OUR MISSION

The Division of Clinical Research (DCR), Department of Obstetrics and Gynecology at Washington University School of Medicine provides specialized facilities and services to support clinical research in women’s reproductive health.

Our mission is to foster collaborative, multidisciplinary research aimed at improving women’s health.

WASHINGTON UNIVERSITY IN ST. LOUIS

OB/GYN Department Ranks 16th in the Nation in Federal Research Funding

Washington University School of Medicine, Department of Obstetrics and Gynecology is one of the leading recipients of extramural and intramural funding, fueling an innovative environment of research and training in women’s health. According to Dr. George Macones, the Department of OB/GYN is currently 16th in the nation for federal research funding, rising from the 34th position in 2009. In 2010, the Department received a total of $7.4 million in extramural research support. Grant funding has increased almost $4 million from 2006 to 2010.

As the OB/GYN research efforts in the department grow, there are increasing opportunities for training and fellowship grants that promote and support young investigators. The T32 is a NIH/NRSA Training Grant that provides postdoctoral investigators the opportunity to conduct clinical and translational obstetric and gynecological research. In our department, the T32 training grant supports the work of fellows Drs. Nora Kizer, Lorie Harper, and Katie Goetzinger. Starting in July, the T32 will also support Drs. Molly Stout and Colleen McNicholas.

T32 support occasionally comes from other institutions and departments to support junior investigators at Washington University. A T32 grant from the Division of Infectious Diseases supports pre-doctoral student, Kristina Stemler in her research in the Mysorekar Lab. Fellows Drs. Patricia Jiminez and Kerri Luzzo are supported by a T32 grant from the University of Pennsylvania.

Dr. Emily Jungheim and Dr. Amber Cooper are supported by an NIH career development award (K12 grant) through the Women’s Reproductive Health Research (WRHR) Career Development Program. This program provides mentored career development for junior faculty in OB/GYN to support their transition to independent research careers in women’s reproductive health. Other large research training grants at Washington University include the BIRCWH (Building Interdisciplinary Research Careers in Women’s Health) Award, a prestigious NIH and Office of Research in Women’s Health (ORWH)-funded grant that supports Dr. Tessa Madden in her research of women’s health. Family Planning fellows, Dr. Amy Stoddard and Dr. Zevidah Vickery, have support from a postdoctoral training program through the CTSA and from the Society of Family Planning.

The Department is committed to supporting both clinical and basic research and integrating research with education. Dr. Macones believes that what sets us apart as a premier academic department is our goal of creating and disseminating new knowledge and excellence in doing so. This research includes basic, translational, and clinical investigation.
Dr. David Eisenberg is an Assistant Professor of Obstetrics and Gynecology in the Division of Clinical Research. He joined the Washington University School of Medicine Faculty in August 2009. He attended the University of Alabama School of Medicine in Birmingham, Alabama, after graduating magna cum laude from University of Pittsburgh with a BS in Neuroscience. He completed his residency in Obstetrics & Gynecology at Northwestern University's Prentice Women's Hospital. He remained at Northwestern University where he completed a Fellowship in Family Planning & Contraception and a Masters in Public Health.

Dr. Eisenberg's areas of clinical interest include family planning and contraceptive counseling, general gynecology, obstetrics, minimally invasive and laparoscopic surgical techniques, routine health care maintenance including cervical cancer screening, testing and treatment of sexually transmitted infections, evaluation and treatment for menopause symptoms. His research interests are primarily clinical in the areas of reproductive health, sexually transmitted diseases, family planning and contraception. He is working on clinical research projects including the Contraceptive CHOICE project, a study of generic hormonally-active IUDs, and the provision of long-acting reversible contraceptives (LARC) in the immediate postpartum period. He is also interested in issues surrounding abortion and post-abortion complications as well as international family planning efforts. He has authored two book chapters, multiple clinical reviews and research articles in women's health.

When asked by the Washington University Institute for Public Health about opportunities for interdisciplinary collaboration on public health initiatives in the future he stated:

“There has never been a more crucial time for clinicians, social workers, public health officers, scientists and educators to work together toward a healthier society. The debates over the future of health care in the US require all the stakeholders to play a part in ensuring public health policies promote health in a proactive manner rather than the traditional model of treating disease after it has developed. I hope to work with students, fellows, post-docs and faculty in the various departments of Washington University and the greater St. Louis community to design clinical research whose findings might have direct application to public health policy. It is important that we advocate for programs that produce better health outcomes for individuals and communities.”
Indira Mysorekar, PhD
Assistant Professor
Department of Obstetrics and Gynecology
Department of Pathology and Immunology
Washington University School of Medicine

Dr. Mysorekar is an Assistant Professor of Obstetrics & Gynecology and Pathology & Immunology. She joined the Washington University School of Medicine Faculty in 2008. Dr. Mysorekar was born in India where she lived for the first 8 years of her life, before moving with her family to East Africa. She lived there until she was 15 and then came to North Canton, OH as an exchange student and graduated from high school in 1989. Indira obtained a combined BS/MS degree in Molecular Biology from the University of Lund in Lund, Sweden in 1994. Following that, she moved to St. Louis, MO where she conducted her doctoral work in the laboratory of Dr. Jeffrey Gordon at Washington University, and received a Ph.D. degree in Developmental Biology in 2002. Her interest in bladder epithelial biology then led her to join the Hultgren laboratory as a postdoctoral fellow in 2003. There she developed and characterized mouse models to study adult urinary bladder epithelial stem cell biology and mechanisms underlying chronic and recurrent urinary tract infections (UTIs), common infectious diseases in women.

