Shaping the Future of Research

A Strategic Plan for the National Heart, Lung, and Blood Institute

Welcome from the Director

I am delighted to present the Strategic Plan of the National Heart, Lung, and Blood Institute. This plan reflects the intellectual energy of over 600 individuals representing an international spectrum of expertise in areas of relevance to the Institute's mission. We are proud of the important role that the Institute has played historically in shaping the prevention and treatment of heart, lung, and blood diseases worldwide. We look forward with great enthusiasm to building upon this tradition and broadening our impact in the years to come. We invite you to join us in this grand adventure.

With best wishes,

Elizabeth G. Nabel, M.D.

Director

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The National Heart, Lung, and Blood Institute (NHLBI) has a distinguished record of supporting and guiding seminal advances in heart, lung, and blood research that have yielded unprecedented improvements in the Nation's health. Building on the Institute's numerous accomplishments, we now have an opportunity to develop a heart, lung, and blood research agenda for the United States that will lead to even greater successes. This is our challenge—and our obligation, as stewards of Federal research dollars.

Heart, lung, and blood research can be expected to change dramatically over the next several decades in response to the major drivers of research activity: information technologies that link scientists and their findings globally and instantaneously; accelerating health care costs; an aging population of baby boomers who can expect to live longer, more productive lives, even in the face of chronic diseases; and the development of increasingly sophisticated research tools and databases.

This strategic plan is intended to provide the NHLBI with a guide for its research and training programs over the next 5 to 10 years. It is not intended to provide a detailed implementation plan to address the challenges it identifies—that will be developed by the Institute over the life of the strategic plan in consultation with the National Heart, Lung, and Blood Advisory Council (NHLBAC) and with representatives from the research community and the public—and it is not intended to address matters that are beyond the scope of the Institute's mandate. We expect that implementation of the plan will require the Institute to continue to develop and explore effective ways to collaborate with other agencies of the Federal government; with other governmental agencies, both domestic and foreign; and with nongovernmental organizations, both public and private. Our success in implementing the plan will be evaluated on an ongoing basis by the Institute with advice and guidance provided by the NHLBAC.

This strategic plan reflects the wisdom, advice, and judgment of more than 600 individuals who participated in its preparation, all of whom are identified in the Appendix. We are indebted to them and to the scientific communities they represent for their commitment to the excellence and productivity of the Institute. Their further participation in the strategic plan will ensure its successful implementation and its continued evolution in response to new challenges and discoveries. We are also indebted to the many individuals and organizations that contributed their insights to the plan during the time that it was open for public comment.

I. Executive Summary

The National Heart, Lung, and Blood Institute provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and to enhance the health of all individuals so that they can live longer and more fulfilling lives. The breadth of the Institute's programs reflects the breadth of its mandate, which includes three of the four leading causes of death in the United States. To achieve its vision, the NHLBI stimulates basic discoveries about the causes of disease, speeds the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public.

This strategic plan is intended to provide the NHLBI with a guide for its research and training programs over the next 5 to 10 years. Investigator-initiated research has long constituted the largest share of the NHLBI research portfolio, and it is our intention to maintain that historical commitment. In fact, we expect that much of the plan will be realized through our investment in investigator-initiated research. Institute investments guided by this plan will be directed largely toward programs that either will enable or complement investigator-initiated activities.

The plan consists of a set of goals that reflects the successive movement of scientific discovery from "form to function" (Goal 1), "function to causes" (Goal 2), and "causes to cures" (Goal 3), with research challenges identified for each of the goals and a set of strategies to address the plan as a whole.

The goals are as follows:

Goal 1: To Improve Understanding of the Molecular and Physiological Basis of Health and Disease, and To Use That Understanding To Develop Improved Approaches to Disease Diagnosis, Treatment, and Prevention.

Challenge 1.1: To delineate mechanisms that relate molecular events to health and disease.

1.1.a. Develop a detailed understanding of the molecular, cellular, and physiological mechanisms that maintain health from embryonic development to the end of the human lifespan.

1.1.b. Identify intracellular targets of key signaling and transcriptional pathways in normal and pathological states.

1.1.c. Determine key genetic variants that are associated with specific diseases and delineate the molecular mechanisms that account for susceptibility or resistance to disease.

1.1.d. Define molecular, cellular, and organ-specific responses to environmental challenges and the mechanisms by which heritable and non-genetic factors interact in disease initiation and progression and in therapeutic response.

1.1.e. Determine the role of systemic pathological processes, such as inflammation, immunity, and infection, in the development and evolution of disease.

Challenge 1.2: To discover biomarkers that differentiate clinically relevant disease subtypes and that identify new molecular targets for application to prevention and diagnosis—including imaging, and therapy.

1.2.a. Identify molecular signatures that allow complex disease phenotypes to be stratified into clinically relevant categories.

1.2.b. Develop in vivo molecular imaging methods and probes for investigating the biology of disease processes.

Goal 2: To Improve Understanding of the Clinical Mechanisms of Disease and Thereby Enable Better Prevention, Diagnosis, and Treatment.

Challenge 2.1: To accelerate the translation of basic research findings into clinical studies and trials and to promote the translation of clinical research findings back to the laboratory.

2.1.a. Integrate advances in regenerative biology to develop clinically feasible applications.

2.1.b. Apply discoveries in nanotechnology to the development of new diagnostic and therapeutic strategies.

2.1.c. Integrate, analyze, and share extant and emerging genotypic and phenotypic data.

Challenge 2.2: To enable the early and accurate risk stratification and diagnosis of cardiovascular, lung, and blood disorders.

2.2.a. Exploit noninvasive imaging methods to detect and quantify subclinical disease.

2.2.b. Apply new discoveries in biomarkers to improve risk assessment, diagnosis, prognosis, and prediction of response to therapy.

Challenge 2.3: To develop personalized preventive and therapeutic regimens for cardiovascular, lung, and blood diseases.

2.3.a. Improve the understanding of interactions between genetic and environmental factors that influence disease development and progression and response to therapy.

2.3.b. Identify and evaluate interventions to promote health and treat disease in genetically defined patient subgroups by altering developmental or environmental exposures including drugs, diet and exercise, sleep duration and quality, and infectious agents and allergens.

Challenge 2.4: To enhance the evidence available to guide the practice of medicine, and improve public health.

Goal 3: To Generate an Improved Understanding of the Processes Involved in Translating Research into Practice and Use That Understanding To Enable Improvements in Public Health and To Stimulate Further Scientific Discovery.

Challenge 3.1: To complement bench discoveries and clinical trial results with focused behavioral and social science research.

3.1.a. Develop and evaluate new approaches to implement proven preventive and lifestyle interventions.

3.1.b. Develop and evaluate policy, environmental, and other approaches for use in community settings to encourage and support lifestyle changes.

3.1.c. Develop and evaluate interventions to improve patient, provider, and health care system behavior and performance in order to enhance quality of care and health outcomes.

Challenge 3.2: To identify cost-effective approaches for prevention, diagnosis, and treatment.

3.2.a. Evaluate the risks, benefits, and costs of diagnostic tests and treatments in representative populations and settings.

3.2.b. Develop research designs, outcome measures, and analytical methods to assess prevention and treatment programs in community and health care settings across populations and lifespan.

Challenge 3.3: To promote the development and implementation of evidence-based guidelines in partnership with individuals, professional and patient communities, and health care systems and to communicate research advances effectively to the public.

