

# Women's Health Working Group Report: Analysis of Existing Strengths, Critical Gaps, and Opportunities for Collaboration

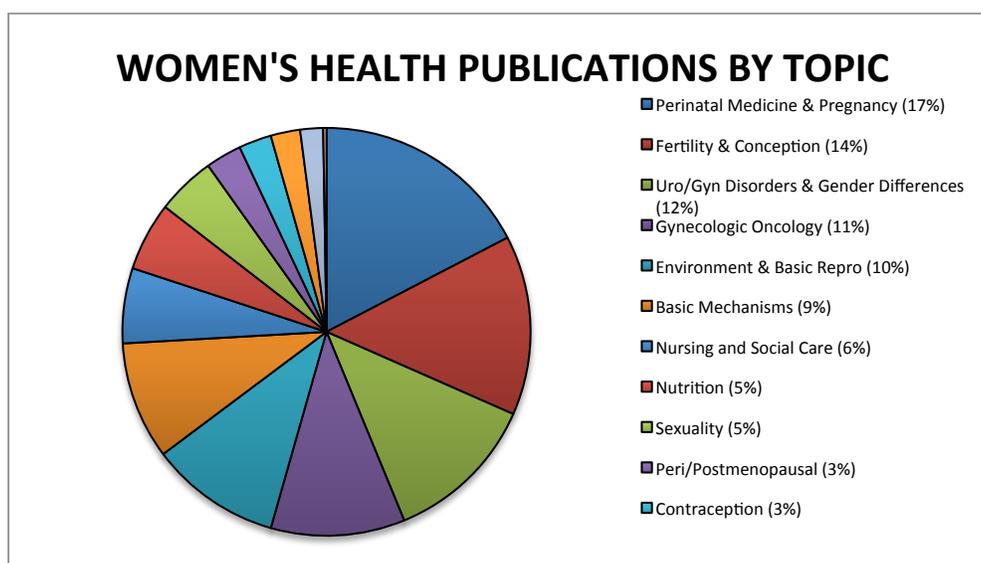
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## **Analysis**

### **Existing strengths**

New Jersey is home to almost 9M people, over half of whom are female. Data confirm that the biological and gender differences of women impact both their overall health and their disease outcomes. The area of perinatal health is a key focus area, since research on women, especially pregnant women, has been limited due to fetal teratogenic concerns. Further, the health of women has significant impact on the wellness of children, family and community. Women are more often disadvantaged in their ability to access medical and dental care for both themselves and their young children, as well as more frequently consume health care due to reproductive pathology, pregnancy, increased vulnerability to HIV/AIDS, poverty, and physical, sexual and emotional violence. New Jersey's preterm birth rate is 11.2%, higher than both New York and Pennsylvania. The New Rutgers is in the unique position to lead both the state and the nation in women's health.

**Women's Health Publications:** A search of PubMed for Women's Health-related publications by Rutgers University (including UMDNJ legacy) from 2009-2014 yielded 386 publications. Papers were categorized into one of 14 topics. Perinatal medicine and pregnancy, fertility and conception were the two primary areas of publication by Rutgers faculty.