She joined the Department of Ob/Gyn at WUSM as an Assistant professor in 2008. Her research program encompasses studies of chronic and recurrent UTIs to fundamental mechanisms of urinary bladder development and homeostasis, to bladder cancer biomarkers and to development of better strategies for treatment of recurrent UTIs. Dr. Mysorekar is an Investigator in Prematurity Research from the Burroughs-Wellcome Fund, and a recipient of the Pathway to Independence (K99/R00) 5-year award from the National Institutes of Health among others. As a postdoctoral fellow, she received the Ruth L. Kirschstein National Research Service Award from the National Cancer Institute, the Infectious Disease Scholars Program Postdoctoral Fellowship award and as a graduate student, she was awarded the Academic Women’s Network Leadership Award for Outstanding Student from Washington University School of Medicine in 2002.

The Mysorekar lab uses multipronged approaches to understand the cellular and molecular details of adult stem cell biology of the mammalian urinary bladder; investigating the mechanisms by which recurrent UTIs might occur and a role for the sex hormone, estrogen, in modulating susceptibility to UTIs and regulating regeneration following infection/injury to collectively aid in the development of better therapeutic regimens for treating UTIs. She has published landmark papers in Nature, Cell Host and Microbe, PNAS in these subject areas.

Most recently, Dr. Mysorekar has expanded her research programme to investigate new etiologies for preterm birth, a leading cause of perinatal morbidity and mortality. She has assembled a multidisciplinary team with broad expertise to conduct multifaceted studies and begin uncovering new paradigms for occult placental infection and inflammation leading to prematurity.

The Mysorekar lab is a large and lively group comprising a senior scientist, a postdoctoral fellow, an Ob/Gyn resident, two graduate students, a histologist, a research technician, a clinical research assistant, and undergrads and summer students. The lab is located in the beautiful new BJC-Institute for Health, on the 10th floor.

Along with doing research and running a lab, Dr. Mysorekar enjoys travelling, cooking, photography, gardening and spending time with her husband and fellow WUSM faculty, Dr. Jason Mills, and their three children, Maya (14y), Macy (11y) and Anand (8y).
What’s Happening at the DCR

Below is a list of current studies conducted within the Division.

**OBSTETRICS**

**3D DOPPLER AND IUGR**
*Pl: Katie Goetzinger, MD • CRNC: Linda Odibo, RN, BSc, MN*
A prospective cohort study to determine if IUGR fetuses are more likely to exhibit evidence of altered cerebral blood flow compared to normal fetuses when quantified using 3-D power Doppler studies. Recruitment will occur in the Obstetric Ultrasound department in the Center for Advance Medicine, and 300 patients will be enrolled: 150 IUGR and 150 controls.

**BACTERIAL-HOST INTERACTIONS IN BLOOD AND AMNIOTIC FLUID**
*Pl: Amanda Lewis, PhD*
The aim of the study is to examine the impact of bacterial surface carbohydrate structures on mechanisms of survival in blood and amniotic fluid and the potential consequences of bacterial products on proinflammatory cytokine induction. Approximately 100 samples of each of the following specimens: blood, umbilical cord blood, and amniotic fluid, through the Women and Infant’s Health Specimen Consortium over a 2-year period.

**BLADDER FLAP STUDY**
*Pl: George Macones, MD, MSCE • Co-Pl: Methodius Tuuli, MD, MPH • CRNC: Patty Fogertey, RN, MSN*
A randomized controlled trial to evaluate the effects of omitting the bladder flap creation at cesarean section. A total of 258 patients over 33 weeks gestation undergoing a primary or repeat non-emergent cesarean section will be enrolled.

**CERVICAL DOPPLERS IN PREGNANCY**
*Pl: Helen Kay, MD • RA: Lyndsay Roy*
We hypothesize that cervical Doppler studies will reflect vascular remodeling during pregnancy and thus may be a useful tool to assess cervical softening and dilation in pregnancy. As the cervical artery undergoes vascular changes throughout gestation to enhance blood flow to the cervix, the intravascular resistance will decrease and the Doppler indices, including the S/D ratio and the PI ratio, will decrease. We hypothesize that cervical Doppler indices will progressively change throughout each trimester. A total of 100 women will be enrolled in the Obstetric Ultrasound department in the Center for Advance Medicine.

