications before (there are a few exceptions to this requirement). HIV viral load must be greater than 1,000 copies. Participants who are already known to be resistant to any anti-HIV medicines will not qualify for this research study.

## ➤ AIDS #2

**OVERVIEW:** This research study will compare different starting times of anti-HIV medicines for HIV-positive people who have a severe infection caused by a weakened immune system (acute opportunistic infections) or severe bacterial infections. Participants will be randomly assigned (like a flip of a coin) to one of two groups (or “Arms”). The first Arm will start anti-HIV medicines within 2 weeks of starting therapy for the infections. The second Arm will start anti-HIV medicines at least one month (and up to over 7 months) after starting ther-

apy for the infections, depending on the medical needs of the participant. Certain anti-HIV medicines are supplied by the research study at no cost.

**CRITERIA:** Participants must be HIV-positive person, 13 years of age or older, who has a severe infection caused by a weakened immune system (acute opportunistic infection) or severe bacterial infection, and who has never taken anti-HIV medicines (with a few exceptions).

## ➤ AIDS #3

**OVERVIEW:** This research study will look at the timing of starting anti-Hepatitis C and anti-HIV medicines. One purpose of the research study is to determine whether there are benefits to starting anti-HIV medicines before starting anti-Hepatitis C medicines. Participants will be randomly assigned (like a flip of a coin) to one of two groups (or “Arms”). The first Arm will start taking anti-HIV medicines before starting anti-Hepatitis C medicines. Participants in the second Arm will start taking anti-Hepatitis C medicines without taking anti-HIV medicines. Participants in the second Arm will start taking anti-HIV medicines if medically required and/or at the advise of their HIV primary care physician. Anti-HIV and anti-Hepatitis C medicines are provided by the research study at no cost. Research participants are provided compensation.

**CRITERIA:** Participants must be an HIV and Hepatitis C co-infected person, 18 to 65 years of age. HIV viral load must be greater than 1,000 and CD4+ cell count 300 or more. Participants must not have taken anti-HIV medicines for more than 7 days within the last six months before starting the trial, and must not need to start anti-HIV medicines upon entry into the study.

## ➤ Alcohol Dependence and Bipolar Disorder Study

**Overview:** The Addiction Recovery Services of University Hospitals of Cleveland is conducting clinical research on the treatment of Alcohol Dependence in adults with Bipolar I Disorder, a mood disorder that affects more than four million people in the United States. This research study is designed to look at the safety and effectiveness of a medication used with lithium or depakote for the treatment of alcohol dependence in adults with Bipolar I Disorder.

**CRITERIA:** Participants must be between 21 and 60 years old, with a history of recent heavy drinking and have the diagnosis of Bipolar I Disorder and Alcohol Dependence.

## ➤ Alzheimer's Disease #1

**OVERVIEW:** Valproate is an anticonvulsant drug that may be helpful in reducing the occurrence of problem behaviors in Alzheimer's disease (AD). This research study will test whether Valproate is effective in delaying, weakening or preventing difficult behaviors and whether it has any effect on memory and thinking in people with early stage AD.

**CRITERIA:** Participants must have mild to moderate Alzheimer's disease, between the ages of 55 and 90, and have not experienced agitation or psychosis since the onset of AD.

## ➤ Alzheimer's Disease #2

**OVERVIEW:** This research study is designed to determine whether imaging of the brain through MRI and PET scans (neuroimaging) every six months

can help predict and monitor the onset and progression of Alzheimer's disease. In addition to neuroimaging, the study will collect and test blood and, for some participants, cerebral spinal fluid, to determine if biomarkers can predict and monitor the disease.

**CRITERIA:** Participants must be between 55 and 90 years of age, be in good general health, be fluent in English, and have either memory problems or a diagnosis of early Alzheimer's disease. Participants must be willing to undergo the test procedures and have a study partner.

## ➤ Alzheimer's Disease #3

**OVERVIEW:** This research study is designed to compare the effects of different types of antioxidants (vitamins that may protect against cell damage) to help select the best combinations of antioxidants for future, larger studies. The levels of chemicals in the blood and in the brain and spinal fluid (cerebrospinal fluid) will be measured to see how well and safely different types of antioxidants can be used in patients with Alzheimer's disease.

**CRITERIA:** Participants must be between the ages 60 and 85 and have been diagnosed with mild to moderate Alzheimer's disease.

## ➤ Amyotrophic Lateral Sclerosis

**OVERVIEW:** ALS is a devastating disease that eventually affects respiratory function. Treatment options for respiratory function are limited to no treatment, non-invasive or invasive ventilation. Stimulation of the Diaphragm in Amyotrophic Lateral Sclerosis is an investigation of a diaphragm pacing system. The ultimate goal is to determine whether

providing electrical stimulation to the diaphragm muscle will maintain diaphragm muscle strength therefore, decreasing the rate of respiratory decline in ALS. This is a minimally invasive, low risk surgical procedure that laparoscopically implants electrodes into the diaphragm muscle. These electrodes are attached to a stimulator. The stimulator delivers electrical impulses to the diaphragm causing diaphragm contraction.

**CRITERIA:** Participants must be over 18 years of age, have a confirmed diagnosis of ALS, have no significant co-morbidities, and a Forced Vital Capacity (FVC) between 50-80% to enroll.

