

# National Heart, Lung, and Blood Institute

CONGRESSIONAL JUSTIFICATION FY 2022

Department of Health and Human Services National Institutes of Health



# DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

#### National Heart, Lung, and Blood Institute (NHLBI)

| FY 2022 Budget Table of Contents                | Page No. |
|---|----------|
| Director's Overview                             | 3        |
| IC Fact Sheet                                   | 9        |
| Major Changes in Budget Request                 | 11       |
| Budget Mechanism Table                          | 13       |
| Appropriations Language                         | 14       |
| Summary of Changes                              | 15       |
| Budget Graphs                                   | 16       |
| Organization Chart                              | 17       |
| Budget Authority by Activity                    |          |
| Justification of Budget Request                 | 19       |
| Program Descriptions                            | 19       |
| Appropriations History                          | 29       |
| Authorizing Legislation                         | 30       |
| Amounts Available for Obligation                | 31       |
| Budget Authority by Object Class                | 32       |
| Salaries and Expenses                           | 33       |
| Detail of Full-Time Equivalent Employment (FTE) | 34       |
| Detail of Positions                             | 35       |

**Cover page:** The endothelial cells that line the inside of blood vessels are held tightly together by specialized proteins including actin (red) and cadherin (blue). Photo credit: Christopher V. Carman and Roberta Martinelli, Harvard Medical School, Boston, Mass.

#### **Director's Overview**

The need for research across the spectrum—from discovery science to disease epidemiology and clinical trials—has perhaps never been more critical to the Nation's health than it is right now. The National Heart, Lung, and Blood Institute (NHLBI) is committed to building on its legacy of excellence in research, training, and health education and outreach to reduce the burden of heart, lung, sleep, and blood disorders. By leveraging its established population-based studies, clinical trial networks, data science platforms, and other assets, NHLBI is at the vanguard of research to contain the COVID-19 pandemic and the long-term consequences of SARS-CoV-2 infection, as well as a concerning rise in maternal morbidity and mortality. In all these endeavors, the Institute is committed to ensuring that the research process and its advances reach underserved communities where the risk and prevalence of chronic disease is highest, toward improving the health of *all* Americans.



Dr. Gary H. Gibbons, Director

#### **Investing in Discovery to Develop Future Treatments and Cures**

Benjamin Franklin once said, "Investment in knowledge pays the best interest." That still rings true today. Investments in basic research fuel the knowledge and innovation that can bring forward new interventions, treatments, and even cures. For decades, NHLBI has supported research to understand the biology of the many cell types involved in blood flow. This includes red blood cells that carry oxygen throughout the body, platelets that come together to form clots and heal wounds, and endothelial cells that line the inside of blood vessels. Fundamental research has revealed a trove of sticky cell-surface proteins that regulate interaction among these cell types. One of these, P-selectin, has been eyed as a target of potential new therapies against metastatic cancer, as well as the blood clots that lead to heart attacked and stroke. In the early 2000s, NIH/NHLBI-funded researchers found that P-selectin contributes to abnormal blood flow in patients with sickle cell disease, creating masses of sickled red cells that can lead to episodes of severe pain or crisis. 1,2 With further support from NHLBI and industry, researchers ultimately developed an antibody that inhibits P-selectin, crizanlizumab, which is now approved for reducing sickle cell crises. 3

Remarkably, our understanding of platelet aggregation and blood clotting (coagulation) has proven useful in understanding the pathogenesis of COVID-19, as well as potential treatments. Researchers have noted that people with severe COVID-19 tend to have a high risk of blood clots, now called COVID-19-associated coagulopathy (CAC), which can lead to fatal blockages in the brain, heart, or lungs.<sup>4</sup> A robust armamentarium of anticoagulant drugs could be one of our best options for preventing severe illness and death from COVID-19.

<sup>&</sup>lt;sup>1</sup> pubmed.ncbi.nlm.nih.gov/11535535/

<sup>&</sup>lt;sup>2</sup> pubmed.ncbi.nlm.nih.gov/15280090/

<sup>&</sup>lt;sup>3</sup> pubmed.ncbi.nlm.nih.gov/27959701/

<sup>&</sup>lt;sup>4</sup> pubmed.ncbi.nlm.nih.gov/32840379/

#### Rapid Mobilization to Address Urgent Public Health Needs

Soon after COVID-19 emerged, it became clear that the disease has severe effects on the heart, lungs, blood, and blood vessels; and that people with underlying health conditions such as chronic lung disease, cardiovascular disease, obesity, and diabetes are at higher risk for severe outcomes from COVID-19. Bolstered by \$103.4 million in additional support from the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), NHLBI quickly developed a multi-pronged response strategy to address the high risk of COVID-19 in people with preexisting chronic conditions and to identify treatments that could slow or stop its punishing effects on the body. A key part of this strategy was to leverage existing assets, including clinical trial networks and community-based cohort studies, to conduct research at an unprecedented pace. The Institute took a similar approach in rapidly mobilizing to address an outbreak of lung injury and deaths related to vaping in 2019. (See box on p. 18.)

In August 2020, NHLBI launched the Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies (CONNECTS), <sup>5</sup> which brings together multiple existing clinical trial networks to quickly test therapies with the potential to slow or stop COVID-19 progression. As part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative, CONNECTS is conducting a series of clinical trials to evaluate the safety and effectiveness of anticoagulants (blood thinners) to treat adults with COVID-19. (See box on p. 23 for more about NHLBI's response to COVID-19.) Supported by funding provided to NIH through the Consolidated Appropriations Act of 2021, the NHLBI is also leading an initiative to address "Long COVID" and other unexplained symptoms that can persist or appear long after acute SARS-CoV-2 infection, known as post-acute sequelae of SARS-CoV-2 (PASC). The initiative seeks to understand the underlying biology of PASC and its clinical spectrum, and ultimately to identify effective means of treatment and prevention.

#### **Understanding and Reducing Health Disparities in COVID-19 and Chronic Disease**

In the United States, COVID-19 has taken its toll on almost every community. But some groups—especially African Americans, Hispanic/Latinos, and American Indian/Alaska Natives—have suffered more than others, with increased rates of infection, hospitalization, and deaths compared to whites. Again, building on its established history of engaging communities in research, NHLBI co-leads a trans-NIH effort with the National Institute of Minority Health and Health Disparities (NIMHD) called the Community Engagement Alliance (CEAL) Against COVID-19 Disparities. This initiative connects researchers to trusted leaders and organizations in communities hardest hit by COVID-19, helping them work together to address misinformation, increase the use of practices to prevent spread of the virus, and ensure that clinical trials include people in these communities, so that the treatments and vaccines developed will work for everyone.

The high toll of COVD-19 in communities of color stems in part from other health disparities, such as severe obesity, which is more than twice as prevalent in Black (13.0 percent) and

.

<sup>&</sup>lt;sup>5</sup> nhlbi-connects.org/

<sup>&</sup>lt;sup>6</sup> covid19community.nih.gov/

Hispanic (12.9 percent) adolescents than in Whites (4.9 percent).<sup>7</sup> Research increasingly shows that social determinants of health—conditions in the places where people live, learn, work, and play—have a role in these disparities.<sup>8</sup> For these reasons, NHLBI continues its long-standing support of cohort studies of minority and rural populations, such as the Jackson Heart Study (JHS) of cardiovascular health in African Americans. A new community engagement component of JHS is putting 20 years of the study's findings into action by turning traditional gathering places, like barbershops and churches, into health information hubs. NHLBI has broadened its reach and launched a new study to address the high burden of chronic disease in rural America. The Risk Underlying Rural Areas Longitudinal (RURAL) study will include 4,600 people ages 25-64 in 10 low-income counties in the South, to work toward understanding and reducing rural health disparities.<sup>9</sup>

We believe that research to address health disparities is more effective when researchers work in partnership with the impacted communities. In keeping with that principle, a new initiative—Disparities Elimination through Coordinated Interventions to Prevent and Control Heart Disease Risk (DECIPHER)—will work to address disparities through community-based participatory research. For sickle cell disease (SCD), an inherited blood disorder that primarily affects African Americans, patients are working with researchers through the SCD Implementation Consortium to address challenges in providing evidence-based care for SCD, and they are playing an integral part in the Cure Sickle Cell Initiative, which aims to bring gene-based therapies for SCD into clinical trials in the next several years.

#### Improving the Heart Health of Young Women and Mothers

Another tragic health disparity that requires rigorous scientific study is the high rate of maternal morbidity and mortality in the United States, especially among women of color, who are two to four times more likely to die from a pregnancy complication than White women. 10 Cardiovascular disease is the leading cause of pregnancy-related death, and an increasing number of young American women have one or more cardiovascular risk factors—such as obesity, sleep apnea, or high blood pressure. A recent analysis looking at blood pressure trajectories over decades found that in women, blood pressure elevation occurs earlier and progresses more rapidly throughout life, compared to men. 11 For these reasons, addressing maternal morbidity and mortality will require a life-course approach that focuses on improving women's heart health before, during, and after reproductive age.

NHLBI supports a spectrum of mechanistic and clinical studies to understand the impact of sex as a biological variable and to improve women's heart health across the lifespan. For example, the Chronic Hypertension and Pregnancy (CHAP) trial is examining the safety and effectiveness of using medication to treat mild hypertension in pregnancy, which is typically deferred for severe hypertension. <sup>12</sup> Enrollment of 2,400 women of diverse race and ethnicity from 62 sites across the United States is nearly complete and study results are expected by the end of 2021.

<sup>&</sup>lt;sup>7</sup> pubmed.ncbi.nlm.nih.gov/32857101/

<sup>&</sup>lt;sup>8</sup> www.cdc.gov/socialdeterminants/index.htm

<sup>&</sup>lt;sup>9</sup> www.theruralstudy.org/

<sup>&</sup>lt;sup>10</sup> www.cdc.gov/reproductivehealth/maternalin fanthealth/pregnancy-relatedmortality.htm

<sup>&</sup>lt;sup>11</sup> pubmed.ncbi.nlm.nih.gov/31940010/

<sup>&</sup>lt;sup>12</sup> clinicaltrials.gov/ct2/show/NCT02299414

Other research has shown that sleep disorders during pregnancy can adversely impact maternal and child health. For example, a study of 1.4 million maternal and newborn records found that children born to mothers with sleep apnea during pregnancy were more likely to have birth defects, be admitted to neonatal ICU, or require resuscitation at birth. A trial funded in part by the NHLBI is now investigating whether treating sleep apnea among pregnant women can improve outcomes for mother and child.

