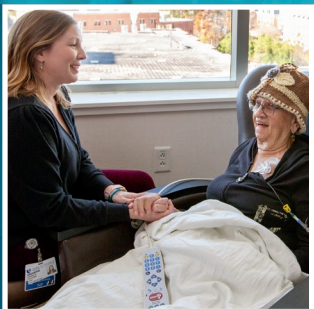


WINTER 2020

# DUKE OB/GYN

#wedeliver



Innovation  
in Women's  
Health

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## MISSION

**Deliver better health and hope to all women and their families** through compassionate care, innovation, education and discovery

## VISION

**Set the global standard of excellence and lead the future of women's healthcare**

## CORE VALUES

**Excellence**  
**Integrity**  
**Innovation**  
**Diversity and Inclusion**  
**Teamwork**  
**Continuous Improvement**  
**Community**  
**Advocacy**



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# MESSAGE FROM THE CHAIR

## **Excellence. Innovation. Continuous Improvement. Advocacy.**

These are powerful words, and words that exemplify Duke Ob/Gyn. They are among our Department's Core Values, and they come to life through research, education and patient care, as you will see in this issue of our annual publication.

Our faculty and trainees are committed to continuing on this path of excellence. Duke Ob/Gyn's Residency Program is **ranked #6 in the nation** by Doximity, offering an outstanding clinical experience, and unique opportunities in global health, community service and world-class research.

Although impossible to showcase all of the phenomenal work the Department has accomplished, and what our future holds, here are a few examples of what this issue includes – and why I am proud as an alumnus (Residency '98; Fellowship '01), and now as Chair, to lead Duke Ob/Gyn:

- **Career development programs** support junior faculty and provide individualized mentoring from nationally recognized Duke leaders and researchers. These programs offer community partnerships and increase opportunities for diversity, and for training scholars from groups underrepresented in biomedical research. Read about Duke's BIRCWH and KURe programs, and much more.
- Research and state-of-the-art techniques for treating fibroids put Duke Ob/Gyn at the forefront in gynecologic care. I'm proud to announce that the \$20 million, 5-year **Comparing Options for**

## **Management: Patient-centered Results for Uterine Fibroids (COMPARE-UF)**

registry has now been completed, yielding impactful research that will help improve the lives of many women. Led by **Evan Myers, MD, MPH**, since its inception in September 2014 and funded by a \$20 million award from the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI), the multicenter registry is comprised of women undergoing common procedures for fibroids. Although funding ends next year, we're in discussions about developing a next-generation registry that will allow women anywhere to enroll and submit their data online.

- A study that demonstrates the association between cannabis use in men and a specific gene in sperm implicated in autism made international headlines. Senior author is **Susan Murphy, PhD, Division Chief of Reproductive Sciences**.
- Urogynecologist **Cindy Amundsen, MD**, Roy T. Parker Professor of Obstetrics and Gynecology, recently was awarded a five-year, \$760,000 grant supported by the NIH/NICHD for the American Urogynecologic Society/Duke Urogynecology Clinical Research Educational Scientist Training (UrogynCREST) Program.
- Duke Ob/Gyn was awarded a **\$5.3 million multi-year SPAN contract**. The study aims to explain different factors contributing to newborn health, which lead into childhood growth and development, and lifelong health outcomes. The Maternal-Fetal Medicine Division also

recently expanded services at its high-risk obstetrics clinic, adding cardiology services.

- Despite global efforts, women in underserved areas around the world continue to face challenges with many health issues. Through partnerships and mobile technology, initiatives led by **Megan Huchko, MD, MPH**, are underway to address this.
- Advancements in the treatment of women's cancers are promising, and research in gynecologic oncology has led to a new protocol for surgery. Additional studies in this specialty are possible thanks to a **\$1 million Kay Yow Cancer Fund Award to Angeles Secord, MD, MHS, and Duke Cancer Institute**.

I hope you enjoy reading about, and are inspired by, the work we are doing.

Sincerely,



**Matthew D. Barber, MD, MHS**  
E.C. Hamblen Professor and Chair,  
Duke Ob/Gyn

# NEW INNOVATIONS IN TREATING FIBROIDS

BY JANE BLACK

Uterine fibroids are common benign tumors that occur in 70 to 80 percent of women before age 50. They often cause bleeding and pain, and impact activities of daily living. Through a strategic commitment to clinical and translational research, Duke Ob/Gyn is bringing innovative treatments to the forefront of leading edge care.

## New patent offers hope

In August of 2019, Duke University School of Medicine Professor Emerita and former Duke Ob/Gyn Vice Chair for Research **Phyllis Leppert, MD, PhD**, (along with colleagues), was issued a patent titled "Treatment Method and Product for Uterine Fibroids Using Purified Collagenase." The patent is for treating uterine fibroids by injecting or inserting collagenase derived from *Clostridium histolyticum* (CCH). The patent was issued based on research conducted in Duke Ob/Gyn and published in the ***American Journal of Obstetrics and Gynecology* (November 2016)**: "Loss of stiffness in collagen-rich uterine fibroids after digestion with purified collagenase *Clostridium histolyticum*" (senior author Dr. Leppert; first author **Friederike Jayes, DVM, PhD**; co-authors were Duke faculty and staff at the time the study was conducted). The issuance of the patent follows positive data from a Phase 1 clinical trial for the treatment of uterine fibroids at Johns Hopkins University; Drs. Leppert and Jayes are co-investigators.

## READ MORE: Recognizing Heterogeneity in Fibroids Could Expand Treatment Options

— Duke Health *Clinical Practice Today*



"Research conducted at Duke demonstrated that this purified bacterial collagenase successfully digested the collagen in uterine fibroid tissue by evaluation of the collagen content in injected tissue, compared to control tissue using histological methods," Dr. Leppert stated. "The stiffness of the tissue was significantly reduced, suggesting that collagenase could be a potential treatment for uterine fibroids, as they grow by an accumulation of collagen. The clinical trial results showed that in some patients, the collagenase treatment even reduced the pain due to fibroids, and this data was presented at the American Society for Reproductive Medicine (ASRM) meeting in the fall of 2019."

The Phase 1 clinical trial met the primary endpoint of safety and tolerability with no observed clinically significant adverse reactions. Statistically significant reductions in collagen content were observed as compared to control fibroids with a median reduction of 39 percent ( $p < 0.05$ ), as well as statistically significant reductions in collagen distribution as compared to control fibroids with an average reduction in density of collagen bundles of 21 percent.

In the study conducted at Duke, the collagen content of the fibroids studied was high and ranged from 37 to 77 percent. Treatment with collagenase decreased collagen content to 20 percent and in some instances even below 3 percent. Transmission electron microscopy confirmed complete digestion of the collagen fibrils, according to Dr. Leppert.

