What is the General Clinical Research Center (GCRC)?

The General Clinical Research Centers (GCRC) were created by the federal government to provide medical and clinical researchers with research resources to help them prevent, detect and treat diseases. Primarily located within medical centers, the GCRC at Oregon Health & Science University is one of 78 of this type of government-sponsored research centers nationwide. GCRC’s were created for researchers to enable them to have greater access to study participants, not patients hospitalized for drug company study, can also be conducted in a GCRC. The inpatient GCRC is located in the Multnomah Pavilion, a building that housed the original hospital at OHSU. However, do not think of a research study visit as being “in” the hospital. All of the people admitted to the GCRC are study participants, not patients hospitalized for illnesses. While staying in the GCRC, you will wear your own clothes, have your own room, bathroom, TV, telephone and have access to a computer and VCR. The dieticians on staff will strive to honor your dietary requests.

The nurses and technicians who work in the GCRC are specialists in implementing research protocols. All study participants are closely monitored by nurses throughout their hospital research studies. The nurses in the inpatient GCRC have had training with the investigators in the Parkinson Center of Oregon on numerous studies and are familiar with the specific needs of Parkinson’s. All of the required movement testing, blood draws, IV’s and study medications are administered by the GCRC staff. Often, Parkinson’s study participants are required to be “off” medications overnight — that is, Parkinson’s medications are not given. Open the “Oldie-But-Goodie” you’re taking and toss the stairs with mobility, an aide on staff will be available for you.

While study activities will keep you busy each day, you will have plenty of opportunity in your time in the GCRC to do your own thing. Besides enjoying the fabulous hilltop views, there are cafes, a gift shop and a health club (for $8/day) on campus available to use when you are not required to be in the GCRC for testing or observation.

For more information on what it’s like to be a participant in a GCRC, call the GCRC at 503-494-5472.

GENE THERAPY

by Jay Nutt, M.D.

Gene therapy for Parkinson’s disease is now being tested in people with PD at various research centers. Gene therapy refers to inserting genes that will be taken up by nerve cells in the brain and then make proteins that could relieve symptoms of PD and perhaps reverse some of the damage to dopamine neurons. The genes are carried in a harmless virus and are injected into the particular parts of the basal ganglia that could benefit from more of the protein made by the gene.

Three trials are underway in PD. One trial is inserting the gene for neuritin, a growth factor that is similar to GDNF for which there is evidence of a restorative function for dopamine neurons. A second study is putting in a gene that will help with the conversion of levodopa to dopamine in the basal ganglia. The third study is placing an enzyme in the subthalamic nucleus to reduce the excitability of this structure. All three studies are phase 1 studies which means that they are to assess the tolerability of the treatment; whether it has any beneficial effect. All three studies have not found any significant toxicity so that it is expected that clinical trials to examine the effects of the treatments on the symptoms of PD will be initiated soon.

“Gene therapy promises not only the possibility of a cure but also the potential for a greater understanding of the disease process,” said Kirk McFarland, MD, a neurologist at OHSU. “Parkinson’s disease is a complex disorder that we hope to unravel through this innovative treatment.”

The research center staff members are experts at making one feel comfortable. It is always nice to meet other volunteers and hear about their progress with whatever illness they are facing. I have convinced several friends to volunteer as controls for ongoing studies. They all have come away feeling they have not been pampered, while, at the same time, doing some good.”

Betty Wyatt
Phases of Studies by Trish Kirchhoff, R.N.

A majority of the clinical trials that are conducted at the Parkinson Center of Oregon involve investigational new drugs. These investigational new drugs are developed by pharmaceutical companies and have undergone years of testing in the laboratory on animal and human cells and in animal experiments. If these stages of drug testing are promising enough, the pharmaceutical company provides the data to the Food and Drug Administration (FDA) requesting approval to proceed to the next phase of human testing. This experimental drug is now called a Investigational New Drug (IND).

Clinical testing of the IND is usually conducted in successive stages or phases. The number of participants at each phase increases, and the number of tests that will be done increases.

