Projects Seeking Investigators and Patients

There are multiple clinical research projects seeking investigators and patients.

Physicians affiliated with the KUSM-W Department of Obstetrics and Gynecology can conduct clinical research through the clinician's own private practice, or through Cypress Medical Research Center (CMRC).

CMRC houses research staff with experience managing and facilitating industry-sponsored clinical trials research. CMRC is not affiliated with the KUSM-W, however, multiple physicians in our Department have served as investigators on clinical trials and can attest to their skill.

In the past, our clinicians have recruited and enrolled patients in clinical trials regarding treatment for endometriosis, vulvar/vaginal atrophy, and uterine fibroids.

Physicians have the option of referring patients that meet eligibility requirements, or can seek co-investigator positions on the clinical trials.

If you are interested in any clinical trials conducted through CMRC, please see page 2 (CMRC) of this newsletter, or contact Bryan Baker, RN, MSM, CCRC, for more information.

Contact Information:
Bryan Baker
Phone: (316) 425-6333
Email: bryan@cypressmrc.com

Study Spotlight: ROBIN Trial

Dr. Edgar LeClaire and Dr. Rachel Wykes, PGY-3 are conducting an investigator-initiated, double-blinded, randomized controlled pilot trial.

The study aims to assess the effectiveness of Belladonna and opiate suppositories as an adjunct to standard analgesia for improved Botox (Allergan®) injections into the bladder.

The study is currently enrolling patients. Patients must have elected to receive injection therapy for treatment of overactive bladder (OAB), neurogenic detrusor overactivity (NDO), or refractory interstitial cystitis (IC), and have failed initial medical management.

If you have any questions about this study or have patients that may potentially be eligible, please contact Dr. LeClaire via email at edgar.leclaire@awhobgyn.com or by phone at 316-219-6777.
Dr. Jamie Peregrine Dubaut (2015, graduate) and Dr. Locke Uppendahl, PGY-4 successfully matched to fellowship programs in Oklahoma and Minnesota, respectively. Both also gave oral presentations on their senior research projects at two national meetings this past Fall.

Best wishes as you both start a new chapter in your medical careers!

### CMRC Clinical Research Studies

**Currently Enrolling**

**Endometriosis (Bayer 15832):** To compare the efficacy and safety of BAY 98-7196 (aromatase inhibitor and progestin IVR) versus leuprolelin/leuprolide acetate to placebo in women with symptomatic endometriosis over 12-week period.

**Postpartum Depression (Sage 547-PPD-202):** To determine the efficacy and safety of SAGE-547 infused intravenously for 60 hours in reducing depressive symptoms in subjects with PPD compared to placebo.

**Nausea/vomiting among pregnant adolescents (Duchesnay PED-301):** To compare the efficacy and safety of Diclegis® for the treatment of nausea and vomiting in pregnant adolescents aged 12-17 years versus placebo.

**Adenomyosis (Evidera EVA-16301):** Understand symptoms, impact and disease experience of patients with adenomyosis and those with adenomyosis and endometriosis (patient interviews).

**Potential Upcoming Studies**

**Uterine fibroids (Abbvie M12-815):** 1) To assess the efficacy, safety and tolerability of elagolix 300 mg BID in combination with E2/NETA (estradiol 1.0 mg/norethindrone acetate 0.5 mg QD), versus placebo to reduce heavy menstrual bleeding associated with uterine fibroids in premenopausal women 18 to 51 years of age, and 2) to characterize the impact of E2/NETA on the safety/tolerability [including bone mineral density and other hypoestrogenic side effects] and efficacy of elagolix.

**Endometriosis (Abbvie M14-702):** Evaluate the efficacy and safety of elagolix 200 mg administered BID in combination with add-back therapy, NETA administered QD and elagolox 200 mg BID in combination with standard dose E2/NETA QD versus placebo at 6 months in premenopausal women with moderate to severe endometriosis-associated pain.

**Recurrent bacterial vaginosis (Starpharma SPL7013-017 & 018):** Pending.

**Vulvar/vaginal atrophy (Glenmark GLK-1502):** To evaluate safety and efficacy of generic estradiol vaginal cream to referenced estradiol cream or placebo on Vaginal cytology, vaginal pH, and Most Bothersome Symptom of VVA over 14 days of treatment.

**Vulvar/vaginal atrophy (Novum/Teva 71436001):** Compare safety, efficacy and bioequivalence of generic versus branded estradiol cream at the end of 7 days of treatment.
As we head into 2016, I want to say thank you to our faculty and staff for supporting the scholarly activity goals of the Department. The growth in research, quality improvement, and academic leadership is astounding.

I anticipate that the new year will bring about many changes for our Department, but we are all strong and committed to the excellent reputation we have created for ourselves over the years.

