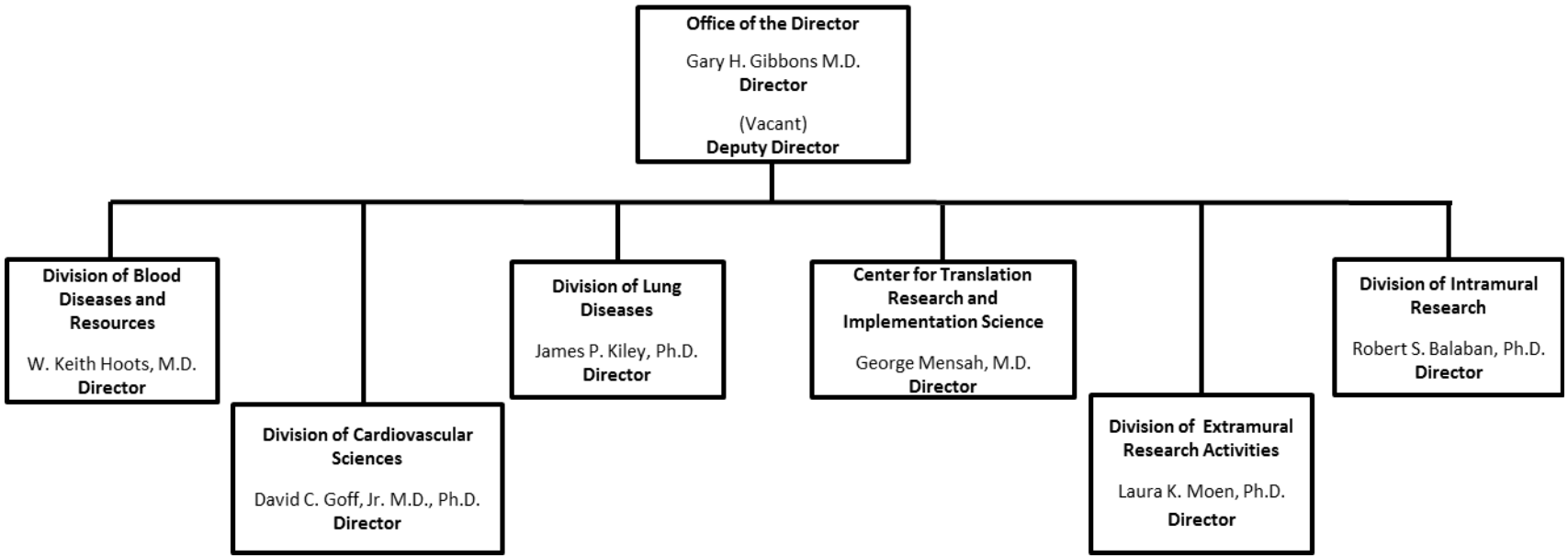
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute (NHLBI)

NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood, Institute



NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, $2,534,803,000.

NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute

Amounts Available for Obligation[1]
(Dollars in Thousands)

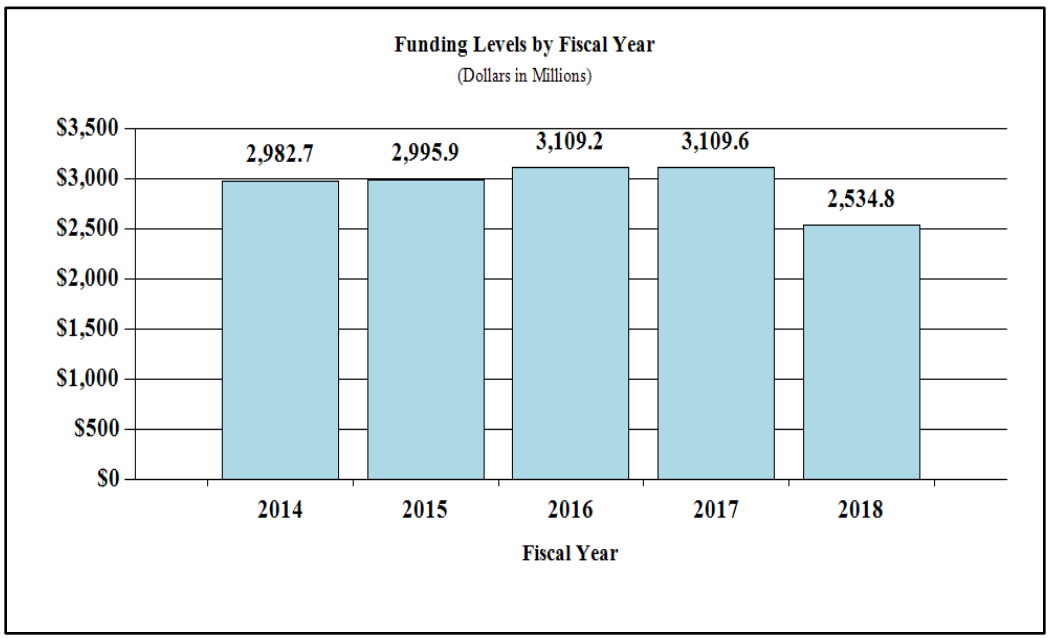
Source of Funding	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Appropriation	$3,115,538	$3,115,538	$2,534,803
Mandatory Appropriation: (non-add)	-	-	-
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	-5,923	0
Sequestration	0	0	0
Zika Intra-NIH Transfer	-4,312	0	0
Subtotal, adjusted appropriation	$3,111,226	$3,109,615	$2,534,803
OAR HIV/AIDS Transfers	-2,005	0	0
Subtotal, adjusted budget authority	$3,109,221	$3,109,615	$2,534,803
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$3,109,221	$3,109,615	$2,534,803
Unobligated balance lapsing	-159	0	0
Total obligations	$3,109,062	$3,109,615	$2,534,803