Phase I

This first phase of testing on humans is done primarily to determine drug safety. This testing is usually done with a small number (20-100) of healthy volunteers. These are people who are not diagnosed with the disease for which the drug is being tested. Some of the trials are conceived, designed and conducted only to test new surgical, diagnostic, or physical therapy approaches. Other clinical trials in Parkinson’s disease, Huntington’s disease, dystonia and tic disorders are conceived, designed and conducted only to test new surgical, diagnostic, or physical therapy approaches. Some of these trials include studies of new drugs, new surgical approaches, new diagnostic may or may not be different. What is important, however, is that researchers decide proper dosages and look at side effects caused by the drug. Some phase I studies can provide information on the drug’s effectiveness.

Phase II

Phase II trials are done on several hundred people diagnosed with the disease for which the drug is being tested. The drug, if found to be effective, will continue to evaluate its safety by testing it on a larger number of people. Data from this phase studies include efficacy testing, safety testing, side effects of the drug, and dosages and dosing schedules. Phase II studies usually involve a placebo-drug comparison, which means that one group of study participants is given the experimental drug and another group of study participants is given the placebo drug. Often, quite often, studies in phase II are double-blind studies. A study is double-blind when the researcher and the study participant do not know who is taking the experimental drug and who is getting the placebo or sugar pill. Only about 30 percent of experimental drugs pass this phase of testing. In order to complete both phase I and II testing, the drug must be shown to be both effective and safe.

Phase III

Phase III trials are performed on thousands of people, either by the General Clinical Research Center (GCRC) or a private clinical research center. They do not involve placebo-drug comparison but can involve the example of the effects of food on absorption of levodopa from the gut. As part of these studies, we brought in many patients to the General Clinical Research Center (GCRC) to study the effect of food on the absorption of levodopa from the gut. As part of these studies, we brought in many patients to the General Clinical Research Center (GCRC) to study the effect of food on the absorption of levodopa from the gut.

The core of every clinical trial is the protocol or the study plan. The protocol describes the study plan in detail and is the set of criteria that individuals must meet to be included in the study (for example, people diagnosed with Parkinson’s disease in the last five years). The protocol includes the study population, eligibility criteria, and exclusion criteria. It usually contains information for the effect of the disease on the participants. It may require patients to stop taking other medicines that could interact with the new drug. It may also require patients to keep a record of their daily activities.

What are the potential benefits of participating in a clinical trial?

Clinical trials may allow access to new treatments before they become available to the general public.

Clinical trials offer the possibility of receiving new treatments before they become available to the general public. Clinical trial participation is usually voluntary, and there are no guarantees. However, participation in a clinical trial is an important commitment that should be made with the help of your family and health care professionals.

Institutional Review Board (IRB), which includes doctors and scientists as well as lay people.

Clinical Trials 101 by Pamela Andrews

It is not uncommon to read an article or hear a new report saying, “A new study has shown...”, for example, that a new drug is effective for treating a disease. These studies are usually conducted in a laboratory setting where the researchers are able to control many factors that might influence the results. As a result, these studies are usually not seen in Parkinson’s disease and vice versa. This may extend to Lou Gehrig’s disease (ALS), Huntington’s disease, and Alzheimer’s disease.

Clinical trials are conducted by the Parkinson Center of Oregon as a step in the drug development process. This process involves a series of clinical studies before a dose is selected and larger trials are begun. The investigators at the Parkinson Center of Oregon are involved in the early phases of clinical trials, opening up new avenues for the treatment for PD.

Throughout each of these phases of studies, the investigators and drug companies can gain valuable information about the effectiveness of the drug and its potential side effects. They may also be able to find new ways to treat the disease by analyzing the data collected during each phase. If a drug is found to be effective in the early stages of clinical trials, it may be approved by the FDA and released for use to the public sooner.

Clinical Trials 101

Clinical trials are an important component of the drug development process. They are sponsored and paid for by two main sources: government agencies and pharmaceutical companies. All U.S. research projects are carefully monitored and regulated by the Food and Drug Administration (FDA). At the local level, such as at Oregon Health & Science University, all trial activities are also regulated by a panel of experts called an

Finding Another Piece in the puzzle by Mary Ann Haggerty, RN

What is a clinical trial? Is it a study of the safety and effectiveness of a new drug, treatment, or device? Clinical trials are the fastest and safest way to find new treatments for the slow progression of a disease. They are sponsored and paid for by two main sources: government agencies and pharmaceutical companies. Government agencies fund clinical trials through grants, and pharmaceutical companies fund clinical trials through profits from sales of prescription drugs. Clinical trials are an important component of the drug development process.