#### Making Data Science More Accessible and Training the Next Generation

With recent funding increases, NHLBI has been able to build one of the world's largest and most ethnically diverse collections of health-related data from research volunteers, including wholegenome sequencing data (a person's complete set of DNA). NHLBI's Trans-Omics for Precision Medicine (TOPMed) program has amassed nearly four petabytes of de-identified genomic, clinical, imaging, and environmental data from more than 161,000 participants in 80 diverse population-based studies, including NHLBI's landmark Framingham Heart Study, the Jackson Heart Study, and the Hispanic Community Health Study/Study of Latinos. These data are available through a secure cloud-based platform called the BioData Catalyst, which has tools for analyzing large datasets, and sharing results in real-time. The BioData Catalyst provides a virtual collaborative workspace that makes TOPMed data findable, accessible, interoperable, and reusable (FAIR) to all qualified researchers, the vast majority of whom lack their own data science resources.

The BioData Catalyst is also building a community of practice that will help train the next generation of data scientists. In 2019 and 2020, the NHLBI funded early-career investigators across the country as part of a new BioData Catalyst Fellows program. <sup>15</sup> One fellow with a background in astrophysics found that her true passion was grappling with the complexities of massive datasets; she is one of more than 30 uniquely skilled individuals who are exploring and refining this new data ecosystem. NHLBI expects to fund additional fellows and is supporting other innovative programs, such as Challenge competitions, to train early-stage investigators and leverage their talents to support the NHLBI mission. For example, many data scientists and early-stage investigators competed in the Big Data Heart Failure Challenge launched in 2020 and helped bring new ideas forward to improve management of heart failure, a disorder that affects about 6.5 million Americans. In addition, a new Hope for Sickle Cell Challenge is intended to build awareness about sickle cell disease, while creating opportunities for college and graduate students to be mentored in community-based team research.

NHLBI will continue to be dedicated and accountable in its mission to improve diagnosis, treatment, and prevention of heart, lung, blood, and sleep disorders, including emergent public health threats such as COVID-19. It is critical for these efforts to focus on vulnerable and underserved populations—including racial/ethnic minorities and women—and to be carried out in partnership with patients, professional societies, foundations, federal and state agencies, and the Nation's brightest scientific talent.

<sup>&</sup>lt;sup>13</sup> pubmed.ncbi.nlm.nih.gov/31981755/

<sup>&</sup>lt;sup>14</sup> clinica ltria ls.gov/ct2/show/NCT02086448

<sup>&</sup>lt;sup>15</sup> biodatacatalyst.nhlbi.nih.gov/fellows/cohort1

#### Overall Budget Policy:

The FY 2022 President's Budget request is \$3,845.7 million, an increase of \$181.0 million or 4.9 percent compared with the FY 2021 Enacted level. Included in this amount is \$30.0 million for the CEAL initiative, which will connect researchers to trusted leaders and organizations in communities hardest hit by COVID-19, helping them work together to ensure that the treatments and vaccines developed will work for everyone. In addition, the request includes \$50.0 million for health disparities research, including DECIPHeR and other initiatives to address health disparities. Increases are distributed across all programmatic, basic, epidemiologic, translation, and clinical research areas.



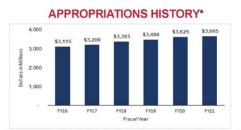






## **ABOUT THE NHLBI**

- The NHLBI is the nation's leader in supporting research and training on the prevention and treatment of heart, lung, blood, and sleep disorders.
- We were established in 1948 to address rising rates of cardiovascular disease – which includes heart disease and stroke and has been the nation's leading cause of death for 100 years.
- Our mission has expanded to lead NIH research efforts in lung diseases, including asthma and chronic obstructive pulmonary disease (COPD).
- We lead research on blood transfusion and blood diseases, such as sickle cell disease.
- In 1993, we became the home for the National Center on Sleep Disorders Research (NCSDR), which coordinates NIH programs related to sleep biology and disorders.
- The NHLBI's research advances scientific knowledge, improves public health and saves lives.



\*In FY20, NHLBI received \$103 million in supplemental appropriations through the CARES Act (not shown). The FY22 President's budget request is \$3,846 million.

Gary H. Gibbons, M.D., is director of the National Heart, Lung, and Blood Institute (NHLBI), the third largest institute at NIH. He received his M.D. from Harvard Medical School and has served on the faculty at Harvard, Stanford University, and the Morehouse School of Medicine in Atlanta.

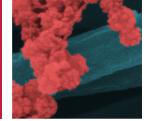
| Facts and Figures <sub>**</sub> |       |  |  |  |  |
|---------------------------------|-------|--|--|--|--|
| FTEs                            | 817   |  |  |  |  |
| Awards                          | 968   |  |  |  |  |
| Pls                             | 1,211 |  |  |  |  |
| ESI Success Rates***            | 30.2% |  |  |  |  |
| K Award Success Rates***        | 38.6% |  |  |  |  |

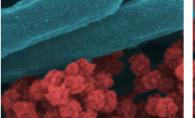
### **Current Major Initiatives**

- The NHLBI supports the Trans-Omics for Precision Medicine (TOPMed) program, which has collected whole genome sequences from 155,000+ participants in NHLBI cohort studies who represent many different races, ethnicities, and geographic areas. TOPMed also includes clinical and environmental data and will help researchers decipher the complex mechanisms of chronic heart, lung, blood, and sleep disorders.
- The NHLBI's new BioData Catalyst is a data science platform where researchers can collaborate and innovate. It provides researchers with tools to access, share, and analyze large-scale datasets, including TOPMed data, that they would not be able to collect or maintain on their own.
- The NHLBI supports research to reduce maternal morbidity and mortality, especially among African American and American Indian/ Alaska Native women, who are at
- higher risk than white women. The NHLBI's approach takes into account women's health across their lifespan before, during, and after their reproductive years.
- Because COVID-19 impacts heart, lung, and blood health, the NHLBI has a multi-pronged strategy to address the pandemic, including clinical trials to identify new therapies and population-based studies to examine outcomes, as well as risk and protective factors.

<sup>\*\*</sup> FTEs, awards, and extramural principal investigators are FY20 data. Awards = non-competing research project grant awards.
\*\*\* These success rates were averaged over 3 years (FY18, 19, 20) and calculated as (# awards/# of percentiled applications x 100). For more about percentiles, see <a href="https://grants.nih.gov/grants/peer-review.htm#Summary">https://grants.nih.gov/grants.nih.gov/grants/peer-review.htm#Summary</a>.









A highly magnified image of SARS-CoV-2 virions (red) produced by human airway epithelial cells in the lungs. Credit: Camille Ehre, Ph.D., University of North Carolina School of Medicine.

## Accomplishments in...

#### **Heart Health**

- For more than 70 years, the Framingham Heart Study (FHS) has uncovered risk factors and prevention strategies for heart disease, and is now examining links between heart and brain health.
- The SPRINT trial found that intensive blood pressure treatment can reduce the risk of death from cardiovascular disease among people over age 50. These findings helped change the 2017 national hypertension guidelines.
- An NHLBI-funded study shows the power of leveraging community norms to bring proven interventions to high-risk communities. Blood pressure screening at barbershops helped reduce high blood pressure among African American men in the study.
- The Bench to Bassinet Program supports research that has helped many children with congenital heart disease (CHD) thrive. It has amassed genomic data on 10,000+ patients and is being leveraged to conduct a five-year study on multisystem inflammatory syndrome in children (MIS-C), a rare condition affecting some children with COVID-19.

#### **Lung and Sleep Health**

- Based on findings that unique types of asthma require unique therapies, the Precision Interventions for Severe and/or Exacerbation-Prone Asthma (PrecISE) Network is developing precision medicine approaches for severe asthma.
- In collaboration with federal and nonfederal partners, the NHLBI developed the COPD National Action Plan, which is guiding efforts to reduce the burden of COPD, especially in rural and underserved communities.
- NHLBI-funded research in mice has found that chronic disturbed sleep can disrupt the production of a key

- hormone that reduces inflammation, which can lead to an increased risk for atherosclerosis.
- Researchers supported by NCSDR discovered the genes and cellular pathways that regulate the **body's internal clock**, earning them the 2017 Nobel Prize in medicine.

#### **Blood Health**

- The Cure Sickle Cell Initiative is working to bring new gene-based therapies into clinical trials, and a collaboration with the Bill & Melinda Gates Foundation will help bring these cures to low-resource settings.
- The Recipient Epidemiology and Donor Evaluation Study (REDS), first launched 30+ years ago to help keep the blood supply safe from HIV, is now expanding the reach of antibody tests for COVID-19.
- For people with hemophilia, a rare genetic disorder that can cause severe bleeding, NHLBI-funded research helped develop factor replacement therapy — the infusion of clotting proteins into the blood.

#### **Health Disparities**

- Modeled after FHS, the Jackson Heart Study and Strong Heart Study are shedding light on heart disease risk in African Americans and American Indians, respectively.
- The newly established RURAL study will focus on the lung and heart health of people living in rural counties of the Southeastern United States.
- The Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk (DECIPHER) program is studying how to move evidence-based interventions into communities where the burden of chronic disease is high.

#### **RESPONDING TO COVID-19**

The NHLBI established the Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies (CONNECTS) to test therapies that may slow or stop COVID-19 progression. By leveraging its diverse population studies, the NHLBI is examining factors that affect the risk of severe acute illness from SARS-CoV-2 infection. The Institute also has taken a leadership role in:

- The NIH Community Engagement Alliance (CEAL)
   Against COVID-19 Disparities, which aims to
- reduce the impact of COVID-19 on the hardest hit communities by providing accurate, timely information about COVID-19 research and preventive measures, including vaccines.
- An initiative launched in February 2021 to address "Long COVID" and other unexplained symptoms that can persist or appear long after acute SARS-CoV-2 infection, known as post-acute sequelae of SARS-CoV-2 (PASC).

#### Major Changes in the Fiscal Year 2022 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanisms and activity detail; and these highlights may not sum to the total change for the FY 2022 budget request for the NHLBI, which is \$3,845.7 million, an increase of \$181.0 million from the FY 2021 Enacted level. In FY 2022, the overall increase of 4.9 percent is distributed across multiple programmatic areas including basic, translational, and clinical research. NHLBI is committed to the continuous support for key strategic priorities along with other scientific areas of the Institute's research portfolio. Within the FY 2022 request level, NHLBI will pursue its highest research priorities through strategic investments and careful stewardship of the appropriated funds.

#### Research Project Grants (RPGs) (\$127.7 million; total \$2,661.2 million):

NHLBI will increase total funding for RPGs by 5.0 percent in FY 2022, resulting in funding 1,013 competing RPGs, approximately 2,844 noncompeting RPG awards, and 193 awards to small businesses to stimulate research technology.