**CERVICAL FOLEY + CYTOTEC VS CYTOTEC FOR CERVICAL RIPENING AND LABOR INDUCTION**
*Pl: Jeanine Carbone, MD • CRNC: Patty Fogertey, RN, MSN*
A randomized controlled clinical trial to compare the efficacy of the combination of the cervical foley bulb and cervical misoprostol (Cytotec) to cervical misoprostol (Cytotec) alone for cervical ripening and induction of labor. A total of 122 patients with Bishop’s scores of ≤ 6 (unfavorable cervix) requiring induction of labor will be enrolled.

**DIABETES STUDY**
*Pl: Alison Cahill, MD, MSCI • CRNC: Danielle Frueh, RN, BSN*
Sponsored by a Thrasher Grant
A prospective study aimed at assessing optimal predictors of fetal macrosomia, birth trauma, or combined neonatal morbidity outcomes in diabetic pregnant women. Recruitment occurs in the antepartum clinic, BJH and CAM. A total of 340 pregnant women will be enrolled over a four-year period.

**ELECTRONIC FETAL MONITORING STUDY**
*Pl: Alison Cahill, MD, MSCI • CRNC: Carla Chung RN; BSN, Danielle Frueh, RN, BSN*
Sponsored by a Robert Wood Johnson Grant
A retrospective cohort study aimed at identifying which characteristics of fetal heart rate decelerations are associated with fetal acidemia at delivery. This is done by quantitatively analyzing electronic EFM recordings in the second stage of labor, and comparing these characteristics between women who deliver an infant with an umbilical cord pH ≤ 7.10 to those with a cord pH > 7.10. A total of 5,000 charts will be reviewed over a three-year period.
GESTATIONAL WEIGHT GAIN IN THE OBESE GRAVIDA
PI: Lorie Harper, MD • CRNC: Patty Fogertey, RN, MSN
A prospective cohort study enrolling 245 women prior to 20 weeks gestation who have pre-pregnant BMI’s > 30. The aim of the study is to examine the impact of gestational weight gain on maternal and neonatal pregnancy outcomes. We will also investigate the relationship between serum biomarkers of adiposity and pregnancy outcomes. Patients will be enrolled through the WIHSC.

INTRAUTERINE GROWTH RETARDATION AND METABOLOMIC PROFILES
PI: Marwan Shinawi, MD
This is a sub-study of the Women and Infant’s Health Specimen Consortium Study aimed at analyzing maternal serum metabolomic fingerprints and correlate them with fetal and newborn metabolomes. Although not a direct aim of this study, the feto-maternal metabolomic data can be correlated in long-term studies with developmental delays, cognitive disabilities, and behavioral abnormalities. The study will collect blood, urine, amniotic fluid, and umbilical cord blood from approximately 150 women with normal pregnancies and 30-50 women with fetal IUGR through the WIHSC.

IUGR STUDY
PI: Anthony Odibo, MD, MSCE • CRNC: Linda Odibo, RN, BSc, MN
A prospective cohort study aimed at comparing the ability of two antepartum tests, (Doppler flow studies of feto-placental vessels and biophysical profile), to optimally determine the timing of delivery of preterm intrauterine growth-restriction pregnancies. Recruitment occurs in the Obstetric Ultrasound Department, BJH and the Center for Advanced Medicine.
A total of 318 pregnant women will be enrolled.

MELISSA STUDY: MATERNAL BLOOD IS SOURCE TO ACCURATELY DIAGNOSE FETAL ANEUPLOIDY
PI: Anthony Odibo MD, MSCE • CRNC: Linda Odibo RN, BSc, MN
Sponsored by Artemis Health Inc.
A prospective, multi-center observational study with blinded, nested case control analyses. The primary objective of the study is to determine the performance characteristics (sensitivity and specificity) of the Artemis Health Prenatal Aneuploidy Diagnostic Test to detect fetal trisomy 21 compared to karyotype results from fetal cells obtained from amniocentesis or CVS. Recruitment occurs in the Obstetric Ultrasound Department in the Center for Advanced Medicine and Missouri Baptist Medical Center. A total of 10,000 women will be recruited study wide and 400 at Washington University.

METABOLIC CONDITIONS AND PREGNANCY
PI: Marwan Shinawi, MD
This is a sub-study of the Women and Infant’s Health Specimen Consortium Study aimed at analyzing the newborn metabolomes and correlate this with maternal serum metabolomic fingerprints in health and diseases (IUGR and metabolic conditions). Approximately 200 specimens will be collected through the WIHSC and the Predicting Adverse Pregnancy Outcomes study.

OCCULT INFECTIONS AND PRETERM DELIVERY
PI: Indira Mysorekar, PhD • RT: Rebecca Gunkel • RA: Carolyn Bower
Sponsored by Burroughs Wellcome
A prospective study aimed at determining which pathogenic bacteria are present as occult, intracellular reservoirs in endometrial/placental tissues in women with preterm birth and to evaluate whether pre-existing infection disrupts placental development. Recruitment will occur on Labor and Delivery at BJH.