So what is just a clinical trial? It is a study of the safety and effectiveness of a new drug, treatment, or device. Clinical trials are the fastest and safest way to find new treatments for the slow progression of a disease. They are sponsored and paid for by two main sources: government agencies and pharmaceutical companies. Government agencies fund clinical trials through grants, and pharmaceutical companies fund clinical trials through profits from sales of prescription drugs.

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Clinical trials 101

by Pamela Andrews

It is not uncommon to read an article or hear a news report saying, “A new study has shown...,” for example, that butter is bad for you or that chocolate is good for you. As consumers, we think about how it affects our bodies and what we should do about it. But do we really understand the science or the methodology behind these studies? Clinical trials are the backbone of medical research and are the only way to advance treatment and cure for diseases.

Clinical trials are research studies in which people volunteer to be participants. They assess the safety and effectiveness of new treatments and medicines. Clinical trials are the first step in bringing new and potentially life-saving treatments to patients. The FDA does not approve a new drug or medicine for widespread use until it has been shown to be effective and safe in clinical trials.

Types of Clinical Trials

There are several types of clinical trials, each with its own unique purpose and design. Here are some of the most common types of clinical trials:

1. Phase I trials: These trials are the first to test a new treatment or drug in human volunteers. They are usually small, involving a few dozen participants, and are designed to determine the safety and maximum tolerated dose of the new treatment.

2. Phase II trials: These trials further test the safety and effectiveness of a new treatment or drug in a larger group of participants, typically hundreds or thousands. They may include different groups of patients to test the treatment’s effectiveness in different populations.

3. Phase III trials: These trials are the largest and most rigorous type of clinical trial. They are designed to confirm the safety and effectiveness of a new treatment or drug in a large group of patients, usually thousands or tens of thousands.

4. Phase IV trials: These trials are conducted after a drug has been approved for sale by the FDA. They are used to gather additional information about the drug’s safety and effectiveness in real-world settings.

5. Phase IIb/IIIa trials: These trials are conducted to further evaluate a new treatment or drug, typically in a larger group of patients than Phase II trials.

What is a clinical trial?

A clinical trial is a research study designed to evaluate the safety and effectiveness of a new treatment or drug. Participants in a clinical trial are usually randomized into different groups to ensure that the results are unbiased. The trial typically includes a control group and one or more treatment groups.

Why should I participate in a clinical trial?

Participating in a clinical trial can be a valuable opportunity for patients who are interested in finding new and potentially life-saving treatments. Clinical trials can also help advance medical research and provide crucial information that can lead to new treatments and cures.

What are the potential risks of participating in a clinical trial?

Clinical trials can be risky, and there is a chance of experiencing side effects or adverse events. Participants in clinical trials may also not be able to receive the standard of care that they normally would receive. It is important to understand the potential risks and benefits of participating in a clinical trial before making a decision to enroll.

What are the potential benefits of participating in a clinical trial?

Participating in a clinical trial can provide important benefits, including:

1. Access to new treatments: Participants in clinical trials may have access to new treatments that are not yet available to the general public.

2. Filling a research gap: Clinical trials can help fill gaps in medical knowledge and provide important information that can lead to new treatments and cures.

3. Contributing to medical research: Participating in a clinical trial can contribute to medical research and help advance the field.

4. Potential for long-term benefits: Clinical trials can provide patients with long-term benefits, such as improved quality of life and reduced symptoms.

What is the potential impact of clinical trials on future treatments?

Clinical trials are essential for the development of new treatments and medicines. They help ensure that new treatments are safe and effective for patients. Clinical trials also help identify potential side effects and adverse events, which can help guide future research and development.

Conclusion

Clinical trials are an essential part of medical research and are the only way to advance treatment and cure for diseases. By participating in clinical trials, patients can have access to new treatments and help advance medical research.

Questions to Ask When Entering a Research Study

As a patient with Parkinson’s disease, learning as much as you can about the clinical trials being conducted is important. Here are some questions you should ask your research staff about the clinical trial(s) being conducted:

1. What is the study being done by?
2. How long will the study last?
3. How many visits will I need to make to the study site?
4. What kinds of treatments do I have to take part in?
5. What are the benefits and the risks?

It is important to understand that there are benefits and drawbacks to all research studies. Some research studies may not benefit you directly, but will contribute to medical research, future treatment and disease prevention. Other studies may have a direct benefit to you. It is very important that you have the opportunity to make an informed decision about participating.