### ➤ Arthritis, Hip

**OVERVIEW:** This 13-week research study will look at the safety and efficacy of an investigational medication in the treatment of pain due to primary hip osteoarthritis. The study location is our Beachwood office.

**CRITERIA:** Participant must be at least 40 years of age, have been diagnosed with primary hip osteoarthritis, have symptoms present for at least three months, and must be taking a non-steroidal anti-inflammatory drug (NSAID) or simple analgesic. As a qualified participant, you will receive all study-related examinations and investigational study medication at no cost.

### ➤ Arthritis, Knee #1

**OVERVIEW:** This research study will look at an investigational medication injected into the knee to treat knee pain. Participants will receive a total of three knee injections over 3 months. This study is being conducted in our Beachwood office.

**CRITERIA:** Participants must be 18 years of age or older and have a diagnosis of osteoarthritis or have knee pain greater than three months.

### ➤ Arthritis, Knee #2

**OVERVIEW:** This research study will evaluate the proper placement of a pain patch for knee osteoarthritis pain. All qualified participants will receive the pain patch and will be instructed on patch placement over the 9-week duration of the study. The study center is located in Beachwood.

**CRITERIA:** Participants must be at least 45-years old, must have osteoarthritis in the knee, and must have knee pain when walking on a flat surface.

### ➤ Arthritis, Knee #3

**OVERVIEW:** This research study is designed to understand the use of pain medication during walking in people who have osteoarthritis of the knees. Eligible participants will receive two doses of study medication (one dose of active study medication and one dose of placebo medication) and will be asked to walk on a flat surface for intervals of 20 minutes, until the pain becomes uncomfortable or sooner than 20 minutes for any other reason. Participation will last 4 weeks and the study visits will be conducted at the Beachwood office.

**CRITERIA:** Participants must be at least 45 years of age or older, have been diagnosed with osteoarthritis of the knees, and have knee pain when walking on a flat surface.

## ➤ Attention Deficit /Hyperactivity Disorder (ADHD), Adults

**OVERVIEW:** This research study will examine how atomoxetine (Strattera) in the treatment of ADHD in adults and how ADHD affects family functioning. Eligible participants who meet screening criteria will be closely monitored with frequent clinical visits with a physician. Clinical care, evaluations, medications and laboratory tests done as part of the research study will be provided at no cost to the participant.

**CRITERIA:** Participants must be between 18 and 55 years of age, be in a relationship with a person of the opposite sex and have a biological child between 6-12 years old living with them.

## ➤ Barrett's Esophagus

**OVERVIEW:** This study is designed to determine whether there is an increased incidence of Barrett's esophagus or esophageal cancer in the relatives of persons with Barrett's esophagus or esophageal cancer. The Division of Gastroenterology is contacting siblings, children, and parents of patients with Barrett's esophagus or esophageal cancer, who have had symptoms of gastroesophageal reflux disease (GERD) or heartburn. Using a very thin scope, we can examine the esophagus to check for Barrett's without the need for sedation. This procedure takes no more than 10 minutes.

**CRITERIA:** Participants should be parents or siblings of patients with Barrett's esophagus or esophageal cancer.

## ➤ Bipolar Disorder, Adults

**OVERVIEW:** The NIMH Center for Bipolar Disorder of University Hospitals of Cleveland and Case School of Medicine is conducting clinical research on the treatment of symptoms related to Bipolar Disorder, a mood disorder that affects more than four million people in the United States. This research study focuses on the treatment of symptoms of bipolar disorder in participants who have not been diagnosed, or who have been previously diagnosed with major depression. The goal of the research study is to look at the effectiveness and safety of Depakote ER which has been used for depressive episodes and anxiety. This study will last for 6 weeks, with an additional 6 months of treatment for participants who have a good response to the study medication.

**CRITERIA:** Participants must be 18 years of age and older and be experiencing symptoms of Bipolar Disorder including sadness, loss of interest in activities, sleep disturbances, lack of concentration, excessive energy, and inappropriate anger or irritability.

## ➤ Bipolar Disorder #1, Adolescents and Adults

**OVERVIEW:** The NIMH Center for Bipolar Disorder of University Hospitals of Cleveland and the Case School of Medicine is conducting clinical research on the treatment of symptoms related to Bipolar Disorder, a mood disorder that affects more than four million people in the United States. This research study will last for up to 28 weeks, and is looking at a combination of medications for treatment. The goal of the research is to

compare the effectiveness and safety of the use of two medications (lithium and depakote) versus three medications (lithium, depakote, and lamictal). Throughout participation in this research study, symptoms will be actively monitored and any changes in condition will be reviewed and appropriately treated.

**CRITERIA:** Participants must be at least 16 years of age and be experiencing symptoms related to depression. Participants should have a diagnosis of Bipolar Disorder, although participants do not need to have been diagnosed with Bipolar Disorder. Participants will receive an evaluation and diagnosis free of charge. Participants cannot have used Lamictal (lamotrigine).

### ➤ Bipolar Disorder #2, Adolescents and Adults

**OVERVIEW:** The NIMH Center for Bipolar Disorder of University Hospitals of Cleveland and Case School of Medicine is conducting clinical research on the treatment of Bipolar Disorder in patients who also have problems with alcohol or drug use. This research study will last up to 28 weeks, and is looking at a combination of medications for treatment. The goal of the research is to compare the effectiveness and safety of the use of two medications (lithium and depakote) versus three medications (lithium, depakote, and lamictal). Throughout participation in this research study, symptoms will be actively monitored and any changes in condition will be reviewed and appropriately treated.

