For Immediate Release
Friday, September 16, 2011

Contact:
NIH Communications
301-496-5787

NIH, DARPA and FDA collaborate to develop cutting-edge technologies to predict drug safety

President Obama announced today that the National Institutes of Health will collaborate with the Defense Advanced Research Projects Agency (DARPA), and the U.S. Food and Drug Administration to develop a chip to screen for safe and effective drugs far more swiftly and efficiently than current methods, and before they are tested in humans. The chip will be loaded with specific cell types that reflect human biology. It will be designed to allow multiple different readouts that can indicate whether a particular compound is likely to be safe or toxic for humans. DARPA and NIH will run separate and independent programs, but they will work closely to ensure maximum benefit and efficiencies. For example, DARPA and NIH will facilitate collaborations between researchers and FDA to advance the goals of both programs. This fall, the two agencies, in coordination with FDA, will solicit proposals from industry, government labs, academic institutions, and other research organizations on how best to develop the chip, bringing together the latest advances in engineering, biology, and toxicology to bear on this complex problem.

"Drug toxicity is one of the most common reasons why promising compounds fail," Francis S. Collins, M.D., Ph.D., NIH director said. "We need to know which ones are safe and effective much earlier on in the process. This is an unprecedented opportunity to speed development of effective therapies, while saving time and money."

Over the next five years, the NIH plans to commit up to $70 million and DARPA will commit a comparable amount to this effort. This groundbreaking effort is an example of the types of innovative projects that would be led by the proposed National Center for Advancing Translational Sciences (NCATS). NCATS would help identify barriers to progress and provide science-based solutions to reduce costs and the time required to develop new

drugs and diagnostics. FDA will help determine how this new technology can be utilized to assess drug safety, prior to approval for first-in-human studies.

"We know the development pipeline has bottlenecks in it, and everyone would benefit from fixing them,"Collins said. "What we need are entirely novel approaches to translational science, to take full advantage of the deluge of new biomedical discoveries that have been made in recent years."

As proposed, NCATS will study the steps in the process of diagnostics and therapeutics development, identify the bottlenecks, and experiment with innovative methods to streamline the process. By focusing on developing innovative new tools and methods for therapeutics development, as opposed to developing therapeutics themselves, NCATS will enable others to bring safer and more effective medical products to market in less time. In this way, NCATS will complement, and not compete with, the work of the private sector and other NIH translational science efforts.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.