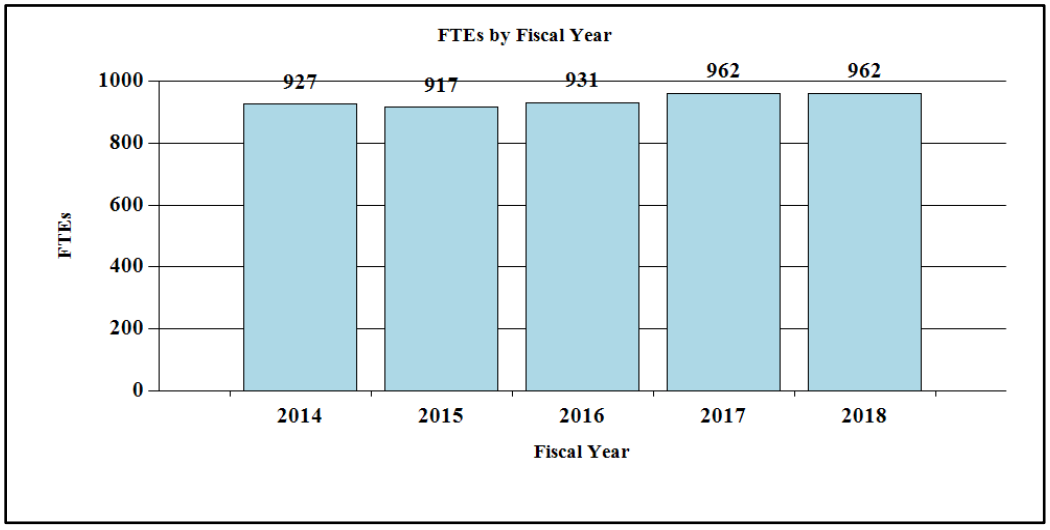
[1] Excludes the following amounts for reimbursable activities carried out by this account:

FY 2016 - $15,622 FY 2017 - $15,800 FY 2018 - $15,977

Fiscal Year 2018 Budget Graphs

History of Budget Authority and FTEs:





NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2017 Amount Authorized	FY 2017 Annualized CR	2018 Amount Authorized	FY 2018 President's Budget[1]
Research and Investigation	Section 301	42§241	Indefinite	$3,109,615,000	Indefinite	$2,534,803,000
National Heart, Lung, and Blood Institute	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$3,109,615,000		$2,534,803,000

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2008	$2,894,341,000	$2,965,775,000	$2,992,197,000	$2,974,900,000
Rescission				$51,972,000
Supplemental				$15,542,000
2009	$2,924,942,000	$3,025,500,000	$3,006,344,000	$3,015,689,000
Rescission				$0
2010	$3,050,356,000	$3,123,403,000	$3,066,827,000	$3,096,916,000
Rescission				$0
2011	$3,187,516,000		$3,182,524,000	$3,096,916,000
Rescission				$27,192,768
2012	$3,147,992,000	$3,147,992,000	$3,036,189,000	$3,084,851,000
Rescission				$5,830,368
2013	$3,076,067,000		$3,085,390,000	$3,079,020,632
Rescission				$6,158,041
Sequestration				($154,545,663)
2014	$3,098,508,000		$3,077,916,000	$2,988,605,000
Rescission				$0
2015	$2,987,685,000			$2,997,870,000
Rescission				$0
2016	$3,071,906,000	$3,035,062,000	$3,135,519,000	$3,115,538,000
Rescission				$0
2017[1]	$3,113,533,000	$3,190,474,000	$3,242,685,000	$3,115,538,000
Rescission				$5,923,000
2018	$2,534,803,000			

[1]Budget Estimate to Congress includes mandatory financing.