PANORAMA: PREDICTING NEONATAL ACIDEMIA AND NEUROLOGIC INJURY WITH INTRAPARTUM FETAL HEART RATE MONITORING
PI: Alison Cahill, MD, MSCI • CRNC: Monica Anderson, RN, BSN; Carla Chung, RN, BSN; Danielle Frueh, RN, BSN; Tracy Burger RN, BSN
Sponsored by a NIH/NICHD RO1 grant
A prospective study aimed at determining which fetal heart rate deceleration characteristics, are associated with an infant umbilical cord arterial pH ≤ 7.10. The study also aims to develop and validate a clinical predictive index to identify specific fetuses at high risk for acidemia based on characteristics of EFM recordings. Recruitment will occur at Barnes-Jewish Hospital with a total of 7,150 mothers and 200 babies over a five-year period.
PLACENTAL FUNCTION STUDY  
PI: Methodius Tuuli, MD, MPH • CRNC: Linda Odibo, RN, BSc, MN  
This is a prospective cohort study of pregnant women between 18-22 weeks gestation who are undergoing their second trimester fetal anatomy scan. The study aims to determine if a single parameter of placental structure, blood flow, or analyte secretion in the second trimester predicts sub-optimal pregnancy outcome and to determine if combination of first trimester and second trimester placental assessment and analyte secretion improve the predicative value of the model to predict adverse pregnancy outcome. A total of 1,500 women will be recruited from the Obstetric Ultrasound Department, Center for Advanced Medicine.

PLACENTAL LACTATE LEVELS BY NMR SPECTROSCOPY  
PI: Helen Kay, MD • RA: Carolyn Bower; Jen Bick  
The aims of the study are to determine parameters to optimize visualization of the lactate peak in the human placenta by proton NMR spectroscopy, to quantify the lactate using an external reference and to compare lactate levels measured by NMR spectroscopy to published levels in the literature. A total of 20 placentas from normal, term, vaginal and cesarean section deliveries will be collected.

POLYMICROBIAL SYNERGISM IN ADVERSE PREGNANCY OUTCOMES  
PIs: Anthony Shanks, MD, Amanda Lewis, PhD, Jenifer Allsworth, PhD  
This is a longitudinal study in order to examine whether combinations of bacterial inhabitants in the reproductive and urinary tracts are associated with higher risks of adverse pregnancy outcomes. Urine and vaginal swabs collected during prenatal visits will be obtained through the WIHSC.

PREDICTING ADVERSE PREGNANCY OUTCOMES  
PI: Anthony Odibo, MD, MSCE • CRNC: Linda Odibo, RN, BSc, MN  
This is a prospective cohort study of pregnant women between 11-14 weeks gestation undergoing their first trimester aneuploidy scan. The aim of the study is to determine if a single parameter of placental structure, blood flow, or analyte secretion predicts sub-optimal pregnancy outcome. The study includes doppler evaluation of uterine arteries, assessment of placental volume, maternal serum for free beta-hCG and PAPP-A, with the addition of ADAM12s, PP13 and PIGF levels. A total of 1,500 women will be recruited from the Obstetric Ultrasound Department, Center for Advanced Medicine over a three-year period.

A PHASE 3B, MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND STUDY OF HYDROXYPROGESTERONE CAPROATE INJECTION, 250 MG/ML, VERSUS VEHICLE FOR THE PREVENTION OF PRETERM BIRTH IN WOMEN WITH A PREVIOUS SINGLETON SPONTANEOUS PRETERM DELIVERY  
PI: George Macones, MD, MSCE • RA: Molly Meyer  
Sponsored by Hologic  
A prospective placebo controlled study aimed at determining if weekly injections from 16 weeks gestation of 17P given intramuscularly weekly will reduce the incidence of preterm labor in women with a history of a previous preterm delivery. Recruitment will occur in the ante-partum clinic, and the Center for Advanced Medicine. A total of 20 women will be enrolled.

SLEEP DEPRIVATION DURING PREGNANCY  
PI: George Macones, MD, MSCE, Jen Jen Chang, PhD • RA: Molly Meyer  
A longitudinal prospective cohort study to ascertain the prevalence and risk factors of chronic sleep deprivation during pregnancy and its effects on postpartum depression and spontaneous preterm delivery. A total of 356 nulliparous women will be recruited from the antenatal clinic in BJC and the Center for Advance Medicine over a three-year period.

TUPAC: TREATMENT UTILITY OF POSTPARTUM ANTIBIOTICS IN CHORIOAMNIONITIS  
PI: Anthony Shanks, MD • CRNC: Patty Fogerty, RN, MSN  
A randomized controlled clinical trial to determine if prophylactic antibiotics are required post-cesarean delivery for pregnancies with treated chorioamnionitis. Target enrollment is 398 laboring patients with the diagnosis of chorioamnionitis who require delivery via cesarean section.
THE ST. LOUIS NEONATAL GUT MICROBIOME INITIATIVE

*PI: Barbara Warner, MD* • *CRC: Christine Kramer*

Sponsored by the Children’s Discovery Institute of St. Louis Children’s Hospital
A twin birth cohort study aimed at testing the relative roles of host genotype versus early environmental exposures (mother, diet, etc) on gut microbial ecology. This will compare how similar the microbial community is for identical twins to non-identical twins in the first year of life. Recruitment will occur at Center for Advanced Medicine, Labor and Delivery at BJC, and Missouri Baptist Hospital. The study aims to enroll 100 mothers and 25 monozygotic twin pregnancies over 34-weeks gestation.