#### Research Centers (-\$3.0 million; total \$17.3 million):

A shift in the receipt of research applications that are normally supported under this mechanism to other Program Announcements and/or Funding Opportunity Announcements for research projects will reduce funding requirements in this mechanism and increase other research mechanisms.

#### Other Research (\$24.0 million; total \$287.2 million):

NHLBI will increase funding for Other Research by 9.1 percent, which is a \$24.0 million increase compared to the FY 2021 Enacted level. The increase will support major initiatives and is distributed across all programmatic areas and basic, translational or clinical research. The CEAL initiative is a large part of the increase which targets community engagement in response to COVID-19.

#### Research and Development (R&D) Contracts (\$18.4 million; total \$371.2 million):

NHLBI will increase funding for Research and Development Contracts by 5.2 percent, which is a \$18.4 million increase compared to the FY 2021 Enacted level of \$352.8 million. These increases are distributed across all programmatic areas and basic, translational or clinical research to continue stimulating research and development focused on strategic priorities and programmatic goals.

#### Intramural Research (IR) (\$6.9 million; total \$237.4 million):

NHLBI will increase funding for Intramural Research by 3.0 percent, which is a \$6.9 million increase compared to the FY 2021 Enacted level of \$230.5 million. These increases are distributed across scientific and clinical research that leads to better understanding of biology and clinical pathology.

#### Research Management and Support (RMS) (\$4.3 million; total \$147.2 million):

NHLBI will increase funding for Intramural Research by 3.0 percent, which is a \$4.3 million increase compared to the FY 2021 Enacted level of \$142.9 million. These increases are distributed across all programmatic areas of RMS.

#### Budget Mechanism - Total<sup>1</sup>

| MECHANISM                                 | MECHANISM FY 2020 Final FY 2021 Enacted |             | FY 2022 P    | resident's Budget | FY 2022<br>+/-<br>FY 2021 Enacted |             |              |           |
|---|---|-------------|--------------|-------------------|-----------------------------------|-------------|--------------|-----------|
|   | No.                                     | Amount      | No.          | Amount            | No.                               | Amount      | No.          | Amount    |
|   |   |             |              |                   |                                   |             |              |           |
| Research Projects: Noncompeting           | 2,809                                   | \$1,781,079 | 2,821        | \$1,797,063       | 2,844                             | \$1,894,505 | 23           | \$97,442  |
| Administrative Supplements                | (140)                                   | 21,470      | (105)        | 15,974            | (106)                             | 14,500      | (1)          | -1,474    |
| Competing:                                | (140)                                   | 21,470      | (103)        | 13,974            | (100)                             | 14,300      | (1)          | -1,4/4    |
| Renewal                                   | 140                                     | 83,735      | 143          | 85,374            | 140                               | 87,764      | -3           | 2,390     |
| New                                       | 828                                     | 515,482     | 834          | 525,571           | 873                               | 550,287     | 39           | 24,716    |
| Supplements                               | 020                                     | 313,462     | 0.54         | 323,371           | 0/3                               | 330,287     | 0            | 24,/10    |
| Subtotal, Competing                       | 968                                     | \$599,217   | 977          | \$610.945         | 1.013                             | \$638.051   | 36           | \$27,106  |
| Subtotal, RPGs                            | 3,777                                   | \$2,401,766 | 3,798        | \$2,423,982       | 3,857                             | \$2,547,056 | 59           | \$123,074 |
| SBIR/STTR                                 | 187                                     | 109,591     | 186          | 109,529           | 193                               | 114,151     | 7            | 4,622     |
| Research Project Grants                   | 3,964                                   | \$2,511,356 | 3,984        | \$2,533,511       | 4,050                             | \$2,661,207 | 66           | \$127,697 |
| Research Floject Grants                   | 3,704                                   | \$2,311,330 | 3,764        | \$2,555,511       | 4,030                             | \$2,001,207 | 00           | \$127,077 |
| Research Centers:                         |   |             |              |                   |                                   |             | 1            |           |
| Specialized/Comprehensive                 | 5                                       | \$15,011    | 10           | \$19,261          | 10                                | \$16,886    | 0            | -\$2,374  |
| Clinical Research                         | 0                                       | 015,011     | 0            | 015,201           | 0                                 | 0           | 0            | 02,57     |
| Biotechnology                             | 0                                       | 806         | 0            | 642               | 0                                 | 0           | 0            | -642      |
| Comparative Medicine                      | 0                                       | 455         | 0            | 455               | 0                                 | 455         | 0            | 0.2       |
| Research Centers in Minority Institutions | 0                                       | 0           | 0            | 0                 | 0                                 | 0           | 0            | 0         |
| Research Centers                          | 5                                       | \$16,271    | 10           | \$20,358          | 10                                | \$17,341    | 0            | -\$3,017  |
|   |   |             |              | ,                 |                                   | ,           |              |           |
| Other Research:                           |   |             |              |                   |                                   |             |              |           |
| Research Careers                          | 801                                     | \$141,928   | 779          | \$139,820         | 763                               | \$140,853   | -16          | \$1,033   |
| Cancer Education                          | 0                                       | 0           | 0            | 0                 | 0                                 | 0           | 0            | 0         |
| Cooperative Clinical Research             | 39                                      | 12,847      | 39           | 10,534            | 39                                | 10,268      | 0            | -267      |
| Biomedical Research Support               | 0                                       | 0           | 0            | 0                 | 0                                 | 0           | 0            | 0         |
| Minority Biomedical Research Support      | 0                                       | 0           | 0            | 0                 | 0                                 | 0           | 0            | 0         |
| Other                                     | 152                                     | 108,298     | 152          | 112,862           | 166                               | 136,078     | 14           | 23,216    |
| Other Research                            | 992                                     | \$263,073   | 970          | \$263,216         | 968                               | \$287,199   | -2           | \$23,983  |
| Total Research Grants                     | 4,961                                   | \$2,790,701 | 4,964        | \$2,817,085       | 5,028                             | \$2,965,748 | 64           | \$148,663 |
|   |   |             |              |                   |                                   |             |              |           |
| Ruth L Kirschstein Training Awards:       | <u>FTTPs</u>                            |             | <u>FTTPs</u> |                   | <u>FTTPs</u>                      |             | <u>FTTPs</u> |           |
| Individual Awards                         | 519                                     | \$24,822    | 521          | \$25,742          | 523                               | \$26,368    | 2            | \$626     |
| Institutional Awards                      | 1,500                                   | 94,628      | 1,538        | 95,647            | 1,538                             | 97,766      | 0            | 2,119     |
| Total Research Training                   | 2,019                                   | \$119,450   | 2,059        | \$121,389         | 2,061                             | \$124,134   | 2            | \$2,745   |
|   |   |             |              |                   |                                   |             |              |           |
| Research & Develop. Contracts             | 566                                     | \$347,093   | 577          | \$352,808         | 596                               | \$371,175   | 19           | \$18,367  |
| (SBIR/STTR) (non-add)                     | (8)                                     | (11,090)    | (7)          | (10,000)          | (5)                               | (7,500)     | (-2)         | (-2,500)  |
|   |   |             | ,            |                   |                                   | ***         | ]            |           |
| Intramural Research                       | 409                                     | 226,275     | 467          | 230,503           | 482                               | 237,418     | 15           | 6,915     |
| Res. Management & Support                 | 408                                     | 141,740     | 495          | 142,918           | 480                               | 147,206     | -15          | 4,288     |
| SBIR Admin. (non-add)                     | (0)                                     | (581)       | (0)          | (650)             | (0)                               | (300)       | (0)          | (-350)    |
| Construction                              |   | 0           |              | 0                 |                                   | ام          | 1            | (         |
| Buildings and Facilities                  |   | ő           |              | ő                 |                                   | ٥           | 1            | 0         |
| Total, NHLBI                              | 817                                     | \$3,625,258 | 962          | \$3,664,703       | 962                               | \$3,845,681 | 0            | \$180,978 |

<sup>&</sup>lt;sup>1</sup> All items in italics and brackets are non-add entries.

#### NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

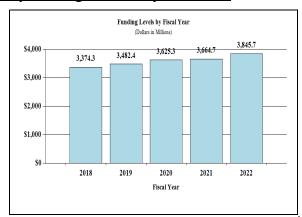
For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, [\$3,664,811,000]\$3,845,681,000.