Justification of Budget Request

National Heart, Lung, and Blood Institute

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.
Budget Authority (BA):

	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
BA	$3,109,220,949	$3,109,615,000	$2,534,803,000	$574,812,000
FTE	931	962	962	0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

Over nearly 70 years, research supported by the National Heart, Lung, and Blood Institute (NHLBI) has led to life-saving interventions for people with cardiovascular diseases, pulmonary diseases, and blood disorders. Fundamental discovery science remains critical to this progress. Thanks to continuing discoveries regarding the mechanisms of disease, there are unprecedented opportunities to realize the promise of precision medicine, an approach that accounts for each person's unique biology and risk profile. With each research breakthrough, NHLBI recognizes the need to address challenges in bringing new therapies to patients and the necessity of a diverse and talented scientific workforce along the entire research spectrum, from early discovery to clinical implementation. In FY 2018 NHLBI will continue to translate basic research into new, more precisely tailored strategies to prevent and treat heart, lung, blood, and sleep disorders.

Supporting Fundamental Research to Understand Human Biology
About one-third of American adults are at risk of heart attack and stroke from high blood pressure, but many are able to control their risk through diet and medications. This vast array of interventions would not have been possible without sustained investments in basic research into how the cardiovascular system works in both health and disease. Nobel Prize-winning efforts to understand human physiology have revealed that the heart, kidney, liver, lung, and adrenal glands work together to produce various hormones that make up the renin-angiotensin-aldosterone system. Drugs targeting this system—which include angiotensin-converting enzyme (ACE) inhibitors, direct renin inhibitors, and angiotensin II receptor blockers—have since revolutionized treatment for hypertension and heart failure.

NHLBI continues to leverage these basic research findings to save lives. For example, the NHLBI-funded Systolic Blood Pressure Intervention Trial (SPRINT) recently showed that intensive blood pressure management, below a commonly recommended target, can reduce the risk of death from cardiovascular events by about 25 percent for people aged 50 and older, and by more than 30 percent for people 75 and older.[1] With an eye toward future health advances,

[1] http://jamanetwork.com/journals/jama/fullarticle/2524266

NHLBI also continues to invest in basic research. For example, NHLBI-funded investigators recently found that small molecules called microRNAs can influence blood pressure in mice and thus may be new targets for intervention.[2]

Understanding Disease to Develop New Approaches to Prevention and Treatment

Progress in data science and human genomics, the study of the entire set of our genes, is opening new avenues toward a future in which therapies will be precisely tailored to an individual's unique biology. The NHLBI Trans-Omics for Precision Medicine (TOPMed) program[3] supports the collection and analysis of whole-genome data from diverse populations in existing NHLBI-funded studies. By combining genomic data with environmental, clinical, and imaging data, TOPMed will explore the earliest points of transition from health to disease in conditions such as heart attack and asthma. These efforts will yield insights into gene-environment interactions that could serve as new therapeutic targets.

NHLBI also supports research to resolve the under-representation of minorities in genomic research, which has real-world consequences. For example, a recent NIH-funded study found that genetic testing for hypertrophic cardiomyopathy—an inherited heart condition—is more likely to produce a false positive diagnosis in African Americans than in whites.[4] Investigators with NHLBI's TOPMed program are working to address this issue through whole-genome studies across many different populations. As this effort grows, it will lead to powerful reference tools for identifying genetic risk factors and designing more accurate genetic tests for disease.

Bringing Effective Prevention and Treatment into Clinical Practice

To ensure that research discoveries translate into public health benefits, NHLBI has expanded its support for implementation science—the development and evaluation of methods to ensure that clinical research findings are adopted into healthcare practice. The Institute's implementation science programs are designed to support research through collaborative partnerships among investigators working in translational and clinical research, medical practitioners, patients and patient groups, and community-based organizations.