VDAART: VITAMIN D ANTENATAL ASTHMA REDUCTION TRIAL

*PI: Robert Strunk, MD* • *CRNC: Danae Larson, RN, BSN* • *RA: Jennifer Byers, Yvonne Burrage*

Sponsored by a NIH Grant
A multi-centered randomized double blind controlled trial to determine whether sufficient vitamin D supplementation in the pregnant mother is associated with reduced incidence of asthma in the child during the first three-years of life. Our primary outcomes will be doctor’s diagnosis of asthma and/or recurrent wheeze in the child at age three-years. A total of 290 patients at Washington University will be recruited over two years.

GYNECOLOGY

BMI: CHANGE IN BMI AND CONTRACEPTION STUDY

*PI: Zevidah Vickery, MD* • *RA: Leslie Nash*

As a retrospective sub-study of the Contraceptive CHOICE Project (CHOICE), our goal is to measure the change in body weight and body mass index (BMI) between baseline and 12 months in women who use the ENG implant, LNG-IUC, or depot medroxyprogesterone acetate for at least 11 months and to compare these measures to users of the copper IUC. We plan to enroll 100 participants in each group.

BACTERIAL-HOST INTERACTIONS IN VAGINAL FLUIDS

*PI: Amanda Lewis, PhD* • *Co-PI’s Jenifer Allsworth, PhD, Tessa Madden, MD, MPH*

We have shown that sialidase activity can have a profound impact on the physical properties of proteins involved in mucosal immunity that are modified with sialic acid residues. Using clinical samples from women with or without BV, we aim to further characterize how sialidases may be involved in the initiation and complications of this infection using molecular, tissue culture, and animal models. Approximately 800 vaginal swabs will be collected through the VAST study over a 3 year period.

THE CONTRACEPTIVE CHOICE PROJECT

*PI: Jeffery Peipert, MD, PhD* • *Project Director: Gina Secura, PhD, MPH*

Sponsored by an anonymous foundation
The study aim is to reduce the number of unintended pregnancies in the St. Louis area by providing no cost contraception of a woman’s choice for three years, including STD and HIV testing and STD treatment. Recruitment occurs at the Division of Clinical Research, as well as multiple family planning clinics in the St. Louis region. A total of 10,000 women will be enrolled over a four-year period with follow-up for three-years after enrollment.

COMPUTERIZED CONTRACEPTIVE DECISION MAKING TOOL

*PI: Tessa Madden, MD* • *Project Director: Gina Secura, PhD, MPH*

Sponsored by a Society of Family Planning (SFP) Grant
The aim of this study is to conduct the formative research necessary to develop a computerized decision-making tool that incorporates the social and cultural factors that influence women’s contraceptive decisions; and therefore increase satisfaction, knowledge, and decision certainty with the contraceptive decision-making process. Through focus groups, surveys and initial assessments among women and clinicians, a web-based interactive computerized tool will be developed and pilot tested among participants of the Contraceptive CHOICE Project.
DXA: WEIGHT CHANGE AND CONTRACEPTION STUDY
*PI: Zevidah Vickery, MD • RA: Leslie Nash*
As a prospective sub-study of the Contraceptive CHOICE Project (CHOICE), our goal is to measure the change in body weight, body mass index (BMI), and body composition measured by dual-energy x-ray (DXA) technology between baseline and 12 months in women using the ENG implant, LNG-IUC, or depot medroxyprogesterone acetate and to compare these measures to users of the copper IUC. We will also examine whether appetite and physical activity change during this time period. Enrollment began in December 2010; 115 participants will be enrolled in each group. In addition, among the first 40 participants, we will compare body composition results of the DXA scan to results using a bioelectric impedance scale.

IMMEDIATE POST-PARTUM INSERTION OF ETONOGESTREL SUBDERMAL IMPLANT CONTRACEPTIVE DEVICE
*PI: David Eisenberg, MD, MPH*
Sponsored by ACOG Bayer grant
A sub study of the contraceptive CHOICE project to determining if receiving Implanon™ immediately post-partum affects bleeding profiles compared to women who receive an interval Implanon™ insertion. A further aim of the study is to compare the proportion of women who report bleeding at 6 months after Implanon™ insertion between women who receive the implant immediately post-partum versus interval placement.