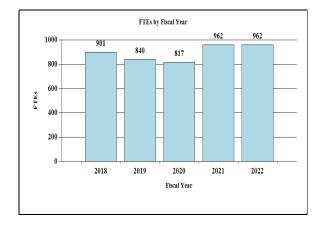
#### Summary of Changes

| FY 2021 Enacted<br>FY 2022 President's Budget                                      | -            |                    |              | \$3,664,703<br>\$3,845,681 | 1           |                               |
|--|--------------|--------------------|--------------|----------------------------|-------------|-------------------------------|
| Net change   |              |                    |              | \$180,978                  | 1           |                               |
| . ceremings  | FY2          | 2021 Enacted       | FY 2022      | President's Budget         | Built-In Cl | nange from FY 2021<br>Enacted |
| CHANGES  | FTEs         | Budget Authority   | FTEs         | Budget Authority           | FTEs        | Budget Authority              |
| A. Built-in:   |              |                    |              |                            |             |                               |
| 1. Intramural Research:  |              |                    |              |                            |             |                               |
| <ul> <li>a. Annualization of January 2021 pay increase &amp; benefits</li> </ul>   |              | \$91,667           |              | \$94,408                   |             | \$800                         |
| b. January FY 2022 pay increase & benefits   |              | 91,667             |              | 94,408                     | 1           | 3,406                         |
| c. Paid days adjustment  |              | 91,667             |              | 94,408                     |             | -348                          |
| d. Differences attributable to change in FTE                                       |              | 91,667             |              | 94,408                     |             | 3,056                         |
| e. Payment for centrally furnished services  |              | 31,046             |              | 32,598                     |             | 1,552                         |
| f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs | <b>├</b>     | 107,790            |              | 110,411                    |             | -1,550                        |
| Subtotal   |              |                    |              |                            |             | \$6,915                       |
| 2. Research Management and Support:  |              |                    |              |                            |             |                               |
| Annualization of January 2021 pay increase & benefits                              |              | \$69,436           |              | \$71,550                   | 1           | \$598                         |
| b. January FY 2022 pay increase & benefits   |              | 69,436             |              | 71,550                     |             | 2,648                         |
| c. Paid days adjustment  |              | 69,436             |              | 71,550                     |             | -264                          |
| d. Differences attributable to change in FTE                                       |              | 69,436             |              | 71,550                     |             | -4,208                        |
| e. Payment for centrally furnished services  |              | 3,562              |              | 3,740                      |             | 178                           |
| f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs | <b>↓</b>     | 69,920             |              | 71,915                     |             | 4,902                         |
| Subtotal   |              |                    |              |                            |             | \$3,853                       |
| Subtotal, Built-in   |              |                    |              |                            |             | \$10,769                      |
|  | FY2          | 2021 Enacted       | FY 2022      | President's Budget         |             | Change from FY<br>21 Enacted  |
| CHANGES  | No.          | Amount             | No.          | Amount                     | No.         | Amount                        |
| B. Program:  |              |                    |              |                            |             |                               |
| 1. Research Project Grants:  |              |                    |              |                            |             |                               |
| a. Noncompeting  | 2,821<br>977 | \$1,813,037        | 2,844        | \$1,909,005                |             | \$95,968                      |
| b. Competing c. SBIR/STTR  | 186          | 610,945<br>109,529 | 1,013<br>193 | 638,051                    | 36<br>7     | 27,106                        |
| C. SBIR/STIR Subtotal, RPGs  | 3,984        | \$2,533,511        | 4,050        | 114,151<br>\$2,661,207     |             | 4,622<br>\$127,697            |
|  |              |                    |              |                            |             | ·                             |
| 2. Research Centers  | 10           | \$20,358           | 10           | \$17,341                   | 0           | -\$3,017                      |
| 3. Other Research  | 970          | 263,216            | 968          | 287,199                    | -2          | 23,983                        |
| 4. Research Training   | 2,059        | 121,389            | 2,061        | 124,134                    | 2           | 2,745                         |
| Research and development contracts   | 577          | 352,808            | 596          | 371,175                    | 19          | 18,367                        |
| Subtotal, Extramural   |              | \$3,291,282        |              | \$3,461,057                |             | \$169,775                     |
|  | FTEs         |                    | FTEs         |                            | FTEs        | ·                             |
| 6. Intramural Research   | 467          | \$230,503          | 482          | \$237,418                  |             | \$0                           |
| 7. Research Management and Support   | 495          | 142,918            | 480          | 147,206                    | -15         | 434                           |
| 8. Construction  |              | 0                  |              | 0                          |             | 0                             |
| Buildings and Facilities   |              | 0                  |              | 0                          |             | 0                             |
| Subtotal, Program  | 962          | \$3,664,703        | 962          | \$3,845,681                | 0           | \$170,209                     |
|  |              |                    |              |                            |             |                               |

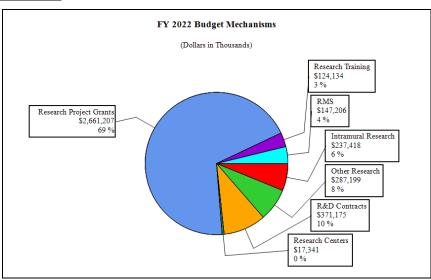
#### Fiscal Year 2020 Budget Graphs

#### History of Budget Authority and FTEs:

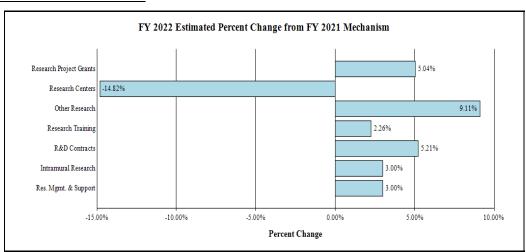




#### Distribution by Mechanism:

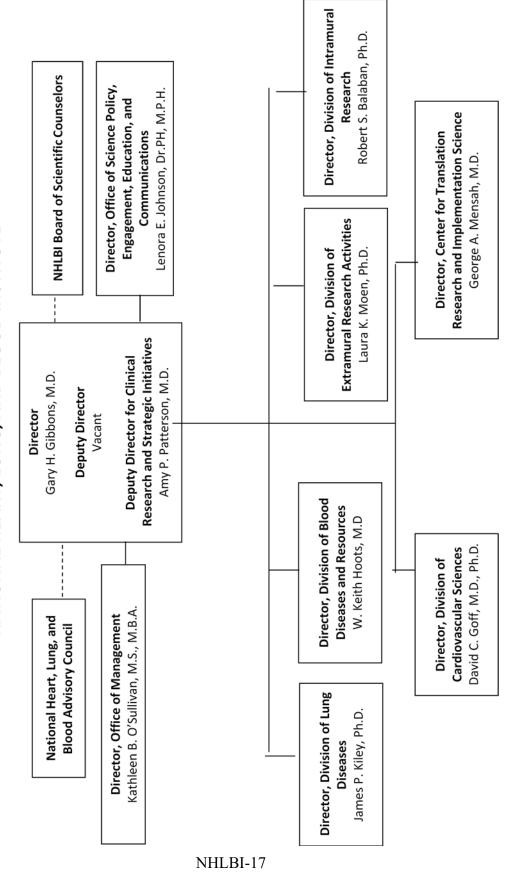


#### Change by Selected Mechanisms:



NHLBI-16

# NATIONAL INSTITUTES OF HEALTH NATIONAL HEART, LUNG, AND BLOOD INSTITUTE



# Budget Authority by Activity<sup>1</sup> (Dollars in Thousands)

|   | FY  | 2020 Final  | FY 2 | 021 Enacted |     | 22 President's<br>Budget |     | Y 2022<br>+/-<br>021 Enacted |
|---|-----|-------------|------|-------------|-----|--------------------------|-----|------------------------------|
| Extramural Research                             | FTE | Amount      | FTE  | Amount      | FTE | Amount                   | FTE | Amount                       |
| <u>Detail</u>                                   |     |             |      |             |     |                          |     |                              |
| Center for Translation, Implementation Sciences |     | \$50,973    |      | \$54,506    |     | \$84,163                 |     | \$29,657                     |
| Heart and Vascular Diseases                     |     | 1,951,800   |      | 1,969,197   |     | 2,043,930                |     | 74,733                       |
| Lung Diseases                                   |     | 785,516     |      | 793,724     |     | 834,667                  |     | 40,943                       |
| Blood Diseases and Resources                    |     | 468,954     |      | 473,855     |     | 498,298                  |     | 24,443                       |
| Subtotal, Extramural                            |     | \$3,257,243 |      | \$3,291,282 |     | \$3,461,057              |     | \$169,775                    |
| Intramural Research                             | 409 | \$226,275   | 467  | \$230,503   | 482 | \$237,418                | 15  | \$6,915                      |
| Research Management & Support                   | 408 | \$141,740   | 495  | \$142,918   | 480 | \$147,206                | -15 | \$4,288                      |
| TOTAL   | 817 | \$3,625,258 | 962  | \$3,664,703 | 962 | \$3,845,681              | 0   | \$180,978                    |

<sup>&</sup>lt;sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

#### **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 2021         | FY 2022            | FY 2022 +/-   |
|-----|-----------------|-----------------|--------------------|---------------|
|     | FY 2020 Final   | Enacted         | President's Budget | FY 2021       |
| BA  | \$3,625,258,000 | \$3,664,703,000 | \$3,845,681,000    | \$180,978,000 |
| FTE | 817             | 962             | 962                | 0             |

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

#### **Program Descriptions and Accomplishments**

Cardiovascular Diseases: The cardiovascular disease (CVD) program provides leadership and supports basic, clinical, population, and health services research on the causes, prevention, and treatment of cardiovascular diseases, including heart attack and heart failure, high blood pressure, stroke, arrhythmias, adult and pediatric congenital heart disease, cardiovascular complications of diabetes and obesity, and other CVDs. It also offers research training and career development opportunities and supports the development of innovative technologies.

This program is committed to promoting heart health across the lifespan and reducing the burden of CVD, which is the number one cause of death for men and women in the United States—about one of every three deaths in 2017. As part of this commitment, the program supports clinical trial networks that test interventions, devices, and procedures to improve treatment of heart and vascular diseases. As one example, for decades, there has been uncertainty about how to treat the most deadly and common type of heart disease—ischemic (or coronary) heart disease—in which the arteries become blocked and cannot pump enough blood to the heart. The NHLBI's International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) was designed to compare two common approaches for managing ischemic heart disease. In this study of over 5,000 patients, about half were treated with an invasive approach that included stenting, bypass surgery, and medications, while the other half were treated with lifestyle changes and medications but not surgery. The study found that both approaches produced similar outcomes after three years of follow-up. However, the invasive

approach offered better symptom relief and quality of life for patients with chest pain. 16,17 These results will help inform decisions about the best treatment options for each patient.

In 2019, NHLBI renewed its commitment to the Cardiothoracic Surgical Trials Network (CTSN), which brings together scientists and surgeons at medical sites across the country to move research from the proof-of-concept stage into clinical trials. A new phase 3 trial will examine how to manage patients after coronary artery bypass surgery, in which blood vessels from elsewhere in the body are rerouted or transplanted to substitute for blocked coronary arteries. After this surgery, many patients develop atrial fibrillation (AFib)—an abnormal heart rhythm that can lead to heart attack and stroke—which is treated with antiplatelet therapies such as aspirin. The PACeS trial is evaluating whether adding oral anticoagulants (blood thinners) to antiplatelet therapy can further reduce the risk of heart attack and stroke for such patients. 18

NHLBI is also robustly addressing how to prevent or improve outcomes for the 6.2 million adults living with heart failure (HF), in which the heart fails to pump enough blood to meet the body's needs. In HF with preserved ejection fraction (HFpEF), the heart contracts normally, but fills with blood too slowly. It accounts for about 50 percent of all HF and has limited treatment options. In 2020, NHLBI announced HeartShare, a new funding opportunity to conduct largescale analysis of clinical, laboratory, and imaging data from patients with HFpEF to characterize mechanisms of disease and identify therapeutic targets. 19 NHLBI also initiated a Big Data challenge competition calling upon researchers to mine data from past and ongoing HF studies to define subtypes of adult HF and new subtype-specific approaches to managing the disease.<sup>20</sup> The five winners were announced in November 2020.

