Dear Friends,

There are still significant knowledge gaps regarding sex- and gender-based differences in health—especially at the research level. Despite the knowledge of sex differences in drug reactions being known for nearly 50 years, many scientists are just now beginning to examine sex as a variable outside reproductive health. It is important to address sex and gender at the earliest part of the research discovery process—as well as at the clinical trial stage—to determine how male/female reactions to various drugs may differ and how diseases can vary in either sex.

This month's e-newsletter provides an overview clinical research and how you can be involved as an active participant engaged in sex-inclusive care.

Sincerely,

The Institute Staff
Clinical research is a branch of healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products, and treatment regimens intended for human use. Clinical research directly involves a particular person or group of people where certain behaviors and interventions might be analyzed. A clinical trial follows a pre-defined protocol, led by a researcher, where participants have the opportunity to play a more active role in their own health care. Often, participants in clinical trials access new treatments and help others by contributing to medical research.

However, not all participants in clinical trials are "sick" or "being treated." Indeed, oftentimes clinical trials require control groups--or groups of average, healthy individuals, to serve as a comparison to a studied population.

**Sex Differences in Clinical Science--Why Should You Participate in Clinical Research?**

Until the 1990's, males were considered the standard model of human biology, and differences in females were 'atypical' or 'anomalous.' It wasn't until 1993, with the passage of the NIH Revitalization Act, that women and minorities were regularly included in clinical research studies. However, this act merely mandated the inclusion of women and minorities in research, and did not mandate studying sex as a research variable--like we do time and temperature, for instance. This means that research done on both males and females, without considering the different reactions between the sexes, surfaces new treatments that are inadequately studied in each sex and applied to both men and women without taking sex-based differences into account.

This research gap came into the spotlight in 2014 when the drug Ambien, a popular sleep drug, was found to have adverse effects in women. Clinical trials testing Ambien did use both men and women subjects, however, the reactions recorded in male and female subjects were compiled and averaged instead of examining the effects by each sex. Therefore, it was found that the drug metabolized more slowly in women's bodies, leaving women impaired the following morning after taking Ambien. In response, the FDA halved the recommended dosage for women taking Ambien, a first in sex-specific drug labeling! Watch the 60 Minutes segment featuring Dr. Melina Kibbe of the Women's Health Research Institute at
Northwestern that shed light on this issue. The unfortunate 'norm' of neglecting the adequate inclusion of women as a variable in research was later discussed on an episode of *The Colbert Report*. Issues surrounding the inclusion of sex as a variable in research studies are gaining traction--and it is time to become active participants in clinical science!

**Clinical Trial FAQ's**

So you think you may be interested in clinical trials--but you still have some questions--we've got you covered! Clinical research can seem complicated if you're not familiar with them, but we're here to help.

**Q: I've heard there are clinical trials and observational studies--are those the same?**

A: Clinical trials and observational studies are the two main types of clinical studies. In clinical trials, participants receive interventions--such as drugs, devices, procedures, or changes in participants' behavior--that the researcher is testing on the subjects. Clinical trials may compare these intervention results to a standard that is already available, to a placebo, or to no intervention. The goal of clinical trials is to determine if a new treatment approach is helpful, harmful, or no different than available alternatives.

Participants in observational studies, in contrast, are not assigned to specific interventions by the research investigator. These participants are observed to see if any over-arching lifestyle trends impact the studied population. For instance, investigators might observe a group of older women to learn about the effects of different lifestyles on cardiac health.

**Q: Who conducts clinical studies?**

A: Clinical studies are led by principal investigators, often medical doctors, as well as a research team that includes doctors, nurses, social workers, and other health care professionals. Clinical studies can be funded by pharmaceutical companies, academic medical centers, voluntary groups, and federal agencies such as the National Institutes of Health (NIH) or the U.S. Department of Defense.
Q: Who can participate in clinical studies?

A: Each study has its own standards outlining who can participate. This is called eligibility criteria, and it is listed in the protocol. Some researchers may seek participants suffering from certain illnesses or conditions, while other studies are seeking healthy participants--this varies depending on the study. The factors that allow someone to participate in a clinical study are called inclusion criteria. These may be based on factors such as age, gender, the type and stage of disease, previous treatment history, and other medical conditions.

Q: If I want to participate in a clinical study, how am I protected?

A: All clinical studies trials involve informed consent, which is a process where researchers provide potential and enrolled participants with information about a clinical study--including possible risks and benefits. This can help you decide whether or not you would like to enroll or continue to participate in the study. In general, a person must sign an informed consent document prior to participating in a study to show that information on risks, penitential benefits, and alternatives were all discussed and understood by the participant. To be clear, informed consent is not the same thing as a contract--participants have the right to withdraw from a study at any time, even if the study is not over.

