

PEOPLE



St. Jude Children's Research Hospital

James R. Downing, MD, was appointed CEO of St. Jude Children's Research Hospital in Memphis, TN, effective July 15. He succeeds William E. Evans, PharmD,

who is retiring from the position after 10 years to pursue pharmacogenomics research full time.

Downing joined St. Jude in 1984 and became its scientific director and executive vice president in 2004 and deputy director in 2011. Richard J. Gilbertson, MD, PhD, who directs the institution's cancer center, has now assumed the role of scientific director as well.

A world leader in pediatric cancer research, Downing studies the genetic basis of cancer and has overseen the Pediatric Cancer Genome Project, which produced groundbreaking discoveries for four types of brain tumors, four subtypes of childhood leukemia, and other cancers.



E. Center-Smith

James P. Allison, PhD

The first Tang Prize for Biopharmaceutical Science has been awarded to **James P. Allison, PhD**, chairman of immunology at The University of Texas MD Anderson Cancer Center, and

Tasuku Honjo, MD, PhD, professor of immunology and genomic medicine at Kyoto University in Kyoto, Japan, for their research leading to cancer immunotherapy. Established in

2012, the biennial prize provides a cash award of about \$1.3 million and a research grant of about \$350,000.

Allison was one of two scientists who identified CTLA-4 as an inhibitory receptor on T cells, and he developed an antibody to block it. An FDA-approved drug based on his antibody (ipilimumab; Yervoy) is now used to treat melanoma. Honjo discovered PD-1, another immune checkpoint receptor on T cells. PD-1 inhibitors are under development for the treatment of cancer.



E. Center-Smith

Tasuku Honjo, MD, PhD

NIH to Require Both Sexes in Preclinical Studies

The NIH announced a new policy in May that will require federally funded scientists to include both males and females in cell and animal studies. The requirement will affect some of the more than 300,000 researchers awarded competitive grants each year by the NIH, which invests about \$30 billion annually in medical research.

In a commentary published in *Nature* explaining the policy, Francis Collins, MD, PhD, director of the NIH, and Janine Clayton, MD, director of the agency's Office of Research on Women's Health, advise scientists to include more female lab animals and cells in their experiments. "The over-reliance on male animals and cells in preclinical research obscures key sex differences that could guide clinical studies. And it might be harmful: women experience higher rates of adverse drug reactions than men do," they write (*Nature* 2014;509:282-3).

One reason cited for the avoidance of female animals is an unwarranted concern that reproductive cycles and hormone changes would confound study results. Another reason is decades of laboratory conventions that have relied on male-only models.

Cancer researchers may be conducting gender-biased preclinical studies, but not in the way suggested by the NIH commentary, says Norman Sharpless, MD, director of the University of North Carolina (UNC) Lineberger Comprehensive Cancer Center in Chapel Hill and co-lead of UNC's Mouse Phase 1 unit.

"I do not believe they considered studies in oncology, where we use female mice considerably more often than male rodents. So it's a valid point both ways—to use only males or only females is not representative," he says.

In Sharpless's lab, where mice are used to study cancer and aging, female mice considerably outnumber male mice. The reason is cost: Male mice are more likely to fight, so it's cheaper to use female mice that can be housed long-term at greater density, Sharpless says.

The NIH will roll out the new policy in phases beginning in October 2014.

Researchers seeking NIH grants must report their plans for including and comparing male and female animals or cells unless their research qualifies for an exception, such as research on reproductive organs. Reviewers will consider those plans when awarding grants, and the NIH will monitor whether grantees comply with such plans.

The agency also says it will work closely with publishers of scientific journals to encourage reporting of sex and gender analyses from NIH-funded research.

To help offset the added expense of studying both sexes, Sharpless predicts cancer researchers may use smaller cohorts of male and female animals. "If males and females can be pooled in the analysis—and often they can be—then the statistical power will not be decreased," he says.

Smaller sample sizes would however make studies less powerful if males and females are affected differently, Sharpless adds. "If sexes can't be pooled, we should be studying females and males independently, which is exactly the point of the policy."

Sharpless says his main concern is an overly heavy-handed enforcement of the new policy. "I'm worried someone will have a proposal that has brilliant science, but they won't get funded because they forgot to include a paragraph in their grant about inclusion of males and females," he notes. "Having said that, this is still a good idea." ■

MSKCC Launches Center for Molecular Oncology

Memorial Sloan Kettering Cancer Center (MSKCC) in New York, NY, launched in May the Center for Molecular Oncology (CMO), a program its leaders say will deliver personalized treatment options to more cancer patients.

Established with a \$100 million gift from Marie-Josée and Henry R. Kravis, the CMO expands the ability to perform genetic profiling in the clinic beyond cancers such as lung and colon for which profiling is standard of care, says CMO director David Solit, MD. "The center will allow us to offer genetic testing for cancers such as bladder, prostate, ovarian, endometrial,

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Cancer Discovery 2014;4:860.

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