Project Title: *Putting the SeXXY in Research*: A New Center for Sex and Gender in Health at the Perelman School of Medicine at the University of Pennsylvania

Name and Institution:

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Background, Challenge or Opportunity: Despite the obvious sex or gender differences in the epidemiology and phenomenology of many health conditions affecting human populations, few research studies are designed to address their contribution to the pathophysiology or treatment of these conditions.

Purpose/Objectives: Through the promotion of cross-school, collaborative research with scientific and financial support for considering sex or gender in outcomes of interest, the Penn Center for Sex and Gender in Health will promote inter- and trans-disciplinary research that;

- 1) Meets the National Institutes of Health (NIH) mandates for inclusion with respect to sex and gender;
- 2) Leads to greater opportunities for additional NIH funding;
- 3) Enhances understanding of the role of sex and gender in personalized medicine.

Methods/Approach: Development of the Center has been a two-stage process to date. The first stage has been to establish among key stakeholders an understanding of the relevance of sex and gender in health-related research. The second stage will be to demonstrate the return on investment to support a greater financial commitment to the Center.

• Stage 1 Activities and Accomplishments

- *Meeting with Key Stakeholders:* Through discussions with leaders at the Provost and Dean offices, we have obtained pilot funding to support the Co-Director's (Epperson and Bale) efforts towards Center/Institute development.
- Submitted application for the Building Interdisciplinary Research Careers in Women's Health (BIRCWH): This federal source of funding could provide infrastructure support for the program and salary for 2 junior faculty whose research focuses on sex and gender in health.
- Conduct survey of research protocols for focus on sex or gender: We have initiated a collaboration with the Penn Institutional Review Board (IRB) to conduct a review of 100-200 research protocols approved within the previous year. The goal is to conduct a needs assessment and to develop standards for assessing the impact of our Center on inclusion of sex or gender in research when appropriate.

• Stage 2 Activities and Accomplishments:

- *Obtain ongoing support for the Center*: Working with the Provost Office and Development at Penn to create a source of on-going revenue.
- *Establish an internal Pilot Funding Program*: Pilot grants will enhance the quality of research in sex and gender and lead to greater external funding.

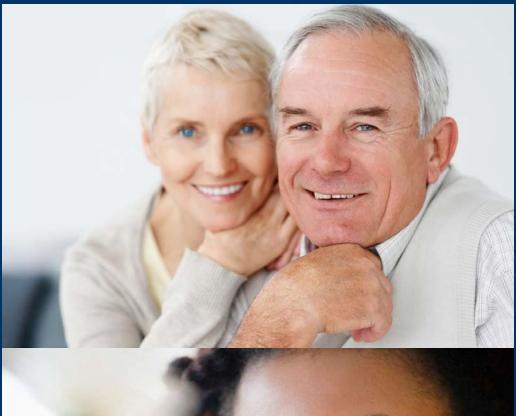
Outcomes and Evaluation Strategy: Outcomes of interest are 1) the number of new research protocols that appropriately include sex or gender as moderators or outcomes, 2) the number of funded grants that result from Center input, 3) the amount of on-going support for the Center from internal and external sources.



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SEX & GENDER ARE KEY TO...







PERSONALIZED MEDICINE

PUTTING THE SEXXY IN RESEARCH: A New Institute for the Study of Sex and Gender in Health at the Perelman School of Medicine

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RATIONALE/OPPORTUNITY

- Despite the obvious sex or gender differences in the epidemiology and phenomenology of many health conditions, few research studies are designed to address their contribution to the pathophysiology or treatment of these conditions.
- Figure 1 highlights a few of the disorders that occur more frequently in male or females, respectively. Sex bias for the disorders listed in the middle are modified by other individual factors such as age, types of sports activities, and/or reproductive function.
- In 1993, the National Institutes of Health (NIH) created a mandate to include women in NIHfunded studies. Although now just over half of clinical research participants are female, studies examining the impact of sex and reproduction on outcomes of interest are lacking.
- **Recent commentary from the Director of the** National Institutes of Health, Dr. Francis S. Collins and the Director of the Office of Research on Women's Health, Dr. Janine A. Clayton emphases the importance of balancing sex in cell and animal studies (Collins & Clayton, Nature 509:282-83, 2015)

PURPOSE/OBJECTIVE

- In two stages, we will establish a university-wide institute to promote inter- and trans-disciplinary research focusing on the role of sex and gender in health. The Institute will...
 - Address the NIH mandate for inclusions with respect to sex and gender;
 - Provide additional opportunities for NIH funding;
 - Improve health outcomes by enhancing understanding of the role of sex and gender in personalized medicine.