One such program seeks to transform care for patients with sickle cell disease (SCD), many of whom do not receive adequate treatment. Based on NHLBI-funded research, the drug hydroxyurea is recommended for pain in children with severe SCD.[5] It also reduces blood flow velocities in the brain, a key predictor of stroke in these patients.[6] Yet a recent study found that nearly one in five children hospitalized for complications of SCD did not receive hydroxyurea.[7] The NHLBI SCD Implementation Consortium seeks to bridge these gaps. In FY 2016, the program funded eight sites across the country, where investigators will work with community groups and care providers to develop new frameworks for SCD care across the life span.

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[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4567475
[3] https://www.nhlbi.nih.gov/research/resources/nhlbi-precision-medicine-initiative/topmed
[4] http://www.nejm.org/doi/full/10.1056/NEJMsa1507092
[5] http://jamanetwork.com/journals/jama/fullarticle/1902235
[6] http://www.sciencedirect.com/science/article/pii/S0140673615010417
[7] https://www.ncbi.nlm.nih.gov/pubmed/26797936

Sustaining a Collaborative and Diverse Research Community
In 2016, NHLBI released its Strategic Vision, which will guide the Institute's solicited research activities for the coming decade.[8] To develop the Vision, NHLBI launched an ambitious effort to engage a broad array of partners—including scientists, medical professionals, patients, patient advocates, and others. The Strategic Vision will evolve to address future opportunities that emerge from new discoveries and ongoing engagement between NHLBI and its partners.

One objective of the Strategic Vision is to sustain the nation's preeminence in biomedical research by investing in a new generation of scientists that reflects the nation's diversity and breadth of talent. To this end, NHLBI is pursuing innovative strategies to facilitate career development for early-stage investigators. For example, in FY 2016, NHLBI launched a unique Emerging Investigator Award (R35) mechanism that supports a research program, rather than a single project, to help turn early-stage investigators into scientific leaders. This seven-year award is intended to reduce the administrative burden of multiple grant submissions, and to provide a more nimble platform for supporting high-risk/high-reward research.

Overall Budget Policy**:** The FY 2018 President's Budget request is $2,534.803 million, a decrease of $574.812 million compared with the FY 2017 Annualized CR level. These reductions are distributed across all programmatic areas and basic, epidemlogy or clinical research.

Program Descriptions and Accomplishments

Cardiovascular Diseases: This program supports research on the causes, diagnosis, treatment, and prevention of cardiovascular disease (CVD), including coronary artery disease, myocardial infarction and ischemia, heart failure, arrhythmia, sudden cardiac death, congenital heart disease in adults and children, vascular dementia, cardiovascular disease complications of diabetes and obesity, and hypertension. The program's efforts span the full spectrum of basic, translational, and clinical research.

Since its beginnings, NHLBI has been at the forefront of efforts to identify biological mechanisms and interventions for CVD. One landmark effort is the Framingham Heart Study, which began in 1948 in Framingham, Massachusetts, and has identified several modifiable risk factors for CVD, including hypertension, cholesterol imbalance, smoking, lack of physical activity, and diabetes. More recently, the study has expanded to include genetic research, and has found genetic variants associated with hypertension[9] and heart failure.[10] Moreover, data from the original study cohort, their children, and grandchildren will be analyzed through the NHLBI TOPMed program to identify new risk factors and biomarkers related to heart, lung, blood, and sleep disorders.

[8] http://www.nhlbi.nih.gov/about/documents/strategic-vision
[9] http://www.nature.com/ng/journal/vaop/ncurrent/full/ng.3660.html
[10] http://journals.plos.org/plosgenetics/article?id=10.1371/journal.pgen.1006034

With growing recognition that CVD can have a profound and negative impact on cognitive health, Framingham investigators are also exploring whether CVD biomarkers can be used to predict cognitive decline. They recently reported that in adults aged 30-45, stiffening of the aorta (the body's main artery) is associated with signs of brain injury detectable by MRI.[11] Other NHLBI-funded studies are also exploring the relationship between CVD and cognitive health, including SPRINT Memory and Cognition IN Decreased Hypertension (SPRINT-MIND), which will examine whether intensive blood pressure management reduces the likelihood of dementia after age 50.

The Cardiovascular Diseases program also supports basic research to discover novel targets for therapy. For example, it has been known for decades that cells called macrophages help clear away atherosclerotic plaque, but the mechanisms controlling this process have been elusive. NHLBI investigators recently identified a protein inside plaque called CD47 that repels macrophages and thus allows plaque to accumulate.[12] In mouse models of atherosclerosis, injection of antibodies to block CD47 function reduced the formation of plaque. These findings implicate CD47 as a new target for potential therapies against atherosclerosis.

