LOCATIONS

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<th>Location</th>
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<tr>
<td>Hospital of the University of Pennsylvania</td>
<td>1000 Courtyard Building 1300 Spruce Street Philadelphia, PA 19104</td>
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<tr>
<td>Pennsylvania Hospital</td>
<td>Spruce Building 7th floor 810 Spruce Street Philadelphia, PA 19107</td>
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<tr>
<td>Center for Research on Reproduction and Women’s Health</td>
<td>Hospital of the University of Pennsylvania 1355 Biomedical Research Building II/III 421 Curie Boulevard Philadelphia, PA 19104</td>
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<td>Abramson Cancer Center</td>
<td>of the University of Pennsylvania 16 Penn Tower 3400 Spruce Street Philadelphia, PA 19104</td>
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<td>Chestnut Hill Hospital</td>
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TO SCHEDULE AN APPOINTMENT

To schedule an appointment with a Penn gynecologic oncologist, please call us toll-free at 1-800-789-PENN.

PENN Medicine, a non-profit organization, is a world-renowned institution dedicated to discoveries that will advance patient care throughout the world and to the education of the physicians and scientists of tomorrow to carry on this legacy of excellence. Through your generous support, we can continue our mission to further medical excellence through research, patient care and education. Please contact us at 215-898-8094 to learn how you can support PENN Medicine by making a gift.
# Table of Contents

- **Ovarian Cancer**  
  Research on Early Detection, Prevention and Advanced Therapy .................................................. 2
- **The Center for Research on Early Detection & Cure of Ovarian Cancer** ........................................ 4
- **Early Detection & Prevention Program** ............................................................................................... 5
- **Advanced Therapeutics Program** ......................................................................................................... 10
- **Ovarian Cancer Biology & Pathogenesis Program** .............................................................................. 14
- **Gynecologic Oncology at Penn** ........................................................................................................... 15
- **Clinical Trial Information** ................................................................................................................... 16
Ovarian Cancer
Research on Early Detection, Prevention and Advanced Therapy

Ovarian cancer remains the most important cause of death from reproductive cancers in women. In fact, half of all deaths from cancer of the genital tract are due to ovarian cancer. Despite advances in chemotherapy, the death rate from ovarian cancer has not changed significantly in more than four decades. Further, the majority of women are diagnosed with advanced disease.

Ovarian cancer statistics
- Ovarian cancer is the 5th leading cause of cancer-related deaths among women.
- One in 65 women in the United States will develop ovarian cancer.
- A woman dies from ovarian cancer every 45 minutes in the United States.
- The majority of women with ovarian cancer are diagnosed with advanced disease (Stage III or IV).
- Approximately half of the patients with ovarian cancer are diagnosed before the age of 55 and most patients diagnosed with advanced disease do not live longer than two or three years beyond the time of diagnosis.
- The need for early detection is crucial — if caught in Stage I, the five-year survival rate from ovarian cancer is over 90 percent. If caught in Stage III or IV the survival rate is less than 35 or 10 percent, respectively.

The critical factors accounting for these statistics include:
- Lack of early detection methods for ovarian cancer—as a result, two-thirds of patients have advanced disease that has already spread to the abdominal cavity and sometimes also the chest at the time of diagnosis.
- Lack of prevention methods—except for rare hereditary ovarian cancers (which account for less than 10 percent of all ovarian cancers), we do not understand the cause of ovarian cancer and therefore, cannot define populations of women at risk. In addition, short of removing the ovaries surgically, we do not have effective prevention strategies.
- Failure of current therapeutics—the vast majority of patients currently diagnosed with advanced ovarian cancer will fail conventional chemotherapy within one to three years.

Ovarian Cancer Symptoms
- Pelvic or abdominal pain or discomfort
- Vague but persistent gastrointestinal upsets such as gas, nausea, and indigestion
- Frequency and/or urgency of urination in the absence of an infection
- Unexplained weight gain or weight loss
- Pelvic and/or abdominal swelling, bloating and/or feeling of fullness
- Ongoing unusual fatigue
- Unexplained changes in bowel habits
EARLY DETECTION & PREVENTION PROGRAM

A lack of early detection or prevention strategies is presently a major cause of poor outcomes in ovarian cancer patients. A screening test for ovarian cancer could save many lives. If cancer is detected early, the cure rate can be greater than 90 percent, but if cancer is detected late, the cure rate can fall to less than 30 percent.