Additionally, in December 2018, Dr. Jayes and **Darlene K. Taylor, PhD** (Adjunct Faculty), were each awarded \$25,000 in Duke-NCCU collaborative research grants to advance studies to deliver drugs via LiquoGel™ to treat uterine fibroid tumors. LiquoGel was developed by Dr. Taylor during her time as a Duke-BIRCWH\* scholar and has the potential of delivering three drugs simultaneously in one injection. The targeted technology could transform uterine fibroid therapy for the seven in 10 women and eight in 10 black women suffering with uterine fibroid tumors.

**\*Read more about BIRCWH and career development programs, page 8**

## \$20 million, 5-year, multicenter COMPARE-UF Registry completed

In September 2014, the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI) awarded \$20 million for a 5-year, multicenter registry of women undergoing common procedures for fibroids: **Comparing Options for Management: Patient-centered Results for Uterine Fibroids (COMPARE-UF)**. **Evan Myers, MD, MPH**, Walter L. Thomas Professor in the Division of Women's Community and Population Health, was the overall Principal Investigator, leading the registry coordinating center at the Duke Clinical Research Institute.

The registry is now completed. Information was collected prospectively before and at six weeks, one, two and three years after undergoing a procedure at one of nine centers. In addition, women report on quality-of-life and symptoms using standard measures. Analyses have started over the past year.

"Not surprisingly, there are a number of important differences between women choosing different treatments in terms of fibroid history, size and number of fibroids and symptom severity," said Dr. Myers. "In our analyses, we're able to control for these differences so that when we compare outcomes, the patients are as 'similar' as possible. We've focused initially on hysterectomy and myomectomy – both result in big improvement in quality-of-life at six to 12 weeks and at one year. We're starting to look at less common treatments and longer-term outcomes. Although funding ends next year, we're in discussions about developing a next-generation registry that will allow women anywhere to enroll and submit their data online."

## New procedure uses radiofrequency ablation, improves recovery time

In December 2019, **Craig Sobolewski, MD**, Division Chief of Minimally Invasive Gynecologic Surgery at Duke Ob/Gyn, led the first surgical team in North Carolina that utilized a new minimally invasive surgical technology to treat fibroids by ablating them using radiofrequency (RF) energy. The Acessa ProVu procedure

incorporates a laparoscopic ultrasound device that allows surgeons to locate the fibroids intraoperatively, and then uses image guidance technology, along with real-time laparoscopic visualization, to direct a small RF needle into the fibroid. Along with Dr. Sobolewski, Duke providers trained to offer this option to women in the southeastern United States are **Arleen Song, MD, MPH**; **Amy Broach, MD, MS**; and **MargEva Cole, MD** (pictured below).

"This combination of direct laparoscopic visualization of the anatomy, along with ultrasonographic imaging, allows us to identify the interface between the capsule of the fibroid and the surrounding normal uterine muscle to ensure that only the pathology is being treated and the normal myometrium is being spared," said Dr. Sobolewski. "I am thrilled that we are now able to offer the women of our community this treatment, which is the most minimally invasive surgical option available, and allows patients to get back to normal routines more quickly than current options."

"Already there has been enthusiastic interest from women in NC, SC, VA and GA who are looking for less invasive ways to treat their uterine fibroids while sparing the uterus," noted Dr. Cole.



In addition, studies have shown that using intraoperative ultrasound directly on the surface of the uterus itself can potentially identify more fibroids than traditional abdominal or vaginal ultrasound or MRI. Once placed within the substance of the fibroid, the RF energy heats the tissue to a temperature of at least 90 degrees Celsius; that heat destroys the fibroid tissue. The destroyed tissue is absorbed and removed naturally by the body, and the fibroid volume shrinks over time. The reduction in the size of the fibroids is what eventually improves the patient's symptoms, according to Dr. Sobolewski.

"Because there are no myometrial incisions, and the tissue is treated via coagulative necrosis as opposed to hypoxic necrosis, patients have very little pain with this procedure," Dr. Sobolewski said. "As a result, they are discharged more quickly, require little or no post-operative narcotics, and return to normal activities substantially faster."



**Duke is in the process of becoming a multi-institutional ULTRA (Uterine Leiomyoma Treatment with Radiofrequency Ablation) registry site and anticipates being able to enroll patients in the near future. Patients undergoing the Acessa ProVu procedure, and who choose to participate in this prospective observational cohort study, will be followed for three years to document long-term outcomes in patients who have undergone the procedure. Photo by Ken Huth.**

# STUDY DEMONSTRATES ASSOCIATION BETWEEN CANNABIS USE IN MEN, ALTERATION IN GENE IN SPERM IMPLICATED IN AUTISM

BY SARAH AVERY  
DUKE HEALTH NEWS OFFICE

A specific gene associated with autism appears to undergo changes in the sperm of men who use marijuana, according to new research from Duke Health.

The gene change occurs through a process called DNA methylation, and it could potentially be passed along to offspring.

Published online August 27, 2019 in the journal *Epigenetics*, the researchers said the findings do not establish a definitive link between cannabis use and autism, but the possible connection warrants further, urgent study, given efforts throughout the country to legalize marijuana for recreational and/or medicinal uses.

"This study is the first to demonstrate an association between a man's cannabis use and changes of a gene in sperm that has been implicated in autism," said senior author **Susan Murphy, PhD**, Associate Professor in the Department of Obstetrics & Gynecology at Duke University School of Medicine.

**"This study is the first to demonstrate an association between a man's cannabis use and changes of a gene in sperm that has been implicated in autism."**

**— Susan K. Murphy, PhD, Division Chief, Reproductive Sciences, Duke Ob/Gyn**

Dr. Murphy and colleagues, including lead author and PhD student Rose Schrott, conducted studies using human biologics and animal models to analyze differences between the sperm of males who smoked or ingested marijuana compared to a control group with no such exposures.

In earlier work, published in December, the researchers noted several gene alterations in the sperm of men who smoke marijuana. The current study homed in on specific genes, notably one called Discs-Large Associated Protein 2, or DLGAP2. This gene is involved in



transmitting neuron signals in the brain and has been strongly implicated in autism, as well as schizophrenia and post-traumatic stress disorder.

"We identified significant hypomethylation at DLGAP2 in the sperm of men who used marijuana compared to controls, as well as in the sperm of rats exposed to THC compared to controls," Schrott said. "This hypomethylated state was also detected in the forebrain region of rats born to fathers exposed to THC, supporting the potential for intergenerational inheritance of an altered sperm DNA methylation pattern."

The Duke team found that there was a sex-based difference in the relationship between DNA methylation and gene expression in human brain tissues. In both male and female brain tissues, increased DNA methylation was associated with decreased gene activity. This relationship was strongest in females, and seemed to be less well maintained in males, though the reason for this is unknown at this time. This anomaly was notable, because the ratio of boys to girls with autism is 4:1, and there are sex differences in the neurobehavioral symptoms.

