

**MEMORANDUM OF UNDERSTANDING**

**Between**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**And**

**DEPARTMENT OF COMMERCE  
Technology Administration  
National Institute of Standards and Technology**

The National Institute of Standards and Technology (NIST) within the Technology Administration of the Department of Commerce and Department of Health and Human Services (HHS) agree that it is in the best interests of both parties and the American people to develop a strategic partnership that leverages each Department's core expertise and resources to facilitate science and technology innovation to improve human health and the U.S. economy.

**GOAL: To Promote the Development and Delivery of Medical Technology Innovation**

**PURPOSE**

The purpose of this Memorandum of Understanding is to establish a framework for cooperation between the Department of Health and Human Services (HHS) and the Department of Commerce's (DoC) National Institute of Standards and Technology (NIST) in support of medical technology innovation. The cooperating Departments are encouraged to work closely to expedite the development and availability of groundbreaking technologies for the diagnosis and treatment of disease.

To advance this vision, HHS and DoC intend to build and support new collaborations between (A) the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ), and (B) the National Institute of Standards and Technology (NIST). HHS and DoC also intend to utilize and strengthen relevant existing programs, enhance coordination of existing Federally-supported programs, and determine the need for new initiatives that serve to speed the development and delivery of medical technologies to market.

## BACKGROUND

*Innovation fosters the new ideas, technologies, and processes that lead to better jobs, higher wages and a higher standard of living.* For advanced industrial nations no longer able to compete on cost, the capacity to innovate is the most critical element in sustaining competitiveness. The effective development and efficient delivery of new medical technologies are fundamental underpinnings of our national ability to provide high quality healthcare. Pioneering advancements in such areas as drugs, biological products, and medical devices are critical components of medicine's advancing capacity to push back the borders of disease and disability. At present, a substantial opportunity exists to harmonize the contributions of key Federal programs in promoting the development of such technologies and facilitating their delivery in a well-optimized way.

The Council on Competitiveness has identified the cooperation and collaboration within the federal government as one key metric to maintaining the United States as an engine of innovation. In this spirit, these signing Departments will partner and leverage strengths and resources to bring pioneering medical technologies to the American people.

HHS is the United States government's principal agency for *protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.* HHS fills fundamental roles in the scientific research, regulation, and reimbursement of new medical technologies through the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality.

As an agency of the Technology Administration in the Department of Commerce, NIST is charged with *developing and promoting measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life.* The mission is carried out intramurally through scientific research in seven major laboratories, as well as extramurally, through research grants, both in close collaboration with U.S. industry.

The complementary and synergistic roles of NIST and the HHS motivate the increased cooperation planned by this MOU. It is believed that the interface of the physical and life sciences will spawn the most revolutionary technological developments. The new relationship established herein bridges a biological/medical Department with one steeped in the physical science and engineering tradition of quantitative measurement.

HHS, the lead Department for medical and biological science and technology, provides the research into disease cause, formulation and progression. NIST, the lead agency for measurement science infrastructure, provides new tools, standards and data for validation and implementation of technology. This Memorandum of Understanding provides a framework to combine the complementary roles of HHS and NIST for an array of inter-Departmental collaborations to facilitate development and delivery of innovative medical technologies. While no funds are transferred by this document, it is expected that more

detailed collaborations and associated interagency agreements will be developed between HHS agencies and NIST as a result of this Memorandum.

## **AUTHORITY**

This MOU is authorized under Section 3 of the National Institute of Standards and Technology Act (15 U.S.C. 271 et. seq.) which provides for cooperation between NIST and other Federal agencies and by Section 301 of the Public Health Service Act which authorizes agencies in the Public Health Service to cooperate with public authorities and scientific institutions, and Sections 1142, 1862(a)(1)(E) and 1868 of the Social Security Act.

## **AGREEMENT**

The Department of Health and Human Services and the Department of Commerce agree to collaboratively undertake specific programs to facilitate the development and delivery of new innovative medical technologies. These collaborations will be identified from discussions that occur as a result of this Memorandum and specific initiatives between NIST and the individual agencies of HHS will be established in subsequent interagency agreements, as needed. These initiatives are expected to include but are not limited to:

### **A. STRATEGIC, POLICY, AND PROGRAM COORDINATION**

- Working to coordinate the design and development of new initiatives to promote the development and delivery of innovative medical technologies.
- Participating in an interdepartmental forum on innovative medical technology, as a regular venue for dialogue; information exchange; and harmonization of policy, program planning, and strategic decision-making
- Arranging staff exchanges for the pursuit of collaborative efforts.

### **B. STREAMLINING THE PATHWAY FROM DISCOVERY TO DELIVERY**

- Identifying ways to overleap hurdles in the existing processes
- Establishing mechanisms to improve efficiency of research, regulatory, reimbursement activities and deliverables

### **C. EDUCATIONAL AND INFORMATIONAL INITIATIVES**

- Providing joint support for workshops, conferences, and other venues on topics of high relevance to medical technology innovation
- Participating in new technology- or disease-focused forums
- Co-training the next generation of interdisciplinary scientists

**D. RESEARCH INITIATIVES**

- Sharing of research priorities, and jointly supporting research of common interest
- Coordinating strategic plans for support for key research topics

**PERIOD OF AGREEMENT**

This agreement becomes effective upon acceptance by both parties, and will continue in effect indefinitely. It may be modified by mutual written consent or terminated by any (either) party upon a 30-day advance written notice to the other party.

**FUNDING**

Activities undertaken pursuant to this MOU shall be subject to the availability of funds. Each Party to this MOU is responsible for its own costs, unless otherwise provided for in a separate written agreement.

**APPROVAL/SIGNATURES**

Tommy Thompson  
Secretary  
U.S. Department of Health and Human Services

Theodore W. Kassinger  
Deputy Secretary of Commerce  
U.S. Department of Commerce