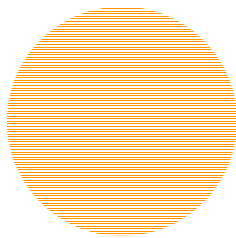


Highlighting Current Topics in Women's Health Research

Special Interest Articles:

- Focus on Black Cohosh & Menopause
- Focus on Dr. Margery Gass
- Focus on study visits



Individual Highlights:

- Spotlight on Physicians 2
- Spotlight on New Staff 2
- Current Study Highlights 3
- From the Managers' Desk 4

RMR Celebrates 15 years

Reproductive Medicine Research (RMR) celebrates its 15th year in 2003. Since its inception in 1988, the center has been and is currently associated with the Department of Obstetrics and Gynecology at the University of Cincinnati, College of Medicine.

Many of the products we have studied over the years are now on the market. These include testing the Nova Sure endometrial ablation system, the development and use of the vaginal contraceptive ring, and the drug Fosamax for the prevention and treatment of osteoporosis.

Michael Thomas, MD has directed the center since 2001. With Jared Robins, MD as Associate Director and Rose Maxwell, Ph.D. as Manager of Clinical Research the center is in good hands.

Dr. Thomas is a leader in the field of infertility with research interests in contraception, infertility, hormone replacement therapies, and the effects of menopause on women of color. He is

the Principal Investigator for the Contraceptive Clinical Trials Network.

Dr. Robins has an active research program that includes a federal grant to study osteoblast gene expression, with research interests in osteoporosis, bone metabolism, menstrual cramps, and development of gynecological surgery devices. He also serves on a local Institutional Review Board.

Drs. Margery Gass and Daniel Williams are also affiliated with the center (see *Spotlight on Our Physicians* for more about Dr. Gass). Dr. Williams has research interests that include: in vitro fertilization, endocrinological disorders, and menopause.

Dr. Maxwell (see *New Manager of Clinical Research* article) and the experienced staff of study coordinators (Pat Johnson, LPN & Theresa Crouch) and nurse practitioners (Debbie Boerschig, RNC & Tiffany Kirsch, RNC) provide quality research and excellent patient care at the center.

New Manager of Clinical Research

Big changes are already happening at Reproductive Medicine Research with the arrival of Dr. Rose Maxwell. Dr. Maxwell joined the center on July 7, 2003 as the new Manager of Clinical Research.

Dr. Maxwell earned her Ph.D. in psychology at the University of Cincinnati. She completed the Social Psychology program in Dec. 1996, with focus areas in organizational development and statistics. Her primary research interests have included family interaction patterns,

gender identity, parenting styles, single parents, and mate selection.

She has spent the last 6 years at a local psychiatry research lab where she served as Statistician and Lab Manager.

Dr. Maxwell brings a wealth of knowledge in key areas including clinical trials, organizational leadership, and process improvement that will greatly benefit the center.

Her goal is to continue the quality research performed at the center by maintaining a customer focus.



*Dr. Gass was the
2002-2003
President of the
North American
Menopause
Society.*



Margery Gass, MD

In the News - Black Cohosh & Menopause

Black Cohosh is receiving some big attention in the treatment of menopausal symptoms. CNNMoney (July 15, 2003 issue) summarizes some of the findings reported in "Menopause: A Journal of the North American Menopause Society."

The journal article provides the most comprehensive review of safety data for black cohosh (*Cimicifuga racemosa*) to date.

This is good news for women who are not interested in or not able to use traditional hormone replacement therapies.

You may remember recent results from the Women's Health Initiative in which long-term HRT use was found to increase women's risk of breast cancer, heart attacks, and stroke and blood clots.

"As menopausal women increasingly

turn to alternatives, scientific evaluation of the safety and efficacy of the products is very important," says Margery Gass, MD, Professor of Clinical Obstetrics and Gynecology at the University of Cincinnati College of Medicine and President of the North American Menopause Society.

The most studied commercially available formulation, RemFemin® Menopause, has been shown to have no effects on hormone levels or the growth of specific cell lines associated with some cancers. Other common herbal remedies, e.g., soy and red clover, do have effects on estrogen levels, although these effects are weak.

The results of clinical trials in humans show a low rate of adverse events with black cohosh. Of the adverse events that were reported, the majority were mild and did not require termination of treatment. (See *Black Cohosh* on page 3)

Spotlight on Our Physicians - Margery Gass, MD

Dr. Gass is Professor of Clinical Obstetrics and Gynecology in the Department of OB/GYN at the University of Cincinnati College of Medicine and Director of the University Hospital Menopause and Osteoporosis Center in Cincinnati, OH. She is a Fellow of the American College of Obstetricians and Gynecologists. Dr. Gass is also a Board of Trustees Member and President (2002-2003) of the North American Menopause Society.