Program Portrait: Programs to Increase Diversity among Individuals Engaged in Health-Related Research (PRIDE)
FY 2017 Level: $2.294 million
FY 2018 Level: $3.136 million
Change: + $0.842 million

In order to realize continued improvements in the nation's health, the NHLBI Strategic Vision emphasizes the importance of continuing to nurture a scientific workforce that reflects the nation's diversity. Through a multi-pronged approach to diversify the biomedical workforce, NHLBI supports diversity supplements on existing grants and awards, training programs (T32) for institutions that promote diversity, as well as a focused Request for Applications for career development awards for individuals from diverse background (K01). However, the Institute recognizes the importance of dedicated efforts at every stage of the research pipeline to achieve the goal of a diverse biomedical workforce that represents the diversity of the U.S., poised to address the emerging scientific opportunities and challenges of today.

NHLBI's Programs to Increase Diversity among Individuals Engaged in Health-Related Research (PRIDE) initiative aims to broaden the demographic profile of biomedical research by enhancing the research skills of postdoctoral students and junior faculty from underrepresented backgrounds and/or with disabilities to support their scientific career advancement and successful competition for external research funding.[13] The PRIDE initiative supports summer institutes in which each scholar is paired with an experienced scientist with shared research interests. PRIDE emphasizes grant writing and other opportunities to build sustainable independent careers that meet the nation's future heart, lung, blood, and sleep disorder research needs. To date, PRIDE and its predecessor program have matriculated six cohorts inclusive of 204 scholars, of which 68 percent were female, 67 percent were African American, and 27 percent Hispanic or Latino.[14] Early outcomes from PRIDE and its predecessor program demonstrate increased publications, grants, promotion, and tenure rates of participants as well as attainment of important manuscript and grant skills.

[11] http://hyper.ahajournals.org/content/67/3/513.long
[12] http://www.nature.com/nature/journal/v536/n7614/full/nature18935.html
[13] https://www.nhlbi.nih.gov/research/training/PRIDE-research-programs
[14] TK Rice, et al. Mentored Training to Increase Diversity among Researchers in the Biomedical Sciences: The NHLBI Summer Institute Programs to Increase Diversity (SIPID) and the Programs to Increase Diversity among Individuals Engaged in Health-related Research (PRIDE). In preparation.

Lung diseases: This program supports research on the causes, diagnosis, treatment, and prevention of lung diseases. Research areas include asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, critical care and acute lung injury, sleep-disordered breathing, developmental biology and pediatric pulmonary diseases, immunology and fibrosis, lung cell and vascular biology, and pulmonary complications of AIDS and tuberculosis. The research portfolio is designed to support science that yields an integrated understanding at the molecular, cellular, and systems level to prevent and treat lung disease.

More than 15 million Americans have COPD, which causes inflammation of the lungs and a progressive decline in lung function. It is the third leading cause of death in the U.S., and kills more women than men each year.[15] NHLBI has a long history of innovative research in COPD. Although there is currently no cure, NHLBI-funded studies have shown that treatments such as anti-inflammatory steroid medications can slow disease progression for some patients. NHLBI-funded work also has shown that smoking is a powerful risk factor for COPD, and current studies are exploring genetic risk factors—with the expectation that COPD may exist as many, genetically definable subtypes, each with distinct treatment responses.

In one recent study of patients taking steroid medication for COPD, researchers found that the expression patterns of ~300 genes in the lungs (i.e., whether genes were turned on or off) could be used to distinguish responders vs. non-responders. To further explore genetic pathways in COPD, genomic data from people with the disease will be analyzed through the NHLBI TOPMed program. In parallel, NHLBI continues to support clinical trials to improve and personalize existing treatment approaches for COPD. For example, the Long-Term Oxygen Treatment Trial (LOTT) recently confirmed that, on average, supplemental oxygen is beneficial for severe COPD—but not for moderate cases—indicating a need for further research to improve outcomes for these patients.[16]

Given the significant impact of COPD on public health, NHLBI will continue to support research to understand its etiology, to develop improved diagnostic tools and treatments, and to empower people with COPD and their families to better manage the disease and its effects on daily life. In 2016, the Institute worked with other federal entities, patient advocacy groups, and other non-governmental organizations to develop a COPD National Action Plan.[17] Early in 2016, NHLBI convened a COPD Town Hall at which more than 200 attendees—including patients, caregivers, health professionals, industry, academic leaders, and federal partners—helped lay the groundwork for the plan. The plan was released for public comment in September 2016, and NHLBI expects to finalize it in early 2017.