"It's possible that the relationship between methylation and expression is modified if the methylation change we see in sperm is inherited by the offspring," Dr. Murphy said. "In any event, it's clear that the region of DNA methylation within DLGAP2 that is altered in association with cannabis use is functionally important in the brain."

Dr. Murphy said the study's sample size was small – including 24 men, half who used marijuana and half who didn't – and could not account for confounding factors such as diet, sleep and exercise, but the findings should prompt continued research.

"Given marijuana's increasing prevalence of use in the U.S. and the increasing numbers of states that have legalized its use, we need more studies to understand how this drug is affecting not only those who smoke it, but their unborn children," Dr. Murphy said. "There's a perception that marijuana is benign. More studies are needed to determine whether that is true."

In addition to Dr. Murphy and Rose Schrott, study authors include Kelly Acharya, MD; Nilda Itchon-Ramos; Andrew B. Hawkey, PhD; Erica Pippen; John T. Mitchell, PhD; Scott H. Kollins, PhD; and Edward D. Levin, PhD. The study was funded in part by the John Templeton Foundation (60564). The work was part of the CIPHERS project.



## DUKE AWARDED 5-YEAR AUGS UROGYNCREST GRANT

Urogynecologist **Cindy Amundsen, MD**, Roy T. Parker Professor of Obstetrics and Gynecology, recently was awarded a five-year, \$760,000 grant supported by the NIH/NICHD for the American Urogynecologic Society/Duke Urogynecology Clinical Research Educational Scientist Training (UrogynCREST) Program.

As Principal Investigator and Program Director, Dr. Amundsen has built a team of Duke experts in health services, medical informatics and prediction modeling by collaborating with faculty from the Departments of Biostatistics and

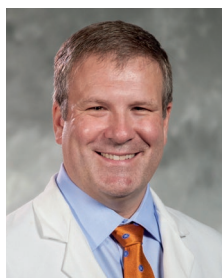
Bioinformatics, Medicine, Ob/Gyn and Population Health. The team collaborates with clinical leaders and mentors across the U.S. to implement interactive, remote training in health services research for junior faculty involved in female pelvic floor disorders.

The UrogynCREST program prepares participants to recognize the critical role that data play in delivering high quality healthcare. The program will target urogynecology faculty across the country who are at the assistant professor level and who seek careers in health services research and analytics.

## NATIONALLY ACCLAIMED FPMRS RESEARCH

**CAPABLE** Trial results published in *The Lancet Gastroenterology & Hepatology*

Results of the **Controlling Anal Incontinence by Performing Anal Exercises with Biofeedback or Loperamide (CAPABLE)** trial were published



online in *The Lancet Gastroenterology & Hepatology* (Sept. 2019), noting that fecal incontinence is widespread, but remains an under-researched medical problem that seriously impacts quality of life.

Women with fecal incontinence but normal stool consistency should not expect significant improvement from common first-line treatments, with little therapeutic difference between options emerging from the CAPABLE trial, researchers reported. Combination

treatments, however, may be slightly more beneficial than individual therapies. First author was **J. Eric Jelovsek, MD, MMed, MSDS** (pictured, left).

**ESTEEM, SUPeR published in JAMA**

Pelvic Floor Disorders Network (PFDN) studies conducted at Duke University (a national PFDN research site) recently were published in the *Journal of the American Medical Association*. Urogynecologists **Alison Weidner, MD, MMCI**, and **Anthony Visco, MD**, co-authored the two studies, **Effects of Surgical Treatment Enhanced with Exercise for Mixed Urinary Incontinence (ESTEEM)**, and **SUPeR: Study of Uterine Prolapse Procedures- Randomized Trial**, respectively. Both studies researched patient outcomes in Female Pelvic Medicine and Reconstructive Surgery.

ESTEEM: The study notes that surgery for stress urinary incontinence (leaking that occurs with a cough or sneeze) improves symptoms of another form of incontinence, called urgency urinary incontinence, in women who have both types. Dr. Weidner and colleagues'

research found that one year after treatment, both groups had significant improvements in both types of urinary incontinence symptoms, measured using a questionnaire. Incontinence symptoms were slightly better in the combined group, but did not differ greatly from the sling only group.

SUPeR: Two surgical procedures used to correct vaginal prolapse – one to remove the uterus and one that supports the uterus with mesh – have comparable three-year outcomes, according to the SUPeR study. To date, the randomized clinical trial provides the longest-term comparison of the procedures, and researchers will continue to follow the patients for a total of five years. The study was designed to compare effectiveness/ adverse events of the two strategies.

Dr. Visco, Division Chief of Female Pelvic Medicine and Reconstructive Surgery, was a co-author of the study, findings from which did not show significantly lower rate of the composite prolapse outcome after three years (noting that further research is needed to assess whether vaginal mesh hysteropexy is more effective than vaginal hysterectomy with uterosacral ligament suspension).

# CAREER DEVELOPMENT PROGRAMS SUPPORT CLINICIAN SCIENTISTS

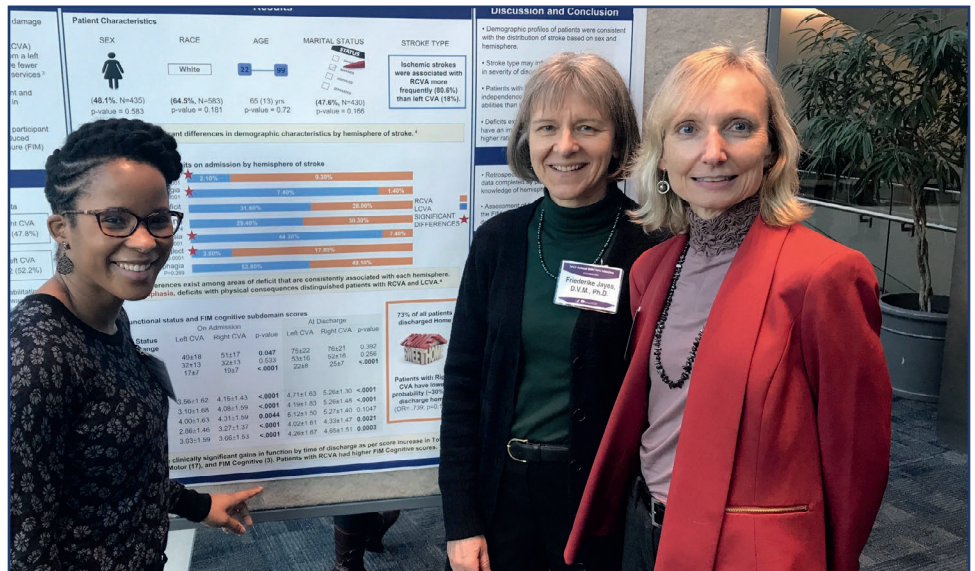
BY JANE BLACK

Duke Ob/Gyn is committed and dedicated to ensuring junior faculty are supported through career development programs and funding. Awardees receive individualized mentoring from nationally recognized Duke leaders, training on grant writing, protected research time and opportunities to develop leadership and networking skills.