Dr. Gass received her MD from the University of Cincinnati College of Medicine, where she also completed an internship and residency. Dr. Gass joined the faculty at the University of

Cincinnati College of Medicine in 1984. Her research areas include hormone replacement therapy, osteoporosis, and female sexuality. She is the principal investigator on 7 research studies at our center. She is also the principal investigator of the Women's Health Initiative at the University of Cincinnati.

Dr. Gass serves on the editorial boards of *Menopause: The Journal of the North American Menopause Society* and *Menopause Management*. In addition, Dr. Gass has been a reviewer for numerous journals in menopause and OB/GYN.



Black Cohosh *(cont. from page 1)*

The lead author of the journal article, Tieraona Low Dog, MD at the University of New Mexico Department of Family and Community Medicine, notes that these adverse events may be related to the formulation of black cohosh. Dr. Low Dog recommends using a trusted manufacturer and avoiding combination products.

Black Cohosh (RemiFemin) can safely be taken continuously, twice a day, for six months at a time. It is the most studied herbal supplement for menopause symptoms, and is the #1 OB/GYN-

recommended over-the-counter menopausal therapy.

Researchers continue to encourage further research in order to fully understand the use of black cohosh for the treatment of menopausal symptoms.

There are more than 20 clinical trials and open monitoring trials already in progress for RemiFemin Menopause.

Ask your doctor or call our center to see if there is a trial near you.



Call us for more information about any of these active studies.

We love referrals!

Update on Current Studies

Contraception Studies:

- ❖ Diaphragm/Spermicide Study - testing the effectiveness of an investigational spermicide used with a diaphragm.

Menopause-Related Studies:

- ❖ Hot Flash Study - testing the effectiveness of a natural herbal remedy for treating hot flashes.

Treatment Studies:

- ❖ Vaginal Infection Study - testing the safety and effectiveness of an investigational vaginal cream for treating bacterial vaginosis.
- ❖ Vaginal Atrophy Study - testing the effectiveness of an investigational medication for the treatment of vaginal atrophy.



Tiffany joins us on Mondays & Tuesdays at our Holmes Hospital office.

Spotlight on Our Staff - Tiffany Kirsch, CNP

Tiffany joins us part-time on Mondays and Tuesdays at our Holmes Hospital office. Tiffany received her Master of Science degree in Nursing from Creighton University in May 2000. She has worked in a variety of settings including Creighton Family Healthcare, and the Emergency Department of Clarkson Hospital in Omaha.

She joins us to assist our full-time Nurse Practitioner, Debbie Boerschig, CNP. You are likely to see her performing

exams and working on patient files when she is here.

Tiffany spends the rest of her week (Wednesdays and Thursdays) at the Center for Reproductive Health at University Pointe in West Chester, the new UC Physicians location that opened its doors last Fall.

For Tiffany, Fridays are spent with her daughter.



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for Women's Health

We're on the Web!

See us at:

www.ResearchforWomen.com

From the Manager's Desk

I am so excited to be here! As I began settling in, I felt that it was important to create a newsletter as an outlet for information about our center and what we do here.

The projects we are working on are amazing! The products and medications we are testing have so much potential for changing healthcare options for women. Some of these products are likely to become the next over-the-

counter medications for common female health problems. Other products could be the birth control methods of the future.

In upcoming issues, I will be highlighting our current projects, our doctors, and our staff. I will keep you posted about new developments for medications and products we have studied.

My door is always open so please stop in and say "Hi".
Rose

The Educated Consumer of Research

The importance of study visits:

Participating in a research study is one way you can make a difference in the future of healthcare. There are several things to keep in mind when you decide to participate in any research study.

- ❖ Many studies have set visit schedules, making it difficult for us to be completely flexible

when we schedule your visits.

- ❖ It is important to complete all aspects of each visit, including returning your medication and completing your diaries.
- ❖ Research data are less meaningful when you don't complete all study visits.

About Our Organization...

Reproductive Medicine Research is committed to innovative scientific research in women's health.

Under the directorship of Drs. Michael Thomas and Jared Robins, and Dr. Rose

Maxwell as Manager of Clinical Research, the center has a dedicated and experienced staff of nurses, nurse practitioners, and study coordinators.

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