[15] https://www.cdc.gov/copd/index.html
[16] http://www.nejm.org/doi/full/10.1056/NEJMoa1604344
[17] http://www.nhlbi.nih.gov/health/educational/copd/cnap/cnap.htm

Program Portrait: Improving Critical Care for Acute Respiratory Distress Syndrome

FY 2017 Level: $10.843 million
FY 2018 Level: $10.471 million
Change: -$ 0.372 million

Acute respiratory distress syndrome (ARDS) is a type of acute lung injury that severely reduces blood oxygen levels and the amount of oxygen delivered to the brain and body organs. Mortality for ARDS varies by age, with lower rates for children and young adults compared to older adults. Since it was founded in 1994, the NHLBI-funded ARDS Clinical Trial Network (ARDSNet) has enrolled over 5,000 patients in 10 controlled studies and one observational study. These studies have improved survival, informed best practices for treating patients with ARDS, optimized methods for ARDS clinical trials including the validation of new outcome measures, and collected biospecimens to support future ARDS research.[18]

While ARDSNet data suggest the overall mortality due to ARDS has declined from 40 to 25 percent over the last two decades, participants at an NHLBI-sponsored workshop have turned their eyes toward the significant challenges that remain—including the need for clinical trials on earlier treatment and prevention.[19] NHLBI hopes to meet this challenge in part through its funded Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network which consists of 12 clinical centers and one clinical coordinating center. From 2014-2021, PETAL will build on ARDSNet as it aims to test new treatments or approaches to improve clinical outcomes for patients at risk for or who already have ARDS.[20] As mortality declines, it will become increasingly important to study interventions that help improve the overall quality of life for patients who survive ARDS and live longer with its physical and mental complications, which include loss of muscle control and reduced cognitive ability. NHLBI is leading an effort to encourage high quality in-patient implementation science research that can help patients with ARDS. Implementation research can help develop critical care practices based on emerging data and assure that these best practices are widely adopted and used in critical care settings that frequently see ARDS patients.

Blood Diseases: This program supports research on the use of blood and blood components for transfusion and cellular therapeutics. It also is responsible for research on the causes, prevention, and treatment of nonmalignant blood diseases, including anemias, such as SCD and thalassemia; premalignant processes, such as myelodysplasia and myeloproliferative disorders; abnormalities of hemostasis and thrombosis, such as hemophilia; and immune dysfunction.

About five million Americans receive blood transfusions each year, which necessitates a robust and safe supply of donated blood. While blood transfusions save lives, they have the potential to transmit viruses such as HIV, Hepatitis, West Nile Virus, Dengue, and Zika. NHLBI's Recipient Epidemiology and Donor Evaluation (REDS)-III program supports comprehensive research to maintain and improve the safety and benefits of blood transfusion. The program supports research domestically and internationally, and therefore provides data on the risk of transfusion-transmission for a variety of infectious agents with distinct global distributions.

REDS-III currently supports several studies to examine the incidence of Zika, Dengue, and Chikungunya infections among blood donors and recipients. These studies are focused on populations in the U.S. (for Zika) and in South America (for all three viruses). Collectively, the studies also are investigating the symptoms and clinical outcomes associated with these viruses, and the risks of transmitting these viruses via blood. One study is investigating the clinical consequences of Chikungunya, Dengue, and Zika virus infection in patients with SCD in Brazil,

[18] http://www.ardsnet.org/index.shtml
[19] http://www.atsjournals.org/doi/full/10.1164/rccm.201001-0024WS
[20] http://petalnet.org/

with special attention to patients who receive regular transfusions. An animal study is examining the efficacy of novel methods to eliminate infectious Zika virus from donor blood. Together, these studies are expected to improve a variety of blood safety practices, including the screening and processing of donated blood.