The Duke University School of Medicine currently holds four National Institutes of Health (NIH)-funded K12-Career Development awards. Two of these are administered within Duke Ob/Gyn under the leadership of **Cindy Amundsen, MD**, and **Friederike Jayes, DVM, PhD**. The awards each have a different emphasis:

**The K12 Multidisciplinary Urologic Research (KURe)** program attracts scientists interested in benign urology research and is funded by the NIH/ National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The success of Duke's KURe program has been recognized by the NIH; the program was recently awarded a supplemental grant to support two additional scholars, for a total of five KURe scholars at one time. Duke's program is unique in that it attracts individuals with diverse scientific and academic backgrounds who utilize a broad range of research methodologies and who apply and adapt their expertise to benign urologic conditions.

**The Building Interdisciplinary Research Careers in Women's Health (BIRCWH)** program is sponsored by the NIH Office of Research on Women's Health and the *Eunice Kennedy Shriver* NIH/National Institute of Child Health and Human Development. The Duke-BIRCWH program has established an innovative partnership between Duke and North Carolina Central University, a Historically Black College/University. This partnership strengthens Duke Ob/Gyn's goal of increasing diversity and training underrepresented scholars from groups underrepresented in biomedical research. BIRCWH trains



**At the annual BIRCWH Grantees Meeting held at NIH in Bethesda, MD, in December 2019: Jamila Minga, PhD, NCCU Scholar; Friederike Jayes, DVM, PhD, Program Coordinator for BIRCWH and KURe career development programs at Duke; and Cindy Amundsen, MD, KURe Principal Investigator and Program Director, and BIRCWH Program Director.**

those investigating women's health and health disparities, as well as sex/gender elements of health and disease across a woman's lifespan.

Duke is one of only 20 **BIRCWH** program sites and has been funded for 18 years to support the career development of 24 selected BIRCWH Scholars.

"Becoming a BIRCWH or KURe Scholar is a competitive process. The specific requirements differ slightly for each career development program. However, the scholar must have a junior faculty position at Duke (KURe scholars can be postdoctorates or in their last year of fellowship training) and be within a certain number of years from either their postdoctoral research experience or terminal doctoral degree," said Dr. Amundsen, Roy T. Parker Professor of Obstetrics and Gynecology, KURe Principal Investigator and Program Director, and BIRCWH Program Director.

The general concept of any career development award is to provide the selected scholar with time and resources

to establish their research career, Dr. Amundsen noted. Each selected scholar has unique needs and the program is tailored to provide each scholar with a plan to give them the best opportunities. In order for the scholar to secure their own grant funding, they need strong publications and recognition in the field. Once appointed, scholars begin to work toward the transition to independent support (NIH-R01 grants or individual K awards) at the end of three years, as those utilizing under three years of support will remain eligible to compete for individual career development awards (such as the K01, K08 and K23). Alumni scholars have gone on to lead their own multidisciplinary research teams and become mentors and leaders in their fields.

"Much of my success can be attributed to recognizing the importance of developing scientific collaborations with individuals who, because of their training, bring novel ideas on how to investigate better ways to diagnose and treat various conditions," said Dr. Amundsen. "We have had scholars who are early junior faculty or early in their postdoctoral training and others who



have been research scientists for several years. This ability to work together in a multidisciplinary approach advances care for women. We are committed to leading career development programs that provide opportunities and support for the next generation of highly skilled individuals and to provide them with the tools to build a team of scientists who will advance research in women's health."

**Community Partnership**

"I think scientific research is exciting and important and difficult. It takes a community to train and support the people and the projects that will make a difference to human health," stated Dr. Jayes, an Assistant Professor in Ob/Gyn who focuses on the physiology and endocrinology of the female reproductive system. She serves as the program coordinator for both the BIRCIWH and the KURe. She also directs the Duke Clinical Translational Science Institute-funded Community of Scholars program that connects scholars and mentors with resources and with each other.

"One of Duke's three BIRCIWH Scholars is selected from NCCU, and the partnership allows that junior faculty

member to focus on career development and research," Dr. Jayes noted. "NIH is interested in increasing the racial and ethnic diversity in the biomedical workforce. By supporting an NCCU scholar, Duke is contributing to the goal of developing a more diverse workforce that will work on improving women's health. NCCU Scholars receive an adjunct appointment at Duke, which helps ensure that that scholar has access to all Duke resources."

**Diversity Program Consortium – National Research Mentoring Network Funding**

In July 2019, Dr. Jayes received funding as Duke's Principal Investigator for a five-year NIH consortium grant titled "The Science of Mentoring, Networking and Navigating Career Transition Points." The grant was received through the National Research Mentoring Network. The Duke portion of the budget is

\$1,272,542. Dr. Jayes will collaborate with corresponding PI **Susan Girdler, PhD**, of the UNC School of Medicine (Department of Psychiatry).

The U01 mentoring grant is funded by the Diversity Program Consortium, which is a trans-NIH program (funded by NIH's Common Fund and managed by The National Institute of General Medical Sciences). Duke Ob/Gyn is one of only 11 sites nationally to have been selected by the Office of the Director of the NIH to employ a rigorous experimental approach to identifying best mentoring practices for biomedical researchers from racially or ethnically underrepresented groups.

The UNC-Duke proposal investigates peer mentoring for junior faculty at the transition from assistant to associate

*Continued, page 14*



**Duke is one of only 11 sites nationally to have been selected by the office of the Director of the NIH to employ a rigorous experimental approach to identifying best mentoring practices for biomedical researchers from racially or ethnically underrepresented groups.**

**PERSPECTIVES: ALUMNI SCHOLARS**

**Nazema Siddiqui, MD, MHSc**  
*Former KURe Scholar*



*"Since completing my fellowship, I knew that I wanted a research career. Career development awards have given me the opportunity to pursue intentional research training. Personally, as a clinician and surgeon, reducing my clinical time for research training was a difficult transition. However, it was an essential step in moving my career forward. Initially, I was a K12 scholar on the Duke KURe program. The protected time and laboratory*

*training allowed me to successfully compete for a K23 Mentored Patient-Oriented Career Development Award, which amounted to \$575,000 over three years."*

**Chad Grotegut, MD, MHSc, MBA**  
*Former BIRCIWH Scholar*



*"I was lucky enough to secure a spot as a K12 BIRCIWH Scholar. The protected time and mentorship that this training grant provided me were absolutely critical to my success in academic medicine. Without the mentorship and without the protected time that the BIRCIWH afforded, I firmly believe that I would not have been successful. The BIRCIWH led to an NIH K08 award, which eventually led to*

*an R01, with School of Medicine Bridge funding and a patient division director keeping me afloat between."*

**BIRCIWH Scholars (Duke Ob/Gyn) also include Geeta Swamy, MD; Andra James, MD, MPH; and Haley Moss, MD, MBA.**

# DUKE OB/GYN AWARDED \$5.3 MILLION MULTI-YEAR SPAN CONTRACT STUDY OF PREGNANCY AND NEONATAL HEALTH



BY SARAH BRADY

Over the next five years, Duke Ob/Gyn faculty and researchers will work collaboratively to study pregnancy and neonatal health as part of **The Study of Pregnancy And Neonatal health (SPAN)**, funded by The Division of Intramural Population Health Research (DIPHR) of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). The award for the first 18 months is \$995,000, and the total award will be \$5.3 million upon completion of the multi-year contract.