The research laboratory activities of the Early Detection & Prevention Program focus on improving the outcomes of ovarian cancer by facilitating earlier detection. These include the development of new blood tests, new imaging tools, and other innovative techniques to detect ovarian cancer early. The center also focuses on reducing the occurrence of ovarian cancer through the development of prevention methods. These include identification of risk factors, exploration of environmental causes of ovarian cancer, and development of preventive treatments including a vaccine.

PENN’S CENTER FOR RESEARCH ON EARLY DETECTION & CURE OF OVARIAN CANCER

The Department of Obstetrics and Gynecology, the Center for Research on Reproduction and Women’s Health, the Abramson Cancer Center, and the University of Pennsylvania Health System and School of Medicine are launching a new Center for Research on Early Detection & Cure of Ovarian Cancer. Directed by George Coukos, MD, PhD, the center’s goal is to identify new detection methods, develop new prevention approaches and therapies, and improve the quality of life for women with ovarian cancer.

The center provides an infrastructure for ovarian cancer research and treatment and serves as a catalyst to unite existing talent at Penn, recruit new investigators and promote interdisciplinary collaboration in the field of ovarian cancer research.

This new center has three major research programs:

- OVARIAN CANCER EARLY DETECTION & PREVENTION PROGRAM
- OVARIAN CANCER ADVANCED THERAPEUTICS PROGRAM
- OVARIAN CANCER BIOLOGY & PATHOGENESIS PROGRAM
RECENT ADVANCES IN EARLY DETECTION OF OVARIAN CANCER

George Coukos, MD, PhD, is conducting cutting-edge research in the area of early detection of ovarian cancer, with a focus on tumor vasculature. Tumor blood vessels are distinct from blood vessels of normal organs; they are overgrown and irregular. Dr. Coukos hypothesized that tumor vasculature expresses unique molecular markers that are ideal targets for diagnosis as well as therapy.

Dr. Coukos’ lab recently discovered the unique molecular make-up of vascular cells in ovarian cancer. Because these molecules are bound to the surface of tumor blood vessels, they can be used to visualize tumors in the body using molecular imaging or even to attack tumors with smartly designed killer bullets (targeted therapy). In addition, some of these molecules may be shed into the blood stream. These can be detected using a blood test. This discovery generates unique opportunities for the development of early detection tools using serum biomarkers or molecular imaging as well as targeted therapy.

Presently, Dr. Coukos’ research laboratory is collaborating with other Penn scientists and investigators around the U.S. to develop and validate antibodies against these new tumor vascular markers. Detection of vascular molecules with specific antibodies allows for the visualization of tumors. These antibodies could also be injected intravenously into patients to detect tumor vasculature using molecular imaging such as molecular ultrasound or PET scan.

The clinical activities of the Ovarian Cancer Early Detection & Prevention Program will include a clinic for the screening and prevention of ovarian cancer. Several Penn clinicians and clinical epidemiologists/biostatisticians collaborate on the implementation of clinical trials. The program will offer clinical protocols of screening with risk calculation, imaging and molecular testing, and when appropriate, trials of chemoprevention and vaccine prevention.

This new program focuses initially on women with a family history of breast or ovarian cancer or hereditary BRCA1 and BRCA2 gene mutations. These women have a lifetime risk of up to 40 percent (BRCA1) or 20 percent (BRCA2) to develop ovarian cancer and are more likely to die of ovarian cancer than breast cancer in the absence of prevention. Working together with the Cancer Risk Evaluation Program and the Bren Rowan Breast Program, the Ovarian Cancer Early Detection & Prevention Program addresses ovarian cancer-specific issues in these women. Additionally, working with the Gastrointestinal Cancer Risk Evaluation Program and Penn Fertility Care, the program developed protocols for women with other genetic or acquired reproductive conditions that may predispose them to ovarian cancer.
RECENT ADVANCES IN OVARIAN CANCER PREVENTION

Penn investigators have made important contributions toward understanding the behavior of ovarian cancer and identifying optimal ways to manage patients with hereditary mutation of BRCA1 and BRCA2. Stephen Rubin, MD, and colleagues discovered that patients with hereditary ovarian cancer have better prognosis than patients with nonhereditary tumors. In addition, Tim Rebbeck, PhD, of Penn’s Abramson Cancer Center and Center for Clinical Epidemiology and Biostatistics, and Susan Domchek, MD, who directs the Cancer Risk Evaluation Program, have shown the effects of prophylactic surgery and hormonal therapy, and have conducted ground-breaking research to optimize the management of patients with hereditary mutation of BRCA1 and BRCA2.