A PHASE 3, RANDOMIZED, MULTI-CENTER, OPEN-LABEL STUDY OF A LEVONORGESTREL-RELEASEING INTRAUTERINE SYSTEM AND MIRENA® FOR LONG-TERM REVERSIBLE CONTRACEPTION
*PI: David Eisenberg, MD, MPH • RA: Kristen Powers*
Sponsored by Medicine 360
A Phase III, multi-center, randomized study aimed at evaluating whether the safety and effectiveness of LNG 20 intrauterine contraceptive system compared to the Mirena. A total of 150 women will be recruited at the Division of Clinical Research.

MISTIC: MIRENA INTRAUTERINE SYSTEM TIMING OF INSERTION CONTROLLED TRIAL
*PI: Lorie Harper, MD • Co-PI: David Eisenberg, MD, MPH*
This substudy of the CHOICE Contraceptive Project is a randomized control trial with the aim of determining the timing of Mirena® insertion that results in the greater proportion of women with a Mirena in place at 6 months post-partum. Women requesting the Mirena for post-partum contraception will be enrolled at CHOICE sites at 36 weeks gestation or greater and will be randomized at the time of vaginal delivery to receive the Mirena immediately post-placenta or at 4-8 weeks post-partum. Approximately 200 women will be randomized.

OVARIAN RESERVE AND JUVENILE/ADULT RHEUMATOID ARTHRITIS & SPONDYLOARTHITIS
*PI: Amber R. Cooper, MD • CRNC: Mary Koenig, RN*
Sample analysis supported by Beckman Coulter, Inc.
This is a prospective study aimed at evaluating ovarian reserve in females 4-50 years of age with the diagnosis of RA, JRA/JIA, or SPA (spondyloarthritis). The purpose is to evaluate the effects of disease severity and biologic/cytotoxic therapies on ovarian function. Recruitment of patients is at SLCH and the Rheumatology Clinic at the Center for Advanced Medicine and will continue until 300 patients are enrolled.

REPRODUCTIVE OUTCOMES IN OBESE WOMEN WITH INFERTILITY
*PI: Emily Jungheim, MD*
A prospective cohort study of obese versus non-obese women undergoing in-vitro fertilization with the objective to study potential contributions of leptin, and adiponectin to poor reproductive outcomes among obese women. Recruitment will occur in the Department of Reproductive Endocrinology and Infertility. Approximately 450 IVF cycles and seven patients will be recruited from each group.
THE ROLE OF ESTROGEN AND THE MODULATION OF UROTHELIAL BARRIERS AND COURSE OF URINARY TRACT INFECTIONS

*PI: Indira Mysorekar, MD; Mallika Anand, MD • RA: Megan Isaaco-Schmid*

A prospective study aimed at understanding the role of estrogen in urinary tract infections and specifically interaction between bacteria and bladder tissue and how it may or may not vary depending on estrogen levels. A total of 300 patients will be recruited from BJC and the Center for Advanced Medicine antepartum clinics.

STEPS: STUDY TO EVALUATE MALE PARTNER SCREENING

*PI: Jeffrey F. Peipert, MD, PhD • RA: Shatesha Boyce*

A randomized controlled trial comparing home- with clinic-based urine screening for sexually transmitted infections (STIs) in men. The aim of the study is to evaluate the acceptability of STI screening and the screening rates achieved with home- versus clinic-based approaches. A total of 500 men will be enrolled.

THE VAST STUDY

*PI: Jenifer Allsworth, PhD • CRNC: Linda Odibo, RN, BSc, MN*

A prospective cohort study nested within the Contraceptive CHOICE Project that seeks to evaluate the role of genomic variation in Human Leukocyte Antigens in susceptibility to bacterial sexually transmitted infections (Chlamydia trachomatis and Neisseria gonorrhoeae). A total of 1,000 women between the ages of 18 and 45 years will be recruited.

VITAMIN D AND VAGINAL FLORA

*PI: Jenifer Allsworth, PhD • Danae Larson, RN, BSN*

A substudy of the Vitamin D Antenatal Asthma Reduction Trial that will evaluate the impact of Vitamin D supplementation during pregnancy on vaginal flora. Up to 150 women will be recruited.

WHSC: WOMEN AND INFANT'S HEALTH SPECIMEN CONSORTIUM

*PI: Ann Gronowski, PhD; Kelle Moley, MD; Jenifer Allsworth, PhD; Marwan Shinawi, MD • CRC: Christine Kramer • RA: Lyndsay Roy*

Sponsored by a Children’s Discovery Institute Grant

The study aim is to create a structure to facilitate the collection of patient specimens for women and infant’s health research. The bank will provide specimen collection, specimen storage and processing, as well as the maintenance of a comprehensive database of outcomes data for five hypothesis driven projects. This process will be completed by working together with the ICTS’s Translational Pathology and Molecular Phenotyping (TPMP) core. Recruitment will occur at Washington University Reproductive Endocrinology and Infertility Center, the Center for Advanced Medicine, Barnes Jewish Women’s Health Clinic and Labor and Delivery. Approximately 1500 women will be enrolled by the end of the year.

