

Magee Womens Research Institute and Foundation

Research Development Report

Reporting Period:

July 1, 2009 - June 30, 2010

Commercial Development of Research

Despite recent economic challenges, our research at Magee-Womens Research Institute and Foundation (MWRIF) continued to seek ways to partner with the pharmaceutical and biotechnology industry, and find commercial partners or applications for our research in the areas of reproductive biology and women's health. Our current research support from industrial sources has been 5%, similar to the total research support from industrial sources for US universities, hospitals and research institutions (which in recent years has been 7%, based on an annual survey of the Association of University Technology Managers).

Several areas of our academic research are particularly suitable for commercial development, and some of them have been supported directly or indirectly (through collaborations) by the health research formula fund. A significant part of our commercial development of research centers on infections and their prevention in the female reproductive tract. The Pharmaceuticals Laboratory at MWRIF is actively involved in the development of microbicide products. Such development will provide a pharmaceutical product that can be used to prevent the infection of HIV and potentially other sexually transmitted diseases. To this end, the group, which includes members previously supported by the health research formula fund, currently works on a number of drug candidates with potential in HIV prevention. The group works with a number of entities to further develop these products. For example, the group interacts with CONRAD on drug candidates for which CONRAD currently holds the development license. Other examples for relevant initiatives include a study with ProteoGenix, Inc, designed to identify bacterial vaginosis infections. Similar initiatives include testing for certain HPV genotypes from Pap smears, and a study with Bayer that targets the safety and contraceptive efficacy of a contraceptive intrauterine system.

A group at MWRIF that studies preeclampsia (with some of its members currently supported by the health research formula fund) has established a relationship with Abbott to assist in developing and testing predictive biomarkers for preeclampsia. Researchers from this group also work currently with Theranos Corporation to identify markers that could be used in a "Point of Care" assay to predict/diagnose preeclampsia or to follow progression. One example includes the use of uric acid as a practical and useful predictive component of this set. Notably, research on uric acid in preeclampsia was supported in 2007 by the health research formula fund. Research previously supported by the health research formula fund also contributed to the development of an assay of maternal plasma *sc-kit* concentrations, which were found to be reduced early in pregnancy in many women who subsequently develop preeclampsia. Such a blood assay may

also prove useful in distinguishing preeclampsia or eclampsia from gestational hypertension in a pregnant subject.

Lastly, our gynecological oncology group, including members recently supported by the health research formula fund, 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. An important strategy is to work closely with the Gynecologic Oncology Group (GOG) and develop new protocols at the cutting edge of gynecological oncology research.

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. Faculty members of MWRIF are the primary source of intellectual property, either through the invention of new products or processes, or through know-how and expertise in certain fields. To manage the fast-growing commercialization activities, OTM employs intellectual property protection experts, specialized licensing managers, business development and technology marketing professionals, education and outreach teams, and reporting and compliance personnel. Our researchers interact closely with the OTM to ensure compliance and adherence to standard agreements. The Office of Technology Management at the University of Pittsburgh provides support and documentation for the following activities:

- Patent Assignment
- Copyright Assignment
- Confidential Disclosure Agreement
- One-way Confidentiality Agreement
- Mutual Confidentiality Agreement
- Materials Transfer Agreement

Training Students and Health Professionals

Training the next generation of reproductive biology and women's health scientists is a top priority at MWRIF. Therefore, we have established training programs at essentially all levels of academic development. Most importantly, at the faculty level, we now have two NIH-funded programs, which center on early faculty career development in the field of Reproductive Sciences and Womens Health. These are Building Interdisciplinary Research Careers in Women's Health (BIRCWH), and Women's Reproductive Health Research (WRHR) Career Development Program, both K12 NIH grants. These programs provide funds to support a total of seven young faculty who have completed research training and need additional, specialized training as they embark on research careers in the areas of reproductive sciences and medicine. Other junior faculty trainees are supported by grants from the Reproductive Sciences Development Program (RSDP), and the American Association of Obstetricians and Gynecologists Foundation (AAOGF).

Additional training venues include:

- a. MWRIF provides research infrastructure and support for postdoctoral scholars. In this program, MWRIF supports four MD or PhD postdoctoral 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 \$40,000/year for two years. Graduates of our programs have been generally very successful in advancing their career and in securing NIH funds for their subsequent research. One of our recent post-doctoral trainees has recently received a K99/R00 grant. Finally, we are in the process of applying for two NIH T32-funded programs designed to expand opportunities for postdoctoral training.
- b. 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. If medical students wish to delay their clinical training and spend a year learning research in the field of reproductive biology, we provide additional support toward this goal.
- c. 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.
- d. One of our researchers directs an NIH-sponsored (T15) short course in the area of reproductive development in partnership with industry.

All MWRIF programs support the recruitment of women, minorities, disadvantaged and disabled scholars.

Commercial Research Development Training

As a part of our mission we 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. For example, the University's Office of Enterprise Development (OED, within the Office of the Senior Vice Chancellor for Health Sciences) 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, foster closer ties to industry, assists in the development of new life sciences 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 K12 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 faculty/researchers, consultants, commercialization of inventions, the requirements to disclose outside interests to various entities and in various media, 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 the Microbicide Trial Network, which is administered at MWRIF, there are a number of trainees who are exposed not only to pharmaceuticals research but also 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. Other venues include submission of faculty interests and research through the Faculty Research Interests Project (FRIP) of the University of Pittsburgh, which is regularly reviewed by businesses. A critically important venue to stimulate interest in our projects involves science presentations at national academic meetings, which are also attended by industry. This, for example, led recently to great interest in our researchers' work that centers on meshes used for surgery for pelvic floor disorders. Lastly, we are nearing the deployment of our web site, which will include announcement of our developments and research progress to potential business enterprises.

Research Development Collaboration

MWRIF has several ongoing collaborative research projects with various institutions, local independent research companies and commercial enterprises. Our gynecological oncology researchers are a part of the Gynecologic Oncology Group, which includes numerous academic institutions around the country, and pursue 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 three large academic institutions networks, the Obstetrical-Fetal Pharmacology Research Units Network, the Maternal Fetal Medicine 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 Urinary Incontinence Treatment Network, a group of researchers from academic institutions nationwide who conduct research on the treatment of urinary incontinence.

Investigators at MWRIF also share collaborations with researchers at out-of-state academic institutions, such as the University of Washington in Seattle, the University of Texas in San Antonio, the University of Louisville, the University of North Carolina, and Ohio State University, to name a few. Our investigators are also a part of several large national and international research networks and consortia, designed to enhance acquisition of knowledge, share technological resources and improve economies-of-scale. For example, the international Microbicide Trial Network, which is based at MWRIF, includes sites in India, Malawi, Puerto-Rico, South-Africa, Uganda, Zambia, and Zimbabwe. The network focuses mainly on testing the safety, effectiveness, and acceptability of microbicide products that women use to protect themselves against HIV.