Penn investigators are working to develop vaccines for the prevention of ovarian cancer. The first ovarian cancer prevention vaccine, using dendritic cells loaded with Her-2 and hTERT, was recently initiated at Penn. In this trial, led by Christina Chu, MD, a Penn gynecologic oncologist, they are testing the hypothesis that vaccination against these two tumor proteins could prevent tumor recurrence in patients with HLA-A2 blood type and stage III or IV ovarian cancer who have experienced a complete response to front line chemotherapy.

If safety and efficacy of this vaccine are confirmed, this approach may be applied to earlier stages of the disease, vaccinating patients with stage I or II disease who are at risk of tumor recurrence. Eventually, similar approaches may be used to prevent ovarian cancer in healthy women with family history of hereditary ovarian cancer due to BRCA1 and BRCA2 mutations.

These molecular imaging techniques are not available presently for clinical testing but the required underlying technology has been developed by Penn investigators and can be translated to the detection of ovarian cancer through new collaborations that the Center for Research on Early Detection & Cure of Ovarian Cancer aims to establish. Furthermore, markers secreted into the blood stream could lead to the creation of antibody-based diagnostic blood tests. Clearly, this project holds enormous potential for advancing the ability to detect ovarian and other reproductive cancers.

Additional investigators in the center are working to develop blood tests for early detection of ovarian cancer. David Speicher, PhD, of the Wistar Institute, is an international leader in tumor proteomics — the study of the structure and function of proteins. He is using innovative proteomic discovery approaches to identify proteins that might indicate the presence of ovarian cancer.

Tumor vasculature is abnormal and has unique molecular make-up, which could enable Penn investigators to develop novel cancer detection tools. Left top and bottom, Detection of tumor vessels in tissue using molecular staining, targeting a specific vascular marker. Middle, Detection of a novel vascular marker in blood. Right top, Example of molecular imaging of patient using CPTET to detect a pelvic tumor. Right bottom, Use of ultrasound to detect vasculature in a patient. Penn intends to develop molecular imaging techniques that specifically recognize tumor vasculature.
Lymphocyte therapy uses lymphocytes recovered from the patient’s tumor or blood, which are manipulated in the laboratory to acquire the ability to recognize and kill a tumor. Expanded to huge numbers, they are then re-infused into the patient. This approach is expected to bring major contributions to ovarian cancer and is based on the discovery in Dr. Coukos’ lab that ovarian cancer is immunogenic; i.e., it can be recognized and attacked by lymphocytes.

Additional investigators are working toward developing new therapeutic approaches in ovarian cancer. Jerry Glickson, PhD, is engineering chemotherapy-loaded nanoparticles that specifically target ovarian cancer cells, in order to develop new ways to deliver chemotherapy to tumors with increased efficacy and reduced toxicity. Phyllis Gimotty, PhD, and Dr. Coukos are working to identify tumor markers that will enable them to select patients for individualized therapy.

The Advanced Therapeutics Program also conducts clinical trials to test new therapies emerging from the laboratory. The facilities for the new clinical program will be located in the Perelman Center for Advanced Medicine, expected to open in 2008.

Cellular therapeutics are prepared at the Penn Cell and Vaccine Production Facility, directed by Bruce Levine, MD. Therapies expected to be available for clinical trials within 12 to 24 months include lymphocytes recovered from tumors and processed in the laboratory to develop potent tumor-killer cells; lymphocytes modified with gene therapy approaches to recognize and kill tumors and potent tumor vaccines.

Clinical investigators at Penn are also testing the latest in chemotherapy and targeted molecular therapy for ovarian cancer. Penn Gynecologic Oncology is a member of the Phase I/II program of the Gynecologic Oncology Group, a national organization running clinical trials in ovarian cancer. The Ovarian Cancer Center tests new chemotherapy drug compounds with promising activity in ovarian cancer. Furthermore, the Developmental Therapeutics Program, directed by Peter J. O’Dwyer, MD, works to test the effectiveness of new drugs in treating cancer. Through clinical trials, the team is testing novel compounds in ovarian cancer, including combinations of drugs that shut off the blood supply to tumors with chemotherapy at a dosage that patients can tolerate.
Recent Advances

The Coukos laboratory has been exploring the use of adoptive T cell therapy for ovarian cancer. This approach involves using T cells that can specifically recognize and kill ovarian cancer cells.

T cells may be derived from tumors removed surgically, or from peripheral blood. T cells removed from tumors following surgery can be manipulated in the lab to select T cells that specifically recognize and kill tumors. T cells with tumor specificity can then be expanded in the lab using technology developed by Dr. June. Billions of T cells can be developed within weeks and can then be re-infused to the patient.