**CRITERIA:** Participants must be 16 years of age and older, be experiencing symptoms related to depression, have current

Alcohol Abuse/Dependence, or Substance Abuse/Dependence and have a diagnosis of Bipolar Disorder, although participants do not need to have been diagnosed or treated previously for Bipolar Disorder. Potential participants will receive an evaluation and diagnosis at no cost. Participants cannot have used Lamictal (lamotrigine).

### ➤ Bipolar Disorder, Older Adults

**OVERVIEW:** This research study compares lithium and valproate (Depakote) in the treatment of older adults with bipolar manic (high mood) and hypomanic episodes (slightly high mood). The study compares the side effects and effectiveness of the medications on symptoms and quality of life. Lithium and valproate are FDA approved for use in treating bipolar disorder.

**CRITERIA:** Participants must be age 60 or older, have bipolar disorder, and currently be experiencing manic (high mood) or hypomanic (mildly elevated mood) symptoms.

### ➤ Bladder Function, Women

**OVERVIEW:** This research study will evaluate the usefulness of urodynamic testing which is a test that measures bladder function.

**CRITERIA:** Participants must be adult females with urinary problems which may include incontinence or leaking of urine while coughing, sneezing, or performing physical activity. Participants may also have a bathroom problem with leakage of urine due to an inability to get to a bath room quickly.

## ➤ Cancer, Ovarian, Fallopian Tube or Peritoneal

**OVERVIEW:** This research study is designed to compare two treatments for ovarian, fallopian tube or peritoneal cancers. One treatment uses the investigational drug BAY 43-9006 alone. The other treatment uses the experimental drug in combination with two FDA-approved cancer treatment drugs, carboplatin and paclitaxel. Participants have an equal chance of being assigned to either treatment group.

**CRITERIA:** Participants must be at least 18 years of age and must have recurrent, measurable, epithelial ovarian cancer, primary peritoneal cancer or fallopian tube cancer that is considered platinum sensitive. Participants must have received prior therapy with a platinum-based regimen before study enrollment. Participants must have adequate bone marrow function and must not need an IV to stay hydrated or for nutritional support. Participants of childbearing potential must agree to use adequate contraception.

## ➤ Chemotherapy Effects on Hearing

**OVERVIEW:** This research study is designed to help identify how to best measure side effects of chemotherapy related to hearing. Participants enrolled in this study will be tested during their chemotherapy sessions. The four 45-minute physical assessments during a 12-week period will include measurements of hearing and sense of vibration using a tuning fork. Blood pressure will be taken using two types of blood pressure machines in three positions: laying, sit-

ting and standing. This is an observational study that does not use any investigational drugs or therapy.

**CRITERIA:** Participants must be between the ages of 21 and 85 and scheduled to receive chemotherapy; either cisplatin/taxol combination or biotherapy with interferon alpha. Participants must be enrolled before starting chemotherapy. Patients with hearing impairment are not eligible.

## ➤ Colon Cancer

**OVERVIEW:** The Colon Cancer Sibling Study is a family research study funded by the National Cancer Institute to identify new genes related to the development of colon polyps or colon cancer. Participation involves the collection of a blood sample and authorization of release of medical records related to cancer screenings.

**CRITERIA:** Participants must have been diagnosed with colon polyps or colon cancer before age 65 OR have a living brother or sister with one of these diagnoses. Affected and unaffected family members including siblings and parents are eligible to participate.

## ➤ Crohn's Disease

**OVERVIEW:** This research study is designed to look at the safety and effectiveness of an oral study drug called AST-120 in participants who have Crohn's disease with a draining fistula (an abnormal connection from one part of the intestine to another part of the intestine or the outside of the body).

**CRITERIA:** Participants must be between 18 and 65 years of age, must not have received infliximab within the past year and have a diagnosis of Crohn's disease with at least one draining fistula.

## ➤ Depression, Adolescents

**OVERVIEW:** This research study will examine the use of escitalopram (Lexapro) in the treatment of children suffering from depression. Lexapro is FDA approved for use in adults. Eligible participants who meet screening criteria will be closely monitored with frequent clinical visits with a physician. Clinical care, evaluations, medications and laboratory tests done as part of the research study will be provided at no cost to the participant.

**CRITERIA:** Participants must be between 12 and 17 years of age, and be either boys or girls who meet the research criteria for depression – sadness, irritability, withdrawn, and lack of interest.

## ➤ Depression, Adolescents

**OVERVIEW:** This study will examine the use of escitalopram (Lexapro) in the treatment of children suffering from depression. Lexapro is FDA approved for use in adults. Eligible participants who meet screening criteria will be closely monitored with frequent clinical visits with a physician. Clinical care, evaluations, medications, and laboratory tests done as part of the research study will be provided at no cost to the participant.

**CRITERIA:** Participants should include boys and girls between 12 and 17 years of age who meet diagnostic criteria for depression—sadness, irritability, withdrawn, lack of interest, etc.