New state-of-the-art cardiac imaging tools are enabling clinicians to more rapidly diagnose and treat patients with a number of heart disorders, including cardiac arrhythmia (irregular heartbeat). Locating the origin of an arrhythmia within the heart is often important for treatment. An NHLBI-funded team recently developed a technique that uses ultrasound to see electrical waves moving through the heart with each beat, called electromechanical wave imaging (EWI). In a study of 55 patients, they found that EWI successfully located 96 percent of arrythmias, while standard electrocardiography (ECG), which uses electrodes to record heartbeats, had a success rate of 71 percent. 21 Other new artificial intelligence (AI) technologies are able to analyze conventional ultrasound images of the heart (echocardiogram) and identify subtle signs of heart disease that are missed by standard techniques.<sup>22</sup>

Another technology with the potential to transform CVD treatment is **3D-bioprinting**, which can be used to generate heart and vascular (blood vessel) tissue. In one recent study, researchers designed a bioprinting device that uses fractal geometry to build simple organic resins into

NHLBI-20

pubmed.ncbi.nlm.nih.gov/32227755/
 pubmed.ncbi.nlm.nih.gov/32227753/

<sup>&</sup>lt;sup>18</sup> clinicaltrials.gov/ct2/show/NCT04045665

<sup>&</sup>lt;sup>19</sup> grants.nih.gov/grants/guide/rfa-files/RFA-HL-21-015.html

<sup>&</sup>lt;sup>20</sup> nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/NHLBI-heart-failure-data-challenge

<sup>&</sup>lt;sup>21</sup> pubmed.ncbi.nlm.nih.gov/32213631/

<sup>&</sup>lt;sup>22</sup> pubmed.ncbi.nlm.nih.gov/32269341/

#### RAPID RESEARCH TO ADDRESS THE **HEALTH EFFECTS OF VAPING**

Electronic (e-)cigarettes, which became available to U.S. consumers in 2007, work by heating liquids that typically contain nicotine and other additives to produce a smokeless aerosol. E-cigarette use, or vaping, was steadily embraced as a healthy alternative to conventional cigarettes, 1 especially among young people, and by 2019, one in four 12th graders reported having vaped in the past 30 days.<sup>2</sup> In spring 2019, the health risks of vaping came into tragic focus when reports began to emerge of e-cigarette, or vaping, product use-associated lung injury (EVALI). NHLBI has a legacy of supporting high-impact research on tobacco, including studies that linked conventional smoking to chronic diseases. Thanks to these continuing investments, the Institute prepared to address EVALI. For example, by November 2019, data from the Centers for Disease Control and Prevention had linked many EVALI cases to use of vaping liquids containing tetrahydrocannabinol (THC)—the active ingredient in marijuana—as well as vitamin E acetate—an agent used to dilute THC.3 NHLBI-funded researchers quickly pursued these leads, and in February 2020, reported that e-cigarette vapor containing vitamin E acetate causes lung injury in mice similar to that seen in EVALI patients.4 These strong links between vitamin E acetate and EVALI led the Food and Drug Administration (FDA) to advise that vitamin E acetate should not be used in vaping products. Although EVALI cases subsided in late 2019, the long-term health risks from vaping remain largely unknown, and NHLBI continues to provide robust support for research on this topic. Researchers and federal officials convened by NHLBI have proposed resources to help speed progress, including patient question naires to better characterize vaping behaviors, and systems to share data and specimens.5

<sup>1</sup>pubmed.ncbi.nlm.nih.gov/27890516/

<sup>2</sup>pubmed.ncbi.nlm.nih.gov/31532955/

cdc.gov/mmwr/volumes/68/wr/mm6845e2.htm

pubmed.ncbi.nlm.nih.gov/32101656/

pubmed.ncbi.nlm.nih.gov/32243764/

complex tubular networks that mimic human vascular networks, such as an artificial network of lung alveoli (air sacs) surrounded by vasculature.<sup>23</sup> Others have developed an approach to print 3D collagen, the main protein in the body's fibrous tissues, and then embed cells within it to produce several complex heart tissues including capillaries, valves, and ventricles.<sup>24</sup> Such techniques could one day be used to repair damaged heart or vascular tissue, or to engineer bioartificial hearts.

#### Budget Policy:

The FY 2022 President's Budget request is \$2,043.9 million, an increase of \$74.7 million or 3.8 percent compared with the FY 2021 Enacted level.

Lung Diseases: Since its inception in 1969, the NHLBI's Division of Lung Diseases has focused on translating basic scientific research into more effective treatments and patient care. The lung program supports research on the causes, diagnosis, prevention, and treatment of lung diseases and sleep disorders, while also supporting the researchers of the future. Some areas covered include asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, sleep-disordered breathing, acute lung injury, pulmonary complications of HIV/AIDS, pediatric lung diseases, pulmonary fibrosis and other rare lung disorders, including lymphangioleiomyomatosis.

**Asthma** is the most prevalent chronic respiratory disease worldwide. It can profoundly affect quality of life and is a major contributing factor to missed time from school and work. Decades ago, NHLBI helped bring inhaled corticosteroids into the clinician's toolbox for asthma, and the Institute now supports research to more precisely tailor interventions based on growing knowledge about the variable symptoms, severity, and underlying mechanisms of asthma. The PrecISE clinical trial network, with 30 locations across the country, will evaluate several novel and approved treatments for asthma by targeting them to defined groups of patients who share

pubmed.ncbi.nlm.nih.gov/31048486/
 pubmed.ncbi.nlm.nih.gov/31371612/

similar characteristics, such as genetic factors or biomarkers. The need for more personalized treatments is especially important in light of new findings showing that a variety of patient characteristics—such as ethnicity, overweight/obesity, and sensitivity to household allergens—can influence susceptibility to asthma as well as its severity. <sup>25,26</sup> In 2020, NHLBI also led an **update of the 2007 national asthma guidelines**, which help health care providers and patients make treatment decisions. The updated recommendations include guidance on the use of a new inhaled medication, immunotherapy or "allergy shots" (injections of an allergen to desensitize the body), and reducing indoor allergens.

The lung program also supports vigorous research to address chronic obstructive pulmonary disease (COPD), the fourth leading cause of death and third leading cause of disability in the U.S. NHLBI partnered with federal partners, voluntary health organizations, and communities across the country to develop and release the COPD National Action Plan in 2017 and continues to move ahead with its implementation. In 2021, NHLBI will launch an online tracking system to enable all partners to track and share progress. A major priority is to reduce the burden of COPD in rural and underserved communities, in part by improving the use of pulmonary rehabilitation. Although pulmonary rehab has been associated with lower mortality from COPD, less than four percent of eligible patients use it.<sup>27</sup> NHLBI-funded researchers are studying approaches to increase access and adherence to pulmonary rehab, for example, through homebased visits, coaching, and telehealth. NHLBI also continues to make progress unraveling the complex causes of COPD. For example, while smoking is the biggest known risk factor, one in four people with the disease have never smoked.<sup>28</sup> Recently, NHLBI-funded researchers addressed this mystery by analyzing lung scans from 6,529 smoking and non-smoking adults with COPD. They found that people with small airways relative to lung size were more likely to have the disease—even if they did not smoke or have other risk factors.<sup>29</sup> This growing knowledge about early risk factors and signs of COPD will enable earlier treatment and better outcomes.

Recognizing that **lung transplantation** could be a cure for millions of patients with COPD and other advanced lung diseases, the lung division is committed to advancing this approach. While organ transplant outcomes have steadily improved in recent years, the mortality rate for lung transplants remains nearly twice as high as for heart, liver, and kidney transplants. To accelerate advances in lung transplantation, NHLBI is establishing a multi-site Lung Transplant Consortium that will harmonize clinical studies across lung transplant centers. <sup>30</sup> An NHLBI-funded study is also following more than 3,000 patients who have undergone a lung transplant to understand chronic lung allograft dysfunction (CLAD), where the transplanted lung does not function properly. <sup>31</sup> Others are conducting a trial to determine if a biologic approved for use in kidney transplants will help reduce CLAD and improve outcomes for lung transplants. <sup>32</sup>

-

<sup>&</sup>lt;sup>25</sup> pubmed.ncbi.nlm.nih.gov/32369487/

<sup>&</sup>lt;sup>26</sup> pubmed.ncbi.nlm.nih.gov/32479111/

<sup>&</sup>lt;sup>27</sup> pubmed.ncbi.nlm.nih.gov/32396181/

<sup>&</sup>lt;sup>28</sup> cdc.gov/mmwr/volumes/68/wr/mm6824a1.htm?s cid=mm6824a1 w

<sup>&</sup>lt;sup>29</sup> pubmed.ncbi.nlm.nih.gov/32515814/

<sup>&</sup>lt;sup>30</sup> grants.nih.gov/grants/guide/notice-files/NOT-HL-20-752.html

<sup>&</sup>lt;sup>31</sup> projectreporter.nih.gov/project info description.cfm?aid=9952409&icde=50515953

<sup>&</sup>lt;sup>32</sup> reporter.nih.gov/search/vKC8eTko8USDsoXGSB7Veg/projects

The lung program has played a significant role in developing effective therapies for **cystic fibrosis (CF).** The program has supported decades of basic research to understand the structure and function of the CFTR (cystic fibrosis transmembrane conductance regulator), a lung protein that is genetically altered in CF. This work paved the way for industry development of ivacaftor, the first drug to treat the underlying cause of CF, approved by the U.S. Food and Drug Administration (FDA) in 2012.<sup>33</sup> More recently, NHLBI supported clinical trials that led to approval of a triple drug combination that improves lung function in about 90 percent of people with CF. <sup>34,35</sup>

**Sleep** is another important component of the lung division's portfolio. Insufficient sleep is one of the most common health complaints in the United States and is a risk factor for diabetes, hypertension, obesity, and other life-threatening conditions. An NHLBI-funded study of nearly 2,000 middle-aged adults showed that compared to people with regular bedtimes and sleep duration, people with the most irregular sleep patterns had more than twice the risk of CVD after five years of follow-up.<sup>36</sup> As new sleep findings emerge from NHLBI-funded studies, they are uploaded to NHLBI's BioData Catalyst platform, so that researchers can share and analyze the data collaboratively to speed advances in sleep research.

#### **Budget Policy:**

The FY 2022 President's Budget request is \$834.7 million, an increase of \$40.9 million or 5.2 percent compared with the FY 2021 Enacted level.

**Blood Diseases:** NHLBI's blood program is a leader in research on the causes, prevention, and treatment of congenital and acquired blood diseases, including anemias, venous thromboembolism, hemophilia, malaria, and other bleeding disorders. The program also helps ensure the safety of the world's blood supply and supports stem cell biology and new gene and cell-based therapies to repair and regenerate human tissues.