The study aims to explain different factors contributing to newborn health, which lead into childhood growth and development, and lifelong health outcomes. Duke Ob/Gyn faculty from throughout multiple divisions are involved in this initiative, including **Brenna Hughes, MD, MSc** (Division Chief, Maternal-Fetal Medicine); **Anne Steiner, MD, MPH** (Division Chief, Reproductive Endocrinology and Infertility); **Sarah Wheeler, MD**; and **Brita Boyd, MD** (Maternal-Fetal Medicine). Duke faculty member **Kyle Strickland, MD, PhD**, will contribute expertise in placental pathology.

Neonatal health impacts childhood growth and development, and has lifelong implications for cardiometabolic



**This study will allow us to begin to understand the impact that paternal factors have on fetal development, as well as understand the impact of fetal genetic factors, with a focus on African Americans to begin to address racial health disparities in pregnancy outcomes. The infrastructure created with these large cohort studies will also enable us to conduct a trial aimed at determining the optimal timing of delivery for pregnancies affected by gestational diabetes.**

— Brenna Hughes, MD, MSc, Division Chief, Maternal-Fetal Medicine, Duke Ob/Gyn

and mental health outcomes. Research shows there is currently a critical data gap about the determinants of fetal growth and neonatal outcomes, particularly in regard to paternal factors, fetal genetic factors and timing of delivery.

To address these gaps, the SPAN study will examine the following:

- **Paternal cardiovascular health and genetic factors** in association with fetal and neonatal outcomes accounting for maternal factors and pregnancy complications.
- **Fetal genetic and placental epigenetic markers** influencing fetal growth and neonatal outcomes.

- **Optimal timing of delivery** for women with gestational diabetes (GDM) with lowest risk to maternal and neonatal morbidity and mortality.

At Duke, pregnant women and their male partners will be recruited at the Duke Perinatal Clinic in Durham, and clinical practices including Duke Women's Health Associates, Durham Obstetrics & Gynecology, Harris and Smith Obstetrics & Gynecology, the Duke Fertility Center and the Durham County Health Department.

Women must be planning to deliver at either Duke University Hospital or Duke Regional Hospital to participate in the study.

Investigators currently are in the protocol development phase of the contract, and recruitment is scheduled to begin in late fall of 2020. The goal is enrollment of approximately 200 women in the GDM segment of the study, as well as approximately 1,500 women and 750 men in the wider SPAN study.

During the recruitment process, pregnant women will be selected in the first half of their pregnancy and followed through to the end of pregnancy. Once enrolled,

they will complete a baseline visit around the time of their next scheduled prenatal visit or on the same day of enrollment. They will complete an additional visit in the third trimester, provide a biologic sample collection at delivery and complete a questionnaire after delivery. The health of the baby will be assessed in the first several days after delivery, before discharge from the hospital.

“We at Duke are honored to participate in this important series of studies in

collaboration with the NICHD,” said Dr. Hughes. “This study will allow us to begin to understand the impact that paternal factors have on fetal development, as well as understand the impact of fetal genetic factors, with a focus on African Americans to begin to address racial health disparities in pregnancy outcomes. The infrastructure created with these large cohort studies will also enable us to conduct a trial aimed at determining the optimal timing of delivery for pregnancies affected by gestational diabetes.”

## HIGH-RISK OB CLINIC IMPROVES PATIENT ACCESS

BY ALISON ABOUSSLEMAN  
PDC COMMUNICATIONS

Duke Ob/Gyn’s Division of Maternal-Fetal Medicine recently expanded services at its high-risk obstetrics clinic, adding cardiology services. Cardiology was the latest of four sub-specialties that collectively created Duke’s first multi-specialty clinic for treating high-risk pregnancies.

The goal of the groundbreaking model is to improve the quality of care available and convenient access for Duke’s high-risk obstetrical patients – a patient base largely seen by the same specialty providers, all of which traditionally practiced in different physical locations.

“Many high-risk pregnancies have complications that require care from multiple sub-specialists, such as hematologists (for managing blood disorders), endocrinologists (to manage pre-gestational diabetes and complex endocrine disorders), cardiologists (for maternal and/or fetal cardiac disorders) and anesthesiologists (for complex deliveries), among others,” said **Brenna Hughes, MD, MSc**, Division Chief of Maternal-Fetal Medicine. “The traditional model of referring patients out to other specialty clinics can be problematic because it requires additional travel and more cross-clinical communication – both of which can create hurdles for patients and providers. We are delivering the gold-standard in patient-centered care by bringing team-based, multidisciplinary specialists into one clinic.”

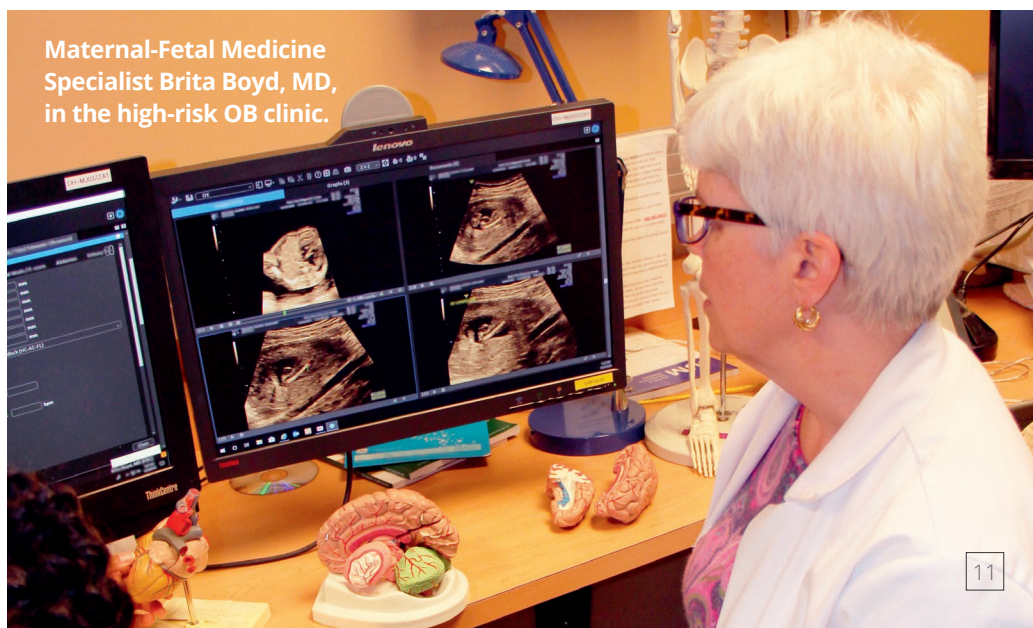
“Our integration of subspecialty care and consultation for the multidisciplinary care of pregnant women allow women with complex medical problems to get conveniently and safely through pregnancy,” added **Andra James, MD, MPH**, maternal-fetal medicine specialist and hematologist.