Furthermore, each federally supported or conducted clinical study that is regulated
by the FDA must be reviewed, approved, and monitored by an institutional review board (IRB). This board is made up of physicians, researchers, and community members to ensure the study is ethical and the rights and welfare of the participants are protected.

Q. How should I prepare for a clinical study?

A. Make sure you are well-informed before entering into a clinical study. It is your researcher's job to make sure you are given adequate information--but you might want to prepare your own questions, too. These are some questions you might ask prior to enrolling in a clinical study:

- What is being studied and why is this intervention being tested?
- What possible interventions might I receive during the trial and how will it be determined which interventions I receive (for example, by chance)?
- How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?
- What will I have to do?
- How often will I have to visit the hospital or clinic?
- How long will the study last?
- What type of long-term follow-up is necessary for this study?

How to Participate in Clinical Trials

Now that you've learned about gender- and sex-differences in research, you may want to take steps to best keep track of your health. Here are some things you can do today:

Join Our Illinois Women's Health Registry to be Matched to Clinical Trials

There has yet to be a significant uptick in female participation in non-sex specific clinical studies (women enrollment remains below half, at 43%) and outcome by sex is not reported in 64% of studies. Our Illinois Women's Health Registry was created to increase female participation in clinical studies. Joining the registry is easy! Just follow this link and fill out your confidential health information. Your information will be added to a database that
researchers can query and draw participants who fit the matching criteria!

As more women participate in research studies, researchers come closer to identifying the sex differences between women and men that affect the prevention, diagnosis, and treatment of disease. If we want to improve knowledge about women’s health for ourselves, our daughters, our granddaughters, and many generations beyond, then we need to assist medical researchers in finding the answers. Join the 7,000 women already enrolled in our Registry and help women and medical professionals in Illinois find out why diseases affect women differently than men! Join Today!

**Encourage the Men in Your Lives to Join the Illinois Men’s Health Registry**

Men are needed just as much as women to best understand health disparities by sex. There are over 150 million men in the United States, and 12% of these men are labeled as having fair or poor health. This past May we launched the Illinois Men's Health Registry to match men to clinical trials. The Illinois Men's Health Registry will aid researchers in preventing disease and improving health conditions in both men and women.

Similar to the Women's Registry, men need only to [click on this link](#) and fill out confidential health information. This will be stored in the Men’s Registry database where researchers can draw names of participants who might be interested in a variety of clinical trials. It only takes a few minutes to input information about your health, yet the impact could last a lifetime. Join Today!

**Stay Informed on Sex Differences in the News**

Our [Women's Health Research Institute Blog](#) is a great resource on sex-differences in conditions, symptoms, and treatment. We provide up-to-date posts of the latest news about women's and men's health, and we also post local clinical trial opportunities for those who may be interested. Please leave comments to our blog posts to further fuel the conversation!

Being in control of your health is an empowering feeling that relatively few of us enjoy. With so many unanswered health disparities in this world, it can be comforting to know how you can do your part in contributing to invaluable medical knowledge. Consider taking an active role in new scientific discovery by seeking out clinical trials today!

**Sources**

Institute Happenings

The Women's Health Research Institute is excited about our launch of Introduction to Reproduction MOOC through Coursera! This is a free, online course covering topics related to reproductive health. Introduction to Reproduction is a crash-course in human reproductive health through fact and biology-based information on a variety of topics. We cover reproductive anatomy, key biological changes during puberty, sexual biology and contraceptive methods, reproductive disorders, and a special introduction to the exciting field of oncofertility. Specific lecture titles are as follows: 1) Reproductive Anatomy & Hormones, 2) Menstrual Cycle, Oocyte Maturation, & Sperm Activation, 3) Sexual Biology, Fertilization, & Contraception, and 4) Reproductive Health & Disorders. Click here to learn more today!

Upcoming Events

October 14, 4:00pm-5:00pm: The Asher Center for the Study and Treatment of Depressive Disorders is presenting How to Get a Seat at the Table: Steps You Can Take to Advance Your Career, presented by Susan M. Essock, PhD, Professor of Psychiatry, Division of Mental Health Services and Policy Research, Department of Psychiatry, Columbia University. This program is geared towards faculty members. Please RSVP to b-
October 20, 12:00pm-1:00pm: The Women's Health Research Institute's monthly research forum featuring Dr. Teresa Woodruff presenting *The Upsetting Truth about Modern Medicine: Why We Need to Balance the Study of Males and Females*. The event will be held in Prentice Women's Hospital, 3rd Fl., Conference Rm. L South. Lunch will be provided. [Click here to register today!](#)

October 30, 11:30am-5:00pm: [Treating Women Differently: The Case for Sex-Based Medicine Symposium](#). This program is designed to facilitate a series of lectures and workshops for clinicians to include sex- and gender-based care in the fields of Cardiology, Dermatology, Gastroenterology, Infectious Disease, Neurology, Pelvic Health, Psychiatry, and Rheumatology. Click here to [learn more](#) and [register](#)!