## ➤ Diabetes and Kidney Disease

**OVERVIEW:** This research study is designed to determine whether the study medication will slow the progress

of kidney disease in individuals with Type II Diabetes. Blood work and urine specimens will be collected to determine if participants are eligible. Half of the participants will receive study medication and half will receive a placebo (no active drug). Study participants will receive study medication and some blood pressure medication at no cost.

**CRITERIA:** Participants must have been diagnosed with type II diabetes and be over 18 years of age and have developed kidney disease. Women may not be pregnant or become pregnant while in the study.

## \*Gynecologic Oncology Study (05-04-41)

### ➤ Cancer Treatment Side Effects

**OVERVIEW:** This research study is designed to reduce certain side effects that may be caused by a specific type of cancer treatment (Doxil). The study will look at the effectiveness of vitamin B-6 (pyridoxine) for the control and/or prevention of “hand-foot syndrome”, (redness, tenderness, and possibly peeling of the palms and soles) due to Doxil-related chemotherapy. The study will look at two groups of participants, one receiving daily vitamin B-6 and the other receiving a daily oral placebo (sugar pill), to see whether vitamin B-6 can reduce or prevent hand-foot syndrome.

**CRITERIA:** Participants must be treated for recurrent ovarian cancer, peritoneal cancer, fallopian tube cancer, metastatic breast cancer or advanced endometrial cancer, and must be starting Doxil chemotherapy at a starting dose of 40mg/m<sup>2</sup> every 4 weeks. Participants

must be well healed, from recent surgery, radiotherapy, or chemotherapy, with a few exceptions like for alopecia (hair loss) or neuropathy (nerve damage). Participant with reproductive potential must use an adequate contraceptive method. Participants must be able to complete questionnaires about their quality of life.

### ➤ Cancer Risk, Ovarian

**OVERVIEW:** The purpose of this research study is to learn more about how to care for women who are at increased genetic risk of ovarian cancer. Participants will be placed in one of two groups in the study: one group is women who choose to undergo preventive removal of the ovaries and fallopian tubes; the other group is women who choose not to have surgery but choose to have screening. In addition, this study will look at the reasons why women decide to undergo screening versus surgery, and how the women feel during this screening period.

**CRITERIA:** Participants must be 30 years of age or older, with no prior history of ovarian cancer and at least one ovary. Additionally, participants should have one of the following criteria: A family or personal history of a BRCA1 or BRCA2 genetic mutation, OR a family history of ovarian and/or breast cancers among at least two first- or second-degree relatives or both cancers in the same person, OR the participant is of Ashkenazi Jewish ethnicity with one first-degree or two second-degree relatives with breast and/or ovarian cancer OR the participant is of Ashkenazi ancestry and has had breast cancer herself OR the participant has a strong probability of having a genetic mutation based on family history.

### ➤ Cervical Lesions

**OVERVIEW:** This research study is designed to test the drug Celecoxib in the treatment of cervical intraepithelial neoplasia (CIN 3-a precancerous lesion of the cervix). Participants on this study are treated with oral celecoxib instead of having the cervical lesions removed with surgery. This study will test the effectiveness and the safety of the drug in women with CIN 3-a of the cervix.

**CRITERIA:** Participants must be 18 years of age or older and be diagnosed with CIN 3 by cervical biopsy. The biopsy should be done between 2 and 8 weeks before enrollment. Participants will also be screened to make sure they match the study criteria. Participants must have a negative pregnancy test and agree to use an acceptable form of contraception. Participants must agree not to take Non Steroidal Anti-Inflammatory Drugs (NSAIDs) and aspirin during the time they are taking the study medication.

### ➤ Cervical Cancer

**OVERVIEW:** This research study is designed to determine whether combining the drug Tirapazamine with Cisplatin during radiation therapy increases the length of time that patients with cancer of the cervix live without their cancer coming back compared to patients who receive Cisplatin and radiation therapy without receiving Tirapazamine. Cisplatin and radiation therapy are standard treatments that are given to treat cancer of the cervix. Tirapazamine is an investigational drug. Eligible participants will be assigned to Group 1 or Group 2 by chance. Participants who are enrolled in Group 1 receive Cisplatin along with external and internal radiation therapy.

Participants enrolled in Group 2 receive Cisplatin and Tirapazamine along with external and internal radiation. There is an equal chance of being assigned to Group 1 or Group 2.

**CRITERIA:** Participants must be 18 years of age or older and have a specific type of cancer of the cervix. Participants must have adequate bone marrow, liver and kidney function. Participants must meet the criteria for chemotherapy and pelvic radiation treatment. Participants of childbearing potential must have a negative pregnancy test and must agree to use an effective form of contraception.

### ➤ Crohn's Disease

**OVERVIEW:** This research study is designed to look at the safety and effectiveness of an oral study drug called AST-120 in participants who have Crohn's disease with a draining fistula (an abnormal connection from one part of the intestine to another part of the intestine or the outside of the body).

**CRITERIA:** Participants must be between 18 and 65 years of age, have a diagnosis of Crohn's disease with at least one draining fistula, and must not have received infliximab within the past year.

### ➤ Glioblastoma

**OVERVIEW:** This research study is designed to determine the effectiveness of adding stereotactic radiosurgery, with the help of a specialized Magnetic Resonance (MR) scan, to standard radiation therapy for participants with a type of brain tumor called glioblastoma. Stereotactic radiosurgery is a way of treating brain tumors with a single high dose of radiation. The type of functional MR

scan used in this study is called MR spectroscopy and is used to take pictures of the brain.