3.3.a. Establish evidence-based guidelines for prevention, diagnosis, and treatment and identify gaps in knowledge.

3.3.b. Develop personalized and community- and health care system-oriented approaches to increase the use of evidence-based guidelines by individuals, communities, health care providers, public institutions, and, especially, by populations that experience a disproportionate disease burden.

3.3.c. Communicate research advances effectively to the public.

The strategies that will be used to address the preceding goals and challenges are listed below:

Strategy 1: Develop and facilitate access to scientific research resources.

Strategy 2: Develop new technologies, tools, and resources.

Strategy 3: Increase the return from NHLBI population-based and outcomes research.

Strategy 4: Establish and expand collaborative resources for clinical research.

Strategy 5: Extend the infrastructure for clinical research.

Strategy 6: Support the development of multidisciplinary teams.

Strategy 7: Develop and retain human capital.

Strategy 8: Bridge the gap between research and practice through knowledge networks.

II. The NHLBI, Past and Present

The National Heart Institute was established in 1948 through the National Heart Act, with a mission to support research and training in the prevention, diagnosis, and treatment of cardiovascular diseases. Twenty-four years later, through the National Heart, Blood Vessel, Lung, and Blood Act, Congress directed the Institute to increase and coordinate its activities to improve understanding and reduce the public health burden of heart, blood vessel, lung, and blood diseases. As a result, the Institute expanded its scientific areas of interest, intensified its efforts related to research on diseases within its purview, and re-emphasized its commitment to training the next generation of investigators in heart, lung, and blood research. It also assumed responsibility for the conduct of educational activities, including the development and dissemination of materials for health professionals and the public, with an emphasis on prevention. During the 1990s, the Institute was directed to expand its mandate to encompass sleep disorders through its administration of the National Center on Sleep Disorders Research and was charged with administering the Women's Health Initiative.

Today, the NHLBI provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives. The breadth of the Institute's programs reflects the breadth of its mandate, which includes three of the four leading causes of death in the United States. While necessarily focusing considerable effort and resources on diseases that affect large numbers of people, the Institute also recognizes its obligation to address those conditions that do not themselves constitute a major public health burden but do impose serious health burdens on affected individuals.

To achieve its vision, the NHLBI stimulates basic discoveries about the causes of disease, speeds the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public. The NHLBI creates and supports a robust, collaborative research infrastructure in partnership with private and public organizations, including academic institutions, industry, and government agencies. The NHLBI collaborates with patients, families, health care professionals, scientists, professional societies, patient advocacy groups, community organizations, and the media to maximize the use of research results and leverage resources to address the public health needs of the Nation.

All activities of the NHLBI are conducted in a spirit of public service and with a commitment to excellence, innovation, integrity, respect, compassion, and open communication.

III. Goals and Challenges

The structure of this plan reflects a successive movement of scientific discovery from "form to function," "function to causes," and "causes to cures." Although research priorities are provided for each of the plan's major goals, the NHLBI recognizes that the relevant fields, available technologies, and emerging biological principles are evolving rapidly. As a result, the NHLBI is committed to remaining vigilant in identifying—and nimble in embracing—critical research opportunities as they arise. The Institute will continue to look to the NHLBAC and to the larger research community for guidance and assistance in implementing the plan and ensuring that it is updated as needed to reflect the latest scientific advances.

The Institute also will continue to look to the larger research community to develop the ideas and conduct the studies that will advance our knowledge of heart, lung, and blood diseases and will enable its application in ways that will improve public health. Investigator-initiated research has long constituted the largest share of the NHLBI research portfolio, and it is our intention to maintain that historical commitment. In fact,

we expect that much of the plan will be realized through our investment in investigator-initiated research and, especially, through those innovative investigator-initiated research projects that entail a high risk but offer the promise of especially high returns. Institute investments guided by this plan will be directed largely toward programs that will either enable or complement investigator-initiated activities.

(Quote)

...we expect that much of the plan will be realized through our investment in investigator-initiated research...

(End Quote)

Goal 1: To Improve Understanding of the Molecular and Physiological Basis of Health and Disease, and To Use That Understanding To Develop Improved Approaches to Disease Diagnosis, Treatment, and Prevention.

To enhance understanding of the molecular and physiological basis of health and disease, the NHLBI has identified two priority objectives. The first is to delineate normal and pathological biological mechanisms. The second is to exploit the emerging understanding of these mechanisms to identify biomarkers of disease. The second challenge provides a natural link to the clinical and translational objectives that are considered subsequently in this plan be arker discovery is to identify markers that can be used to stratify diseases into distinct and clinically relevant molecular subtypes, monitor disease initiation and progression, and uncover potential therapeutic targets.

Challenge 1.1: To delineate mechanisms that relate molecular events to health and disease.

Recent technological advances offer new opportunities for investigating the molecular events associated with health and disease. The developing field of systems biology, for example, allows scientists to identify mechanistic relationships among the numerous individual molecules that constitute larger systems of cells, tissues, and organs and to generate predictive models of molecular, cellular, and physiological processes based on these mechanistic relationships. The models allow scientists not only to understand but also to anticipate the consequences of specific perturbations of molecular events. Such systems-level approaches have numerous applications to heart, lung, and blood investigations.

Since pathology and drug therapy represent medically relevant perturbations of normal biology, systems-level approaches are ideally suited for investigating and providing unique solutions to biomedical problems. Although already widely used in basic studies of health and disease, the combination of "-omics" technologies and integrative

computational methods will increasingly play a major role in efforts to obtain a systems-level understanding of health and disease.

While a systems approach clearly will be important for pursuing Goal 1, many biological functions still are best studied using biochemical and biophysical methods applied at the level of individual or small numbers of molecules rather than at the systems level. Thus, if a complete understanding of normal and pathobiological conditions is to be achieved, future mechanistic investigations must strike a balance between highly reductionist and systems-level approaches, and integrate the two strategies to obtain a holistic view of health and disease.

In fact, no single strategy—however comprehensive—will be able to address every problem of biomedical interest to heart, lung, and blood investigators. More likely, investigational approaches will have to be customized based on the biological process or disease to be studied. Development and dissemination of new technologies throughout the research community will allow investigators the flexibility to draw on core experimental and computational methods that are suited to multiple applications.

1.1.a. Develop a detailed understanding of the molecular, cellular, and physiological mechanisms that maintain health from embryonic development to the end of the human lifespan.

Developing a comprehensive understanding of the mechanisms involved in maintaining human health will require research approaches that are more multidisciplinary and integrative than those relied upon in the past. Scientists currently working in separate fields, such as tissue engineering and gene therapy, will need to work collaboratively to achieve an integrated understanding of relevant biological processes. Processes of interest to NHLBI investigators include tissue repair and regeneration; organ development (with an emphasis on stem cell biology, model organism genetics, and human congenital disorders); intrinsic and extrinsic mechanisms underlying the proliferation, differentiation, maturation, survival, and trafficking of stem and progenitor cells in different contexts; and roles played by growth factors, extra cellular matrix, and cell-cell contact. The resulting information will be critical for understanding physiological mechanisms and applying the information to the development of cell-based therapies.

1.1.b. Identify intracellular targets of key signaling and transcriptional pathways in normal and pathological states.