ONCOLOGY *

A PHASE III TRIAL OF PELVIC RADIATION THERAPY VERSUS VAGINAL CUFF BRACHYTHERAPY FOLLOWED BY PALITAXEL/CARBOPLATIN CHEMOTHERAPY IN PATIENTS WITH HIGH-RISK, EARLY STAGE ENDOMETRIAL CARCINOMA

*PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP*

Sponsored by Gynecologic Oncology Group (NCI), GOG 249 - Cooperative Group

A Phase III randomized trial of pelvic radiation therapy versus vaginal cuff brachytherapy followed by chemotherapy utilizing carboplatin and paclitaxel in women with early stage endometrial carcinoma who are at high risk for recurrence. Group-wide target accrual: 562
A RANDOMIZED PHASE III TRIAL OF CISPLATIN AND TUMOR VOLUME DIRECTED IRRADIATION FOLLOWED BY CARBOPLATIN AND TAXOL VS. CARBOPLATIN AND TAXOL FOR OPTIMALLY DEBULKED, ADVANCED ENDOMETRIAL CARCINOMA
*PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP*
Sponsored by Gynecologic Oncology Group (NCI), GOG 258 - Cooperative Group
A Phase III randomized trial of tumor volume-directed irradiation with cisplatin as a radiation sensitizer followed by chemotherapy utilizing carboplatin and paclitaxel versus chemotherapy utilizing carboplatin and paclitaxel in women who have undergone optimal debulking for advanced endometrial carcinoma. Group-wide target accrual: 804.

A THREE ARM RANDOMIZED PHASE II STUDY OF TAXOL/CARBOPLATIN/BEVACIZUMAB (NSC #704865, IND #7921), TAXOL/CARBOPLATIN/TEMsiROLImUs (NSC #683864, IND #61010) AND IXABePILONe (NSC #710428, IND #59699)/CARBOPLATIN/BEVACIZUMAB AS INITIAL THERAPY FOR MEASURABLE STAGE III OR IVA, STAGE IVB, OR RECURRENT ENDOMETRIAL CANCER
*PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP*
Sponsored by Gynecologic Oncology Group (NCI), GOG 0086P - Cooperative Group
A Phase II randomized trial for the treatment of either advanced stage primary or recurrent endometrial carcinoma. This is a 3-arm trial utilizing chemotherapy with the addition of biologic therapies, either Bevacizumab (a recombinant humanized anti-VEGF monoclonal antibody), Temsirolimus (an mTOR inhibitor) or Ixabepilone (a non-taxane microtubule stabilizing agent) for 6 cycles followed by maintenance treatment with biologic therapy. It includes a translational research component. Group-wide target accrual: 330.

AN OPEN LABEL, SINGLE-ARM MULTICENTER PHASE 2 STUDY OF E7080 IN SUBJECTS WITH ADVANCED ENDOMETRIAL CANCER AND DISEASE PROGRESSION FOLLOWING FIRST-LINE CHEMOTHERAPy
*Site PI: Matthew Powell, MD • Coordinator: Lynne Lippmann, CCRP*
Sponsored by Eisai Pharmaceuticals - E7080
A Phase II study utilizing E7080 (multi-targeted kinase inhibitor of VEGFR, FGFR, PDGFR and c-kit) in the treatment of recurrent endometrial carcinoma in women who have received 1 prior systemic chemotherapy for primary, unresectable or recurrent endometrial carcinoma. This is an oral medication taken daily on a 28-day cycle. It includes a translational research component. There is an optional imaging DCE-MRI component for eligible subjects in which Washington University will participate. Group-wide target accrual: Stage I accrual 47. If second stage is warranted, there will be a total of 130.

BIOBEHAVIORAL INFLUENCES AND THE OVARIAN TUMOR MICROENVIRONMENT
*PI: Premal Thaker MD • Coordinator: Kelly Kallaher*
Sponsored by National Institute of Health
A biobehavioral study designed to understand the relationship between behavioral factors, hormones, and chemicals produced by the body that may help tumor growth in ovarian cancer. The purpose of this study is to better understand the risk factors related to the progression of ovarian cancer. Group wide target accrual: 195

FEASIBILITY STUDY: THERAPEUTIC TARGETING OF STRESS FACTORS IN OVARIAN CANCER PATIENTS
*PI: Premal Thaker MD • Coordinator: Kelly Kallaher*
Sponsored by Gynecologic Cancer Foundation
A feasibility trial to investigate the effect of biobehavioral factors such as stress on how chemotherapy drugs affect tumor growth in these types of cancer. The aim of the study is to determine if the addition of a beta-blocker such as Propranolol (Inderal) is tolerable when given with chemotherapy in the treatment of newly diagnosed ovarian, fallopian tube, or primary peritoneal cancer. This will help us understand an alteration of these behavioral factors will allow chemotherapy to work more effectively. Group wide target accrual: 25
PHASE II STUDY OF CS-1008 IN COMBINATION WITH CHEMOTHERAPY (PACLITAXEL/CARBOPLATIN) IN LOCALLY ADVANCED OR METASTATIC OVARIAN CANCER