Neutrophil extracellular traps (NETs) represent a growing area of research supported by the Blood Diseases program. NETs were discovered in 2004 as an immune defense against infection; they are fibers, mostly composed of DNA, that are released from white blood cells called neutrophils, and can "trap" and kill bacteria.[21] A 2010 study funded by NHLBI found that NETs can also act as a seed for blood clot formation, and thus contribute to deep vein thrombosis (clots that form in the legs and can travel to the lungs).[22] In 2015, NHLBI-funded researchers found that gut bacteria can stimulate aged, dysfunctional neutrophils to linger in the bloodstream and form NETs, which may in turn contribute to blood vessel inflammation in SCD.[23] Active NHLBI-funded projects are addressing the role of NETs in abdominal aortic aneurysm[24] and lupus.[25]

Program Portrait: Sickle Cell Disease in Sub-Saharan Africa Collaborative Consortium
FY 2017 Level: $1.485 million
FY 2018 Level: $1.427 million
Change: -$0.058 million

While NHLBI's SCD Implementation Consortium is funding research to improve care for U.S. adolescents and adults with Sickle Cell Disease, NHLBI is complementing this effort by funding global health research on Sickle Cell Disease in sub-Saharan Africa. NHLBI is funding efforts to bring rapid diagnostic testing to this region to reduce childhood mortality due to SCD and recently funded a Sickle Cell Disease in Sub-Saharan Africa Collaborative Consortium.[26] This Consortium and its data coordinating center will build the infrastructure for a future research network that will advance epidemiological, translational, and clinical studies of SCD in sub-Saharan African nations that lack the financial, human, and operational resources to pursue such investigations independently.

Studying SCD in sub-Saharan Africa will help advance the understanding of SCD and the ability to treat and perhaps cure SCD in the U.S. and globally. More than 75 percent of infants with SCD are born in sub-Saharan Africa. This high prevalence of SCD will enable robust epidemiologic and clinical studies that are otherwise difficult to pursue with American cohorts. Also, because SCD is most prevalent in Americans of African descent, data from future studies of the disease in specific African subpopulations may improve treatment and care for American patients who have a similar genetic background.

Intramural Research: Groundbreaking work in the NHLBI Division of Intramural Research has moved from physics to imaging advances to improved medical procedures for cardiovascular disease that are coming into routine use at the NIH Clinical Center, and are poised for adoption by other major research and medical centers.

[21] http://science.sciencemag.org/content/303/5663/1532.full
[22] http://www.pnas.org/content/107/36/15880.full
[23] http://www.nature.com/nature/journal/v525/n7570/full/nature15367.html
[24] https://projectreporter.nih.gov/project_info_description.cfm?aid=9111039
[25] https://projectreporter.nih.gov/project_info_description.cfm?aid=9050696
[26] http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-17-006.html

For example, NHLBI investigators have developed an improved, more precise method of catheter ablation, which is used to treat arrhythmia (an abnormal heartbeat). An arrhythmia originates in cardiac tissue where the heart's electrical system has become defective, and the goal of catheter ablation is to destroy this defective tissue. During the procedure, one or more catheters is inserted into a vein and guided into the heart to deliver a pulse of radio waves. The catheter can also be used diagnostically, to record and reproduce abnormal heart rhythms. In the conventional ablation procedure, X-ray imaging is used to guide the catheter. One disadvantage of this approach is that the patient is exposed to radiation; another is that the heart and other soft tissues can appear blurred on X-ray images. This makes it difficult to locate and target the source of the arrhythmia, and is a common reason for arrhythmia recurrence after treatment.

The NHLBI team developed a technique that uses magnetic resonance (MR) imaging to guide catheter placement in the heart. Recently, they showed that this technique— called interventional cardiovascular MR (iCMR)—was as successful as the X-ray procedure and faster for navigating certain pulmonary arteries (connecting the heart to the lungs). This is significant, as iCMR has other potential applications, including in angioplasty—the use of a balloon-catheter to widen narrow blood vessels. To date, more than 100 diagnostic iCMR procedures have been performed at NIH.[27]

Intramural researchers also have developed a new method of performing transcatheter aortic valve replacement (TAVR), a procedure widely used to treat stenosis of the heart's aortic valves. In TAVR, a catheter is used to deliver an artificial replacement valve to the heart. Typically, the catheter is fed into the femoral vein in the leg, then used to make a small hole in the vein, from which it is fed into an artery and toward the heart. This method is not always possible in patients with damaged or small femoral arteries, including many women and children. NHLBI investigators developed a procedure for inserting the catheter into the inferior vena cava, the vein that delivers de-oxygenated blood to the heart. In a recent study, the investigators successfully performed this transcaval access TAVR in 99 of 100 patients; in the patient where the procedure failed, the investigators performed TAVR through femoral access.[28]

Research Management and Support (RMS): RMS activities provide administrative, budgetary, logistical, and scientific support in the review, awarding, and monitoring of research grants and clinical trials, training awards, and research and development contracts. RMS activities also include strategic planning, trans-NHLBI coordination, and evaluation of the Institute's programs, as well as regulatory compliance, international coordination, interactions with other federal agencies and Congress, and dissemination of research findings to the public.