Call for Research/QI Ideas!

Do you have a research project idea? Or are you interested in conducting a quality improvement project?

We have a waiting list of medical students interested in conducting research during their 3rd/4th year and are looking for OBGYN projects. Please email jduong@kumc.edu if you have a potential project you’d like to add to our running list or if you are ready to get started!

Statistics Snippet: Our Friend the P-Value

Our dear friend, the p-value. In research, clinicians often look to the p-value to determine whether or not results are “statistically significant.” What does that even mean anymore?

To KISS (keep it simple stupid), the p-value is a number between 0 and 1, and it is used when comparing the means of two samples. So, a p-value less than 0.05 suggests there is enough evidence to presume a real difference between groups from which the samples were drawn. In other words, the p-value gives researchers a measure of strength of evidence against a null hypothesis.

However, there is no definitive proof, and there is still a chance that there is really no difference. Remember, the p-value is more to assess the chance that an observed difference between samples actually exists, rather than used to determine whether a null hypothesis is true or false.

So when we interpret the p-value, avoid drawing steep “true” or “false” conclusions, and instead, remember that the evidence suggests the results may not be merely a coincidence.

Additional Readings:

P-Value and the Theory of Hypothesis Testing: An Explanation of New Researchers

Special points of interest:

- ABOG MOC Articles are available online to download and print
- Grand Round lectures are regularly updated and available with a podcast style recording
- Visit: https://www.wesleyobgyn.com/home.php

Did You Know...Wesley Ob/Gyn Website

Stay connected with listings of current medical students rotating though our clerkship, meet potential resident applicants completing their sub-internship, check out what is on our Department calendar, and if you missed our Wednesday Grand Rounds, check the website to see if a podcast is available.

Dr. Steve Zielke is our go-to person for managing the site. He is currently adding components to the website that can manage database and registry capabilities for the program in the future.

He actively updates and maintains Grand Rounds lectures, presentations, and posts articles for ABOG’s Maintenance of Certification.

Steve Zielke, MD
Wesley Ob/Gyn Webmaster
Recent Research/QI Accomplishments

Since the beginning of the academic year, KUSM-W Department of Obstetrics and Gynecology residents and faculty and faculty have accomplished the following:

**Publications:**
Sobbing J, Duong J, Dong F, Grainger D. Residents as Medical Student Mentors During an Obstetrics and Gynecology Clerkship. Journal of graduate medical education. 2015;7(3):412-416. PMID: 26457148

**Oral Presentations:**
Dubaut J, Dong F, Tjaden B, Grainger D, Duong J, Tatpati L. Prescribing of Compounded and Commercially Available Menopausal Hormone Therapy by Obstetrician-Gynecologists and Family Medicine Physicians. Oral presentation at the 71st American Society for Reproductive Medicine Annual Meeting; October 17-21, 2015; Baltimore, MD.


**Poster Presentations:**


Jacobson LT, Grainger DA, Duong J, Collins TC, Anderson B. Pioneer Baby: A Quality Improvement Initiative to Improve Pregnancy and Birth Outcomes in Rural Western Kansas. Poster presentation at the 2015 American Congress of Obstetricians and Gynecologists Annual District V, VI, VII, VIII, IX Joint Meeting; September 18-20, 2015; Denver, CO.

Bertschy T, Pham T, Duong J, Hervey A, Berg G, Kuhlmann Z. Patient-Involved Structured Debriefings after Cesareans Improve Labor and Delivery Team Perception of Communication and Safety. Poster presentation at the 27th Annual Institute for Healthcare Improvement National Forum; December 6-9, 2015; Orlando, FL.

Important Dates and Reminders

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<th>Event</th>
<th>Date</th>
<th>Notes</th>
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<tr>
<td>February 1-6, 2016</td>
<td>2016 SMFM Annual Pregnancy Meeting (Atlanta, GA)</td>
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<td>March 2-6, 2016</td>
<td>2016 CREOG &amp; APGO Annual Meeting (New Orleans, LA)</td>
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<td>March 19-22, 2016</td>
<td>2016 SGO Annual Meeting (San Diego, CA)</td>
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<td>April 1, 2016 (Anticipated)</td>
<td>2016 AUGS Scientific Meeting Abstract Submission Deadline</td>
<td>May 1, 2016 (Anticipated) 2016 ASRM Annual Meeting Abstract Submission Deadline</td>
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<td>April 21, 2016</td>
<td>KUSM-W 24th Annual Research Forum</td>
<td>June 10, 2016 Daniel K. Roberts Annual Ob/Gyn Update</td>
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<td>June 11, 2016 Ob/Gyn Residency Graduation</td>
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Have questions or information for the next newsletter? Contact Jennifer at jduong@kumc.edu