A Research Study

Before you enroll in a research study, it is important to understand what a research study is and what it involves. A research study is an investigation conducted to answer a question or solve a problem.

Phases of Studies

How to Read a Consent Form

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Conclusion

Clinical trials are an essential part of medical research and are the only way to advance treatment and cure for diseases. By participating in clinical trials, patients can have access to new treatments and help advance medical research.
1) When were you diagnosed with Parkinson’s disease? I was diagnosed in March 1990, just about 16 years ago.

2) What are your hobbies and how has PD affected your activities? Well, I love to fish and I enjoy doing home improvement projects around the house. As the disease has progressed, PD increasingly has affected when and how fast I do things, but not what I do. When my medications are not working as they should, I may have to tip my hat to the PD, say goodbye, and postpone or delay what I’m doing. Ultimately, however, the meds work and I can return to what I was doing. It’s a great object lesson in patience.

3) When did you start getting involved in Parkinson’s research? I can’t say for sure. I think it was 10 or 12 years ago. I was offered the opportunity to be in a trial of a new drug. It sounded interesting, and after reading more about it and discussing the possible risks with my doctor and the PCO staff, I decided to participate. I was interested (though I didn’t lead to “the cure”), and since I didn’t blow up either, I was willing to consider participating in other studies as well. Since then, I’ve been in about 12 or 14 clinical trials all together.

4) What has been beneficial about your experiences in clinical trials? It gives me a good feeling to know that I’m contributing in a way that most people can’t. I can’t do anything about having PD, but by doing it, I can be a test subject. In that way, I can contribute in a way that most people cannot. The fight against Parkinson’s disease will require the contributions of a lot of people, and participation in clinical trials can help, while for everybody, is one unique way that those of us with the disease can help.

5) What has been your favorite experience in clinical trials? It’s an overall experience rather than an individual event. I have really enjoyed working with and getting to know just about everybody at the Parkinson’s Center of Oregon. I feel privileged to be able to work with such dedicated and genuinely nice people who have devoted their careers to doing away with this miserable disease.

6) Have there been any downsides to your involvement in clinical research? There have been a couple of downsides to my involvement in clinical studies. First, there’s no cure. Yet, second, that brain surgery gave me one hell of a headache for a couple of days!

7) Any words of wisdom for other patients with Parkinson’s? Yes. First, hang in there. We’ll get this puzzle that is Parkinson’s disease solved some day, and I have to think it will be sooner rather than later. Second, consider participating in a clinical trial. It’s one way that those of us with PD can contribute to the eradication of the disease that is unlike the contribution that anybody else can make. If you’re interested, talk to your doctor or a PCO staff person.

GENE THERAPY
by Jay Nurt, M.D.

Gene therapy for Parkinson’s disease is now being tested in people with PD at various research centers. Gene therapy refers to inserting genes that will be taken up by nerve cells in the brain and then make proteins that could relieve symptoms of PD and perhaps reverse some of the damage to dopamine neurons. The genes are carried by a harmless virus and are injected into the particular parts of the basal ganglia that could benefit from more of the protein made by the gene.

Three trials are underway in PD. One trial is inserting the gene for neurotrophin-3, a growth factor. This trial has had preliminary success, with some patients showing improvements in their treatment of symptoms. The second trial is using a gene for a different growth factor, which has also shown promise in preliminary results. The third trial is using a gene for a different protein, which has shown promise in preliminary results as well. All three of these trials are ongoing and will continue until the treatment is approved by the Food and Drug Administration.

“The research center staff members are experts at making one feel comfortable. It is always nice to meet other volunteers and hear about their progress with whatever ailment they are being treated for. I have convinced several friends to volunteer as controls for ongoing studies. They all have come away feeling not being pampered while, at the same time, doing some good.”

Betty Wyatt

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A National Parkinson Foundation Center of Excellence

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The PCO at OHSU is a national leader in Parkinson’s disease research and recognized as a National Parkinson Foundation Center of Excellence. The PCO is involved in many other studies that are fully recruited and others that are currently looking for participants. Stay tuned for results from these and other PCO research studies in upcoming issues of the newsletter.