In ongoing efforts, NHLBI's scientific and administrative staff are working to maintain and improve stewardship of clinical trials funded by the Institute. Throughout NHLBI's history, clinical trials have contributed to significant advances in the diagnosis and treatment of heart, lung, blood, and sleep disorders. NHLBI works closely with its clinical research investigator community to design the highest quality studies possible, monitor indicators of success, and

[27] http://link.springer.com/article/10.1007%2Fs11886-015-0580-1
[28] http://www.sciencedirect.com/science/article/pii/S0735109716367699

make early course corrections when necessary. Though NHLBI engages in continuous quality improvement, in 2015, the Institute began a new initiative toward a more performance-based approach to funding and managing clinical trials. This approach requires investigators to submit comprehensive scientific and operational plans for proposed trials, and to specify timeframes and strategies for achieving key milestones in the launch and conduct of the trial. The milestones are intended to help NHLBI and the investigators ensure that trials are completed on time and on budget. In addition, support mechanisms for NHLBI clinical trials are being restructured to ensure more robust planning and set-up before a trial is funded.

Another focus area for the Institute is to optimize the inclusion of women in NHLBI-supported clinical trials, in order to improve understanding of sex as a biological variable. Through the Strategic Visioning process, academic roundtables, and other outreach efforts, NHLBI has engaged scientific, professional, and patient communities to address challenges to the full participation of women in clinical research, and to facilitate appropriate reporting of research outcomes by gender. One of the priorities identified through the Strategic Vision is to probe the risk factors and systemic mechanisms that determine sex-related differences in heart, lung, blood, and sleep health.

NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2016 Actual Civilian	FY 2016 Actual Military	FY 2016 Actual Total	FY 2017 Annualized CR Civilian	FY 2017 Annualized CR Military	FY 2017 Annualized CR Total	FY 2018 President's Budget Civilian	FY 2018 President's Budget Military	FY 2018 President's Budget Total
Center for Translation Research and Implementation Science									
Direct:	14	2	16	17	3	20	17	3	20
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	14	2	16	17	3	20	17	3	20
Division of Blood and Resources									
Direct:	33	-	33	34	-	34	34	-	34
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	33	-	33	34	-	34	34	-	34
Division of Cardiovascular Sciences									
Direct:	116	1	117	123	1	124	123	1	124
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	116	1	117	123	1	124	123	1	124
Division of Extramural Research Activities									
Direct:	93	-	93	91	-	91	91	-	91
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	93	-	93	91	-	91	91	-	91
Division of Intramural Research									
Direct:	433	7	440	450	9	459	450	9	459
Reimbursable:	38	1	39	38	1	39	38	1	39
Total:	471	8	479	488	10	498	488	10	498
Division of Lung Diseases									
Direct:	31	-	31	31	-	31	31	-	31
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	31	-	31	31	-	31	31	-	31
Office of the Director									
Direct:	137	1	138	140	-	140	140	-	140
Reimbursable:	23	1	24	23	1	24	23	1	24
Total:	160	2	162	163	1	164	163	1	164
Total	918	13	931	947	15	962	947	15	962
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2014	12.4
2015	12.5
2016	12.5
2017	12.6
2018	12.6

NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute

Detail of Positions[1]

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	2	2	2
Total, ES Salary	352,672	357,923	364,724
GM/GS-15	97	96	96
GM/GS-14	159	158	158
GM/GS-13	182	193	193
GS-12	85	79	79
GS-11	44	52	52
GS-10	0	0	0
GS-9	51	48	48
GS-8	12	10	10
GS-7	16	13	13
GS-6	4	3	3
GS-5	1	0	0
GS-4	2	0	0
GS-3	4	2	2
GS-2	1	1	1
GS-1	2	2	2
Subtotal	660	657	657
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	2	2	2
Director Grade	3	4	4
Senior Grade	3	5	5
Full Grade	3	4	4
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	12	16	16
Ungraded	282	287	287
Total permanent positions	663	663	663
Total positions, end of year	956	996	996
Total full-time equivalent (FTE) employment, end of year	931	962	962
Average ES Salary	176,336	178,962	182,362
Average GM/GS grade	12.5	12.6	12.6
Average GM/GS salary	107,571	109,615	111,752

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.