For decades, the blood program has been the leading supporter of research on sickle cell disease (SCD), which is caused by gene mutations that affect the oxygen-carrying protein hemoglobin (Hb) in red blood cells. The cells take on a sickle shape and can clog blood vessels, which can lead to severe pain (called crisis), infections, organ damage, and stroke. While transplantation of healthy bone marrow (where red blood cells are made) can cure SCD, this treatment is not an option for most patients, since it requires an immune-matched bone marrow donor. NHLBI launched the **Cure Sickle Cell Initiative** in 2018 to support the development of gene-based cures for SCD that will work for everyone. The initiative includes an analysis to ensure that new therapies will be beneficial to patients in ways that matter to them, including affordability and accessibility. Researchers involved in the Cure initiative helped develop an accurate, affordable, easy-to-use device for point-of-care diagnosis of SCD in low-resource areas.<sup>37</sup> NHLBI is also

<sup>&</sup>lt;sup>33</sup> ncbi.nlm.nih.gov/pmc/articles/PMC6909826/

<sup>&</sup>lt;sup>34</sup> pubmed.ncbi.nlm.nih.gov/31697873/

<sup>35</sup> pubmed.ncbi.nlm.nih.gov/31679946/

<sup>&</sup>lt;sup>36</sup> pubmed.ncbi.nlm.nih.gov/32138974/

<sup>&</sup>lt;sup>37</sup> pubmed.ncbi.nlm.nih.gov/32123889/

an integral part of a collaboration between NIH and the Bill & Melinda Gates Foundation to develop accessible, safe, and effective gene-based cures for SCD in sub-Saharan Africa.

Researchers also continue to unravel the mechanisms of SCD to inform new therapies. Using a mouse model, one team recently found that SCD causes abnormal twists and turns in the blood vessels that supply bone marrow, where red blood cells are made. These disorganized blood vessels deprive the bone marrow of oxygen and could complicate efforts to restore normal red blood cells to patients, such as through bone marrow transplantation or gene therapy. However, the researchers also found that six weeks of blood transfusion restored normal blood vessel architecture in the mice's bone marrow, suggesting a similar protocol could be used as part of cell-and gene-based therapies in patients to improve outcomes.<sup>38</sup>

In addition to gene- and cell-based therapies for SCD, NHLBI supports research into new drug treatments. Since 2017, the FDA has approved two **new drugs to treat SCD**. Through its small business program and later through the SUSTAIN clinical trial, NHLBI supported development of crizanlizumab-tmca, which helps prevent red blood cells from sticking to the blood vessel wall.<sup>39</sup> NHLBI and NIH basic research funding on Hb structure and function also contributed to the development of voxelotor, which improves the ability of Hb to carry oxygen.

Finally, the blood program supports research to improve care for patients who are struggling with SCD now. Many patients with SCD do not receive interventions proven to reduce pain and the risk of stroke, and some have difficulty or concern regarding side effects. To move proven interventions into broader practice, NHLBI established eight geographically diverse centers that comprise the Sickle Cell Implementation Consortium. A recent Consortium survey of 440 adolescents and adults with SCD found that most were pleased with their primary care, but had negative experiences with emergency care for sickle cell crisis. 40 A new Consortium study is testing an approach to help patients receive faster treatment for crisis by embedding each patient's individualized pain treatment plan in their electronic health record so that it can be pulled up quickly on a cell phone or tablet during emergency care. In another study, researchers have worked closely with patients to develop a smartphone app to improve adherence to hydroxyurea, a drug proven to reduce crises; the app is now being tested in a clinical trial.<sup>41</sup>

The blood program also supports research to protect the Nation's blood supply, and to improve the safety and efficacy of blood transfusions, through the Recipient Epidemiology and Donor Evaluation Study (REDS). For example, REDS recently found that iron supplements can help correct iron deficiencies in people who donate whole blood frequently, 42 and that a donor's health-related habits (such as smoking, or drinking caffeine or alcohol) can impact the quality of stored donated blood and transfusions. 43 The REDS program also has been leveraged to help determine how many people in the U.S. have developed antibodies to SARS-CoV-2. These antibodies are an important indicator not only of past SARS-CoV-2 infection, but also the body's

<sup>38</sup> ncbi.nlm.nih.gov/pmc/articles/PMC7273832/

<sup>&</sup>lt;sup>39</sup> pubmed.ncbi.nlm.nih.gov/27959701/

<sup>40</sup> pubmed.ncbi.nlm.nih.gov/32469413/

pubmed.ncbi.nlm.nih.gov/32383683/

<sup>&</sup>lt;sup>42</sup> pubmed.ncbi.nlm.nih.gov/32243609/ <sup>43</sup> pubmed.ncbi.nlm.nih.gov/32385854/

immune response to it, with implications for vaccine development. REDS has analyzed the prevalence of antibodies (seroprevalence) in six cities where COVID-19 was most prevalent from March-August 2020, which helped establish a framework for a nationwide COVID-19 seroprevalence survey led by the Centers for Disease Control and Prevention. 44

#### **Budget Policy:**

The FY 2022 President's Budget request is \$498.3 million, an increase of \$24.4 million or 5.2 percent compared with the FY 2021 Enacted level.

**Implementation Science:** NHLBI's Center for Translation Research and Implementation Science was established in 2014 to serve as a focal point within the Institute for coordinating and advancing research to improve the adoption of evidence-based approaches to treat and prevent disease and promote health. The Center supports research that addresses both domestic and global health disparities and inequities, and training and career development in this research.

To date, there have been very few studies focused on the implementation, scale-up, and maintenance of delivering new interventions to communities where they are needed, and even fewer studies focused on high need, underserved communities. To address this gap, NHLBI recently launched the **DECIPHER** program, and awarded the first projects in September 2020. Seven grantees in different areas of the country will begin working with local communities to evaluate a variety of proven interventions for conditions such as asthma, CVD, and hypertension. In Louisiana, community health workers will partner with local churches to reduce CVD risk in African Americans by promoting lifestyle interventions in line with current CVD guidelines (e.g., healthy diet, physical activity, smoking cessation, weight loss). 45 In rural Colorado, researchers will work with school-based asthma navigators and nurses to test a team approach to asthma control in school children. 46 In Los Angeles, 51 adult primary care clinics will implement culturally tailored multi-level evidence-based strategies to improve blood pressure control in this very large, diverse city. 47

Another implementation research effort is focused on improving diagnosis of a common genetic disorder, **familial hypercholesterolemia (FH).** FH can cause lifelong high levels of LDL (bad) cholesterol and lead to premature heart disease. It is estimated that less than 10 percent of people with FH have been diagnosed, and among those, only half are on life-saving therapies. Screening family members of people with an FH diagnosis (called cascade screening) has proven effective at identifying undiagnosed patients, but is often limited in reach given patient privacy laws and

45 projectreporter.nih.gov/project\_info\_description.cfm?aid=9931807&icde=51724393

<sup>44</sup> cdc.gov/coronavirus/2019-ncov/cases-updates/blood-bank-serosurvey.html

<sup>46</sup> projectreporter.nih.gov/project\_info\_description.cfm?aid=9931020&icde=51724371 projectreporter.nih.gov/project\_info\_description.cfm?aid=10064593&icde=51724340

low availability of FH genetic testing in some areas. In 2019, NHLBI released a new funding opportunity to develop solutions to these barriers. 48

The implementation science program also supports research to address global health disparities, including an effort to address HIV/AIDS and associated chronic diseases. The emergence of effective antiretroviral therapy (ART) for HIV has led to a decline in deaths from AIDS worldwide, but as people with HIV age, they are at higher risk than their peers for chronic heart, lung, blood, and sleep disorders. A new NHLBI initiative is supporting the development of model programs to deliver proven prevention and treatments for chronic diseases associated with HIV among patients in low resource settings in Africa; the program is funding projects in five African countries and a coordinating center in the United States. 49

#### Budget Policy:

The FY 2022 President's Budget request is \$84.2 million, an increase of \$29.7 million or 54.4 percent compared with the FY 2021 Enacted level. This increase will support major health initiatives across the nation, including significant contributions to CEAL and DECIPHER, which focus on health disparities and community engagement to ensure treatments and interventions that improve population health in high-burden communities.

**Intramural Research:** The NHLBI Division of Intramural Research (DIR), located at the NIH campus in Bethesda,

## MOBILIZING TO REDUCE SEVERE ILLNESS AND DEATH FROM COVID-19

By late January 2020, with the emergence of the first peerreviewed reports of COVID-19 outcomes in Chinese patients, it was clear that the disease attacks multiple organs, including the heart and lungs, with potentially fatal effects. By February, NHLBI had formed a COVID-19 response team and developed a strategy to act quickly by leveraging existing assets, including clinical trial networks, population-based studies, and our talented cadre of investigators across the country. The following are early milestones.

- March: NHLBI issued its first funding opportunity to address the disease's impact on the heart, lungs, blood, and blood vessels. The COVID-19 Observational (CORAL) study was also started to examine pathobiology and outcomes among adults hospitalized with COVID-19.
- April: NHLBI launched a clinical trial of hydroxychloroquine for hospitalized COVID-19 patients; by June, the trial was halted because the drug provided no benefit.<sup>1</sup> NHLBI also launched a trial to evaluate convalescent plasma for mild COVID-19.<sup>2</sup>
- July: NHLBI established a "network of networks" (CONNECTS) bringing together nearly 30 existing clinical trial networks to identify and test potential therapies for COVID-19.3
- September: NIH announced that CONNECTS will conduct the ACTIV-4 Antithrombotic clinical trials to test blood-clotting regimens against different stages of COVID-19. To address the disparate burden of COVID-19 in communities of color and ensure their inclusion in research, NHLBI and NIMHD launched the trans-NIH CEAL initiative. 5
- October: The Collaborative Cohort of Cohorts for COVID-19 Research (C4R) was formed to leverage NHLBI's ongoing population-based studies to examine long-termoutcomes of SARS-CoV-2 infection, as well as factors that affect risk and resilience to severe illness. NHLBI also co-funded a five-year study to understand a pediatric disease associated with COVID-19, multisystem inflammatory syndrome in children (MIS-C)

As our knowledge about COVID-19 evolves, NHLBI will continue to pursue the most promising scientific leads and potential therapies, and shed light on the long-term health impacts of SARS-CoV-2.

- 1 clinicaltrials.gov/ct2/show/NCT04332991
- <sup>2</sup> clinicaltrials.gov/ct2/show/NCT04355767
- 3 https://nhlbi-connects.org/
- ⁴ go.usa.gov/x7rtU
- <sup>5</sup> go.usa.gov/x7rtM

Maryland, performs robust scientific and clinical research leading to a better understanding of biology and pathology of heart, lung, blood and sleep systems. The research portfolio is broad,

 $<sup>^{48}\</sup> grants.nih.gov/grants/guide/rfa-files/RFA-HL-22-006.html$ 

<sup>&</sup>lt;sup>49</sup> grants.nih.gov/grants/guide/rfa-files/rfa-hl-20-025.html

ranging from basic research on molecules and cells to clarifying disease mechanisms, to establishing new therapies for human diseases through population studies and clinical trials. It also has a strong training program.