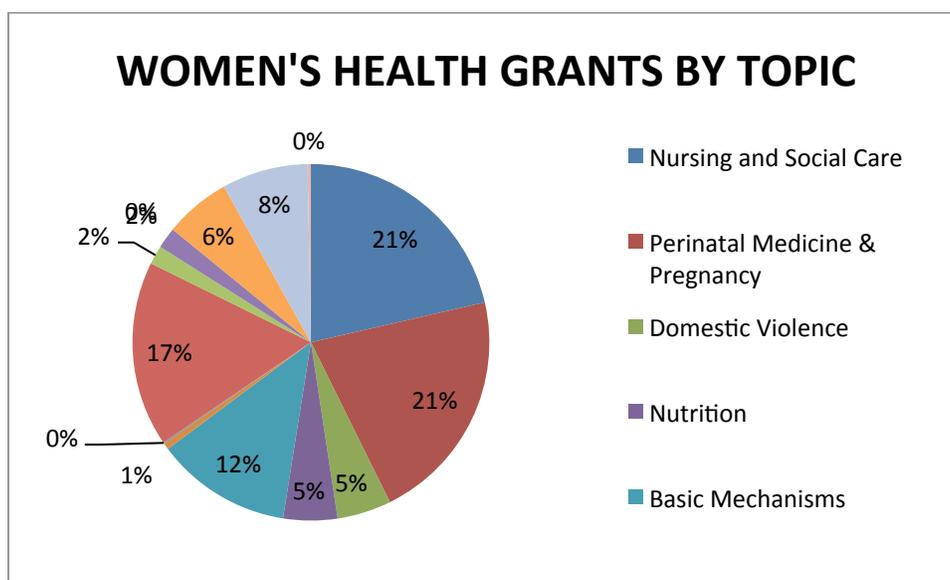


**NIH-Funded Publications.** Filters were applied to differentiate NIH funded work (papers currently undergoing archiving by NCBI would not be captured by this mechanism). Four research areas had publication records that were more than 50% funded by NIH: basic mechanisms of reproduction, nutrition, gynecologic oncology and environmental exposures, [not unexpected, given the strong support by the Cancer Institute of New Jersey (CINJ) and the

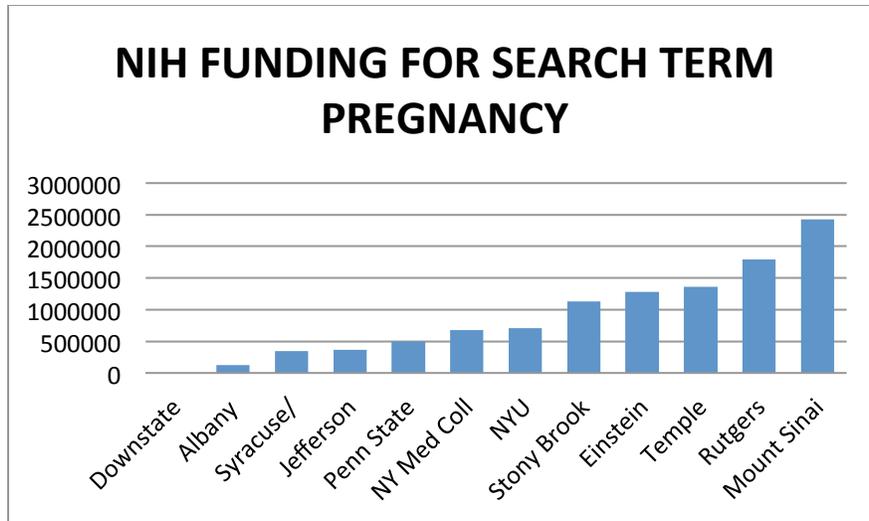
Environmental and Occupational Health Sciences Institute (EOHSI), which both have P30 Center funding from NIH to support activities in Women's Health-related research.

### Women's Health Grants

Grants held by Rutgers [including UMDNJ legacy] faculty were categorized into one of 14 topics; the same as that used for publications. Further, grants with the same title and grant amounts by the same researcher were considered to be renewal of grants and not duplicates. Many of the grants categorized as Nursing and Social Care are programmatic grants which could fall under the rubric of Perinatal Medicine and Pregnancy. Based on total dollar amount of grants, perinatal medicine and pregnancy and Nursing Social Care were the two primary areas of funding by Rutgers researchers. Strong funding records in this area supports selecting perinatal medicine as a signature area for RBHS.



As an analysis for comparator, institutions in our geographic area, the NIH RePORTER was searched for their NIH grant funding for this suggested signature area. Rutgers is near the top of this group. Given the broadness of both our signature topic and our recommended signature area we chose to focus this search on pregnancy as the search term.



**Section I: Perinatal Health as a Signature Area for the New Rutgers**

**A) Strengths:** The New Rutgers has a strong network of faculty, departments, institutes and programs which support this area of women’s health. These include:

**1) Two Maternal Fetal Medicine Divisions (NJMS and RWJMS)**

The Maternal Fetal Medicine divisions are an integral part of obstetrical clinical care, research, translational and clinical research teaching, residency and fellowship training. These divisions oversee two of the states’ Regional Perinatal Centers (one at University Hospital (UH) and one at Robert Wood Johnson University Hospital (RWJUH)). In addition, clinical faculty of the MFM teams, who collaborate with the general obstetrical faculty, work out of/collaborate with several network hospitals that have busy obstetrical services (Jersey Shore Medical Center, Raritan Bay Medical Center, Robert Wood Johnson Hospital at Hamilton, Somerset Medical Center, CentraState and Hackensack University Medical Center). There are 14 MFM faculty and two accredited MFM fellowship programs that train two MFM fellows each year. Additionally, these divisions support the education of 44 Ob/Gyn residents. These divisions have a history of successful collaboration with other departments of their schools, both from a clinical and research perspective. High risk pregnant women are often transferred to these MFM specialists from outside hospitals for subspecialty, tertiary and quaternary care. For example, a clinically important collaborative program involves neurosurgery, neurology and interventional radiology specialists. Pregnant women with arterio-venous malformations (AVM), aneurysm, multiple sclerosis (MS), and stroke are managed through this program.