FIG. 1) SEX DIFFERENCES IN **COMMON HEALTH CONDITIONS**

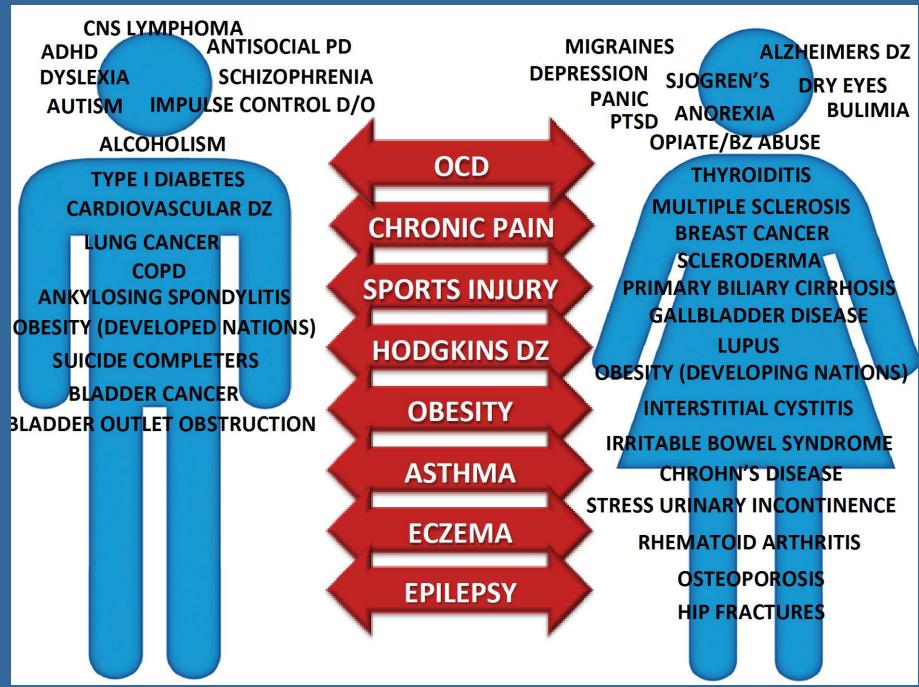


FIG. 2) STAKEHOLDERS AT PENN

INSTITUTE FOR THE STUDY OF SEX AND GENDER IN HEALTH

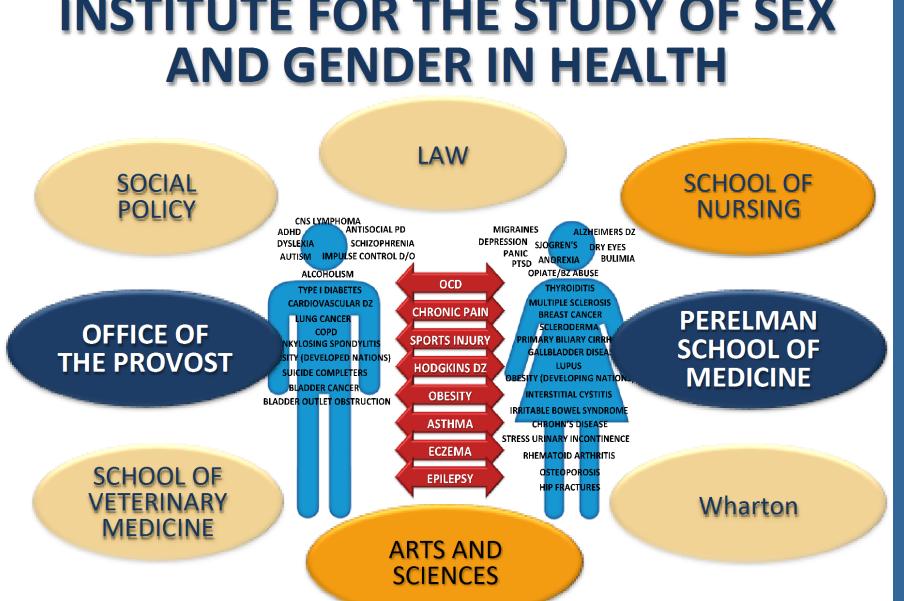


FIG. 2 LEGEND: Schools and Administrations in blue have committed financial support for the Institute through the Excellence Through Diversity Fund. Deans of the schools in bright gold have verbally given their support, but there is no promise of funding as of yet



APPROACH & ACCOMPLISHMENTS



STAGE 1) ESTABLISH RELEVANCE

- **A** Met with key stakeholders: Through discussions with leaders at the Provost and Deans' offices, we have obtained pilot funding to support the Co-Director's (Epperson and Bale) efforts towards Institute development.
- Submitted application for the Building Interdisciplinary Research Careers in Women's Health (BIRCWH): Funding would provide infrastructure support and salary for 2 junior faculty whose research addresses sex and gender in health.
- **Conduct** survey of research protocols for focus on sex or gender: We will conduct a review of 100-200 research protocols approved in 2014-15. The goal is to conduct a needs assessment and to develop standards for assessing the impact of the Institute on inclusion of sex or gender in research when appropriate.
- Align Institute with other university priorities: The Institute's mission & activities are consistent with efforts to enhance diversity and inclusion among faculty, students, trainees and research topics and participants.

STAGE 2) INSURE SUSTAINABILITY

- **♦** Obtain ongoing support for the Institute: Working with Penn Development to create a source of on-going revenue.
- **Setablish an internal Pilot Funding Program: Pilot** grants will enhance the quality of research in sex and gender and lead to greater external funding.

EVALUATION STRATEGY

Outcomes of interest are 1) The number of new research protocols that appropriately include sex or gender as moderators or outcomes, 2) The number of funded grants that result from Institute input, 3) The amount of on-going support for the Institute from internal and external sources