Research in model organisms and human systems has demonstrated that signaling and transcriptional pathways intersect to form higher order regulatory networks. Because the disruption of individual pathways may have adverse consequences that are manifested as disease, detailed characterization of regulatory networks at cellular, tissue, and whole-organism levels is essential. Research must progress beyond an

understanding of static molecular relationships to the development of dynamic, quantitative models that are capable of predicting how subtle environmental or genetic perturbations alter normal function. Such models will help researchers to identify potential targets for therapeutic interventions and to anticipate not only the benefits but also the potential adverse effects of specific interventions. The new models also are expected to provide insights into variations among individuals in the response to interventions, a central goal of personalized medicine. Research to meet the challenge will require the use of emerging technologies such as high-throughput small-molecule gene and protein expression profiling, high-density genotyping, ribonucleic acid interference (RNAi) and chemical screening, protein interaction mapping, and computational methods that allow the integration and interrogation of disparate data sets relevant to heart, lung, and blood experimental systems.

1.1.c. Determine key genetic variants that are associated with specific diseases and delineate the molecular mechanisms that account for susceptibility or resistance to disease.

Most common diseases—including those of the cardiovascular, pulmonary, and hematopoietic systems—have a complex etiology that involves multiple genetic risk factors. Disease severity may vary greatly among affected individuals depending on the presence of genes that either enhance or suppress a disease phenotype. Researchers now are able to identify disease susceptibility, resistance, and modifier loci using the completed human haplotype map in conjunction with new genomic mapping technology that permits cost-efficient detection of common polymorphic variants on a genome-wide scale in thousands of affected individuals and healthy controls. The NHLBI currently supports genetic association studies for a number of common heart, lung, and blood diseases and recognizes the importance of continuing its commitment to this promising area of research. However, conducting an association study is only the first step in identifying a disease gene. Researchers must independently replicate findings from an initial association study in a second cohort and then perform additional fine-mapping studies to select the causative gene from the possible candidates that maps to a chromosomal region of interest. Once researchers have determined that a gene variant contributes to disease susceptibility or resistance, additional research is required to determine its mechanism of action. Investigations that address mechanisms will intersect with other objectives of this strategic plan, notably those focused on gene and protein functions in health and disease. Finally, while some of the genetic variants associated with diseases relevant to the NHLBI mandate will be found at high frequency among affected individuals, rare variants also could be informative for understanding disease pathogenesis and for developing new treatments. The discovery of rare variants awaits the development of less expensive technology for high-throughput deoxyribonucleic acid (DNA) sequencing, and the NHLBI must be prepared to encourage the adoption of such technology as it becomes

available. Similar genetic and genomic approaches also must be applied to pharmacogenomics—the study of individual variations in responses to particular drug therapies—a key element in the development of personalized medicine.

1.1.d. Define molecular, cellular, and organ-specific responses to environmental challenges and the mechanisms by which heritable and non-genetic factors interact in disease initiation and progression and in therapeutic response.

Environmental influences can affect disease susceptibility and phenotypic heterogeneity through their interactions with genes and their effects on proteins and protein metabolites. Environment in this context includes not just toxic exposures but also diet, physical activity, sleep deprivation, psychosocial factors, and—in the case of the developing fetus—maternal factors, all of which may converge to alter the predisposition for developing a disease, the rapidity and degree of its progression, and the response to therapy. Determining the mechanisms by which non-genetic factors perturb normal biology and interact with genetic susceptibility is an important objective of future research. Suitable experimental systems that recapitulate adverse environmental effects and gene-environment interactions are needed for the study of disease development and evolution.

1.1.e. Determine the role of systemic pathological processes, such as inflammation, immunity, and infection, in the development and evolution of disease.

Systemic processes reflect an integration of genetic, infectious, toxic, ischemic, and metabolic insults in acute and chronic disease. Understanding how this integration of multiple stimulants contributes to disease initiation and progression remains an important challenge. Research in this area has the potential to profoundly alter approaches to disease prevention, diagnosis, and treatment.

Challenge 1.2: To discover biomarkers that differentiate clinically relevant disease subtypes and that identify new molecular targets for application to prevention and diagnosis—including imaging, and therapy.

Broadly defined, biomarkers encompass any characteristic that is objectively measured and evaluated as an indicator of genotype, normal biological processes, pathological processes, or responses to therapeutic intervention. Investigations addressing Challenge 1.1 will expand the list of known biological components in numerous cellular and physiological contexts. More important, they will associate the components with specific context-dependent functions and will identify previously unrecognized interactions among individual genes and proteins. Finally, research addressing Challenge 1.1 will pinpoint molecules, pathways, and networks that are perturbed by particular disease processes. Collectively, the findings will enable the extension of basic science discoveries to the identification of markers with predictive, diagnostic, and

prognostic power; to the validation of therapeutic targets; and to the characterization of pathways that are amenable to molecular imaging.

1.2.a. Identify molecular signatures that allow complex disease phenotypes to be stratified into clinically relevant categories.

Traditional diagnostic criteria—including physical examination findings, gross and microanatomical features of affected tissues, or the combined results of conventional laboratory and radiological testing—may not reveal subtle differences among subtypes of a given disease. Because such distinctions can have important prognostic or therapeutic implications, more refined methods are needed to characterize what historically have been considered to be homogeneous disorders. It is becoming increasingly apparent that small sets of molecular markers can be used to subdivide related diseases into clinically meaningful classes. They also can be used to diagnose disease at an early stage, to predict disease progression or eventual regression, and to anticipate the occurrence of desirable or adverse therapeutic outcomes. Moreover, the biomarkers may themselves serve as effective drug targets or may be useful for monitoring and even titrating the response to specific therapies or prophylactic measures. Thus, the identification of new biomarkers forms an essential foundation for the development of personalized medicine.

1.2.b. Develop in vivo molecular imaging methods and probes for investigating the biology of disease processes.

The same knowledge base that will provide new insights into disease mechanisms and enable the identification of potential therapeutic targets also will enable the design of new molecular imaging probes and provide an impetus for the development of new imaging modalities. After initial development and testing in animal models, promising new imaging methods and reagents must be adapted for use in human subjects. Advances in imaging technology may enhance understanding of the natural history of disease and may have subsequent translational applications in routine clinical settings.

Goal 2: To Improve Understanding of the Clinical Mechanisms of Disease and Thereby Enable Better Prevention, Diagnosis, and Treatment.

To increase understanding of the clinical mechanisms of disease initiation and progression and to improve prevention, diagnosis, and treatment, the NHLBI has identified four priority objectives. The first is to enhance the transmission of knowledge between basic and clinical research so that findings in one arena rapidly inform and stimulate research in the other. The second is to apply new approaches and technologies to develop more precise methods of risk-stratification and diagnosis. The third is to advance the nascent field of personalized medicine. The fourth is to enhance the evidence available to guide the practice of medicine and improve public health.

Challenge 2.1: To accelerate the translation of basic research findings into clinical studies and trials and to promote the translation of clinical research findings back to the laboratory.

Remarkable advances have been made in understanding the molecular, genetic, and cellular bases of heart, lung, and blood diseases, and opportunities now exist to uncover practical uses for this new knowledge. The application of the fundamental understanding of biological processes to prevention and management of disease requires creative insights into possible relationships and implications. It will be necessary to identify, measure, and validate targets and pathways that have been detected in basic studies. Improved animal models and new analytic approaches that bridge basic and clinical investigations will be needed to move this work along.

2.1.a. Integrate advances in regenerative biology to develop clinically feasible applications.