1) **Looking for Unique Markers in Cerebrospinal Fluid.**

The purpose of this study is to identify unique biologic markers in the cerebrospinal fluid (the fluid surrounding the brain and spinal cord) in people with Parkinson’s disease. To participate, you must be over 18, have PD, and be willing to undergo a lumbar puncture (where a special needle will be inserted in between two bones in your lower back). 2 visits are required (one for physical examination and a second for the lumbar puncture), but they may be combined on the same day. Participants who complete all study tasks will receive $200. For more information, call Trish Kirchhoff, RN, at (503) 8-1769. eIRB #462

2) **Do you have end of dose wearing off and want to participate in a dopamine agonist study?**

Oregon Health & Science University is conducting a double-blind placebo-controlled crossover study with the FDA approved dopamine agonist, Mirapex. The purpose of this study is to better find out how to treat Parkinson’s disease with the use of dopamine agonist and levodopa. There will be four visits in a period of 8 weeks. You must be diagnosed with Parkinson’s disease and have moderate to severe symptoms presently taking Sinemet and have dyskinesia. Dr. Matthew Brodsky is the clinical investigator responsible for this study and Michele Barnard is the contact person if interested. If you are interested please contact Michele at (503) 494-1382. eIRB #697

3) **Do you have Parkinson’s and untreated depression?**

The Parkinson Center of Oregon is currently conducting a research project for patients with depression that have Parkinson’s disease. The study will examine the use of two FDA approved anti-depressants, Paxil CR and Effexor XR to see how these drugs affect depression in Parkinson’s patients. You must be diagnosed with Parkinson’s disease and have had no recent use of antidepressants. Dr. Matthew Brodsky is the investigator for this study and Michele Barnard is the person to contact if interested in participation at (503) 494-1382. eIRB #1407

4) **Do you have Parkinson’s disease and a living brother or a sister who is also affected?**

The Parkinson Center of Oregon is conducting a study to learn more about the genetics of PD from people with Parkinson’s disease who have a living sibling with the disease. Participation would involve one visit at OHSU consisting of a neurological exam, a blood draw (2-3 tablespoons), and questionnaire, which will take approximately 1 ½ to 2 hours. For more information call Pamela Andrews at 503-494-0965. IRB #5367

5) **Balance/Falls and Parkinson’s disease.**

The purpose of this study is to find out if a medication that increases levels of a brain chemical called acetylcholine will improve balance and reduce falls in people with Parkinson’s disease who have poor balance and are falling or nearly falling on a daily basis. In order to take part in this study, you must be 21 or older. You must have balance impairment that results in 2 falls or near-falls per week. For more information, please call Pamela Andrews at 503-494-0965 IRB# 7950

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**Calendar of Events**

**May 11 - PORTLAND, OR**

Join us at the 2nd Annual Shakers’ Ball! Rob Barteletti has Parkinson’s disease but doesn’t let it stop him. Rob and his band, The Shadows, will share the stage with Reina G. Collins & the Cast- ers Thursday, May 11th at the popular McMenamin’s White Eagle Saloon in north Portland. Doors open at 6:30pm, rockin’ begins at 7pm. The concert’s goal is to heighten awareness of early onset PD and to benefit the PCO and PRO in their fight against PD. Tickets are $20 for adults, $10 for students and 100% of ticket sales go to fight PD, so bring your friends! To order tickets, call PRO @ 503-413-7717.

**May 16 - PORTLAND, OR**

PRO presents: “Legal Documents That Everyone Should Have,” by Richard Schneider, JD. Receive practical advice to safeguard your finances and health care wishes during and after your lifetime. Call PRO to RSVP for this free program at 503-413-7717.

**May 20 - PORTLAND, OR**

**STRIKE OUT PD!**

2nd Annual Bowling Benefit Saturday, May 20, 2006 10:30 a.m. - 1:30 p.m.

Sunset Lanes

12770 SW Walker Road

Beaverton, OR

Please support this event by signing up to bowl, donating raffle items, sponsoring a lane or just coming to watch and have fun! For more information, go to http://artwo.home.comcast.net/wsb/parkie/BowlingBenefit.html

**September 9 - PORTLAND, OR**

PCO’s 23rd Annual Symposium on PD (see information below).

**September 24 - PORTLAND, OR**

Sole Support for Parkinson’s - a fundraising and awareness walk to benefit Parkinson’s Resources of Oregon. For more information: www.solessupport.kintera.org/06 or call 503-413-7717.