**CRITERIA:** Participants must have a diagnosis of a glioblastoma brain tumor, must have had surgery for the tumor, and be well healed after having surgery. Participants must start the study treatment within five weeks of having surgery. Participants must not have already had radiation to the head and neck area.

### ➤ Hair Loss

**OVERVIEW:** The Skin Study Center of the Department of Dermatology is doing basic research into the cellular causes of hair loss (alopecia). Both men and women with permanent hair loss, especially those whose baldness began after age 55, are encouraged to participate. A small scalp biopsy may be taken. Participants will be compensated.

**CRITERIA:** Participants may be male and female participants, age 55 and older with hair loss.

### ➤ Heart Failure

**OVERVIEW:** FUSION II is a research study for patients who have recently been hospitalized with heart failure. The research study is designed to determine whether a medicine called nesiritide (Natrekor<sup>®</sup>) helps heart failure patients feel better or reduce the need to be hospitalized in the future. This medicine is currently FDA approved, and is used to improve shortness of breath in certain patients hospitalized for heart failure. The medicine will be given to patients to use while at home. During the trial, participants will see a heart failure physician, have blood tests, answer questionnaires,

and take the study medicine. Participants will also continue their usual oral medicines. The trial is 6 months long: 4 months of once or twice weekly treatment, and then 2 months of follow-up.

**CRITERIA:** Participants must have moderate to severe heart failure which limits their activities or gives them symptoms at rest, and participants must have been hospitalized at least twice within the past year. Participants must also have reduced pumping function of the heart and also have at least mildly reduced kidney function.

### ➤ High Blood Pressure after Stroke

**OVERVIEW:** The goal of this research study is to find out if the drug nicardipine (Cardene®) can be used for the treatment of high blood pressure that occurs after people have suffered a stroke due to sudden bleeding in their brain. The study medication is given intravenously (into a vein) over a period of 24 hours.

**CRITERIA:** Participants must be 18 years and older, have high blood pressure and must have suffered a stroke due to bleeding in the brain within 6 hours before the start of treatment.

### ➤ HIV, Prevention of Fat Loss

**OVERVIEW:** The HIV Metabolic Research Center is conducting the HIV Lipoatrophy Study to understand how HIV infected adults can avoid the disfigurement of fat loss. This research study is investigating whether adding a nutritional supplement (Nucleomaxx) and/or substituting Viread for other drugs in an anti-HIV regimen can reverse fat loss.

There are two arms to this study: in the first arm participants must be diagnosed with HIV lipoatrophy, receiving a stable AZT (Retrovir) containing regimen and the virus must be under good control; in the second arm participants are about to start their first ARV regimen (treatment naïve). That regimen must contain AZT as one part of the drug cocktail.

**CRITERIA:** Participants must be at least 18 years. Potential participants in either arm may be excluded for any bleeding disorders, diabetes requiring medication, kidney problems, current use of steroids or growth hormones, and/or are pregnant or breastfeeding.

### ➤ Lupus Atherosclerosis Prevention, Children and Young Adults

**OVERVIEW:** This research study is designed to learn more about preventing atherosclerosis (hardening of the arteries) in children and young adults with Lupus. This 3-year study is looking to learn more about preventing atherosclerosis and find out if a drug called Lipitor can help slow down the process of atherosclerosis. The Rheumatologist at Rainbow Babies & Children's Hospital invite you to consider participating in this NIH sponsored study. Compensation for parking and travel will be provided.

**CRITERIA:** Participants must be between the ages of 10 and 21. Participants must also be diagnosed with Lupus and weight 55 lb or more.

### ➤ Lupus, Skin Disease

**OVERVIEW:** The Department of Dermatology is conducting an investigational study for patients with lupus that mani-

ffects in the skin and affects specific cells in the immune system. The research study is approximately 20 weeks long and consists of 21 visits (including two overnight stays in the hospital). Compensation will be provided.

**CRITERIA:** Participants must be between 18 and 60 years old and continue to have skin disease despite standard treatment. Participants who also have lupus that affects the whole body are eligible if their main symptom involves the skin and they do not have serious complications from the disease.

## ➤ Memory Loss

**OVERVIEW:** For nearly 20 years, University Memory and Aging Center researchers have been studying why some people develop problems with memory, thinking, and activities of daily living as they age, while others retain normal memories. The goal of this research project is to create a list of people who might be eligible to participate in other research studies conducted by the University Memory and Aging Center. Participation involves a two-hour visit that includes paper-and-pencil memory testing and a physical assessment based on how the brain looks and works. After this visit, referrals to studies that include genetics, treatment, lifestyle, caregiving, and others may be offered. Visits take place at Fairhill Center, located at 12200 Fairhill Rd., with free parking, and there is no cost to participate.

**CRITERIA:** Participants must have mild memory concerns, or dementia resulting from Alzheimer's disease, stroke or other causes, and are not in nursing homes.

These participants can be any age. Participants with normal memory must be 65 years or older and are not in nursing homes.