“We want to meet our patients where they are and provide care that truly addresses their needs,” said **Alice Cooper, OGNP, RNC**, Medical Director for Women’s Ambulatory Services. “The health and well-being of our patients and families within and outside of our community are what really matters most and because of them, we are collaborating, innovating and evolving like never before. Good healthcare is inclusive and thoughtful and that’s what we strive to provide our patients.”



**Andra James, MD, MPH; Alice Cooper, OGNP, RNC; and Brenna Hughes, MD, MSc, of the high-risk OB clinic.**

Read the  
complete  
article



**Maternal-Fetal Medicine Specialist Brita Boyd, MD, in the high-risk OB clinic.**

# IMPROVING PATIENT CARE WITH GLOBAL PARTNERSHIPS

BY MARY BROPHY MARCUS  
DUKE GLOBAL HEALTH INSTITUTE

From rural towns in Africa and the U.S. to urban settings in Southeast Asia and Europe, it's a vibrant time for research in the field of women's global health. But women around the world still grapple with many health issues, including cancer, HIV/AIDS, maternal health and sexually transmitted infections, according to the World Health Organization (WHO).

**Megan Huchko, MD, MPH,**

Director of the Center for Global Reproductive Health at Duke and Associate Professor of Obstetrics &

Gynecology and Global Health, is among global health researchers and clinicians making inroads in recent years in the area of human papillomavirus (HPV).

Dr. Huchko's work includes several large studies in partnership with the Ministries of Health in central Uganda and western Kenya. Her efforts are aimed at evaluating the best ways to implement HPV-based cervical cancer screening in rural settings, especially in areas where women have limited access to reproductive healthcare. The findings could also help address the issue in the U.S.

Cervical cancer is the second most common cancer in women living in less developed areas of the world, according to WHO. In 2018, there were an estimated 570,000 new cases of cervical cancer worldwide, and approximately 311,000 women died from the disease. More than 85 percent of deaths were in women from low- and middle-income countries.

Through her work, Dr. Huchko wants to improve access to HPV vaccination – which includes a two- or three-shot schedule. She also wants to improve access to screening for precancerous lesions and to follow-up treatment for women who need it. For those whose

disease has become invasive cervical cancer, they require diagnosis, treatment and palliative care, too, said Dr. Huchko.

WHO's cervical cancer screening guidelines, developed in 2013, and its 2018 challenge to the global health community to shoot for the elimination of cervical cancer, have helped build momentum.

"There's this growing movement in western Kenya of medical leaders and politicians to get the government to put funding behind the guidelines," she said, explaining that the Kenyan government passes much of the decision-making power related to health initiatives over to local leaders.

"So now what we're seeing – it's called devolution. It is a decentralized model," said Huchko. "Each county has the autonomy to develop and implement their own strategies to address key health issues for their population. Although there are national recommendations, or protocols, for cancer prevention, there is not a standardized implementation strategy. Reaching women as early as possible is the key. One way we've been doing that is we've had increasing movement toward government partnerships."

In Kenya, Dr. Huchko and colleagues conduct community-based HPV screening using a self-collection method so that no pelvic exam is needed. They offer this screening through door-to-door visits or larger community health campaigns. Their efforts have upped screening coverage from 5 percent to 70 percent in certain areas of rural Kenya.

Very recently, in October 2019, the Ministry of Health in Kenya introduced government-sponsored vaccines, becoming the 12th country in East and Southern Africa to integrate the HPV vaccine into its routine immunization schedule. Dr. Huchko and colleagues are working to expand their messaging to include families and girls eligible for these vaccinations.

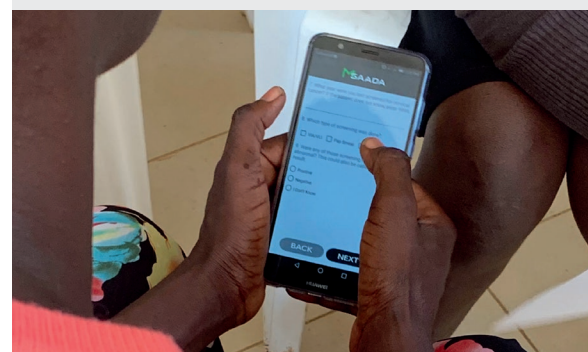


## MSAADA APP OFFERS CERVICAL CANCER EDUCATION TOOL

Despite global efforts, women in underserved areas around the world continue to be caught between effective cervical cancer prevention technologies and environmental realities.

In the summer of 2019, a team of Duke researchers and app developers traveled to Kisumu, Kenya. Led by **Jacob Stocks**, a second-year Master of Science in Global Health student and graduate research assistant at the Duke Center for Global Reproductive Health, the team conducted a pilot usability study of an integrated digital platform called mSaada. The goal of mSaada (meaning "support" in Swahili) is to help facilitate cervical cancer prevention through features such as patient education, results notification, protocol and counseling support and patient trackers, and to encourage more women to come back for follow-up care, according to Stocks.

mSaada will be used by Kisumu community health volunteers (CHVs) during HPV-based cervical cancer screening. By examining data from CHVs, the Duke team hopes to gain a strong understanding of user experience, acceptability and feasibility of the mSaada platform.



**Above:** A study participant works with a partner to practice using the mSaada app. **Top:** Jacob Stocks teaches study participants. Photos by Jacob Stocks.

# RESEARCH LEADS TO NEW PROTOCOL FOR GYNECOLOGIC SURGERY

BY KAREN APPOLD  
DUKE HEALTH  
**CLINICAL PRACTICE TODAY**

New research from Duke has led to a new surgical protocol for women diagnosed with preoperative endometrial intraepithelial neoplasia (EIN). This is a precursor to the most common form of uterine cancer and was previously known as complex hyperplasia with atypia.

