

# **Magee Womens Research Institute and Foundation**

## **Research Development Report**

### **Reporting Period:**

July 1, 2010 - June 30, 2011

### **Commercial Development of Research**

As the economic challenges linger on, our reproductive biology and women's health scientists at Magee-Womens Research Institute and Foundation (MWRIF) strive to deepen our partnership with the pharmaceutical and biotechnology industry, including the timely licensure and commercial development of research discoveries, funded by the health research formula fund. One recent example is the patent application "Soluble CD117 (SC-Kit) for diagnosis of preeclampsia and eclampsia," developed by two past recipients of the health research formula fund, Dr. James Roberts and Dr. Carl Hubel. Our current research support from industrial sources has been 3.4%, similar to the total research support from industrial sources for US universities, hospitals and research institutions.

The field of infections and their prevention in the female reproductive tract stands out among areas that are suitable for commercial development. Specifically, our Pharmaceuticals Laboratory continues to be actively involved in the development of microbicide products, centering primarily on prevention of HIV and other sexually transmitted diseases. The group works with diverse entities to further develop these products. For example, the group interacts with CONRAD on several drug candidates. Other examples of relevant initiatives include a study with ProteoGenix, Inc, designed to identify bacterial vaginosis infections. Other researchers interact with Endoceutics, Inc., in studying the safety of use of DHEA against vaginal atrophy. Our gynecological oncology group interacts with several companies in the development of new cancer treatment protocols. Examples include studies with Boehringer Ingelheim Pharmaceuticals on advanced ovarian cancer, a chemo-response study with Precision Therapeutics on ovarian, peritoneal or fallopian tube cancer, and alike. Another is a phase 2 study of chemotherapy in subjects with advanced or recurrent endometrial carcinoma (Exelixis, Inc.). Geneticists interact with Celula in research on detection and analysis of fetal cells from maternal circulation. Finally, our strategies to increase commercialization activities and the speed of commercial development to reach national standards include on-going discussions between MWRIF's pelvic floor experts and companies that seek to develop improved mesh products for pelvic floor surgery.

### **Research Licensing Agreements**

Researchers at MWRIF are served by the University of Pittsburgh's Office of Technology Management (OTM) through a sub-contract agreement. The OTM is responsible for the protection, management, and commercialization of intellectual property for the University of Pittsburgh, including all standard licensing agreement forms. MWRIF's investigators are the

primary source of intellectual property, either through the invention of new products or processes, or through unique expertise. The OTM employs intellectual property experts, specialized licensing managers, business development and technology marketing professionals, and outreach teams, and reporting and compliance personnel. Our scientists interact closely with the OTM to ensure compliance and adherence to standard agreements. The OTM provides support, documentation and forms for patent assignment, copyright assignment, confidential disclosure agreement, one-way confidentiality agreement, mutual confidentiality agreement, and materials transfer agreement.

### **Training Students and Health Professionals**

One of the prime missions of MWRIF is the training of the next generation of reproductive sciences and women's health scientists. Indeed, our training programs are some of our crown jewels, and include scholars at all levels of academic development.

For faculty, we now have two NIH-funded K12 programs, which center on early faculty career development in reproductive sciences and women's health. These are Building Interdisciplinary Research Careers in Women's Health (BIRCWH), and Women's Reproductive Health Research (WRHR) Career Development Program. Seven junior faculty members are supported by these rich and intense 2-4 year training programs. Two other faculty members are recipients of national-level training grants from the Reproductive Sciences Development Program (RSDP), and from the American Association of Obstetricians and Gynecologists Foundation.

We continue to fund trainees at other levels who seek to gain knowledge in our field. MWRIF provides research infrastructure and support for postdoctoral scholars, supporting 3-4 trainees to perform basic, translational or clinical research in the field of reproduction, development, and women's health. Each of our trainees is supported by \$50,000/year for up to two years. Graduates of our programs have been generally very successful in advancing their career and in securing NIH funds for their subsequent research. At the graduate levels we have increased the number of positions, and for the first time we have also organized a reproductive biology and development course for students at the University of Pittsburgh. Our Clinical Research-Training Award is designed to assist 3-4 OBGYN residents or clinical fellows in pursuing clinical or translational research. This year, three trainees received \$4000 each to pursue their research.

MWRIF offers two types of summer programs that are supported by stipends from MWRIF and community donors. The first is designed for undergraduate college students, where ten students are mentored in our laboratories for eight weeks. The second summer program provides 10-12 stipends for high school students to undergo four weeks of reproductive biology research training, which includes discussions, seminars, and formal teaching. Finally, this year we participated in a new NIH grant application (R25), designed to enhance science education in high-schools in western Pennsylvania (Dr. L. Jacobson, PI). All MWRIF programs support the recruitment of women, minorities, disadvantaged, or disabled scholars.