## ➤ Myasthenia Gravis

**OVERVIEW:** This research study is designed to determine whether thymectomy (surgical removal of the thymus) helps participants with myasthenia gravis (MG) get better compared to using only medications like prednisone that suppress the immune system. Participants with generalized MG will be randomized (like a flip of a coin) to receive prednisone under strict set guidelines OR thymectomy and prednisone with the same prednisone treatment plan. Prednisone is an approved drug for treating MG. Participants are monitored by the study for 3 years. During the 3 years of the study, the participants are monitored by specific examinations of their muscle strength, their prednisone dose, and development of adverse effects.

**CRITERIA:** Participants must be 18 to 60 years old with generalized myasthenia gravis (MG) for less than 3 years. A diagnosis of MG must have been confirmed by positive standard blood test for MG. Participants may be receiving anticholinesterase treatment or prednisone but no other immune suppressing medication. Participants whose eyes are affected by MG or minimal general weakness that would not require the use of corticosteroids (prednisone) are not eligible. Participants must be medically stable (not becoming sicker) to have the thymectomy.

## ➤ Posttraumatic Stress Disorder (PTSD), Children and Adolescents

**OVERVIEW:** This research study is designed for children and adolescents who have experienced a trauma (e.g. sexual/physical abuse, violence, a car accident) and then developed posttraumatic stress disorder (PTSD). The study includes 12-15 weeks of talk therapy specifically aimed at reducing PTSD symptoms. There will be no charge to participants for the therapy.

**CRITERIA:** Participants must be between the ages of 7 and 18, have experienced a trauma that he/she remembers (e.g. physical or sexual assault or an accident) and be suffering from symptoms of PTSD (e.g. intrusive upsetting memories of the trauma, nightmares, fear, sleep problems) due to the trauma. The traumatic event should have occurred at least 12 weeks ago.

## ➤ Posttraumatic Stress Disorder (PTSD), Adults

**OVERVIEW:** This research study is designed to compare two treatments for posttraumatic stress disorder (PTSD) in adults: exposure therapy, a cognitive-behavioral talk therapy, and Zoloft (or sertraline), an antidepressant medication. PTSD is characterized by difficulties such as nightmares, anxiety, and upsetting memories that persist for at least one month after a traumatic event (such as physical or sexual assault, or a serious accident). Eligible participants will be offered at least ten weeks of treatment at no cost. Participants will be interviewed

at the end of treatment and at three, six, twelve, and twenty-four months after receiving treatment. There is no cost to participate and compensation will be provided for the follow-up interviews.

**CRITERIA:** Participants must be between the ages of 18 and 65 and meet the study criteria for chronic PTSD. To be eligible for this study, it must be at least 12 weeks since the traumatic event.

## ➤ Prostate Enlargement

**OVERVIEW:** This clinical research study will evaluate whether an FDA approved medication for enlarged prostate will improve sexual function. The study involves having a physical exam, completing questionnaires about urinary symptoms and sexual function and taking study medication for 3 months. Participants will be asked to make 3 visits to the research study urologist during the course of the 4-month study.

**CRITERIA:** Participants must be men who are between 45 and 74 years of age and are sexually active with a steady partner. Participants must also be diagnosed with an enlarged prostate and have urinary problems and erectile dysfunction.

## ➤ Rheumatoid Arthritis

**OVERVIEW:** This research study will evaluate the safety and effectiveness of a medicine given intravenously (in the vein) for rheumatoid arthritis. This study is being conducted in our Beachwood office.

**CRITERIA:** Participants must have a diagnosis of rheumatoid arthritis after the age of 16 years of age, be on a disease-modifying anti-rheumatic drug (DMARD), and must not have stopped a TNF-inhibitor because it did not work.

## ➤ Psoriasis #1

**OVERVIEW:** The Department of Dermatology is conducting research for adults with moderate to severe plaque psoriasis to evaluate the safety and effectiveness of a medication that is a subcutaneous injection (just underneath the skin). Eligible participants must have at least 10% body surface area involvement. All research-related physical exams, laboratory tests, and medications will be provided at no cost, and parking fees will be reimbursed.

**CRITERIA:** Participants must be 18 years and older with moderate to severe plaque psoriasis.

## ➤ Psoriasis #2

**OVERVIEW:** The Department of Dermatology is conducting a research study to evaluate the effects of a cream applied to the skin for the treatment of psoriasis. All research-related physical exams, laboratory tests, and medications will be provided at no cost, and parking fees will be reimbursed.

**CRITERIA:** Participants must be 18 years and older with mild to moderate plaque psoriasis.

## ➤ Psoriasis #3

**OVERVIEW:** The Department of Dermatology is conducting research for adults with moderate to severe plaque psoriasis to evaluate the safety and effectiveness of a medication that is a subcutaneous injection (just underneath the skin). Eligible participants must have at least 10% body surface area involvement. All research-related physical exams, laboratory tests, and medications will be provided at no cost, and parking fees will be reimbursed.

**CRITERIA:** Participants must be 18 years and older with moderate to severe plaque psoriasis.

## ➤ Skin Conditions, Pre-Malignant and Malignant

**OVERVIEW:** The Skin Study Center in the Department of Dermatology is conducting a research study for adults with Actinic keratoses (AK), Bowen's disease, Squamous cell carcinoma, Basal cell carcinoma, or Mycosis fungoides (MF stages IA, IIA, IB, or IIB). The trial involves a drug, phthalocyanine (Pc4) that is applied over the skin lesion. A laser light activates the Pc4 drug. The light is shone upon the lesion after application of the Pc4 drug solution. The research study lasts for two (2) weeks. All research exams, laboratory tests, treatment, and parking will be provided at no cost.