**2) The Human Genetics Institute of NJ (HGINJ)**

The Human Genetics Institute of New Jersey (HGINJ) has five Core Programs, one of which, the Reproductive Genetics Program, is particularly important to women’s health. HGINJ also includes RUCDR. Researchers at the Human Genetics Institute of New Jersey’s Reproductive Genetics Program use a combination of basic and clinical scientific approaches to understand the genetic basis of reproductive competency. Indeed, the strength of the HGINJ is that it promotes collaborative efforts between basic and clinical scientists interested in reproductive

genetics in different units at Rutgers. In some cases, researchers in the basic science branch of the program identify important genes using the powerful tools of model organisms such as fruit flies, nematodes, and mice. These experiments address fundamental questions concerning gamete production, fertilization and embryonic development that can be applied in a clinical setting to many aspects key to perinatal medicine. In addition, this collaborative approach has the power to identify relevant genes and biomarkers involved in fertility and translate these findings into clinically relevant applications to improve family planning and reproductive options

### **3) RUCDR**

From both the research and possible clinical testing perspective, RUCDR is a significant and unique Rutgers resource. There are no other universities that have these facilities available. RUCDR is the world's largest university-based bio-repository that is perfecting the science of bio-banking, bioprocessing and analytics. RUCDR is CAP-accredited and is capable of doing CLIA certified testing, meaning that it can perform testing that is utilized in clinical settings, in addition to testing in a research setting. Through RUCDR, HGINJ offers a high-throughput genetic analysis facility, with the expertise and resources to coordinate large-scale gene discovery and pharmacogenomics studies from the stages of population identification and sample collection, through high-throughput genotyping and on to comprehensive statistical analyses with novel methods developed at HGINJ.

### **4) Tertiary and Quaternary Care Resources**

RBHS has the subspecialty faculty who can contribute to the care of high risk women in need of tertiary and quaternary care resources, such as those who have undergone heart, liver, kidney and pancreas transplantation. There are strong cardiovascular, hematology, oncology, neurological/neurosurgical, and interventional radiologic services which have the ability to provide care for pregnant women with significant medical conditions.

### **5) The Schools and Institutes of Rutgers**

The School of Public Health, The Cancer Institute of NJ, The Institute for Food, Nutrition and Health, The Pharmacy School, The Child Health Institute, the Dental School and the Cardiovascular Institute are but six integral sources of faculty talent that currently contribute to perinatal medicine. In addition, the child health working group (#13) is focusing on autism as a signature program: the proposed perinatal Institute would enhance this research and contribute to the health care of autistic children from the entry points of pre-implantation, during prenatal care and at the time of delivery onward. The banking of placentas, cord blood, fetal and maternal tissue and blood products would greatly enhance the autism center of excellence. The NJ Department of Health is enthusiastic in collaborating with Rutgers and has an ongoing source of autism funding (~8M/year) through the Governors Council. Another example of joint research is the data being generated from collaboration with the Cardiovascular Institute. By utilizing the NJ MIDAS (myocardial infarction data acquisition system) registry, the group published, "Cardiovascular outcomes after preeclampsia or eclampsia complicated by myocardial infarction or stroke" in Obstetrics and Gynecology. Further, the area of periodontal

health in pregnancy and the newborn could not only be clinically addressed, but also from a research perspective as well.

## **6) Centers of Teaching Excellence and Use of Innovative Teaching Techniques**

The next phase of clinical teaching is the use of virtual clinical worlds with learners as avatars. Rutgers has the software for Wonderbuilders virtual world, which could easily be translated into a force for obstetrical teaching not only in the state, but nationally. There are no other programs geared to the range of obstetrical health care providers. As well, the New Rutgers has the resources of The Center for Teaching Advancement and Assessment Research and the Master Educators' Guild

## **7) Highlight on Placenta Research**

Rutgers University is uniquely qualified to capitalize on the recently launched "Human Placenta Project" by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD/NIH). This strategic research area was announced by NICHD in late 2013 and may be a key funding priority in upcoming years. Rutgers has a strong research team that studies fundamental aspects of placenta development and function including the differentiation of human embryonic stem cells to trophoblasts, drug transport, nutrient disposition, trophoblast invasion, pathology, and regulation of parturition and preterm labor. Recently a Placenta Working Group that includes Rutgers investigators as well as placental biologists was formed.