**EVERY OTHER MONTH at OHSU**

PCO’s Newly Diagnosed Educational Session - Three hour session for people recently diagnosed with Parkinson’s disease and their partners to ask a PD expert all the questions that have arisen since diagnosis. PCO’s Associate Director, Julie Carter, ANP, and a patient, who has had PD for 15 years, provide answers in an informal small group atmosphere. $20/person. Call Amy at the PCO at 503-494-9054 for more information.

**OHSU Parkinson Center’s 23rd Annual Symposium on PD**

“Options & Opportunities”

**SATURDAY, SEPT 9, 2006**

Red Lion Hotel - Jantzen Beach

909 North Hayden Island Drive

Portland, Oregon

Our keynote speaker, Dr. Ron Pfeiffer, is a renowned physician and researcher in Parkinson’s disease (PD) with an emphasis on gastrointestinal dysfunction and PD. He will join PCO medical experts and guests in presenting a unique program of effective approaches to dealing with PD’s troublesome secondary symptoms. PCO director, Dr. Jay Nutt, will present the latest information on PD research. Whether you have PD, know someone who has PD, or are a healthcare professional who cares for people with Parkinson’s, there is valuable information and inspirational pearls for everyone.

See you there!

For more information, call 503-494-9054 or email us at pco@ohsu.edu

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The PCO’s team of research coordinators: (left to right) Pamela Andrews, Michele Barnard, Susan Loehner, Trish Kirchhoff.
6) Healthy Volunteers Needed for Balance Study, OHSU’s Human Balance Disorders Laboratory and Human Spatial Orientation Laboratory are seeking healthy individuals to serve as age-matched controls for patients with neurological involvement for studies in balance function. Participants must be 18-85 years of age, in excellent general health, and have no history of dizziness or balance problems. In exchange for each 2-3 hour session, participants will receive $25-35. Please contact Triana Nagel-Nelson with any questions at 503-418-2602 or nagelnc1@ohsu.edu. eIRB#811

7) Are you interested in an experimental drug study that might help treat fatigue in Parkinson’s Disease? Study drug and evaluations will be provided at no charge. You would receive either real levodopa/accupuncture or placebo. Our subjects will have different chances of placebo, and you will be told if you have a 100%, 50%, or 0% chance of receiving placebo. Study interventions and evaluations will be provided at no charge. Study procedures include TMS (a non-invasive type of brain stimulation), a blood draw, and personality surveys. You must be in good health except for idiopathic Parkinson’s disease. Participation would consist of 4 clinic visits during an 8-week period. If interested, please contact Diana Dimitrova (503-494-7269, dimitrov@ohsu.edu). eIRB #298

8) Help Investigate Fatigue in Parkinson’s Disease. This study investigates how levodopa and acupuncture may affect fatigue and muscle function in people with Parkinson’s disease. You may receive either real levodopa/acupuncture or placebo. Our subjects will have different chances of placebo, and you will be told if you have a 100%, 50%, or 0% chance of receiving placebo. Study interventions and evaluations will be provided at no charge. Study procedures include TMS (a non-invasive type of brain stimulation), a blood draw, and personality surveys. You must be in good health except for idiopathic Parkinson’s disease. Participation would consist of 3 clinic visits. Each visit will last about 3 hours. Study pays $30 for each visit that you attend, for a total of $90 for the entire study. To participate, you must refrain from taking your Parkinson’s medication for 12 hours before the final visits. All study visits and procedures take place at OHSU. If interested, please contact Diana Dimitrova (503-494-7269, dimitrov@ohsu.edu) or Melanie Davis (503-494-4987), eIRB #761

9) DBS Movement Control Study. The purpose of this research is to determine how deep brain stimulation (DBS) and levodopa influence abnormal patterns of gait, balance, face and jaw movements in people with Parkinson’s disease. What is involved in this study?

• Balance Testing: You will be asked to keep your balance on a movable platform, take a few steps or stand quietly while a computer records your body movements.
• Oromotor Testing: In this study you will be asked to voluntarily move your jaw or clench your teeth while a computer records your jaw movements.