“Women with EIN have about a 40 percent chance of having underlying uterine cancer at the time of surgery. We wanted to find out if lymph node assessment was cost effective,” said **Brittany A. Davidson, MD**, a gynecologic cancer specialist and the lead researcher. Their research found that surgeons should still perform a hysterectomy and frozen pathological assessment on these patients, but should defer sentinel lymph node biopsy (SLNB) unless there is a high suspicion for cancer preoperatively. If intraoperative pathologic assessment demonstrates cancer with certain risk features, then a lymph node dissection would be performed.

Dr. Davidson and colleagues conducted the study, published in the December issue of *Gynecologic Oncology*, because the incidence of EIN is rising due to increasing levels of obesity and an aging



population. “With continuous health care reform focused on providing value-based health care, addressing how to manage this growing patient population is a highly relevant area of research,” the study stated.

To perform the study, a decision model was developed from a third-party payer perspective to compare four surgical strategies for managing EIN. The researchers analyzed the base case cost and effectiveness of each strategy. Hysterectomy plus frozen section analysis plus SLNB had an incremental cost-effectiveness ratio of \$168,171 per additional patient who received adjuvant treatment that aligned with their true stage compared to hysterectomy plus frozen section without SLNB, the study reported.

Dr. Davidson advises gynecologists to refer any woman with a diagnosis of EIN to a gynecologic oncologist to discuss her risks for cancer and how to stay healthy. “This could potentially save them from needing a second surgery down the road,” she said.

At Duke, most surgeries for EIN are minimally invasive, even if a patient

has a large uterus or is obese. They are performed with robotic-assisted or laparoscopic approaches, which have better recovery times and decrease risk of postoperative infections and hernias.

Dr. Davidson advises that gynecologic oncology practices considering implementing the new protocol should be aware that it requires intraoperative pathology; however, no costly equipment for sentinel node mapping is necessary.

Looking ahead, Dr. Davidson says more research about prevention, therapeutic options and survivorship are warranted for uterine cancer. “It’s one of the few cancers where incidence and mortality rates are increasing,” she said. “As we clarify which therapies are useful after surgery for uterine cancer and as costs of technologies decrease, performing another cost-effective analysis in the future may be necessary.”

**CITATION:** *Hysterectomy with sentinel lymph node biopsy in the setting of pre-operative diagnosis of endometrial intraepithelial neoplasia: A cost-effectiveness analysis, Gynecologic Oncology, Volume 151, Issue 3, December 2018, Pages 506-512. [bit.ly/2QMS060](https://doi.org/10.1016/j.ygon.2018.10.006)*

## KAY YOW CANCER FUND AWARDS RECORD, DCI \$1 MILLION



Gynecologic oncologist **Angeles Secord, MD, MHSc**, and Duke Cancer Institute have been awarded a \$1 million grant supporting research

for women’s cancers funded by the 2019 Kay Yow Cancer Fund/The V Foundation

for Cancer Research. The grant will support the project “Endometrial Cancer Molecularly Targeted Therapy Consortium.”

The award will be paid in annual installments of \$250,000 over the four-year grant period and was made in honor of NBA All-Star Kevin Durant’s loved one, who lost a battle with cancer.

“We believe that survival for women with endometrial cancer that has spread outside of the uterus will be improved by using abnormal tumor genes and proteins in cancer cells to find treatments that will work better,” Dr. Secord stated. “Our goal is to look more closely at this and determine if new treatments will help women live longer.”



## CAREER DEVELOPMENT

*continued from page 9*

professor, complementing Duke's experience in supporting BIRCWH and KURe scholars at that stage of developing research careers as physician scientists.

"Ultimately, these efforts will help to engage a more diverse field of individuals in biomedical research careers. We are conducting the same randomized controlled study at both sites (Duke and UNC). We are enrolling junior faculty and postdocs from underrepresented racial and ethnic groups who are working toward a career in biomedical research. We will follow the development, self-efficacy and productivity of the participants for the grant period to provide robust data on the contribution of different components of peer mentoring on career success," Jayes noted. "This grant gives me the opportunity to contribute to the science of mentoring."

# CHARLES B. HAMMOND, MD RESEARCH FUND SUPPORTS TRAINEES

Named in honor of former Department Chair and Professor Emeritus **Charles B. Hammond, MD**, the research fund that bears his name was established in 1998 and provides funding to residents, fellows and junior faculty for innovative research in human reproduction, both clinical and basic.

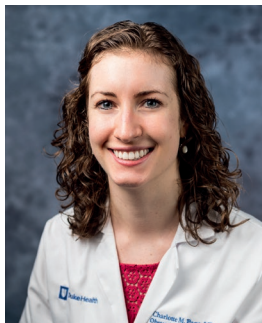
The Charles B. Hammond, MD Research Fund, valued at \$2.6 million, is unique in its commitment to ongoing development of physician-scientists. Through a rigorous and structured review process, the fund provides grants for women's

reproductive health; awards are distributed twice annually.

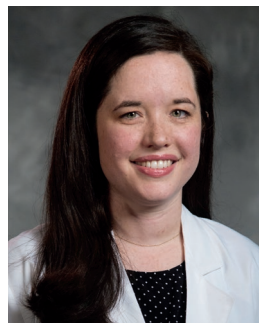
Much of the Department's trainee research presented annually at Charles B. Hammond, MD Research Day is supported by the Hammond Research Fund. Funds are provided for direct research costs for residents, fellows and junior faculty.

At Hammond Research Day, residents and fellows present their research, representing the culmination of months of thoughtful inquiry, hard work and personal and professional growth.

## 2019 Hammond Research Day First Place Winners



**Left: Charlotte Page, MD**  
*First Place Resident Abstract*



**Right: Kelly Acharya, MD**  
*First Place Fellow Abstract*



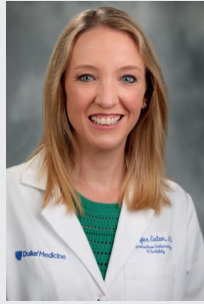
**2019 Hammond Research Day judges, winners and faculty advisers with Department Chair Matthew D. Barber, MD, MHS (far right). Photo by Ken Huth.**

# NEWSWORTHY & NOTEWORTHY

## Highlights in REI



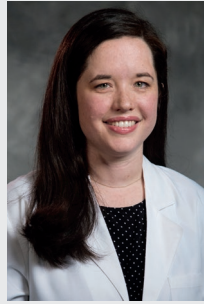
Anne Steiner, MD, MPH



Jennifer Eaton, MD, MSCI



Kathryn Shaia, MD, MHA



Kelly Acharya, MD

### **REI Division Chief Anne Steiner, MD, MPH, Editor of Fertility and Sterility Reviews**

Dr. Steiner serves as inaugural editor-in-chief of the new journal *Fertility and Sterility Reviews*, which publishes systematic reviews in the specialty of REI.