Alternatively, T cells derived from blood can be engineered in the lab using gene therapy to recognize tumor targets. These T cells with tumor specificity can then be expanded in the lab and re-infused to the patient.

Dr. Coukos’ laboratory is also engineering lymphocytes that recognize tumor vascular targets with the aim of attacking and destroying the tumor vasculature, crucial for tumor survival and growth beyond 2 to 3 millimeters. Dr. June’s lab is engineering lymphocytes to redirect them against tumor cell targets. In this approach, lymphocytes are made capable of attacking tumor cells.

Early evidence of the power of immune therapy in ovarian cancer is provided by the results obtained at Penn in a clinical trial of gene-immunotherapy using adenovirus delivering interferon-beta. One patient with ovarian cancer metastatic to the chest was treated with this approach. Following a single administration of this vector, dramatic response of the tumor was documented. This response was further strengthened by addition of a drug that shuts off blood supply to the tumor. These data show that immune therapy and combination with biological therapy holds marked promise in ovarian cancer.

The laboratories of Drs. Coukos and June have also discovered mechanisms of tumor immune evasion in ovarian cancer and are developing approaches to enhance tumor response to immune therapy. These approaches will be available in clinical trials soon.
OVARIAN CANCER BIOLOGY AND PATHOGENESIS PROGRAM

The Ovarian Cancer Biology & Pathogenesis Program has a fundamental discovery focus with the aim to understand the pathogenesis and biology of ovarian cancer. Several multi-disciplinary laboratories focus on various aspects of ovarian cancer genomics, genetics, immunology and biology. The discoveries within the laboratories are crucial for the Early Detection & Prevention Program as well as the Advanced Therapeutics Program.

Recent Advances

Recent Advances at Penn in Ovarian Cancer Biology & Pathogenesis

One recent advance relates to the discovery by Dr. Coukos that vascular leukocytes, a population of blood cells with endothelial immunophenotype, play an important role in tumor vasculature in ovarian cancer and other tumors. Since the results were published, additional papers have validated this concept. This discovery offers novel opportunities for biomarker discovery and development of cancer therapeutic strategies.

Further evidence is provided by the discovery of the molecular profile of tumor vascular cells in ovarian cancer. This discovery generates unique opportunities for the development of serum biomarkers, molecular imaging and targeted therapy in solid tumors.

The laboratories of Lin Zhang, MD, and Dr. Coukos discovered that miRNA genes, a recently identified class of genes, are amplified or deleted in ovarian cancer and other solid tumors. This discovery offers a new explanation of gene changes in ovarian cancer and provides new opportunities for the discovery of biomarkers and the development of cancer therapeutics.

Penn investigators are currently developing new platinum-derived drugs for use as chemotherapy and are studying the issue of chemotherapy resistance in ovarian cancer. Finally, Penn investigators are unveiling the molecular make-up of ovarian cancers to identify genes that determine tumor behavior, response to treatment and clinical outcome.

Gynecologic Oncology at Penn

A leader in the field of gynecologic oncology

Penn physicians and scientists from the Division of Gynecologic Oncology, the Abramson Cancer Center, the Joan Karnell Cancer Center and the Center for Research on Reproduction and Women’s Health are working together to increase knowledge about gynecologic cancer and to find new ways to prevent and treat these diseases. This combined effort has enabled research advances to more quickly benefit patients and has made Penn a leader in ovarian cancer research.

Innovation

Penn’s Division of Gynecologic Oncology is proud to be a pioneer in establishing and developing the subspecialty of gynecologic oncology. It continues to hold a national reputation for outstanding patient care and providing innovative treatment approaches. U.S. News & World Report consistently ranks Penn among the top in the nation for cancer and women’s health services.

Expertise

Penn has more full-time board certified gynecologic oncologists than any other health system in the Philadelphia region and offers the only advanced training program for this specialized field in the region.

Integrated Care

Another distinguishing factor is Penn’s team approach to patient care. Gynecologic oncologists work closely with other Penn specialists and patients’ personal physicians to provide comprehensive, integrated care.
CLINICAL TRIALS: HELPING TO ADVANCE CANCER CARE

None of the recent advances in cancer care would have been possible without clinical trials — studies that test new ways to prevent, detect, diagnose and treat cancer.

Why are clinical trials important?
Before a new treatment is made available to the public, it must undergo a clinical trial. These strictly monitored and carefully evaluated studies test the treatment’s safety and efficacy in three phases:

- **Phase I** – Determines how the new treatment will work. For example:
  - What is the best dose? How many times a day should it be administered?
- **Phase II** – Determines whether the new treatment has an anticancer effect.
  - Does it shrink the tumor?
- **Phase III** – Compares the new treatment against the standard treatment for the disease. Every patient in a Phase III trial receives either the standard treatment for a specific cancer or the treatment being investigated. A common misconception is that some patients receive placebos and this has kept many patients from participating in cancer clinical trials.