Allogeneic and autologous stem cells and cell-based therapies hold great potential for treating heart, lung, and blood diseases. Advances in hematopoietic stem cell biology and in the ability to manipulate such cells in vitro, including gene transfer, have moved the field closer to clinical application. Research is needed on the selection of cells and their propagation, production, dose, timing and method of administration; adjunctive pharmacology; viability after delivery; and effects on organ function, healing, and microvascular perfusion. Much work must be done to define and overcome genetic and immunologic barriers to successful allogeneic stem cell transplantation. The feasibility of organ, tissue, blood vessel, and blood regeneration/restoration with xenogeneic and allogeneic cells also is ripe for further exploration.

Tissue engineering offers the possibility of improving function and host response in many heart, lung, and blood vessel diseases through the creation of durable, functional, biocompatible implants. Considerable basic research (e.g., the development of artificial scaffolds and other tissue constructs or the manipulation of growth factors to generate an adequate supply of blood vessels and nerves) has brought the field to a point where testing in humans may be feasible.

2.1.b. Apply discoveries in nanotechnology to the development of new diagnostic and therapeutic strategies.

Drug delivery and therapeutics, molecular imaging, diagnostics and biosensors, and tissue engineering and biomaterials are all areas in which nanotechnology is expected to play a key role in the future. Of relevance to the NHLBI is the potential application of nanotechnology to the diagnosis and treatment of vulnerable plaque; tissue repair, engineering, and remodeling for the restoration of blood vessels and heart and lung tissue; the diagnosis, treatment, and prevention of lung inflammatory diseases; the development of multifunctional devices to monitor the body for the onset of thrombotic

or hemorrhagic events and precisely regulate the release of therapeutic drugs; and the development of in vivo sensors to monitor patients for sleep apnea. Clinical testing of nanoparticles and nanodevices is not likely to begin for 5 to 10 years, and another 5 years will probably be needed before materials could be used in clinical practice. However, applications of nanotechnology that are less invasive (e.g., diagnostic blood tests) could become available much sooner. Success in bringing nanotechnology to the bedside will depend on collaborations among biologists and physicians, materials scientists, physicists, and engineers. Particular emphasis should be placed on conducting the necessary preclinical and clinical studies to assess the potential health risks associated with nanotechnologies.

2.1.c. Integrate, analyze, and share extant and emerging genotypic and phenotypic data.

Biomedical research already has generated volumes of data from advances in "-omic" technologies and biomedical imaging, and an overwhelming amount of new information can be expected from such developments as affordable individual genome sequencing, real-time metabolomics, and electronic medical records. Realizing the full potential of these data will require a significant partnership between biomedical researchers, mathematicians, systems engineers, statisticians, and computer scientists. The NHLBI expects to play a key role in developing and supporting an information infrastructure that embodies comprehensive standards for biomedical information related to heart, lung, and blood diseases and sleep disorders, including controlled vocabularies, ontologies, data models, and data representation formats; that facilitates the integration of data from the molecular level to the systems level in health and disease; and that encourages and enables the broad sharing and use of research data with appropriate attention to privacy.

Challenge 2.2: To enable the early and accurate risk stratification and diagnosis of cardiovascular, lung, and blood disorders.

Over the past several decades, multiple observational and intervention studies supported by the NHLBI have identified and refined the definition of risk factors for heart, lung, and blood disorders. Opportunities now exist to improve the precision of risk estimates across the lifespan for individuals and populations, to identify abnormalities before disease is clinically evident, and to develop strategies for preventing the development or progression of subclinical disease. Progress in this area hinges on the identification, measurement, and validation of biological pathways and targets for intervention.

2.2.a. Exploit noninvasive imaging methods to detect and quantify subclinical disease.

Many disease processes relevant to the NHLBI mission—plaque formation in atherosclerosis, destruction of alveoli in emphysema—are known to progress silently

over the course of decades. The use of sensitive imaging technology would shed light on mechanisms of initiation, progression, and reversal of disease and would enable the measurement of the clinical outcomes of interventions. For example, a pressing need exists for advances in noninvasive imaging that can accurately assess risk for myocardial infarction before and after therapeutic intervention. Such advances not only could be of immediate benefit to patients but also could shorten the time required to test new therapeutic agents by reducing the need for clinical trials that rely on clinical end points. Similarly, better methods for imaging an evolving thrombus would markedly improve the diagnosis of patients with arterial and venous thrombosis. To make the most of opportunities in this area, magnetic resonance imaging, computerized tomography, the rapidly evolving techniques of molecular imaging, and other imaging modalities may be integrated with genomic technologies and biomarkers and validated in clinical trials.

2.2.b. Apply new discoveries in biomarkers to improve risk assessment, diagnosis, prognosis, and prediction of response to therapy.

As noted in Challenge 1.2, biomarkers are broadly defined to encompass any characteristic that is objectively measured and evaluated as an indicator of genotype, normal biological processes, pathological processes, or responses to therapeutic intervention. Biomarkers are needed in clinical medicine to detect early tissue injury and document disease progression. They may prove particularly valuable in providing clues to disease etiology. Focused and rapid biomarker discovery and validation have already yielded significant benefits for subgroups of patients identified as being at risk for a wide variety of disorders. Association studies using "-omic" technologies are expected to uncover many new biomarkers that may become useful tools for evaluating risk and individual responsiveness to interventions in populations and, ultimately, for identifying new therapeutic targets. An improved ability to detect subclinical diseases and monitor disease progression could potentially transform clinical decision-making and enhance the participation of patients in lifestyle choices and behaviors that affect clinical outcomes.

Challenge 2.3: To develop personalized preventive and therapeutic regimens for cardiovascular, lung, and blood diseases.

Personalized medicine is based on the concept that all individuals have unique characteristics defined by their genome and that human variability in health and disease is determined by genetic makeup in combination with environmental exposures. If the vision of personalized medicine becomes a reality, it will enable clinicians to select appropriate medications and dosages to achieve high efficacy and avoid adverse reactions, thereby improving outcomes and potentially reducing health care costs. More efficient drug development is also likely to result: testing new drugs

only in patients likely to experience a benefit could speed the process of getting drugs to market.

2.3.a. Improve the understanding of interactions between genetic and environmental factors that influence disease development and progression and response to therapy.

Over the past 50 years, great advances have been made in understanding the roles of such environmental influences as diet, exercise, sleep, psychosocial factors, socioeconomic status (SES), and air and water quality on the development of disease. Environmental and lifestyle or behavioral factors are known to contribute to the initiation or progression of many common disorders of the heart, lungs, and blood. Even single-gene disorders are now acknowledged to have complex genetic and environmental modifiers of expression and severity. Exploration of the interactions between genetic and environmental factors has now become essential to explain the development, progression, and outcome of many diseases. Key to success in this area will be the development of more precise measures of environmental exposures and more robust definitions of clinical phenotypes.

The NHLBI will capitalize on its rich resource of studies that enable the association of whole-genome single-nucleotide polymorphisms with clinical phenotypes. The identification of such associations will enhance the understanding of complex traits and will permit investigators to explore the relationship between genetic variants, gene expression, and gene function. The application of these "-omic" approaches may lead to more sophisticated analyses of risk and individual responsiveness to interventions in populations.

2.3.b. Identify and evaluate interventions to promote health and treat disease in genetically defined patient subgroups by altering developmental or environmental exposures including drugs, diet and exercise, sleep duration and quality, and infectious agents and allergens.