**CRITERIA:** Participants must have had a skin biopsy with a proven diagnosis of: Actinic keratoses (AK), Bowen's disease, Squamous cell carcinoma, Basal cell carcinoma, or Mycosis fungoides (MF stages IA, IIA, IB, or IIB). Participants must not be undergoing any anti-cancer therapy within two weeks prior to the trial. Participants must stop using photosensitizing medications for the two weeks prior to enrollment.

## ➤ Sleep Apnea

**OVERVIEW:** This research study will evaluate individuals who have frequent breathing pauses during sleep (sleep apnea) and are at risk for diabetes. This study is designed to look at changes in glucose (sugar), as well as changes in lipids (fats), quality of life, sleepiness, and blood pres-

sure in participants with sleep apnea and borderline diabetes. Participants will be treated with two months of breathing therapy and two months of sham, or fake, breathing therapy. The study will see if the breathing therapy improves sleep problems which in turn may prevent participants from developing diabetes.

**CRITERIA:** Participants must have problems with their glucose but not diabetes, have sleep apnea, be between the ages of 18 and 75, and are to be in good health without obvious daytime sleepiness. A glucose test and a home sleep study for sleep apnea for patients who are at high risk for these conditions will be provided at no cost to those individuals who have not had these specific tests.

## ➤ Stroke and Insulin Resistance

**OVERVIEW:** The Department of Neurology is conducting a research study to determine whether pioglitazone, a medication used to treat diabetes, may help prevent another stroke in patients who have been diagnosed with insulin resistance and who have already suffered a stroke. Participants will be randomly assigned to receive either pioglitazone or placebo. This study may or may not benefit the participant. Participants will be asked to return to University Hospitals for a clinic visit three to four times the first year and then once a year for three years. Parking will be reimbursed but there will be no other compensation.

**CRITERIA:** Participants must be 45 or older, must have suffered an ischemic stroke within 180 days of participation and must be insulin resistant. Participants will have a blood test at the begin-

ning of the study to determine if they are insulin resistant or not.

## ➤ Stroke #1

**OVERVIEW:** This research study is designed to evaluate the use of a clot-removing device in people who have had a recent stroke and are not eligible for currently approved therapy. The clot-removing device, Merci® Retrieval System, is designed to remove the clot and restore blood flow.

**CRITERIA:** Participants must be between 18 and 85 years of age. Participants must have had a stroke within 3 to 8 hours of enrolling into the study, and not be eligible for currently approved therapy for blood clots.

## ➤ Stroke #2

**OVERVIEW:** The Neurological Institute Clinical Trials Unit is conducting a research study to find out if treatment with either aspirin alone or aspirin and Plavix® help to prevent another stroke in people who recently suffered a “lacunar stroke”. A lacunar stroke causes small areas of damage to the inner part of the brain and is due to blockage of small blood vessels in the brain. Both aspirin and Plavix® are prescribed by physicians to prevent stroke, but it has not been determined if either aspirin alone or aspirin and Plavix® are more effective in preventing another stroke in people who have already had a lacunar stroke. Participants will be randomly assigned to either aspirin or aspirin and Plavix®. In addition, participants will be assigned to one of two groups of blood pressure control. This study may not benefit the participants. The study is expected to last about two years. There will be 3 to 5 visits over the first 3 to 4 months and

then visits will be scheduled every three months. Parking will be reimbursed, but there will be no other compensation.

**CRITERIA:** Participants must be 40 or older and must have suffered a lacunar stroke within 6 months of participation.

### ➤ Stroke #3

**OVERVIEW:** This research study is designed to compare two treatments for individuals who have a Patent Foramen Ovale (PFO; an opening in the heart) and who had a recent stroke. One option is to close the PFO using the AMPLATZER PFO Occluder, which is a device that helps to close the PFO using a minimally invasive procedure. The other option is to treat with medication alone, which is the current standard of care.

**CRITERIA:** Participants must be between the ages of 18 and 60 years with a PFO, and must have had a stroke within the last 90 days of enrollment.

### ➤ Stroke #4

**OVERVIEW:** This research study is designed to evaluate the effect of human serum albumin in participants who have suffered a stroke. Human serum albumin is a natural protein that is approved for other uses, but it is not approved for use in stroke. Participants will be randomly assigned (as in the toss of a coin) to receive one dose of either human albumin or placebo (sugar pill).

**CRITERIA:** Participants must be 18 years of age or older, and must have suffered a stroke within 5 hours of receiving treatment.

### ➤ Stroke #5

**OVERVIEW:** Standard rehabilitation does

not restore normal, safe walking to many stroke survivors. Functional Neuromuscular Stimulation (FNS), using intramuscular electrodes (applying electrical stimulation to the muscles), has been shown to help retrain walking patterns for people who have had a stroke more than one year ago. This study is designed to look at the benefits of FNS and treadmill training for people who have had a stroke in the past year. Participants who qualify will be provided with 48 treatment sessions with a physical therapist for gait training at no cost.

**CRITERIA:** Participants must be 21 years of age or older. Participants must be medically stable (not becoming sicker) and must have had a stroke within the past 1 to 11 months. Participants cannot have a pacemaker or chronic, worsening medical condition. Participants will be screened by a physician and therapist to determine whether they are eligible to participate in this study.

