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**Position Statement: Women’s Health Research Institute on Sex Equity in Research and Care—updated October 1, 2014**

The Women’s Health Research Institute at Northwestern University is committed to the full inclusion of both sexes in all levels of medical research: basic science, translational and clinical research. In addition, we promote the transformation of this knowledge into sensitive clinical care for all people. Advocacy related to this issue has been a driving force behind the WHRI since its inception in 2007.

Recently, the Women’s Health Research Institute and its Leadership Council, a multidisciplinary panel of researchers, scientists and clinicians, have published a number of academic articles promoting sex inclusion, provided authoritative information and interviewees for the *CBS 60 Minutes* program broadcasted in February that publicly unleashed this topic, and wrote a letter to Dr. Francis Collins at NIH urging policies be developed that will require sex inclusion in all NIH funded basic research. We are delighted that the NIH announced in a commentary published in May, that it will begin developing policies and guidelines to ensure that preclinical research funded by NIH considers males and females (Clayton JA. *Nature.* May 2015).

The WHRI, in their letter to Director Collins, addressed the following:

* XX-XY knowledge gap which remains in basic, preclinical and clinical research, must be eliminated.
* Outcomes by sex are not reported in 64% of clinical studies, and sex-specific analysis remains low.
* Only 14% of medical device studies include sex as an outcome measure and only 4% included a subgroup analysis for female participation
* Majority of scientific publications using rodents do not report the sex of the study animals and even when they do, the findings are not reported by sex.
* Increased knowledge about sex variability early in the drug and device development must become the norm in order to:
* Reduce cost in later testing phases
* Reduce adverse drug effects that occur more often in women in the marketplace
* Improve the efficacy of drugs based on a "personalized approach" to medical care
* NIH should require researchers to include sex as a study variable.
* Include the sex of study subjects—cell, animal and human—or give justification if they are not included.
* Report the outcomes in publications by sex
* Include any sex differences or lack of differences in study reports.

Since the May announcement, a number of actions have occurred toward sex equity in the scientific pipeline.

* The FDA released its  *Action Plan to Enhance the Collection and Availability of Subgroup Data,* on August 18, that includes 27 action steps that address the quality of data collection, reporting and analysis; barriers to subgroup inclusion in clinical trials; and availability and transparency of sub group data in new drug/device applications. These are non-binding recommendations.
* The NIH announced its recent investment of $10.1 million in supplemental funding to support researchers who study the effects of sex in pre-clinical and clinical studies.
* *A Request for Information: Consideration of sex as a Biological Variable in Biomedical Research* was released by the NIH seeking input from the research community and interested stakeholder on sex inclusion.
* The NIH has formed a trans-NIH working group to inform the development of sex based policies.

In addition to these federal announcements, a number of articles, blogs, and social media conversations have been published on sex inclusion –both pro and con—keeping the dialogue current. A WHRI Leadership Council member has published an article (Yoon et al. *Surgery.* Sept 2014*)* that found that 600 projects (out of 2,347 studies) used animal or cells in their study and 22% did not state the sex studied. Of those that included sex, 80% only used males, 17 % used females and 3% used both. Similar results were found in cell research. As a result of these findings, editors of the five surgical journals reviewed for this article will now require authors to state the sex of the animals/cells they used and if they do not use both, explain why.

The Leadership Council of the WHRI continues to advocate the following steps toward sex equity in research:

* Require researchers to report sex of subjects and outcomes by sex
* Train researchers on experimental design that includes sex variables
* Educate proposal reviewers on sex inclusion design elements
* Monitor inclusion policy compliance better
* Encourage institutional research center cores to identify services that focus on sex variables
* Develop FAQs for stakeholders on sex inclusion
* Educate journal editors on the importance of sex based reporting
* Add sex variables to medical school curriculum
* Encourage professional societies to develop and disperse sex based clinical guidelines
* Increase awareness on the importance of sex in medical research to all.