PI: David Mutch, MD • Coordinator: Lynne Lippmann, CCRP
Sponsored by Daiichi Pharmaceutical
Phase II trial in the treatment of newly diagnosed ovarian or primary peritoneal carcinoma, Stage III or IV who have undergone suboptimal debulking. This study utilizes the chemotherapy regimen of Carboplatin and Paclitaxel along with CS-1008, an antibody to DR5 proteins. This antibody appears to kill tumor cells while leaving the normal cells unaffected. Group wide target accrual: 40

PATIENT, PHYSICIAN AND NURSE FACTORS ASSOCIATED WITH ENTRY ONTO CLINICAL TRIALS AND COMPLETION OF TREATMENT FOR WOMEN WITH PRIMARY OR RECURRENT INVASIVE CARCINOMA OF THE UTERINE CORPUS OR UTERINE CERVIX

PI: David Mutch, MD • Coordinator: Lynne Lippmann, CCRP
Sponsored by Gynecologic Oncology Group (NCI), GOG 247 - Cooperative Group
The purpose of this study is to identify factors which predict whether or not patients with the diagnosis of primary or recurrent invasive carcinoma of the uterus or cervix go onto clinical trials. This study will look at whether factors such as where the patient lives, her beliefs or concerns, her finances, and the beliefs of her physician or nurse affect whether or not she is enrolled onto a clinical trial. Group-wide target accrual: 370

A PHASE II EVALUATION OF SU11248 (SUNITINIB MALATE) (IND #74019, NSC #736511) IN THE TREATMENT OF PERSISTENT OR RECURRENT CLEAR CELL OVARIAN CARCINOMA

PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP
Sponsored by Gynecologic Oncology Group (NCI), GOG 254 - Cooperative Group
A Phase II study of sunitinib malate (a receptor tyrosine kinase inhibitor) as a treatment for recurrence of ovarian cancer (in women who have had 2 or less prior cytotoxic treatments) in which either the primary or recurrent tumor shows at least 50% clear cell histology. It includes a translational research component. Group-wide target accrual: Stage 1 accrual 22, total 56.

PHASE II EVALUATION OF AMG102 IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CARCINOMA

PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP
Sponsored by Gynecologic Oncology Group (NCI), GOG 170P - Cooperative Group
A Phase II study of AMG 102 (a fully human monoclonal antibody) in the treatment of women with recurrent ovarian, primary peritoneal or fallopian tube carcinoma who have received 1 or 2 prior regimens. Treatment is given intravenously every 2 weeks until disease progression or adverse effects prohibit further therapy. It includes a translational research component. Group-wide accrual: 26 in first stage, an additional 23 if study re-opens for additional accrual.

PROSPECTIVE STUDY OF RISK-REDUCING SALPINGO-OOPHORECTOMY (RRSO) AND LONGITUDINAL CA-125 SCREENING AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER: EXTENDED FOLLOW-UP OF SELECT GOG-0199 STUDY PARTICIPANTS

PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP
Sponsored by Gynecologic Oncology Group (NCI), GOG 8199 - Cooperative Group
This is an extension of the original GOG 199 study for women at increased genetic risk of developing ovarian cancer. The original study follow-up lasted 5 years and this extension study will extend the follow-up an additional five years for women who were initially on GOG 199 and who meet the criteria for this study. Washington University is one of the five Data Coordinating Centers for this study. Group-wide target accrual: 1916.

*Sampling of current studies
GRANTS AWARDED

Barnes Jewish Hospital Foundation
PI: Donald Nelson, MD | Award period: 7/1/10-6/30/11
Virginia S. Lang Chair in Obstetrics and Gynecology

Burroughs Wellcome Foundation
PI: Indira Mysorekar, PhD | Award period: 4/1/11-3/30/15
Occult Infections in the Etiology of Preterm Birth

T32HD055172
Katherine Goetzinger, MD | Award Period 7/1/10 to 6/30/12
Reproductive epidemiology training program at Washington University in St. Louis. This is part of the T32 training grant program at Washington University.

T32HD055172
Molly Stout, MD | Award Period 7/1/11 to 6/30/13
Reproductive epidemiology training program at Washington University in St. Louis. This is part of the T32 training grant program at Washington University.

T32HD055172
Colleen McNicholas, MD | Award Period 7/1/11 to 6/30/13
Reproductive epidemiology training program at Washington University in St. Louis. This is part of the T32 training grant program at Washington University.
Publications

If we missed your publication, please let us know and we will be happy to include it in the next issue of the newsletter.

The amino acids upstream of NH(2)-terminal dileucine motif play a role in regulating the intracellular sorting of the Class III transporters GLUT8 and GLUT12.
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Bibee KP, Illsley NP, Moley KH.

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Dewdney SB, Mutch DG.

Inferior vena cava filter placement in the gynecologic oncology patient: A 15 year institutional experience.
Dewdney SB, Benn T, Rimel BJ, Gao F, Saad N, Vedantham S, Mutch DG, Zighelboim I.
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