### ➤ Stroke #6

**OVERVIEW:** This research study is designed to improve arm function after stroke. Two types of treatment will be offered: 1) robotics motor learning (ROB ML); and 2) FNS motor learning (FNS ML). Eligible participants will receive treatment 5 days per week for 12 weeks at no cost.

**CRITERIA:** Participants must be 21 years of age or older and have difficulty using their arm as a result of a stroke. Participants must be medically stable (are not becoming sicker) and are eligible to participate at least 12 months after their stroke. Participants are not eligible if they have a pacemaker or have had more than one stroke.

## ➤ Urea Cycle Disorders

**OVERVIEW:** The Longitudinal Study of Urea Cycle Disorders (UCDs) will follow individuals with UCDs so that more can be learned about the natural history of all eight forms of the disorder. Information will be collected to help monitor disorder progression, treatments for the disorders (including drug therapy and liver transplantation), and the effects of the disorder and treatments on participants. This research study may help provide physicians with the information they need about UCDs and their treatments to help families coping with UCD make the best decisions about management and treatment. Additionally, information gathered through this study will be shared with participants and may lead to better informed individuals with UCDs.

**CRITERIA:** Participants may be individuals of all ages with any of the eight urea cycle disorders. There are factors that could exclude some people with UCDs from participating.

## ➤ Spinal Cord Injury

**OVERVIEW:** “Electrical activation of the diaphragm for ventilatory assist” is a clinical research study investigating a new diaphragm pacing system in quadriplegic patients who require a mechanism ventilator. This is a minimally invasive, low-risk surgical procedure implanting electrodes laparoscopically into the diaphragm muscle. These electrodes are attached to a stimulator that delivers an electrical impulse causing the diaphragm to contract. This enables a person to breath without their mechanical ventilator.

**CRITERIA:** Participants must be at least 18

years of age, have a cervical spinal cord injury, be dependant on mechanical ventilation, and have functioning bilateral phrenic nerves.

## ➤ Skin Study

**OVERVIEW:** The Skin Study Center of the Department of Dermatology is doing basic research into the cellular causes of psoriasis. Individuals with and without psoriasis are needed for blood and/or tissue samples. Participants will be compensated.

**CRITERIA:** Participants with and without psoriasis are welcome.

## ➤ Women’s Health #1, Post Menopausal Hot Flashes

**OVERVIEW:** Many women experience symptoms of hot flashes and night sweats after menopause. If you are ready to try low dose hormone therapy to relieve these symptoms, you may be eligible to participate in a research study being conducted by the Department of Obstetrics and Gynecology. Qualified participants receive medical examinations, mammograms, and lab tests as well as the study medication at no cost. Compensation is provided.

**CRITERIA:** Participants must be between the ages of 45 to 65, naturally menopausal (without periods for at least 6 months) or at least 6 weeks after a hysterectomy, having 7 or more hot flashes with sweating in 24 hours, and willing to attend 6 study visits over a 20 week period at a suburban office.

## ➤ Women's Health #2, Preterm Birth Prevention

**OVERVIEW:** This research study is for pregnant women who are at high risk of recurrent preterm birth. Prophylactic administration of progesterone has been shown to decrease the incidence of delivery before 37 weeks of gestation. This study will test the effectiveness of a progesterone vaginal gel compared to Placebo (sugar pill). Qualified participants will receive study medication at no cost. Compensation is provided.

**CRITERIA:** Participants must be pregnant women between 18 and 45 years of age and have a history of a spontaneous preterm delivery from 20 to 36 weeks gestation, with the immediate preceding pregnancy or a shortened cervix as measured this pregnancy by transvaginal ultrasound. Participants must be 16 to 22 weeks gestation at the time of enrollment.

## ➤ Women's Health #3, Birth Control

**OVERVIEW:** The Department of Obstetrics and Gynecology, MacDonald Clinical Trials Unit, is conducting a research study involving an investigational non-hormonal method of birth control. The primary purpose of this study is to determine the effectiveness of an experimental vaginal gel compared to the use of a standard spermicide. This study is for women between the ages of 18 and 40 who are willing to use the study drug before sex as their primary method of birth control

**CRITERIA:** Participants must be mentally and physically healthy women who are sexually active, able to become pregnant, but wish to use contraception at this time. Participants must be in a stable sexual relationship with a single partner for at least 4 months. To participate in the study, you must be willing to use this study drug as your primary method of birth control. Qualified participants will receive medical examinations and study drug at no cost. Compensation is provided.

## ➤ Women's Health # 4, Effects of Chemotherapy

**OVERVIEW:** This research study will use blood tests and (optional) ultrasound imaging to help doctors learn more about hormone levels and other aspects of ovarian structure and function before, during, and after chemotherapy. Side effects of chemotherapy can include changes in how a woman's ovaries look (structure) and how they work (function). Participants enrolled in this observational study will be asked to visit our office about three times in one year; starting before chemotherapy begins and ending approximately 6 months after completing treatment. This observational study does not use any investigational drugs or therapy as a part of the research.

**CRITERIA:** Participants must be female, between the ages of 14 and 35 and scheduled to receive chemotherapy. Participants should also have started their menstrual periods but do not have to be having regular periods at the time of enrollment. Participants must enroll before starting chemotherapy.