For the second time in a decade, NHLBI intramural staff have been on the frontlines responding to deadly viruses. In 2014, they made vital contributions to understand and control a deadly outbreak of Ebola virus in West Africa. Now DIR investigators have been working tirelessly to address the global COVID-19 pandemic. In February 2020, the NHLBI clinical director led an international team charged with safely evacuating Americans from a cruise ship off the coast of Japan with more than 700 passengers testing positive for COVID-19. This team also provided the antiviral drug remdesivir to severely affected patients on a compassionate use basis, helping to set the stage for larger randomized clinical trials of the drug. <sup>50</sup> In the fall, DIR scientists began working with the NIH Clinical Center and industry in a trial to examine how patients with severe COVID-19 respond to fostamatinib, a small molecule that can inhibit inflammation and is FDA-approved to treat a rare autoimmune blood clotting disorder. 51

Other DIR labs are conducting basic research on COVID-19. For example, one group has been working to determine how SARS-CoV-2 exits infected cells and spreads to other cells. Most viruses are released from cells by secretory vesicles, small packets that are used to send hormones and other signals. However, by studying a stripped down, non-infectious SARS virus, DIR researchers found these viruses are instead released from lysosomes<sup>52</sup>, which are acid-filled compartments that degrade waste and toxins, like a garbage disposal. The fact that lysosomes do not destroy SARS-CoV-2 suggests the virus might also interfere with their essential cell clean-up functions, which may explain some of the disease's complex symptoms.

DIR continues to make advances in non-COVID related research, too. For example, DIR investigators developed a new type of magnetic resonance imaging (MRI), called quantitative myocardial perfusion mapping, that improves identification of patients with heart disease who have two or more blocked coronary arteries.<sup>53</sup> DIR researchers have also developed new biological imaging approaches to visualize the dynamic behavior of mitochondria—the power houses within our cells—which may lead to new therapies for mitochondrial disorders, heart disease, and muscular dystrophy.<sup>54</sup>

#### **Budget Policy:**

The FY 2022 President's Budget request is \$237.4 million, an increase of \$6.9 million or 3.0 percent compared with the FY 2021 Enacted level.

Research Management and Support (RMS): RMS activities include administrative and technical functions that support and enhance the effectiveness of the Institute's research

pubmed.ncbi.nlm.nih.gov/33011115/
 pubmed.ncbi.nlm.nih.gov/31706841/

<sup>&</sup>lt;sup>50</sup> www.nejm.org/doi/full/10.1056/NEJMoa2007016?query=featured coronavirus

<sup>&</sup>lt;sup>51</sup> rigel.com/news-events/press-releases/detail/296/rigel-announces-nihnhlbi-sponsored-trial-of-fostamatinib

<sup>&</sup>lt;sup>52</sup> https://www.nih.gov/news-events/news-releases/nih-scientists-discover-key-pathway-lysosomes-coronavirusesuse-exit-cells.

investments. This includes providing administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants and clinical trials, training awards, and research and development contracts. RMS functions also encompass strategic planning, trans-NHLBI and NIH coordination, evaluation of the Institute's programs, regulatory compliance, international coordination, interactions with other Federal agencies and Congress, and dissemination of research findings to the public.

#### Budget Policy:

The FY 2022 President's Budget request is \$147.2 million, an increase of \$4.3 million or 3.0 percent compared with the FY 2021 Enacted level.

#### **Appropriations History**

| Fiscal Year   | Budget Estimate to<br>Congress            | House Allowance                                | Senate Allowance                        | Appropriation   |
|---------------|---|--|---|-----------------|
| 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    | 42,723                                    | ¥=,,===,==,==,==                               | V 2 7 2 2 7 2 7 2 7 2 7 2 7 2 7 2 7 2 7 | \$0             |
| 20171         | \$3,113,533,000                           | \$3,190,474,000                                | \$3,242,685,000                         | \$3,206,589,000 |
| Rescission    | 1., ., ., ., ., ., ., ., ., ., ., ., ., . | 4-777  | ve, ye ee                               | \$0             |
| 2018          | \$2,534,803,000                           | \$3,256,521,000                                | \$3,322,774,000                         | \$3,383,201,000 |
| Rescission    |   | . , , ,  | . , , ,                                 | \$0             |
| 2019          | \$3,112,032,000                           | \$3,423,604,000                                | \$3,490,171,000                         | \$3,488,335,000 |
| Rescission    | 40,000,000                                | <del>,</del> , , , , , , , , , , , , , , , , , | 42, 12 0, 1 1, 1, 1                     | \$0             |
| 2020          | \$3,002,696,000                           | \$3,658,822,000                                | \$3,694,771,000                         | \$3,624,258,000 |
| Rescission    |   | . , , ,  | . , , ,                                 | \$0             |
| Supplemental  |   |  |   | \$103,400,000   |
| 2021          | \$3,298,004,000                           | \$3,655,428,000                                | \$3,728,307,000                         | \$3,664,811,000 |
| Rescission    |   |  |   | \$0             |
| 2022          | \$3,845,681,000                           |  |   |                 |

<sup>&</sup>lt;sup>1</sup> Budget Estimate to Congress includes mandatory financing.

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

Authorizing Legislation

|   | PHS Act/       | U.S. Code | 2021 Amount | FY 2021 Enacted | 2022 Amount | 2022 Amount FY 2022 President's Budget |
|---|----------------|-----------|-------------|-----------------|-------------|--|
|   | Other Citation | Citation  | Authorized  |                 | Authorized  |  |
| Research and Investigation                | Section 301    | 42§241    | Indefinite  |                 | Indefinite  |  |
|   |                |           |             | \$3,664,703,000 | _^          | \$3,845,681,000                        |
| National Heart, Lung, and Blood Institute | Section 401(a) | 42§281    | Indefinite  |                 | Indefinite  |  |
|   |                |           |             |                 |             |  |
| Total Budget Authority                    |                |           |             | \$3,664,703,000 |             | \$3.845.681.000                        |

#### Amounts Available for Obligation<sup>1</sup>

| Source of Funding                   | FY 2020 Final | FY 2021 Enacted | FY 2022 President's<br>Budget |
|-------------------------------------|---------------|-----------------|-------------------------------|
| Appropriation                       | \$3,624,258   | \$3,664,811     | \$3,845,681                   |
| Secretary's Transfer                | 0             | 0               | 0                             |
| OAR HIV/AIDS Transfers              | 1,000         | -108            | 0                             |
| Subtotal, adjusted budget authority | \$3,625,258   | \$3,664,703     | \$3,845,681                   |
| Unobligated balance, start of year  | 0             | 0               | 0                             |
| Unobligated balance, end of year    | 0             | 0               | 0                             |
| Subtotal, adjusted budget authority | \$3,625,258   | \$3,664,703     | \$3,845,681                   |
| Unobligated balance lapsing         | -395          | 0               | 0                             |
| Total obligations                   | \$3,624,863   | \$3,664,703     | \$3,845,681                   |

#### Budget Authority by Object Class<sup>1</sup>

|           |   | EV 2021 E       | FY 2022 President's           | FY 2022                   |
|-----------|---|-----------------|-------------------------------|---------------------------|
|           |   | FY 2021 Enacted | Budget                        | +/-<br>FY 2021 Enacted    |
| Total cor | mpensable workyears:                                    |                 |                               |                           |
|           | Full-time equivalent                                    | 962             | 962                           | 0                         |
|           | Full-time equivalent of overtime and holiday hours      | 1               | 1                             | 0                         |
|           | Average ES salary                                       | \$195           | \$199                         | \$4                       |
|           | Average GM/GS grade                                     | 12.8            | 12.8                          | 0.0                       |
|           | Average GM/GS salary                                    | \$124           | \$127                         | \$3                       |
|           | Average salary, Commissioned Corps (42 U.S.C. 207)      | \$115           | \$118                         | \$3                       |
|           | Average salary of ungraded positions                    | \$132           | \$135                         | \$3                       |
|           | OBJECT CLASSES  | FY 2021 Enacted | FY 2022 President's<br>Budget | FY 2022<br>+/-<br>FY 2021 |
|           | Personnel Compensation                                  |                 |                               |                           |
| 11.1      | Full-Time Permanent                                     | 66,754          | 68,273                        | 1,519                     |
| 11.3      | Other Than Full-Time Permanent                          | 35,612          | 36,423                        | 810                       |
| 11.5      | Other Personnel Compensation                            | 4,677           | 4,783                         | 106                       |
| 11.7      | Military Personnel                                      | 2,264           | 2,327                         | 63                        |
| 11.8      | Special Personnel Services Payments                     | 11,472          | 11,733                        | 261                       |
| 11.9      | <b>Subtotal Personnel Compensation</b>                  | \$120,780       | \$123,539                     | \$2,759                   |
| 12.1      | Civilian Personnel Benefits                             | 38,545          | 40,592                        | 2,047                     |
| 12.2      | Military Personnel Benefits                             | 1,778           | 1,828                         | 49                        |
| 13.0      | Benefits to Former Personnel                            | 0               | 0                             | 0                         |
|           | Subtotal Pay Costs                                      | \$161,103       | \$165,958                     | \$4,855                   |
| 21.0      | Travel & Transportation of Persons                      | 1,699           | 1,730                         | 31                        |
| 22.0      | Transportation of Things                                | 350             | 356                           | 6                         |
| 23.1      | Rental Payments to GSA                                  | 0               | 0                             | 0                         |
| 23.2      | Rental Payments to Others                               | 2               | 2                             | 0                         |
| 23.3      | Communications, Utilities & Misc. Charges               | 569             | 579                           | 10                        |
| 24.0      | Printing & Reproduction                                 | 0               | 0                             | 0                         |
| 25.1      | Consulting Services                                     | 112,091         | 107,940                       | -4,151                    |
| 25.2      | Other Services  | 100,478         | 102,510                       | 2,031                     |
| 25.3      | Purchase of goods and services from government accounts | 205,304         | 206,085                       | 781                       |
| 25.4      | Operation & Maintenance of Facilities                   | 667             | 667                           | 0                         |
| 25.5      | R&D Contracts   | 123,400         | 124,516                       | 1,116                     |
| 25.6      | Medical Care  | 2,355           | 2,442                         | 87                        |
| 25.7      | Operation & Maintenance of Equipment                    | 15,964          | 16,307                        | 343                       |
| 25.8      | Subsistence & Support of Persons                        | 15,904          | 10,507                        | 0                         |
| 25.0      | Subtotal Other Contractual Services                     | \$560,260       | \$560,467                     | \$208                     |
| 26.0      | Supplies & Materials                                    | 15,009          | . ,                           |                           |
| 31.0      | Equipment   | 5,187           | 5,281                         | 94                        |
| 32.0      | Land and Structures                                     | 6,035           | 6,143                         | 109                       |
| 33.0      | Investments & Loans                                     | 0               | 0                             | 0                         |
| 41.0      | Grants, Subsidies & Contributions                       | 2,914,487       | 3,089,882                     | 175,395                   |
| 42.0      | Insurance Claims & Indemnities                          | 0.              | 0                             | 0                         |
| 43.0      | Interest & Dividends                                    | 2.              | 2                             | 0                         |
| 44.0      | Refunds   | 0               | 0                             | 0                         |
|           | Subtotal Non-Pay Costs                                  | \$3,503,600     | \$3,679,723                   | \$176,123                 |
|           | Total Budget Authority by Object Class                  | \$3,664,703     | \$3,845,681                   | \$180,978                 |