Disease development and progression are influenced not only by genetic factors but also by developmental and environmental exposures. In recent years, researchers have focused on identifying, measuring, and understanding the effects of such exposures to provide a basis for the development of new interventions. Systems biology approaches for modeling the complex interactions between genetic and environmental factors provide valuable information for identifying potential interventions. Basic researchers are developing in vivo systems and tools for preclinical testing of new therapies. They are also developing new cell and animal models based on knowledge of susceptibility genotypes and relevant exposures. Large cohort studies that include measures of exposure to drugs, allergens, and infectious agents, as well as information about diet, exercise, sleep duration and quality, and psychosocial factors, offer a wealth of information for generating hypotheses. In the future, the value of data

from basic, clinical, and cohort studies will be enhanced by the standardization of definitions of phenotypes, diseases, exposures, and outcomes. In addition, the creation of shared databases with information from multiple studies will facilitate the integration and analysis of results. Clinical testing of new interventions will be informed not only by epidemiological and basic studies of the effects of particular exposures but also by results of genetic and genomic studies that allow researchers to sort patients into genetically defined subgroups. Such clinical tests are expected to enable developmental and environmental interventions that are tailored to individuals.

Challenge 2.4: To enhance the evidence available to guide the practice of medicine, and improve public health.

The NHLBI will continue to build upon a long and distinguished tradition of excellence in the conduct of clinical trials to generate new knowledge to improve the prevention, diagnosis, and treatment of heart, lung, and blood diseases. Many of the current rigorous standards of evidence upon which practice guidelines are based derive from NHLBI-supported randomized clinical trials. The Institute remains committed to continuing to generate new evidence that will inform disease prevention, diagnosis, and treatment.

Goal 3: To Generate an Improved Understanding of the Processes Involved in Translating Research into Practice and Use That Understanding To Enable Improvements in Public Health and To Stimulate Further Scientific Discovery.

To realize its public health objective, the Institute must find ways to extend the full benefits of scientific advances to all of the diverse populations that constitute the American public. Many evidence-based approaches to prevent and treat heart, lung, and blood diseases have not been uniformly applied in clinical and community practice. Further research is needed on the translation process itself to expedite and expand the adoption of biomedical advances into clinical practice and individual health behaviors. The NHLBI will evaluate new ways to disseminate and implement proven prevention and treatment approaches to improve public health. Research to address issues that are directly relevant to clinical and community practice, such as how best to apply what is already known to be effective, is a priority.

Opportunities exist for the NHLBI to collaborate with community-based practice networks to conduct multidisciplinary research that would address important behavioral issues and facilitate the evaluation of new approaches to prevent, diagnose, and treat disease. The new Clinical and Translational Science Awards (CTSAs) of the National Institutes of Health (NIH) and the Practice-Based Research Networks of the Agency for Healthcare Research and Quality both offer the potential for leveraging Institute resources.

Challenge 3.1: To complement bench discoveries and clinical trial results with focused behavioral and social science research.

Behavioral and psychosocial factors are known to play an important role in the development and progression of heart, lung, and blood diseases. For example, diet and physical activity are critically involved in the development of cardiovascular disease risk factors, such as hypertension, dyslipidemia, obesity, diabetes, and untreated sleep apnea and reduced sleep duration, are risk factors for obesity, hypertension, and diabetes. The success of many therapeutic regimens, even highly effective ones, depends on patient adherence. Stress and depression are other behavioral factors known to be associated with cardiovascular disease risk and progression.

Despite widespread recognition of the importance of health behaviors, only a relatively small percentage of adults regularly follow relevant recommendations. Because influences on health behaviors are diverse, ranging from individual (e.g., knowledge and motivation), to familial (e.g., expectations and role models), to environmental (e.g., workplace and school policies, social and cultural norms, and physical environments), they are best studied in complex environments. In the clinical setting, a widely acknowledged "quality gap" exists in which proven effective preventive and therapeutic strategies are not consistently followed, a function of both patient behavior and provider practice. The gap is greater among Americans with limited resources and minority groups.

If research findings are to improve the public's health, they must be translated into practice. Because it is often not clear how best to do so, the translation process itself needs study. Methods especially are needed to adapt interventions to address the needs of minority populations.

3.1.a. Develop and evaluate new approaches to implement proven preventive and lifestyle interventions.

Although research has uncovered a number of preventive and lifestyle interventions that are effective in small, controlled studies, it is often not clear how to implement them on a larger scale. Family- and community-based approaches offer particular promise for reaching much of the population. Although major life events (e.g., school transitions, entry into the workforce, retirement) often result in increased risk, they also may present opportunities to implement effective preventive strategies. Research also is needed to evaluate the extent to which risk stratification and application of personalized approaches can improve effectiveness.

3.1.b. Develop and evaluate policy, environmental, and other approaches for use in community settings to encourage and support lifestyle changes.

The successful national effort to reduce tobacco use illustrates the efficacy of policy and environmental approaches to promote healthy lifestyles. Environmental factors may also affect health behaviors. Examples include the influence of public policy decisions on physical activity, nutrition (e.g., portion sizes, marketing practices, retail food choices), and adequate sleep in students and workers. Research is needed to identify factors that are important influences on behavior and health and to determine how they can be changed in a cost-effective way.

3.1.c. Develop and evaluate interventions to improve patient, provider, and health care system behavior and performance in order to enhance quality of care and health outcomes.

Integrating behavioral and social sciences research with clinical research is crucial for developing successful strategies to improve health care. An improved understanding of the factors that influence patient, provider, and health care system behaviors may facilitate the development of new approaches to reduce the "quality gap." A range of such interventions as economic incentives and performance measures for providers could be evaluated. Wide-scale adoption of electronic health records could enable tracking of the delivery and outcome of medical innovations, evaluation of factors that are associated with care-delivery patterns, and testing of new interventions. Studies are needed to identify and evaluate "patient-centered" approaches, such as incorporating patient preferences into clinical decision-making, and to reduce the inappropriate use of diagnostic tests and treatments.

Challenge 3.2: To identify cost-effective approaches for prevention, diagnosis, and treatment.

To achieve a substantial improvement in the health of the Nation, more cost-effective approaches to prevent, diagnose, and treat heart, lung, and blood diseases are needed. Research on community applications of evidence-based clinical practices will be undertaken to document current practice patterns and factors associated with high-quality clinical care; identify the relative contributions of secular trends and interventions; integrate data from rare diseases and newly emerging data on prevalent diseases to develop, evaluate, and revise evidence-based clinical best practices; and translate findings into educational messages for providers, patients, and the general public and assess their effects on behaviors and health status.

3.2.a. Evaluate the risks, benefits, and costs of diagnostic tests and treatments in representative populations and settings.

Surveillance systems that allow for the rapid analysis and communication of health status can provide data on the effectiveness of community-based and population-based interventions. Dissemination of results is the most critical part of the research effort, yet much remains to be learned about how to do so effectively. New disciplines

such as bioinformatics may transform established public health education approaches. Social marketing approaches and diffusion-of-innovation models may provide insights that can help refine preventive and therapeutic efforts. The NHLBI will initiate collaborations and public-private partnerships to facilitate evaluations of new treatment approaches. The new CTSAs are models of interdisciplinary teams and streamlined, non-redundant core facilities that may transform translational research. Industry—including health plans, disease management companies, and purchasers—is a rich source of data and will be included in the research enterprise. Research on health services and outcomes can evaluate clinically feasible interventions to improve the delivery of evidence-based preventive and therapeutic approaches.