### **Jennifer Eaton, MD, MSCI, Appointed Chair of SART Research Committee**

Dr. Eaton is serving as Vice Chair for the Society for Assisted Reproductive Technology Research Committee through October 2020; she then will serve a 3-year term as Chair. As Chair, she will also be a member of the SART Executive Council. Dr. Eaton is Medical Director of Assisted Reproductive Technology and Director of the Oocyte Donation Program at Duke Fertility Center.

### **Fellow Kathryn Shaia, MD, MHA, Receives Foundation for Embryonic Competence Grant**

Dr. Shaia, REI Fellow, was awarded funding in the amount of \$15,000 by the The Foundation for Embryonic Competence. The title of the research project is "The role of progesterone

in preimplantation human embryo metabolism." Dr. Shaia's faculty mentor is **Thomas Price, MD**. The goal of this study is to assess whether progesterone treatment increases mitochondrial activity with consequential changes in gene expression in cleavage-stage embryos.

### **Alumna Kelly Acharya, MD, Joins REI, Prematurity Prevention Program**

Dr. Acharya, a graduate of Duke Ob/Gyn's Residency and Reproductive Endocrinology and Infertility (REI) Fellowship programs, joined the faculty in the Duke Fertility Center this fall. Dr. Acharya leads the growing Duke onco-fertility and fertility prevention program. She also will be providing the full range of REI clinical services and working with the Prematurity Prevention Program. "We have noticed an increasing number of consults to the Duke Prematurity Prevention Program for recurrent pregnancy loss and preterm birth in the setting of uterine anomalies. Dr. Acharya will bring a fresh perspective and unique skillset," stated **Sarah Wheeler, MD**, Program Director.

### **Geeta Swamy, MD,**

who previously served as Vice Dean and Associate Vice Provost for Scientific Integrity in the Duke University School of Medicine, has been appointed Associate Vice President for Research. She continues to lead the Duke Office of Scientific Integrity, which moved from the School of Medicine to have university-wide responsibility for scientific integrity. Its charge includes advancing scientific integrity, services and training; conflict of interest; misconduct in research; and the Duke Office of Research Initiatives, which encompasses research onboarding and navigation programs, as well as the institutional research incident response team.



Dr. Swamy recently participated in the **Joint Committee on the Research Environment Summit at the White House**, representing Duke University School of Medicine and Duke University in support of working collaboratively to improve the research community. Panel discussions included representatives from the White House Office of Science and Technology Policy, National Institutes of Health, State Department, Association of American Medical Colleges and the National Security Agency/Central Security Service, among others.

### **Alison Weidner, MD, MMCi, REACH Equity Award Recipient**

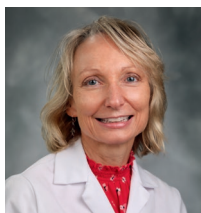
Dr. Weidner received a 2019 Duke Center for Research to Advance HealthCare Equity (REACH Equity) voucher award for her project titled "Improving patient/provider engagement and communication via a mobile app (Prepped)." This health information app helps patients to prepare for provider visits by identifying questions that specifically address their information needs.



## Leadership Roles: Duke School of Medicine

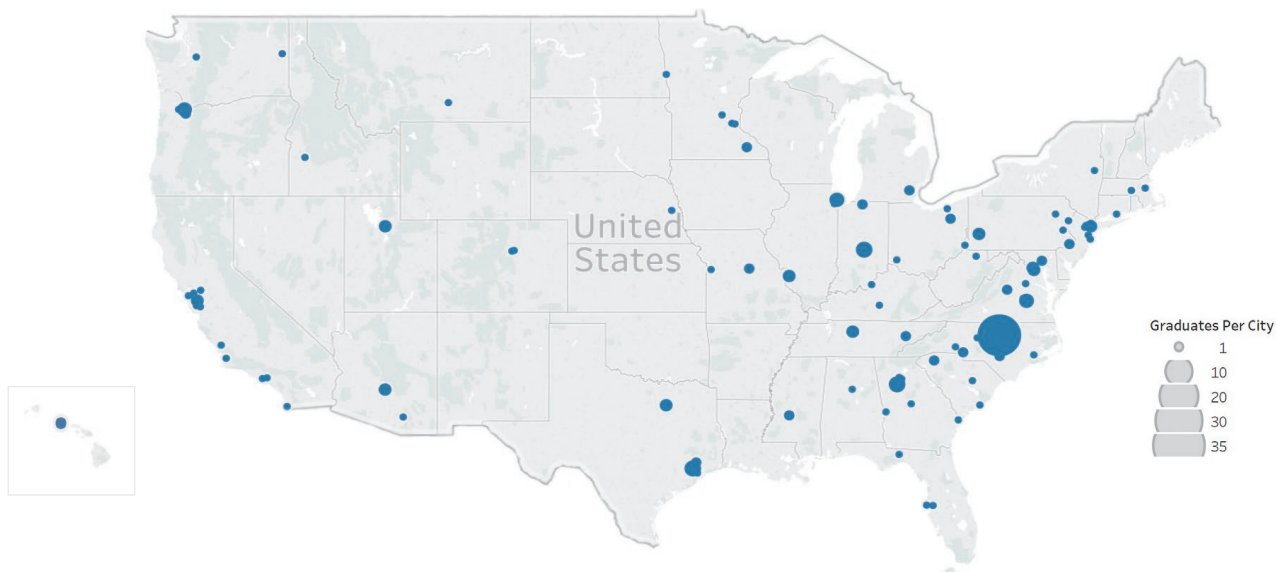
**Cindy Amundsen, MD**, left, has been named Vice Chair of the Clinical Appointments, Promotions and Tenure Committee.

**Elizabeth Livingston, MD**, right, has been elected Vice Chair of the Admissions Committee for the Duke University School of Medicine. Dr. Livingston also serves as President of the North Carolina Obstetrical and Gynecological Society.



Department of Obstetrics and Gynecology  
DUMC 3704 Durham, NC 27710

## Alumni Updates: Where Duke Ob/Gyn's Graduates Are Now



**2000-2019**  
By the Numbers



**197**  
Unique graduates  
(Residents and  
Fellows)



**35**  
States where  
graduates now  
provide care



**5**  
Top states where alumni  
practice outside of NC:  
CA, TX, GA, PA, VA

Alumni: Please take a moment to let Duke Ob/Gyn know where you are now by filling out a brief online survey at [bit.ly/ObGynAlumniSurvey](https://bit.ly/ObGynAlumniSurvey)

**ALUMNI:  
VISIT THE  
CARTER  
SOCIETY  
WEBSITE**

[bit.ly/CarterSocietyWebsite](https://bit.ly/CarterSocietyWebsite)



**SAVE THE  
DATES**

**2020 Carter Society  
Annual Meeting**  
October 15, 2020  
Roanoke, Virginia

**2021 Carter Society  
Annual Meeting**

October 14, 2021  
St. Louis, Missouri

**2022 Carter Society  
Annual Meeting**

October 13, 2022  
Durham, North Carolina



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