## **Commercial Research Development Training**

We continue to educate our trainees in the commercial development and application of research. Training in this area is available for students, residents, clinical and postdoctoral fellows and faculty, and includes formal courses and hands-on training. Formal training in the commercial application of research is available through resources at the University of Pittsburgh, and is highly recommended as a part of the curriculum of our junior faculty. For example, the University's Office of Enterprise Development acts as a resource for health sciences faculty, including MWRIF faculty, pursuing entrepreneurship and interactions with industry. The office acts as a catalyst to stimulate academic-industry collaborations, fosters closer ties to industry, assists in the development of new start-up companies in the Pittsburgh region, and consequently, promotes economic growth in western Pennsylvania. Formal seminar series that focus on commercializing medical discoveries, accelerating the development of post-genomics interventions and entrepreneurship are also available. We encourage our faculty trainees to take courses in these areas in order to enhance their training in this important part of research training.

An important component in training toward commercial research development is the education in the basic concepts, values, and policies related to the conduct of research. Topics available through courses and on-line modules include informed consent, design and justification of randomized trials, research with vulnerable populations, and ethical aspects of research. Training also emphasizes conflict of interest (COI), and discusses financial COIs, the underlying ethical principles associated with COI, and the risks of unmanaged COIs. The program includes important management tools, policies related to researchers, consultants, commercialization of inventions, the requirements to disclose outside interests, COIs related to technology transfer and start-up companies, and sanctions that apply for violations of COI policies. We also provide hands-on training in this area. For example, within MWRIF's Microbicide Trial Network there are a number of trainees who are exposed to the essential components of pharmaceutical product development such as project management, timelines and milestones, regulatory issues, patient acceptability, commercial scale up issues, and partnership with industry.

## **Outreach to Businesses Regarding Recent Research Developments**

In order to outreach to businesses regarding recent research developments we have submitted registration information on several innovations to the Office for Technology Management at the University of Pittsburgh School of Medicine. In addition, investigational new drug (IND) applications are being submitted to the FDA. These are developed with the long-term intention of stimulating the potential for commercialization of these products through partnerships with industry. A critically important venue to stimulate interest in our projects involves science presentations at national academic meetings, which are also attended by industry. Other venues include details of our research on the new MWRIF web site ([www.mwrif.org](http://www.mwrif.org)), which details our developments and research progress to potential business enterprises. We submit faculty interests and research through the Faculty Research Interests Project (FRIP) of the University of Pittsburgh, which is regularly reviewed by businesses.

## **Research Development Collaboration**

The development of new collaborative research projects is essential at times when resources are scant, and groups must work together to sustain productivity at times of diminishing resources. One of our researchers and a recent recipient of the health research formula fund, Dr. James Roberts, is a part of the University of British Columbia (Canada) initiative, funded by the Bill and Melinda Gates Foundation, and designed to test new community level strategies for the monitoring, prevention, and treatment of pre-eclampsia. Dr. Roberts is responsible for integrating data and biological materials from prior or ongoing studies of pre-eclampsia, and establishing data and biomarker acquisition tools common to the entire project.

Other ongoing collaborative research projects include projects by our gynecological oncology researchers, as a part of the Gynecologic Oncology Group. This group includes numerous academic institutions around the country and pursues critical questions related to treatment protocols for women with gynecological cancer. Gynecological oncology specialists also interact with Genentech, Novartis, Bristol-Myers Squibb, Abbott and others in studies related to chemotherapeutic drug protocols in women with ovarian, fallopian tube or peritoneal cancer.

Our researchers in the field of pregnancy are a part of two large academic institutions networks, the Obstetrical-Fetal Pharmacology Research Units Network and the Preterm Birth in Nulliparous Patients Network, which address pivotal questions in care for low- and high-risk women. Urogynecologists and pelvic floor specialists at MWRIF are members of the new NIH Pelvic Floor Disorders Network, which conducts research on the treatment of pelvic floor abnormalities, including urinary incontinence.

Investigators at MWRIF also share collaborations with many researchers at academic institutions nationwide. Lastly, our international Microbicide Trial Network, which is based at MWRIF, includes sites in India, Malawi, Puerto-Rico, South-Africa, Uganda, Zambia, and Zimbabwe. The network assesses the safety, effectiveness, and acceptability of anti-HIV microbicide products.