3.2.b. Develop research designs, outcome measures, and analytical methods to assess prevention and treatment programs in community and health care settings across populations and lifespan.

New approaches are needed that can accommodate nontraditional family patterns, low SES, and immigrant status. The "microculture" of immigrant families, including their eating, drinking, and sleeping patterns, health literacy, and responses to major life events, can influence not only their interactions with the health care system but also their health. Successes over several decades have enabled people with congenital diseases to live beyond childhood, but too often inadequate data are available to guide their treatment as adults. Data systems that can characterize patient demographics, including SES, access to health care, patterns of health care use, family structure, work roles, quality of life, and clinical health status, could be used to identify clinical best practices and educate providers. Research designs and analytic methods are needed to enable valid analyses of interventions delivered at a "group" level (e.g., at worksites or in clinical practices) and to assess the efficacy of preventive interventions that seek to achieve long-term public health improvements through small individual changes. Evaluations of the cost-effectiveness of interventions require methods that are relevant to society as a whole and consider all relevant costs as well as quality of life.

Challenge 3.3: To promote the development and implementation of evidence-based guidelines in partnership with individuals, professional and patient communities, and health care systems and to communicate research advances effectively to the public.

Too often, evidence-based guidelines that distill the best available scientific knowledge into recommended actions for individuals, communities, and health care systems to improve health outcomes are not fully adopted into practice. Addressing this challenge will require efforts to promote the implementation of evidence-based guidelines by individuals, communities, health care providers, and public institutions; to influence public policy by promoting and implementing evidence-based guidelines; and to reduce health disparities with attention to personalized, community, and health

system-oriented approaches to increase the use of proven preventive interventions among vulnerable subgroups.

3.3.a. Establish evidence-based guidelines for prevention, diagnosis, and treatment and identify gaps in knowledge.

The NHLBI will continue to exert national leadership in the development of evidence-based guidelines and promote the concept of integrated guidelines that comprehensively address the known, modifiable risk factors associated with a disease. The NHLBI will continue to take a leadership role in, or serve as a knowledge broker for, guideline development efforts and support ongoing efforts to make the most current scientific evidence publicly available so that professional organizations can develop appropriate guidelines. The Institute will continually assess the nature of the available evidence and identify areas that need additional research to support clinical decision-making.

3.3.b. Develop personalized and community- and health care system-oriented approaches to increase the use of evidence-based guidelines by individuals, communities, health care providers, public institutions, and, especially, by populations that experience a disproportionate disease burden.

Systems approaches will be developed to speed the implementation of knowledge in health care and community settings; foster partnerships among practitioners, patients, family members, community organizations, and community health workers; and create environments that support healthy choices and reduce known risk factors. Linkages among interested groups that previously operated independently will be encouraged to realize efficiencies through cooperation. As appropriate, the NHLBI will work with other government agencies and with private-sector organizations to encourage reliance on evidence-based guidelines in setting policies that affect health behaviors and care. Policy changes (e.g., regarding reimbursement practices, performance measures, and accreditation standards) can be highly effective in stimulating the development and implementation of evidence-based guidelines and influencing the behaviors of providers, patients, and health systems. School and worksite environments can foster improvements in lifestyle behaviors and risk factor screening practices.

Substantial evidence indicates that health, SES, and psychosocial factors are inextricably linked and that health disparities exist even among individuals at the same SES level who are from different population groups. Efforts to raise the health of minority groups to the level enjoyed by the majority population must recognize that discrimination in living conditions, educational systems, health care systems, and work settings can adversely influence health. Because they share an understanding of their local environment, including an appreciation of prevalent psychosocial factors and cultural beliefs, community groups and local health providers must be involved in efforts

to promote community acceptance of science-based health information. Outcomes from community health promotion and evaluation projects can inform the development of new dissemination models at the personalized/individual, community, and health care system levels. The Institute will support partnerships and linkages that enhance the understanding of contributions of individual health behaviors, community-based organizational and environmental policies, and health systems innovations to reducing health disparities.

3.3.c. Communicate research advances effectively to the public.

The objective of all NHLBI public education activities is to motivate the audience to become active users of health information. The Institute will continue to investigate and evaluate new communication and social-marketing approaches to communicate research advances with the goal of engaging all interested parties. They include members of the research community who generate new knowledge; governmental agencies, national voluntary and professional organizations, credentialing bodies, and foundations that translate and disseminate knowledge; individuals engaged in clinical practice and in community programs who apply the science to improve health outcomes and share their experiences with others; and workers in the knowledge technology field who develop and implement new systems that can link various knowledge communities and promote performance-focused and science-based approaches.

The Institute will continue to develop public education programs, as needed, to address areas of major public health concern, such as heart failure, partnering with professional societies, patient-advocacy groups, community-based organizations, and Federal entities to ensure that uniform health messages are disseminated. In addition to encouraging individuals and communities in health promotion and disease prevention efforts, the Institute will stress the importance of their involvement in the research process by emphasizing that new health-related information can be generated only with their cooperation and participation.

IV. Strategies

Implementation of this plan will require a diversity of approaches to address the scientific challenges previously identified that will enable sharing of both knowledge and resources. This section presents the strategies that the NHLBI intends to employ to facilitate the conduct of research; enhance interdisciplinary work; speed early stage translation of basic discoveries; ensure cross-fertilization of basic, clinical, and epidemiologic discoveries; and maximize the resultant public health benefit of the information created. As the challenges identified in this plan are met and as new ones emerge, the NHLBI will identify and embrace new strategies. The Institute also will

continue to look to the NHLBAC and to the larger research community for guidance to ensure that these strategies are updated as needed to reflect the rapidly changing environments of research and public health issues.

(QUOTE)

As the challenges identified in this plan are met and as new ones emerge, the NHLBI will identify and embrace new strategies.

(END QUOTE)

Strategy 1: Develop and facilitate access to scientific research resources.

Lack of access to costly technologies often limits what individual investigators can accomplish. It is not practical for every laboratory, department, or even institution to develop many technical capabilities involving expensive equipment, scarce materials, large amounts of space, and specialized technical expertise. Such services can be more efficiently provided by centralized facilities that are dedicated to a single activity or a set of related functions and can ensure appropriate quality control oversight and realize economies of scale. Centralized facilities can also significantly enhance the productivity of individual investigators by allowing them to focus on pursuing hypothesis-driven scientific questions rather than on obtaining the resources needed to address them.

Support will be provided for core genomics, proteomics, chemical, and RNAi screening; small-animal imaging; and other technologies as they become available or are requested by the research community. Adoption of new and cheaper DNA sequencing methods for large-scale re-sequencing projects is one example of a need that is likely to arise in the very near future.

The Institute will strategically support tissue and animal repositories, databases, and information systems dedicated to the support of NHLBI projects. In creating such resources, careful attention will be paid to center capacity, regional distribution, and standardization of methods so that quality services are made available expeditiously to all who require them. Formal mechanisms will be established to ensure equitable access to the resources without imposing onerous requirements on investigators.

Strategy 2: Develop new technologies, tools, and resources.

In addition to making existing technologies widely available, the NHLBI will continue to invest in the development of new methods for laboratory investigations. Areas requiring attention include genomics; proteomics; metabolomics; bioinformatics (especially integrative computational tools); imaging probes and modalities (for studies at the level of whole animals, cells, and individual molecules); nanotechnology; tissue engineering;

gene knock-out, knock-down, and knock-in methods in whole animals; and gene and cell-based therapies.

