

# RMR News

Highlighting Current Topics in Women's Health Research

*Special Interest Articles:*

- Focus on the Drug Development Process
- Focus on Dr. Jared Robins
- Focus on the IRBs

*In The News...*

## Understanding the Drug Development Process

The drug development process is a long one. There are several steps in the process, some of which take years to complete. Understanding this process can lead to a greater appreciation of the end result.

**1. Pre-clinical stage** - the drug is tested in animals. Many drugs do not make it past this stage.

**2. Investigational New Drug (IND) application** is filed with the FDA. The application includes pre-clinical study results and plans for testing the drug in humans. The FDA decides if it is safe to start testing the drug in humans.

**3. Clinical trials** - after an Institutional Review Board (IRB) approves the study protocol(s), clinical trials in humans begin. There are 4 phases:

**Phase 1** - performed with healthy volunteers to determine safety, side effects, and how the drug is processed in

the body. If the results of these studies are acceptable, Phase 2 studies can begin.

**Phase 2** - performed with volunteers who have a particular disease/condition to determine effectiveness, safety, and short-term side effects. Some volunteers receive the investigational drug, while others may receive a placebo or a standard treatment. If the results of these studies show that the drug is effective, Phase 3 studies can begin.

**Phase 3** - performed with different groups of volunteers (with a particular disease/condition) to determine safety, effectiveness, different dosages, and effects when used with other drugs.

**Phase 4** - performed after FDA approval to determine new uses, effects with different groups of volunteers, long-term effects, and different dosages.

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*Individual Highlights:*

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## Spotlight on Our Physicians - Jared Robins, MD



Jared Robins, MD

Dr. Robins is an Assistant Professor in the Division of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at the University of Cincinnati, College of Medicine. He is a Women's Reproductive Health Research Scholar with the National Institutes of Health (NIH) which includes a federally-funded grant for the study of osteoblast gene expression.

Dr. Robins came to the University of Cincinnati as a Fellow in 1998, and joined the faculty in 2001. His research interests include osteoporosis, bone

metabolism, hormone replacement therapy, infertility, epidemiological issues in obstetrics and gynecology, menstrual cramps, and abnormal uterine bleeding. He has published several articles and a book chapter on these topics.

He maintains a clinical practice with Drs. Thomas and Williams at the Center for Reproductive Health and has been the Principal Investigator on several industry-sponsored and investigator-initiated clinical trials. He also serves as a member of a local Institutional Review Board (IRB).



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4. **New Drug Application (NDA)** to the FDA includes all animal and human study results, information about how the drug is processed in the body, and how the drug is manufactured. The FDA will decide if the application should be formally reviewed.

5. **FDA Review** - involves a review team of medical doctors, chemists, microbiologists, pharmacologists and other experts who evaluate all the study results. They judge whether the drug is safe and effective for its proposed use based on the information

in the NDA. The amount of time required for the FDA review varies. Drugs intended to treat life threatening conditions like HIV, cancer, etc. go through a high priority review process that may take around 3-4 months\*. Drugs intended to treat conditions where there are no current treatments are also given a priority review, taking about 6-8 months\*.

\* these are only estimates and are not based on actual time for FDA review of new drug applications.

## *Update on Studies*

### *Contraception Studies:*

- ❖ Spermicide Study - testing the effectiveness of an investigational spermicide compared to a current over-the-counter spermicide.

### *Reproductive-Age Studies:*

- ❖ Menstrual Cramp Study - testing the effect of topically applied heat on uterine tone.

### *Menopause-Related Studies:*

- ❖ Hot Flash Study - testing the effectiveness of an investigational medication for the treatment of hot flashes.

### *Possible Studies in the Future:*

We are always seeking new studies of cutting-edge research for medications and devices to improve women's health. Some of the more common areas include:

- ❖ Osteoporosis prevention
- ❖ Contraception
- ❖ Menopause-related conditions (hot flashes, etc.)
- ❖ Endometriosis
- ❖ Low Libido

If you are interested in studies in these areas, call us to have your name added to our database. We will be happy to call you when we have a new study.

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

*We love referrals!*

## **Spotlight on Our Staff - Deborah Boerschig, CNP**

Debbie has worked with us for over 4 years as a Study Coordinator. She is a Nurse Practitioner and brings many years of experience in women's health nursing from her experience at Planned Parenthood.

You may have already met her if you have ever come to our center. She spends the

majority of her time working on grant projects such as the current spermicide study. In addition, she performs physical and pelvic exams and/or blood draws as needed for our other studies.

Debbie's commitment to providing excellent healthcare and her dedication to women's health are important to both our volunteers and our center.



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for Women's Health*

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*We're on the Web!*

*See us at:*

*[www.ResearchforWomen.com](http://www.ResearchforWomen.com)*

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## From the Manager's Desk

I have heard in the news that the FDA new drug review process is too slow. Would you have it any other way?

The review process is just that, a review. The job of the FDA is to decide if a new drug is safe enough to be used and whether it is an effective treatment for a particular condition. That's a huge responsibility.

Before the FDA ever receives a new drug application, drug companies must perform

the clinical trials. This is the most time consuming part of new drug development, lasting many years. Sometimes one study could last several years. The clinical trials period can be even longer if study recruitment is slow.

If I could wave a magic wand to speed up new drug development, I would ask more people to think about being volunteers for clinical trials. What an easy way for all of us to help!

*Rose*

## The Educated Consumer of Research

### *What is an IRB?*

IRB stands for Institutional Review Board. It may also be called an Ethics Review Board. The purpose of an IRB is to evaluate a study protocol (a detailed description of the study) according to several ethics codes and regulations (both national and international) to assure protection of subjects (human or animal).

IRB members will approve a study if they

believe the benefits of the study (to the person and to society) are greater than the potential risks involved for participants. A study can begin only if an IRB has approved it.

Throughout the study, the IRB must be notified if serious adverse events (e.g., serious illness, severe side effects, death) occur. An IRB can stop a study if they believe the risks to participants become unacceptable.

### **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.