## **8) Development of the First Bioterrorism Center for Pregnant Women**

New Jersey Medical School is home to the federally funded Center for Biodefense and Bioterrorism. Also, in collaboration with Jersey Shore Medical Center (JSMC), an academic campus of the RWJMS, this area would be an integral part of the Perinatal Institute. There is expertise within Rutgers, with faculty serving on the Department of Defense Bioterrorism Committee for Anthrax since 2002. The Bioterrorism Committee, which has members from the CDC, FDA, and NIH has identified a need for the federal government to develop additional resources for vulnerable populations, such as pregnant women. Pregnant women have different physiologic considerations, varying responses to infections and treatment, and safety restrictions that have not and are not addressed by federal guidelines which seek to treat the majority of the population in times of crisis. With the documented need, the critical mass of specialists in infection and specifically bioterrorism issues at Rutgers/RBHS, and the university's East Coast location, with the Newark campus in close proximity to New York City, Rutgers is in an ideal position to request ~12 million in funding over 5 years for this initiative.

### **Critical Gaps**

**1) Reimbursement:** Reimbursement structure for health care in NJ, especially charity care, is an impediment to caring for a segment of the population served by the faculty. The percentage of patients seen by the faculty that are covered by charity care is high; at NJMS it is 18% charity care and 17% self-pay. Without specialized programs under grant and alternative funding, inadequate services for subsets of the NJ population will continue.

**2) The IRB:** The IRB is a significant impediment to obtaining and maintaining grant funding, especially regarding clinical trials and multicenter awards. For example, the loss of the NIH/NIA funded (and ~13M dollars), Study of Women Across the Nation (SWAN) to legacy UMDNJ was directly due to difficulties with timely approval and an inadequate, inappropriate IRB review process. These types of issues are still ongoing and prevalent, and are a significant impediment to obtaining and maintaining funding. Issues frequently cited by the faculty include: inefficiency of the review process, adversarial interaction by the IRB to investigators, the IRB not having a complete understanding of issues and giving conflicting messages each time the same protocol is reviewed, the IRB shutting down a study for several months without acknowledging that the federal government is paying to conduct the study, the IRB only allowing review of one issue at a time (such that other issues on the same study cannot be presented until previous ones are resolved by the IRB), the IRB meeting only once monthly, the IRB stopping studies that had already been approved because of new reviewers raising a new set of questions, abruptly halting well established Registries, and the IRB not supportive of the research mission.

**3) Contracting:** Timely contracting, specifically in review and approval of contracts, is an issue for investigators. Although this is a challenge more so for industry sponsored clinical trials, it is not limited to them, as recently World Bank funding was lost.

**4) Central repository of research:** There is no central repository of publications and research activities of faculty. The information provided to the working group regarding publications by Rutgers researchers was not comprehensive and the only way to procure such information was to do a literature search for each individual faculty member. Attempting to identify faculty, fellows and graduate students with similar interests is only possible through networking, literature searching, and luck.

**5) Lack of NIH proposal support:** In legacy UMDNJ schools, faculty have had limited resources to assist in NIH grant submission, resulting in lower grant proposal productivity. Some examples of grant support activities not uniformly offered by legacy UMDNJ schools include grant writing staff to assist in proposal writing, proposal review mechanisms, junior faculty grant writing mentoring by identified senior faculty, and financial support for external pre-submission grant review. Individual departments appear to have varying levels or no support for grant writing activities, such as support for analysis of preliminary data, administrative assistance in preparing NIH proposals, training funds, etc.

### **Opportunities for Collaboration**

Rutgers has a unique opportunity to expand and enhance collaborations in the area of perinatal medicine. Currently, there is no mechanism to promote collaborations, particularly translational between basic researchers and clinicians. With the obvious depth of faculty expertise/experience, the large percentage of the NJ population who would be served and the ability to utilize the significant strengths of The New Rutgers, including both medical schools, dental school, nursing school, RUCDR, the HGINJ, The School of Public Health, The Pharmacy School, The NJ Institute for Food, Nutrition and Health (IFNH), The Cancer Institute of NJ and the Public Health Research Institute (PHRI). This Perinatal initiative would build into its structure

the IT capabilities for faculty to network and share data. In addition, there is no unifying entity for perinatal medicine in New Jersey, or in any other state. Rutgers can be the leader.