Animal models are a critical resource. Support is required for efforts to create new animal models that closely emulate the pathology of human disorders and that can be used not only for mechanistic investigations but also for evaluations of new therapies. The need for new animal models is certain to expand rapidly, as additional human disease susceptibility genes are discovered in genome-wide association studies. To accommodate the increased need, new experimental approaches for qualitatively and quantitatively perturbing model organism orthologs and for studying interacting genetic and non-genetic factors will be required.

Given that the new technologies, tools, and resources needed by NHLBI investigators also will be used by investigators who are supported by other funding sources, opportunities for their development through partnering arrangements—with other NIH components as well as with other government agencies and with private sector organizations—will be explored. The NHLBI also will undertake projects that complement and extend other resource development efforts, as exemplified by such existing programs as the Pharmacogenetics Research Network and the Knockout Mouse Project, and perhaps enable the development of new collaborative networks or other approaches to stimulate preclinical efforts. By seeking involvement in additional research opportunities of this type, the NHLBI can both enhance community-wide activities and provide valuable resources for the benefit of its own investigators, thereby yielding benefits for all interested parties.

Strategy 3: Increase the return from NHLBI population-based and outcomes research.

The NHLBI has made extensive and highly productive investments in population-based and outcomes research that have not only addressed specific scientific questions but also provided real-world perspectives on disease burden, risk factors, and the effectiveness of medical care. If the full value of these studies is to be realized, however, the Institute must address several critical needs.

The Institute will take a leadership role in developing national standards for nomenclature and informatics to facilitate the sharing of phenotypic data. Common collection methods, definitions, and exchange formats for data are needed to enable linkages among studies of complex diseases. Data from studies that are not large enough individually to examine gene-environment interactions, risks and benefits of interventions, or risk factor associations in subgroups could be pooled to address those issues. Nomenclature standards that are easily implemented, universally accessible, broadly applicable, and yet flexible enough to accommodate advances in technology and science (e.g., newly identified risk factors and disease end points) are

needed. Data repositories that include informatics tools for data analysis and promote data-sharing (while ensuring data security and participant confidentiality) are needed.

The Institute will selectively complement ongoing surveillance of local and national incidence, prevalence, practice patterns, and outcome measures in diverse populations. Up-to-date figures are critical for detecting important scientific and public health trends, and they also can be used to uncover health disparities and monitor efforts to reduce them. Documentation of the influence of sociocultural environments, psychosocial traits and stressors, lifestyles, economic resources, access to health care, and other factors can reveal pathways that contribute to disease burden and therapeutic response. Surveillance of practice patterns can enable assessment of the effects of clinical guidelines on physician prescribing practices and can facilitate the identification of barriers to implementing best practices. Efforts will focus on enhancing and combining data from existing data collection systems, partnering with public and private organizations that collect and use electronic health information (e.g., insurers, large health care systems, other government agencies), and developing new approaches to capture data in diverse populations.

The value of existing studies could be enhanced by adding new genetic, social, environmental, and psychological measures. Because even such well-defined environmental exposures as smoking have been difficult to measure, this effort may call for new technologies to enable accurate assessments of risk. New analytic methods are needed to integrate the large volumes of data obtained in population research to permit examinations of gene-environment and gene-gene interactions and of reversible heritable changes in gene function. Population studies can provide an appropriate context for evaluating and translating new technologies for imaging and "-omics" into clinical applications. The introduction of "-omics" technologies into population studies will require interactions among epidemiologists, geneticists, clinicians, bioinformaticians, statisticians, and "-omics" scientists and the creation of new resources to be shared with the scientific community in a manner consistent with participant consent. Large-scale "-omics" studies are likely to require new paradigms, including public-private partnerships.

Strategy 4: Establish and expand collaborative resources for clinical research.

Coordinated resources are needed to facilitate the conduct of disease-oriented studies and speed the application of basic science observations to clinical problems. The network approach to translational and clinical research has been successful and will be expanded to additional areas of science.

Disease-oriented Internet portals could enable access to information and tools for use in research and patient care. They would serve not only as an essential resource for integrative understanding of heart, lung, and blood disorders but also as a stimulus for

community-wide collaborations. To be effective, portals must be interoperable with other data and information resources to allow users to develop a comprehensive understanding of relevant diseases, particularly multi-system and multi-organ syndromes. They also will facilitate the sharing and linking of disparate data types (e.g., sequences, single nucleotide polymorphisms, phenotypes, disease mechanisms) and the development of data-management tools, strategies for analysis, and data-visualization approaches.

The new NIH network of CTSAs offers great promise for investigators interested in conducting research in community settings, affording them access to an integrated and organized resource. A serious challenge for the NHLBI continues to be the delay typically experienced between the time that an intervention is shown to be effective and when it is broadly adopted by health practitioners, patients, and the public. One potential way to reduce the delay would be to encourage broader community involvement in research to increase the general awareness of ongoing studies and increase interest in research outcomes. The Institute views the CTSAs as an important resource for stimulating community involvement in clinical research whenever appropriate.

Strategy 5: Extend the infrastructure for clinical research.

The NHLBI will develop a comprehensive process for establishing priorities for large clinical trials. As part of the process, advice will be solicited from a broad range of interested parties, including individual investigators, expert panels, industry, other Federal agencies (e.g., Centers for Medicare and Medicaid Services, Food and Drug Administration), patients, and nonacademic medical practitioners through their professional societies. Also needed are explicit criteria to be used in deciding among proposed trials to ensure that the most pressing questions are addressed. Establishing standards for the design, conduct, and interpretation of clinical studies and trials will ensure that the answers are scientifically valid and applicable to diverse populations.

The process of initiating and conducting clinical trials will be refined. Templates and educational materials will be developed to guide clinical trial investigators as they pursue a research idea from study design to implementation. Standardized definitions of end points and adverse events, streamlined reporting procedures of adverse events, and improved methods for analyzing data from early-phase trials are also needed. Controlled vocabularies, ontologies, data models, and data representation formats will be developed for major areas within the Institute's mission to enable data sharing and study comparisons. NHLBI-supported researchers will be encouraged to adopt the same Federal standards already used by clinical systems in order to facilitate the research use of data stored in clinical databases within health care organizations. In addition, the NHLBI will work with other components of the NIH and the Department of

Health and Human Services toward facilitating clinical research by reducing the regulatory burden associated with the initiation and conduct of clinical studies.

The scientific return from the Institute's substantial investments in time and resources represented by large-scale clinical trials can be increased by facilitating important ancillary studies. In addition to providing mechanisms for the timely funding of ancillary studies not included in the original trial protocol, efficiency may be gained by incorporating substudies of known broad interest and applicability into the initial funding action. Ancillary studies to validate imaging findings and biomarkers with clinical outcomes, studies that establish repositories for use by the research community, and biostatistical methodology development will be included in the initial design of trials whenever possible. The Institute also recognizes the value of community- and practice-based research and their potential for further increasing the return on its clinical trial investments, and it will continue to encourage and support such efforts.

Strategy 6: Support the development of multidisciplinary teams.

Interdisciplinary collaborations are becoming ever more critical to all areas of research related to the mission of the NHLBI. Increasingly, clinicians and biologists are requiring the expertise of individuals in quantitative disciplines, including computer science, mathematics, physics, and engineering. The NHLBI encourages this trend by including in research initiatives, wherever appropriate, a requirement that diverse groups of scientists be assembled to work together on a common problem. The Institute will consider supporting "virtual centers" to enable collaborations that are focused on expertise and are independent of geography. Given the currently available electronic and Web-based communication technologies, geography is no longer a barrier.