<sup>&</sup>lt;sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

#### **Salaries and Expenses**

| OBJECT CLASSES                                   | FY 2021 Enacted | FY 2022 President's<br>Budget | FY 2022<br>+/-<br>FY 2021 |
|--|-----------------|-------------------------------|---------------------------|
| Personnel Compensation                           |                 |                               |                           |
| Full-Time Permanent (11.1)                       | \$66,754        | \$68,273                      | \$1,519                   |
| Other Than Full-Time Permanent (11.3)            | 35,612          | 36,423                        | 810                       |
| Other Personnel Compensation (11.5)              | 4,677           | 4,783                         | 106                       |
| Military Personnel (11.7)                        | 2,264           | 2,327                         | 63                        |
| Special Personnel Services Payments (11.8)       | 11,472          | 11,733                        | 261                       |
| Subtotal Personnel Compensation (11.9)           | \$120,780       | \$123,539                     | \$2,759                   |
| Civilian Personnel Benefits (12.1)               | \$38,545        | \$40,592                      | \$2,047                   |
| Military Personnel Benefits (12.2)               | 1,778           | 1,828                         | 49                        |
| Benefits to Former Personnel (13.0)              | 0               | 0                             | 0                         |
| Subtotal Pay Costs                               | \$161,103       | \$165,958                     | \$4,855                   |
| Travel & Transportation of Persons (21.0)        | \$1,699         | \$1,730                       | \$31                      |
| Transportation of Things (22.0)                  | 350             | 356                           | 6                         |
| Rental Payments to Others (23.2)                 | 2               | 2                             | 0                         |
| Communications, Utilities & Misc. Charges (23.3) | 569             | 579                           | 10                        |
| Printing & Reproduction (24.0)                   | 0               | 0                             | 0                         |
| Other Contractual Services:                      |                 |                               |                           |
| Consultant Services (25.1)                       | 112,091         | 107,940                       | -4,151                    |
| Other Services (25.2)                            | 100,478         | 102,510                       | 2,031                     |
| Purchases from government accounts (25.3)        | 113,226         | 117,919                       | 4,693                     |
| Operation & Maintenance of Facilities (25.4)     | 667             | 667                           | 0                         |
| Operation & Maintenance of Equipment (25.7)      | 15,964          | 16,307                        | 343                       |
| Subsistence & Support of Persons (25.8)          | 0               | 0                             | 0                         |
| Subtotal Other Contractual Services              | \$342,426       | \$345,343                     | \$2,917                   |
| Supplies & Materials (26.0)                      | \$15,009        |                               | \$271                     |
| Subtotal Non-Pay Costs                           | \$360,055       | \$363,290                     | \$3,235                   |
| <b>Total Administrative Costs</b>                | \$521,159       | \$529,248                     | \$8,090                   |

#### **Detail of Full-Time Equivalent Employment (FTE)**

|  | I                | FY 2020 Final |       | FY 2021 Enacted |          | FY 2022 President's Budget |  |          |       |
|--|------------------|---------------|-------|-----------------|----------|----------------------------|--|----------|-------|
| OFFICE/DIVISION  | Civilian         | Military      | Total | Civilian        | Military | Total                      | Civilian   | Military | Total |
|  |                  |               |       |                 |          |                            |  |          |       |
| Center for Translation Research and Implementation Science   |                  |               | 1.0   | 1.2             |          |                            | 1.2  |          |       |
| Direct:  | 11               | 1             | 12    | 13              | 1        | 14                         | 13   | 1        | 14    |
| Reimbursable:  |                  |               |       |                 | -        |                            |  |          |       |
| Total:   | 11               | 1             | 12    | 13              | 1        | 14                         | 13   | 1        | 14    |
| Division of Blood and Resources                              |                  |               |       |                 |          |                            |  |          |       |
| Direct:  | 24               | 1             | 25    | 29              | 1        | 30                         | 29   | 1        | 30    |
| Reimbursable:  | -                | -             | -     | -               | -        | -                          | -  | -        | -     |
| Total:   | 24               | 1             | 25    | 29              | 1        | 30                         | 29   | 1        | 30    |
| Division of Cardiovascular Sciences                          |                  |               |       |                 |          |                            |  |          |       |
| Direct:  | 110              | 1             | 111   | 129             | 1        | 130                        | 128  | 1        | 129   |
| Reimbursable:  | _                |               |       |                 | _        | -                          | -  | _        |       |
| Total:   | 110              | 1             | 111   | 129             | 1        | 130                        | 128  | 1        | 129   |
| Division of Extramural Research Activities                   |                  |               |       |                 |          |                            |  |          |       |
| Direct:  | 92               |               | 92    | 109             |          | 109                        | 109  |          | 109   |
| Reimbursable:  | 92               | -             | 92    | 109             | -        | 109                        | 109  | -        | 109   |
| Total:   | 92               | _             | 92    | 109             | -        | 109                        | 109  | -        | 109   |
| Total.   | 92               | -             | 92    | 109             | -        | 109                        | 109  | -        | 109   |
| Division of Intramural Research                              |                  |               |       |                 |          |                            |  |          |       |
| Direct:  | 382              | 13            | 395   | 436             | 14       | 450                        | 451  | 14       | 465   |
| Reimbursable:  | 14               | -             | 14    | 17              | -        | 17                         | 17   | -        | 17    |
| Total:   | 396              | 13            | 409   | 453             | 14       | 467                        | 468  | 14       | 482   |
| Division of Lung Diseases                                    |                  |               |       |                 |          |                            |  |          |       |
| Direct:  | 33               | _             | 33    | 39              | _        | 39                         | 39   | _        | 39    |
| Reimbursable:  |                  | _             | -     | _               | _        | _                          | _  | _        | _     |
| Total:   | 33               | -             | 33    | 39              | -        | 39                         | 39   | -        | 39    |
| Office of the Director                                       |                  |               |       |                 |          |                            |  |          |       |
| Direct:  | 133              | 2             | 135   | 171             | 2        | 173                        | 157  | 2        | 159   |
| Reimbursable:  | 133              | -             | 155   | 1/1             | -        | 1/3                        | 157  | -        | 157   |
| Total:   | 133              | 2             | 135   | 171             | 2        | 173                        | 157  | 2        | 159   |
|  |                  |               |       |                 |          |                            |  |          |       |
| Total  | 799              | 18            | 817   | 943             | 19       | 962                        | 943  | 19       | 962   |
| Includes FTEs whose payroll obligations are supported by the | NIH Common       | Fund.         |       |                 |          |                            |  |          |       |
| FTEs supported by funds from Cooperative Research and        | 0                | 0             | 0     | 0               | 0        | 0                          | 0  | 0        | 0     |
| Development Agreements.  FISCAL YEAR                         |                  | Ţ.            |       |                 |          | ,                          | The state of the s |          | ·     |
| FISCAL YEAR  | Average GS Grade |               |       |                 |          |                            |  |          |       |
| 2018   | 12.7             |               |       |                 |          |                            |  |          |       |
| 2019   | 12.7             |               |       |                 |          |                            |  |          |       |
| 2020   |                  | 12.7          |       |                 |          |                            |  |          |       |
| 2021   |                  | 12.8          |       |                 |          |                            |  |          |       |
| 2022   | 12.8             |               |       |                 |          |                            |  |          |       |

#### Detail of Positions<sup>1</sup>

| GRADE  | FY 2020 Final | FY 2021 Enacted | FY 2022 President's<br>Budget |
|--|---------------|-----------------|-------------------------------|
| Total, ES Positions                                      | 2             | 2               | 2                             |
| Total, ES Salary   | 384,849       | 389,236         | 398,091                       |
| General Schedule   |               |                 |                               |
| GM/GS-15   | 80            | 97              | 97                            |
| GM/GS-14   | 148           | 178             | 178                           |
| GM/GS-13   | 172           | 204             | 204                           |
| GS-12  | 59            | 69              | 69                            |
| GS-11  | 38            | 45              | 45                            |
| GS-10  | 0             | 0               | 0                             |
| GS-9   | 33            | 37              | 37                            |
| GS-8   | 3             | 3               | 3                             |
| GS-7   | 6             | 7               | 7                             |
| GS-6   | 2             | 2               | 2                             |
| GS-5   | 0             | 0               | 0                             |
| GS-4   | 5             | 5               | 5                             |
| GS-3   | 4             | 4               | 4                             |
| GS-2   | 2             | 2               | 2                             |
| GS-1   | 1             | 1               | 1                             |
| Subtotal   | 553           | 654             | 654                           |
| Commissioned Corps (42 U.S.C. 207)                       |               |                 |                               |
| Assistant Surgeon General                                | 1             | 1               | 1                             |
| Director Grade   | 5             | 5               | 5                             |
| Senior Grade   | 6             | 6               | 6                             |
| Full Grade   | 6             | 6               | 6                             |
| Senior Assistant Grade                                   | 1             | 1               | 1                             |
| Assistant Grade  | 0             | 0               | 0                             |
| Subtotal   | 19            | 19              | 19                            |
| Ungraded   | 243           | 287             | 287                           |
| Total permanent positions                                | 574           | 675             | 675                           |
| Total positions, end of year                             | 817           | 962             | 962                           |
| Total full-time equivalent (FTE) employment, end of year | 817           | 962             |                               |
| Average ES salary  | 192,424       | 194,618         | 199,046                       |
| Average GM/GS grade                                      | 12.7          | 12.8            | 12.8                          |
| Average GM/GS salary                                     | 121,806       | 124,352         | 127,182                       |

 $<sup>^{\</sup>mbox{\scriptsize 1}}$  Includes FTEs whose payroll obligations are supported by the NIH Common Fund.