We will compare balance and oromotor coordination once before and once after DBS surgery. Travel expenses and an honorarium will be paid. Please contact Triana Nagel-Nelson with any questions at 503-418-2602 or nagelnc1@ohsu.edu. IRB#4925

10) Electronically Measuring Walking Speed May Help to Learn More About Parkinson’s disease. Oregon Health & Science University is conducting a study among newly diagnosed patients with Parkinson’s disease. The purpose of this study is to learn if we can use a home monitoring system to measure walking speed, which may help us find better ways to measure motor problems that occur in PD. There will be 4 visits over a period of 6 months. To participate you must be:

• Between 18-85 years of age.
• Newly diagnosed with Parkinson’s disease (showing symptoms for a maximum of three years).
• On no anti-Parkinson drugs and not anticipated to require treatment with carbidopa/levodopa for at least 1 year or, if treated with carbidopa/levodopa, each dose must be less than 200mg. Study participants must also experience periods of wearing “off” between doses.
• Able to stop their Parkinson’s medication from 10 PM the night before the study visit until 9 AM the day of the visit. Study subjects must be continuously under the skin). In order to participate you must be at least 35 years of age, be diagnosed with PD for at least 3 years, presently taking carbidopa/levodopa (Sinemet for at least 1 year, and must not have unstable cardiovascular disease or history of clinically significant cardiac arrhythmias. For more information, please contact Trish Kirchhoff RN. 503 418-1769. IRB# 1290

11) OHSU is currently participating in a large national study evaluating DBS for the treatment of Parkinson’s Disease. Neurosurgeons at OHSU have been performing Deep Brain Stimulation (DBS) surgery for several years. In this surgery, electrodes are implanted deep in the brain, and connected by a wire extension to a battery-operated device (similar to a pacemaker), which is implanted just beneath the skin in the chest or abdomen. This generator can then be “programmed” to deliver a mild electrical impulse to an area of the brain that controls movement. Patients most likely to benefit from DBS are those with advanced disease, who get a good response from Sinemet, and who do not have dementia or mental illness. Most patients having this surgery will experience decreased Parkinson’s symptoms, and longer “on time” with less dyskinesia. There are openings for at least twelve more subjects to enter this study. For more information about DBS, call Susan Loehner, RN, at 503-494-7950. IRB# 1114

12) Share your experience being diagnosed with Parkinson’s disease. The purpose of this study is to learn from a patient’s perspective more about his or her needs at the time of diagnosis and during the early diagnosis period. There will be a one time phone interview for 30-45 minutes. In order to participate, you must have a diagnosis date of no longer than two and a half years. For additional information or to participate in this study, please contact Michele Barnard at 503-494-1382. IRB# 1870

13) Help us learn more about motor fluctuations that occur in Parkinson’s disease. There will be 1 to 2 outpatient visits, and a 3-day inpatient stay. The study drug, apomorphine, is FDA approved for subcutaneous (under the skin) injection. In this study you will be given subcutaneous infusion (this means that the study drug will be given continuously under the skin). In order to participate you must be at least 35 years of age, be diagnosed with PD for at least 5 years, presently taking carbidopa/levodopa (Sinemet for at least 1 year, and must not have unstable cardiovascular disease or history of clinically significant cardiac arrhythmias. For more information, please call Pamela Andrews at (503) 494-0965. eIRB #1924

15) Study of effectiveness of combined immediate release and controlled release carbidopa-levodopa. The purpose of this study is to compare the “on” time a Parkinson’s disease subject experiences on four separate occasions following a specific dose of carbidopa-levodopa. Each subject will receive in a random double-blind, placebo controlled order one of the following doses on each of their four study visits:

• Two immediate release 25/200mg carbidopa-levodopa tablets
• One controlled release 50/200mg carbidopa-levodopa tablet
• One IPX054 50/200mg tablet
• One IPX054 62.5/250mg tablet

The investigational drug called IPX054 is formulated from a layer of immediate release and a layer of extended release carbidopa-levodopa. The investigators are looking to see if a combination of immediate and extended release carbidopa-levodopa helps to prolong “on” time. Participation in this study will take approximately two months with one screening visit and four study visits. Study participants must be able to stop their Parkinson’s medication from 10 PM the night before the study visit until 9 AM the day of the visit. Study subjects must be currently treated with carbidopa-levodopa and each dose must be less than 200mg. Study participants must also experience periods of wearing “off” between doses. If you are interested in this study contact Trish Kirchhoff in the Parkinson Center of Oregon at (503) 418-1769. eIRB #1987

“The staff at the PCO is very compassionate, understanding, and always available for help and support. I would recommend involvement in research as a means to feel empowered and an opportunity to make a valuable contribution.” Dan Baker