Why participate in a clinical trial?
- If a new treatment proves effective in a study, it could become a new standard of treatment.
- Having different types of patients (females of various ages, races or ethnicities) participate is important in determining the effectiveness of treatment.

How does a patient enroll?
The first step is to talk to a doctor or nurse to find out if there is a clinical trial that is appropriate. Before enrolling in a clinical trial, patients and their families will undergo informed consent. At this time, the study’s investigator will explain:

- The purpose of the trial
- How long the trial will last
- Whether the patient is eligible for participation
- Benefits and possible risks or side effects
- The role of the patient

Participation in a clinical trial is voluntary. A patient can leave a trial at anytime without penalty.
Center for Research on Early Detection & Cure of Ovarian Cancer

A Team Approach

Cancer experts from the University of Pennsylvania Health System and School of Medicine, the Abramson Cancer Center, Department of Obstetrics and Gynecology and The Wistar Institute are working together to increase knowledge about ovarian cancer.

**TEAM MEMBERS INCLUDE:**

- **George Coukos, MD, PhD**  
  Director, Center for Research on Early Detection & Cure of Ovarian Cancer
- **Celso R. Garcia**  
  Associate Professor of Obstetrics and Gynecology  
  Associate Chief, Division of Gynecologic Oncology
- **Stephen C. Rubin, MD**  
  Franklin Payne Professor of Gynecologic Oncology  
  Chief, Division of Gynecologic Oncology  
  Department of Obstetrics and Gynecology
- **Thomas Randall, MD**  
  Chief, Gynecologic Oncology, Pennsylvania Hospital  
  Assistant Professor  
  Department of Obstetrics and Gynecology
- **Christina Chu, MD**  
  Assistant Professor  
  Department of Obstetrics and Gynecology
- **Lin Zhang, MD**  
  Research Assistant Professor  
  Department of Obstetrics and Gynecology
- **Lori Smith, CRNP**  
  Certified Registered Nurse Practitioner  
  Department of Obstetrics and Gynecology
- **Simone Kutler, BS, MT (ASCP)**  
  Research Coordinator  
  Department of Obstetrics and Gynecology
- **Cathi Ybarra RN, BSN**  
  GOG Research Program Manager  
  Division of Gynecologic Oncology
- **Jane Houdeshel, MSN, RN**  
  Chemotherapy Nurse  
  Department of Obstetrics and Gynecology

- **Carl H. June, MD**  
  Director, Translational Research Programs  
  Professor, Department of Pathology and Laboratory Medicine  
  Abramson Family Cancer Research Institute
- **Susan M. Domchek, MD**  
  Director, Cancer Risk Evaluation Program  
  Assistant Professor of Medicine  
  Abramson Cancer Center of the University of Pennsylvania
- **Bruce Levine, MD**  
  Director, Clinical Cell and Vaccine Production Facility  
  Associate Professor, Transfusion Medicine Division  
  Pathology and Laboratory Medicine  
  University of Pennsylvania Health System
- **Lisle L. Lin, MD**  
  Assistant Professor, Department of Radiation Oncology  
  University of Pennsylvania Health System
- **Peter J. O’Dwyer**  
  Professor and Director, Developmental Therapeutics Program  
  Division of Hematology/Oncology  
  Abramson Cancer Center of the University of Pennsylvania
- **David W. Speicher, PhD**  
  Professor and Program Co-Leader  
  Molecular and Cellular Oncogenesis Program  
  The Wistar Institute
- **Chaitanya R. Divgi, MD**  
  Professor of Radiology; Professor of Radiation Oncology  
  Professor, Wistar Institute; Member, Abramson Cancer Center of the University of Pennsylvania  
  Chief, Division of Nuclear Medicine & Clinical Molecular Imaging  
  Hospital of the University of Pennsylvania
- **Jerry Glickson, PhD**  
  Director of Molecular Imaging  
  Professor of Radiology  
  Department of Radiology
- **Phyllis Gimotty, PhD**  
  Associate Professor of Biostatistics  
  Center for Clinical Epidemiology and Biostatistics  
  Department of Biostatistics and Epidemiology
- **Tim Rebbeck, PhD**  
  Director, Center for Genetics and Complex Traits  
  Associate Director for Population Science  
  Abramson Cancer Center of the University of Pennsylvania  
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Division of GYN Oncology

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