Development of multidisciplinary teams will require greater recognition in the research community, and especially in universities and medical schools, of the accomplishments of groups rather than individuals. It will also likely entail collaborations on research programs among the various Institutes and Centers of the NIH. To facilitate the transition to and acceptance of this new research paradigm, the NHLBI and other funding agencies will have to work closely with academic institutions to ensure that proper recognition is accorded to all participants. Acknowledging the value and appropriateness of a co-principal investigator in individual research project grants is a good start, but more needs to be done.

One approach to promoting interdisciplinary research is for the NHLBI to establish seed funding for Research Centers of Excellence. By providing infrastructure support, Centers can serve as a focal point within an institution for research in heart, lung, and blood diseases as well as attract the interest of investigators who are unaffiliated with the Center but who have potentially related skills and expertise. To ensure the greatest return on Research Centers of Excellence, eligibility could be limited to institutions that

have been selected for the CTSA, with NHLBI funding provided to enhance the CTSA in areas relevant to the Institute's mission. Consideration will be given to limiting the period of NHLBI support for a Center, to requiring recipient institutions to provide some level of matching funds for the entire award term, and to requiring the institutions to present a plan for transition to continue funding of the Center beyond the period of NHLBI Center support.

Strategy 7: Develop and retain human capital.

The NHLBI and the heart, lung, and blood research community have experienced increasing challenges in the recruitment of young scientists. The Institute is committed to extending the reach of its educational efforts to elementary and high school students, and it will continue to expand its support of science education in the schools to ensure a steady supply of enthusiastic and creative young scientists.

To ensure the continued advance of knowledge related to heart, lung, and blood diseases, the NHLBI must enable a constant renewal of the research workforce. To that end, the NHLBI supports training and career development opportunities for scientists at all career stages. Scientists today are called upon to master increasingly complex technologies, including quantitative methods that may not have been part of their training. The Institute not only will encourage inclusion of courses in statistics and other types of mathematical analysis in postdoctoral training for scientists in biomedical disciplines but also will enable hands-on training experiences in relevant quantitative areas. To avoid extending what is already a lengthy training experience for most scientists; the added materials will be accompanied by measures to shorten the overall training period, such as providing incentives to both mentors and trainees who meet certain milestones.

To afford scientists with expertise in quantitative and analytical areas the opportunity to contribute to biomedical research, the Institute will offer programs to enable them to acquire relevant basic biomedical knowledge. One way of doing so would be to foster reciprocal cross-training during the postdoctoral years for individuals with predoctoral training in biomedical disciplines and quantitative disciplines. This could also serve as a stimulus for interdisciplinary studies among the next generation of scientists.

New investigators face the challenge of obtaining a first individual research project grant (R01) in competition with applications from more experienced individuals. The NHLBI will continue its policy of giving new investigators an advantage by funding them at higher pay scales and ensuring expedited re-review of applications that are highly meritorious but do not receive funding on first submission. The NHLBI recognizes the critical role of mentoring to ensure success in research careers and will work with host institutions to develop new approaches to foster mentoring for young faculty members.

The Institute also recognizes that initial funding for a new investigator is often not sufficient to establish a research career; the first competing renewal is critical. Partial bridge funding, perhaps in a cost-sharing mechanism with host institutions, might provide adequate support for an unsuccessful applicant to maintain a research program, while a revised application is pending.

The Institute recognizes its obligation to established scientists. They often are required to develop new skills to respond to changes in research directions and new scientific opportunities. Training programs of "continuing biomedical education" and support for mini-sabbaticals are two possible approaches to aid established investigators in acquiring needed expertise.

Strategy 8: Bridge the gap between research and practice through knowledge networks.

The NHLBI has a long history of establishing and maintaining networks to fulfill its mandate to translate science-based information into clinical practice and public health behavior. The Institute will explore new network approaches to promote collaborations among researchers that enable them to develop evidence-based initiatives to improve public health.

The NHLBI will create individual knowledge networks focused on disease priorities—based on their burden to society—to connect researchers to health practitioners by facilitating interaction among those who generate new knowledge, those who translate and disseminate it, and those who use it. The networks will provide an avenue for identifying knowledge gaps that need to be addressed by future research and for speeding translation into practice through use of more effective approaches to synthesizing and organizing evidence. It is expected that knowledge networks will constitute a public resource that will enable research and prevention programs internationally as well as domestically. Development of a Cardiovascular Knowledge Network (CKN) is the first step. The knowledge network concept can then be expanded to encompass other diseases based on the lessons learned in the first 3 years of operation of the CKN.

The CKN will require a new informatics infrastructure that supports knowledge-sharing and rapid interaction between researchers and practitioners as well as close surveillance of cardiovascular health data to guide research and development of preventive efforts, particularly for selected populations. Other important aspects include community strategies that pool resources to create environments that support healthy choices and reduce known risk factors over the entire lifespan, incentives to stimulate the adoption of beneficial behaviors, personalized health care strategies that address individual needs, and social marketing communication strategies to promote social norms that improve cardiovascular health.

Broad scientific literacy is essential to enable full public participation in policy decisions posed and informed by scientific advances and full individual participation in the active maintenance and management of their own health. Citizens, patients, family members, and investors must be able to critically evaluate new information, assess areas of ambiguity, and appreciate the implications of personal and public decisions related to health. The NHLBI will participate in improving science education in elementary and secondary schools and in improving higher education for nonscientists as well as scientists.

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Information and Resources

NHLBI Resources

NHLBI Home Page
http://www.nhlbi.nih.gov

NHLBI Strategic Plan
http://apps.nhlbi.nih.gov/strategicplan/

NHLBI Information for Researchers
http://www.nhlbi.nih.gov/resources/index.htm

NHLBI Information for Health Professionals
http://www.nhlbi.nih.gov/health/indexpro.htm

NHLBI Information for Patients and the Public
http://www.nhlbi.nih.gov/health/index.htm

NHLBI Clinical Trial Database
http://apps.nhlbi.nih.gov/clinicaltrials/

NHLBI Funding Training and Policies
http://www.nhlbi.nih.gov/funding/index.htm

NHLBI Training and Career Development Web Site
http://www.nhlbi.nih.gov/funding/training/

NHLBI Research and Policy Update Listserv
http://www.nhlbi.nih.gov/resources/listserv/index.htm

NHLBI Fact Book
http://www.nhlbi.nih.gov/about/factpdf.htm

NIH Resources

NIH Home Page
http://www.nih.gov

NIH Center for Scientific Review
http://cms.csr.nih.gov/

NIH Forms and Applications
http://grants.nih.gov/grants/forms.htm

NIH Grants and Funding Opportunities
http://grants1.nih.gov/grants/index.cfm

NIH Public Involvement
http://www.nih.gov/about/publicinvolvement.htm

Discrimination Prohibited

Under provisions of applicable public laws enacted by Congress since 1964, no person in the United States shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program and activity) receiving Federal financial assistance. In addition, Executive Order 11141 prohibits discrimination on the basis of age by contractors and subcontractors in the performance of Federal contacts, and Executive Order 11246 states that no federally funded contractor may discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. Therefore, the National Heart, Lung, and Blood Institute must be operated in compliance with these laws and Executive Orders.